Advertising of Medicines and Medical Devices

2021

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Overview

Advertising of pharmaceuticals and medical devices is a challenging area for the Life Sciences and Healthcare industry.

The legal framework is constantly changing. Due to very few laws in this area, there are significant differences between jurisdictions. With the emergence of new forms of (social) media, the legislators are regularly needing to revise existing provisions for advertising and to enact new laws. Furthermore, since the advertising of these 'specific goods' is subject to strict regulations in order to protect the public as well as professionals, compliance with applicable laws and interpretation of the local authorities is essential.

This guide provides high level information on life sciences and healthcare advertising in 27 jurisdictions and offers a quick and simple understanding of the applicable laws. The guide covers, amongst others, different types of advertising, regulatory aspects as well as legal consequences of non-compliance.

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JURISDICTION: Austria

1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	• The primary legal source is the Medicinal Products Act (*Arzneimittelgesetz* – AMG). In addition, the Austrian Act Against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb* – UWG) must be observed; parallel provisions of the UWG and the AMG are applicable cumulatively. • The most important legal source regarding medical devices is the Medical Devices Act (*Medizinproduktegesetz* – MPG). The provisions of the UWG must also be observed when it comes to advertising of medical devices.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	• The Code of Conduct of the Austrian Pharmaceutical Industry Association (PHARMIG) plays a central role in the determination of the legitimacy of advertising measures. Additionally, the code of conduct of the Association of Austrian Pharmaceutical Manufacturers (IGEPHA) can be named as another self-regulatory code of conduct. • For medical devices there is the Code of Conduct of the Advocacy of the medical device companies in Austria (Austromed), which, however, does not explicitly contain provisions on advertising of medical devices. Besides, the IGEPHA Code of Conduct also covers some rules regarding the advertising of medical devices.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	• There are no licenses/approvals/fees required for advertisements of medicines and medical devices.
4. Does the law regulate the advertising of prescription-only and over-the-counter medicines differently?	• Yes. The distinction plays an important role regarding advertisements that are addressed to the general public: while advertising of non-prescription medicines to the general public is permitted under certain conditions, advertising of prescription medicines to the general public is generally prohibited (please see below Q5).
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	• Advertising may only be carried out for drugs that are authorised for marketing in Austria. Advertising must be objective, must not contain any exaggeration of effects or guarantees of success and must be compatible with the product labelling, instructions for use (IFU) and summary of product characteristics (SmPC). • A general ban on advertising to the general public applies to prescription medicines, non-prescription medicines with names that contain the same fantasy word or the same customary scientific term as a prescription medicine, medicines that are included in the Reimbursement Code of the Austrian Sick Fund, and registered homeopathic drugs. • In addition to the above, several restrictions apply to the content of advertising to the general public, the most

	significant ones being (a complete list can be found in § 53 (1) AMG): – Pictorial representations of HCPs or health institutions; – Elements which make a medical examination or surgical intervention appear superfluous, in particular by offering remote diagnosis or treatment; – Claim of absence of side effects and comparative advertising; – Claims that the drug may improve the patient's normal good health or that it may be harmed if the patient does not take the drug; – Addressed mainly or exclusively to children; – Recommendation by scientists, HCPs or third parties who may encourage the consumption of medicines due to their high profile; – Promotion as a natural product to demonstrate efficacy and safety; – Tempting to incorrect self-diagnosis through detailed description or presentation of the anamnesis. • Medical devices must not be labelled, presented or advertised in a way that is not in accordance with the facts or deceptive. • A general advertising ban towards the general public applies to prescription medical devices, those intended exclusively for use by HCPs on or for the patient and medical devices that according to their instructions for use may only be used by the consumer in connection with medical treatment.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	• Advertising may in principle only be carried out for drugs that are authorised for marketing in Austria. However, it is possible to advertise medicines that do not have a marketing authorisation in Austria to HCPs at international scientific events that are predominantly attended by participants from abroad. • No premium or financial/material benefit may be granted, offered or promised to persons entitled to prescribe or supply medicines in the course of sales promotions. Excluded are benefits of insignificant value and have relevance for the medical or pharmaceutical practice. • Furthermore, the granting of benefits in kind to persons entitled to prescribe or supply medicines is not permitted with respect to medicines that are included in the Reimbursement Code of the Austrian Sick Fund. • Restrictions also apply with regard to the distribution of free medical samples. They can only be distributed upon written request by an HCP in the smallest available packaging and with the imprinted statement "unsellable medical sample" ("*unverkäufliches Ärztemuster*"). Only certain quantities are permitted per doctor.

	• HCPs entitled to prescribe or supply medical devices may not be granted, offered or promised any premiums or financial or material advantages. Excluded are those of low value and of no relevance to medical practice.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	• Advertisements in printed or electronic media or via telecommunication for medicines for which a summary of product characteristics (SmPC) is to be published must contain the essential information about the medicine in accordance with the SmPC in a clearly readable form. • The following information must be included: – Name of the drug; – Qualitative and quantitative composition of active substances; – Fields of application; – Contraindications; – Personal details of the holder of the authorisation or registration; and – Prescription or pharmacy obligation. Furthermore, all sales documents supplied to HCPs authorised to prescribe or supply medicines must, in addition to the short prescribing information, indicate the date on which the documents were drawn up or last amended. • No premium or financial/material benefit may be granted, offered or promised to persons entitled to prescribe, supply or involved in the use of medicinal products in the course of sales promotions. Excluded are benefits of insignificant value that have relevance for the medical or medical-technical practice. Advertisements that are addressed to HPC may not contradict the instructions for use or other information that has been approved in a conformity assessment procedure.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	• Advertisement for medicines directed to the general public must include at least the following information: – Name of the medicine and the scientific name of its active substance (this does not apply in the case of more than one pharmacologically active ingredient); – Information essential for the correct use of the medicine; and – Clearly visible indication that adverse effects may also be caused and that the instructions for use must therefore be strictly observed or the advice of a doctor or pharmacist sought; in acoustic or audiovisual media the indication must be in acoustic form. • Advertisement for medical devices directed to the general public must include at least the following information: – Name of the medical device; – Purpose of the medical device;

		– Information essential for the correct use of the medical device; – Clearly visible indication of possible adverse effects; and – If applicable, clearly visible indication that adverse effects may also be caused and that the instructions for use must therefore be strictly observed or the advice of a doctor, pharmacist or dentist sought; in acoustic or audiovisual media the indication must be in acoustic form.
9.	Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	• Advertising claims (also including retrospective analyses) must be sufficiently scientifically substantiated, and therefore they must be evidence-based. • Scientific information contained in promotional materials must be based on the current state of scientific knowledge. References to "data on file" (unpublished scientific studies, company-internal data, etc.) are not allowed due to the lack of verifiability of the information contained therein.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	• Advertisements directed at the general public must not contain any comparative reference to other medical devices, medications or treatments that represent the advertised product as equivalent or superior. It is forbidden to make individual references, in particular by naming or graphic illustration. The reference to active substances is also prohibited in case the active substance is part of the trade name. • Comparative advertising directed at HCPs is generally permitted. Statements must be up-to-date, verifiable and complete. Quotations, including references, must be reproduced exactly from specialist literature. Furthermore, statements must neither be misleading nor discredit the medical device, the drug or the active substance of a competitor.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	• When advertising on the internet, the general rules apply to both general public and professional advertising. • When operating a website and/or social media page, the rules for service providers according to the E-Commerce Act must be complied with.
12.	Please describe the enforcement mechanism. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	• Control and supervision of the advertising regulations is the responsibility of the Federal Office for Safety in Healthcare (*Bundesamt für Sicherheit und Gesundheitswesen – BASG*). • The BASG can request information, carry out on-site inspections and issue various orders and measures to establish a legally compliant state. • For offences against the advertising provisions, provided that the actions are not subject to criminal sanctions, penalties of EUR 25,000, in the repetition case of EUR 50,000 may be imposed. • Violation of UWG may result in claims for injunctive relief, removal, damages and publication of judgements as well as

	reimbursement of costs. These claims may be asserted by competitors and certain organisations.
13. Any future developments?	• The EU medical device regulation 2017/745 contains advertising related provisions. Advertisements shall not mislead the user or patient by: – Ascribing functions and properties to the device which the device does not have; – Creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have; – Failing to inform on the likely risks associated with the use of the device; – Suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out. • Application of the Medical Device Regulation is postponed by one year until 26 May 2021 due to the outbreak of COVID-19.

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JURISDICTION: Bosnia and Herzegovina

1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	• The primary legal source regarding advertising of medicines and medical devices in Bosnia and Herzegovina is the Law on medicines and medical devices, adopted at state level ("Official Gazette of B&H", No. 58/08) (*Zakon o lijekovima i medicinskim sredstvima*). • The secondary legal source is the Rulebook on the manner of advertising medicines and medical devices ("Official Gazette of B&H" No. 40/2010) (*Pravilnik o načinu oglašavanja lijekova i medicinskih sredstava*).
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	• Yes, there is a Code of Conduct of the Association of Innovative Medicine Manufacturers of Bosnia and Herzegovina (*Udruženje inovativnih proizvođača lijekova u Bosni i Hercegovini-"UIPL")* which governs the advertising of prescription-only medicines to professional public (*stručnoj javnosti*) and communication between healthcare professionals and medicine manufacturers (UIPL is a member of the European Federation of Pharmaceutical Industries and Associations). • In addition, the Agency for medicines and medical devices of Bosnia and Herzegovina (*Agencija za lijekove i medicinska sredstva BiH-"ALMBIH"),* established by the Law on medicines and medical devices is the supervisory body for the field of medicines and medical devices that are manufactured and used in Bosnia and Herzegovina.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	In general, medicines and medical devices are only advertised in B&H on the basis of a marketing authorisation license issued in accordance with the Law on medicines and medical devices of B&H. A legal entity with its seat in B&H, which is a marketing authorization license holder in B&H (or the holder of the certificate of registration in the register of medical devices) must organize its service, or designate a person in charge of advertising and providing information on medicines and medical devices that are placed on the market. The license holder must: • Have at their disposal and at the request of the pharmaceutical inspection, copies of all advertisements, together with an indication to which users they are intended, the method of publication and the date of first publication; • Ensure that the persons who advertise the medicine or medical device to the professional public are properly trained; • Ensure that the decisions of the pharmaceutical inspection regarding the advertising of medicines / medical devices are fully implemented without delay;

	• Provide the pharmaceutical inspection with all the information necessary to monitor the advertising of medicines and medical devices.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	• Yes. • This distinction plays an important role regarding advertisements that are addressed to the general public in such a manner that, while advertising of non-prescription medicines to the general public is permitted under certain conditions, advertising of prescription-only medicines to the general public is generally prohibited (please see below).
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	As a general rule, a medicine cannot be advertised to the general public unless it has an authorisation license, while advertising of a medical device to the general public is not allowed if the medical device does not have a certificate of entry in the register of medical devices. • Pursuant to applicable legislation, it is prohibited to advertise the following medicines to the general public: – Prescription-only medicines; – Medicines issued at the expense of compulsory health insurance; – Medicines containing narcotic drugs or psychotropic substances. In addition, when advertising medicines and medical devices to the general public, it is not allowed to: – State that the medicine or the medical device has no adverse effect; – State that taking/using the medicine or medical device guarantees success in the treatment of the disease; – State that a certain medicine or medical device is undoubtedly better than other medicines or medical devices; – State that it is good to take the medicine and the medical device even when there are no signs of illness; – State that not taking/using some medicines or medical devices may adversely impact health; – State that the medicine or the medical device is safe and effective because of its natural origin; – State that medicines and medical device represent dietary, cosmetic or other product of mass use; – State that using the medicine or medical device may avoid medical examination, advice or surgery and to determine a diagnosis and offer advices about the treatment by post or e-mail; – Indicate that a recommended medicine and medical device may be replaced by other medicine and medical device;

	– Advertise exclusively or mainly to children and where children are shown taking the medicine or medical device, or that a medical device is available to children without the presence of adults; – Include recommendations from healthcare professionals or scientists and recommendations from people who could encourage the use of medicines and medical devices because of their popularity; – Specify the notice of the inclusion of medicine and medical device in the list of medicines and medical devices that are issued at the expense of the compulsory health insurance; – Use the disease history or display diagnostic procedures that could lead to wrong self-diagnosis or self-treatment; – Use of inappropriate, disturbing or misleading expressions and images of changes in the human body caused by disease, injury or effect of some medicine or medical device to the human body or parts of the body; – Refer to inappropriate, harassing or deceptive evidence of healing. Other restrictions are also proscribed such as TV advertising, print media etc.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	During the advertising process to the professional public, main restrictions are that it is not allowed to: • Encourage the professional public that one medicine or medical device can be replaced by another medicine or medical device from the same treatment group without a clear medical indication; • Make statements or conclusions on the efficiency of the medicine or medical device which are subject of clinical trials in the country or abroad; • Advertise a medicine or medicinal device that is in the process of amending the summary of medicine characteristics and the approved patient instruction; • Provide a summary of the medicine characteristics, relevant information from the summary of medicine characteristics, or an approved patient instruction using font sizes less than 3mm or other printing methods that make it unable to read and understand; • Publish the information intended for professional public through the mass media; • Diminish the importance of the warnings on precaution or adverse reactions listed in the approved summary of medicine characteristics; • Diminish the therapeutic value of another medicine or medicinal device or to in any other way raise doubt about the value of another medicine and medical device; • Use the name of the competent Ministry of Health, Agency, or legal entities participating in the examination procedure,

	and placing the medicine or medicinal device on the market; • Use of material protected by any form of intellectual property protection without the prior consent of the owner; • Use of postcards or other forms of written mail whose content may be accessible or readable by persons other than professional public; • Use of the telephone, fax, email or other electronic systems of persons belonging to the professional public without their express prior consent of advertisement. Other restrictions are also proscribed.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	Each advertisement for medicines or medical devices directed only to professional public must contain essential information on the medicine or medical device, identical to those in the summary of medicine characteristics or patient instructions. Advertising to professional public must contain at least the following information: • The number of the authorisation; • The manner of publication; • The name and address of the authorisation holder; • The name and the international name of the active substance(s); • Approved indications, contraindications, precautions and frequent adverse reactions; • The dosage, instructions of use and warnings. All information in the promotional material, that are part of advertising of a medicine / medical device, must be accurate, up-to-date, verifiable and sufficient to enable the professional public to form their own opinion on the therapeutic value of the particular medicine / medical device. In addition, all promotional materials must include a date of production or a date of modification.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	An advertisement for medicines / medical devices that is directed to the general public must include: • The name of the medicine or medical device, or the international name of the medicine; • Information necessary for the proper use of the medicine or the medical device; • Notification for the patient to carefully read the package instructions or the instructions on the external packaging or container.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are	• In general, advertising of medicines and medical devices must provide true and scientifically proven information about medicines and medical devices in compliance with ethical criteria, and in order to ensure their adequate and rational use, without misleading the users. The advertising for the medicine must also be in accordance with the

	based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	summary of main medicine characteristics and the approved medicine manual. • Statements, tables and other graphic material taken from medical journals or other scientific material which are part of the promotional material must be faithfully reproduced with the indication of the exact sources.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	• As stated above, when advertising medicines or a medical devices to the general public, it is not allowed to: – State that a certain medicine or medical device is undoubtedly better than other medicines or medical devices; – Indicate that a recommended medicine and medical device may be replaced by other medicine and medical device. • When advertising medicines and medical devices to a healthcare professional, it is not allowed to: – Encourage the professional public that one medicine or medical device can be replaced by another medicine or medical device from the same treatment group without a clear medical indication; – Diminish the therapeutic value of another medicine or medicinal device or to in any other way raise doubt about the value of another medicine and medical device.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	• In case of internet advertising, the warning ‘‘Read the package leaflet carefully before use. Consult your doctor or pharmacist for information on indications, precautions and adverse reactions to the medicine and the medical device’’ must be an integral part of the main / home page of the advertisement and not its link.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	• Pharmaceutical-inspectorial supervision over the implementation of the relevant law and regulation derived therefrom is performed by the pharmaceutical inspection, i.e. the inspection formed within the Agency for medicines and medical devices of Bosnia and Herzegovina as the relevant supervisory body. • Duties of the pharmaceutical inspection are performed by pharmaceutical inspectors, i.e. Agency inspectors. • A legal person will be issued a fine in the range of 5.000 BAM to 15.000 BAM (approx. 2.555 EUR to 7.670 EUR) if it does not comply with the relevant provisions related to the advertisement of medicines or medical devices.
13.	Any future developments in your jurisdiction?	• An initiative to prepare and submit a proposal for the new Law on medicines and medical devices of B&H as soon as possible in order to harmonize this regulation with the new EU regulations was recently accepted at the Parliamentary Assembly of B&H.

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JURISDICTION: Bulgaria

1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	• Medicines – The advertising of medicinal products is mainly regulated under the Medicinal Products in Human Medicine Act, promulgated in State Gazette Issue 31, dated 13 April 2007, as amended ("**MPHMA**"). – Regulation No 1 dated 25 January 2012 on the requirements for the advertising of medicinal products, promulgated in State Gazette Issue 10, dated 3 February 2002 ("**Regulation**"). • Medical Devices – The Medical Devices Act, promulgated in State Gazette Issue 46, dated 12 June 2007, as amended ("**MDA**"). – Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ("**Regulation 745**"). – Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU ("**Regulation 746**"). Other general pieces of legislation that can apply as well include: – The Protection of Consumers Act, promulgated in State Gazette Issue 99, dated 9 December 2005, as amended ("**PCA**"). – The Competition Protection Act, promulgated in State Gazette Issue 102, dated 28 November 2008, as amended ("**CPA**"). – The Radio and Television Act, promulgated in State Gazette Issue 138, dated 24 November 1998, as amended ("**RTA**"). – The Code of Professional Ethics of Healthcare Practitioners in Bulgaria, promulgated in State Gazette Issue 79, dated 29 September 2000, as amended ("**Code of Ethics**"). – The Code of Professional Ethics of Dental Healthcare Practitioners in Bulgaria, promulgated in State Gazette Issue 34, dated 25 April 2006, as amended ("**Dental Code of Ethics**").

2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	• Medicines Yes. The main codes of conduct are the following: the Code of Ethics of the Bulgarian Generic Pharmaceutical Association (BGPharma); and the Code of Ethics of the Research-Based Pharmaceutical Industry in Bulgaria (last amended on 22 October 2014) ("**Arpharm Code**"). • Medical Devices The general legal regulations applicable to advertising apply with respect to medical devices along with the ethics codes applicable to advertisement professionals (the National Advertising and Commercial Communication Ethics Rules of Bulgaria adopted on 25 September 2009 by the National Council for Self-Regulation) and healthcare professionals, e.g. the Code of Ethics and the Dental Code of Ethics mentioned above.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	• The general public: – Advertising of a medicinal product shall be authorised in advance by the Executive Director of the Bulgarian Drug Agency ("**BDA**"). For this purpose, the marketing authorisation holder shall submit to the BDA a standard application, enclosed with a set of documents, including, inter alia, a project of the advertising, which should be clear, contain understandable text and allow evaluation of all of elements of the advertising. – The project of the advertising is subject to assessment by the Advertising Expert Council with the BDA. If the project is considered not compliant with the requirements of the MPHMA, the BDA would issue to the applicant an instruction to remedy the default within a one-month term. – The timeline for providing the advertising authorisation or motivated refusal is one month as of the date of filing of the application. The advertising could also be considered tacitly approved, if the BDA has not issued a motivated refusal within the statutory term. – The advertising authorisation is specific to the medicinal product and will only be valid for the term of validity of the marketing authorisation. • Healthcare professionals ("**HCPs**"): The advertising to HCPs is not subject to authorisation, but to a notification procedure to the BDA, whereby the applicant submits an advertising project, in accordance with the requirements of the MPHMA and the Regulation. No specific licenses/approvals/fees are required for medical devices to be advertised to either the general public or healthcare professionals.

4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	• Yes. POMs cannot be advertised to the general public.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	• Medicines As a general note (applicable to both POMs and OTCs) advertising shall be allowed only for medicinal products for which a marketing authorisation has been issued. The content of the advertisement must correspond to data from the medicinal product summary approved in the course of the marketing authorisation and shall present only indications specified in the course of the marketing authorisation. The advertisement of a medicinal product must only suggest its correct use, objectively presenting its therapeutic indications, without exaggerating possibilities for treatment, prevention or diagnosis using the medicinal product concerned. The advertisement must not contain misleading information. The advertisement may not contain an offer and/or promise of a gift and/or another material or nonmaterial benefit. A medical specialist or a person claiming to be a medical specialist may not engage in direct or indirect advertising of medicinal products in the printed and/or electronic media, as well as on the internet. In addition to the above, advertising to the general public is regulated by the MPHMA and the Regulation. The general requirements for advertising shall apply. The MPHMA specifies that only non- prescription drugs (OTCs) can be subject to promotion and advertising to the general public. The Regulation provides further details with respect to the content of over- the-counter advertising to the general public. As a general statement, the advertising of medicinal products intended for the general public including in the premises or on the windows display of pharmacies and drug stores shall be clearly identifiable as advertising of a medicinal product. The Regulation provides a list of forbidden content when advertising to the general public, including advertising creating the impression that the use of the medicinal product excludes the necessity of medical consultation or surgical intervention; or implies that the effects of the medicinal product are guaranteed without side effects, or that human health can be improved upon using the medicinal product. This list is not exhaustive. The Regulation also prohibits advertising of narcotics and the provision of samples to the general public. According to the National Advertising and Commercial Communication Ethics Rules of Bulgaria, medicines, disinfection liquids, cleaning materials, acids, washing

	powders and any products hazardous for health should not been shown as accessible for children without parental supervision and no children using such materials should be shown in commercial communication. • Medical Devices According to Regulations 745 and 746, in the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by: – Ascribing functions and properties to the device which the device does not have; – Creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have; – Failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; – Suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out. Only CE marked medical devices may be promoted and placed on the market. Non-CE marked medical devices may be exhibited at trade fair and exhibitions. No national specific restrictions applicable to the advertising of medical devices exist apart from the general rules applicable to advertising in general. In addition to that, according to the Code of Ethics, any signs or symbols on the plates in front of doctors' offices, on letterheads and prescriptions, in phonebooks and other materials shall not have the nature of an advertisement.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	• Medicines The general requirements for advertising of medicinal products (as stated in the previous section 5) shall apply. In addition, the Regulation enumerates the content of advertising to healthcare professionals. It is forbidden to indicate in advertising materials any data from unpublished trials or research or with unverified clinical importance, as well as to exclude or "downplay" contra indications or adverse events. The information contained in the advertising shall be accurate, updated, exhaustive and verifiable and shall allow healthcare professionals to develop their own opinion on the therapeutic importance of the medicinal product. Tables, citations or other information taken from published medicinal literature shall be accurately reproduced and the source correctly provided.

	• Medical Devices The general requirements for advertising of medicinal products (as stated in the previous section 5) shall apply.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	• Medicines The Regulation enumerates the content of advertising to healthcare professionals: – Information complying with the data of the Summary Patient Notice, where the date of its last approval is indicated; – Means of prescribing of the medicinal product; – Quality and quantity composition, INN of the active and additional substance if necessary for the proper use of the medicinal product; – Name and address of the marketing authorisation holder, or its authorised representative, where healthcare professionals may receive full information on the advertised medicinal product. The advertising may include the price and conditions for entire or partial reimbursement by the National Health Insurance Fund. • Medical Devices There are no specific requirements applicable to the information that must appear in advertisements directed only to healthcare professionals for medical devices.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	• Medicines The advertising of medicines to the general public shall contain: – The trade name of the medicinal product and its INN; – Express information that this advertising is for a medicinal product; – Information necessary for the correct use of the medicinal product; – Age limit above which the medicinal product can be used; – The statement: “Read the patient notice before use”; – The statement: “Homeopathic product” if it is one; – Reminder of the necessity of renewal of the vaccination, where relevant in vaccination advertising; and – The number and date of the authorisation for advertising or of the application in case of tacit authorisation. Further requirements may be applicable depending on the type of product and advertising used.

		• Medical Devices According to Regulations 745 and 746, in the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by: – Ascribing functions and properties to the device which the device does not have; – Creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have; – Failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; – Suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out. There are no national specific requirements applicable to the information that must appear in advertisements directed to the general public for medical devices except the requirement that the purpose of use of the medical device has to be indicated in, among others, advertising materials.
9.	Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	• As noted above, tables, citations or other information taken from published medicinal literature shall be accurately reproduced and the source correctly provided in the advertisement to HCPs. • It is forbidden to indicate in advertising materials any data from unpublished trials or research or with unverified clinical importance. • The purpose of use of a medical device shall be the purpose of use indicated on the label provided by the manufacturer, in the instructions for use and/or advertising materials.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	There are no specific rules in the MPHMA or Regulation regarding comparative advertising. However, the competition law rules will apply. Comparative advertising is allowed in cases expressly provided for under the CPA, specifically if: • It is not misleading and does not constitute unfair commercial practice; • It compares goods or services meeting the same needs or intended for the same use; • It compares objectively one or more characteristic features of the goods and services which are essential, comparable and representative of such goods and services, including their prices; • Does not lead to confusion between the advertiser and its competitors, or between its trademarks, brand names, other

	distinctive features, goods and services and those of its competitors; • Does not discredit or defame competitors' trademarks, brand names, other characteristic features, goods, services, activities or positions; • Compares goods having the same designation of origin; • Does not take unfair advantage of the popularity of the competitors' trademark, brand name or other distinctive features of the competitors or the designation of origin of competing goods; • Does not present the goods or services as an imitation or copy of goods or services with a registered trademark or brand name. The Arpharm Code contains specific requirements with respect to comparative advertising. Any promotion and advertising, which points directly or indirectly to a competitor or to a product of a competitor, is considered comparative promotion and advertising. The information and statements contained in comparative promotion and advertising must comply with the Arpharm Code, be factually correct and be proved through reference to the respective source. When comparative advertising refers to studies that were not intended to directly compare the properties and characteristics of the advertised medicinal products or create for comparisons, this must be explicitly stated in the advertisements. Comparative advertising is forbidden if it: • Specifies medicinal products that have different therapeutic indications in comparison with the medicinal product that is the subject of the promotion or advertising; • Does not objectively clarify one or several of the main, relevant properties and peculiarities of the medicinal products concerned; • Creates confusion in respect to the company conducting the promotion and advertising and its competitors, or with respect to the medicinal products subject of the promotion and advertising, as well as to the medicinal products used as comparison, or regarding the trademarks of the medicinal products specified; • Contains statements defining the medicinal products used for comparison as an "imitation or copy" of the medicinal product, which is the subject of the promotion or advertising; • Contains unfavourable statements concerning the products, activity, personal or business standing of a competitor or its employees; or if • Contains the brand name of the competitive medicinal product or the name of the competitor.

11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	• Internet advertising is briefly regulated under the MPHMA. The Arpharm Code expressly provides that it covers the cases of advertising by Internet, without further detail. Compliance of Internet advertising and the MPHMA or Arpharm Code is controlled by the BDA and the Arpharm Ethics Committee, respectively. • The general prohibition of advertising of medicinal products subject to medical prescription applies to Internet advertising, with the exception of campaigns for vaccination conducted by the marketing authorisation holder, as approved by the BDA.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	The competent authority to monitor compliance of advertising with the MPHMA is the Executive Director of the BDA. The observance of the ARPharM Code is controlled by the Arpharm Ethics Committee. Other competent authorities are the Competition Protection Commission ("**CPC**") and the Consumer Protection Commission. • Penalties under the MPHMA: The MPHMA provides for monetary sanctions of different levels depending on the type of breach and the person in breach. The sanctions for violations of the provisions in relation to advertising of medicinal products can amount up to 10,000 EUR. Broadcasters, publishers and distributors of the advertising are also subject to sanctions if they are found to be in breach of the MPHMA provisions. • Penalties under the Arpharm Code: The monetary sanctions range between 1,000 EUR to 3,500 EUR, depending on the nature and seriousness of the offence. • Competition law sanctions: The CPA expressly forbids certain types of misleading and comparative advertising. The sanctions imposed by the CPC in cases of a breach of the CPA provisions are very severe. They can be up to 10% of the aggregate annual turnover of the infringer for the previous financial year. Affected competitors may bring damages claims before the regular civil courts in case they have suffered damages in result of such breach. • Consumer law sanctions: Sanctions for violation of the prohibition for offering or selling POMs through distant means of communication can be up to EUR 7,500. Other violations (concerning certain provisions as regards unfair commercial practices) can be punished with up to EUR 25,000 per occurrence.

13. Any future developments in your jurisdiction?	• With respect to the advertisement of medicinal products, there are no future developments envisaged in the short-term. Regarding medical devices, it can be expected that national legislation will be aligned with Regulations 745 and 746 at some point despite the direct application of the regulations.

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JURISDICTION:	China
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	• The main laws and regulations which are applicable regarding advertising of **medicines** in the People's Republic of China ("**PRC**") include the: – Advertising Law of the PRC; – Interim Measures for the Administration of Internet Advertising; – Drug Administration Law; – Implementing Regulations of the Drug Administration Law; and – Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Dietary Supplements and Foods for Special Medical Purpose. • The main laws and regulations which are applicable regarding advertising of **medical devices** in the PRC include the: – Advertising Law of the PRC; – Interim Measures for the Administration of Internet Advertising; – Regulations on Supervision and Administration of Medical Devices; – Measures for the Management of Medical Device Advertisements; and – Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Dietary Supplements and Foods for Special Medical Purpose.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	Yes, there are other legal regimes that govern the advertising of medicine and medical devices in the PRC. Code of practice covering all advertisements: • The Industry Self-Regulatory Codes of China Advertising Association ("**CAA**"). Code of practice covering **medicines**: • The Code of Practice of the R&D-based Pharmaceutical Association Committee ("**RDPAC**"). Code of practice covering **medical devices**: • The Ethics with Interaction with Chinese Healthcare Professionals published by China Association for Medical Device Industry ("**CAMDI**").
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to:	Medicines • Non-prescription drugs can be advertised to both the general public and healthcare professionals upon approval from the local provincial branches of the National Medical

a) the general public? b) healthcare professionals?	Products Administration ("**NMPA**") where the applicant (drug licence holder or authorised distributor, Chinese agent of imported drugs) is located. If the advertisement is to be announced out of the approved province, a record shall be filed with the local authorities located in the location that the advert is to be published. Please note that, if the advertisement only publicizes the name of a non-prescription drug, such approval is not required. • Prescription drugs shall not be advertised on mass media or promoted in any other manner targeting the public. Prescription drugs may be advertised on the medical or pharmaceutical journals jointly approved by the National Health Commission and NMPA. The approval and record regimes for prescription drugs is the same as the corresponding regimes for non-prescription drugs. Similarly, if the advertisement only publicizes the name of a prescription drug, approval is not required. Medical Devices • Medical device advertisements are under a similar approval regime with the above-mentioned drug advertisements. There are no different requirements for advertisements targeting public and healthcare professionals.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes. In the PRC, the law regulates prescription drugs and non-prescription drugs differently. For prescriptions-only medicine: • Prescription drugs may be advertised on the medical or pharmaceutical journals jointly approved by the Ministry of Health and NMPA, but shall not be advertised on mass media or promoted in any other manner targeting at the public. • Pharmaceutical companies are prohibited from distributing medical or pharmaceutical journals which contain prescription drug advertisements to the public for free. • Where the name of a prescription drug is the same as its trademark or business name of the manufacturer, the trademark or business name in question shall not be used on any media other than medical or pharmaceutical journals. • The name of a prescription drug or the trademark and business name which are registered with the name of a prescription drug shall not be used to name various events. • The warning to be used in prescription drug advertisements must be "This advertisement is for pharmaceutical professionals only". For over-the-counter medicines: • A non-prescription drug advertisement shall not contain difficult or confusing medical or pharmaceutical terms which may mislead the public about the effect and safety of the proposed drugs.

	• Non-prescription drugs can be advertised on mass media or promoted in other manners targeting the public. • A non-prescription drug advertisement must ensure that it is clearly non-prescription, by indicating in the advertisement the over-the-counter (OTC) logo. • The warning to be used in non-prescription drug advertisements must be “Please consult the instruction or a pharmacist before purchase and use”. • Where the name of a non-prescription drug is used in an activity, releasing the product name of the drug in question is sufficient.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	The general restrictions on advertising medicines and medical devices can be divided into restrictions concerning products and restrictions concerning advertisements themselves. Medicines • Restrictions concerning drugs – It is strictly forbidden to make advertisements for anesthetics, psychotropic drugs, toxic drugs and radioactive drugs. – Formulations prepared by medical institutions, drugs that do not have a Drug Licence and drugs specifically required by the army may not be advertised. • Restrictions concerning advertisements for drugs – Adverts must include the general name of the drug, information, drug advertisement licence number and drug production licence number, and the name of the manufacturing or trading enterprise. – The information provided should be true and in accordance with the law and the approved registration information. The advert must not contain any information that is false, unscientific, or a categorical assertion or warranty of any described function. – Adverts shall not be released in publications for minors or broadcasted in TV channels, programs or sections for minors. • Please note that the above regimes apply for both the advertisements of non-prescription drugs to the general public and the advertisements of prescription drugs for healthcare professionals only. Medical Devices • Restrictions concerning medical devices – Adverts for specific devices are forbidden by NMPA from manufacturing, trading or using. – Adverts for devices for medical institution’s internal use are prohibited. • Restrictions concerning advertisements for medical devices

	– Adverts must contain the name of the approved medical device, the name of the manufacturing enterprise, registration certificate number and advertisement licence number. – All information must conform to the product certificate issued by the NMPA. – Medical devices may not target children. Adverts must not be published in children publications, media channels, programs or columns.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	Medicines • Please see above answer for Q5. Medical Devices • The main restrictions applicable to the advertising of medical devices to healthcare professionals are similar to the restrictions to the general public. Please see the answer for Q5.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	Medicines • As mentioned above, advertisements for prescription drugs directed only to healthcare professionals for medicines shall include: – The common name of the proposed drug; – The warning; – Pharmaceutical advertisement approval number; – Drug approval number; – The name of the drug manufacturer or trader; – Advertisements for prescription drugs shall further be prominently marked with the words "this advertisement is for medical and pharmaceutical professionals to read only". Medical Devices • The regulatory regime does not distinguish the requirements on the advertisements for the general public and healthcare professionals. The information that must appear in advertisements must include: – The approved name of the medical device; – The name of the medical device manufacturer; – The certificate number of the medical device; and – The medical device advertisement approval number. • Further, advertisements for medical device products recommended for personal use must be marked: “Please read the product manual carefully or purchase and use it under the guidance of medical staff”. In case of contraindications or precautions in the registration certificate of a medical device, the advertisement shall

	prominently indicate the words "Detailed contraindications and precautions can be found in the instructions".
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	Medicines • As explained above, the requirements for the non-prescription drug adverts must be the same as the content of adverts set out in Q7. • Those for over-the-counter (OTC) drugs shall further be prominently marked with the logo for OTC drugs and the words "please buy and use following the drug instructions or under the guidance of pharmacists". Medical Devices • Please see answers for Q7.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	Any data, statistics, research result, summary, quotation and other quoted information used in an advertisement shall be authentic and accurate, with the source indicated. If the quoted information is subject to a scope of application or a valid period, the scope of application or valid period shall be clearly indicated. Regarding content specifying the rate of cure or effectiveness and content such as “research findings”, “experiments or data proofs” that cannot be scientifically proven, these should not be contained in the medicine advertisements or medical device advertisements.
10. Are there specific rules for comparative advertisement of medicines and medical devices?	Yes. Information about comparing the effectiveness or safety of the proposed drugs or medical devices with that of others must not be advertised.
11. Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	Yes. Interim Measures for the Administration of Internet Advertising is a general regulation that covers all internet advertisement. In addition to the general rules for online advertising, direct communication such as E-mails and text messages that contain advertisements must only be sent with the consent of the receiver. The Interim Measures for the Administration of Internet Advertising also provides specific rules for medical advertisement: • Medicines and medical devices cannot be published on the internet without examination and approval. • The internet or the social media postings shall not publish in disguised form advertisements for medical treatment, pharmaceuticals, medical devices and healthcare food by way of introducing knowledge on health or health maintenance or by other means.
12. Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	As mentioned above, the provincial level branches of NMPA will examine and approve the medical advertisements. The local branches of the State Administration for Market Regulation (“**SAMR**”) of different levels will be in charge of the enforcement against any illegal advertisements, including supervising and punishing such illegal advertisements.

	Non-compliance advertisements may be subject to the liabilities below: • Civil liability for damaging the consumers' interests. • Administrative liability including: – An order for the cessation of the publishing of advertisements; – An order for the advertisers to eliminate the ill-effects within a specified corresponding scope; – Fines up to 2 million RMB or a multiple (3x10x) of total advertising fees (e.g. up to 5 times for foods making disease treatment or prevention claims); – Revocation of business licence; – Revocation of the approval for advertisement; and – Prohibition from publishing advertising for one year. • Criminal liability – Fixed-term imprisonment of not more than two years of criminal detention; and/or – Fine.
13. Any future developments in your jurisdiction?	The SAMR issued the Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Dietary Supplements and Foods for Special Medical Purpose ("**Interim Measures**") on 24 December 2019, which took effect on 1 March 2020. The Interim Measures are an overall regulation, which unified the different regulations that apply to advertisements of different medical products. According to the Interim Measures, the competent regulatory authority for such advertisements is the SAMR and its provincial local branches. The Interim Measures provide the standards of reviewing such advertisements, which generally clarify what can and cannot be contained in an advertisement and the kind of products prohibited from advertising. The Interim Measures also set up an online unified review and approval process for the advertisements of different products and also establish a publication regime, which publishes the advertisements approved for public viewing. After the implementation of the Interim Measures, the Measures on the Examination and Approval of Drug Advertisements; the Standards for Examining and Publication of Drug Advertisements; the Standards for Examining and Publication Medical Device Advertisements and the Measures on the Examination and Approval of Medical Devices Advertisements were abolished.

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JURISDICTION: Colombia	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	Decree 677/1995 • Resolution 4536/1996 • Resolution 4320/2004 Decree 4725/2005
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	It exists indeed a self-regulatory code for medicaments advertisement, issued by the R&D pharma products Guild (called Afridro). However, this is not really enforceable, it is merely a self-regulating list of best practices.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	OTC medicines may obtain approval before the National Medicines Market Approval Authority called INVIMA for advertisement pieces for the general public. This procedure needs to be conducted prior to the advertisement pieces being used. The same applies for low risk medical devices. Prescription medicines and high risk medical devices cannot be advertised to the general public. Medical information material addressed to healthcare professional is allowed and does not need to the approved by INVIMA.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes. Prescription-only cannot be advertised to the general public, but OTC may indeed.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	Cannot contravene general rules applicable to education, health, nutrition or therapeutic. Cannot be untrue or deceitful. Cannot make pejorative comparison for other brands, products, or companies. For prescription products, promotions, raffles or the like are not allowed. Must have been previously approved by INVIMA. Must be truthful and not deceitful.

6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	Must be truthful and not deceitful. Must be truthful and not deceitful.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	In the materials addressed to the health professionals, indications and therapeutic uses must be specified without omitting contraindications, side effects, administration and drug dependence risks, precautions and warnings known by the manufacturers. No specific requirements but all information must comply with the technical evidence available.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	The following phrases must be included in the advertisement: It is a medicine; Do not exceed your consumption; market approval number; Read indications and contraindications; If symptoms persist, consult a doctor. “ No specific phrases or wording are required.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	There are no specific requirements as per the scientific data to be included in advertisements. Generally, no advertisement pieces addressed to the general public include in-depth scientific information. Pieces addressed to healthcare professionals include in-depth scientific data, but there are no specific requirements, as long such information may be considered truthful and not deceitful.
10. Are there specific rules for comparative advertisement of medicines and medical devices?	No. General rules for comparative advertisement (it is allowed in the country) applies.
11. Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	No. General rules for advertisement, notwithstanding the media in which it is promoted, apply to Internet postings.
12. Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	INVIMA monitors the market, and in case non-compliant, non-approved advertisement is detected, an administrative probe will be started. The main penalty as a consequence of this probe is normally a fine. However, in extreme cases the penalty may be the cancellation of the market approval for the product.

13. Any future developments in your jurisdiction?	Not that we are aware of.

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JURISDICTION: Croatia	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	a) Medicines Primary legal sources are: – the Medicines Act (Croatian: "***Zakon o lijekovima***"); – - the Bylaw on Advertising of Medicines (Croatian: "***Pravilnik o načinu oglašavanja o lijekovima***"); and – - the Act on Preventing Conflicts of Interest (Croatian: "***Zakon o sprječavanju sukoba interesa***"). b) Medical Devices Primary legal sources are: – the Medical Devices Act (Croatian: "***Zakon o medicinskim proizvodima***"); – the Act on the Implementation of Regulation (EU) 2017/745 on Medical Products and Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices (Croatian: "***Zakon o provedbi Uredbe (EU) 2017/745 o medicinskim proizvodima i Uredbe (EU) 2017/746 o in vitro dijagnostičkim medicinskim proizvodima***"); and – the Act on Preventing Conflicts of Interest (Croatian: "***Zakon o sprječavanju sukoba interesa***")
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	a) Medicines Yes, there are industry codes, such as the Code of conduct of innovative pharmaceutical companies of the Croatian Association of Innovative Pharmaceutical Initiative ("***iF!***"). b) Medical Devices No code of conduct yet. However, CROMED - (Croatian: "***Udruga industrije medicinskih proizvoda***") was established in 2017, as a national association of MedTech Europe.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	a) Medicine No particular licence / approval is necessary specifically for advertising, but there are statutory limitations as to what can be advertised. Croatian legislation considers advertising of a medicine as any form of information intended to encourage their prescribing, issuance, sale and consumption in written, oral, pictorial, audio, electronic, digital or other form. Prescription-only products medicine can be advertised only to healthcare professionals (as well as in in professional literature, at professional and scientific conferences), while advertising such medicine to the general public is forbidden. The latter prohibition does not apply to public health activities for the promotion of immunization, seroprophylaxis and chemoprophylaxis according to the program adopted by the Minister in accordance with the

	Law on Protection of the Population from Infectious Diseases. Over-the-counter medicines can be advertised both to the general public and to healthcare professionals. Moreover, advertising of a medicine that does not have a marketing authorization in the Republic of Croatia is forbidden, except at professional and scientific conferences and in the professional literature (provided that the procedure for granting a marketing authorization in accordance with is initiated and that only the common name of the drug is used, without specifying the manufacturer). In any case, it is forbidden to state in the advertisement that the medicine has curative properties if it does not have the approval for marketing as a medicine, or if it is not registered as a traditional herbal medicine. b) Medical devices Advertising of medical device is allowed towards both the general public and healthcare professionals only if such devise meet the legal requirements prescribed by the Medical Devices Act. The exception to this rule is envisaged for medical devices intended for exhibitions, demonstrations, fairs, etc. Such products must have a visible sign that they are not intended for placing on the market or putting into use. Medical devices intended exclusively for use within healthcare industry activities may be advertised solely to healthcare professionals. Any misleading claims about the medical devices are expressly forbidden.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes. The distinction plays an important role regarding advertisements that are addressed to the general public. While advertising of over-the-counter medicines to the general public is permitted under certain conditions as listed below, advertising of prescription-only medicines to the general public is generally prohibited. Conditions that need to be fulfilled in order to advertise an over-the-counter medicine to the general public are: • The advertisement needs to contain: (i) at least information listed in Q 8(a); (ii) a declaration stating: “Read the package leaflet carefully before use and ask your doctor or pharmacist for the risks and side effects” (“*Prije upotrebe pažljivo pročitajte uputu o lijeku, a o rizicima i nuspojavama upitajte svog liječnika ili ljekarnika*”); and (iii) must not be misleading and it must be clearly visible that is an advertisement. • The text “Paid medicine advertisement” (“*Plaćeni oglas o lijeku*”) should appear on the visible part of an article (i.e. print or published on the Internet) with a font size equal to or larger than the font size of other content of the article.

5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	a) Medicines Advertising is forbidden as explained under Q 3. Therefore, the main restrictions applicable to the advertising of over-the-counter medicines are: – Advertising may only be carried out for medicines that have marketing authorisation approval for the territory of Croatia. However, if the procedure of a marketing authorisation has been initiated and if only a common name is used as a name of the medicine without specifying the manufacturer, then it would be allowed to advertise such medicines in the literature or at professional/scientific meetings (this restriction does not apply to scientific and professional international conferences held in the Republic of Croatia); and – Advertising must be objective, must not contain any exaggeration of effects or guarantees of success and must be compatible with the product labelling, instructions for use (IFU) and summary of product characteristics (SmPC); – Print articles and articles published on the Internet must contain a statement: "Paid advertisement on the medicine" ("*Plaćeni oglas o lijeku*"), which should appear on the visible part of the article with a font size equal to or larger than the font size of the other content in the article. Further, several restrictions as to the content of advertising of the over-the-counter medicines to the general public, the most significant ones being (a complete list can be found in Article 10 of the Bylaw on Advertising of Medicines): – Forbidden use of a claim on absence of side effects/non-toxic/no risk of addiction; – Forbidden use of a claim that a medicine may improve the patient's health or that patient's health may be harmed if the patient does not take the medicine; – Advertising claim must not be addressed mainly or exclusively to children; – Advertising claim must not contain a recommendation by scientists, HCPs or third parties who may encourage the consumption of medicines due to their high profile; and – Advertising claim must not contain a promotion as a natural product to demonstrate efficiency and safety. b) Medical Devices It is prohibited to advertise medical devices which do not meet the requirements prescribed by the Law on Medical Devices, except for medical devices intended for exhibitions, demonstrations, fairs etc. Such products must have a visible label indicating that they are not intended for placing on the market nor for use.

	Misleading advertising of medical devices is forbidden. Advertising of medical devices must not contain information listed in Q 8(b).
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	a) Medicines The main restrictions applicable to the advertising of medicines to HCPs (a complete list can be found in Articles 15 and 22 of the Bylaw on Advertising of Medicines) are: – Forbidden use of a claim which suggest that a medicine or its active substance has any particular characteristics, quality or effect, if such claim cannot be based on evidence; – The word “safe” must not be used when describing a medicine without the necessary explanation; – The word “new” must not be used to describe a specific medicine of the MA holder which is available in the Republic of Croatia for a period exceeding one year from the date of placing on the market; – No premium or financial/material benefit may be granted, offered or promised to persons entitled to prescribe or supply medicines in the course of sales promotions. Excluded are benefits of insignificant value i.e. HRK 70.00 (VAT excluded) and have relevance for the medical or pharmaceutical practice. HCPs restrictions of HRK 70 applies to HCP employed in public health institutions. However, HCPs employed in private health institutions are subject to anticorruption and criminal law; and – Free medical samples can only be distributed upon written request by HCP in the smallest available packaging and with the imprinted statement “Free medical sample – not for resale” (“*besplatni uzorak – nije za prodaju*”). Only certain quantities are permitted per doctor. b) Medical Devices Advertising is forbidden in cases as explained under Q 3(b). When advertising medical devices to HCPs authorised to recommend, prescribe and issue medical devices, it is not permitted to provide any gifts or items or promise of a reward or a privilege, unless they do not exceed a value of HRK 70.00 (VAT excluded) and are related to the practice of the HCP. Such gifts may not be provided in response to a request from HCP. HCPs restrictions of HRK 70.00 applies to HCP employed in public health institutions. HCPs employed in private health institutions are subject to anticorruption and criminal law.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines?	a) Medicines The following information must appear in advertisements directed only to HCPs:

b) medical devices?	– Essential information on the medicine in accordance with the information given in the SmPC and the approved package leaflet in the Republic of Croatia; – Whether it is issued based on the prescription or over the counter; – Personal details of the marketing authorisation holder; – Name of the medicine and international name of the active substance; – Approved indications and contraindications; – Precautions and frequent side effects; – Dosage and method of use and warnings; and – Last approved SmPC and package leaflet. Promotional materials addressed only for HCPs must contain a statement: "Only for HCPs" (Croatian: "*Samo za zdravstvene radnike*") and must indicate the date on which they were drawn up or last amended. b) Medical Devices The Law on Medical Devices prescribes only information which are not allowed to be used in advertisement. For further information please refer to Q 8(b). Please note that, medical devices intended to be used solely for the purpose of performing a health care activity may be advertised exclusively to healthcare professionals.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	a) Medicines Advertisement for over-the-counter medicines directed to the general public must include at least the following information: – Name of the medicine and the scientific name of its active substance (this does not apply in the case of more than one pharmacologically active ingredient); – Information essential for the correct use of the medicine; and – Clearly visible indication that adverse effects may also be caused and that the instructions for use must therefore be strictly observed or the advice of a doctor or pharmacist sought; in acoustic or audio-visual media the indication must be in acoustic form. b) Medical Devices The Law on Medical Devices prescribes only information which are not allowed to be used in advertisement. Therefore, several restrictions as to the content of advertising of the medical devices, (a complete list can be found in Article 60) are: – Advertising claim must not be addressed mainly or exclusively to children;

		– Advertising claim must not encourage the abandonment of basic generally accepted therapeutic procedures; – Advertising claim must not endanger human dignity; and – Advertising claim must not contain a promotion as a natural product to demonstrate efficiency and safety.
9.	Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	Advertising on medicines to the general public must not contain scientists or HCPs statements which would, based on their health care reputation, encourage to use medicine. On the other hand, scientific information (e.g. citations, tables) taken from medical journals or other scientific papers for the purpose of promotion of the medicines to the HCPs must be faithfully transmitted. Advertising on medical devices to the general public must not contain: a) unfamiliar scientific terms for common medical conditions; and b) scientists or HCPs statements which would, based on their health care reputation, help with the promotion of a medical device. Condition under b) applies as well on advertising of medicines to the general public.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	Comparative advertisement of medicines and medical devices is not permitted (i.e. must not contain any comparative reference to other medical devices/medicines).
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	Yes, there are specific provisions for advertisement of medicines on the internet/in social media. As a general rule, it is permitted to advertise medicines on the internet, in accordance with the Bylaw on Advertising of Medicines. In addition, the content of websites should be separated, according to the category of users into the section intended for the: a) general public; and for b) HCPs. Also, it must be updated regularly (i.e. for each webpage/topic unequivocally displayed the date when the content was last modified). Websites which are intended solely for the HCPs need to be protected by the username and the password. Websites which are available to use by the general public may contain the list of prescription-only medicines, only if the name of the medication and faithful reproduction of approved instructions for the drug are also listed. Further, when advertising over-the-counter medicine on the internet, it is mandatory to state (in the advertisement or notice): “Read the package leaflet carefully before use and ask your doctor or pharmacist for the risks and side effects” (“*Prije upotrebe pažljivo pročitajte uputu o lijeku, a o rizicima i nuspojavama upitajte svog liječnika ili ljekarnika*”). The warning must be an integral part of the advertisement (i.e. not a link). In case of television advertisement, the subject warning must be displayed independently (i.e. in a separate frame) and clearly readable. Advertising of the medicine must not be misleading and must be clearly visible that it is an advertisement. For print articles and

		articles published on the Internet in which the medicine is advertised, the text "Paid medicine advertisement" ("*Plaćeni oglas o lijeku*") should appear on the visible part of the article with a font size equal to or larger than the font size in other parts of this article. (A complete list of provisions can be found in Article 23 of the Bylaw on Advertising of Medicines). When advertising medical products on the internet, the general rules apply to both general public and professional advertising.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	Control and supervision of the advertising regulations is the responsibility of the Pharmaceutical Inspection of the Ministry of Health (*Farmaceutska inspekcija Ministarstva zdravstva*). The subject inspection can request information, carry out on-site inspections and issue various orders and measures to establish a legally compliant state. The claims may be asserted by competitors and certain organisations. The Medicines Act prescribes monetary penalties in the amount of approx. EUR 13,333.00 to EUR 20,000,00 for responsible (legal or natural) person which advertise medicines contrary to the provisions of the mentioned act. The Law on the Implementation of Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices prescribes monetary penalties in the amount of approx. EUR 13,333.00 to EUR 93,000.00 for legal person in case of advertising a medical device, by using text, names, trademarks, images or symbols that could mislead the user or patient as to: • purpose of the medical device and its safety by attributing to the product functions and features that it does not have; • creating the wrong impression regarding treatment or diagnosis, functions or properties that the medical device does not have; • failing to inform of the potential risk associated with the use of the medical device in accordance with its intended use. Competition law risks are mainly for payments/advantages granted to HCPs/labs, driving patient footfall and therefore earnings for the included HCPs/labs.
13.	Any future developments in your jurisdiction?	• Currently, there are no future developments envisaged, with respect to the advertisement of medicines/medical devices.

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JURISDICTION: Czech Republic

1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	The main law applicable for advertising in general, inclusive for medicines and medical devices, is Act No. 40/1995 Coll., on the Regulation of Advertising, as amended (the "**Advertising Act**") and Act No. 89/2012 Coll., the Civil Code, as amended (the "**Civil Code**").
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	There are several associations which associate manufacturers / suppliers of medicines or medical devices. Such associations usually have their internal codes of conduct which are binding upon the members of such associations. In relation to medicines, the most active in the Czech Republic is the Association of Innovative Pharmaceutical Industry (AIFP), which is a Czech member of EFPIA. In relation to medical devices, the most active in the Czech Republic is Czech Association of Suppliers of Medical Devices (CzechMed).
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	There are no specific licenses / approvals / fees required for medicines or medical devices to be advertised either to the general public or healthcare professionals in the Czech Republic. In general, only a registered medicine can be subject to advertisement in the Czech Republic.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes, the law in the Czech Republic regulates the advertising of prescription-only and over-the-counter medicines differently. The main distinction is that in relation to a general public, only the over-the-counter-medicines (which do not contain narcotic or psychotropic substance) can be advertised. In relation to the healthcare professional, all registered medicines, i.e. including both over-the-counter and prescription-only medicines, can be advertised.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	Advertising of medicines to the general public must not involve prescription-only medicines and medicines containing narcotic or psychotropic substances. The provision of samples of medicines to the general public shall be prohibited. Furthermore, advertising of medicines aimed at the general public must not: • give an impression that consultation with a doctor, medical intervention or treatment is unnecessary, in particular, by offering diagnosis or distance treatment, • indicate that the effects of the administration of the relevant medicine are guaranteed, not associated with undesirable effects or are better or equivalent to those of another treatment or other medicine;

	• imply that the use of a medicine will improve the health of the person using it; • imply that the non-use of a medicine may adversely affect the health of persons, with the exception of vaccination actions approved by the Ministry of Health • be aimed exclusively at persons under the age of 15; • recommend a medicine by reference to the advice of scientists, health professionals or persons who are not, but who, by virtue of their actual or anticipated social status, could encourage the consumption of medicines; • indicate that the medicine is a food or cosmetic product or another consumer good; • imply that the safety or efficacy of the medicine is only guaranteed because of its natural origin; • by describing or describing in detail the specific course of a particular case, lead to a possible erroneous self-diagnosis; • point out the possibility of healing in an inappropriate, excessive or misleading manner; • use in an inappropriate, exaggerated or misleading way a representation of changes in the human body caused by a disease or injury or the effect of a medicine on the human body or parts thereof. Where advertising to the general public is intended as a reminder of a medicine, it shall not contain any information other than the name of the medicine as specified in the marketing authorisation, or its international non-proprietary name or trademark. The Czech law does not currently set down any specific rules for the advertising of medical devices and, thus, only the general rules need to be followed, such as that the advertisement cannot be contrary to good manners, discriminate race, sexuality or nationality, etc. However, there is an amendment to the Advertising Act pending in the legislative process which introduces detailed rules on advertisement of medical devices. Please see our response to Q. 13 below for more details.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	In the context of advertising of medicines to healthcare professionals, it is prohibited to offer, promise or provide gifts or other benefits, unless they are of negligible value and are related to the professional activities they carry out. The extent of the free hospitality and accommodation provided: • at a meeting attended by experts to promote the prescription, sale, supply or consumption of medicinal products for human use, or • at a meeting of experts held for professional or scientific purposes, must be proportionate, secondary to the main purpose of the meeting, and not extend to persons other than the healthcare professional.

	Healthcare professionals shall not seek or accept any of the aforementioned prohibited benefits in connection with advertising of any medicine. Samples of medicinal products for human use may only be provided in exceptional cases to persons authorised to prescribe them, in a limited number per calendar year, each sample shall correspond to the smallest package of medicine and marked “Not for sale” or “Free sample”. Preparations containing narcotic and psychotropic substances must not be provided. Samples of medicinal products for human use may only be provided at the written request of the prescribing person, signed and dated. Where advertising to professionals is intended as a reminder of a medicine, it shall not contain any information other than the name of the medicine as specified in the marketing authorisation, or its international non-proprietary name, if any, or trademark. The Czech law does not currently set down any specific rules for the advertising of medical devices and, thus, only the general rules need to be followed, such as that the advertisement cannot be contrary to good manners, discriminate race, sexuality or nationality, etc. However, there is an amendment to the Advertising Act pending in the legislative process which introduces detailed rules on advertisement of medical devices. Please see our response to Q. 13 below for more details.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	The advertisement of medicines directed only to healthcare professionals shall contain: • accurate, up-to-date, verifiable and sufficiently complete data to enable professionals to form their own views on the therapeutic value of a medicine. Data taken from professional publications or professional publications must be accurately reproduced and their source indicated; • essential information according to the approved summary of product characteristics, including the date of approval or last revision; • information on the method of dispensing the medicine pursuant to the marketing authorisation; • information on the method of reimbursement from public health insurance funds. The sales representative must, at each visit made to advertise a medicine, provide the healthcare professional with a summary of the product characteristics of each medicine advertised and information on the pricing of these medicines. Currently, the advertisement of medical devices to the healthcare professionals is not subject to any specific mandatory requirements and, thus, only general rules will apply. There is, however, an amendment to the Advertising Act pending in the legislative process which introduces detailed rules on advertisement of medical devices. Please see our response to Q. 13 below for more details.

8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	The advertisement of medicines directed to the general public must: • be formulated in such a way as to make it clear that the product is a human medicinal product; • contain the name of the medicine as specified in the marketing authorisation. If a medicine contains only one active substance, the advertising shall include the common name of that medicinal product; • contain the information necessary for the correct use of the medicine; • contain a clear, clearly legible, in the case of printed advertising, a careful reading of the package leaflet. Currently, the advertisement of medical devices to the healthcare professionals is not subject to any specific mandatory requirements and, thus, only general rules will apply. However, there is an amendment to the Advertising Act pending in the legislative process which introduces detailed rules on advertisement of medical devices. Please see our response to Q. 13 below for more details.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	See response ad 7. In addition, all information included in the advertisement must be in compliance with the information in the summary of product characteristics. Within the advertisement, it is only possible to include results of clinical trials, which were taken into account in the summary of product characteristics or if they confirm or precise the information in the summary of product characteristics. In the advertisement of medicines towards healthcare professionals, it is possible to include information from scientific publications. In such a case it is necessary to include the source of such information and the information must be in line with the summary of product characteristics.
10. Are there specific rules for comparative advertisement of medicines and medical devices?	There are no specific rules for comparative advertisement of medicines and medical devices. The general provisions applicable under the Civil Code shall apply. Comparative advertising is permitted in terms of making comparisons in the following cases: • if it is not misleading; • if it only compares goods or services which satisfy the same need or which are intended for the same purpose; • if it objectively compares one or several relevant, important, verifiable and typical properties of goods or services, including price; • if it compares goods with a designation of origin only to goods of the same designation; • if it does not disparage a competitor, its position, its activities or its results, or their identification, or unfairly benefits therefrom; and

		• if it does not offer goods or services as an imitation or copy of goods or services identified by a trademark of a competitor or by the competitor's name. Comparative advertisement of medicines and medical devices is permitted only if it is directed to healthcare professionals.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	Same aforementioned rules apply to advertising on the Internet and other forms and carriers of advertising. In addition, it is permitted to distribute information on prescription-only medicines, provided that this information is accessible only to those who seek it and such advertised medicine is represented by a depiction of packaging and full-scope and accurate information from the leaflet or summary of the product characteristic as agreed in the process in the process of registration. It is prohibited to advertise medicines online with information modified only for promotional purposes. This position was also confirmed by the judgment of the ECJ in Case C-316/09 (MSD Sharp & Dohme GmbH v Merckle GmbH). With the exception of the above, it is necessary to ensure access to advertising aimed at the professional public in such a way as to ensure that they are mainly visited by professionals, at least by declaring that they are professionals, by acknowledging the definition of a professional and by acknowledging the risks to which a person other than a professional is exposed when accessing a website intended primarily for professionals. Czech law does not currently set down any specific rules for the advertisement of the medical devices on the internet / in social media. Therefore, only general rules will apply. There is, however, an amendment to the Advertising Act pending in the legislative process which introduces detailed rules on advertisement of medical devices. Please see our response to Q. 13 below for more details.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	The State Institute for Drug Control (the "**SIDC**") is the supervisory body for the advertising of medicines in compliance with the Advertising Act (with the exception of advertising done via TV or radio broadcast). The SIDC may impose a financial sanction up to CZK 5,000,000 (approx. EUR 190,000) for non-compliance.
13.	Any future developments in your jurisdiction?	An amendment to the Czech Advertising Act is currently pending in the legislative process. The amendment introduces rules on advertising of medical devices (incl. *in vitro* diagnostic device) which are very similar to the rules on advertising of medicines. Similarly to the medicines, rules on advertising of medical devices will differ depending on whether the advertisement is directed to general public or to healthcare professionals. Under the new rules, it is not permitted to advertise towards general public medical devices which are, pursuant to the manufacturer's instructions, determined to be used by healthcare professionals, or which can be dispensed only on the basis of a prescription. It is neither permitted to provide samples of medical devices to general public.

	Any sponsorship and hospitality provided to healthcare professionals must be adequate and secondary to the main purpose of the event. An advertisement on medical devices cannot refer to a specific public authority. As the new rules on advertisement of medical devices are very similar to the rules on advertisement or medicines, please refer to our above responses for more information.

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JURISDICTION: France

Rules applicable to the advertising of veterinary medicines are not addressed in this questionnaire.

1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	a) **Medicines**: The main rules applicable regarding advertising of medical devices were amended by (i) law n° 2011-2012 dated December 29, 2011 on strengthening the health safety of medicines and health products and (ii) decree n° 2012-741 dated May 9, 2012 on medicine advertising. These provisions are codified in articles L.5122-1 to L.5122-16 and R.5122-1 to R.5122-26 of the French public health Code. b) **Medical devices**: The main rules applicable regarding advertising of medical devices were created by (i) law n° 2011-2012 dated December 29, 2011 on strengthening the health safety of medicines and health products and (ii) decree **n° 2012-743 dated May 9, 2012 on medical devices advertising.** These provisions are codified in articles L.5213-1 to L.5213-7, L.5122-1 and R.5213-1 to R.5213-11 of the French public health Code. To the provisions which are specific to medicines or medical devices, provisions of the French consumer Code are also applicable: • Article L.121-1 to L.121-5 of the French consumer Code on unfair and misleading practices; • Article L.122-1 to L.122-7 of the French consumer Code on comparative advertising.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of a) medicines? b) medical devices? If yes, please indicate these.	a) **Medicines**: There are no self-regulatory codes of conduct *per se* but the National Agency for the Safety of Medicines and Health Products ("**ANSM**") enacts some regulatory codes of conduct governing the advertising of medicines. Their guidelines focus either on advertisement to the general public or to HCP. Some guidelines are specific to (i) a therapeutic class: antibiotics, vaccines, hypnotics and anxiolytics for instance or (ii) to the media support of the promotion of the medicine (whether it airs on tv, radio or on the internet). b) **Medical devices**: The ANSM enacts some regulatory codes of conduct governing the advertising of medical devices: • Guidelines on advertisement on MD; • Policy on communication and promotion of healthcare products on the internet and e-medias;

3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to a) the general public? b) healthcare professionals?	a) **To the general public**: • For medicines: Advertising is allowed only for medicines that are not reimbursed i.e. financed by compulsory health insurance scheme and/or subject to a medical prescription (see section 4 hereafter). Advertising to the general public for medicines or vaccine advertising campaigns (see section 4 hereafter) are subject to prior authorisation by the ANSM, known as an "***advertising visa***" or "***visa GP***". • For medical devices: There is no prior approval or license requirement for medical devices advertisement. However, there is an ex-post control: if the advertisement does not comply with minimal information defined by law, the director of the ANSM can, after formal notice, prohibit the said advertisement. Besides, advertising of medical devices with high-risks for human health is subject to prior authorisation by the ANSM. b) **To healthcare professionals**: • For medicines: Since 2012, advertising of medicines to HCP is also subject to prior authorisation by the ANSM. Companies must receive a "*visa PM*". • For medical devices: There is no approval or license requirement for medical devices advertisement. However, there is an ex-post control: if the advertisement does not comply with minimal information defined by law: the director of the ANSM can, after formal notice, prohibits the said advertisement. Besides, advertising of medical devices with high-risks for human health is subject to prior authorisation by the ANSM. c) **Fees** The application for authorisation for the advertising ("*advertising visa*") of medicines and medical devices (when necessary, as mentioned hereabove) involves the payment of a €510 fee.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes. Advertising to the general public is prohibited for prescription-only medicines. Advertising of such products is only authorised to HCPs.
5. What are the main restrictions applicable to the advertising of a) medicines b) medical devices	a) **Medicines**: Advertising is only allowed for medicines that have been authorised for marketing in France. Moreover, advertising

to the general public?	for a medicine is prohibited when the benefit/risk ratio is reassessed. Advertising to the public for a medicine is permitted only on condition that (i) it is not subject to medical prescription, (ii) that none of its various presentations is reimbursable by compulsory health insurance schemes and (iii) that its marketing authorisation or registration does not include a prohibition or restriction on advertising to the public because of a possible risk to public health, in particular where the medicinal product is not suitable for use without the intervention of a doctor for the diagnosis, initiation or monitoring of treatment. By way of derogation, advertising campaigns for tobacco cessation products or for vaccines subject to medical prescription or reimbursable may address the general public (under certain conditions for non-institutional advertising campaigns for vaccines). Advertising to the public for medicines or above-mentioned vaccine advertising campaigns are subject to prior authorisation by the ANSM (see section 3 hereabove). The provision of free samples of medicines to the general public is prohibited. In addition to the mandatory information that must be included in advertisements intended for the general public (see section 8 hereunder), an advertisement for a medicine may not contain any element that: – Would make medical consultation or surgery appear superfluous, in particular by offering a diagnosis or recommending treatment by correspondence; – Suggests that the effect of the medicine is insured, that it is free of adverse effects, or that it is greater than or equal to that of another treatment or medicine; – Would suggest that a normal state of health can be improved by the use of the medicine; – Suggests that a normal state of health may be affected in the event of non-use of the medicinal product (this prohibition does not apply to advertising campaigns for vaccines or tobacco cessation products); – Would be addressed exclusively or mainly to children; – Would refer to a recommendation from scientists, health professionals or persons who, although they are neither scientists nor health professionals, may, by their reputation, encourage the consumption of the medicinal product concerned; – Assimilates the medicine to food, a cosmetic product or another consumer product; – Suggests that the safety or efficacy of the medicine is due to the fact that it is a natural substance; – Could lead, by a detailed description of symptoms, to a false self-diagnosis;

	– Would abusively, frighteningly or misleadingly use visual representations of alterations in the human body due to illness or injury; – Excessively or misleadingly presents the action of the medicine in the human body; – Would refer to certificates of healing; – Would insist on the fact that the medicine has received a marketing authorization or has been registered; – Would include offers of bonuses, objects or products of any kind or direct or indirect material benefits of any kind whatsoever. b) **Medical devices**: Only medical devices that have a CE marking may be advertised. • Reimbursed medical devices: In principle, advertisement to the general public of medical devices reimbursed, even partially, by compulsory health insurance schemes is prohibited. However, by way of exception, advertising to the general public of reimbursed medical devices posing a low risk to human health (classes I and II,a) is authorised. • Non-reimbursed medical devices: The advertising to the general public of non-reimbursed medical devices is authorised and subject to ex-post control. However, advertising of certain medical devices posing a significant risk to human health is subject to prior authorisation by the ANSM. • Prohibited statements: Advertising must not be misleading or pose a risk to public health. In addition to the mandatory information that must be included in advertisements intended for the general public (see section 8 hereunder), an advertisement for a medical device (reimbursed or not) may not contain any of the elements listed hereabove for medicines in section 5.a. c) **In vitro diagnostic medical devices** Advertising to the general public of in vitro diagnostic medical devices is authorised and subject to ex-post control. Nonetheless, advertising of in vitro diagnostic medical devices whose failure is likely to cause a serious health risk is subject to prior authorisation by the ANSM. Only in vitro diagnostic medical devices that have received a certificate attesting their performance and compliance with essential requirements concerning the safety and health of patients, users and third parties (e. g. CE marking) may be advertised.

	Advertising must not be misleading or pose a risk to public health. In addition to the mandatory information that must be included in advertisements intended for the general public, an advertisement for an in vitro diagnostic medical device may not contain any element that: – Makes medical consultation or surgery appear superfluous, in particular by offering a diagnosis by correspondence; – Suggests that a normal state of health can be improved by the use of the in vitro diagnostic medical device; – Suggests that a normal state of health may be affected if the in vitro diagnostic medical device is not used; – Would be directed exclusively or mainly at children; – Would refer to a recommendation from scientists, health professionals or persons who, although not scientists or health professionals, may, by their reputation, encourage the use of in vitro diagnostic medical devices; – Could lead, through a detailed description of symptoms, to false self-diagnosis; – Abusively, frighteningly or misleadingly uses visual representations of alterations in the human body due to illness, injury or disability; – Would refer to certificates of healing; – Insists that the in vitro diagnostic medical device has been certified; – Would include offers of bonuses, items or products of any kind or direct or indirect material benefits of any kind.
6. What are the main restrictions applicable to the advertising of a) medicines b) medical devices to healthcare professionals?	a) **Medicines**: Advertising to HCPs for medicines or above-mentioned vaccine advertising campaigns is authorised but subject to prior authorisation by the ANSM (see section 3 hereabove). Advertising may not mention the position taken with regard to a medicine by an administrative or advisory authority in a manner likely to alter the meaning or objectivity of that position. Free samples of medicines may be given to persons authorized to prescribe or dispense medicines in in-house pharmacies but only at their request (and only for some products and in limited quantities). These samples may not contain substances classified as psychotropic or narcotic drugs, or to which the regulation of narcotic drugs is applied in whole or in part. They must be identical to the pharmaceutical specialties concerned and marked: "free sample". b) **Medical devices**:

	Advertising to HCPs of medical devices and in vitro diagnostic medical devices is authorised and subject to ex-post control. Nonetheless, advertising of medical devices and in vitro diagnostic medical devices whose failure is likely to cause a serious health risk is subject to prior authorisation by the ANSM.

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JURISDICTION:	Germany
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	The advertising of medicines and medical devices is governed by the Law on Advertising in the Health Sector (*Heilmittelwerbegesetz, or HWG*). The German Law against Unfair Competition (*UWG*) contains more general advertising rules that also apply to advertising of medicines and medical devices.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	The law is supplemented by a number of self-regulatory codes of conduct that apply to members of the respective self-regulatory organisation only (membership is voluntary). Such self-regulatory codes are: • Medicines – Codes of Conduct of the Freiwillige Selbstkontrolle für die Arzneimittelindustrie eV (FSA): ▪ FSA Code of Conduct on the Collaboration with Healthcare Professionals; ▪ FSA Code of Conduct on the Collaboration with Patient Organisations. – Codes of Conduct of the Arzneimittel und Kooperation im Gesundheitswesen eV (AKG): ▪ AKG Code of Conduct for Healthcare Professionals; ▪ AKG Code of Conduct on the co-operation with patient organisations. • Medical Devices – Bundesverband Medizintechnologie e.V. (BVMed): Code of Conduct Medical Devices.
3. What kind of licenses/approvals/ fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	Under German law, no licences/approvals/fees are required, neither for advertisements of medicines nor for medical devices. The German system is rather based on a prior self-assessment by the company responsible for the advertising.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes, under German law, any advertising of prescription-only medicines to the general public is prohibited (while OTC medicines may – subject to some restrictions, see question 5 below – be advertised to the general public).
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	• Medicines The advertising of prescription-only medicines is limited to healthcare professionals (doctors, dentists, veterinarians, pharmacists and persons who are allowed to trade with these medicines). Hence, the advertising of prescription-only medicines to the general public (even to nurses) is prohibited. In this regard, only communication that can be considered as non-promotional is permitted. However, as soon as a company's campaign has a promotional purpose

	and/or a specific product is mentioned or allusions to it are made, the campaign risks to be seen as product-related advertising. Hence, only advertising of OTC medicines is in principle allowed to the general public – subject to the following main restrictions: – Advertising may not refer to certain diseases mentioned in Section 12 *HWG* and advertising may not be related to medicines which contain psychotropic active ingredients; – Any advertising for unauthorised medicines is prohibited, including advertising for indications or dosage forms that are not covered by an existing marketing authorisation ("*off-label-advertising*"); – Comparative advertising is prohibited; – Subject to very limited exceptions, it is prohibited to offer or give advertising gifts or other benefits to consumers in connection with the promotion of medicines (Section 7 *HWG*). Further, advertisements must comply with: – General principles on advertising (e.g. no misleading; claims according to which medicines are attributed a therapeutic efficacy or effects must be substantiated by reliable scientific data); and – Medicine-specific rules set out in Section 11 *HWG*, e.g. advertisements must not refer to recommendations or testimonials by scientists, HCPs or celebrities, as such information may encourage the consumption of medicines; claims must not use statements made by third parties, such as letters of thanks or recommendations, if this is done in a misleading manner; the use of medical case histories and references thereto is prohibited, if this is misleading or can lead to an incorrect self-diagnosis; contests, prize draws or other procedures the result of which is dependent on chance are prohibited; advertising must not be aimed predominantly at children under the age of 14. • Medical devices Advertisements directed to the general public must comply with: – General principles on advertising (e.g. no misleading; claims must be substantiated by reliable scientific data); and – Medicine-specific rules set out in Section 11 *HWG* (e.g. claims must not use statements made by third parties, such as letters of thanks or recommendations, if this is done in a misleading manner; advertising must not be aimed predominantly at children under the age of 14) and Section 7 HWG (subject to very limited exceptions, it is prohibited to offer or give advertising gifts or other

	benefits to consumers in connection with the promotion of medical devices). Further, advertising for medical devices may not refer to certain diseases mentioned in Section 12 HWG.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	The following main restrictions apply to the advertising of medicines (be it prescription-only or OTC) and medical devices: • Promotional claims must be based on sufficient and reliable scientific evidence (this applies in particular to claims in which medicines and /or its active ingredients or medical devices are attributed a therapeutic efficacy, certain effects or other benefits and to superiority claims); • If the data/study that justifies the claim is mentioned (e.g. in a footnote), this reference must be complete, correct and able to serve as scientific evidence (if the reference does not justify the claim, German courts will consider the claim, regardless of whether it can be scientifically substantiated by another study not cited, as misleading only for formal reasons); • Pursuant to Section 7 *HWG* it is, subject to very limited exceptions, prohibited to offer or give advertising gifts or other benefits to healthcare professionals in connection with the promotion of medicines or medical devices. Further, any advertising for unauthorised medicines is prohibited, including advertising for indications or dosage forms that are not covered by an existing marketing authorisation ("*off-label-advertising*").
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	• Medicines Advertisements, regardless of whether referring to prescription-only or OTC medicines, must contain the following mandatory information (*Pflichtangaben*): the pharmaceutical company's name and registered place of business, the name of the medicine, its composition, therapeutic indications, contraindications as well as side effects (if any), warnings (in so far as such warnings need to be labelled on containers and outer packaging) and the indication "prescription only" (if applicable). Such mandatory information must be clearly set out, well separated from the other advertising claims and easily legible. Only advertisements that are intended solely as a "reminder" (*Erinnerungswerbung*) do not have to contain the aforementioned mandatory information. An advertisement is intended as a reminder if it refers exclusively to the name of the medicine and/or only to the company's name or trade mark or the active pharmaceutical ingredient. In addition, any advertising referring to scientific or medical publications must clearly name the authors, the time of publication and the correctly quoted reference (Section 6 *HWG*). • Medical devices The *HWG* does not provide any mandatory information in advertisements for medical devices (irrespective of whether

	directed to healthcare professionals or to the general public).
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	• Medicines Advertisements directed to the general public must contain the following mandatory information (*Pflichtangaben*): the name of the medicine, its therapeutic indications and warnings (if any). Such mandatory information must be clearly set out, well separated from the other advertising claims and easily legible. The advertising must also contain – well separated from the other advertising claims and easily legible – the following advice: "*For further information on risks and side effects, please read the package leaflet and consult your physician or pharmacist*." Only advertisements that are intended solely as a "reminder" (*Erinnerungswerbung*) do not have to contain the aforementioned mandatory information (see question 7 above). In addition, any advertising referring to scientific or medical publications must clearly name the authors, the time of publication and the correctly quoted reference (Section 6 HWG). • Medical devices See question 7 above.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	German courts do consider a clinical study to be sufficient evidence to support a promotional claim (including comparative advertisement, see question 10 below) if the study fulfils the recognised "gold standard": it must be designed as a prospective randomised, controlled and double-blind clinical trial with an adequate statistical analysis that has been published and is thus opened towards scientific discussions. If the study does not meet these criteria (e.g. in case of retrospective analyses of clinical studies, such as subgroup analyses or meta-analyses in which data generated in different studies is pooled, or in case of data on file), the promotional claim needs to make sufficiently clear that it is – as the case may be – based on scientific data that is not published (data on file) or that it is based on data with certain limitations (with naming the limitations the indirect evidence is subject to).
10. Are there specific rules for comparative advertisement of medicines and medical devices?	Under German law, comparative advertising for medicines (whether prescription-only or OTC) is not allowed if it is directed to the general public. By contrast, comparative advertising for medicines addressed to HCPs or for medical devices (irrespective of whether addressed to the general public or to HCPs) is – subject to the following restrictions – allowed: • General Rules Pursuant to Section 6 *UWG* the advertisement must, inter alia, compare products indented for the same purpose; it may only compare, in an objective manner, relevant, verifiable and representative features of the goods concerned. The advertising may not take unfair advantage of the marks of a competitor or discredit or denigrate the competitor's goods or business circumstances.

		• Special Rules for Medicines German courts require that a promotional claim for medicines or medical devices is substantiated by reliable scientific evidence. Any comparative advertising must be based on a clinical head-to-head study.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	There are no specific legal provisions for advertisements on the internet/in social media postings. However, the general restrictions apply (with certain peculiarities): • Access Restrictions on Websites Since advertising for prescription-only medicines is limited to HCPs, it is necessary to restrict access to comply with German law (if prescription-only medicines are involved). German law does not provide for a specific mechanism to restrict access. However, restricting access by providing a tick-box question ("Are you an HCP?") is not sufficient. In practice, most companies use access control systems with registration requirements (such as DocCheck). • Mandatory Information (*Pflichtangaben*) In advertisements for medicines, whether prescription-only or not, the mandatory information must be displayed (see question 7 above). However, on the internet and in social media postings a visible link that directly and without detours leads to such information is considered sufficient by German courts. • Social Media: Only OTC medicines In practice, the advertising on social media is limited to OTC medicines (as advertising for prescription-only medicines is not allowed to the general public and an access restriction, as used for websites, is technically not feasible on social media).
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	In Germany, the rules on advertising for medicines and medical devices are primarily enforced by civil courts. If a company allegedly violates a provision of the *HWG*, such violation is at the same time an act of unfair competition. As a consequence, many alleged *HWG* violations are pursued among competitors or by industry and consumer protection associations. In light of the usually high time-pressure in advertising cases, many of the court cases are interim injunction proceedings. In such civil litigation courts can grant injunctive relief by issuing a cease-and-desist order (*Unterlassung*), which is the most important remedy in practice. The rules of the *Heilmittelwerbegesetz* may also be enforced by public authorities through administrative offence proceedings (*Ordnungswidrigkeitenverfahren*), which, however, rarely happens in practice. Finally, there are arbitration boards established by self-regulatory industry associations that adjudicate on violations of industry codes of conduct. However, such boards are only competent for infringements committed by the voluntary members of the corresponding association. Further, in very rare circumstances, an offence against the prohibition of misleading advertising under Section 3 *HWG* can

	lead to criminal proceedings initiated by the locally competent state prosecutors.
13. Any future developments in your jurisdiction?	The new EU Regulation 2017/745 on medical devices that will apply from 26 May 2021, contains, inter alia, advertising rules for medical devices.

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JURISDICTION:	Hungary
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products ("**Medicines Thrift Act**") • also applicable to medical devices qualifying as medical aids; Decree no. 3/2009 (II. 25.) of the Minister of Health on the detailed rules concerning the promotion of medicinal products for human use and medical aids, the registration of persons carrying out promotional activities and the commercial practices towards consumers in respect of medicinal products and medical aids ("**Promotional Decree**") – • also applicable to medical devices qualifying as medical aids; Act XLVIII of 2008 on the Basic Requirements and Certain Restrictions of Commercial Advertising Activities ("**Advertisement Act**"); Act XLVII of 2008 on the Prohibition of Unfair Business-to-Consumer Commercial Practices ("**Unfair Commercial Practices Act**"); Act CLV of 1997 on Consumer Protection ("**Consumer Protection Act**"); Act LVII of 1996 on the Prohibition of Unfair Trading Practices and Unfair Competition ("**Competition Act**").
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of a) medicines? b) medical devices? If yes, please indicate these.	Yes. The main codes of conducts are the following (note: the list is not exhaustive): • Medicines: Code of Ethics for Pharmaceutical Communication of the Association of the Innovative Pharmaceutical Manufacturers and other associations ("**Code of Ethics for Pharmaceutical Communication**"); • Code of Conduct for the Association of Innovative Pharmaceutical Manufacturers (note: the code will enter into force on 1 January 2021); • Summary and position of the National Institute of Pharmacy and Nutrition on promotional activities related to the subject matters covered by the Public Consultation on Promotion Supervision held on September 12, 2019 (note: this is a non-binding document, including the interpretation of the authority on the laws); • Medical Devices: Code of Conduct of the Association of Health Technology Suppliers and Medical Device Manufacturers ("**ETOSZ Code of Conduct**"); • Hungarian Code of Advertising Ethics of the Hungarian Advertising Self-Regulatory Board and other associations ("**Code of Advertising Ethics**").

3. What kind of licenses/approvals/ fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	• The general public: There are no specific rules for the licensing of the advertisement of medicines and medical devices to the general public. Under the general legal rules, in connection with advertising relating to products which are subject to prior quality control or conformity assessment, the advertiser shall supply a statement to the advertising service provider that the product has been inspected or certified and found suitable for marketing. In the absence of such statement, no advertising may be published. • healthcare professionals ("**HCPs**"): – medicines/medical devices qualifying as medical aids: If a promoter of medicinal products or medical aids (e.g. the MAH or authorised distributor; "**Promoter(s)**") wishes to engage in promotional activities (e.g. in advertising prescription-only-medicine ["**POM**"] or over-the-counter medicinal products ["**OTC**"] in a more professional context to HCPs), it shall notify the Hungarian National Institute of Pharmacy and Nutrition ("**OGYÉI**") thereon and pay an administrative service fee of HUF 101,500 (app. EUR 281). On behalf of the Promoters the medical sales representatives carry out the promotional activity. The sales representatives must be registered with OGYÉI which issues a certificate on the registration. The administrative service fee (i) for the registration is HUF 100,000 (app. EUR 277) / sales rep, and (ii) for the certificate is HUF 12,900 (app. EUR 36) / sales rep. Promoters are required to pay HUF 832,000 (app. EUR 2,305)/month for medical sales representatives, and HUF 83,000 (app. EUR 230)/month for sales reps promoting medical aids. (For certain SMEs, a diminished amount is applicable). – medical devices not qualifying as medical aids: N/A
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes. POMs cannot be advertised to the general public.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	• Medicines/medical devices qualifying as medical aids: Under the relevant legal rules, all the information included in the commercial communication shall be in conformity with the SmPC and the package leaflet of the medicinal product, or with the instructions for use of the medical aid. Under the specific legal rules, it is prohibited to: – Conduct any commercial practices relating to a product with no valid MAH;

	– Promote any medicinal products or medical aids subsidised by the social security system to the general public; – Advertise medicinal products and medical aids to children. It is also prohibited to publish an advertisement if it relates to: – A medicinal product/medical aid that is not authorised to be marketed or used in Hungary; – A medicinal product that contains narcotics or psychotropic materials; – An investigational medicinal product; – An OTC product holding the same name as a POM; – A medical aid that bears the same name as (and differs only in designation or number from) a medical aid subsidised by the social security system. The advertisement shall not contain references or expressions which may mislead the consumer with respect to the characteristics and effects of the product. It is prohibited to provide or offer any gifts, product samples or gift certificates (coupons) to patients and customers directly, or by way of healthcare providers, that is intended to promote the use of a specific medicinal product/the products of a specific MAH/a specific medical aid subsidised by the social security system. The Code of Ethics for Pharmaceutical Communication prescribes that (i) commercial practices shall appear as neutral information, (ii) it shall clearly appear that it advertises medicinal products, (iii) the materials must not resemble to and should be distinguished from independent professional, scientific publication. Claims for a special merit, property, or capability of a medicinal product/active ingredient can only be used if such are well founded and scientifically proven. • Medical devices not qualifying as medical aids: Aggressive, misleading and unlawful comparative advertising is prohibited. No advertisement may be published if it, amongst others, (i) incites a behaviour endangering personal safety, (ii) may harm the physical, intellectual or moral development of children. In the medical field, inter alia, the advertising of any devices for carrying out abortions is strictly prohibited.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	• Medicines/medical devices qualifying as medical aids: All the information included in a commercial communication relating to a medicinal product/medical aid shall be in conformity with the SmPC and the package leaflet of the medicinal product, or with the instructions for use of the medical aid. It is prohibited to conduct any commercial practices relating to a medicinal product with no valid MAH.

	In the course of promotional activity towards HCPs, a medicinal product/medical aid shall be presented or communicated in such detail to enable the HCP to form an opinion on the use thereof. • Medical devices not qualifying as medical aids: Same rules apply as in the case of advertisements to the general public.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	• Medicines/medical devices qualifying as medical aids: In case the medicinal product/medical aid subsidised by the social security system, the promotional material shall include the price, amount and reimbursement price of the medicinal product and/or the medical aid. All the information must be accurate, verifiable and up-to-date. The date on which the document was finalised or last updated must also be indicated. Quotations, tables and other illustrative material from medical journals or other scientific sources shall be presented in a faithful manner to the original and include the exact source and date of the publication. The Code of Ethics for Pharmaceutical Communication prescribes further requirements re the content of the promotional materials presented/provided to HCPs in relation to a medicinal product. • Medical devices not qualifying as medical aids: Under the ETOSZ Code of Conduct, the promoted device must be described in such detail that HCPs can offer a well-based opinion about the device. All the information and documentation provided during the promotion must be detailed, verifiable and up-to-date.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	• Medicines/ medical devices qualifying as medical aids: The advertisement of OTC medicinal products/medical aids not subsidised by social security may be published if: – The product is clearly identified as a medicinal product or as a medical aid; – The advertisement includes the name of the medicinal product (also the internationally used common name if it contains only one active substance), or the name of the medical aid; – The advertisement contains the information necessary for the correct use of the medicinal product or medical aid; – The advertisement demonstrates the medicinal product and the medical aid based on the SPC or the user's manual; – The advertisement contains the warning text (in HU) for medicinal products: "Regarding risks and side effects, please read the package leaflet or consult your physician or pharmacist." or for medical aids:

		"Regarding risks, please read the instructions for use or consult your physician." • Medical devices not qualifying as medical aids: Under the Code of Advertising Ethics, claims referring to important characteristics of the product shall be valid and supported by impartial professional examination.
9.	Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	• Medicines/medical devices not qualifying as medical aids: See the answer under Question 7. In relation to scientific data the Code of Ethics for Pharmaceutical Communication further establishes that: – the source must be clearly specified; – the original information must be faithfully reproduced; – the artwork cannot be misleading; – the data published in the referenced publications may be displayed graphically under the specific conditions prescribed by the Code. • Medical devices not qualifying as medical aids: Under the ETOSZ Code of Conduct, quotes, charts and other visual materials from medical journals or scientific sources must be introduced in a form near the original and the exact source must be indicated. Under the Code of Advertising Ethics, an advertisement should not misuse research results or quotations from technical and scientific publications. Scientific terminology or vocabulary should not be used in a misleading way. Advertising can be based on market research data if the research was made by scientific methodology, professional diligence.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	There are no rules in the sector specific laws for comparative advertisement. (However, the Competition Act prescribes general requirements for these advertisements that must be taken into consideration.) According to the Code of Ethics for Pharmaceutical Communication all claims in comparative advertisements serving as the basis for comparison shall be objective. The comparison should be relevant and it should compare one or more essential, dominant, characteristic and verifiable properties of the medicinal products in an objective way. Only comparable aspects are permitted to be compared. Superlatives shall only be used to describe specific and sufficiently substantiated facts. Further, no differentiation shall be made between originator and follow-on medicinal products unless the difference is scientifically demonstrated. Pursuant to the Code of Advertising Ethics, nourishment or health related comparisons must be placed on proved foundations/supported objectively and are clearly understandable.

11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	There are no rules in the sector specific laws for advertisement of medicines and medical devices on the internet/in social media postings. The Code of Ethics for Pharmaceutical Communication states, amongst others, that the name or international non-proprietary name of a POM or a medicinal product subsidised by the social security system as a domain name or part of a domain name shall only be used if the website operator ensures that the information is only available to HCPs.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	The following bodies are competent for assessing infringing advertisements addressed to the general public: • The Hungarian Competition Authority ("**HCA**"), where the alleged practice potentially affects the competition; • The Hungarian consumer protection agencies ("**CPAs**") in any other cases; – With the proviso that OGYÉI is entitled to monitor the compliance with the rules of the Medicinal Thrift Act and the Promotion Decree. In case of infringement, both HCA and CPAs are entitled to prescribe certain conducts (e.g. terminating the practice, publishing corrective statement, etc.) and impose fines. The HCA may impose fines up to the 10 % of the net income generated in the previous business year by the whole group of undertakings being liable. The CPAs may impose fines up to the 5 % of the net income generated in the previous business year by the company being liable, but max. HUF 2 billion (app. EUR 5.541 million; other lower thresholds may be applied under special circumstances). • Medicines/medical devices qualifying as medical aids: In addition, OGYÉI is the competent authority in case of infringement of the provisions on the promotion of medicinal products/medical aids towards HCPs. OGYÉI may, amongst others, impose a fine in the amount of: – Between HUF 500,000 (app. EUR 1,385) and HUF 25,000,000 (app. EUR 69,264) in the case of authorised distributors; – Between HUF 500,000 (app. EUR 1,385) and HUF 500,000,000 (app. EUR 1,385,272) in the case of Promoters, MAHs and manufacturers; – Between HUF 500,000 (app. EUR 1,385) and HUF 5,000,000 (app. EUR 13,853) in the case of medical sales representatives. The fines may be imposed cumulatively. In case of repeated or serious infringements, OGYÉI may even ban the Promoter from engaging in promotional activities for a period of between 6 months and 3 years.

	Violation of the Code of Ethics for Pharmaceutical Communication result in the ethical procedure of the Communication Ethics Committee. • Medical devices not qualifying as medical aids: Violation of the ETOSZ Code of Conduct may result in the ethical procedure of the ETOSZ Ethics Committee.
13. Any future developments in your jurisdiction?	With respect to the advertisement of medicinal products, there are no future developments envisaged. Regarding medical devices, the new EU regulations will contain more specific rules with regard to the prohibition of misleading advertisement. The Hungarian laws which will amend the regulations shall be revised as soon as those are adopted.

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JURISDICTION:	Italy
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	Advertising of medicines is regulated in a specific section of Legislative Decree no. 219/2006 ("**Code of Medicines**"). In addition, the Ministry of Health issued specific guidelines on the advertising of non-prescription medicines (SOP) and OTC, as well as on the use of social media in the context of the medicines advertising. Advertising of medical devices is regulated in a specific section of Legislative Decree no. 46/1997. The Ministry of Health then adopted some acts to specify the discipline, issuing the Ministerial Decree no. 93/2006 and some Guidelines on the use of various advertising channels such as paper publications, call centres or social media. Furthermore, if the advertising is aimed to consumers, the advertisers will also be obliged to comply with the provisions set forth in the Legislative Decree no. 206/2005 ("**Consumer Code**").
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	Yes, the most relevant codes of conduct are: • **Code of Self-Discipline of Commercial Communication** prepared by the Institute of Advertising Self-Regulation. This Code contains rules applicable to all types of advertising but dedicates a section to the advertising of "Medicinal products and healing treatments". • **Farmindustria Code of Conduct and Confindustria Dispositivi Medici Code of Conduct**. Farmindustria is the Italian pharmaceutical companies' trade association. Confindustria Dispositivi Medici is the Italian trade association of medical devices' manufacturers and distributors. The Codes represent the commitment of the industry not only to abide by specific laws in force but also to operate on the basis of transparent standards of conduct that regulate the various circumstances in which corporate activities take place. The Codes also include some rules dedicated to advertising.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	Advertising of medicines and medical devices to the public always requires the authorisation of the Ministry of Health. A specific application for each single advert, even if the same advert is released through several different media, shall be submitted to the Ministry of Health for an authorisation to market drugs and medical devices to consumers. Should the Ministry of Health not provide this authorisation within 45 days of the date of the application, it is deemed to have been granted. The authorisation lasts for 24 months. The fee to be paid to the Ministry of Health is equal to €380,10 for each text, for each product and for each media both for medicines and for medical devices. The authorisation is not required for: • Institutional advertising referring to the name or field of activity of the supplier or distributor, provided that it does not boast specific properties of the products;

	• Promotions consisting in the sale of multiple packs at the price of the unit pack or through similar methods. Advertising to Healthcare Professionals do not need to be authorised. With regard to medicines only, the marketing material shall firstly be submitted to AIFA and, ten days after the submission, it can be delivered to the HCPs. No actual authorisation is required, there is only a duty to submit it to AIFA. The material cannot be used only if AIFA prohibits it.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes, advertising to the public of medicines that can be purchased on prescription only is prohibited.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	• Promotion of medicines to the public is only permitted if the drugs are non-prescription or do not need the intervention of a doctor for diagnostic purposes. The following kinds or drugs are not to be promoted to consumers at all: – Drugs which are available on medical prescription only; – Drugs which contain psychotropic or narcotic substances; and – Drugs which are totally or partially reimbursed by the National Health System. • Advertising to the public of a medicine product cannot contain any element that: – Suggest that it is not necessary to consult a doctor or surgery, in particular by offering a diagnosis or proposing a cure by correspondence; – Suggests that the efficacy of the medicinal product free from side effects or greater or equal to another treatment or another medicine; – Suggests that the medicine can improve the normal state of good health of the subject; – Suggests that the non-use of the medicine can have detrimental effects on the normal state of good health of the subject; – Is aimed exclusively or mainly at children; – Includes a recommendation from scientists, health professionals or persons widely known to the public; – Assimilates the medicinal product to a food product, a cosmetic product or another consumer product; – Suggests that the safety or efficacy of the medicine is due to the fact that it is a “natural” substance; – May lead to incorrect self-diagnosis; – Improperly, impressively or deceptively refers to claims of healing;

	– Improperly, impressively or deceptively uses visual representations of alterations of the human body due to illness or injury, or of the action of a medicine on the human body or on a part thereof. Furthermore, it is not permitted to give consumers free samples or to give them promotional offers on drugs. Finally, it is worth to consider that some supplementary rules are provided by the Guidelines of 25 July 2017 and 7 May 2018 by the Ministry of Health on the use of: emails, call centres, websites, messages, social Media (Facebook, Instagram and YouTube) in non-prescription medicines (SOP) and OTC advertising. • Advertisements of medical devices to the public are limited as follows: – Advertisements of medical devices which can be used upon medical prescription only and/or require the assistance of HCPs to be used are forbidden; – Advertisements of medical devices which can be used lacking the requirements under 1 above is allowed provided that they are duly authorised by the Ministry of Health. As an exception to the above, mere accessories of medical devices (e.g. frames for glasses) are not subject to the rules on medical devices' advertisements insofar as they are chosen by the patient only on the basis of aesthetic factors, thus not taking into account medical aspects.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	• Marketing activities can only be directed to HCPs who are authorised to prescribe or supply the relevant drugs. Marketing material shall firstly be submitted to AIFA and, ten days after the submission, it can be delivered to the HCPs. In general terms the following marketing activities are permitted with regard to HCPs: – Verbal information; – Delivery of promotional material; – Free samples (although it very strictly regulated in terms of quantity); – Scientific congresses and conventions; – Refresher courses; – Visits to companies' laboratories; – Investigators' meetings; – Scholarships and scientific consultancy. Exaggerated statements, universal and exaggerated claims and comparisons without any objective basis are inadmissible. Use of email, automated calling systems and other electronic communication aiming at divulging promotional material regularly approved by AIFA is prohibited, unless the company holds a prior written and

	informed consent from the HCPs to whom the material is addressed. • As a preliminary remark, it is worth recalling that no authorisation is necessary for advertisements directed towards healthcare professionals only. Indeed, rules generally address advertisements towards patients. Advertisings towards healthcare professionals, although being not subject to authorisation, are considered advertisement nonetheless: therefore, they shall be truthful, fair and have a clear promotional purpose. Finally, it is worth to consider that some supplementary rules are provided by the Guidelines of 20 December 2017 by the Ministry of Health on the use of: emails, call centres, websites, messages, social media (Facebook, Instagram and YouTube) in medical devices' advertising
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	• Marketing statements must always be substantiated by documented and verifiable evidence. The minimum particulars to be included in all advertising are: – The information listed in the summary of the product characteristics, – The supply category of the drug, and – The selling price and the conditions under which it can be reimbursed by the national health system. The promotional material may also include the name of the drug, the name of the active ingredient, together with the name of the license holder and of the co-promoter, if any. • The elements present in the advertisement must be consistent with the label and the instructions for use of the product. The advertisement must: (i) encourage a rational use of the medical device; (ii) be truthful, fair and not misleading; (iii) have a clear advertising purpose which must not be concealed by the presence of too many information of different nature. The advertisement shall contain the following elements: (i) the statement "*E' un dispositivo medico CE*" (it is a EC medical device); (ii) the denomination of the product and its class; (iii) a clear urging to read the warnings and/or the instructions for use. In advertisements on printed materials, the urging shall be in a font no smaller than 9, whereas in case of audio-video advertisements, the urging must be stated in a clear and normal-paced manner. In case the advertisements are published online on websites, or in specific areas thereof, which are meant exclusively for healthcare professionals, undertakings shall set up a specific disclaimer warning user that the information therein contained is aimed to healthcare professionals only.

8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	Promotion to consumers of a medicine shall: • Clearly allow to understand that the message is a promotion about a medicine: • Include the following minimum information: – The name of the drug as well as the name of the active ingredient (the latter only if the drug contains only one active ingredient); – The information necessary for correct use of the drug; – An express and legible invitation to read carefully the instruction on the package leaflet or on the outer packaging. In case of promotional messages included in newspapers or periodical press, such an invitation must be in font size nine. The advertisement shall then contain the number and the date of the authorisation thereof or, should the latter case occur, the date of the application. • The elements present in the advertisement of a medical device must be consistent with the label and the instructions for use of the product. The advertisement must: (i) encourage a rational use of the medical device; (ii) be truthful, fair and not misleading; (iii) have a clear advertising purpose which must not be concealed by the presence of too many information of different nature. The advertisement shall contain the following elements: (i) the statement “E’ un dispositivo medico CE” (it is a EC medical device); (ii) the denomination of the product and its class; (iii) a clear urging to read the warnings and/or the instructions for use. In advertisements on printed materials, the urging shall be in a font no smaller than 9, whereas in case of audio-video advertisements, the urging must be stated in a clear and normal-paced manner. The following content is not allowed: (i) content that induces a wrongful self-diagnosis; (ii) content that makes the consultation of a doctor appear unnecessary; (iii) content that may induce the patient to believe that the lack of use of the medical device will be detrimental to his health and/or to believe that the use of the medical devices bears no contraindications; (iv) content that makes misleading reference to the healing capacities of the product; (v) messages exclusively or mainly addressed to children; (vi) messages by scientists, medical practitioners or notorious people. The advertisement must be in Italian. In case words in a foreign language are present (e.g. technical expressions), they must be translated and appropriately explained. The advertisement shall then contain the number and the date of the authorisation thereof or, should the latter case occur, the date of the application.
9. Please summarise the requirements for scientific data indicated in	Please refer to answer no. 7.

	advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	Moreover, please note that: • All elements of advertising of a medicinal product must be in accordance with the SmPC; • The information disclosed must be compliant with the documentation submitted for the purpose of obtaining the MA or its updates; • Articles, tables and other illustrations taken from medical journals or scientific works must be reproduced in full and faithfully, with the exact indication of the source; • For homeopathic or anthroposophical medicinal products without therapeutic indications, the doctor can be provided with the documentation useful for remembering posology and fields of application through publications taken from one of the European pharmacopoeias or from the homeopathic or anthroposophical literature. In the latter case, it must be stamped in a visible manner that are indications for which there is currently no scientifically proven evidence of the efficacy of the homeopathic or anthroposophical medicinal product.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	No, there are not specific rules provided for medicines and medical devices other than the general provisions set by the Consumer Code.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	Yes, the Ministry of Health expressly regulated the matter of online advertising by issuing several Guidelines. As to medicines, Guidelines of 25th July 2017 and 7th May 2018 are relevant. The scope of application only regards advertising of non-prescription (SOP) and OTC advertising. On this regard, please note the following: a) **Institutional Websites**: Are the websites owned by the company that promotes its image or logo without any promotional intent of the products. On such institutional websites it is possible (without the prior authorisation of the Ministry of Health) to publish the list of its own non-prescription and self-medication medicines, reporting only the Information Leaflet and the image of the package. b) **Company Facebook pages of product or brand**: They are admitted on condition that for all the contents therein published the “comments” and “reactions” (like, emoticon) are deactivated and that it is reported the disclaimer “The Ministry of Health authorizes only the advertising content. Any comments are the sole responsibility of the user, the company dissociates itself from the comments of the users.”. The Guidelines then provide for specific rules on the publication of contents (posts, images, videos). c) **Messenger platform**: The use of the Messenger platform is allowed for sponsored messages, previously authorised, provided that the some functions are disabled (comment, share, like reactions, emoticons). d) **YouTube Channel**: The use of the YouTube platform is allowed for the dissemination of advertising messages

	(image, script, video, audio) provided that they have obtained prior authorisation from the Ministry of Health and on condition that the company guarantees some limitations to the use of the social network (e.g. the deactivation of "comments"). e) **Instagram**: It is possible to include images or short authorised video advertisements in the "Stories" section where users, in viewing such images / videos, do not have the possibility to comment on them, express reactions or share them. When viewing the video, by clicking on "find out more", it is possible to be brought back directly to the external product site, previously authorised by the Ministry. f) **Information for healthcare professionals**: Must be accessible exclusively to the aforementioned operators, even when it is broadcast via the internet. Therefore, companies must guarantee that the website has an encrypted area can be accessed with a password, to be released to doctors, pharmacists and other health professionals, after they have sent the data necessary for their identification. Furthermore, even in the context of websites freely accessible to the general public, links to areas intended for the information of HCPs must have a barrier of access for those who are not HCPs. As to medical devices, Guidelines of 20th December 2017 are relevant and provides for the same rules listed in let. a) to e) above. On the contrary, the applicable rule on the advertisings addressed exclusively to HCPs is slightly different and provides that when such advertisings are disseminated via internet, the websites intended exclusively for HCPs, must include a special "disclaimer" stating that the information contained therein is exclusively for professional operators.
12. Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	Control and supervision of the advertising regulation is the responsibility of the Ministry of Health. The Ministry is in charge of authorising the adverts as well as carrying out inspections and controls. Failing to comply with it will cause the Ministry of Health to issue the following orders: • Immediate cessation of the advertisements; • Diffusion of a rectification message at the company's expenses; • Payment of a pecuniary sanctions from EUR 2.600 to EUR 15.600.

13. Any future developments in your jurisdiction?	• With regard to the advertisement of medicinal products, there are no future developments envisaged. As to the medical devices, the new EU medical device regulation 2017/745 contains advertising related provisions.

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JURISDICTION:	México
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	The main legislation for medicines and medical devices advertisement is The General Health Law (*Ley General de Salud*) ("**GHL**"), and its Regulations (*Reglamento de la Ley General de Salud en materia de publicidad*) ("**HLR**"). These norms are supplemented by The Federal Consumers Protection Law (*Ley Federal de Protección al Consumidor*), The Rules of the Federal Consumer Protection Law (*Reglamento de la Ley Federal de Protección al Consumidor*) and a variety of Mexican Official Standards ("**NOMs**") covering specific technical issues such as manufacturing best practices, post – marketing controls, surveillance of labelling, among others. The Federal Commission for the Protection against Sanitary Risks ("**COFEPRIS**"), is the agency in charge of the surveillance and authorisation of medicines and medical devices advertisement.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	• There are 3 industrial associations that have issued Codes of Practices for the implementation of the regulation for medicines advertisement: – The Council of Ethics and Transparency of the Pharmaceutical Industry ("**CETIFARMA**"): i) The Code of Ethics and Transparency of the Pharmaceutical Industry; ii) The Code of Good Practices of Promotion (Code of GPP); and iii) The Code of Good Practices of Interaction of the Pharmaceutical Industry with Patient Organizations. – The Nacional Advertisement Regulation Council ("**CONAR**"): i) Advertisement Ethics Codes; and ii) Sectorial Ethics Code. – The Over the Counter Medicines Association ("**AFAMELA**"): AFAMELA Advertisement Ethics Code. • Medical Devices Companies follow CETIFARMA and CONAR self-regulatory codes.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	On general basis, Article 79 of HLR sets forth that the Advertisement of medicines, including vitamins and herbal remedies, and medical devices to the general public requires a permit granted by COFEPRIS, as well as advertisement to health services, unless these are carried out by a private practitioner (single individuals). Advertisement to health professionals, only require a notice to be filed before COFEPRIS. Promotional activities also only require a notice. • For medicines, the advertisement authorization is based on the classification made by the risk analysis of the product in the GHL. While over-the-counter medicines ("**OTCs**") can be advertised to the general public, prescription medicines are limited to advertisements targeted only to healthcare professionals. • For medical devices, the general rule is that the authority indicates in the premarket clearance that advertisement is limited to healthcare professionals, except when at the moment of filing the pre-market clearance application the

	applicant requests to be authorized to advertise the product to the general public and includes evidence that proves the advertisement does not present a risk to public health. Only in this case medical devices can make advertisement to general public. Article 195 of the Federal Rights Law sets forth the services provided by the health authority shall be paid for each product, type of message and event in accordance with the following: • Television and internet: 1,150.00 USD • Cinema, video: 160.00 USD • Radio: 114.00 USD • Print Press: 40.00 USD • Brochures: 26.00 USD • Outdoor advertisement: 202.00 USD The abovementioned fees apply both for medicines and medical devices.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes, only over the counter medicines can be advertised to the general public; the purpose of said advertisements is to inform the public about the characteristics of the products, their therapeutic properties and the form of use. Prescription-only medicines advertisement can only be targeted to healthcare professionals. The purpose of this restriction is to prevent the misuse of medicines, avoiding potential harms to the population's health.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	• According to article 44 of the HLR medicines advertisement will not be authorized to the general public when: – It is presented as a definitive solution as preventive, curative or rehabilitative treatment of a certain disease; – It indicates or suggest its use in relation to symptoms and conditions different that those expressed in the premarket clearance; – Disrupt the information authorized by COFEPRIS; – Promote its consumption through draws, raffles, competitions collectibles, or events in those who chance is involved; – Promote consumption by offering any other product or service in return; – Use statements or testimonials that may confuse the public or that are not supported. – Use cartoons techniques that can confuse or induce minors to consume the products; – Neglect the preventive messages command by regulation, when applicable. • The fine for the violation of this article range $ 33,546.00 to $44,727.00 USD.

	• According to article 55 of the HLR medical devices advertisement will not be authorized to the general public when: – They promote unhealthy practices if the product is not use properly; – It is presented as a definitive solution in the preventive, curative or rehabilitative treatment of a certain disease, unless this has been completely proved;
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	According to article 42 of the HLR, advertisements directed to healthcare professional can only be published in specialized media, including specialty pharmaceutical dictionaries and directories of medicines, and the must be based on the approved prescription information of the corresponding medicine or medical device. In all cases the premarket clearance number of the product shall be included prior publication. In the case of web pages containing information targeted to healthcare professionals, the responsible of the content must file an advertisement notice before COFEPRIS and explain the digital security mechanisms to prevent access from non-healthcare professionals' users. The Code of GPP states that the relations between pharmaceutical industry personnel and health care professionals should encourage the development of a medical practice committed to patients' well-being, based on truthful and accurate information, tested, and up-to-date scientific evidence.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	• According to article 42, medicines advertisement shall include the following information: – The distinctive denomination; if applicable; – Generic denomination; – The pharmaceutical form and formulation; – Therapeutic indications; – Pharmacokinetics and pharmacodynamics; – The contraindications; – General precautions; – Restrictions of use during pregnancy and lactation; – Secondary and adverse reactions, – Alterations in the results of laboratory tests; – Precautions regarding effects of carcinogenesis, mutagenesis, teratogenesis and on fertility; – Dosage and administration route; – Manifestations and management of overdose or accidental intake; – The presentation or presentations; – Storage and handling recommendations; – Protection messages;

	– Laboratory name and address; – The premarket clearance number issued by COFEPRIS. • If any of the above data does not exist, that circumstance must be expressly stated. • All the information in the guides to prescribe a medicine should be authorized previously in the medicine premarket clearance. • Medical devices advertisement shall include the following information: – The premarket clearance issued by COFEPRIS. – The references to support the scientific information.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	The advertisement of medicines directed to the general public shall comply with the indications approved by COFEPRIS in the premarket clearance of the product. This must include the message either in visual, print, hearing for radio, and print and hearing for cine and television the following caption: “Consult your physician”, and also the precautions messages when the use of the medicine can represent any danger in the presence of a disease pattern, breastfeeding or pregnancy status. For medical devices, the advertising shall include captions that prevent self-treatment; according with article 56 of HLR, the advertisement directed to the general public shall be brief, concise and easy to understand, contribute to hygienic education, and state if the use of the product represents a risk for health.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	Pursuant article 11 of HLR, the advertiser shall prove the statements made on the advertisement about the quality, origin, purity, conservation, nutritious properties and benefits which requires technical and scientific information requested by the Minister of Health. Scientific data must not be presented to audiences that do not have the professional knowledge to interpret it. All scientific data shall comply with the obligation set forth for the process of data in the General Health Law Rules for Clinical Research (*Reglamento de la Ley General de Salud en materia de Investigación Clínica*).
10. Are there specific rules for comparative advertisement of medicines and medical devices?	According to Mexican laws comparative advertisement is permitted, if the comparison has been made between equals, intended to inform the public, and it is not tendentious, false or exaggerated. The Industrial Property Law and the Federal Consumer Protection Law contains provisions related to actions that can be filed against the party responsible for harmful comparative advertisement.
11. Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	There are no specific provisions for advertisement of medicines and medical devices on the internet or social media. Internet and social media posting shall comply with all the applicable advertisement regulation. Moreover, Article 2 of the HLR defines advertising as, “*the activity comprehending any process of creation, planning, execution and circulation of ads in media*

		channels which aims to promote the sales of consumption of products and services", and a broadcast medium as "*the one used to spread the commercials or information to the general population including television, cinema, radio, mail or any other communication system either print, electronic, digital or by any other technologies*". The general scope of application applies therefore to all advertising, regardless of whether it is published on internet or social media platforms.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	COFEPRIS Surveillance Department monitors the compliance of medicines and medical devices advertisement provisions, by remote and on-site surveillance programs. In very specific cases COFEPRIS and the Federal Prosecutor for the Consumer Protection (**PROFECO**) may coordinated actions against a violation of the corresponding laws and regulations. Both authorities may order the suspension of an advertising in breach of legal framework in order to modify such ads. If not modified or the modification is considered not to comply with legal provisions, COFEPRIS and PROFECO may suspend the advertising activities, seize the advertise product and/or impose a fines according to articles 110, 111 and 112 from the HLR which may vary from $9,000 to $73,000 USD depending on the severity of the violation.
13.	Any future developments in your jurisdiction?	On June of 2019, COFEPRIS revoked the Advertisement Guidelines for OTC and prescription medicines. Recently COFEPRIS announced that the agency is working on new guidelines that should be published in 2021. These new guidelines should have been published in 2020 but were delayed due to the pandemic caused by the virus Sars-CoV-2.

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JURISDICTION: The Netherlands	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	**The Medicines Act** is the primary law on advertising of medicines. In addition, the Dutch Civil Code (6:194-196) on misleading or comparing advertising must be taken into account. **The Medical Devices Act** is the primary law on medical devices, but the law does not have a specific section on advertisement. Advertising is regulated in some self-regulatory codes. The Dutch Civil Code (as mentioned above) must also be taken in consideration.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	The details on medicine advertisement are regulated in the **Code of conduct on Pharmaceutical Advertisement (''Code PA'')**. With regard to advertisement to the public of medicines that are not prescription-only or Opium Act-listed, the **Code for Advertising of Medicinal Products to the General Public (''Code AGP'')** is applicable. The **Code on Advertisement for Medical (self-care) Devices (''Code AMD'')** sets out the standards on advertisement to the public of medical devices in pharmaceutical form with physical effect (medical devices that are very similar to medicines), to the extent that such medical devices are intended to be used by the public without the intervention of a healthcare professional. Advertisement regarding all other sorts of medical devices or advertisement to healthcare professionals is unregulated at the moment, except for the general clauses on misleading or comparing advertising in the Dutch Civil Code.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	• All **permitted** (see under 4) advertisements on medicines to the general public must have a valid authorisation number issued by the Inspection Board for the Public Promotion of Medicines (Keuringsraad Openlijke Aanprijzing Geneesmiddelen or KOAG). This rule does not apply to medical devices, but in case of a conflict it will be taken in consideration if a medical device does have a valid authorisation number. • There is no licensing-system in the Netherlands for advertising of medicines or medical devices to healthcare professionals. The criteria and rules are set out in legislation and codes (if any) and the industry is expected to comply with them.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Prescription-only medicines and medicines that are not prescription-only but do contain a forbidden (but regulated) substance as mentioned in list I or II of the Opium Act may never be advertised to the general public. • Over-the-counter medicines are divided into three groups; • UA – only available at pharmacies; • UAD – only available at pharmacies and drugstores; • AV – freely available.

	Advertisement for over-the-counter medicines is permitted, except for medicines that contain a forbidden substance as mentioned in list I or II of the Opium Act.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	Advertising of prescription-only and Opium Act-listed medicines to the general public is prohibited and advertisement of medicines that have not received a market authorisation is always prohibited. For all other medicines; advertisement must comply with the Medicines Act (art. 87/88/89), the advert may not conflict with the SmPC text from the registration file of the medicine, neither may it be contrary to the information in the package leaflet and on the packaging. Advertising that does not promote the rational use of a medicine is prohibited, for example: • To provide free samples of medicines; • To make direct or indirect price offers, issue vouchers or hold ‘‘refund promotions’’; • Make the purchase of the medicine a condition for participation in competitions. There are no restrictions applicable to the advertising of medical devices to the general public, except for medical devices in pharmaceutical form with physical effect (medical devices that are very similar to medicines), to the extent that such medical devices are intended to be used by the public without the intervention of a healthcare professional. The main restrictions applicable to such advertising: • The product itself must be compliant with the Medical Devices Act and delegated legislation; • Advertising is only permitted for self-care relating to indication that can be determined by the user himself without the intervention of a doctor/healthcare professional, or that has been determined once by a doctor and treated with other means; • Advertisement may not conflict with the information on the packaging and the enclosed instructions; • It is forbidden to state the extent or speed of weight loss that could be lost by using medical self-care aids intended for weight management/slimming. (Neither may a competition element occur.)
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	• Advertisement of medicines that have not received a market authorisation is prohibited. Other restrictions applicable to advertising of medicines to healthcare professionals are: – It is prohibited to provide a sample containing a substance as referred to on list I or II of the Opium Act; – The advertisement may not be misleading or deceiving; – The advertising shall be designed in such a way that its promotional nature is recognised; – Also see under 9 of this questionnaire.

	• There is no specific legislation or Code for advertising of medical devices to healthcare professionals.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	• All written advertising to healthcare professionals shall comply with the requirements in de Code PA and shall include, in conformation with the SPC, information about: – The name of the medicinal product; – The name and address of the party responsible for marketing the products; – The qualitative and quantitative composition of the active ingredients; – The pharmaco-therapeutic group, to the extent relevant; – The pharmaceutical form; – The principal: ▪ therapeutic indications; ▪ adverse reactions (according to frequency and severity); ▪ warnings (precautions connected with prescription and use); – the contra-indications; and – the classification of the medicinal product (prescription-only or not) for the purposes of supply. The information must be provided in a position and in a font justified by the importance of the information. • There is no specific legislation or Code for advertising of medical devices to healthcare professionals.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	• Advertisement to the public of medicinal products is regulated in the Code AGP and must include the following information: – The name of the medicinal product; – The generic name of the active substance, if the product contains only one active ingredient; – The indications and contra-indications; – An explicit request to read the package leaflet or the text on the outer packaging • Advertisements on medical devices in pharmaceutical form with physical effect (medical devices that are very similar to medicines), to the extent that such medical devices are intended to be used by the public without the intervention of a healthcare professional must include the following information: – The name of the medical self-care device; – The notion ‘medical device’; – The main uses and the situations in which use is discouraged;

		– An explicit request to read the instructions.
9.	Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	• Prescription-only and Opium Act-listed medicines The advertising must be consistent with the government-approved SPC of the medicinal product, as prescribed by or pursuant to the act. In promoting the rational use of the medicinal product, vague terms or superlatives must be avoided. The claim must be accurate, up-to-date and truthful, correct and verifiable in its detail. The advertisement must give the healthcare professional comprehensive and accurate impression of the (clinical) efficacy of the medicinal product according to the authorisation information, the adverse reactions and the contra-indications. All passages must provide source references, be accurately quoted from the publications and the use of the quote may not detract from the tenor of the publication. The quoted publication must reflect the latest state of scientific knowledge and technology. No general restrictions on the data must be used. • Advertisement of medicines to the general public Advertisement of medicines (Code AGP) must give an objective representation of facts and may not be dissaving or exaggerate its characteristics. It must be made clear that it is a medicinal product. The medicine cannot be equated with a food, cosmetic product or other consumer good. Furthermore, claims as ‘‘best’’ are not allowed because they are almost never truly correct and ‘‘natural (in origin)’’ may only be used when it is proven to be correct and relevant to differentiate from similar products. The therapeutic indication should appear in the advertising as the primary reason for use. Secondary qualities should not be used as a primary reason for purchasing. The advertisement may not promise a certain outcome or result. A medicine may only be promoted as ‘new’ for a period of two years. • Medical devices in pharmaceutical form Advertisement for a medical device in pharmaceutical form with physical effect (medical devices that are very similar to medicines), to the extent that such medical devices are intended to be used by the public without the intervention of a healthcare professional (Code AMD) must give an objective representation of facts and may not be dissaving or exaggerate its characteristics. It must be made clear that it is a medical device. It cannot be equated to a medicinal product, health-product, food, cosmetic product or other consumer good. Furthermore, claims as ‘‘best’’ are not allowed because they are almost never truly correct and ‘‘natural (in origin)’’ may only be used when it is proven to be correct and relevant to differentiate from similar products.

		The therapeutic indication should appear in the advertising as the primary reason for use. Secondary qualities should not be used as a primary reason for purchasing. The advertisement may not promise a certain outcome or result. A medical device may only be promoted as 'new' for a period of two years.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	Yes, there are specific rules for comparative advertising. • Prescription-only and Opium Act-listed medicines If the advertising makes a comparison with another substance or another medicinal product and if it names a competitor or a medicinal product marketed by a competitor, explicitly or implicitly, it is necessary to consider whether care has been taken: – That the comparison is not misleading: that the medicinal products being compared provide for the same need or are intended for the same purpose, and that the comparison objectively compares one or more of the medicinal product's fundamental, relevant, verifiable and typical properties, for example their (clinical) efficacy; – That the comparison does not unnecessarily prejudice the value of those other substances or medicinal products; – That the comparison does not discredit the authorisation holder of those other substances or preparations, its trade name and/or the brand name of those other substances or medicinal products; – That the comparison does not cause any confusion between the substances or medicinal products being compared and their brand names and/or between the relevant authorisation holders and/or their trade names; – That the comparison does not present medicinal products as an imitation or copy of medicinal products with a protected trade mark or a protected trade name; – That the advertising does not constitute an unfair advantage as a result of the reputation of a competitor's brand name or trade name or as a result of other distinctive characteristics of a competitor; – That the comparison is scientifically verifiable as accurate and in conformity with the latest state of the art; – That the comparison is comprehensive in terms of the effect, adverse reactions, indications, contra-indications and the other relevant data of the substances or medicinal products being compared, and, in general, has otherwise attempted to observe due care not only vis-à-vis the other parties in the industry, but also vis-à-vis the party targeted by the advertising. • Advertisement of medicines to the general public and medical devices in pharmaceutical form

		Any implicit or explicit comparison with other medicines or medical devices should be demonstrably correct and should not detract from the value of other products. Furthermore, comparisons are subject to the following conditions: no use of brand names is allowed, it has to regard similar products and the comparison should cover all relevant features.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	The main rule is that conditions that apply "offline" also apply "online". Advertising via social media shall be conducted in conformity with and in the spirit of the rules of conduct for oral and written advertising, taking account of the specific nature of this method. The range of social media is not limited to national borders. The Dutch Codes are only applicable to advertisement accessible in the Netherlands and aimed at the Dutch audience. General rules that apply to social media as well: • Advertising must always be recognizable as such; • The person who sends the message or is (partly) responsible for its content must be recognizable; • Quantification of the addressees; • Responsibility for the content of their own websites and referenced / linked media
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	Compliance with the Medicines Act is monitored by the Inspection for Health and Youth Care (*Inspectie voor gezondheidszorg en jeugd*). In case of a vialation of the Act, the sanction can be: • An administrative fine till the maximum of €450.00. • To suspend or terminate the trade or provision of a medicinal product. • Withdraw a medicine or substance from the market. *It is current practice that the Inspection only imposes a fine in case of a violation of the advertisementprovisions.* Compliance with the Code of Conduct for Pharmaceutical Advertising is monitored by the Code Commission (Codecommissie CGR). If a complaint has been ruled valid, the Code Commission can impose the following measures or sanctions: • A reprimand; • An order to immediately cease the act complained of and/or to (further) refrain from doing the act, or in the case of a challenged omission, to act in accordance with the Code of Conduct; • An order to take the measures necessary to guarantee compliance with the Code in the future; • A rectification order; • An order to recall distributed material; • Publication of the decision on different media including the sanction or measure imposed.

	The Inspection for Health and Youth Care, the Code Commission and the KOAG have made working agreements in which they have divided the different competences. In general, the Code Commission deals with all complaints or violations of the advertisement rules. This is only different when the Inspection beliefs the violation causes an imminent threat to the public health or safety, or when it concerns another serious violation of the advertisement provisions. In that case, the Inspection will take over. The Advertising Code Committee (Reclame Code Commissie) (Code Committee and the Board of Appeal are responsible for assessing whether advertising is made in accordance with the provisions of the Dutch Advertising Codes (meaning in this case: the Code AGP and the Code AMD)). The Advertising Code Committee can judge a complaint as unfounded or founded. If the complaint is found founded by the Commission, then they can do a ‘‘recommendation’’ in which they recommend the advertiser to no longer advertise in such way. The Commission can also decide to provide a ‘‘non-binding advice’’ or to issue a press release.
13. Any future developments in your jurisdiction?	N/A

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JURISDICTION: North Macedonia	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	The Law on Medicines and Medical Devices, Official Gazette of Republic of North Macedonia nos. 106/07, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 154/15, 228/15, 7/16, 53/16, 83/18, 113/18 и 245/18, which entered into force on 13 September 2007, ("**Law on Medicines**") stipulates the manner of advertising medicines and medical devices (jointly referred to as "**Medical Products**"). Additionally, the Guidebook on the Manner of Advertising on Medicines and Medical Devices, Official Gazette of Republic of North Macedonia no. 66/2008 ("**Guidebook on Advertising**"), which is a bylaw passed in accordance with the Law on Medicines and entered into force 28 May 2008, comprehensively regulates the manner of Medical Products advertising.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	Except the above-stated regulations, no other bylaws/codes of conduct regulate the manner of advertising Medical Products further.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	The market authorisation holders and the producers are entitled to advertise over-the-counter Medical Products to the general public upon prior approval from the Agency on Medicines and Medical Devices ("**Agency**"). Furthermore, the Agency determines the fees for obtaining such an approval, as follows: • Compensation for assessing the documentation submitted to the Agency in the procedure for obtaining an approval in case of advertising in print media (newspaper/magazine advertisement, poster, brochure, flyer, banner and billboard) or in the electronic media, is equal to: – EUR 200 for one pharmaceutical form, strength and size of package; – EUR 200 for each additional pharmaceutical form advertised in the same advertisement; – EUR 100 for each additional strength of the same pharmaceutical form advertised in the same advertisement; and – EUR 100 for each additional size or type of the package of the same pharmaceutical form and strength in the same advertisement. • Compensation for assessment of the documentation for any form of advertising to the general public in the amount of EUR 200. The Law on Medicines does not require special approval for advertising to healthcare professionals. Namely, the advertising of

	Medical Products to healthcare professionals could be performed only by market authorisation holders for the sale of Medical Products in North Macedonia by publishing advertisements in professional magazines and publications as well as by directly informing the healthcare professionals who prescribe the Medical Products.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	The main difference between the regulations that refer to the advertising of these two categories of medicines is the ban of advertising prescription-only medicines ("**POM**") to the general public. POM may be advertised only under the following conditions: • The purpose of the advertising should be to inform the expert public about the properties and the therapeutic effects of the Medical Product; • The target of advertising should be limited to the following categories of healthcare professionals: – Healthcare workers that prescribe, sell, or issue the Medical Product. – Conduct or influence the procurement for a pharmacy or specialised store or other health institution. – Graduated pharmacists or other experts in production, wholesale trade or retail trade. – Experts employed in the Ministry on Health or in the Agency.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	Please note that the same main restrictions are applicable for medicines and for medical devices. Therefore, when advertising Medical Products to the general public, following elements must not be present: • Allegations that the expenses for the Medical Products will be borne by the Health Insurance Fund, except in cases of epidemics; • Indications about the price of the Medical Products; • Recommendations on the properties of the Medical Products which encourage the use of the Medical Products; • Famous persons who might influence usage due to their popularity; • Disease histories or diagnostic procedures that may lead to misdiagnosis or self-diagnosis; • Inappropriate, disturbing or misleading indications of changes of the human body caused by the disease, injury or by some Medical Products; • Data or conclusions on the efficiency of the Medical Products which is still a subject of clinical trial in North Macedonia or abroad; • Data on the disease, diagnosis, or therapeutic procedures or the Medical Products used in the treatment procedure of specific people;

	• Children using or intending to use the Medical Products; • Children must not be the target of the advertisement; and • Free samples may not be given to the general public and the name of the pharmacy that sells the Medical Products or the wholesaler of the Medical Products must not be indicated during advertising. In addition to all of the above, the Guidebook on Advertising prohibits leaving certain impressions on the consumer (e.g. the impression that taking Medical Products is beneficial for the health, even when no signs of illness).
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	The Law on Medicines differentiates between three forms of Medical Products advertising to healthcare professionals: • Promotion; • Providing free samples; • Sponsoring expert gatherings. Please note that the same main restrictions are applicable for medicines and for medical devices. All forms of advertising are strictly regulated, but the most comprehensively regulated restrictions apply to the promotion of Medical Products, i.e. following actions are forbidden: • Encouraging prescription, issuance, purchase of Medical Products, or giving any recommendation for using or purchasing Medical Products by offering and rewarding money, giving gifts or any other benefit, • Encouraging the expert public to replace one Medical Product with another Medical Product from the same therapeutic group, without clear medical indications; • Drawing conclusions about the effects of a Medical Products subject to clinical trials in North Macedonia or abroad; • Promoting a Medical Product during the process of changing the summary of Product characteristics ("**SmPC**") and/or the patient-user guidelines; • Using a SmPC and/or a patient-user guideline, with small letter size, or another type of printing that prevents easy reading and comprehension of the text; • Publishing information through the media used in the process of advertising the health facilities, or specialised stores; • Diminishing the significance of the precautions or adverse reactions to the Medical Product stated in the approved SmPC as well as in the user guide; • Reducing the therapeutic value of another Medical Product with marketing authorisation or in any other way to raising doubts about the value of another Medical Product;

	• Using employees of the Ministry on Health, the Agency or other persons that participate in Medical Products advertising; • Using materials protected as intellectual property without prior consent of the owner; • Using postcards or other forms of written messages which may be seen by the general public; and • Using telephone, fax, electronic mail or other electronic media without explicit prior consent from the owner.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	Please note that the same information should be included in the advertisements of medicines and medical devices to healthcare professionals. Generally, the advertising to healthcare professionals should include information on a Medical Product's characteristics and its therapeutic effects. Mandatory information is stipulated only for promotion of Medical Products, i.e. the marketing authorisation holder is obliged to indicate: • The date of obtaining the marketing approval; or • The date of the last change of the marketing approval, as well as updated, relevant or duly transmitted data with indication of the source; and • Information on the manner of issuance of the Medical Product i.e. over the counter or prescription-only. In addition to the above information, the advertisement to healthcare professionals may present information about the retail price of the Medical Products;
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	Please note that the same information should be included in the advertisements of medicines and medical devices to the general public. Therefore, when advertising to the general public, the message should at least contain: • The name of the Medical Product; • The method of use and data necessary for the proper use of the Medical Product, • Visible, legible and understandable written or spoken warning to the user about carefully reading the user guide and consulting a doctor or pharmacist about the possible risk and adverse reactions (the exact of form of this warning is given in the Guidebook on Advertising).
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	The Guidebook on Advertising contains only a general requirement on indicating true and scientifically proven data in the advertisement. Generally, advertising of Medical Products must be made in accordance with the approved user guide, whilst in case of medicines, compliance with the SmPC is also required.

10.	Are there specific rules for comparative advertisement of medicines and medical devices?	The Law on Medicines and the Guidebook on Advertising explicitly forbid the comparative advertisement of Medical Products in North Macedonia.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	When advertising on the internet, the mandatory warning for carefully reading the user guide and consulting a doctor prior to usage (referred to also in question 8, point 3) must be an integral part of the start page (or home page) of the advertisement.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	The compliance monitoring is conducted by the Agency via pharmaceutical inspectors. Pharmaceutical wholesalers with turnover above MKD 10,000,000 or approx. EUR 162,602 are subject to mandatory inspection conducted by two pharmaceutical inspectors, two tax inspectors and one custom official. If the advertising is unlawful, the pharmaceutical inspectors are entitled to forbid it and to order destruction on all materials used for that purpose. A fine in the amount of EUR 50,000 will be imposed on the legal entity, if it: • Advertises prescription-only Medical Products to the general public; • Prescribes false characteristics, highlights its positive effects, uses improper manner in describing its effects, compares Medical Products with other ones or uses any other manner that is misleading for the consumer, • Advertises by addressing children; • Distributes free samples to the general public; • Advertises Medical Products without marketing authorisation; or • Advertises Medical Products used only in healthcare institutions. A fine in the amount of 30% thereof will be imposed on the responsible person within the legal entity, whilst the responsible employee will be fined a sum of EUR 5,000 up to EUR 7,500. A fine in the amount of EUR 30,000 will be imposed on the legal entity, if it: • Violates the statutory general rules for advertising Medical Products to healthcare professionals; • Promotes Medical Products by exceeding the scientific-expert purposes; or • Misinforms the general public on Medicine Product's characteristics. A fine in the amount of 30% thereof will be imposed on the responsible person within the legal entity, whilst the responsible employee will be fined a sum of EUR 3,000 up to EUR 4,500.

13.	Any future developments in your jurisdiction?	In respect of the advertising of Medical Products, there is no publicly available indication that any development is planned for the near future.

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JURISDICTION: Peru	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	In Peru, the advertising regulations of medicines and medical devices are included in: • Law on Pharmaceuticals, Medical Devices and Sanitary Products – Law N° 29459; • Regulation for the registration, control and sanitary surveillance of pharmaceutical products, medical devices and sanitary products – Legislative Decree N° 016-2011-SA; • The National Politics of Medicines – Ministerial Resolution N° 1240-2004/MINSA- and • The Administrative Directive regulating the activities of medical visitors or other agents of pharmaceutical companies in health establishments – Ministerial Resolution N° 413-2015 / MINSA; • The Technical Health Standard that establishes the Ethical Criteria for the Promotion and Advertising of Pharmaceutical Products, Medical Devices and Health Products – Ministerial Resolution N° 474-2020-MINSA; • Law of Repression of Unfair Competition – Legislative Decree No. 1044; • The Code of Protection and Defence of the Consumer – Law No. 29571.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	In Peru, the following ethical criteria must be taken into consideration: • The Ethical Criteria for the promotion of medicines of World Health Organization – WHO; • The Ethical Criteria for the Promotion, Propaganda and Advertising of Medicines of the Pan-American Network for the Harmonization of Pharmaceutical Regulations of WHO – RED PARF; • The Andean Ethical Criteria for the Promotion and Publicity of Medicines of the Andean Health Agency of the Andean Community – CAN.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	The advertising of over-the-counter medicines and medical devices does not require prior approval or a licence. The advertising of prescription-only medicines and medical devices is prohibited. Pharmaceutical companies that wish to advertise their products to health care professionals should request an admission authorisation from their medical visitors or other agents annually before the General Directorate of Health – ("**DIGEMID**") or the Headquarters of each public or private health facility.

4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes, it does.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	For prescription-only medicines and medical devices, the Peruvian Law prohibits advertising directed to the general public. In that sense, the Peruvian Law stipulates that the advertising of these medicines and medical devices must be directed to healthcare professionals and must be carried out through medical visitors or other agents of pharmaceutical companies, who must be duly accredited.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	For the advertising of medicines and medical devices to healthcare professionals, medical visitors or other agents of pharmaceutical companies should not interfere with the activities of healthcare professionals with patients in health facilities.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	In the case of medicines, the advertising must contain the information on the data sheet filed to obtain the sanitary registry. In the case of medical devices, the advertising must contain its technical report filed to obtain the sanitary registry. In both cases, such information must be given in a legible, visible, truthful, accurate, complete and updated manner according to the information filed to obtain the sanitary registry. Also, advertising that disseminates scientific, clinical or pharmacological information must be supported and updated in the medicines and medical devices sanitary registry. In any type of printed material, in which medicines and medical are promoted and publicized, the technical and scientific information approved by the DIGEMID, as well as other relevant information as appropriate, must be disseminated in such a way that it is understandable, accessible, and consistent with what is authorized in its sanitary registry and/or mandatory health notification, thus promoting its easy reading and application. If the announcements about the introduction of prescription-only medicines and medical devices are disseminated in mass written media, they must contain the following information: • Name of the medicine or medical devices; • International Common Name of the Active Pharmaceutical Ingredient – IFA, even if it contains up to 3 Active Pharmaceutical Ingredient(s) – IFA(s), under the name clearly and legibly; In the case of a homeopathic product, the phrase “Homeopathic Product” must be entered, followed by the scientific name of the natural resource used in its formula; • Pharmaceutical form; • The amount of Active Pharmaceutical Ingredient – IFA (expressed in unit dose or concentration) of each. In the

	case of a homeopathic medicinal product, the degree of dilution must be recorded; • Form of presentation; • Sanitary Registry Number; and • Name, address and / or telephone number of the holder of the sanitary registry, specifically indicating that there is more information available about the product. If the product is imported, it also bears the name, address and / or telephone number of the importer. The messages, symbols and images that are disseminated in the promotion and advertising of medicines and medical devices must not distort, or mislead or confuse the origin, results, benefits, characteristics, benefits or indications approved by the DIGEMID.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	For advertising over-the-counter medicines and medical devices, it must contain the main precautions and warnings according to its sanitary registries, included the number of the sanitary registry granted by DIGEMID. Also, the advertising of over-the-counter medicines and medical devices that refer to therapeutical prescriptions or the pharmacological action of the product must contain or refer to the main precautions and warnings that must be observed in its uses. In any type of printed material, in which medicines and medical are promoted and publicized, the technical and scientific information approved by the DIGEMID, as well as other relevant information as appropriate, must be disseminated in such a way that it is understandable, accessible, and consistent with what is authorized in its sanitary registry and/or mandatory health notification, thus promoting its easy reading and application. The messages, symbols and images that are disseminated in the promotion and advertising of medicines and medical devices must not distort, or mislead or confuse the origin, results, benefits, characteristics, benefits or indications approved by the DIGEMID.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	The scientific data indicated in advertisements must be the same approved in its medical registry and must accord to ethical parameters that will be established by DIGEMID. The promotion and advertising of medicines and medical devices must not contain exaggerations or inaccuracies about the therapeutic, nutritional, cosmetic, diagnostic, preventive properties or of any nature that are not consistent with those authorized, recognized or previously updated in their sanitary registration and/or health notification submitted to DIGEMID. It is not allowed to claim that a medicine or medical device is completely innocuous or safe, if it does not have technical or scientific support.
10. Are there specific rules for comparative advertisement of medicines and medical devices?	It is not allowed to suggest or claim that a medicine or medical device is safer or more effective compared to others, without verifiable scientific evidence. Also, the Law of Repression of Unfair Competition – Legislative Decree No. 1044 – establishes that comparisons made between competitors and a company's own products in an advertisement must be objective and pertinent.

11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	For prescription-only medicines and medical devices, advertising on the internet or social media is not allowed. For over-the-counter medicines and medical devices, the rules for internet advertising are the same as those for audiovisual and print media, which are the following: • Advertising in print media must record the corresponding technical information of the sanitary registry in a visible and legible way, proportionally adjusting to the size of the advertisement. The minimums font size is eight points. • The advertising in audiovisual media must record the information of the main precautions and warnings about the pharmaceutical product or medical device, in a clear, legible manner, and with a font size that is perceptible by the viewer. Written legends require a duration proportional to the duration of the advertising. Finally, email advertising should not encourage self-medication or be misleading.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	In Peru, the Bureau of Competition and Consumer Protection – INDECOPI is the authority tasked with enforcing the advertising legislation through the application of penalties, precautionary and corrective measures. Penalty proceedings for advertising infractions can be initiated ex officio at the initiative of INDECOPI or at the request of a party through a claim that may be filed by consumers, competitors or an authority such as DIGEMID. In the case of fair competition infractions, the Commission of Repression of Unfair Competition of the INDECOPI is the supervisory body for advertising infractions. In these cases, the penalties for advertising infractions range from a maximum of USD$62,000.00 (approx.) for minor infractions, USD$309,000.00 (approx.) for serious infractions and USD$865 000.00 (approx.) for very serious infractions. On the other hand, while commercial advertising is understood as a supplier's commitment to the consumer, the Commission for the Protection of the Consumer is the supervisory body that deals with how consumers are affected by misleading advertising. Penalties for advertising infractions range from a maximum of USD$62,000.00 (approx.) for minor infractions, USD$186,000.00 (approx.) for serious infractions and USD$556,000.00 (approx.) for very serious infractions. Also, the bureau of medicines and medical devices, DIGEMID, is tasked with monitoring the compliance of the medicines and medical devices legislation.

13. Any future developments in your jurisdiction?	• The Commission for the Suppression of Unfair Competition of INDECOPI has published the Informative Guide on Digital Advertising, especially focused on advertising by influencers. that will allow opinion leaders and content managers to transparently disseminate information about products or services that they share with their followers on social networks, which could be considered as advertising.

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JURISDICTION: Poland	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	The main act providing the legal framework for advertising of medicinal products is *the Pharmaceutical Law of 6 September 2001 together with the implementing Ordinance of the Minister of Health of 21 November 2008 on the Advertising of Medicinal Products*; The most important act regulating the advertising of medical devices is *the Act on Medical Devices of 20 May 2010*. Additional (stricter) principles applicable to advertising of both: medicines and medical devices being subject to reimbursement from public funds arise from *the Act of 12 May 2011 on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses, and Medical Devices.*
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	The most important self-regulatory codes adopted by associations of entities operating respectively in the pharmaceutical and medical devices sector include: • *The Code of Good Practice for the Pharmaceutical Industry* was established by the Employers' Association of Innovative Pharmaceutical Companies INFARMA on the basis of the Code of the European Federation of the Association and Pharmaceutical Industry (EFPIA). The Code is open not only to innovative companies, but also to other pharmaceutical industry entities and their organisations; • *The Code of Ethical Business Practice*, adopted by the Polish Chamber of Commerce for Medical Devices POLMED as an implementation of the MedTech Europe Code of Ethical Business Practice tailored to the Polish regulatory realities.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	There are no specific licences, approvals or fees required to advertise medicines and/or medical devices in Poland.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes. Under Polish law, it is generally prohibited to address advertising to the general public related to: (i) medicinal products dispensed exclusively on the basis of a prescription, or (ii) products whose name is identical to the name of such a medicinal product. The prohibition only does not apply to some specific protective vaccines.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	The general principles applicable to the advertising of medicines addressed to both the general public and healthcare professionals, are as follows: (i) advertising may be conducted exclusively by the MAH (i.e. the *Marketing Authorisation Holder*) or upon the order of the MAH; (ii) it is prohibited to advertise medicinal products which have not been authorised for marketing in Poland; (iii) it is also prohibited to provide information

	inconsistent with the Summary of Product Characteristics; (iv) advertising must not be misleading, should present the product objectively and should inform about its reasonable use; (v) advertising must not involve an offer or promise of any indirect benefits for purchasing the medicinal product or for the delivery of evidence that the medicinal product has been purchased; and (vi) advertising may not be addressed to children or contain any elements addressed to children. Additionally, the advertising addressed to the general public must not (i) involve celebrities, scientists, healthcare professionals or persons implied to be healthcare professionals presenting the medicinal product or (ii) refer to recommendations made by such people. Furthermore, the advertising of medicinal products addressed to the general public must not suggest that: (i) a medical consultation or surgical operation is unnecessary; (ii) even a healthy person taking the medicinal product can enhance his/her own health; (iii) failure to take the medicinal product may cause the health of the specific person to deteriorate (with the exception of specific vaccinations); (iv) the medicinal product is a foodstuff, cosmetic or represents other consumer goods; or (v) the efficacy or safety of use of the medicinal product arises from its natural origin. The advertising of medicinal products addressed to the general public must also not: (i) assure that taking the medicinal product guarantees the appropriate effect, is unaccompanied by adverse reactions or that the effect is better than or equivalent to that of another treatment or medicinal product; (ii) lead to erroneous self-diagnosis by presenting detailed descriptions of case histories and disease symptoms; (iii) contain improper, alarming or misleading terms referring to graphically represented pathologies, human body injuries or actions of the medicinal product on the human body or its parts; and/or (iv) justify the use of the medicinal product by the fact of its marketing authorisation. Regardless of the above, it is prohibited to address to the general public advertising related to medicinal products: (i) dispensed exclusively on the basis of a prescription; (ii) containing narcotic agents and psychotropic substances; and/or (iii) registered as reimbursed medicines or whose name is identical with such medicines. Promotional materials, presentations and product information concerning medical devices must not be misleading by: (i) assigning properties, functions and/or activities to the device that the device does not have; (ii) giving the false impression that the treatment or diagnosis with the device will certainly succeed, or failure to inform about the expected risk associated with using the device in accordance with its intended use or for a longer period than anticipated; (iii) suggesting the use or properties of a device other than those declared when the conformity assessment was carried out.

6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	• For general rules applicable to medicinal products advertising regardless of its addressees, please see Q5 above. Additionally, for persons qualified to prescribe medicinal products and persons trading in medicinal products, it is prohibited to advertise medicinal products by providing, offering or promising pecuniary advantages, gifts and various types of facilitation, prizes, trips, and organising and financing medicinal product promotional meetings at which the hospitality towards participants is not limited to the main purpose of the meeting. At the same time, it is prohibited to accept the advantages and benefits referred to above. These prohibitions do not apply only to giving or accepting objects of a value not exceeding PLN 100.00 (about EUR 23.00), which are related to the medical or pharmaceutical practice and bear a mark advertising a specific company or medicinal product. Advertising of medicinal products which involves the free-of-charge delivery of product samples may be addressed exclusively to persons qualified to prescribe medicinal products. Additionally, such advertising is admissible only provided that specific conditions listed in the Pharmaceutical Law have been met (e.g. the person qualified to prescribe medicinal products submitted a written request for the supply of a sample, each sample must be marked as “free sample – not for sale”, etc.). In any case, however, it is not possible to provide samples of medicinal products free of charge that contain narcotic agents or psychotropic substances. Advertising for medicinal products addressed to persons qualified to prescribe medicinal products or to persons trading in medicinal products should contain information consistent with the Summary of Product Characteristics and information on the dispensing category, and in the case of medicinal products entered in the lists of reimbursed medicinal products, also the official retail price and the maximum amount of supplementary payment made by the patient. • Please see the answer to Q6 above with regard to medical devices.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	The advertising of a medicinal products addressed to persons authorised to issue prescriptions or persons trading in medicinal products must contain the following data: (i) the name of the medicinal product and commonly used name; (ii) qualitative and quantitative composition in terms of active substances and those excipients that are essential for the proper use of the medicinal product; (iii) pharmaceutical form; (iv) therapeutic indication or indications for use; (v) dosage and method of administration; (vi) contraindications; (vii) special warnings and precautions for use; (viii) side effects; (ix) indication of the MAH; (x) marketing authorisation number and name of the issuing authority; (xi) other information consistent with the Summary of Product Characteristics; (xii) information on the dispensing category; and in the case of medicinal products entered in the lists of reimbursed

		drugs, also (xiii) the official retail price and the maximum amount of supplementary payment made by the patient. There are no specific requirements with regard to advertisements of medical devices addressed to healthcare professionals.
8. a) b)	What information must appear in advertisements directed to the general public for: medicines? medical devices?	• The advertising of a medicinal product to the general public must contain the following data: (i) the name of the medicinal product; (ii) the name of the commonly used active substance, and in the case of a medicinal product containing more than 3 active substances, the term "combined product"; (iii) the dose of the active substance or concentration of the active substance, excluding the combined product; (iv) the pharmaceutical form; (v) therapeutic indication or indications for use; (vi) contraindications; (vii) indication of the MAH. Additionally, such an advertisement must contain a warning of strictly defined content. • There are no specific requirements with regard to advertisements of medical devices addressed to the general public.
9.	Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	The documentation concerning medicinal products supplied to persons qualified to prescribe medicinal products or to persons trading in medicinal products should be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned, and should include the date of its development or last revision. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works should be faithfully reproduced and the precise sources indicated. Moreover, scientific data, analyses, research results taken from professional literature or scientific journals in order to facilitate verification and assimilation of information presented in the advertisement of a medicinal product must be provided in line with the original and together with their source and date of publication or last update.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	Comparative advertising of medicines is regulated in pharmaceutical law to a very limited extent only. As mentioned above, the applicable legislation states that the advertising of medicinal products addressed to the general public must also not (among other things) claim that taking the medicinal product is better than or equivalent to, that of another treatment or medicinal product. There are no specific rules regarding comparative advertising of medical devices.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	There are no specific rules on the advertising of medicines and/or medical devices on the Internet or in social media.
12.	Please describe the enforcement mechanism in your jurisdiction.	The Main Pharmaceutical Inspector ("**MPI**") supervises the compliance of advertising with the provisions of the

	Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	Pharmaceutical Law. The MPI may order, by way of a decision: (i) that advertising in violation of the provisions of the Pharmaceutical Law cease; (ii) that the issued decision be published in places where advertising in violation of the provisions of the Pharmaceutical Law appeared as well as an erratum to the erroneous advertising; (iii) the remedying of the deficiencies found. Regardless of the above, breaching some of the above-mentioned regulations on advertising of medicinal products may be deemed an offence punishable by a fine. Supervision over medical devices is the responsibility of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Disseminating misleading information or promotional materials concerning medical devices may constitute a criminal offense punishable by a fine, restriction of liberty or imprisonment.
13.	Any future developments in your jurisdiction?	As the EU medical devices regulation 2017/745 is going to come into force in 2021, a draft act providing for related national regulations, in particular, provisions concerning advertising of medical devices, is currently subject to public consultation. This act is to replace the currently applicable *Act on Medical Devices of 20 May 2010* after being adopted by the Polish Parliament and signed by the President of the Republic of Poland.

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JURISDICTION: Romania

1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	• Law no. 148/2000 on advertising; • Audiovisual Law no. 504/2002; • Law no. 95/2006 on the healthcare reform; • Ministry of Health Order no. 194/2015 approving the Norms for the valuation and approval of advertising of medicinal products for human use; • National Audio-visual Council Decision no. 220/2011.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of a) medicines? b) medical devices? If yes, please indicate these.	There are several industry associations in Romania, that have their internal codes of conduct, binding on their members. In relation to medicines, the most relevant association is the Romanian Association of International Medicines Manufacturers (ARPIM)(member of EFPIA). In relation to medical devices, the most active associations in Romania are the Romanian Association of the Self-Care Industry (RASCI) and the Association of Suppliers of Medical Products (AFPM) (the latter, a member of MedTech Europe).
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to a) the general public? b) healthcare professionals?	**Medicines:** • The advertising materials for over-the-counter medicinal products ("**OTC**"), as well as the educational materials, destined for the general public/patients, must be approved by the National Agency for Medicines and Medical Devices in Romania ("**ANMDMR**") before they are placed on the market. This obligation is born by the marketing authorisation holder. The fee is calculated based on a specific formula[1]. • It is prohibited to advertise to the general public (among others) prescription-only-medicines ("**POM**"), and medicines prescribed and released in the health insurance system. • The advertising materials for POMs or OTCs destined for the healthcare professionals do not need prior approval from ANMDMR. They will be verified randomly or upon notification by ANMDMR after they are placed on the market. **Medical devices:** • Under Romanian law, no specific licence/approval/fee is required for / applies to the advertising of medical devices.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes, as detailed in response to question 3 above.

[1] For advertising materials – RON 550 (approx. EUR 120) X the number of marketing authorizations included in the material X the number of the communication channels X 1 (for 6 months) or 2 (for 12 months).
For educational materials – RON 350 (approx. EUR 70) X the number of marketing authorizations included in the material X the number of the communication channels X 1 (for 6 months) or 2 (for 12 months).

5. What are the main restrictions applicable to the advertising of a) medicines b) medical devices to the general public?	**Medicines:** • It is prohibited to advertise medicines to the general public: – if such medicines do not hold a valid marketing authorisation in Romania; – without the approval of ANMDMR (where such approval is required); – if such medicines are POMs or they contain narcotic or psychotropic substances (with the exception of vaccination campaigns performed by the pharmaceutical industry and approved by the Ministry of Health); – if such medicines are prescribed and released in the health insurance system. • In addition, the advertising materials must not include information: – suggesting that proper medical consultation or surgical intervention is not necessary, especially by offering certain suggestions for diagnosis or long-distance treatment; – suggesting that the medicinal product has a guaranteed effect or it does not cause adverse reactions; – suggesting that the patient's health condition cannot be improved unless he/she uses the advertised medicinal product; – suggesting that the patient's health condition may worsen unless he/she uses the advertised medicinal product; – aimed exclusively or mainly at children; – emphasising a certain recommendation from healthcare professionals whose celebrity could encourage the consumption of such medicinal products; – suggesting that the medicine is a food, cosmetic or other consumer product; – suggesting that the medicine's safety or efficacy is due to the fact that it is a natural substance; – that may constitute, through a detailed description or representation of a case, an incentive to an incorrect self-diagnosis; – offering assurances regarding healing, in inappropriate or misleading terms; – that improperly, impressively or deceptively uses visual representations of alterations of the human body due to illness or injury, or of the action of a medicine on the human body or on a part thereof; – falsely stating that there is a marketing authorisation in force for a particular product;

	– presenting violence (even stylized); – using diminutives or other words (expressions) meant to trigger an emotional response from the users' side; – presenting messages, images from campaigns of other types of products (cosmetics, food supplements, medical devices etc.). **Medical Devices:** • Under Romanian law, there are certain rules and restrictions in case of radio and TV advertisement of medical devices. In brief, it is prohibited to: – advertise a medical device released based on medical prescription; – broadcast advertising materials where healthcare professionals, medical associations or pharmacists recommend the use of medical devices; – broadcast advertising materials in TV shows for children or during the commercial breaks preceding or subsequent to the broadcast of such shows.
6. What are the main restrictions applicable to the advertising of a) medicines b) medical devices to healthcare professionals?	**Medicines:** • The following restrictions apply in case of advertising medicines to healthcare professionals: – it is prohibited to advertise a medicinal product prior to the issuance of the marketing authorization, as well as to advertise a medicinal product outside its approved therapeutic indication; – it is prohibited to state that a medicinal product has no adverse reactions, toxicity or dependence risks, except as documented in the summary of a product characteristics; – it is prohibited to promise and receive gifts, benefits in cash or in kind for the purpose of prescribing or to release medication; – it is prohibited to advertise a medicinal product by misleading health professionals through statements that one drug is better or safer than another unless there is scientific support for this statement; – it is prohibited to present messages in the printed advertising materials stating or only suggesting that the use of the medicinal product does not bear any risks, except for cases documented in the summary of product characteristics; – it is prohibited to leave advertising materials in places accessible to the general public, as are, but are not limited to, pharmacies, waiting rooms of medical offices, hospitals and clinics etc. **Medical devices:** • See question 5 above.

7. What information must appear in advertisements directed only to healthcare professionals for a) medicines? b) medical devices?	**Medicines:** • Advertisements, regardless of whether referring to POMs or OTCs, must contain at least the following mandatory information: – name of the medicinal product and the active substance (INN = International Non-proprietary Name); – pharmaceutical form and formulation; – doses for each administration mode / route and for each therapeutic indication, as the case may be; – the date of the first marketing authorisation or of the authorisation's renewal; – the other essential information in the summary of product characteristics; – date of revision of the text (for summary of product characteristics); – the statement: "This promotional material is intended for health professionals"; – how the medicine is dispensed and the type of prescription on which it is dispensed; – the information from the summary of product characteristics shall be printed using the minimum font size of 10, regardless of the font used. **Medical devices:** • Romanian law does not provide any mandatory information in advertisements for medical devices (irrespective of whether directed to healthcare professionals or to the general public). • Note, the local industry associations' codes of practice may include specific requirements on the matter, applicable to their members.
8. What information must appear in advertisements directed to the general public for a) medicines? b) medical devices?	**Medicines:** • Advertisements of OTCs and vaccination campaigns performed by the pharmaceutical industry and approved by the Ministry of Health, must contain at least the following mandatory information: – the name of the medicinal product, as well as the international non-proprietary name (if the medicinal product contains a single active substance); – the information necessary for the correct use of the medicinal product (therapeutic indication, recommended dose in accordance with the therapeutic indication); – an explicit and readable invitation to carefully read the instructions in the package leaflet or on the outer packaging, formulated in accordance with the provisions in force;

		– "reminder" type materials must include the name of the medicinal product and the invitation to read the instructions on the package leaflet or on the outer packaging, as the case may be. **Medical devices:** • See question 7 above.
9.	Please summarize the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	See question 7 above. In addition, any quotation, table and other illustrative material taken from medical publications or other scientific work, that are destined for usage in advertisement directed to healthcare professionals, must be reproduced faithfully and with the exact indication of the source (references). Also, all illustrations from the promotional materials, including graphs, various images, photos and tables, taken from published studies must meet the following conditions: • they must clearly indicate the exact source(s) of the illustrations; • they must be faithfully reproduced, unless adaptation or modification is necessary, in which case one must clearly state that the illustrations have been adapted and/or modified; • they must not to mislead in any way in relation to the information about the medicine.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	There are specific legal provisions for comparative advertisement in relation to medicines, as detailed below. Comparative advertisement of medicines directed to the general public is prohibited. By contrast, comparative advertisement of medicines (whether POMs or OTCs) directed to the healthcare professionals is permitted unless: • the comparison is misleading; • the brand name of a competitor is used; only international non-proprietary names may be mentioned; • one compares drugs that have different therapeutic indications or different pharmaceutical forms; • one does not objectively compare one or more essential, relevant, verifiable and representative characteristics of certain medicinal products, including the price; • one creates confusion on the market between the entity that advertises and a competitor or between different brands, international non-proprietary names or other distinctive signs of the entity that advertises and those belonging to a competitor; • one discredits or denigrates the trademark, international non-proprietary name, other distinctive signs, activities or any other characteristics of a competitor; • one incorrectly takes advantage of the reputation of a trademark, the international non-proprietary name, the

	distinctive signs of a competitor or any other characteristics of a competitor without having evidence in support of those stated. With regard to medical devices, the local industry associations' codes of practice may include specific requirements on the matter, applicable to their members.
11. Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	There are specific legal provisions for advertisement of medicines on the internet, as detailed below. Advertisement of medicines on the internet includes: webpages, e-mails, forums, blogs or any other form of electronic support, except for social networks or Android, iOS or any other mobile application. The advertisement on the internet, irrespective of the form in which it is made, must be valuated and approved by ANMDMR. Every webpage must comprise at least information about: • the identity and address (both physical and electronic) of webpage's sponsor; • complete references regarding the source(s) of all medical information included on the webpage; • the target audience of the webpage; • the number of the advertising visa and date of issuance; • relevant information for investors, media and the general public, including financial data, descriptions of research and development programs, list of products in the portfolio, discussions on regulations affecting the company and its products, information for potential future employees; • non-promotional information on health education, characteristics of diseases, prevention methods, screening and treatment, as well as other information with the intention of promoting public health; • relevant aspects of therapeutic alternatives, including, where appropriate, surgery, diet, behavioural change and other interventions that do not require the use of medicines; • the latest approved information, package leaflet and summary of product characteristics of the advertised medicines; • non-promotional aspects for patients and the general public regarding the OTC portfolio of the pharmaceutical company; • links to a complete, unmodified copy of any public assessment report issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) or by a relevant national competent authority; • the recommendation for visitors to consult a health professional for more information. It is prohibited to advertise medicines through email, mobile phones (SMS) or social networks. The advertisement of POMs on the internet to healthcare professionals is permitted under the following conditions:

		• the marketing authorisation holder must prove that access to such information is restricted to persons other than health professionals through a valid and verifiable password system; the information provided must contain the full summary of product characteristics; • website providers must ensure that the materials posted on the website do not contain information inconsistent with applicable national and international regulations. With regard to medical devices, the local industry associations' codes of practice may include specific requirements on the matter, applicable to their members.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	ANMDMR is the body that monitors compliance with the requirements of the law on advertising medicines (whether POMs or OTCs). In case of non-compliance with the requirements of the law on advertising medicines (POMs and OTCs), ANMDMR can apply a fine ranging between RON 10,000 (approx. EUR 2,100) and RON 30,000 (approx. EUR 6,300). This fine can be applied to the manufacturer, importer, wholesale distributor, marketing authorization holder or the representative of the marketing authorization holder. The National Consumer Protection Agency, the Ministry of Finance, the Romanian Audiovisual Council are the bodies that monitor compliance with the general advertisement provisions. They can apply various fines and sanctions for non-compliance with the advertisement provisions, depending on the type of infringement. These sanctions include the suspension, withdrawal or cancellation of certain authorisations, and the withdrawal of certain products from the market.
13.	Any future developments in your jurisdiction?	The new EU Regulation 2017/745 on medical devices that will apply from 26 May 2021, contains, *inter alia*, advertising rules for medical devices. With respect to the advertisement of medicines, there are no future developments envisaged.

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JURISDICTION: Russia	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	The Russian Federal Law on Advertising dated 13 March 2006 № 38-FZ (the "**Law on Advertising**").
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	The advertising of medicines is also partially governed by the self-regulatory Code of Practice of the Association of International Pharmaceutical Manufacturers (the "**Code**"). Besides, there are Recommendations on compliance with legislation on OTC medicines adopted by the Federal Antimonopoly Service of the Russian Federation and several industrial associations, including the Association of International Pharmaceutical Manufacturers (the "**Recommendations**"). The Recommendations are the practical guidance on promotion of OTC medicines which is not legally binding.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	No licences, approvals or fees are required to advertise medicines and medical devices in Russia.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	The advertising of OTC over-the-counter (OTC) medicines is regulated less strictly. The OTC medicines may be advertised to general public. The advertisement of RX is *only permitted* in specialised printed publications directed to HCPs only and at the professional events in healthcare area (conferences, congresses, etc.).
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	The advertisement of OTC medicines and medical devices to general public may not: • Be addressed to minors; • Contain any reference to specific cases when someone has been cured or when somebody's health has improved as the result of the application of the object of advertising; • Contain an expression of gratitude by actual persons in connection with the use of the object of advertising; • Create the idea that the object of advertising has advantages by making reference to the fact of trials having been completed which are mandatory for the state registration of the object of advertising; • Contain the assertion or assumption that the target audience of the advertisement have certain diseases or health disorders; • Assist in causing a healthy person to gain the impression that he/she should use the object of advertising;

	• Create the impression that there is no need to visit a medical doctor; • Guarantee a positive effect from the object of advertising, its safety, efficiency and lack of side effects; • Present the object of advertising as a biologically active supplement and food supplement or as other goods that are not medicines; and/or • Contain the assertion that the safety and/or effectiveness of the object of advertising is guaranteed by its natural origin. Furthermore, the advertisement of medicines and medical devices to the general public must contain a warning notice “There are the contraindications” or“Please consult your physician”. Finally, the general rules on advertising provided by the Law on Advertising are to be observed. In particular, advertising must be fair and truthful. Also, the advertising may not use an image of a medical worker or pharmacist unless the advertising is addressed to medical workers and pharmacists only and placed in a specialised journal or at public events (conferences, seminars) of a medical nature.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	All the restrictions mentioned in answer to question 5 above are also applicable when advertising to HCPs except for the following that may be ignored: • Prohibition from making references to specific cases when someone has been cured by a promoted medicine or medical device (e.g. the advertisement to HCPs may contain such references); • Restriction on expression of gratitude by actual persons in connection with the use of the object of advertising (i.e. the advertisement to HCPs may do so); • The warning notice “There are the contraindications” or “Please consult your physician.”
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	If an advertisement for medicines or medical devices is directed to healthcare professionals only, it must be clearly stated on the advertisement material. The advertising must be fair and truthful and based on the SmPC.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	The advertising must be fair and truthful and based on the SmPC. The advertisement of medicines and medical devices to the general public must contain a warning notice “There are contraindications” or“Please consult your physician”. All the restrictions mentioned in answer to question 5 above must be respected.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such	The data must be relevant to the advertising material and be exact, reliable and confirmed by a valid reference to the SmPC or a scientific source. Furthermore, if the scientific data is used in advertising it should not create the impression that administration of the medicine or medical

	as subgroup analyses or meta-analyses etc.)?	device will guarantee a positive outcome (e.g. it is not permitted to refer in the advertisement to scientific studies with a 100 % positive result for patients, even if such results have been officially published).
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	Technically, Russian law doesn't directly prohibit comparative advertising. However, such practice is uncommon and complicated in Russia by the lack of comparison methodology approved by law. The approach of authorities to comparative advertisements is rather judgmental and often leads such advertising to be considered as an incorrect comparison and/or unfair competition. Nevertheless, should one decide to proceed with a comparative statement, the following rules are to be taken into account. Owing to the general rules of advertising, any comparison must be correct. An incorrect comparison of advertised goods may be interpreted as unfair competition and penalised. From a practical standpoint, it could be difficult to produce an absolutely correct comparison. Such a comparison supposes: • The same parameters of comparison; • The comparison of all the parameters which are to be of importance for the compared goods; and • Using the same and correct methodology of comparison, etc. According to the Recommendations, comparison of medicines with different international non-proprietary names but with the same indications for use are also permissible, provided that clear and reliable criteria are applied. The Code also does not provide for a detailed methodology of comparison for advertising medicines, keeping only a general statement that "comparative advertising should be correct, compare identical characteristics, and should not mislead consumers through the absence of any significant information in the advertisement" (clause 2.3.6 of the Code).
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	The same rules and laws are applicable to Internet advertising as to any other kind of advertising. The authorised Russian bodies try to control the Internet advertising including by penalising violators with the use of notarised printed copies of web-pages, even if the message/web-page gave occasion to proceedings have been already deleted by the violator. However, control over Internet advertising is not yet as effective as the control over the advertising on tangible media due to the obvious complexity of such control (difficulties in fixation and evidence of violations, simplicity to delete/amend information, etc.). Nevertheless, there is a trend of increase in cases regarding the Internet advertising, including advertising posted in social media.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	The Russian Federal Antimonopoly Service, (the "**FAS**") is the competent authority entitled to prevent further publication of any advertisement which fails to comply with the law, as well as to insist on terminating the distribution of advertising violating applicable laws.. Failure to comply with the rules governing the advertising of medicines may be subject to an administrative penalty that could

	range from 200,000 roubles (approx. EUR 2,250) up to 500,000 roubles (approx. EUR 5,600). The FAS is responsible for enforcing the penalty. The FAS maintains strict control over the advertising activities and regularly holds pharmaceutical companies responsible for their advertising materials not following the law. According to the FAS, despite the significant decline in the number of violations, relatively large share of advertising violations in Russia relates to the advertising of medicines, medical devices and dietary supplements (around 5% of the total amount of advertising violations committed during 2019). A company that believes that a competitor's advertisement materials are not in compliance with Russian legislation may file a complaint with the FAS. If the FAS's decision is not to the satisfaction of the complainant, it is entitled to appeal the decision in a state court.
13. Any future developments in your jurisdiction?	No significant legal developments in the area of advertising of medicines and medical devices are expected in Russia in the near future.

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JURISDICTION: Saudi Arabia (KSA)	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	• Medicines In general, the Implementing Regulations of Medical Establishments and Products Law of 2019 (the "**Regulations**") briefly address advertisements of prescriptive and non-prescriptive medicines. The Rules and Procedures for Approving Advertising of Non-prescriptive Pharmaceutical Products (the "**Rules**") deal with the advertisement and marketing of (i) non-prescriptive skin-related pharmaceutical products for humans, (ii) herbal products, and (iii) non-prescriptive veterinary products. • Medical Devices Medical devices in KSA are subject to: – Medical Devices Interim Regulations ("**Interim Regulations**")[2] – MDS—G11 Guidance on Medical Devices Advertising Requirements[3] issued by the Saudi Food and Drug Authority ("**SFDA**") "**Guidance**").
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	Saudi Code of Pharmaceutical Promotional Practices in KSA ("**Code**") largely addresses the relation between drug companies and manufacturers on the one hand and health practitioners on the other. The Code discusses the promotion of pharmaceutical products generally, regardless of whether such products are prescriptive or over the counter. The Code is an ethical code for practicing pharmaceutical promotion. All pharmaceutical companies/plants working in KSA and in the health sector, physicians, and pharmacists either working in the private or public sectors should adhere to this Code.[4]

[2] Issued by Saudi Food and Drug Authority Board of Directors Decree Number (1-8-1429) and dated 27 December 2008, and amended by Saudi Food and Drug Authority Board of Directors Decree Number (4-16-1439) dated 27 December 2017 and published in Umm Al-Qura Journal year (86) issue number (4249) dated 17 April 2009.
[3] Version Number:1.1, Version Dated 1/5/2016
[4] The Code provides that the advertisement or promotion of pharmaceutical products in general should be in conformance with the Islamic Sharia, social traditions, ethical, and cultural fundamentals of this society.
The Code further provides that a pharmaceutical product must not be promoted for sale or supply before issuing the marketing authorization licence and all advertising and promotional materials for a pharmaceutical product must be approved and certified by the SFDA.
There is another Code of Ethics for Healthcare Practitioners, although it does not provide for advertisement of medical devices or medicines.
Finally, it is relevant to note Article 10/A of the Law of Practicing Healthcare Professions which provides that "*A healthcare professional is prohibited from advertising or promoting himself, directly or indirectly*", *and the Implementing Regulations, Article 10/A states that "the health practitioner should avoid the means of publicity that have commercial nature and refrain from consultations that are not based on a scientific basis…*

3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	For medicines, the Rules provide that prior approval of the SFDA should be sought before any advertisement of pharmaceutical products is made to the general public. Likewise, the Code provides that a marketing authorisation licence should be sought before promoting pharmaceutical products, and that the promotional materials should be in line with the usage as approved by the SFDA. With regard to the advertisement of medicines to the general public, the Rules provide that there is a non-refundable fee payable to the SFDA for seeking approval for the underlying advertisements. Advertising or marketing material for medical devices should likewise be approved by the SFDA before its use and it must be submitted on an ongoing basis ("**MDMA**"). Approval from the SFDA can be obtained in two ways[5] and there is no fee for seeking approval for the advertisement of medical devices.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes, the advertising and marketing of prescription-only and over-the -ounter medicines is regulated differently in KSA. It is relevant to note Article 36 of the Regulations, which prohibits the advertisement of prescriptive pharmaceutical and herbal products, with the exception of publication in magazines, conferences and workshops and scientific publications that are directed to medical practitioners. Article 36 further provides that non-pharmaceutical and herbal products may only be advertised after the approval of SFDA. The Code deals with promotion and advertisement in the context of medical practitioners and covers pharmaceutical products generally whereas the Rules specifically deal with the advertisement and marketing of (i) non-prescriptive skin-related pharmaceutical products for humans, (ii) herbal products, and (iii) non-prescriptive veterinary products. Further, the Rules clarify at the outset that advertising may only be carried out for non-prescriptive products[6]. It is understood from the Rules that 'advertisement' is discussed in the context of advertising to the general public.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	As per the Rules, the following are some of the restrictions and controls applicable on the advertisement of non-prescriptive pharmaceutical products to the general public: • Only non-prescriptive products can be advertised. • The product should be registered with the SFDA.

[5] There are two situations for submitting of advertising and marketing material:
A. as part of MDMA procedure, the applicant is required to submit all the advertising and marketing material that will be used in the KSA. This situation is applicable when the advertising and marketing material:
• is prepared and submitted by a local manufacturer, or
• is prepared by an overseas manufacturer and submitted by its authorised representative, and
B. separate approval, which is called a medical devices advertising licence ("MDAL"). This situation is applicable when the advertising and marketing material are prepared and submitted by a licensed distributor or a registered healthcare facility on its own behalf.
[6] (Rule 2(1))

	• Advertisements should only be made during the validity of the respective approval. The validity of an approval for advertising products is one *Hijri*[7] year. • Advertisements should comply with the principles of *Sharia* and should not violate public decency. • Advertisements should not provide incorrect or misleading information, or information that is unclear and that is susceptible to inappropriate interpretation. Article 41 of the Interim Regulations provides for restrictions applicable to the advertising of medical devices as follows: • The advertising of a medical device for which the SFDA has not issued a marketing authorisation is prohibited. • All advertisement material must be approved by the SFDA. • The advertising material must not mislead the user regarding the performance of the medical device as specified by the manufacturer. • The advertising to the general public, including on the internet, must avoid misleading lay persons. • Any advertising to persons qualified to use medical devices must include the relevant information compatible with their specific needs. • Medical sales representatives must have sufficient knowledge to be able to provide appropriate information about the medical devices they promote.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	As per the Code, below are some of the restrictions and controls on promotion of pharmaceutical products: • Promotional material should comply with the principles of *Sharia* and societal norms. • Exaggeration of the characteristics of pharmaceutical products should be avoided, unless such claim could be scientifically proven. • The effectiveness or quality of pharmaceutical products registered in KSA should not be put in doubt. • A claim that a pharmaceutical product does not have side effects should not be made, unless it can be scientifically proven. Likewise, the Interim Regulations provide that the medical sales representative/promoters must have sufficient knowledge to be able to provide appropriate information about the medical devices they promote.
7. What information must appear in advertisements directed only to healthcare professionals for:	With regard to the medicines, the Code provides that the promotional material of pharmaceutical products should include, among other things, the following:

[7] Islamic

a) medicines? b) medical devices?	• Trade name and generic name. • Name and address of the company/agent responsible for marketing. • Usage, dosage and method of use. As regards the medical devices, the Interim Regulations and Guidance does not distinguish advertisements directed to lay persons and healthcare professionals but does require that the advertising should not mislead the lay person[8]. Further, the Guidance provides that the advertising and marketing material must be in English, where it is intended for professionals, but for the lay persons it should be in Arabic.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	As per the Rules, the following is some of the information that must appear in advertising for non-prescriptive pharmaceutical products to the general public: • The approval number of the SFDA should appear on the advertisement. • The trade name of the product and the active ingredient. • The statement: "this product has several side effects, for more information please consult a doctor or a pharmacist and read the information leaflet". Certain statements are to be included in advertisements depending on the nature of the product being advertised. For medical devices, please see response in above Q7.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	The Rules provide that the content of advertisements of non-prescriptive products should be in line with the patient information leaflet as well as the summary of product characteristics. The Code further provides that any medical claim should be supported by scientific reference. Scientific studies and references should be clearly reproduced leaving no room for misinterpretation. For medical devices, the SFDA requires, among other things, the information about the relevant medical device along with the scientific supporting documents or evidence with reference for any medical claim.

[8] Guidance provides that the advertising and marketing material must:

- *not mislead the user regarding the performance of the medical device as specified by the manufacturer. o avoid misleading lay persons, when advertising to the general public, including on the internet.*
- *include the relevant information compatible with professional specific needs, when advertising to professionals.*
- *include the following:*
  - *name of device.*
  - *name and address of manufacturer. o document control reference number (it is required in case of as part of MDMA procedure).*
  - *medical devices advertising licence number (it is required in case of separate approval).*
- *not include the SFDA logo nor the establishment National Registry Number, that is issued through SFDA's MDNR, but may include the Medical Device National Listing Number issued through SFDA's MDMA.*
- *not include phrases that might be misinterpreted. o not violate the Saudi law of "Printed Materials and Publication".*

10.	Are there specific rules for comparative advertisement of medicines and medical devices?	There are no specific rules for comparative advertisement of medicines and/or medical devices except that the Rules provide that advertisements for non-prescriptive pharmaceutical products should not harm the reputation of other products or provide incorrect information. The Code provides that any comparison between different pharmaceutical products should be based on comparison points that are relevant to the product. The advertising and comparison should not be misleading or give a dishonest impression about the other products.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	The Rules provide that online advertisements for non-prescriptive pharmaceutical products should be available on the webpage provided by the applicant, and should not redirect visitors to other websites. It is further provided that online advertisements should not include information about medical practitioners. With regard to the medical devices, Interim Regulations provide that the advertising and marketing material must avoid misleading lay persons, when advertising to the general public, including advertisements on the internet.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	As regards the advertisement of medicines, no enforcement mechanism is provided in the Rules regarding the failure to comply therewith when advertising to the general public. However, Article 37 of the Regulations provides that the SFDA may impose the following penalties in respect of violations of the Regulations: • Warning; • A fine not exceeding SAR 100,000/-; • Closure of the medical establishment for up to 60 days; and/or • Cancelling the licence of the establishment. For medical devices, the SFDA is fully authorised to ensure compliance with the advertisement provisions, failing which the SFDA may withdraw or restrict the medical devices including taking any of the following actions: • Suspending the licence. • Terminating the licence. • Recalling the product from the market. • Withdrawing the marketing authorisation.
13.	Any future developments in your jurisdiction?	SFDA releases from time to time various draft rules and regulations for public commentary before these drafts become effective. Currently, we are not aware of any future developments that may affect the responses above.

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JURISDICTION: Serbia	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	The primary legal source is the law on medicines and medical devices ("*Official Gazette of RS*", No. 30/2010, 107/2012, 113/2017, 105/2017). The Rulebook on the Method of Advertising Medicines or Medical Devices ("Official Gazette of RS", Nos. 79/2010 and 102/2018) (hereinafter: "**Rulebook**") is applicable cumulatively. The primary legal source is the law on medical devices ("**Official Gazette of RS**", No. 105/2017). The Rulebook on the Method of Advertising Medicines or Medical Devices ("**Official Gazette of RS**", Nos. 79/2010 and 102/2018) (hereinafter: "**Rulebook**") is applicable cumulatively.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	The Association of Innovative Medicine Manufacturers has the Code of Conduct regarding advertisement of prescription-only medicines and communications with healthcare professionals.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	Yes. The Agency for Medicines and Medical devices has to approve every advertisement and advertising material beforehand, according to the Law.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes. The Rulebook explicitly states that it is forbidden to advertise prescription-only medicines to the general public.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	The Law states that it is forbidden to advertise the following medicines to the general public: • Prescription-only medicines; • Medicines issued at the expense of health insurance funds; • Medicines containing narcotic drugs or psychotropic substances; • Tuberculosis medicines; • Medicines for sexually transmitted diseases; • Medicines for infectious diseases; • Medicines for chronic insomnia; • Medicines for diabetes and other metabolic diseases.

	This list is exhaustive; however, the Ministry of Health may add other medicines to the list above. Further, it is forbidden to advertise medicines to the general public by directly addressing children, for medicines that are intended for their treatment. It is further forbidden to give free samples of medicines to the general public. It is not allowed to advertise a medicine to the general public where children are shown taking the medicine or medical device, or that a medical device is available to children without the presence of adults. Advertising of a medicine to the general public must not be exclusively or mainly aimed at children. It is prohibited to sponsor scientific and promotional meetings exceeding necessary costs, ie to provide bigger financial, material or other benefits. Advertising of a medicine to the general public is not allowed while listing the name of the pharmacy, private practice, specialist store, and business name of an entity that carries out wholesale trade in which the medicine or medical device can be purchased. When advertising medical devices (but it also refers to medicines), the general public cannot be given impression that: • The medical device has no adverse effects; • It is not necessary to consult a doctor before applying the medical device; • With the use of medical device, medical examination, advice or surgery can be avoided, • Using the medical device guarantees success in the treatment of the disease; • A particular medical device is the best, ie better than other medical devices; • The medical device is good to take or apply when there are no signs of illness, ie to improve health; • The health of the person not using the medical device will be damaged, except in the case of a campaign conducted by the Ministry of Health (prevention of epidemics), in accordance with the law; • The medical device is food, cosmetics or other product of general use; • The medical device is registered in the Register of Medical Devices, that is, it will be registered in the succeeding time period; • The recommended medical device may be replaced with another medical device; • The medical device is harmless and effective because of its natural origin.

6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	The Rulebook regulates advertising of medicines to the healthcare professionals, and it specifically does not allow: • Encouragement to prescribe, dispense, obtain, recommend the use or purchase of a medicine, by offering and giving a reward in money, by giving gifts or by giving and providing any other material and non-material benefits, or by promising or giving some privilege or reward; • Encouraging the healthcare professionals that one medicine can be replaced by another medicine from the same treatment group without a clear medical indication; • Make claims or reach conclusions on the efficiency of the medicine subject to clinical trials in the country or abroad, except in the case of post-marketing non-interventional clinical trial of a drug or medical device; • Promote a medicine that is in the process of amending the summary of medicine characteristics and the package leaflet; • Use a summary of a medicine's characteristics and the instructions for a medicine whose letter size is less than 3 mm, or the use of another ways of printing that make it easy to read and understand; publish information through the media, which is used in the advertising process of health institutions, ie private practices, that is, veterinary organisations and specialised stores; • Diminish the importance of warnings about precautionary measures or adverse reactions to the medicine listed in the summary; • The characteristics of the drug and the drug package; • Diminishing the therapeutic value of other medicines authorised by the medicines or in any other way raising suspicion of the value of another medicine; • Using the name of the ministry competent for health affairs, the ministry competent for veterinary affairs, the Agency, that is, persons participating in the process of examination and authorisation of a medicinal product; • Using material protected by any form of intellectual property protection without the prior consent of the owner; • Using postcards or other forms of written items whose content may be accessible or readable by persons other than healthcare professionals; • Using telephone, fax, e-mail or other electronic systems of persons belonging to the group of healthcare professionals without their explicit prior written consent, in such a way that advertises or informs them about their work.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines?	The advertising of medicines and medical devices to the healthcare professionals must include basic information on the medicine regarding the medicine's licence, ie data that are harmonised with the summary of medicinal characteristics, as well as data related to the medicine issuance regime.

b) medical devices?	The above-mentioned information must be accurate, up-to-date, verifiable and sufficiently complete for the recipient to form his or her opinion on the therapeutic value of a particular medicine, and there needs to the date when the medicine was made or last revised. The Rulebook specifically states that advertising materials intended for the professional public must be labelled “professional public only”. For the purpose of informing the healthcare professionals about the characteristics of a new medicine being promoted, it is permissible to give one small package of a new medicine with the note on the packaging: “Free sample, not for sale”.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	Advertising for medicines and medical devices must contain clear information indicating that the product being advertised is medicine or medical device and must not be misleading. The advertising must contain information relating to: • The name of the medicine or the name of the medical device, in accordance with the law; • Means of use and data necessary for the proper use of the medicine, ie use of the medical device; • A visible, legible and comprehensibly written, drawn or spoken warning to the patient or user to read carefully the medication instructions and the instructions for use of the medical device and to consult the doctor about the possible risk, as well as about adverse reactions to the medicine or medical device; or a pharmacist, and for veterinary medicines – with a vet.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	The information on the medicinal product or medical device must be true and scientifically proven and must not mislead the professional and general public. Information is given about the proper and rational use of the medicine or medical device, while respecting ethical standards. The advertising for the medicine must be in accordance with the summary of medicine characteristics and the medicine manual approved by the Serbian Agency for Medicines and Medical Devices. The advertising of the medical device must be in accordance with the approved manual for the medical device. When advertising medicine or medical devices to the general public, it is not allowed to use: • Medical history or presentations of diagnostic procedures that could lead to misdiagnosis or self-diagnosis; • Inappropriate, disturbing or misleading expressions and pictorial presentation of changes in the human body caused by disease, injury or action, of a drug or medical device on the human body or body parts. When advertising a medicine or medical device to the general public, it is not allowed to make claims or conclusions about the effectiveness of the medicinal product or medical device that is the subject of a clinical examination in the country or abroad. Also, it

		is not allowed to collect and present personal data on the illness of a particular person or group of persons, diagnoses, therapeutic procedures used in the treatment procedure, as well as the medicine and medical device used in the treatment of a specific person or groups of faces. The material used to promote the medicine must contain information on the date the licence for the issuance of the medicine was obtained, or the date of the last change, that is, the addition to the licence from the summary of the medicine characteristics, citations, tables or other data taken from medical journals or other scientific papers which must be updated, relevant and faithfully conveyed citing literature and an accurate source of information.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	When advertising medicine or a medical device, to the general public, it is not allowed: • Give the impression that a particular medicine or medical device is better than other medicines and medical devices; • Indicate that the recommended medicine or medical device may be replaced by another medicine or medical device. When advertising medicine and medical devices to a healthcare professional, it is not allowed to: • Encourage them to believe that one medicine can be replaced by another medicine from the same treatment group without a clear medical reason; • Diminish the therapeutic value of other authorised medicines or in any other way raise suspicion of the value of another medicine. Given that it is not allowed to say that certain medicine is better than another, in practice comparative advertisement would be useless for either type of advertising.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	No, all provisions indicated above are the same for internet/social media advertisements.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	The Ministry of Health supervises the implementation of the laws and the Rulebook. The Ministry exercises supervision through the Inspector for Medicines and Inspector for Medical Devices. The penalty for non-compliance with the law regarding advertising medicine is a monetary fine in the amount from RSD 800,000 to 2,000,000 (approx. EUR 6,500 – 17,000). The penalty for non-compliance with the law regarding advertising medical device is from RSD 1,500,000 to 3,000,000 (approx. EUR 12,000 – 25,500).

13.	Any future developments in your jurisdiction?	• No, for the time being, no developments have been announced.

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JURISDICTION: Slovakia	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	• The primary legal source is Act No. 147/2001 Coll. on Advertisement, as amended ("**Act on Advertisement**"); • Act No. 308/2000 Coll. On Broadcasting and Retransmission, as amended ("**Act on Broadcasting**"); • Act No. 362/2011 Coll. on Drugs and Medical Devices, as amended ("**Act on Medicine**"); • Act No. 136/2001 Coll. On Protection of Competition, as amended; • Act No. 250/2007 Coll. on Consumer Protection, as amended.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	Yes, the main codes of conducts are the following (note: the list is not exhaustive): • **EFPIA Code** – EU pharmaceutical regulatory law, which represents a collection of ethical rules agreed by EFPIA members for the Promotion of Medicinal Products to HCPs and the interactions with HCPs, HCOs and POs, with the intent of guaranteeing that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility. This code applies to all types of communication and interaction (traditional and digital); • **Ethical code of the Pharmaceutical Industry of the Slovak Republic** issued by Association of Drug and Health Device Suppliers – main role is to ensure compliance with high standards of medicine and medical devices advertising in general; • Ethical code of Association of Innovative Pharmaceutical Industry; • **Ethical code of Advertising issued by the Advertising Standards Council** – self-regulatory code which lists the ethical principles of advertising in general.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	There are no specific rules for the licencing of advertisement of medicines and medical devices to the general public. The medical representative who advertises medicine to healthcare professionals must have professional training and sufficient scientific information in order to provide the most accurate and complete information regarding the advertised medicine. Such training must be arranged by the holder of decision on registration of respective medicine. Further, the holder of the decision on registration of medicine must make available a sample of any advertisement produced by his business alongside with declaration on persons it is designated for and date of the beginning of its usage. Moreover, the holders of decision on registration of medicine are obliged to notify the Ministry of Health on the amount of expenses spent for marketing, advertisement and non-monetary

	considerations provided to providers of healthcare services. Furthermore, the holders of decision on registration of medicine must notify the National Health Information Centre on healthcare professionals who attended scientific or other educational events funded by the persons advertising their product.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes. The distinction plays an important role regarding advertisements that are addressed to the general public: while advertising of non-prescription medicines to the general public is permitted under certain conditions, advertising of prescription medicines to the general public is generally prohibited.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	The advertisement of medication not registered in the Slovak Republic, containing narcotic, psychotropic drugs or supplements, prescription-only and over-the-counter medicines covered by health insurance is prohibited, with exception of vaccination campaigns allowed by the Ministry of Health of the Slovak Republic and advertisement towards persons authorised to prescribe medication and issue medicine. In general, advertisement of medicine must not be deceptive or obfuscatory, must encourage rational usage of the medicine by providing objective information on characteristics of the medicine and must comply with data stipulated in the SmPC. In addition to the above, several restrictions apply to the content of advertising to the general public, the most significant ones being (a complete list can be found in § 8 of the Act on Advertisement): • Advertised medication must be unambiguously identified, and it must be obvious that it's an advertisement; • An advertisement must include the name of the medication as well as the name of the medicament, necessary information about correct usage of medication, expressed and comprehensible request for careful reading of the written information for users; • An advertisement must not include any information that would: (i) induce the impression that medical examination or medical surgery is unnecessary, (ii) offer determination of diagnosis or method of treatment via correspondence; • An advertisement must not be focused exclusively on children etc. Only general rules of advertising as stipulated in the Act on Advertisement apply to the advertising of medical devices (i.e. the advertisement must comply with competition rules, advertisement shall not endanger mental and physical health of people or promote violence etc.). Further, also general rules of codes of conduct listed in our answer to Question 2 must be observed (i.e. advertisement must include the name of medical device, advertising of medical devices shall not include data which could lead to false self-assessment of health condition etc.).
6. What are the main restrictions applicable to the advertising of: a) Medicines b) medical devices	All essential information must be in conformity with the SmPC and the medication must be classified according to the output mode. Further, the advertisement must include the date of issuance or the date of updating thereof. The documentation, as a part of the medication advertisement, must include accurate and up to date information, which is verifiable and sufficient enough for the

to healthcare professionals?	addressee to come to their own opinion about the therapeutic value of medication. Price offerings, charts or any other materials used for illustration purposes taken over from medical publications, or other scientific resources used in documentation must be truthfully reproduces and true and exact sources must be identified. The Act on Advertisement prohibits offering or any kind of gifts, monetary benefits or profits to the person authorised to prescribe or issue medication. Further several restrictions also apply to provision of samples of medicine and organisation of scientific events. Only general rules on advertising apply to the advertising of medical devices (please see our answers to Question 4 above).
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	Please see our answer to question 6 above. Only general rules on advertising apply to the advertising of medical devices (please see our answers to Question 4 above).
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	Advertised medication must be unambiguously identified, and it must be obvious that it's an advertisement. Further, advertisement must include the name of medication as well as the name of the medicament, necessary information about correct usage of medication, expressed and comprehensible request for careful reading of the written information for users. Please see our answers to Question 4 above.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	Scientific data used in the advertisement must be up-to-date, clearly identifiable by the average customer mostly by stating the source and relevant time information. All the information must be evidence-based.
10. Are there specific rules for comparative advertisement of medicines and medical devices?	In general, comparative advertising is admissible if it complies with restrictions stipulated in the Act on Advertisement (e.g. it is not deceptive, does not cause confusion between companies, compares products or services, which satisfy the same needs or are used for the same purpose etc.). The comparative advertisement is allowed in advertisements for the general public as well as for healthcare professionals. The advertisement must objectively compare products used for the same purposes or needs and at the same time compare at least one of specific, typical, essential and verifiable characteristics of products (medications). The price can be the subject of comparison as well.
11. Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	There are no specific rules for advertisement of medicines and medical devices on the internet/in social media posting. The same restrictions must be applied as in the case of any other advertising

		method. The codes of conduct listed in our answer to Question 2 must be observed.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	Monitoring of compliance in the advertisement of medicine and medical devices sector is carried out by several public bodies, which include: • **The State Institute for Drug Control** supervise the advertisement of medications pursuant to the Act on Advertisement. The State Institute for Drug Control reviews the propagation of advertising based on notifications of medication advertisements, delivered by the propagator along with the information of target group and the commencement date of the advertising campaign. • Penalties include prohibition of advertising and a monetary penalty amounting up to EUR 166 000. • Further, the **Ministry of Health** also supervises compliance with respective provisions of the Act on Medicine (some of these also briefly touch upon the subject of advertising). If the Ministry of Health identifies breaches, it may impose a fine amounting to up to EUR 25 000. • Moreover, the **Council for Broadcasting and Retransmission** supervises the broadcasted advertisement, among the sanctions it may impose include a fine or a broadcast of a notification on its breach of law etc.
13.	Any future developments in your jurisdiction?	**The EU Medical Device Regulation 745/2017** will come into force in May 2021; it contains advertising-related provisions.

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JURISDICTION: Slovenia	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	The main legal sources are: • Medicines: – Medicinal Products Act (*Zakon o zdravilih*) – **Rules on Advertising of Medicines** (*Pravilnik o oglaševanju zdravil*) • Medical Devices: – **Medical Devices Act** (Zakon o medicinskih pripomočkih) – **Rules on Medical Devices** (Pravilnik o medicinskih pripomočkih) **Decree on Restrictions and Duties of Public Employees as regards Acceptance of Gifts** (*Uredba o omejitvah in dolžnostih javnih uslužbencev v zvezi s sprejemanjem daril*) applies for medicines and medical devices (note that amendments in regulation of gifts are expected).
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	Yes. The main codes in this area are: • Medicines: – The Slovene Code of Medical Ethics (*Kodeks zdravniške etike*), – **The Code on Cooperation with Healthcare Professionals** (*Kodeks sodelovanja z zdravstvenimi delavci*), **The Disclosure code** (*Kodeks transparentnosti*) and – **The Patient Organization Code** (Kodeks sodelovanja z združenji bolnikov). In 2019, these codes have been merged at a European level into the European Federation of Pharmaceutical Industries and Associations ("**EFPIA**") Code. This change is yet to be reflected in Slovenia. • Medical Devices: – No national code exists, however the MedTech Europe Code of Ethical Business Practice applies. The following codes are applicable to advertising of both medicines and medical devices: • **The Slovene Advertising Code** (*Slovenski oglaševalski kodeks*) • **The Ethical Code of Collaboration between Doctors, The Pharmaceutical Industry and Companies Active in Healthcare** (*Etični kodeks sodelovanja med zdravniki, farmacevtsko industrijo in podjetji, ki sodelujejo na področju zdravstva*).
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	In the case of medicines, advertising can only be carried out by holders of marketing authorisations for medicines, which need to be obtained from the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia ("**JAZMP**"). Marketing authorisation holders must, prior to the commencement of the advertising of medicines, notify the JAZMP of medical sales representatives for the advertising of medicines. The medical sales representatives must be entered into a register with the JAZMP. This applies both to advertising to the general public and to healthcare professionals.
4. Does the law in your jurisdiction regulate the advertising of	Yes, different regimes apply for prescription-only and over-the-counter medicines.

prescription-only and over-the-counter medicines differently?	Any medicinal product that is covered by a marketing authorisation may be advertised to healthcare professionals (healthcare professionals are persons, authorised to prescribe medicines). Advertising of prescription-only medicines is allowed only to healthcare professionals. Only over-the-counter medicines (those, that are not subject to medical prescription and those, the advertising of which is allowed in the specific marketing authorisation) may be advertised to the general public.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	• Medicines: Only over-the-counter medicines for which marketing authorisation has been obtained and the advertising of which is explicitly allowed by the JAZMP in the specific marketing authorisation may be advertised to the general public. Advertising must include mandatory information about the medicine such as name of the medicine, information on application of medicine and explicit advice to discuss the information, or any medication difficulties with their doctor or pharmacist. The advertising elements must comply with the summary of the main characteristics of the medicine. The products must be presented objectively, without exaggeration and not in a misleading way. The advertising of a medicines must not contain any information that: – Gives the impression that a medical consultation with a physician or a surgical operation is unnecessary; – Indicates that the effects of taking the medicine are guaranteed, that the medicine is devoid of adverse reactions or that it is better than, or equivalent to, another medicine or treatment; – Suggests that the health of a person can be enhanced solely by taking the advertised medicine; – Suggests that the health of the person could be affected by not taking the advertised medicine; – Is directed exclusively or principally at children; – Refers to a recommendation by scientists, health care professionals or other publicly renowned persons who, because of their media influence, could encourage the consumption of a medicine; – Suggests that the safety or efficacy of the medicinal product is due to its natural origin; – Could lead to erroneous self-diagnosis; – Uses improper, alarming or misleading terms regarding possibilities of recovery; – Uses misleading terms, pictorial presentations of changes in the human body caused by disease or injury, or the action of a medicine on the human body. No samples of medicines may be distributed to end users for promotional purposes. • Medical Devices: Only medical devices that comply with the Medical Devices Act may be advertised. An exemption from this applies for advertising of medical devices at fairs or exhibitions if a disclaimer is attached, stating that they are not for sale or to be used until they comply with the law. Medical devices used solely for performing of healthcare services may be advertised only to healthcare professionals.

	The advertising of medical devices may not include information that: – Indicates that the effects of using the medical device are guaranteed or equivalent to another treatment; – Suggests that the health of a person can be enhanced solely by using the advertised medical device; – Suggests that the health of the person could be affected by not using the advertised medical device; – Is directed exclusively or principally at children; – Refers to a recommendation by scientists, health care professionals or other publicly renowned persons who, because of their media influence, could encourage the consumption of a medical device; – Could lead to erroneous self-diagnosis; – Uses improper, alarming or misleading terms regarding possibilities of recovery. Pursuant to the Slovene Advertising Code, the advertising of both medicines and medical devices for commonly known diseases must not include scientific terms that are not commonly known.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	• Medicines Medicines covered by a marketing authorisation may be advertised to healthcare professionals in scientific publications or directly where that is necessary to inform the healthcare professionals about the safe and correct administration of medicines. If the healthcare professionals work within public healthcare services, the advertising may only take place during the time dedicated to preparation for work and not in the time dedicated to being spent with patients. Note that informing healthcare professionals about characteristics and effects of medicines, sponsorship and organisation of promotional meetings, sponsorship of scientific conferences attended by healthcare professionals authorised to prescribe medicines and distribution of samples of medicines is also deemed as advertising. Additionally, inducing persons to prescribe medicines by way of promising or giving any financial or material benefits is deemed as advertising. Such benefits are not allowed unless they are of a small amount (as defined in the **Decree on restrictions and duties of public employees as regards acceptance of gifts** – note that amendments in regulation of gifts are expected) and intended for use in medical or pharmaceutical activity. • Medical Devices The provisions for advertising to the general public apply. In addition, medical devices intended for use only by healthcare professionals may only be advertised to healthcare professionals. When advertising both medicines and medical devices to healthcare professionals, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised unless they are of a small amount (as defined in the Decree on restrictions and duties of public employees as regards acceptance of gifts (note that amendments in regulation of gifts are expected)) and intended for use in medical or pharmaceutical activity. Pursuant to the Slovene Code of Medical Ethics, medical doctors may not participate in advertising medicines or medical devices.

7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	• Medicines Any promotional materials targeted at healthcare professionals must include: – Name of the medicine; – Essential information, consistent with the summary of product characteristics (including ingredients, therapeutic indications, mode of administering, summary of side effects) alongside the date of when this information was collected or last modified; – Supply classification of the medicine; – When appropriate, the selling price. Advertising must be accurate, balanced, fair, objective and sufficiently complete to enable the healthcare professionals to form his/her own opinion of the therapeutic value of the medicine concerned. It must be based on an up-to-date evaluation and must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Advertising claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. The marketing authorisation holder must ensure that any advertising to healthcare professionals only targets and reaches the persons authorised to prescribe medicines. Informational materials intended for healthcare professionals should be labelled “for expert public”. • Medical Devices If samples of medical devices are distributed, a sample must be labelled as “sample”. Please also see Question 6 above.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	• Medicines In advertising materials, medical products need to be unambiguously presented as medicines. Advertising must include: – Name of the medicine; – Information necessary for the correct use of the medicine; – Visible graphic, written or spoken warning: “Carefully read instructions before use! Before use, consult a doctor or a pharmacist about risks and side effects.” • Medical Devices If samples of medical devices are distributed, a sample must be labelled as “sample”. Please also see Question 5 above.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	Pursuant to the EFPIA Code, when advertising refers to published studies, clear references must be given. Quotations from medical and scientific literature must be faithfully reproduced. Advertising claims must be capable of substantiation which must be promptly provided in response to reasonable requests from healthcare professionals.
10. Are there specific rules for comparative advertisement of medicines and medical devices?	When advertising medicines to the general public, advertising that indicates that a medicine is better or equivalent to other medicine or treatment is prohibited. Comparative advertisement of medicines to healthcare professionals is generally permitted, however it must be based on

	relevant and comparable aspects of medicines and must not be misleading or disparaging.
11. Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	No, the general rules apply.
12. Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	The responsible authority for enforcement in this field is the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia ("**JAZMP**"). Alongside regular inspections, the inspecting officers of the JAZMP can act on the basis of notifications, anonymous reports and information available in the media and online. In case of minor violations for which extenuating circumstances have been found, the JAZMP may decide to issue a warning. If the JAZMP deems the violation to be serious, it is authorised to issue the following fines. • Regarding medicines: – A fine of between EUR 800 and EUR 4,000 may be imposed on a legal entity that fails to notify the JAZMP of the list of expert staff members to be entered in the register of medical sales representatives prior to the commencement of the activity of medicinal product advertising; – A fine of between EUR 8,000 and EUR 120,000 may be imposed on a legal entity if: ▪ It advertises and markets products presented as having properties for treating or preventing disease in human beings if they are not covered by the Medicinal Products Act as medicinal products; or ▪ It presents to patients and customers products that are not covered as medicinal products as having properties for treating or preventing disease in human beings; or ▪ It advertises advanced therapy medicinal products prepared on a non-routine basis, their preparation or therapeutic use; or ▪ It violates the abovementioned rules on advertising to either general public or healthcare professionals. • Regarding medical devices: – A fine of between EUR 15,000 and EUR 150,000 may be imposed on a legal entity if: ▪ It advertises a medical device contrary to the abovementioned rules; or ▪ It advertises the properties and modes of use of medical devices in a deceptive way. An appeal against the JAZMP's decision may be brought before the court.

13. Any future developments in your jurisdiction?	No developments regarding advertising of medicines are anticipated in the near future. Regarding medical devices, new EU regulations containing more specific rules regarding prohibition of misleading advertisement will be fully applicable in May 2021 (for medical devices) and May 2022 (for in vitro diagnostic medical devices). Amendments in regulation of gifts are expected in the near future.

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JURISDICTION: Spain

1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	• Applicable to both medicines and medical devices – General Advertising Act 34/1998 of 11 November ("**Advertising Act**"). – General Health Act 14/1986 of 25 April. – Re-casted Act on guarantees and rational use of medicines and medical devices passed by Royal Decree Legislative 1/2015 of 24 July. • Medicines – Royal Decree 1416/1994 of 16 October on advertising of medicines for human use ("**RD 1416/1994**"). – Circular 6/95 issued by the Spanish Agency of Medicines and Medical Devices ("**AEMPS**"), further developing RD 1416/1994. – Guidance dated June 2019 issued by the Ministry of Health on advertising to the general public of medicines for human use, further developing RD 1416/1994 ("**Guidance June 2019**"). – Guidance dated April 2016 issued by the Government of the Autonomous Region of Catalonia on the advertising of medicines for human use, further developing RD 1416/1994. • Medical Devices – Royal Decree 1591/2009 of 16 October on medical devices.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	Please find below the most relevant Spanish codes governing the promotion and advertising of medicines and medical devices, as well as the interaction with Healthcare Professional ("**HCP**") and Healthcare Organisations: • Medicines – Farmaindustria Code (reference medicines). – ANFEP Code (OTC medicines and other self-care products). – AESEG Code (generic medicines). • Medical Devices – FENIN Code.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	• General public – Medicines: no licenses/approvals/fees required. – Medical devices: prior authorisation. • HCPs – Medicines: prior communication.

	– Medical devices: no licenses/approvals/fees required.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes, mainly that the advertising of prescription-only medicines addressed to the general public is prohibited.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	• Medicines Advertising to the general public is prohibited in the following cases: – Unauthorised medicines. – Prescription-only medicines. – Medicines under research. – Medicines reimbursed by the Spanish National Health System ("**SNS**"). – Medicines containing narcotics or psychotropic substances. • Medical Devices Advertising to the general public is prohibited in the following events: – Medical devices reimbursed by the SNS. – Medical devices applied by HCPs.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	Under Spanish laws and regulations on medicines and medical devices, in order to guarantee the independence of the decisions relating to the prescription, dispensing, and administration of medicines and medical devices from commercial interests, the following is prohibited: • Medicines Offer any type of incentive, bonus, discount, pecuniary advantages or advantages in kind, premium or gift directly or indirectly to HCPs involved in the prescription, dispensing and administration of medicines or to their relatives and cohabitants, with the exception of those of negligible value and irrelevant to the practice of medicine or pharmacy. • Medical Devices Grant, offer or promise premiums, pecuniary advantages or advantages in kind to HCPs who prescribe the devices, as well as to their relatives or persons with whom they live. In the context of "undue granting", the relevant Codes applicable to both pharma and medical device companies provide for a number of rules governing interaction with HCPs, as well as other issues relating to promotional materials.
7. What information must appear in advertisements directed only to healthcare professionals for:	• Medicines In general terms, the information and promotion aimed at HCPs must be in accordance with the technical and

a) medicines? b) medical devices?	scientific information authorised by the AEMPS and must be rigorous, well-founded and objective and not misleading, in accordance with current legislation, and comply with the technical specifications. In particular, such information/promotion must, at least, include: – The essential product information, as per the data contained in the technical specifications, including, at least: name of the medicine; qualitative and quantitative composition; complete clinical data; incompatibilities; instructions for use/handling, and name and address of the marketing authorisation holder; – Prescription and dispensation regime; – The different presentations of the medicine, if any, and the dosage and/or pharmaceutical form; and – The retail price, reimbursement conditions, and, where appropriate, an estimate of the cost of treatment. • Medical Devices In general terms: – Technical data necessary for an objective assessment to be made of the usefulness of the medical device; and – Conformity of the product with the legislation in force, as well as the contraindications and possible secondary effects that could derive from the use of the products.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	• Medicines Advertising of medicines to the general public must include the following information: – To be carried out in such a way that the advertising nature of the message is obvious, and it is clearly specified that the product to be advertised is a medicine. – Name of the medicine, as well as the common name when the medicine contains a single active ingredient. – Essential information for the correct use of the medicine, as well an express and clearly visible invitation to read carefully the instructions on the package leaflet or on the outer packaging, and the recommendation to consult the pharmacist on its correct use. – Identifying data and recommendations determined by the Ministry of Health to avoid their abuse and to prevent the risks derived from their normal use. – Essential information to promote its rational use. – Not include expressions that provide assurance of a cure, or testimonies about the virtues of the product, or

	from professionals or persons whose notoriety may induce consumption. – Not use as an advertising claim the fact of having obtained a health/sanitary authorisation in any country or any other required authorisation, sanitary registration number or certification. Please note that the Spanish laws and regulations on medicines provide for a number of restrictions when advertising medicines which must be observed. • Medical Devices – Advertising of medical devices to the general public must mention the conformity of the product with the legislation in force, as well as the contraindications and possible secondary effects that could derive from the use of the products. – Advertising of products to the general public must not include any reference to a health authority or to recommendations made by scientists, HCPs or other persons who, by reason of their reputation, are likely to encourage their use.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	As a general rule, the information and promotion aimed at HCPs must be in accordance with the technical and scientific information authorised by the AEMPS and must be rigorous, well-founded and objective, and not misleading, in accordance with current legislation, and comply with the technical specifications. With regard to other provisions relating to scientific data when advertising medicines, please note the following: • The advertising of a medicine addressed to the general public may not include any element referring to a recommendation made by scientists, HCPs or other persons who may, by reason of their reputation, encourage the consumption of medicines. • With respect to documentary advertising, quotations, tables and other illustrations taken from medical journals or scientific works and used in advertising, material must be faithfully reproduced, the source being accurately stated.
10. Are there specific rules for comparative advertisement of medicines and medical devices?	According to the Advertising Act, comparative advertising is deemed to be unfair when is not based on essential and similar characteristics of the products or services, which cannot be objectively proven, or when the products or services subject to comparison are not similar or one of them is unknown or has a limited participation in the market. Pursuant to the regulations applicable to the advertising of medicines: • Comparative advertising is only allowed when it is intended for HCPs authorised to prescribe or dispense medicines. • The advertising of a medicine addressed to the general public may not include any element which suggests that its effect is guaranteed, that it has no side effects, or that it's

	effect is greater than or equal to that of another treatment or medicine. In addition to the above, the Farmaindustria Code sates that comparative advertising cannot be degrading, and comparisons must be based on comparable and notable circumstances.
11. Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	Advertising of medicines and medical devices on the internet/social media has not been addressed by the Spanish laws and regulations governing medicines and medical devices yet. Therefore, and in general terms, it is commonly accepted that advertising through "digital media" is subject to all the controls and requirements provided for in the Spanish laws and regulations applicable to (traditional) advertising of medicines and medical devices. However, it is worth mentioning that the Guidance June 2019, which further develops the provisions of the RD 1416/1994 relating to medicines aimed at the general public, has included for the first time a section on "digital media" covering advertising on (i) websites; (ii) APPS; (iii) banners, post, social network ads, and other media ads digital; and (iv) digital media ads with limited space (microbanners, tweets, Search Engine Marketing, etc.).
12. Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	In general terms, the failure to comply with the relevant rules applicable to the advertising of medicines and medical devices may entail administrative infringements punishable with the relevant fines, being the competent authorities for monitoring compliance with such rules both the AEMPS and the health authorities of the different Autonomous Regions. However, it is quite common that disputes among pharma and medical device companies, respectively, are settled by the relevant self-regulation system/bodies (Farmaindustria, Autocontrol, Fenin, etc.). Likewise, the failure to comply with advertising/unfair competition rules may lead to civil and/or criminal liability.
13. Any future developments in your jurisdiction?	The Regulation (EU) 2017/745 on Medical Devices, which entry into force was foreseen for 26 May 2020 has been postponed by one year and therefore it will fully apply from 26 May 2021. This postponement responds to the need to ensure the permanent availability of medical devices on the Union market, including those that are of vital importance in the context of the COVID-19 outbreak and the public health crisis resulting from this. In the context of the Spanish market, a bill of royal decree on promotion of medicines and medical devices is currently being discussed within the Ministry of Health. One of its goals is to adapt the regulations to the current demands, in which there is a clear predominance of digital and audiovisual media.

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JURISDICTION: Switzerland

1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	**Medicines** • The key statutes regulating advertising and promotion of medicinal products are: – The Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, "**TPA**"). – The Federal Ordinance on Advertising for Medicinal Products ("**OAMP**"). – The Federal Ordinance on Integrity and Transparency in the context of Therapeutic Products ("**OITTP**"). • In addition, the Unfair Competition Act ("**UCA**") and the general anti-bribery offences set out in the Swiss Criminal Code may be relevant and restrict advertising activities. **Medical devices** • The key statutes regulating advertising and promotion of medical devices are: – The Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, "**TPA**"). – The Federal Medical Devices Ordinance ("**MedDO**"). • In addition, the Unfair Competition Act ("**UCA**") and the general anti-bribery offences set out in the Swiss Criminal Code may be relevant and restrict advertising activities.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	**Medicines** • Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code). • Code of Conduct of the Pharmaceutical Industry in Switzerland on cooperation with Healthcare Professional Circles and Patient Organisations (Pharma Cooperation Code). **Medical devices** • Swiss Medtech Code of Ethical Business Practice.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	**To the general public** Public advertising in print or electronic media for analgesics, sleeping drugs, sedatives, laxatives and appetite suppressants must be submitted to the Swiss Agency for Therapeutic Products ("**Swissmedic**") for approval prior to publication, if the information on the medicinal product mentions a potential for abuse or dependence (art. 23 (1) OAMP). Furthermore, Swissmedic may require a marketing authorisation holder who seriously or repeatedly infringed the provisions on advertising of medicinal products to have all of its advertising materials pre-approved by Swissmedic for an appropriate period of time (art. 23 (2) OAMP).

	To healthcare professionals No licenses or approvals are required for professional promotion for therapeutic products. However, in case of serious or repeated infringement(s) of the provisions on advertising of medicinal products, Swissmedic may require the marketing authorisation holder to submit future advertising material to the authority for prior approval (see answer to Q 3.1).
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes. The distinction is important as different restrictions apply. In particular, advertising of prescription-only medicinal products/medical devices directed at the general public is prohibited, as opposed to OTC medicinal products and medical devices (see answer to Q 5 below).
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	**Medicines** For both advertising of medicinal products and medical devices, advertising shall be deemed unlawful if it is misleading or contrary to public order and morality (art. 32 (1) (a) TPA). In addition, the Unfair Competition Act also provides relevant provisions on misleading advertising (in particular art. 3 (b), (e) and (i) UCA). Advertising of medicinal products is only admissible once they have received marketing authorisation from Swissmedic or a cantonal authority (art. 32 (1) (c) TPA). Advertising is unlawful if it may incite an excessive, abusive or inappropriate use of medicinal products (art. 32 (1) (b) TPA). Also, advertising of prescription-only medicinal products (i.e. medicinal products in categories A and B) directed at the general public is prohibited (art. 32 (2) (a) TPA). Advertising of OTC medicinal products (i.e. categories D and E) directed at the general public is regulated in great detail. It is allowed, provided that all information is in accordance with the latest drug information approved by Swissmedic; in particular, only indications and possible uses approved by Swissmedic may be advertised (art. 16 (1) OAMP). The properties of the medicinal product must be presented in a correct manner and without exaggeration (art. 16 (2) OAMP). Advertising must be recognisable as such (clearly separated from mere editorial contributions; art. 16 (3) OAMP). In deviation of the EFPIA Code of Practice 2019, the use of the term "new" is admissible for a period of 18 months after initial approval of the medicinal product in Switzerland (art. 16 (4) OAMP). The distribution of sample packs to the general public is also restricted: the samples must be provided free of charge and the sample pack must be marked as “free sample”. Furthermore, they must not contain more than a recommended daily dose. Samples of medicinal products in category D (dispensing after consultation by a specialist) must not be offered for self-service (art. 19 OAMP). **Medical devices** For both advertising of medicinal products and medical devices, advertising shall be deemed unlawful if it is misleading or contrary

	to public order and morality (art. 32 (1) (a) TPA). In addition, the Unfair Competition Act also provides relevant provisions on misleading advertising (in particular art. 3 (b), (e) and (i) UCA). Advertising of medical devices for direct dispensing or for direct use by the general public is restricted to the claims contained in the product information (art. 21 (1) MedDO). This principle is also reflected in art. 69 (1) revised MedDO. Misleading statements concerning the efficacy and performance of a medical device are prohibited (art. 21 (2) MedDO). Art. 69 (2) revised MedDO specifies that especially misleading statements on the intended purpose, safety and performance of a medical device, are prohibited. With regard to prescription-only medical devices or medical devices that are placed on the market for exclusive use by professionals, advertising to the general public is prohibited (art. 21 (3) MedDO). Art. 69 (3) revised MedDO stipulates that public advertising is prohibited for medical devices that are intended exclusively for use by professionals. Art. 69 revised MedDO will enter into force on May 26, 2021 (at the same time as the MDR in the EU).
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	**Medicines** For both advertising of medicinal products and medical devices, advertising shall be deemed unlawful if it is misleading or contrary to public order and morality (art. 32 (1) (a) TPA). In addition, the Unfair Competition Act also provides relevant provisions on misleading advertising (in particular art. 3 (b), (e) and (i) UCA). Advertising of medicinal products is only admissible once they have received marketing authorisation from Swissmedic or a cantonal authority (art. 32 (1) (c) TPA). Advertising is unlawful if it may incite an excessive, abusive or inappropriate use of medicinal products (art. 32 (1) (b) TPA). All information must be in accordance with the latest drug information approved by Swissmedic; in particular, only indications and possible uses approved by Swissmedic may be advertised (art. 5 (1) OAMP). The statements made must be exact, balanced, factually accurate and verifiable (art. 5 (3) OAMP). Advertising must be recognisable as such (clearly separated from mere editorial contributions; art. 5 (4) OAMP). In deviation of the EFPIA Code of Practice 2019, the use of the term "new" is admissible for a period of 18 months after initial approval of the medicinal product in Switzerland (art. 5 (6) OAMP). The distribution of sample packs is only allowed upon initiative and written request of an HCP and only in a small number per product, year and HCP. The sample pack must be marked as “free sample” (art. 10 OAMP). In addition, Art. 55 TPA provides that persons who prescribe, dispense, use or purchase for such purposes prescription-only medicinal products, and organisations which employ such persons, must not be granted undue advantages. The provision contains a list of advantages that are not considered undue. These are: (i) benefits of modest value relevant to medical or pharmaceutical practice; (ii) support for research, education and

	training, provided that certain criteria are met; (iii) compensation for equivalent consideration, in particular for orders and deliveries of therapeutic products; (iv) price discounts or refunds granted on the purchase of therapeutic products, provided that they have no influence on the choice of treatment. The details are set down in the Ordinance on Integrity and Transparency in the context of Therapeutic Products. **Medical devices** For both advertising of medicinal products and medical devices, advertising shall be deemed unlawful if it is misleading or contrary to public order and morality (art. 32 (1) (a) TPA). In addition, the Unfair Competition Act also provides relevant provisions on misleading advertising (in particular art. 3 (b), (e) and (i) UCA). Advertising of medical devices is restricted to the claims contained in the product information (Art. 69 (1) revised MedDO). Misleading statements concerning the efficacy and performance of a medical device are prohibited (art. 21 (2) MedDO). Art. 69 (2) revised MedDO specifies that especially misleading statements on the intended purpose, safety and performance of a medical device, are prohibited. Art. 69 revised MedDO will enter into force on May 26, 2021 (at the same time as the MDR in the EU). Article 55 TPA (see answer to Q 6.1 above) does currently not apply in the context of OTC medicinal products and medical devices. However, *de lege ferenda*, advantages related to the prescription, dispensing, use or purchase for such purposes of medical devices will also be governed by Art. 55 TPA and the OITTP. The extent of the expansion of scope of Art. 55 TPA is unclear yet, as the Federal Council can exempt certain MD classes. The amended Art. 55 TPA is not expected to enter into force before 2022. Moreover, the Swiss Medtech Code of Ethical Business Practice provides for specific rules regarding material benefits granted to HCPs. One of the most important principles is that grants or charitable donations shall no longer be provided to individual HCPs, but directly to the qualifying organisation or entity.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	**Medicines** According to art. 6 OAMP, the following information must be included: • Name of the medicinal product (brand). • Active ingredient(s) with the official abbreviated designation, should such exist. • Name and address of the marketing authorisation holder. • At least one indication or possible use, as well as dosage and method of use. • Restrictions on use, adverse reactions and interactions. • Category of the medicinal product determined by Swissmedic.

	• Indication that detailed information is to be found in the published product information. • Withdrawal periods for veterinary medicinal products for food-producing animals. **Medical devices** There is no obligation to provide any information on the use, performance, efficacy or other characteristics of the medical device. However, if such information is provided, the claims are restricted to those contained in the product information only (Art. 69 (1) revised MedDO).
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	**Medicines** According to art. 16 (5) OAMP, advertising of medicinal products in categories C and D must contain the following information: • Name of the medicinal product (brand). • Name of the marketing authorisation holder. • At least one indication or possible use. • The explicit indication that the medicinal product is authorised and that the package leaflet/package information should be read. • Withdrawal periods for veterinary medicinal products for food-producing animals. **Medical devices** There is no obligation to provide any information on the use, performance, efficacy or other characteristics of the medical device. However, if such information is provided, the claims are restricted to those contained in the product information only (art. 21 (1) MedDO and Art. 69 (1) revised MedDO).
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	**Medicines** • Professional promotion: According to art. 5 (5) OAMP, the advertising statements of medicinal products must be based on and reflect the current state of scientific knowledge. They may only refer to clinical trials conducted and published or accepted for publication in accordance with the rules of Good Clinical Practice and to data collections such as meta-analyses or reports on practical experience published in a recognised scientific medium. These publications must be quoted verbatim, in full and with the exact source. • Promotion directed at the general public: According to art. 22 (g) OAMP, advertising must not mention or refer to scientific publications, clinical studies, expert opinions, certificates or recommendations made by scientists, HCPs, well-known personalities or medical-pharmaceutical laypersons. **Medical devices** It can be deduced from the prohibition of misleading advertising that promotional advertising claims must be in accordance with the

		clinical evaluation or testing of a medical device (if performed at all).
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	**Medicines** • Professional promotion: Art. 7 OAMP provides that comparisons with other medicinal products are admissible if scientifically correct and based on equivalent clinical trials or data collection fulfilling the requirements of art. 5 (5) OAMP (for these requirements see answer to Q 9.1 above). • Promotion directed at the general public: Comparative advertising is allowed within the limits of art. 22 (c) OAMP. According to this provision, advertising that creates the expectation that the effect of a medicinal product corresponds to, or is superior to, another treatment or to another medicinal product is prohibited. **Medical devices** The MedDO does not provide for specific rules. However, art. 3 (e) UCA applies, according to which comparisons of goods must be made in a correct manner.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	**Medicines** • Promotion directed at the general public: For advertising of medicinal products in categories C and D in electronic media, a special note stating that the product is an authorised product and that a specialist may be asked/the package information should be read must be displayed/inserted. Furthermore, specifications regarding the design and the font size must be observed (art. 17 OAMP). In addition, public advertising in print or electronic media for analgesics, sleeping drugs, sedatives, laxatives and appetite suppressants must be submitted to Swissmedic for approval prior to publication, if the information on the medicinal product mentions a potential for abuse or dependence (art. 23 (1) OAMP; see also answer to Q 3.1). • Professional promotion: Such advertising may not be made publicly accessible on the Internet. It must be provided with suitable technical and password-protected access restrictions to ensure that it is only made available to HCPs (art. 5a OAMP). **Medical devices** There are no specific regulations for medical devices advertised on the Internet. The general rules apply.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	The TPA provides for administrative measures as well as administrative criminal measures in case of an infringement. **Administrative measures**: Among other measures, Swissmedic and the Federal Office of Public Health may confiscate inadmissible advertising media and hold in official storage, destroy or prohibit them. In the event of serious or repeated infringements of advertising regulations, advertising for a particular therapeutic product may be temporarily or permanently prohibited and the

	prohibition may be made public at the expense of those responsible (see art. 66 (2) (f) and (g) TPA). Furthermore, Swissmedic may require a marketing authorisation holder who seriously or repeatedly infringed the provisions on advertising of medicinal products to have all of its advertising materials pre-approved by Swissmedic for an appropriate period of time (art. 23 (2) OAMP). **Administrative criminal measures**: The Federal Office of Public Health is the authority in charge of prosecuting the rules on inducement (art. 55 TPA). Infringements against art. 55 TPA are punished with a custodial sentence of up to three years or a monetary penalty (art. 86 (1) (h) TPA).
13. Any future developments in your jurisdiction?	Note that the Swiss Pharma Code and the Swiss Pharma Cooperation Code were revised on May 14, 2020. The revisions will come into effect on January 1, 2021. Furthermore, the prohibition of promising and accepting undue advantages (Art. 55 TPA) will *de lege ferenda* also be relevant for medical devices companies (see answer to Q 6.2). The revised law and ordinance is not expected to enter into force before 2022. Switzerland adapts it medical devices rules to the new EU regulations (the MDR and IVDR) by revision of the Medical Devices Ordinance (see answers to Q 5.2 and 6.2) and by issuing a new Ordinance on Clinical Trials with Medical Devices. The revised MedDO and the new Ordinance on Clinical Trials with Medical Devices will, in alignment with the MDR and IVDR, be applicable from May 26, 2021.

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JURISDICTION: Turkey

1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	**Medicines** • Consumer Protection Law No. 6502 ("**Law No. 6502**"); • Trade Advertising and Unfair Trade Practices Regulation; • Pharmaceuticals and Medical Preparations Law No. 1262 ("**Law No. 1262**"); • Advertising Measures for Medicinal Products for Human Use Regulation ("**Medicinal Products Advertising Regulation**"); • Establishment and Broadcasting of Radio and Television Services Law No. 6112 ("**Law No. 6112**"); • Organization and Duties of the Ministry of Health and Related Institutions Decree-Law; and • Turkish Commercial Code No. 6102 ("**Law No. 6102**"). **Medical devices** • on Organization and Duties of the Ministry of Health and related institutions Decree-Law; • Placing on the Market, Advertising and Notification of Medical Devices Regulation ("**Medical Devices Advertising Regulation**"); • Law No. 6502; and • Law No. 6102.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	Yes, there are codes of self-regulation and the most important ones are listed below: **Medicines** • The Association of Research-Based Pharmaceutical Companies ("**AIFD**") is a member of the IFPMA Federation of International Pharmaceutical Manufacturers and Associations ("**IFPMA")** and Federation of European Pharmaceutical Industries and Associations ("**EFPIA**"). The AIFD consists mainly of foreign pharmaceutical companies such as Amgen and Novartis and provides self-regulatory codes of conduct for its members, such as: – Competition Rules Compliance Guideline; and – AIFD Code of Practice. • The Pharmaceutical Manufacturers Association of Turkey ("**IEIS**") provides the second major self-regulatory code of conduct for the advertising of medicines. • IEIS has implemented its own policy since 1990. Prepared for the purpose of establishing a self-regulatory mechanism among its members, the policy allows for the monitoring of such activities by a Supervisory Board.

	• The Pharmaceutical Industry Association of Turkey ("**TISD**"). • The TISD Advertising Guidelines regulate the advertising of medicinal products. • The Turkish Pharmaceutical Exporters Platform ("**TIIP**") is an organization linked to the IEIS that develops strategies and guidelines to increase the export volume of Turkish pharmaceutical manufacturers and strengthen the international promotion of Turkish pharmaceuticals. • Turkish Medical Doctors Association ("**TTB**"). • The TTB Principles on Medical Doctors and the Advertisement of Pharmaceutical Products regulates the advertisement of medicinal products. Accordingly, TTB may oversee advertising activities through an ethics committee. **Medical devices** Although there is no self-regulatory code of conduct specifically for medical devices, the rules of the AIFD and IEIS can also apply to medical devices if companies so wish.
3. What kind of licenses/approvals/ fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	**Medicines** Over-the-counter ("**OTC**") medicines and prescription medicines may not be advertised to the public. However, the public may be informed about products used in vaccination campaigns, organised actions to combat epidemics or other campaigns of the Ministry of Health ("**Ministry**") to promote health - as they are important for the protection of public health - with the approval of the Ministry and within the limits of the policies and procedures established by the Ministry for such products. Products must be registered or authorised in accordance with the relevant Regulation. Accordingly, an authorisation/licence is a certificate issued by the Turkish Agency for Medicine and Medical Devices ("**Agency**") stating that the product in question can be manufactured and marketed in a specific formulation and in a specific pharmaceutical form or strength in accordance with the approved product information. In addition, pharmaceutical sales representatives must obtain a "*Qualification Certificate*" to promote a human medicinal product to (i) doctors, (iii) dentists and (iii) pharmacists ("healthcare professionals") through direct calls. Please also note that the relevant certificate can be obtained after the representative has started working. **Medical devices** Medical devices that can only be used or applied by **healthcare professionals**. According to the Medical Devices Advertising Regulation, a sales centre is defined as an optician, custom-made prosthesis and orthosis centre, hearing aid centre, dental prosthesis laboratory and medical devices sales centre. The advertising staff of the medical device sales centre must be registered in the Agency's electronic system.

4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	No, according to Law No. 1262 and the Medicinal Product Advertising Regulation, advertising of any type of medicinal product to the public is prohibited and advertising to healthcare professionals is only allowed under certain conditions.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	In general, all images, statements or references in advertising that give the impression that a product or service is recommended by health professionals are prohibited. **Medicines** • The advertising of medicinal products to the public, directly or indirectly through any public media or communication channel, including the Internet, is prohibited, whether through programmes, films, television series, news reports or similar media. • No prescription drug or its reduced sample may be supplied to the public directly or indirectly. • Information for the general public may be provided on occasions such as vaccination campaigns and epidemic control, which are important for the protection of public health, or on other campaigns of the Ministry to promote health, with the approval of the Ministry and within the framework of the policies and procedures established by the Ministry for such products. **Medical devices** • Medical devices that can only be used or applied by health professionals may not be advertised directly or indirectly to the public. Announcements approved by the Ministry or the Agency in media channels (i.e. health magazines) aimed at health professionals and website information about distribution centres are not covered by this restriction. • In addition, Law No. 6502 prohibits commercial advertising that misleads consumers or exploits their lack of experience and knowledge, endangers their safety of life and property, encourages the commission of crimes, endangers public health and abuses the sick, the elderly, children and the disabled. • Accordingly, it is prohibited to use the names of the Ministry and associated institutions, as well as the names of health care institutions and persons involved in the research of the medical device, without permission. • According to the provisions of the Medical Devices Advertising Regulation, medical devices sold or used in hearing aid centres, prosthesis and orthosis centres, optician shops and dental prosthesis centres, as well as medical devices that can only be used or applied by healthcare professionals, may not be advertised directly or indirectly to the public. Medical devices that do not fall within this scope may only be advertised in the internet environment where the product is sold. Toothpastes, denture care products for individual use, cotton wool, plasters, etc. are exempt from these restrictions and may be advertised.

	In summary, advertising of medical devices must not be done in a way that endangers the health of the patient, the user or the environment.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	**Medicines** Excluded are advertisements at international congresses held in Turkey and information activities carried out in person by the scientific service of the licence/permit holder at the written request of the doctor/dentist/pharmacist: • Products that have not been registered or approved in accordance with the relevant legislation; • Indications other than those approved by the Agency for products registered or authorised under the Regulation; and • With the exception of promotional activities for the purpose of pharmacovigilance of products procured through international suppliers and purchased by the Social Security Agency under alternative reimbursement schemes, of which the Agency is informed; the products registered or authorised under the relevant Regulation, but for which the Agency grants permission to import against prescription because they are not available on the domestic market, may not be promoted to health professionals. **Medical devices** • It is prohibited to use the names of the Ministry and associated institutions, as well as the names of health care institutions and persons who have been involved in the research of the medical device, without permission. • Medical devices shall not be advertised in a manner that endangers the health of the patient, the user or the environment. • Advertising that may lead to unfair competition may not be made.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	**Medicines** The Therapeutic Products Advertising Regulation does not provide for an obligation to address certain information to healthcare professionals and sets requirements for the information to be given to them. The promotional activity for a product shall be consistent with the information and data contained in the claims approved by the Agency. Advertisements must contain informative and evidence-based medical data about the properties of a product that enable healthcare professionals to form their own opinion about the therapeutic value of the product. If the advertising involves the use of documentation prepared using quotations, tables or other visual material from medical journals or other scientific publications, these materials must be reproduced authentically, with a full reference to the relevant sources.

	When advertising products, doctors, dentists and pharmacists may not be granted, offered or promised any benefits, either in cash or in kind. **Medical devices** Advertising for medical devices must contain the following information: • Indication that the display clearly refers to the unit; • The declaration of conformity of the appliance, its EC certificate, the name and information of the appliance in the documents such as a technical dossier and the compatible appliance names and information; • Information on the label and in the operating instructions of the appliance compatible with the intended use; • Scientific reports and certificates relating to the advertisement, date of issue, contact information and the field of expertise of the preparer (person or institution); and • Evidence-based medical information on any therapeutic effect of the device.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	**Medicines** As mentioned above, advertising of products to the public, directly or indirectly, through any public media or communication channel, including the Internet, is prohibited, whether through programmes, films, television series, news reports or similar media. **Medical devices** Advertising must be in accordance with general principles and the information required by the honesty principle must be made available to the general public.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	If the advertising involves the use of documentation prepared using quotations, tables or other visual material from medical journals or other scientific publications, these materials must be reproduced **authentically, with a full reference to the relevant sources**.
10. Are there specific rules for comparative advertisement of medicines and medical devices?	According to Law No. 6502, comparative advertising may be made for competing goods or services that meet the same needs or are directed towards the same purpose. Law No. 6102 states that advertising that violates the principle of honesty (e.g. unnecessary disparagement of competing products) may lead to unfair competition. The Pharmaceutical Advertising Regulation provides that advertising must not be made with misleading, exaggerated or unsubstantiated information that could encourage unnecessary use of a product or lead to unexpected risks, or by using enticing imagery that is not directly related to the product.

11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	Advertising of products to the public directly or indirectly through public media or communication channels, including the Internet, is prohibited, whether through programmes, films, television series, news reports or similar media. However, the AIFD self-regulatory code regulates the advertising of medicines and provides for this: • Companies are responsible for the websites and social media accounts they have set up or that have been created on their behalf. Appropriate measures must be taken to ensure that there is no content on the websites they support or on their social media accounts that can be perceived as advertising medicines to the general public. • A company may make information about its medicines available to the general public on the company website, provided this is in accordance with laws and regulations. Pharmaceutical companies may develop and promote websites and social media platforms to inform patients and society about diseases and current medical applications.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	Monitoring bodies can be audited under three titles: • Civil law claims The allegedly injured party can demand the following from the courts on the basis of unfair competition: – Declaration of unfair competition; – Prevention of unfair competition; – to pay damages; – Compensation for non-pecuniary damage; – restraining order; – Reimbursement in kind; and – the profit made from the unfair competition act. • Administrative supervision – The Turkish Agency for Medicine and Medical Devices monitors violations of the Medicines Advertising Regulation and the Medical Devices Advertising Regulation. ▪ The Agency may issue a warning or ban advertising activities; ▪ It may impose fines; and ▪ She can file a criminal complaint, which can result in a prison sentence of up to five (5) years. – The Self-Regulatory Commission for Advertising monitors acts of non-compliance with Act No. 6112 and its regulations. Within the framework of the joint commitment to the public, the advisory decisions are not legally binding, but they are binding in practice. The validity of this binding nature is guaranteed by

	the professional and business ethical values of the parties. • Self-audit Self-regulatory mechanisms have their supervisory boards, which monitor the violations of their members. Although their decisions are not legally binding, they can – Application to medical chambers – According to the monitoring of the medical associations, ▪ The infringer may be disclosed by TTB); ▪ It may be addressed to the TTB Disciplinary Committee; and ▪ A report may be made to the Ministry.
13. Any future developments in your jurisdiction?	Unfortunately, no developments are currently planned in our area of responsibility.

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JURISDICTION: Ukraine	
1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	Article 21 of the Law on Advertising No. 270/96-BP dated 3 July 1996 (as amended) (the "**Law on Advertising"**) provides for rules applicable to advertising of medicines and medical devices, while Article 26 of the Law on Medicines No. 123/96-BP dated 4 April 1996 (as amended) (the "**Medicines Law**") provides for specific regulation of advertising and promotion of Rx medicines, as well as OTC medicines, allowed and prohibited for advertising. The Ministry of Health of Ukraine (the "**MoH**") in its Order No. 422 dated 6 June 2012 sets the **criteria for OTC medicines to be assigned to the List of OTC medicines prohibited for advertising**. The said List is approved by the MoH Order No. 876 dated 6 November 2012 (the "**Prohibition List"**) and is updated occasionally by the MoH. In addition, the following laws contain general provisions applicable to advertising of medicines and medical devices: • The Fundamentals of the Health Care Legislation of Ukraine No. 2801-XII dated 4 November 1992; • The Consumer's Rights Protection Law No. 1023-XII dated 12 May 1991; and • The Law on Protection Against Unfair Competition No. 236/96-BP dated 7 June 1996.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	There is no single market-wide self-regulatory code of conduct in Ukraine that would govern the advertising of medicines and medical devices. In the meantime, certain self-regulatory organisations (associations) provide the professional ethics rules in this area, which are mandatory for their members. The notable example is the Code of Pharmaceutical Marketing Practices of the Association of Pharmaceutical Research and Development (APRAD).
3. What kind of licenses/approvals/ fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	Under Article 21(1) of the Law on Advertising, both medicines and medical devices may be advertised to the general public only if they are permitted (approved) for use in Ukraine by the MoH (for medicines) and if they passed Ukrainian national conformity assessment procedure (for medical devices). Article 26(3) of the Medicines Law allows to communicate promotional materials to healthcare professionals regarding both medicines, approved for use, and unapproved medicines on the development stage. No additional permit or approval is required for advertising of medicines or medical devices.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Ukrainian legislation differentiates the advertising medicines to the general public and to healthcare professionals, as well as Rx and OTC medicines. If advertising targets the general public, under Article 21(1) of the Law on Advertising, only OTC medicines not included in the Prohibition List may be advertised. Advertising of Rx medicines

	and OTC medicines from the Prohibition List to the general public is prohibited. Both OTC and Rx medicines may be advertised to healthcare professionals, with certain limitations applicable to the Rx medicines' advertising. Based on Article 26(3) of the Medicines Law promotional materials on Rx medicines may be communicated to healthcare professionals in the form of “information about medicines” in professional medical publications or directly during professional medical events like seminars, conferences, symposia, etc. Such information shall normally include the trade name, product characteristics, side effects, etc. Although “information on medicines” is formally not considered as "advertising”, *de facto*, there is no practical difference between advertising and providing information on Rx medicines to healthcare professionals.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	Under Article 21 of the Law on Advertising, any advertising of medicines and medical devices directed to the general public shall not contain: • references to therapeutic effect in connection to incurable or difficult-to-cure diseases; • information that may give impression that if the medicine or medical device is used the consultation of a doctor is not required; • information that the therapeutic effect of the medicine or medical device is guaranteed; • images of changes in the human body or its parts caused by illness or injuries; • allegations that promote the raise or development of fear of becoming ill or worsen health conditions if advertised medicines or medical devices are not used; • statements that promote self-diagnosis of diseases, pathological conditions and their self-treatment using advertised medical products; • references to medicines, medical devices as the most effective, harmless and free of any side effects; • references to the individual cases of successful use of medicines, medical devices; • recommendations or links to the recommendations of healthcare professionals, scientists, medical institutions and organisations regarding the advertised medicines or medical devices; • special testimonials, appreciations, letters, excerpts of them with recommendations, stories about the use and results of the advertised medicines or medical devices; • images and mentions of names of celebrities, heroes of movies or cartoons, as well as authoritative organisations; • misleading information as to the content, origin, effectiveness, patent protection of the advertised goods; and

	• information that may give impression that the medicine is a foodstuff, cosmetic or other consumer product or that the safety or efficacy of this product is caused by its natural origin. Additionally, the Law on Advertising prohibits advertising of medicines and medical devices with the participation of doctors, other healthcare professionals or individuals, whose appearance imitates the appearance of doctors, healthcare professionals.
6. What are the main restrictions applicable to the advertising of: a) Medicines b) medical devices to healthcare professionals?	Ukrainian legislation does not provide for specific restrictions, applicable to advertising of medicines and medical devices to healthcare professionals. The restrictions listed in Article 21 of the Law on Advertising, mentioned in response to question 5 (immediately above), are applicable neither to advertising of OTC medicines and medical devices, nor to promotional information about Rx medicines targeting healthcare professionals.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	Ukrainian legislation does not contain any specific rules on information that must appear in advertisements for OTC medicines and medical devices, directed only to healthcare professionals. Regulations on promotional materials in the form of "information on medicines" on Rx medicines directed to healthcare professionals (as described in answer to question 4 above) also do not set any specific requirements to the content of such promotional materials, apart from general indication that "*information on medicines*" should contain "*name, product characteristics and potential side effects*" of the advertised medicines. In practice, when communicating promotional materials on Rx medicines in professional medical publications, during professional medical events or directly to healthcare professionals, a written reservation is often made that the information about the Rx medicine is provided exclusively for healthcare professionals and the material is not an advertising.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	In accordance with Article 21(4) of the Law on Advertising the advertisements of both medicines and medical devices directed to the general public must contain the following information: • objective information about the product; • clear indication that the piece of information is an advertisement and the advertised product is a medicine or medical device; • warning that customers need to consult a doctor before using the advertised medicine or medical device; • recommendation for the customer to review the patient information leaflet for the advertised medicine; • text notice "*self-treatment may be harmful for your health*" that must occupy no less than 15% of the space (duration) of an advertisement material. In addition to the above requirements, the restrictions mentioned in answer to question 5 above must also be respected.

9.	Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	The Law on Advertising does not contain any specific requirements or restrictions neither regarding scientific data that may not be indicated in advertisements of medicines or medical devices, nor regarding the data based on which the promotional claims are made. At the same time, some general restrictions from Article 21(5) of the Law on Advertising, listed in response to question 5 above, are applicable to the use of scientific data and promotional claims, and can be interpreted as prohibiting the use of the following scientific claims in advertising of medicines and medical devices targeting the general public: • retrospective analysis of the successful usage of medicines or medical devices (to the extent that such analysis describes individual cases of usage of the medical product or its guaranteed therapeutic effect); • references to studies, conclusions or opinions, including opinions, that "recommend" the advertised medicine or medical device. There are no requirements for scientific data indicated in advertisements targeting healthcare professionals.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	Before 2020 comparisons in advertising medicines and medical devices to the general public were forbidden, even when they did not unfairly discredit competitors. They were useful in providing consumers information on the advantages of the product being advertised vs. other products. Starting from January 2020, this restriction is no longer in force. There are no specific requirements or rules applicable to comparative advertising of medicines and medical devices – therefore, general rules, described in the Law on Advertising and the Law on Unfair Competition, are applicable.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	Neither the Law on Advertising nor any other piece of Ukrainian legislation prescribe any specific rules for advertisement of medicines and medical devices on the internet/in social media postings. At the same time, any advertisements of medicines and medical devices, including those posted on the internet and on social media platforms must comply with the general requirements for advertising of medicines and medical devices, described in responses to questions 5 and 8 above. The rules set by the Law on Protection against Unfair Competition shall be adhered, respectively.
12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	The Law on Advertising contains following enforcement mechanisms: • requirement to the advertiser, advertisement producer/distributor to cease violation of advertisement legislation; • suspension of the dissemination of the advertisement that violates the requirements of the advertisement legislation;

	• imposition of fines on advertisers, advertisement producers/distributors. Compliance with advertisement provisions is monitored by the State Service of Ukraine on Food Safety and Consumer Protection ("**Consumer Protection Service**") (with regards to the protection of consumers' rights) and the Antimonopoly Committee of Ukraine ("**AMCU**") (with regards to protection from unfair competition practices). The AMCU is empowered to investigate the facts of: • dissemination of misleading information; • violations regarding trade dress protection (*i.e.,* illegal usage of trademarks, which leads to the confusion of the products, or copying of the visual appearance of the product); • unfair comparative advertising. The AMCU constantly focuses on the pharmaceutical market, including the cases of unfair competition. In November 2020, the AMCU issued a series of recommendations for pharmaceutical companies targeting the excessive number of violations traced on medicines market. According to these recommendations, the following claims are treated as a sign of unfair competition on the market: • "good quality" of the medicine, as it is presumed that all medicines, authorised for use in Ukraine, are of a good quality; • affordability of the medicines; • leadership market positions without relevant evidence; • fast action of the medicines, which is not confirmed by the instruction for medical use. Failure to comply with the rules governing advertising of medicines and medical devices may result in penalties, which vary depending on the particular type of violation. If the violation is related with the protection of consumer's rights, Consumer Protection Service may impose fines on advertisers in the amount of the five times the value of the distribution of the advertising materials). If advertising violates competition rules, the AMCU may impose a fine on the breaching entity for the amount of up to 5 percent of the legal entity's revenue for the previous calendar year.
13. Any future developments in your jurisdiction?	In 2019 in terms of the EBRD-funded technical assistance project, aimed at bringing Ukrainian legislation in pharmaceutical sector in compliance in EU standards, the new draft law on medicines was developed. In particular, the draft contained several provisions aligning Ukrainian legislation in the sphere of medicines advertising with respective provisions of Directive 2001/83/EC. As of the date of this questionnaire we are not aware of the status of this draft and have no additional information on any other developments in this direction.

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JURISDICTION:United Arab Emirates (UAE)

1. Which laws are applicable regarding advertising of: a) medicines? b) medical devices?	***Federal Law No.8/2019 on Medical Products, Profession of Pharmacy and Pharmaceutical Institutions ("2019 Law").*** The 2019 Law supersedes Law No. 4 of 1983 concerning Pharmaceuticals Profession and Institutions and Law No. 20 of 1995 Concerning Medicines and Preparations derived from Natural Sources. The 2019 Law unites different provisions which regulate how "Medical Products" are controlled in the UAE. "Medical Products" is defined to cover "Medicinal Products" (i.e. pharmaceuticals/prescription drugs), "Medical Devices", and "Healthcare Products" (i.e. generally referring to regulated products, but which could be sold without prescription or OTC). The 2019 Law provides a thorough framework that governs areas such as: (i) import, export, distribution, warehousing and manufacturing; (ii) pricing; (iii) registration; (iv) advertising and promotion; (v) pre and post clinical trials; and (vi) safety reporting and product recalls. With regard to advertisement specifically, the 2019 Law sets out clear conditions around how various categories of Medical Products can be advertised in the UAE. Failure to adhere with the requirements will be considered a criminal offence resulting in fines or imprisonment. Please see response in Q12 below. The 2019 Law is supplemented by the following older Cabinet Decisions and Ministerial Decisions around licensing, content and process for advertising Medical Products. ***Federal Law No. 15/1980 concerned with Publications and Public Matters ("Publications Law").*** The Publications Law states that advertisements on medicines or on pharmaceutical products may only be published after having obtained a special license from MOHAP and also imposes various additional specific obligations/conditions on advertisement of medical products. ***UAE Cabinet Resolution No. 7/2007 on prohibiting the advertisements or promotions of Medical Products without a valid license*** reaffirms the Ministerial Resolution No.430 of 2007 Regulating Health Advertisement by stating that anyone that does not have MOHAP approval and an issued licence is forbidden from advertising and promoting medical products. ***Ministerial Resolution No. 430 of 2007 Regulating Health Advertisement***. Where the subject matter of advertising is specifically related to Medical Products and services, advertisers must comply with special requirements. For example, the advertisement shall contain true and balanced statements and should not deceive the public opinion and must include genuine facts and contents. It is prohibited to publish any advertisements which advertise medicine or pharmaceutical products without the approval of MOHAP. Such an approval shall only be granted if the relevant advertisement complies with the requirements of the applicable regulations. *Ministerial Decision No. 1412 of 2017 on the Approval of the Code of practice of the Marketing and Trading of Medical Products* (the "Code"). The Code sets out details around the nature, form and content of advertisements of Medical Products, and how

	manufacturers and distributors/agents of Medical Products are permitted to engage with the healthcare professional/healthcare sector in promotion of their products. ***UAE Cabinet Decision No. (21) of 2018 on the marketing of relevant feeding products for infants and young children.*** Under this resolution**,** the Cabinet contributes to protecting, encouraging and supporting breastfeeding through regulating the activities of marketing and advertising of foods and nutritional products, which relate to feeding infants and young children. The Cabinet under this resolution also aims at providing appropriate information about the drawbacks of nutritional products to protect young children's health. ***Electronic Media Regulation* 2018 (EMR).** Under the EMR the UAE National Media Council (**NMC**) specifically requires that any advertising of medicine and drugs on the internet/social media requires prior approvals from the competent authorities – alongside a specific licence from the NMC to advertise and promote content electronically, in accordance with the general requirements of the EMR.
2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of: a) medicines? b) medical devices? If yes, please indicate these.	The relevant laws are described above. MoHAP governs and regulates the importation, manufacturing, use and advertising and sale of Medical Products (defined above) in the UAE and is the only authority that issues licenses for these activities, including specific licences for each medical advertisement. Some Emirates have authorities that regulate the policies and overall healthcare quality, e.g. the Dubai Health Authority for the Emirate of Dubai ("**DHA**") and the Health Authority for Abu Dhabi for the Emirate of Abu Dhabi ("**HAAD**"). These Emirate-level regulators will implement specific additional regulations that apply to Medical Products and the overall provision of healthcare within that Emirate, all ultimately falling within the scope of the Federal Laws described a Question 1 above.
3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to: a) the general public? b) healthcare professionals?	Medical Products must have a specific "Market Authorisation" issued by MOHAP prior to any Medical Product being authorised for importation and circulation in the UAE. Similarly, no Medical Product may be advertised, marketed or promoted in the UAE unless and until a Market Authorisation for the product is issued by MOHAP. Such authorisation is only granted if the relevant Medical Product has been duly registered with and classified by MOHAP and once registered and authorised, the relevant Medical Product must only be promoted for the purposes that it was duly authorised for, as set out on its approved Market Authorisation Certificate, which will also set out details of instructions/information and other matters that must appear on product labelling. *(Note, this does not restrict scientific and "non-marketing" exchange of information in scientific journals/magazines/conferences aimed at healthcare professionals.)* The application for advertising/marketing approval can be made online. Typically this is done by a marketing agent based in the UAE as appointed by the manufacturer, who would then be engaged to import and distribute the products in the UAE. . Once Marketing Authorisation has been granted by MOHAP, it is then a

	requirement that all intended advertising/marketing tools are reviewed by MOHAP prior to implementation. The proposed advertising/marketing tools can be uploaded on the MOHAP website electronically, once an account has been registered with MOHAP. Registering the account requires uploading several documents, including the relevant Marketing Authorisation, example product advertisement, and the desired location/type of advertisement, media platform and duration for the approval of that specific advertisement (e.g. 1 month, 3 months, 6 months etc). In addition to the above, the DHA or the HAAD may need to review the contents of the advertising/marketing of medical products/pharmaceuticals prior to them being implemented in that Emirate on a case-by-case basis. The Code does not include any specific professional qualifications/licences required from medical sales representatives when carrying out any advertising activities in the UAE. However, medical sales representatives are expected to demonstrate a good understanding and be adequately trained to present sufficient scientific knowledge when promoting Medical Products. The Code applies to the advertising/marketing and of Medical Products to the general public and healthcare professionals alike.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	Yes. ***2019 Law.*** Article 39 of the 2019 Law prohibits the advertisement of any prescription only drugs. The only exception is the promotion of those prescription only drugs in scientific resources or magazines intended for healthcare practitioners, and then only with the approval of MOHAP. However, the general promotion of non-prescription drugs/products, including non-prescription medical devices, is permitted provided the product has a Marketing Authorisation and the advertisement is approved by MOHAP. ***The Code.*** The Code requires that all advertising/marketing materials, regardless of whether the item is over the counter or a prescription medication, must only be targeted at relevant individuals who require this specific information or would be interested in it. These individuals, in turn, have a right to opt out of receiving such material. Mass distribution of advertising/marketing materials to the public is specifically prohibited.
5. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to the general public?	Please see Question 4 above. In brief, MOHAP approval is required for any advertisement of a Medical Product, including any medicine or medical device. The Code sets out detailed standards (requirements, prohibitions so on) regarding advertising/marketing materials. A key principle under the Code is that marketing materials must be both accurate and comprehensive enough to enable a recipient to form their own opinion as regards the therapeutic value of the Medical Product. The marketing materials must be accurate, balanced, impartial, objective and complete, based on a recent assessment of the medical research/evidence. It must not be misleading through distorted information, exaggeration, unjustified focus, omission or in other ways. The words “safe” or “effective” shall not be used and particular attention shall be given to basic information on the

	safety of the product, such as contraindications, precautions and side effects. The relevant Medical Product must only be advertised/marketed for the purpose that it was duly authorised for by the MoHAP, as set out on its approved labelling. The Publications Law also imposes the following general restrictions on advertising which are also applicable to medicines and medical devices: • Advertisements must be in line with the law and must not breach any rules in the UAE; • UAE traditions, Islamic beliefs and customs must be closely considered and advertisements must not undermine these values; • Advertisements must be clear and concise and must not misdirect individuals; • Advertisements must not disrupt public morale; • Advertisements must not promote the unwanted and excessive use of medicinal products; • Samples must not be given with advertisements. Under the Publications Law and the National Media Advertising Code certain advertising of medicines and medical products is explicitly prohibited due to its content. It is a violation of the law to advertise the following products and services: • Abortions; • Embryo freezing; • Products that are proven to be harmful to individuals; • Treatment or preventing the following diseases: cancer, STDs (sexually transmitted diseases), AIDS (Acquired Immune Deficiency Syndrome), hepatitis, mental and psychological disorders.
6. What are the main restrictions applicable to the advertising of: a) medicines b) medical devices to healthcare professionals?	Please see Questions 4 and 5 above for regular advertisements and specific prohibitions/carve outs regarding healthcare professionals. In addition, the Code sets out detailed provisions regarding how manufacturers/promoters of Medical Products shall promote those products to and engage with healthcare professionals. For example: • marketing via e-mail, SMS or other electronic means of communication requires prior approval of the healthcare professional; • strict and detailed controls are imposed around hospitality and gifts offered to healthcare professionals by medical product companies (or at event sponsored by them); • the free goods which a manufacturer/sales agent can provide to a pharmacy are capped at 15% of the value of underlying invoices for products purchased by the pharmacy. No cash or equivalent benefits are permitted to

	induce regular business from pharmacies/healthcare institutions; • samples of a product may be offered to healthcare professionals allowing them to prescribe those products, provided the samples are in reasonable quantities, stating clearly they are samples, and such samples shall not be sold/traded. Samples must have the phrase “free medical sample – not for sale” written on it in Arabic and English language. Additional restrictions/conditions are imposed on things like sponsorship of medical conferences, education support and so on.
7. What information must appear in advertisements directed only to healthcare professionals for: a) medicines? b) medical devices?	The Code sets out detailed standards (requirements, prohibitions so on) regarding advertising/marketing materials, which (in relation to information in advertisements for specific products) does not distinguish between healthcare professionals and the general public. A key principle under the Code is that marketing materials must be both accurate and comprehensive enough to enable a recipient to form their own opinion as regards the therapeutic value of the Medical Product. The marketing materials must be accurate, balanced, impartial, objective and complete, based on a recent assessment of the medical research/evidence. It must not be misleading through distorted information, exaggeration, unjustified focus, omission or in other ways. The words “safe” or “effective” shall not be used and particular attention shall be given to basic information on the safety of the product, such as contraindications, precautions and side effects. The content, form, location and other aspects of all advertisements of authorised Medical Products must be approved by MOHAP before they can be published in any media, whether to healthcare professionals or to the general public. In assessing each advertisement application, MOHAP will also consider the provisions set out in the Marketing Authorisation Certificate for the relevant product, and the Code.
8. What information must appear in advertisements directed to the general public for: a) medicines? b) medical devices?	Please see Question 7 above.
9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	As noted above, under the Code, all marketing materials must be accurate, balanced, impartial, objective and complete, based on a recent assessment of the medical research/evidence. It must not be misleading through distorted information, exaggeration, unjustified focus, omission or in other ways. The words “safe” or “effective” shall not be used and particular attention shall be given to basic information on the safety of the product, such as contraindications, precautions and side effects. In that context, the Code requires that scientific data used in advertising/marketing must be approved by MOHAP and that it be balanced and accurate. For example, scientific data from the findings of a study may only be quoted if data from another valid, clinically relevant scientific study which contradicts or questions the data of such findings is also published. Study data shall also not be cited or published which might give the recipient a false or

		misleading impression about the nature, scope, outcome, application or importance of the study, and data from animal testing shall not be cited if it might give a distorted impression of the application to humans.
10.	Are there specific rules for comparative advertisement of medicines and medical devices?	The Code requires that statements of comparison between different Medical Products must be based on relevant and comparable aspects of the product. The comparative advertisements must not be misleading or degrade the other product and must be valid and made in a scientifically appropriate and balanced manner. More general rules regarding comparative advertising are also set out under the following laws: ***Federal Commercial Transactions Law No. (18) of 1993.*** The Commercial Transactions Law provides that an advertisement containing false information either about the advertised product or about a product possibly being compared therewith will amount to a form of unfair competition and in terms of this legislation, such advertisements will expose the advertiser to claims for damages. ***Federal Law No. 24/2006 on Consumer Protection (*Consumer Protection Law*).*** The Consumer Protection Law provides that a supplier may not display, offer, promote or advertise any misleading goods that would harm the interests or health of consumers, which may include information about goods that may be misleading.
11.	Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	The Code requires that all intended advertising/marketing tools are reviewed by MOHAP prior to implementation. The proposed advertising/marketing tools for use on social media/internet can be uploaded on the MOHAP website electronically, once an account has been registered with MOHAP. Registering the account requires uploading several documents, including the relevant Marketing Authorisation Certificate for the product. ***Electronic Media Regulation* 2018 (EMR).** Under the EMR the UAE National Media Council (**NMC**) specifically requires that any advertising of medicine and drugs on the internet/social media requires prior approvals from the competent authorities – alongside a specific licence from the NMC to advertise and promote content electronically, in accordance with the general requirements of the EMR. The scope of EMR is broad in nature and covers the presentation or promotion of ideas, goods or services by electronic means or applications, whether paid or unpaid, and it is element of the EMR that catches influencers who use their social media accounts to commercially advertise Medical Products. 'Commercially' in this context, however, is not limited to paid-for activity. Influencers and bloggers who receive non-monetary benefits (e.g. free products or free entry) to promote a particular brand or event will therefore require a licence from the NMC. ***Dubai Health Authority Guidelines for Medical Advertisement Content on Social Media ("SMA Guidelines").*** The SMA Guidelines apply only in the Emirate of Dubai, and reinforce the need for healthcare advertising ***on*** social media (which is very broadly defined to cover a range of platforms***)*** to be accurate and safe. The SMA Guidelines also state that health facilities and healthcare professionals receiving financial or other material

	benefits for promoting healthcare, or non-healthcare, related products or services should have a transparent relationship with the relevant organisation (or individual) and this should be documented and disclosed to their patients. They should also avoid the promotion of: • Non-therapeutic products; • Products and services not directly related to healthcare; • Products and services that are not proven to be healthy or sound; • Products that are not supported by clinical evidence; • Products that affect health adversely. *Commentary: A current nuance of local law that is being debated with the relevant authorities is whether e-commerce platforms constitute "social media platforms" for these purposes, and whether making Medical Products available on their websites constitutes an "advertisement". This is an area of new development, accelerated since the impact of COVID with the introduction of an "E-Pharmacy Licence" for businesses to distribute Medical Products (available for pharmacy distribution or OTC) to customers via their e-platform. If e-commerce platforms are deemed to be "advertising" medical products by having them available for inspection on their virtual shelves, whereas regular supermarkets which might sell OTC products are not deemed to be "advertising" those products by having them available for inspection on their regular shelves, this could create an imbalance between online and in-store sales of OTC Medical Products and those sold via E-Pharmacies.*
12. Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	MOHAP is the primary regulator for all matters relating to advertisement / promotion of Medical Products in the UAE. Under the Code, the Pharmaceutical Licensing Committee of MOHAP can investigate any violations and take any necessary corrective measures against liable parties. At a minimum, fines can be imposed and the offending or non-complying materials will be removed. Under the 2019 Law, individuals or companies that fail to adhere to the requirements under the 2019 Law will be considered to have committed a criminal offence. Non-compliance with the provisions of the 2019 Law is punishable by imprisonment or (more commonly) a fine which would be levied by MOHAP. The duration of imprisonment and the size of fines levied will depend on the nature and scale of the violations. The penalties prescribed under this Pharmacy Law will not prejudice any more severe penalty provided for in any other law. ***EMR.*** The NMC can impose fines of AED 100,000 to 200,000 for publishing advertisements online and on social media without the relevant authorisations from both MoHAP and the NMC.
13. Any future developments in your jurisdiction?	The 2019 Law has consolidated various previous laws which governed this area of law in the UAE. However, some historical regulations still exist outside of the 2019 Law, as described above. We expect further consolidation of those ancillary laws/regulations and improvement of the legal regime in the coming years.

	In particular, the regulations around e-pharmacies and the promotion / sale of regulated Medical Products on e-commerce platforms is an area which needs to be addressed clearly and is currently causing some debate between the authorities and industry stakeholders. There has also been a major change to the laws relating to health data in the UAE in 2019. We expect this to result in some further laws/regulations in the coming years to refine and implement those changes, with input from the medical products sector.

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JURISDICTION: United Kingdom

1. Which laws are applicable regarding advertising of a) medicines? b) medical devices?	**Medicinal Products** The key UK statutes regulating general advertising/promotion of medicines are: • The Human Medicines Regulations 2012/1916, which contain provisions specifically regulating the advertising of medicines; • The Consumer Protection from Unfair Trading Regulations 2008/1277, which regulate general business-to-consumer advertising including of medicines; and • The Business Protection from Misleading Marketing Regulations 2008/1276, which regulate general business-to-business advertising including of medicines. These are supplemented by guidance published by the Medicines and Healthcare products Regulatory Agency (MHRA) setting out its interpretation of the regulations for which it has competence. This guidance is for the most part set out in the "Blue Guide – Advertising and Promotion of Medicines in the UK". The general anti-bribery/anti-corruption offences set out in the Bribery Act 2010 are also relevant to the promotion of medicines. **Medical Devices** At present, the applicable medical devices legislation (the Medicines and Medical Devices Act 2021 and the Medical Devices Regulations 2002) does not explicitly regulate the promotion of medical devices other than to prohibit marketing of devices that do not conform to the Regulations An exception is made for showing these devices at trade fairs or demonstrations with a notice stating they cannot be marketed or put into service until they comply with the Regulations. Under the Protocol on Ireland and Northern Ireland agreed between the EU and UK, the deferred EU Medical Devices Regulation 2017/745/EU ("**EU MDR**"), which will come into mandatory application throughout the EU from 26 May 2021, will apply in Northern Ireland from the same date. Therefore, any advertising of medical devices in Northern Ireland must not infringe the prohibition in the EU MDR on the use of misleading claims in the advertising of medical devices. The EU MDR will not, however, be applicable in Great Britain. Additionally, the new Medicines and Medical Devices Act 2021 provides a basis in primary legislation for the government to make future regulations imposing requirements on persons involved in marketing medical devices. In addition to the regulatory requirements, the advertising of medical devices is regulated by: • The Consumer Protection from Unfair Trading Regulations 2008 (the "**CPRs**"); and • The Business Protection from Misleading Marketing Regulations 2008 (the "**BPRs**").

2. Are there any other legal regimes such as self-regulatory codes of conduct that govern the advertising of a) medicines? b) medical devices? If yes, please indicate these.	**Medicinal Products** In addition to the Regulations and guidelines set out above, there exist industry codes of practice to which companies either voluntarily adhere or agree to adhere as members of the relevant trade associations: • The Association of the British Pharmaceutical Industry (ABPI) Code of Practice is applicable to the advertising of proprietary medicines to healthcare professionals and other relevant decision-makers. Members of the ABPI are bound by the ABPI Code and non-members can voluntarily agree to be bound by the ABPI Code; • The Proprietary Association of Great Britain (PAGB) Professional and Consumer Codes, to which PAGB members agree to adhere, set down rules which relate to advertising of over the counter medicines; and • The UK Code of Non-broadcast Advertising and Direct & Promotional Marketing (CAP Code) and the UK Code of Broadcast Advertising (BCAP Code) are regulatory codes that apply to general non-broadcast (including internet) and broadcast business-to-consumer advertising respectively. The general advertising provisions of the codes apply to medicines promotion and the codes also contain provisions specifically regulating the advertising of medicines. In each case, the codes reflect but also extend beyond the underlying statutory provisions. **Medical Devices** In addition to the legislation set out above, there are self-regulatory codes of practice: • The Association of British Healthcare Industries (ABHI) Code of Practice, including the ABHI Guidelines on Advertisements & Promotions addressed solely or primarily to Healthcare Professionals (the "**ABHI HCP Advertising Guidelines**") and the ABHI Guidelines on Interactions with Healthcare Professionals, a voluntary code, enforced by the ABHI, which binds its members; • The UK Code of Non-broadcast Advertising and Direct & Promotional Marketing (the "**CAP Code**"), enforced by the Advertising Standards Authority (the "**ASA**"), which applies to all advertisers, agencies and media; • The UK Code of Broadcast Advertising (the "**BCAP Code**"), enforced by the ASA, which applies to all advertisements on radio and television services licensed by Ofcom; and • The PAGB Medical Devices Consumer Code, which applies to advertising by PAGB members of self-care medical devices that are within the scope of an existing OTC therapeutic category within the PAGB OTC directory. The PAGB will consider inter-member complaints regarding breaches of the code.

	There are also other sector-specific medical devices trade associations which operate their own codes of practice which regulate advertising amongst other matters, e.g. the Code of Practice for the Promotion of Wound Care Products to Healthcare Professionals of the Surgical Dressing Manufacturers Association (SDMA), which bind their members.
3. What kind of licenses/approvals/ fees (if any) are required for medicines and medical devices to be advertised to a) the general public? b) healthcare professionals?	**Medicinal Products** Subject to very limited exceptions, it is unlawful to advertise a medicinal product unless the medicine is authorised via a marketing authorisation (MA). Alternatively, the product must have been issued a homeopathic medicinal product certificate registration, a traditional herbal registration or a specific authorisation for products where there is a justification for public health reasons. Prior to the grant of a marketing authorisation, pursuant to the ABPI Code, a supplier is permitted to provide *information* to those performing budget planning and management roles at the National Health Service (e.g. Medicines Managers at Clinical Commissioning Groups of the NHS), provided the information is purely factual and non-promotional in nature and there is a potential budgetary implication for the healthcare organisation. Beyond this, the promotion of unlicensed medicinal products is almost entirely restricted, save that limited information about products authorised overseas can be displayed at scientific meetings hosted in the UK. Promotional materials that are subject to the PAGB Consumer Code are submitted to the PAGB for pre-vetting to review the materials' compliance with the PAGB Consumer Code. (See also below for restrictions on advertising to the general public). **Medical Devices** Following the end of the transition period under the withdrawal agreement agreed between the EU and the UK (specifically 11pm UK time on 31 December 2020), different requirements apply in Great Britain (England, Scotland and Wales) compared to those applicable in Northern Ireland. *Northern Ireland* Under the operation of the Protocol on Ireland and Northern Ireland agreed between the EU and the UK, Northern Ireland is assimilated to a member state whilst the Protocol is in application. As such, the advertising requirements of the EU harmonised legislation on medical devices will continue to apply in Northern Ireland and medical devices supplied there will have to be CE marked in accordance with applicable EU requirements before they can be promoted (subject to the exception noted above for trade fairs).

	Great Britain Amendments to the Medical Devices Regulations 2002 effective from 11pm 31 December 2020have introduced a new UKCA marking requirement for devices supplied in Great Britain which will replace the CE marking regime at the end of the transition period on 1 July 2023. From that date medical devices supplied in Great Britain will have to be affixed with a UKCA mark. *Generally in the UK* Generally, before a device may be advertised to any audience it must be covered by an appropriate marking as required in the relevant part of the UK (see above). UK law also makes the 'supply' of devices that do not have a CE or UKCA marking (as applicable), or inappropriately marked medical devices an offence. 'Supply' is defined to include the offer, exposure or possession for supply. The offence therefore catches the advertising of non-marked, or inappropriately marked, medical devices. Off-label advertising is also likely to amount to an illegal 'supply' under UK Regulations.
4. Does the law in your jurisdiction regulate the advertising of prescription-only and over-the-counter medicines differently?	**Medicinal Products** Yes. It is not lawful to promote prescription only medicines to the general public. Additionally, as set out above and below different advertising laws / codes apply depending on whether the medicine is authorised as over-the-counter or prescription-only. **Medical Devices** Not applicable.
5. What are the main restrictions applicable to the advertising of a) medicines b) medical devices to the general public?	**Medicinal Products** Over the counter medicines may be advertised to the general public. Prescription only medicines cannot be advertised to the general public except in the context of a campaign, approved by the UK Government, that relates to the use of a medicinal product in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation or an approved vaccination campaign. In all cases, advertisements must: • comply with the particulars of the Summary of Product Characteristics (SmPC); • not be misleading; and • encourage the rational use of the product by presenting it objectively and without exaggerating its properties. The advertiser must be able to substantiate all claims made in an advertisement. Advertisements must be obviously recognisable as such. Specific restrictions apply and are set out in Regulations 281 to 293 (inclusive) of The Human Medicines Regulations 2012. For example, an advert must not relate to medicinal products which contain narcotic substances, suggest that the safety or efficacy of a medicinal product is related to the fact that it is "natural", suggest it is a food or cosmetic, or lead to the use of the product for inducing abortion.

	Please see response to question 3 above regarding materials within the scope of the PAGB Consumer Code being submitted for pre-vetting by the PAGB. Additionally, the provisions of the CAP Code and the BCAP Code will apply (see below). **Medical Devices** The CPRs (which are generally applicable to consumer advertising) govern marketing communications made to consumers (i.e., individuals acting outside the course of their business). The CPRs prohibit unfair marketing to consumers, including: • Misleading advertising: Where the overall presentation deceives or is likely to deceive the average consumer in relation to various matters, including information about the benefits and risks of the product, and this causes the average consumer to take a transactional decision they would not have taken otherwise; • Aggressive advertising: Practices that significantly impair, or are likely to significantly impair the average consumer's freedom of choice or conduct in relation to the product concerned through the use of harassment, coercion or undue influence, including the exploitation by the trader of any specific misfortune or circumstance of such gravity as to impair the consumer's judgment. Schedule 1 of the CPRs contains a list of commercial practices that are always considered unfair, even if they do not cause the consumer to change their buying decision. The CAP code contains a number of restrictions on the advertising of medical devices, including: • Objective claims must be backed by evidence; • Marketers must not discourage essential treatment for conditions for which medical supervision should be sought; • Marketers must not confuse consumers by using unfamiliar scientific words for common conditions; • Marketers inviting consumers to diagnose their minor ailments must not make claims that might lead to a mistaken diagnosis; and • Marketers should not falsely claim that a product is able to cure illness, dysfunction or malformations. The BCAP contains similar restrictions in the context of broadcast advertising.

6. What are the main restrictions applicable to the advertising of a) medicines b) medical devices to healthcare professionals?	**Medicinal Products** Advertisements for all medicinal products (including prescription-only products) must: • comply with the particulars of the SmPC; • not be misleading; and • encourage the rational use of the product by presenting it objectively and without exaggerating its properties. The advertiser must be able to substantiate all claims made in an advertisement. Advertisements must be obviously recognisable as such. In addition, the Human Medicines Regulations 2012 contain specific restrictions against the provision of gifts and hospitality to members of the healthcare professions. **Medical Devices** The BPRs (which are generally applicable to all B2B advertising) govern advertisements aimed at traders (*i.e.*, persons acting for purposes relating to their trade, craft, business or profession), including healthcare professionals ("**HCPs**"). The BPRs prohibit misleading advertising, defined as advertising which in any way, including its presentation, deceives or is likely to deceive the traders to whom it is addressed or whom it reaches, and by reason of its deceptive nature, is likely to affect their economic behaviour. This includes providing misleading information relating to the characteristics of a product, including the results to be expected from use of the product. In addition, the ABHI HCP Advertising Guidelines govern marketing communications addressed solely or primarily to HCPs by ABHI members. They contain the following general principles: • Advertising must be suitable for the intended audience and must conform to generally acceptable standards of good taste; and • An advertisement should be readily recognisable as such by the intended audience and its commercial intent must be made clear if it is not obvious from the context. They also set out detailed requirements for the accuracy and substantiation of claims and information.
7. What information must appear in advertisements directed only to healthcare professionals for a) medicines? b) medical devices?	**Medicinal Products** Advertisements must be consistent with the Summary of Product Characteristics and set out details of the MA number and MA holder, the name of the product, its active ingredients. They must also contain required prescribing information covering the indications for which the medicinal product is authorised, contra-indications and side effects, method of use and dosage, and cost.

	Short, abbreviated advertisements (such as those in magazines or circulars for prescribers) are permitted subject to certain conditions. They must contain the information set out above, save that information on contraindications and methods of use can instead be made accessible online. **Medical Devices** As explained in response to question 3 above, the advertising of medical devices must be within the scope of an appropriate CE mark or UKCA mark, as applicable. Any claims made in advertising should align with the intended purpose of the device as stated in the declaration of conformity and be sustainable by reference to the technical file and not be misleading.
8. What information must appear in advertisements directed to the general public for a) medicines? b) medical devices?	**Medicinal Products** The advertisement must contain the name of the product, the active ingredient, information necessary for its correct use and an express and clear invitation to read the instructions properly. It must be clear that it is an advertisement and it must be clear the product is a medicine. **Medical Devices** See the response to question 7 above.
9. Please summarize the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?	**Medicinal Products** The applicable legislation does not contain express provisions regarding the standard of evidence and data required to substantiate claims in advertisements. However, the self-regulatory codes do contain express requirements in relation to evidence and cases/decisions under these codes provide additional interpretation of the evidential requirements. These requirements apply to companies subject to those codes but also provide useful guidance for what standards of evidence are likely to be acceptable to comply with the general statutory requirements. For example, the ABPI Code requires that information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. The ABPI Code also provides that when promotional material refers to published studies, clear references must be given. In addition, the ABPI Code provides that substantiation must be provided as soon as possible, and certainly within 10 days, at the request of members of the health professions. Further, where material refers to “data on file” the relevant parts of this data must be provided without delay at the request of healthcare professionals. In general, data must be statistically relevant and be presented in a way which is fair and accurate. It must not be used in a way which is misleading.

	Medical Devices In addition to the general legal requirements that the advertising of medical devices must not be misleading, the ABHI HCP Advertising Guidelines provide that all information and claims must be accurate, balanced, fair, objective and unambiguous and must be based on a fair evaluation of appropriate evidence and reflect that evidence clearly. Clear references must be provided if published studies are referred to and any graphs or tables used must be presented so as to give a clear, fair and balanced view of the matters they deal with. Material reproduced from a published study should not be altered unnecessarily and must not distort or give a false impression of the evidence published in the study. The key issues when using scientific data are their quality, relevance and overall credibility when relied on to support the advertiser's claims. On their own non-refereed articles are unlikely to be adequate substantiation for science-based claims concerning device safety or performance.
10. Are there specific rules for comparative advertisement of medicines and medical devices?	**Medicinal Products** See above in respect of clinical data. An advertisement for a medicinal product directed wholly or mainly at members of the public must not suggest that the effects of taking the medicinal product are better than or equivalent to those of another identifiable treatment or medicinal product. This rule does not apply in relation to advertising of prescription-only medicines to healthcare professionals. The Business Protection from Misleading Marketing Regulations 2008/1276 implement the general requirements relating to comparative advertising in the Comparative Advertising Directive 2006/114/EC and these also apply to the advertising of medicinal products. The ABPI Code sets out specific requirements for comparative advertising, which include that it must not be misleading; medicines for the same needs or intended purposes must be compared; there must be no confusion created between the advertised medicine and a competitor medicine; and the trade marks/names etc. of a competitor must not be denigrated/discredited or taken unfair advantage of. Each of the CAP Code, the BCAP Code and the PAGB Codes also contain provisions specifically regulating comparative advertising. **Medical Devices** The ABHI HCP Advertising Guidelines contain detailed rules on the use of comparative advertising. A comparison shall only be permitted to be used as part of an advertisement if: • It is not misleading; • Devices or services for the same needs or the same intended purpose are compared; • One or more relevant features are compared;

	• No confusion is created between the device or service advertised and that of a competitor or between the advertiser's trade marks, trade names, other distinguishing marks and those of a competitor; • The trade marks, trade names and other distinguishing marks, products, services, activities or circumstances of a competitor are not discredited or denigrated; • No unfair advantage is taken of the reputation of a trade mark, trade name or other distinguishing marks of a competitor; and • The advertiser's devices or services are not presented as imitations or replicas of goods or services bearing a competitor's trade mark or trade name.
11. Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?	**Medicinal Products** In general, no. The same rules apply to online advertising as would apply to other forms of advertising. However, the MHRA considers that prescription only medicines should only be advertised on websites specifically directed to healthcare professionals and clearly marked as such and that use of social media (e.g. twitter) for promotional information concerning prescription medicines is prohibited because of its general availability to non-healthcare professionals. In principle, the information referred to in the response to question 7 above could instead be provided by way of linking to the full SmPC from an internet advertisement instead of including this information in the advert itself. This is the position of the MHRA stated in the Blue Guide. **Medical Devices** The rules governing online advertising are largely the same as those governing other types of non-broadcast advertising. However, online advertising brings its own challenges. For example: • Medical device manufacturers have legal surveillance and reporting obligations to systematically collect, evaluate and to report adverse safety information to the MHRA. If users are permitted to submit comments to manufacturers via online channels as part of their marketing campaigns, this would open up a new avenue through which manufacturers could potentially receive information on incidents, which would have to be monitored and evaluated for possible reporting to the MHRA; • Publicly accessible user comments may constitute off-label promotion, which is likely to amount to an illegal 'supply' under the UK Regulations (see the response to question 3 above).

12.	Please describe the enforcement mechanism in your jurisdiction. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?	**Medicinal Products** The MHRA can enforce the Human Medicines Regulations by way of the criminal law. Penalties can be as severe as an unlimited fine and, in the case of natural persons, up to two years in prison. There is also scope for personal criminal law liability for company officers and senior management if an offence is committed with their consent or connivance or due to their neglect. However, according to memoranda of understanding between the Prescription Medicines Code of Practice Authority (PMCPA) and the ABPI on the one hand, and each of the MHRA and the Serious Fraud Office (SFO) on the other, the PMCPA has jurisdiction in respect of matters covered by the he ABPI Code though each of MHRA and the SFO have jurisdiction to intervene to enforce the law. Companies subject to the jurisdiction of the PMCPA who breach the ABPI Code are liable for administrative costs, public censure and, in the case of particularly serious breaches by ABPI members, suspension of membership or even expulsion from the ABPI, at which point they become subject to the direct scrutiny of the MHRA. All adjudications are made public. Local Trading Standards Authorities and the Competition and Markets Authority (CMA) have competence for enforcing the Consumer Protection from Unfair Trading Regulations 2008 and the Business Protection from Misleading Marketing Regulations 2008/1276. Certain provisions of these regulations can be enforced by way of criminal sanctions. Trading Standards and the CMA may also prohibit the publication of infringing advertising. The self-regulatory CAP Code and BCAP Code are enforced by the Advertising Standards Authority (ASA). The ASA can issue a public adjudication that an advert is in breach of the applicable code, which can create adverse publicity for the infringing company. The ASA can also require a company to withdraw or amend an advertisement. If a company fails to comply with a request to withdraw or amend its advertisement, the ASA may advise the media or others to withhold access to advertising space or trading privileges; broadcasters are required to follow ASA rulings as a condition of their own licences while ASA may also ask online search engines to remove adverts. In addition, ASA may refer the matter to regulators with statutory enforcement powers, such as Trading Standards Authorities. **Medical Devices** The UK Regulations are currently safety regulations for the purposes of the Consumer Protection Act 1987, and are enforceable by the MHRA. The legislation provides for various penalties, ranging from a compliance notice to an unlimited fine and, in the case of individuals, six months' imprisonment and/or unlimited fine. There is also scope for personal criminal law liability for company officers and senior management if an offence is committed with their consent or connivance or due to their neglect. The new Medicines and Medical Devices Act 2021 will substitute new enforcement provisions and powers in place of the Consumer Protection Act 1987 for medical devices. The new enforcement powers will come into effect on a date still to be appointed by the Secretary of State under regulations. Enforcement under the 2021

	Act will be by the MHRA but also additionally by local authorities' Trading Standards Offices for devices which are ordinarily intended for private use or consumption (i.e. consumer devices). A breach of the CPRs can lead to a fine or imprisonment of up to two years, or both. An officer of the company as well as the body corporate itself can be held liable. Further, consumers may bring a civil law claim under the CPRs to enforce against misleading or aggressive advertising, although traders may be able to rely on a due diligence defence. A breach of the ***BPRs*** can result in a fine or up to two years' imprisonment, or both. Complaints about breaches of the ABHI Code may be made to the ABHI Panel, which, if the complaint is upheld, can require the advertiser to cease using the advertising complained of and to pay an administrative charge. Various further sanctions are available to the ABHI Panel, including recommending expulsion of the advertiser from the ABHI and requiring the payment of the Panel's costs. Case reports are published on the ABHI's website and are publicly available. Allegations of breaches of the CAP Code and the BCAP Code are directed to the ASA. The ASA may also make challenges to advertisements of its own volition and adjudicate upon them. The ASA has a range of enforcement options available to it. Where complaints cannot be resolved informally and are upheld at adjudication, the usual sanction is simply to direct that the advertisement not appear again in the same form. However, in particularly serious cases, the ASA has a sliding scale of further enforcement options, which can include alerting media channels not to accept advertising, asking search engines to remove paid-for advertising linking to non-compliant advertising, requiring pre-vetting of advertising or, in the most extreme cases, referring an advertiser to Trading Standards for enforcement under the Consumer Protection from Unfair Trading Regulations.
13. Any future developments in your jurisdiction?	**Medicinal Products** The UK exited the European Union on 31 January 2020. The UK remained subject to EU law until the end of the Brexit implementation period (which ended at 11pm UK time on 31 December 2020). Under the terms of the Withdrawal Agreement, Northern Ireland remains subject to EU law governing the advertising of medicines until at least 1 January 2027. GB regulation of advertising of medicines could in principle now diverge from the existing EU legislation at any time. However, it is not currently expected that there will be any significant changes in the short term. **Medical Devices** See the response to questions 1, 3 and 12. We understand that the MHRA / Department of Health and Social Care will be developing and consulting on the new UKCA mark framework during the course of 2021 / 2022 in readiness for mandatory application in GB from 1 July 2023. This may also include provisions regulating advertising of medical devices.

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