



Advertisement of Medical Devices

Local regulations in Central
and Eastern European countries

June 2023





Introduction

Advertising of medical devices

Local regulations in Central and Eastern European countries

The new medical device regulations, adopted by the European Union (MDR and IVDR regulations), are accompanied by local regulations which are being adopted in the EU Member States. While the EU regulations define the rules for assessing the conformity of medical devices (and, accordingly, in vitro diagnostic medical devices), placing them on the market and exercising post-market surveillance over them, the issues of advertising and promoting these devices are subject to local rules. The provisions of the MDR and IVDR regulations are limited in this respect only to the prohibition of using misleading information / advertising activities.

Economic operators carrying out their business activity in EU Member States, including in particular importers and distributors of medical devices, must adapt their marketing activities to local regulations, ensuring their compliance with national advertising rules. Failure to adapt their marketing activity to local regulations poses the risk of the competent authorities questioning the advertising materials, their forced withdrawal, and even the risk of financial penalties imposed by those local authorities.

For example, Poland introduced new rules on advertising medical devices as of 1 January 2023. The new rules cover forms of advertising, guidelines regarding the content of the advertising, conditions for the commissioning of advertising, archiving advertising materials, supervision of the official authorities over

advertising and imposing financial penalties for the violation of local regulations. Generally, these new provisions have a lot in common with the principles of advertising of medicinal products, as specified by the Polish Pharmaceutical Law.

We took a closer look at the national regulations governing advertising and marketing activities also in other countries of Central and Eastern Europe, including Bulgaria, Croatia, the Czech Republic, Estonia, Hungary, Latvia, Romania, Slovakia and Slovenia. Some of them have not stipulated specific rules on advertising medical devices, so the general advertisement provisions of local law govern advertisement of these products (including Bulgaria, Estonia, Latvia, Slovakia). Whereas, other countries have already set specific regulation in this regard (including Croatia, the Czech Republic, Hungary, Poland, Romania, Slovenia) and for example in case of Hungary, these provisions are quite complex. On next page you will find comparison of the main features of these local regulations.

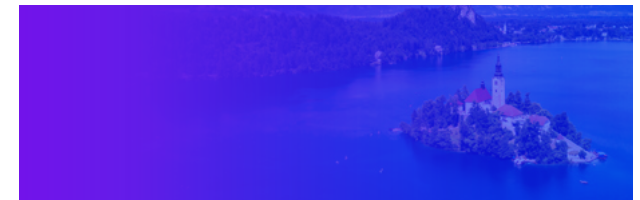
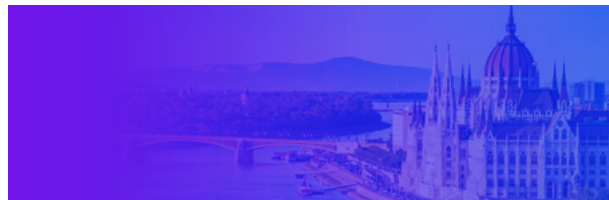
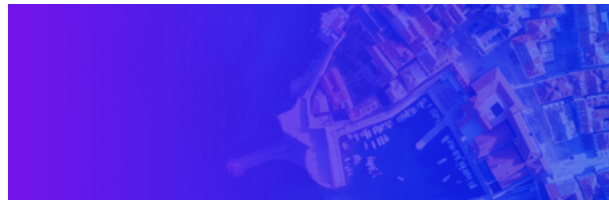
The scope of our report also covers local regulations on the registration of the distributors of medical devices who make them available in those countries. Moreover, we took into account the issues of recognizing expenses incurred on the advertising of medical devices as tax costs.

We hope that the information presented in our report will be useful for you and will allow you to get an idea of the local regulations on the advertising of medical devices applicable in each of these jurisdictions.



	Bulgaria	Croatia	Czech Republic	Estonia	Hungary	Latvia	Poland	Romania	Slovakia	Slovenia
specific regulations		X	X		X		X	X		X
difference between advertising to lay persons and HCPs		X	X		X		X	X		X
HCP prohibited in advertisement	X	X	X		X		X	X		X
specific warnings required			X	X	X		X	X		
financial penalties	X	X	X	X	X	X	X	X	X	X

Contents





Bulgaria

Q01 Are there any local specific regulations regarding the advertisement of medical devices?

No such specific regulations have been adopted.

Please note, that activities related to medical devices are governed in Bulgaria by the Medical Devices Act ('MDA'). Our answers in this table are based on the provisions of the MDA currently in force (as of 7 March 2023). These provisions do not impose any specific requirements related to advertising of medical devices.

The MDA was lastly amended in July 2020, i.e. before the majority of the provisions of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 came into force. A bill amending the MDA in view of these two EU regulations has been submitted to the Bulgarian parliament. Until now, the bill has not been reviewed in parliament. Therefore, the current Bulgarian legal framework related to medical devices may not be fully in line with the provisions of the EU regulations.

Q02 Do such regulations stipulate specific rules on advertising medical devices which are directed at lay persons? Do they distinguish between advertisements directed to lay persons and healthcare professionals?

N/A

Q03 Do these regulations specify which form or kind of advertisements to which they apply?

N/A

Q04 Do these regulations set any specific prohibitions regarding the content of the advertisement? Especially, do they prohibit healthcare professionals to appear in the advertisement of medical devices, or prohibit directing the advertisement towards children?

As mentioned, there are no specific regulations related to advertising medical devices.

However, Bulgarian law prohibits media service providers from distributing any form of commercial communication related to a medical treatment available only on prescription. Whether this rule applies to advertising of medical devices should be assessed on a case-by-case basis, depending on the contents of the advertisement (e.g. if in addition to a medical device the advertisement promotes a medical treatment provided on prescription).

Additionally, there are regulations which govern the ethical and professional standards to be observed by doctors, under which doctors may not allow their name, qualification, or skills to be used for advertising purposes. No such explicit prohibition is prescribed regarding dental practitioners.

Q05 Do these regulations require specific warnings regarding the use of medical devices to be included in the advertisement?

N/A

Q06 Do these regulations limits the advertisement of medical devices in healthcare centres and / or pharmacies?

N/A



Q07

Do these regulations specify the rules for commissioning advertisement activities?

Do they require the archiving of advertisement materials?

N/A

Q08

What are the sanctions for violating the advertisement regulations?

If a media service provider breaches the prohibition mentioned in question No 4, the authorities may fine them between approximately EUR 1,500 and EUR 10,000.

If case a doctor has allowed their name, qualification, or skills to be used for advertising, the following sanctions may be imposed:

- reprimand
- fine of between one and five times the minimum wage (currently between EUR 360 and EUR 1,800, approximately)
- ban on practicing, due to deregistration with the respective medical association between three months and one year.

Q09

Are distributors of medical devices subject to local registration? (Article 30 paragraph 2 of the MDR / Article 27 paragraph 2 of the IVDR)

If yes, what are the specific requirements such distributors need to fulfil to apply for registration?

In Bulgaria, the distribution of medical devices is governed by the Medical Devices Act.

Under that Act, wholesale distribution of medical devices is subject to authorization by the Bulgarian Drug Agency (BDA). In order to apply for authorization, a distributor must:

- be established in the EU/EEA or Switzerland
- provide evidence of his corporate status (corporate excerpt) if not incorporated under Bulgarian law
- provide a list of the categories of medical devices which will be distributed; this list must be prepared according to applicable Bulgarian regulations
- provide a document evidencing payment of the state fee for issuance of the authorization.

Additional documents and information must be submitted if the distributor has premises for storage of medical devices in Bulgaria.

Manufacturers of medical devices established in Bulgaria may carry out wholesale distribution of the medical devices which they have manufactured without authorization from the BDA.

The applicable requirements for retail distribution of medical devices depend on the type of the distributor (e.g. pharmacy, healthcare center).

Separate registration requirements apply to persons placing medical devices on the market or putting such devices into service. These requirements generally apply to manufacturers of devices which typically perform this type of activity.

Q10

CIT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of advertisement costs for income tax purposes, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

For tax purposes, advertising expenses are expenses incurred for the promotion of goods and services, including gifts which bear the trade name or the trademark of the taxable entity, within the limits of the usual activity carried out by the entity. The general conditions for advertising expenses to be recognized for tax purposes also apply, i.e., they should be supported by documents related to the activity of the taxable entity and determined at market levels.

If any of the conditions outlined above is not fulfilled, the taxable base for the period when the respective expenses were incurred is increased by the amount claimed as a tax-deductible expense. Additional tax and interest liabilities will arise as a result. Additional tax implications may also arise if the expenses were incurred in relation to a related party or if the related party benefited from the advertising expenses.

Q11

VAT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of input VAT on advertisement costs, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

There is no specific restriction in the VAT law regarding advertising expenses. Input VAT deduction on advertising purchases is allowed if these are business-related and actually delivered. Nevertheless, if the advertising purchases are unjustified from a regulatory or other statutory perspective, the input VAT deduction can be challenged by the tax authorities.



Croatia

Q01**Are there any local specific regulations regarding the advertisement of medical devices?**

Yes, this is regulated by the Croatian Law on Medical Devices (Official Gazette No. 76/2013; the **'Law'**).

The Law contains only two articles dealing with advertising of medical devices, which primarily regulate content prohibited in advertising.

Q02**Do such regulations stipulate specific rules on advertising medical devices which are directed at lay persons? Do they distinguish between advertisements directed to lay persons and healthcare professionals?**

As per the Law, advertisements for medical devices that are intended for use only by health care professionals can be directed only towards health care professionals.

Q03**Do these regulations specify which form or kind of advertisements to which they apply?**

The Law defines advertising of a medical device very broadly, as "any form of informing the public with the intention of contributing to a particular medical device's prescription, sale and consumption; be it in written, verbal, graphic, audio, electronic, digital, or any other form."

Q04**Do these regulations set any specific prohibitions regarding the content of the advertisement? Especially, do they prohibit healthcare professionals to appear in the advertisement of medical devices, or prohibit directing the advertisement towards children?**

The Law prohibits advertising of a medical device that does not meet the requirements prescribed by the Law (with the exception of medical devices intended to be displayed at exhibitions, fairs and similar, which must contain a clear label that they are not intended for placing on the market / use).

The content of the advertisement must not be deceiving.

Furthermore, an advertisement must not contain the following:

- information that leaves the impression that a medical device guarantees success in treating the disease and that the patient's health can be improved only by using that particular medical device; any factual claims must be supported by evidence;
- information that leaves the impression that the patient's health could worsen should the patient not use that particular medical device;
- information that encourages people to abandon basic generally accepted therapeutic procedures;
- information which is solely or predominantly directed at children;
- information that is confusing for the general public due to use of unfamiliar scientific terms for common health conditions;
- information which refers to statements made by scientists, health care professionals or other influential individuals whose reputation could improve the use of a particular medical device;
- information which states that the medical device is safe just because of its natural origin;
- information that, due to a detailed description of the pathological condition or medical history, could lead to wrong self-diagnosis;

- information that uses inappropriate, disturbing or deceiving claims regarding possibility of recovery;
- information which contains inappropriate, disturbing or deceiving visual images of changes to the human body caused by the disease;
- information which threatens human dignity.

Q05 Do these regulations require specific warnings regarding the use of medical devices to be included in the advertisement?

No.

Q06 Do these regulations limit the advertisement of medical devices in healthcare centres and / or pharmacies?

Please see our answer to question two.

Q07 Do these regulations specify the rules for commissioning advertisement activities?
Do they require the archiving of advertisement materials?

No.



Q08**What are the sanctions for violating the advertisement regulations?**

The State Inspectorate is entitled to prohibit advertising where advertising is not performed in accordance with the Law.

The Law also prescribes fines ranging between HRK 70,000 and HRK 100,000 for a legal entity that breaches the provisions of the Law related to advertising, while fines for its responsible person (e.g. a director) range between HRK 7,000 and HRK 10,000.

** note: as of 1 January 2023, Croatia adopted the euro as official currency. The above amounts are to be converted into euro using the fixed exchange rate of 7,53450.*

Q09**Are distributors of medical devices subject to local registration? (Article 30 paragraph 2 of the MDR / Article 27 paragraph 2 of the IVDR)****If yes, what are the specific requirements such distributors need to fulfil to apply for registration?**

Yes, distributors of medical devices and in vitro medical devices need to register with the Registry of Distributors kept by the Agency for Medicinal Products and Medical Devices of Croatia (**'HALMED'**) before commencing their activity.

HALMED is supposed to render a decision on registration within thirty days from receiving a complete request of the applicant.

However, the local by-law which is going to regulate the registration procedure in more details has not been adopted yet.

Q10**| CIT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of advertisement costs for income tax purposes, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?**

There are no such specific restrictions prescribed by Croatian CIT / VAT legislation. Rather, general rules apply, and thus the tax authorities could challenge the expense if the expense is not related to business purposes of a taxpayer.

Q11**| VAT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of input VAT on advertisement costs, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?**

See above.



Czech Republic

Q01**Are there any local specific regulations regarding the advertisement of medical devices?**

Yes. With effect from 26 May 2021, Act No. 40/1995 Coll. on the Regulation of Advertising, as amended (The **'Act'**), regulates the conditions for advertising medical devices as well as in vitro diagnostic medical devices (**'Medical Devices'**).

In addition to the above, general rules on advertising (e.g. consumer protection legislation) are applicable.

Q02**Do such regulations stipulate specific rules on advertising medical devices which are directed at lay persons? Do they distinguish between advertisements directed to lay persons and healthcare professionals?**

Yes. The Act makes a strict distinction between Medical Devices advertising aimed at the general public (lay persons) and Medical Devices advertising aimed at professionals.

Advertising of Medical Devices for the general public (lay persons) must comply with special rules set by the Act. For example, an advertisement may not (i) give the impression that a medical advice, intervention, or treatment is not necessary, (ii) imply that clinical efficacy is guaranteed, (iii) imply that failure to use a Medical Device may adversely affect a person's health, (iv) refer to the recommendations of scientists or medical experts, (v) refer to the performance of clinical trials/other processes that are a prerequisite for marketing, or (vi) be aimed exclusively at children under the age of 15.

An advertisement must also make it clear, for instance, that the advertised product is a Medical Device and what its trade name and intended purpose are, and the advertisement must include an invitation to read the instructions for use.

Advertising of Medical Devices aimed at professionals has a partially different regulation (e.g. concerning addressees of advertising of this kind, who may be only professionals).

Q03**Do these regulations specify which form or kind of advertisements to which they apply?**

Yes. The Act sets out a demonstrative list of what is specifically considered advertising of Medical Devices. These include:

- visits by sales representatives of Medical Devices to persons authorized to prescribe or dispense them,
- the supply of samples of Medical Devices,
- promoting the prescription, dispensing or sale of Medical Devices by means of gifts, consumer competition, and the offer or promise of any benefit or financial or material reward,
- sponsoring meetings held to promote the prescription, sale, dispensing or use of Medical Devices and attended by professionals; or
- the sponsorship of scientific congresses and other similar meetings attended by experts, and the reimbursement of travel and accommodation costs associated with attending them.

The Act also provides a list stating what is not considered advertising of Medical Devices. In particular, the Act does not apply to:

- correspondence necessary to answer specific questions about a particular Medical Device and any accompanying material of a non-advertising nature,
- sales catalogues and price lists where they contain only a basic description of the characteristics of Medical Devices necessary to identify them,
- information on human health or diseases provided that it does not contain any reference, even indirect, to a Medical Device.



Q04

Do these regulations set any specific prohibitions regarding the content of the advertisement? Especially, do they prohibit healthcare professionals to appear in the advertisement of medical devices, or prohibit directing the advertisement towards children?

Yes. In this respect, the Act expressly prohibits, for example, advertising of Medical Devices aimed at the general public (lay persons) that recommends a Medical Device with reference to the recommendations of scientists, medical professionals or persons who are not such but who, by virtue of their actual or presumed social status, could support the use of the Medical Device. In addition, advertisements for Medical Devices may not in any way refer to specific public authorities, and advertising of Medical Devices aimed at the general public (lay persons) may not be directed exclusively at children under the age of 15. Further content regulations are listed in answer to point two of this questionnaire.

Moreover, some advertising practices are also explicitly prohibited, such as,

- providing samples of Medical Devices that are intended only for use by a medical professional, or that can only be dispensed on prescription, to the general public.
- advertising Medical Devices which are financed in whole or in part by public health insurance, in the form of a consumer competition, consisting of the amount of prescribed, dispensed or used Medical Devices.

Q05

Do these regulations require specific warnings regarding the use of medical devices to be included in the advertisement?

Yes. According to The Act, advertisements for Medical Devices aimed at the general public (lay persons) must contain a clear and, in the case of printed advertisements, easily legible invitation to carefully read the instructions for use of the Medical Device and information relating to its safe use, if there is a requirement to attach them to a Medical Device under specific legislation.

Q06**Do these regulations limit the advertisement of medical devices in healthcare centres and / or pharmacies?**

As regards the advertising of Medical Devices aimed at the general public (lay persons), there is no limitation as to the place of advertising.

However, in the case of advertisements of Medical Devices aimed at professionals and employees of a health service provider, they may only be propagated through means of communication intended primarily for such persons, in particular in professional publications, the professional press, professional audiovisual broadcasts, or by direct communication with such persons.

We are not aware of any other specific regulation that restricts advertising of Medical Devices in healthcare centers or pharmacies

Q07**Do these regulations specify the rules for commissioning advertisement activities?****Do they require the archiving of advertisement materials?**

No. Neither the Act or nor any other Czech legislation provides for any restriction in relation to which persons are entitled to conduct advertising of Medical Devices.

An advertiser is, however, obliged to keep a sample (copy) of each advertisement for at least five years from the date on which the advertisement was last disseminated. Where an administrative procedure has been initiated under this Act before the expiry of that time limit, the advertiser must keep a sample (copy) of the advertisement which is the subject of the administrative procedure until the final decision on that matter. Upon written request, the advertiser must lend a copy of the advertisement to the supervisory authorities free of charge for as long as necessary.

Q08**What are the sanctions for violating the advertisement regulations?**

Under the Act, legal entities can be fined up to CZK 5 million (approximately € 210,000) for the most serious offenses. However, the amount of the fine always depends on the specific offense.

In addition, other sanctions envisaged under general legal regulations (e.g. an admonition, a ban on activity, confiscation of property or an obligation to publish the decision confirming commission of the offense) can also be imposed as a penalty, provided that the statutory conditions are met.

Q09**Are distributors of medical devices subject to local registration? (Article 30 paragraph 2 of the MDR / Article 27 paragraph 2 of the IVDR)****If yes, what are the specific requirements such distributors need to fulfil to apply for registration?**

Yes. Distributors and persons servicing medical devices are obliged to notify the State Institute for Drug Control of their activities as distributors or persons servicing devices before commencing such activities. Based on this notification, the State Institute for Drug Control will assign a registration number to the distributor or person servicing medical devices.

This obligation does not apply to a person servicing exclusively class I risk medical devices or class A in vitro diagnostic medical devices, or to a distributor who supplies exclusively class I risk medical devices or class A in vitro diagnostic medical devices or supplies devices exclusively to a user who is not a healthcare provider.

The notification must state, in particular, the identity of the notifying entity, notified activity (either distribution or servicing), the unique device model identifier (UDI-DI), intended purpose of the device as stated in the instructions for use, and contact details.

Q10

| CIT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of advertisement costs for income tax purposes, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

In general, Czech tax law does not stipulate any specific restrictions in this respect.

The following general criteria apply to the tax deductibility of advertising costs:

- It must be proven that the costs have actually been incurred.
- The costs must be incurred for the purpose of obtaining, securing and maintaining taxable income.
- The costs must be correctly accounted for.
- We recommend having sufficient evidence of the ads (e. g. orders, visual data, photos, broadcasting times, etc.)
- The costs are not specifically excluded from tax-deductible costs in the Income Tax Act.

Q11

| VAT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of input VAT on advertisement costs, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

There are no specific restrictions as to input VAT deductibility of advertisement costs for a Medical Device. The entitlement to deduct input VAT in general depends on the purpose for which the input concerned was acquired, i.e. VAT treatment of the provision of the related Medical Device. We understand that



this relates to the sale of a Medical Device subject to output VAT. For this reason, input VAT from advertising a Medical Device can be deducted. We have not encountered situations in which the input VAT deduction is denied due to an advertisement not being in compliance with advertising regulations.

The following general criteria apply to the input VAT deduction of advertising costs:

- There must be a proper tax document (VAT invoice)
- A purchased advertisement must be used for taxable supplies where input VAT deduction entitlement exists (e.g. sale of Medical Device subject to output VAT)
- In cases of advertising related to VAT-exempt supplies, the related input VAT cannot be deducted (for example sale of a Dental Device is VAT-exempt under certain conditions).

Further, advertising services are in general reviewed by the tax administrator due to their material value and difficulties regarding proof of their factual delivery/receipt. For this reason, we highly recommend that proof of receipt of advertising services is gathered and kept for any tax audit.



Estonia

Q01 Are there any local specific regulations regarding the advertisement of medical devices?

Advertising of medical devices must comply with the general requirements of the Advertising Act. There is no specific regulation on advertising of medical devices.

Q02 Do such regulations stipulate specific rules on advertising medical devices which are directed at lay persons? Do they distinguish between advertisements directed to lay persons and healthcare professionals?

The only difference stems from the intended purpose of the medical device or service: advertisements of medical devices or services intended for professional use must also include this information.

Q03 Do these regulations specify which form or kind of advertisements to which they apply?

The Advertising Act regulates advertising regardless of its form. According to the Act, advertising means information which is made public in any generally perceived form.

Q04 Do these regulations set any specific prohibitions regarding the content of the advertisement? Especially, do they prohibit healthcare professionals to appear in the advertisement of medical devices, or prohibit directing the advertisement towards children?

- In general, the content of advertising must comply with the requirements of the Advertising Act.
- There is a database on medical devices and assistive devices in Estonia. The registration of a device in the database may not be used in advertising.
- Children (under 18 years old) may not be the target group of advertising if it is prohibited to sell the advertised goods or provide the advertised services to children.

Q05 Do these regulations require specific warnings regarding the use of medical devices to be included in the advertisement?

Medical devices accompanied by instructions for use are considered to be technically complex, to contain dangerous substances, or to require specialized knowledge for use within the meaning of the Advertising Act. When they are advertised, the advertisement must advise reading the instructions and, if necessary, consulting a specialist.

Advertising of a medical device or service intended only for professional use must include information to that effect.

Q06 Do these regulations limits the advertisement of medical devices in healthcare centres and / or pharmacies?

No.

Q07**Do these regulations specify the rules for commissioning advertisement activities?****Do they require the archiving of advertisement materials?**

There is no specific regulation regarding the commissioning of advertisement activities.

According to the Advertising Act, advertising must contain, in a clearly distinguishable manner, the name of the person placing the advertisement, and the Estonian or European Community trade mark thereof which is in the process of registration or has been registered, or the domain name thereof.

Q08**What are the sanctions for violating the advertisement regulations?**

Violation of advertising requirements is punishable by a fine up to:

- 300 fine units (one unit = 4 euros) if the violation is committed by a natural person;
- 50 000 euros if the violation is committed by a legal person.

Q09**Are distributors of medical devices subject to local registration? (Article 30 paragraph 2 of the MDR / Article 27 paragraph 2 of the IVDR)****If yes, what are the specific requirements such distributors need to fulfil to apply for registration?**

The Republic of Estonia Health Board must be notified of distribution of a medical device. This is done via the database (referred to above) within ten days of the first distribution of the device.

The distributor must meet the requirements in Article 14(2) of the MDR.

**Q10****| CIT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of advertisement costs for income tax purposes, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?**

According to the Estonian Income Tax Act, all certified expenses incurred by a taxpayer in relation to business during a period of taxation may be deducted from the taxpayer's business income. There are no restrictions on business-related expenses.

Please note that fines and non-compliance levies imposed on the basis of law may not be deducted from business income, i.e. these are subject to CIT in Estonia.

Q11**| VAT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of input VAT on advertisement costs, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?**

Input VAT can be deducted from business-related expenses (no restrictions).

A scenic view of the Hungarian Parliament Building in Budapest, Hungary, situated on the Danube riverbank. The building is a grand Gothic Revival structure with a prominent red dome and multiple spires. The Danube river flows in the foreground, with a few boats visible. In the background, there are green hills and a clear blue sky. A large blue rectangle with the word 'Hungary' in white text is overlaid on the left side of the image.

Hungary

Q01**Are there any local specific regulations regarding the advertisement of medical devices?**

The following legal acts set out the rules on the advertising of medical devices in Hungary:

- 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 (the **'Medicinal Distribution Act'**);
- Act XLVIII of 2008 on the Basic Requirements and Certain Restrictions of Commercial Advertising Activities (the **'Advertising Act'**)
- **Decree no. 3/2009 (II.25.) of the Minister of Health** on the detailed Rules on the Promotion of Medicinal Products and Therapeutic Medical Devices, the Registration of Medical Sales Representatives and Commercial Practices Directed towards Consumers (the **'Promotional Decree'**)
- **Decree 4/2009. no. (III.17.) of the Minister of Health** on medical devices (the **'Medical Device Decree'**)
- **Decree 8/2003. no. (III.13.) of the ESzCsM** on in vitro diagnostic medical devices
- Act CLV of 1997 on Consumer Protection (the **'Consumer Protection Act'**)
- Act XLVII of 2008 on the Prohibition of Unfair Business-to-Consumer Commercial Practices (the **'Unfair Commercial Practices Act'**)

Moreover, the members of the Association of Health Technology Suppliers and Medical Device Manufacturers (Hungarian acronym is ETOSZ) are bound by the ETOSZ Code of Conduct.

Q02**Do such regulations stipulate specific rules on advertising medical devices which are directed at lay persons? Do they distinguish between advertisements directed to lay persons and healthcare professionals?**

Yes.

Regarding medical devices classified as medical aids:

For advertising directed towards healthcare professionals different rules are applicable according to the Medicinal Distribution Act. For example, while it is prohibited to direct advertising of any medical aids subsidized under the social security system towards lay persons, it is permitted to direct this advertising towards HCPs.

Medical aids and medical devices are categories that overlap in Hungarian law. Medical devices may qualify as medical aids if they meet certain criteria. According to the Medical Distribution Act, 'a medical aid' shall mean any medical device made available for personal use to patients suffering a temporary or persistent health impairment or disability (including in vitro diagnostic medical devices for self-testing purposes), and other technical devices for nursing and caring purposes, which are not treated as medical devices, designed for use without the continued presence of a healthcare professional.

Regarding medical devices not classified as medical aids:

The ETOSZ Code of Conduct also sets out specific rules regarding promotion directed towards HCPs.

Q03**Do these regulations specify which form or kind of advertisements to which they apply?****Regarding medical devices classified as medical aids:**

Hungarian law provides for two types of promotion of medical devices: (i) commercial practice and (ii) commercial advertising.

The Medicinal Distribution Act covers and is applicable to “commercial practice”, which is defined as professional or scientific information or any act, omission, course of conduct or representation, or commercial communication including marketing, directly connected with or capable of the promotion, prescription, procurement, sale or supply of medical aid. In the case of public pharmacies, units of institutional pharmacies engaged in supplying medicinal products directly to the general public, and branch pharmacies, the concept of ‘commercial practice’ does not cover the medical services relating to the information to be provided when dispensing medical aids. Furthermore, it does not include consultations conducted by pharmacists.

The Medicinal Distribution Act and the Advertising Act cover the definition of “commercial advertising”, that is any form of communication or information, or the making of a representation in any form with the aim or having the direct or indirect effect of promoting the supply of goods of a fungible nature that are capable of being delivered, including natural resources that can be utilized as capital goods, including money, securities, and financial instruments (jointly referred to as a “product”), and services, immovable property, and rights and obligations (jointly referred to as “goods”), or, in connection with this objective, the representation of the name, the trade mark or the activities of a producer of goods or a provider of services (jointly referred to as “advertising”), excluding the following:

- a) the user’s manual of medical aids,
- b) factual, informative announcements and reference material relating, for example, to pack changes, or adverse-reaction warnings as part of general drug precautions relating to medical aids,
- c) trade catalogues and price lists, provided they include no product claims concerning the application of medical aids.

“Commercial practice” includes commercial activities directed towards both HCPs (i.e. free product samples, supporting events, or the HCP’s participation in certain events) and the general public. “Commercial advertising” should be considered as a form of commercial practice that is directed toward the general public.

Besides the exceptions stated in the definitions, if the activity has no purpose and is not capable of supporting commercial activity, it does not qualify as a commercial practice / advertising i.e. appearance as a sponsor of a media



content, however neither the sponsored content nor the display of the sponsor encourage, or incite, the purchase of the sponsor's product or use of its services.

Regarding medical devices not classified as medical aids:

The MDR / IVDR apply.

Q04 Do these regulations set any specific prohibitions regarding the content of the advertisement? Especially, do they prohibit healthcare professionals to appear in the advertisement of medical devices, or prohibit directing the advertisement towards children?

Regarding medical devices classified as medical aids:

The following rules apply to medical devices classified as medical aids:

- It is prohibited to direct promotion of any medical aids subsidized by the social security system towards the general public.
- The information conveyed in a commercial communication relating to a medical aid must correspond to the information contained in the user manual of the medical aid.
- Advertising of medical aids directed towards children, including advertising in programs or publications aimed at children, is prohibited.

Furthermore, advertising of medical aids for human use directed towards the general public must not contain any reference or expression which:

- claims or gives the impression that a medical consultation or surgical operation is unnecessary or redundant;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medical aid on the human body or parts thereof;

- refers to a recommendation by scientists, health professionals or celebrities;
- suggests that the health of the subject could be affected by not using the medical aid.

Furthermore, advertising may not be published if:

- it concerns medical aid that is not authorized for marketing or use in Hungary;
- it concerns a medical aid that bears the same name as a medical aid for social security subsidies that are available, that differs only in designation or number.

Regarding medical devices not classified as medical aids:

In addition to Article 7 of the MDR (and IVDR), the Advertising Act applies to any commercial advertising, and prohibits in particular advertisements that encourage violent behavior that endangers personal safety and advertising that may impair the physical, mental or moral development of children and young persons.

Q05 Do these regulations require specific warnings regarding the use of medical devices to be included in the advertisement?

Regarding medical devices classified as medical aids:

According to the Promotional Decree, an advertisement must include the following statement in Hungarian: *"For information on the risks, read the Instructions for Use or ask your physician"*.

The Promotional Decree specifies the rules for placing the warning text in different types of advertisements, including written communication, television and radio commercials, as well as the exact wording, placement and timing of the warning text.

Regarding medical devices not classified as medical aids:

The MDR / IVDR apply.



Q06

Do these regulations limit the advertisement of medical devices in healthcare centres and / or pharmacies?

Regarding medical devices classified as medical aids:

The Promotional Decree sets out specific obligations for a promoter if the promotion takes place in healthcare centers and/or pharmacies.

These obligations mainly require that the promotional activities must not obstruct the activities and patient care of the healthcare provider authorized to order, give training on the use of and distribute the medical aid device. The regulation also includes rules for the samples that may be given out by the promoter.

Regarding medical devices not classified as medical aids:

The MDR / IVDR apply.

Q07

Do these regulations specify the rules for commissioning advertisement activities?

Do they require the archiving of advertisement materials?

Regarding medical devices classified as medical aids:

According to the Advertising Act, an 'advertiser' shall mean a person on whose behalf advertisements are disseminated, or who orders the publication of advertisements.

- Advertising may be disseminated only if the advertiser has provided, at the time of placing the order for the advertisement with the advertising service provider - or failing this, at the time of placing the order for publication of the advertisement with the publisher of advertising - its corporate name, registered address, and tax number.
- In connection with advertising relating to products which are subject to prior quality control or conformity assessment in accordance with other specific

legislation, an advertiser must supply a statement to the advertising service provider – or failing this to the publisher of advertising - that the product has been inspected or certified and found suitable for marketing. If the product is not subject to prior quality control or conformity assessment, a statement must be supplied to this effect. If no such statement is made, no advertising may be published.

- Medical aids that are also medical devices may legally be placed on the market in the European Union only if they are CE labelled. Therefore, only CE labelled products, which also complies with the relevant regulations, may be advertised as medical devices. Accordingly, when advertising a medical device, the advertising service provider should check the CE label on the product and ask the advertiser for a declaration in that respect.
- Liability for the content and authenticity of the data and the statements described above lies with the advertiser.

A sample or electronic draft of each commercial communication (specifying the original size or scale of the commercial communication, the addressees, the means of transmission, and the date on which transmission began) must be kept for five years.

Moreover, the data and statement described in question 8 has to be kept for three years from publication of the advertisement.

Regarding medical devices not classified as medical aids:

The MDR / IVDR apply.

Q08

What are the sanctions for violating the advertisement regulations?

Regarding medical devices classified as medical aids:

The advertising of medical aid is generally regulated by the **Advertising Act**, and therefore the liability and sanction rules stated in the Advertising Act apply.

Regarding commercial practice, the following rules apply:

- Liability for any infringement of the regulations laid down in the **Advertising Act** and in the **Promotional Decree** on commercial practices relating to medical aids lies with the person who, in commercial practice, acts for purposes relating to their trade or business and who is directly connected with the promotion, sale or supply of medical aids to which the commercial practice in question pertains.
- That person can be held liable also if the commercial practice is carried out under contract by another person acting on behalf of or for that person.
- Liability for any infringement of the regulations relating to promoters of medical aids lies with the promoter of medical aids; liability for infringement of regulations relating to medical sales representatives lies with the medical sales representative concerned.

Regarding the promotion of medical aids (i.e. advertising directed towards HCPs), the Medical Distribution Act sets out specific sanctions.

- In the event of infringement of the **Distribution Act** or the **Promotional Decree**, the promoter or manufacturer of medical aids can face the following sanctions, imposed by the government body for pharmaceuticals (OGYÉI):
 - ethics proceedings
 - an order to rectify deficiencies and suspension of the activity until this is done
 - fine (from HUF 500 000 up to HUF 5 000 000)
- In the event of repeated or serious infringement of the **Distribution Act** or the **Promotional Decree**, the promoter or a manufacturer of medical aids can face the following sanctions, imposed by the government body for pharmaceuticals (OGYÉI):
 - a promoter of medical aids is banned from engaging in promotional activities (for between three and six years)
 - suspension of the contract of the infringer service provider authorized under a contract for dispensing operations within the social security system,

- the suspension of HCPs' right to prescribe the subsidized medical aids for up to one month.

Regarding medical devices not classified as medical aids:

- Based on the ETOSZ Code of Conduct, infringement of this Code of Conduct may result in additional ethical proceedings against the company in breach.

Q09

**Are distributors of medical devices subject to local registration?
(Article 30 paragraph 2 of the MDR / Article 27 paragraph 2 of the IVDR)**

If yes, what are the specific requirements such distributors need to fulfil to apply for registration?

Before beginning the distribution of a medical device, an economic operator seated in Hungary must notify the National Institute of Pharmacy and Nutrition (**OGYÉI**) to register its details, including in particular its contact details and information regarding the medical device being placed on the market in Hungary (i.a. UDI-DI, type, number, validity date, issuer's ID number of the certificate of compliance, brand or trade name of the device, and whether the medical device is also a medical aid).

These regulations apply to medical devices regardless of whether they are classified as medical aids.





Q10

CIT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of advertisement costs for income tax purposes, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

For CIT purposes, there are no specific restrictions with respect to deductibility of advertisement costs. However, the list of „non-business costs“ is not an exclusive one in the Hungarian CIT Act; hence, it is necessary to consider how the specific expense served the business interest of the economic operator (the taxpayer). This requires looking into the entire fact pattern.

In the event the regulatory authorities challenge the activity (advertisement) of the economic operator for violating the relevant regulations, this could pose a risk of non-deductibility of advertisement costs.

Q11

VAT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of input VAT on advertisement costs, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

From the VAT point of view, there are no specific restrictions either. The general conditions of VAT deduction should be considered (both formal and material) - i.e., the VAT charged on a supply is generally deductible by the customer (the economic operator) if the purchase itself serves the customer's business activities subject to VAT, and the customer is in possession of the related, properly issued invoice.

Similar to the CIT comment, if the activity is challenged from the regulatory side, then the whole fact pattern needs to be reviewed in order to assess the deductibility of the VAT incurred via the advertisement cost.



Latvia

Q01 **Are there any local specific regulations regarding the advertisement of medical devices?**

There are no specific regulations regarding advertising of medical devices in Latvia. Nevertheless, it is crucial to comply with the Advertising Law of the Republic of Latvia.

Q02 **Do such regulations stipulate specific rules on advertising medical devices which are directed at lay persons? Do they distinguish between advertisements directed to lay persons and healthcare professionals?**

No specific rules on advertising medical devices.

Q03 **Do these regulations specify which form or kind of advertisements to which they apply?**

The Advertising Law is applicable to any form or any kind of announcement or endeavour associated with economic or professional activity, intended to promote the popularity of or demand for goods or services.

Q04 **Do these regulations set any specific prohibitions regarding the content of the advertisement? Especially, do they prohibit healthcare professionals to appear in the advertisement of medical devices, or prohibit directing the advertisement towards children?**

Since there is no specific regulation on advertising of medical devices, none of the existing general regulations prohibit a healthcare professional from appearing in an advertisement.

The Advertising Law states that showing violence and war is prohibited in advertising materials. In particular, it is prohibited to

1. express discrimination,
2. exploit the effect created by fear or superstition,
3. depict, use or in any way mention a person (or the property of a person) without the consent of that person,
4. to defame, disparage or ridicule another person, or the activities, name, goods or services or trademarks of another person (Advertising law, Section 4).

In advertising intended for children it is prohibited to

1. include statements, or visual or audio information that could cause them moral or physical harm or create a feeling of inferiority;
2. encourage aggressiveness and violence, or discredit the authority of parents, guardians and educators;
3. draw attention to the fact that the purchase of certain goods or services leads to physical, social or psychological superiority over peers;
4. portray children in dangerous situations etc. (the Advertising Law Section 5).

Q05 **Do these regulations require specific warnings regarding the use of medical devices to be included in the advertisement?**

There are no specific regulations which require specific warnings regarding the use of medical devices to be included in an advertisement.

Q06 **Do these regulations limits the advertisement of medical devices in healthcare centres and / or pharmacies?**

No specific limitations on advertising medical devices in healthcare centres or pharmacies.

Q07

Do these regulations specify the rules for commissioning advertisement activities?

Do they require the archiving of advertisement materials?

An advertiser is entitled to produce, order, disseminate or provide for dissemination only such advertising as does not contravene the Advertising Law and other laws and regulations (Advertising Law, Section 10)

The local law does not stipulate any requirements in respect to the archiving of advertisement materials.

Q08

What are the sanctions for violating the advertisement regulations?

Section 20 of the Advertising Law stipulates that a fine in the amount up to EUR 14 000 can be applied for provision or dissemination of advertising not conforming to the requirements.

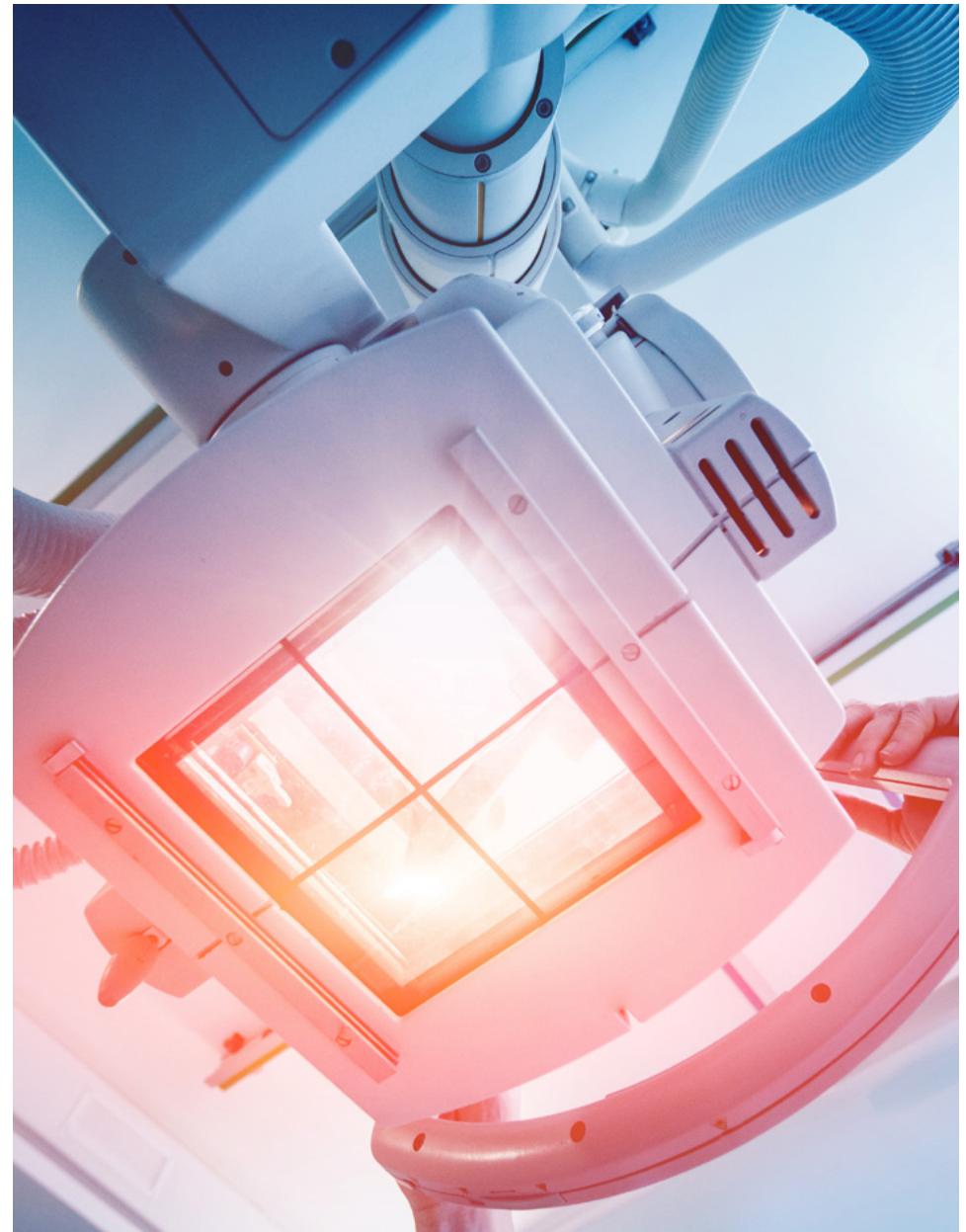
Q09

Are distributors of medical devices subject to local registration? (Article 30 paragraph 2 of the MDR / Article 27 paragraph 2 of the IVDR)

If yes, what are the specific requirements such distributors need to fulfil to apply for registration?

The Medical Treatment Law stipulates that the Cabinet shall determine the procedures for registering information on distributors of medical devices (Medical Treatment Law, Section 34).

Before placing medical devices on the market in the Republic of Latvia, a notification form must be submitted which is provided in Annex 5 to Cabinet Regulation No. 689 "Procedures for registration, conformity assessment,



distribution, operation and technical supervision of medical devices” to the agency or fill it out electronically on the agency’s website (www.zva.gov.lv) and attach a copy of the EC declaration of conformity as well as copies of valid certificates issued by notified bodies.

The agency checks the conformity of the submitted documentation and if any shortcomings are found in the submitted information, the agency informs the applicant and requests clarifications accordingly.

Within ten working days after receiving the information, the agency shall provide public access on its website at least to the data received during the submission process. After this information is made public on the agency’s website, the notification procedure is considered complete.

Once the notification procedure is completed, the applicant is entitled to place the medical device on the market.

(Cabinet Regulation No. 689 (adopted on 28 November 2017) “Procedures for registration, conformity assessment, distribution, operation and technical supervision of medical devices”, Article 26 - 29)

Q10

| CIT | Are there any restrictions (resulting either from tax law or tax authorities’ practice) with respect to deductibility of advertisement costs for income tax purposes, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

Corporate income tax law does not provide for any additional restrictions for advertising costs. If the tax authority challenges whether the company can incur such costs (such challenge must be based on other provisions, if applicable), then such costs most probably would be treated as non-business related and non-deductible, i.e. subject to CIT 20%, calculated as 0.2/0.8.

Q11

| VAT | Are there any restrictions (resulting either from tax law or tax authorities’ practice) with respect to deductibility of input VAT on advertisement costs, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

The Latvian VAT provisions themselves do not restrict input VAT deductibility related to advertisement costs. However, Latvian VAT provisions do not provide a definition as to what is considered an advertisement, thus the VAT deductibility for expenses related to advertisement costs may depend on other laws not related to VAT.



Poland

Q01

Are there any local specific regulations regarding the advertisement of medical devices?

The new Polish Act of 7 April 2022 on medical devices (**'MDA'**) introduces specific regulations regarding advertising of medical devices by economic operators (manufacturer, authorized representative, importer, distributor) in Poland.

The new regulations enter into force on 1 January 2023, however, an advertisement of which distribution started before that date and which does not meet the new requirements may be distributed until 30 June 2023.

Q02

Do such regulations stipulate specific rules on advertising medical devices which are directed at lay persons? Do they distinguish between advertisements directed to lay persons and healthcare professionals?

The MDA stipulates separate rules for advertising medical devices which is directed to lay persons and healthcare professionals.

In particular, advertising of medical devices addressed to the public must be formulated in a way that is understandable to a lay person. This requirement applies also to medical and scientific wording and references in such advertising to scientific research, opinions, literature, or scientific studies and other materials aimed at professional users.

Moreover, the MDA sets out specific prohibitions regarding the content of advertising of medical devices addressed to the public (see below).



Q03**Do these regulations specify which form or kind of advertisements to which they apply?**

The MDA states the types of advertising activity to which it applies, including in particular:

- visiting healthcare professionals to promote medical devices;
- sponsorship of fairs, exhibitions, shows, presentations, conferences, conventions, and scientific congresses for healthcare professionals or people trading in such devices;
- providing samples to promote medical devices;
- presenting a medical device during meetings which are aimed at convincing the participants of the meeting to purchase the device,
- opinions of users of medical devices, if they receive benefits for sharing their opinions publicly (e.g. on social media).

The MDA states also that the following information is not considered advertising:

- commercial catalogs or price lists containing only the trade name, price, or technical specifications of medical devices, and
- information placed on the packaging and / or attached to the packaging, required under the MDA and EU regulations (MDR / IVDR).

Q04**Do these regulations set any specific prohibitions regarding the content of the advertisement? Especially, do they prohibit healthcare professionals to appear in the advertisement of medical devices, or prohibit directing the advertisement towards children?**

Advertising of medical devices addressed to the public (lay persons) may not:

- use the image of healthcare professionals or persons claiming to be such

professionals or showing persons presenting the device in a way suggesting that they are healthcare professionals;

- include a direct invitation addressed to children to buy the advertised medical device or to persuade their parents or other adults to buy it;
- relate to medical devices intended for use by professional users.

In case of medical devices reimbursed from the public funds (financed by the National Health Fund), additional limitations of the promotional activities apply; in particular it is prohibited to provide patients and / or healthcare professionals with any financial and / or personal benefits.

Moreover, general provisions on advertising, including provisions in the Act on Combating Unfair Competition and the Act on Counteracting Unfair Market Practices, apply to the advertising of medical devices.

Q05**Do these regulations require specific warnings regarding the use of medical devices to be included in the advertisement?**

On the basis of the MDA, the Minister of Health ('MoH') issued a regulation specifying the technical conditions for advertising medical devices.

This regulation sets out the rules on placing warnings regarding the use of medical devices to be included in an advertisement. The regulation specifies for instance the text of standard warnings and the rules for placing them in audio (e.g. radio), visual (e.g. press) and audiovisual (e.g. television, Internet) advertisements.

Q06**Do these regulations limit the advertisement of medical devices in healthcare centres and / or pharmacies?**

Advertising of medical devices in pharmacies and healthcare centres (including visiting healthcare professionals) may not hinder the activity conducted at the facility.

The MoH regulation states that advertising of medical devices addressed to the public (lay persons) can be placed in healthcare centres only in waiting rooms for patients.

Q07**Do these regulations specify the rules for commissioning advertisement activities?****Do they require the archiving of advertisement materials?**

Advertising of medical devices may only be conducted by economic operators (manufacturer, authorized representative, importer, distributor).

The economic operator may also approve advertising of the device by another entity on its behalf. However, responsibility for legal compliance of advertising remains with that economic operator.

An economic operator conducting advertising of medical devices addressed to the public is obliged to store the templates of the advertisement and information about the places where they were published for two years from the end of the calendar year in which the advertisement was published. It is also obliged to provide the competent authority with the information on the advertisement, when requested.

Q08**What are the sanctions for violating the advertisement regulations?**

If laws on advertising of medical devices are violated, the competent authority – the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (“URPL”) – may order:

- measures to cure the identified violations or
- the stopping of publishing, displaying or running a given advertisement, or
- publication of an order issued by the authority in places or mass media where the advertisement was published.

Moreover, advertising of medical devices in breach of the law is subject to a fine of up to PLN 2,000,000 (approx. EUR 420,000). Conducting advertising which may mislead a user or patient as to the intended use, safety and operation of a medical device is subject to a fine of up to PLN 5,000,000 (approx. EUR 1,100,000).

Q09**Are distributors of medical devices subject to local registration? (Article 30 paragraph 2 of the MDR / Article 27 paragraph 2 of the IVDR)****If yes, what are the specific requirements such distributors need to fulfil to apply for registration?**

Apart from registration with EUDAMED, which is going to become obligatory for manufacturers, authorized representatives and importers once the system becomes fully operational, the Polish regulations set out separate obligations for distributors (and importers) based in Poland.

Distributors (and importers) based in Poland who bring a medical device into Poland intended for use in Poland are obliged to notify the URPL accordingly within seven days from the date the first device is brought into Poland.

This notification must be produced on an official form and be accompanied by additional information regarding the medical device, such as markings on the device, instructions for use, and templates of promotional materials specifying the intended use of the device (if they are provided along with the device). If the notification is made by the importer, a copy of the declaration of conformity and/or copies of certificates of conformity (if issued) also have to be attached.

Please note that the notification is filed with the URPL once the device is brought into Poland. Therefore, the distributors do not need to wait for the acknowledgement of such notification by the Polish office before they commence selling the device in Poland.

From 1 July 2023, the URPL is planning to launch a web portal for distributors based in Poland who bring medical devices into Poland for the first time, which will be designed for the submission of notifications of medical devices brought into Poland. The new portal is intended only for distributors, as other economic operators (manufacturers, authorized representatives, importers) will be obliged to register via EUDAMED.

The MDA specifies also a separate procedure for Poland-based economic operators for applying for the Single Registration Number ("SRN"), which is needed to register with EUDAMED.



Q10

| CIT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of advertisement costs for income tax purposes, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

In general, the CIT Act does not provide for specific restrictions in this respect. In practice, depending on the facts of the case, tax authorities may try questioning costs of this kind based on other binding restrictions concerning deductibility (e.g. costs of representation).

The right to deductibility for CIT purposes should also be verified in light of conditions resulting from the general definition of tax-deductible costs (in particular, a causal link between the cost and taxable revenue, related business activity, well-documented).

Q11

| VAT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of input VAT on advertisement costs, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

There are no specific restrictions as to input VAT deductibility from purchases of advertising services.

Thus, the right to input VAT deduction should be analyzed based on the general conditions set out in the VAT Act at the moment input VAT becomes deductible, e.g. ties to taxable activities. Also, the reasons for questioning the advertisement should be verified, e.g. whether it is due to a taxpayer's intentional activity or some external factor.

Romania



Q01 **Are there any local specific regulations regarding the advertisement of medical devices?**

Yes, advertising of medical devices is regulated under domestic law.

Q02 **Do such regulations stipulate specific rules on advertising medical devices which are directed at lay persons? Do they distinguish between advertisements directed to lay persons and healthcare professionals?**

Yes, the law distinguishes between advertising activities directed to non-professionals and healthcare professionals (**"HCP"**).

Q03 **Do these regulations specify which form or kind of advertisements to which they apply?**

The law expressly states that the following forms of advertising are included in the advertising of medical devices intended for HCP:

- visits by medical representatives to persons qualified to recommend medical devices,
- provision of samples;
- sponsorship of promotional meetings attended by persons qualified to recommend or distribute medical devices;
- sponsorship of scientific congresses attended by persons qualified to recommend or distribute medical devices and payment of travel and accommodation expenses incurred.

Advertising intended for the general public is permitted only for those medical devices which, due to purpose, are intended to be used without the intervention

of qualified HCPs for the purposes of diagnosis, or recommending or monitoring of treatment, with the advice of pharmacists being sufficient if necessary.

It is also specified that the specific rules on medical devices' label and instructions for use (Annex I, Chapter III, point 23 of the MDR) remain applicable.

Q04 **Do these regulations set any specific prohibitions regarding the content of the advertisement? Especially, do they prohibit healthcare professionals to appear in the advertisement of medical devices, or prohibit directing the advertisement towards children?**

The law prohibits directing advertising of medical devices intended for the general public exclusively towards children and also prohibits in advertising any reference to recommendation by scientists, HCPs or persons who are not in these categories but whose celebrity may encourage the use of the medical device.

In addition to the prohibitions already mentioned, advertising of medical devices intended for the general public must not contain any material that:

- suggests that a medical consultation or surgery is not necessary,
- suggests that a diagnosis or result of a determination made with a medical device is guaranteed and cannot be accompanied by errors, or that the effect of treatment with a medical device is guaranteed and is not accompanied by adverse reactions, or that the effect is better than or equivalent to that of another treatment with another medical device or medicine;
- suggests that the subject's health may be affected if the medical device is not used;
- suggests that the medical device is a cosmetic or relaxation product or other consumer product;
- suggests that the safety or efficacy of the medical device is due to the fact that it is natural;
- may, through a detailed description or representation of a case, lead to incorrect self-diagnosis;



- provides inappropriate, alarming or misleading terms, assurances of a cure through the use of the medical device;

It is prohibited to use inappropriate, alarming or misleading terms, or visual representations of changes in the human body caused by disease or injury or by actions of medical devices on the human body or part of it.

Q05

Do these regulations require specific warnings regarding the use of medical devices to be included in the advertisement?

Yes, according to the rules in force, any advertising material intended for the general public must contain accurate information regarding the intended purpose and the information necessary for the correct use of the medical device, as well as express, legible advice to read the user instructions carefully.

As regards advertising of medical devices directed towards HCPs, it must be addressed to the intended recipients and must contain a clear definition of the intended purpose, provided by the manufacturer, the characteristics and performance of the medical device, and the information necessary for the use of the medical device. In the case of this type of advertising as well, express advice to read carefully the instructions/manual for use of the product and those on the label intended for HCPs must be given.

Q06

Do these regulations limit the advertisement of medical devices in healthcare centres and / or pharmacies?

We have not identified any specific limitations.

Q07**Do these regulations specify the rules for commissioning advertisement activities?****Do they require the archiving of advertisement materials?**

Romanian law provides that advertising of medical devices includes any form of information through direct contact as well as any form of promotion designed to stimulate the distribution, sale or use of medical devices. The law does not expressly regulate commissioning of advertising, nor does it offer details about following procedure. The law merely provides for a general approach.

Q08**What are the sanctions for violating the advertisement regulations?**

Insofar as they are not considered offences, acts committed which do not comply with advertising laws constitute a crime and are punishable by a fine and, where appropriate, an order to cease advertising.

The fine for violating advertising laws is between EUR~2,000 and EUR~4,000.

Q09**Are distributors of medical devices subject to local registration? (Article 30 paragraph 2 of the MDR / Article 27 paragraph 2 of the IVDR)****If yes, what are the specific requirements such distributors need to fulfil to apply for registration?**

The National Agency for Medicines and Medical Devices of Romania ('ANMDDMR') relies on the electronic system provided for in Article 30 (1) of the MDR / Article 27(1) of the IVDR ('EUDAMED'), from where it obtains a single registration number ('SRN') for the manufacturers / authorized representatives / importers. Once the ANMDDMR has obtained the SRN, this is communicated to

the manufacturers / authorized representatives / importers, and the ANMDDMR charges a fee for keeping the companies in the database.

Romanian law does not provide for a separate registration or notification procedure to be followed by the local distributors of medical devices.

Q10**CIT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of advertisement costs for income tax purposes, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?**

As a general rule, for any type of expense registered, care should be taken to comply with deductibility requirements, as per the Romanian legislation and practice. Only as a second step, should attention be paid to the transfer pricing documentation of the amounts registered, if this is the case.

Thus, from a corporate tax perspective, the underlying principle is that expenses may be treated as deductible if they are incurred for business purposes. Further, even if the Fiscal Code applicable starting January 2016 does not specifically refer to the documents needed in order to justify the service expenses, based on the recent practice of the Romanian tax authorities, we believe that the following aspects need to be taken into consideration:

- Written agreement. The services should be covered by written agreements, which includes details regarding the types of services provided, the price methodology, the allocation keys, or other relevant provisions;
- Supporting documents.
- Benefit test.
- Necessity of services.
- Shareholder activities.

In addition to the above, if the expenses are not registered or incurred in compliance with all legal requirements, there is a risk that the expense will be considered non-deductible for corporate income tax purposes.

Such expenses might also cover or involve potential implications at individual level, and this should be analysed thoroughly, as the legislation in this respect can be specific .

It is thus important to note that each situation should be analysed in detail, as each one is specific, especially in a regulated tax and legislative framework such as medtech, pharma and healthcare sector.

Q11

| VAT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of input VAT on advertisement costs, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

As a general rule, if, during a tax audit, the tax authorities find that an expense is non-deductible for corporate income tax purposes, in practice, we have observed that the Romanian tax authorities apply for a similar VAT treatment /adjustment.





Slovakia

Q01**Are there any local specific regulations regarding the advertisement of medical devices?**

No, there is no specific legislation regulating advertising of medical devices in the Slovak Republic.

Act No. 147/2001 Coll. on Advertising, Amending and Supplementing Certain Acts, as amended (the **'Advertising Act'**) is currently in force.

Only the general provisions of the Advertising Act apply to medical devices as regards advertising such devices.

In general, advertising is defined as the presentation of products in any form in order to market them.

Q02**Do such regulations stipulate specific rules on advertising medical devices which are directed at lay persons? Do they distinguish between advertisements directed to lay persons and healthcare professionals?**

Only the general provisions of the Advertising Act apply to medical devices as regards advertising such devices.

Pursuant to **Section 3 (1) of the Advertising Act**, advertising must not:

- a. contain anything derogatory to human dignity, offensive to national sentiments or religious beliefs, or be discriminatory based on sex, race or social origin;
- b. promote violence, vandalism or vulgarity, or incite or condone unlawful conduct;
- c. present a naked human body in a derogatory manner;
- d. present products harmful to the environment or to human, animal or plant life or health without explicitly and clearly pointing out this harmfulness;

- e. endanger the physical health or mental health of a citizen;
- f. present foods and food supplements as if they had the effects of medicinal products;
- g. contain personal data or data on the assets of persons without their prior consent;
- h. refer to statements made by other persons without their prior consent;
- i. interfere with the rights of others without their consent;
- j. abuse the trust of minors, in particular:
 1. encourage behavior that may endanger their health, psychological development, or moral development,
 2. depict them in dangerous situations.

Further, the following shall apply:

- **(Section 3 (2))** Advertising must meet the requirements for public speech, and adhere to the principles of linguistic culture, grammatical and spelling rules, the rules of pronunciation of the Slovak language, and established professional terminology;
- **(Section 3 (3))** Advertising may not be disseminated through an automated telephone dialing system, telefax, or electronic mail without the prior consent of the user receiving the advertisement;
- **(Section 3 (4))** Advertising may not be disseminated by direct mail if the addressee refuses delivery of the advertisement in advance;
- **(Section 3 (5))** Advertising may not be disseminated if it is contrary to good morals, if it presents products the manufacture, sale, provision, or use of which is prohibited, or if it does not comply with the requirements under a special regulation;
- **(Section 3 (6))** Advertising must not present products or services the unauthorized manipulation of which is prohibited by specific regulations.

Q03

Do these regulations specify which form or kind of advertisements to which they apply?

Not in relation to medical devices.

Q04

Do these regulations set any specific prohibitions regarding the content of the advertisement? Especially, do they prohibit healthcare professionals to appear in the advertisement of medical devices, or prohibit directing the advertisement towards children?

As regards advertising, medical devices are subject only to the general provisions of the Advertising Act, as set out in answer 2 above (Section 3 of the Advertising Act).

Therefore, we do not have a national regulation on restrictions such as a ban on the appearance of healthcare professionals or a ban on directing advertising towards children.

Q05

Do these regulations require specific warnings regarding the use of medical devices to be included in the advertisement?

As regards advertising, medical devices are subject only to the general provisions of the Advertising Act, as set out in answer 2 above (Section 3 of the Advertising Act).

Therefore, in relation to the advertising of medical devices, we do not have a national regulation that requires specific warnings (regarding the use of medical devices) to be included in the advertisement.



Q06**Do these regulations limit the advertisement of medical devices in healthcare centres and / or pharmacies?**

As regards advertising, medical devices are subject only to the general provisions of the Advertising Act, as set out in answer 2 above (Section 3 of the Advertising Act).

Therefore, in relation to the advertising of medical devices, we do not have a national regulation governing advertising of medical devices in healthcare centers and / or pharmacies.

Q07**Do these regulations specify the rules for commissioning advertisement activities?****Do they require the archiving of advertisement materials?**

As regards advertising, medical devices are subject only to the general provisions of the Advertising Act, as set out in answer 2 above (Section 3 of the Advertising Act).

Therefore, in relation to the advertising of medical devices, we do not have a national regulation governing commissioning advertising activities.

Q08**What are the sanctions for violating the advertisement regulations?**

In the event of a breach of the Advertising Act, the relevant supervisory authority shall prohibit the dissemination of the advertisement. In the decision prohibiting the dissemination of the advertisement, the supervisory authority may order publication of the decision or parts thereof and order publication of a corrective statement in the mass media.

In the case of comparative advertising, the advertiser is required, at the request of the supervisory authority, to provide evidence of the truth of the factual data in the advertisement within fifteen days of receipt of the request to provide such evidence. If the advertiser does not submit such evidence to the supervisory authority, or if such evidence is insufficient, the comparative advertisement is understood to be inadmissible.

In addition to these measures, the supervisory authority shall impose a fine (description of Section 3 of the Advertising Act is presented in answer 2 above):

- up to EUR 3 320 on an advertiser for a breach of Section 3 (2) of the Advertising Act;
- up to EUR 66 400 on an advertiser for a breach of the general requirements for advertising pursuant to Section 3 (1) lit. a), d), e), f), g), h), i), j), and (3) to (6);
- from EUR 33 200 to EUR 99 600 on an advertiser for a breach of the general requirements for advertising under Section 3 (1) lit. b) and c);
- up to EUR 166 000 on an advertiser for inadmissible comparative advertising.

When imposing a fine, the supervisory authority takes into account the seriousness, duration, and consequences of the offence and whether it is a repeated violation of the Advertising Act.

Q09**Are distributors of medical devices subject to local registration? (Article 30 paragraph 2 of the MDR / Article 27 paragraph 2 of the IVDR)****If yes, what are the specific requirements such distributors need to fulfil to apply for registration?**

Distributors who bring a medical device into the Slovak Republic are obliged to register with the Slovak State Institute for Drug Control.

Distributors of medical devices do not need any permit to operate. Distribution of medical devices is carried out based on a trade license (*živnostenské povolenie – živnosť*).



The obligation to register with EUDAMED (once the system becomes fully operational) is not affected.

Q10 | **CIT** | **Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of advertisement costs for income tax purposes, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?**

Costs incurred in breach of the Slovak Income Tax Act or other acts have to be treated as non-deductible costs. Costs incurred to conduct advertising which are questioned by the regulatory authorities are not tax-deductible in Slovakia.

Q11 | **VAT** | **Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of input VAT on advertisement costs, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?**

There is nothing specific in the VAT Act in this respect. However, the tax authorities may claim that the use of the received unlawful service (such as advertising violating local regulations) does not entitle the company to deduct input VAT on the underlying advertising costs, based on general principles.



Slovenia

Q01**Are there any local specific regulations regarding the advertisement of medical devices?**

Yes. The main act regulating the wholesale of medical devices in Slovenia is the Medical Devices Act ('**MDA**'). Certain detailed rules are also laid down in the Rules on Medical Devices.

Q02**Do such regulations stipulate specific rules on advertising medical devices which are directed at lay persons? Do they distinguish between advertisements directed to lay persons and healthcare professionals?**

There are certain provisions in the MDA which lay down specific rules for advertising of medical devices directed towards healthcare professionals ('*zdravstveni delavci*').

Under the MDA, advertising of medical devices used exclusively to perform medical activities may only be directed towards the expert public (healthcare professionals). Furthermore, where medical devices are promoted with respect to healthcare professionals, no gifts, pecuniary benefits, or benefits in kind may be given, offered or promised unless they are of low value as prescribed for public employees.

Q03**Do these regulations specify which form or kind of advertisements to which they apply?**

Advertising of medical devices means any form of information on medical devices, including also door-to-door information, canvassing activity, or inducement intended to promote the sale or use of medical devices.



Q04

Do these regulations set any specific prohibitions regarding the content of the advertisement? Especially, do they prohibit healthcare professionals to appear in the advertisement of medical devices, or prohibit directing the advertisement towards children?

It is prohibited to advertise medical devices that do not comply with the requirements specified in the MDA. However, economic operators may exhibit medical devices that are not compliant with the MDA at fairs, exhibitions, presentations, and similar events, provided that they visibly indicate that the devices shall not be available for sale or use until they are rendered compliant with the MDA or the respective implementing regulations.

The advertising of medical devices may not contain any information that:

- indicates that the effects of the use of the medical device are guaranteed completely or that its usefulness is equivalent to that of any other treatment;
- suggests that the health of a person can be enhanced solely by using the advertised medical device;
- suggests that the health of a person could deteriorate due to 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 encourage the use of a medical device due to their media influence;
- could, by means of a description or a detailed presentation of a case history, lead to erroneous self-diagnosis;
- uses improper, alarming, or misleading terms regarding possibilities of recovery;
- uses improper, alarming or misleading terms, or pictorial presentations of changes in the human body caused by disease or injury, unless presented in accordance with the established ethical and moral principles, or
- violates or abuses human dignity.

Moreover, it is prohibited to present the characteristics and intended use of a medical device in a misleading way.

Q05

Do these regulations require specific warnings regarding the use of medical devices to be included in the advertisement?

No, the general rules apply.

Q06

Do these regulations limit the advertisement of medical devices in healthcare centres and / or pharmacies?

No, the general rules apply.

Q07

Do these regulations specify the rules for commissioning advertisement activities?

Do they require the archiving of advertisement materials?

No, the general rules apply.

Q08

What are the sanctions for violating the advertisement regulations?

Legal entities shall be fined between EUR 15,000 and EUR 150,000 for the offences of:

- advertising a medical device that does not comply with the requirements

of the MDA or for directing advertising of medical devices used exclusively to perform medical activities towards persons other than healthcare professionals;

- advertising a medical device in a deceptive manner expressly prohibited by the MDA; or
- giving, offering or promising gifts, pecuniary benefits or benefits in kind to the expert public when advertising medical devices unless they are of low value.

Q09

Are distributors of medical devices subject to local registration? (Article 30 paragraph 2 of the MDR / Article 27 paragraph 2 of the IVDR)

If yes, what are the specific requirements such distributors need to fulfil to apply for registration?

Economic operators established in the Republic of Slovenia who carry out business activities connected to medical devices, such as putting them on the market or into service, or making them available on the market, or who have been given a mandate by a manufacturer from a third country to represent them in the EU market, have to register with the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia ('*Javna agencija Republike Slovenije za zdravila in medicinske pripomočke*' – '**JAZMP**') before they begin these.

Such registration is performed by submitting an electronic application via the Slovenian Business Point (SPOT) portal. In exceptional cases, i.e. where the operator does not undertake business with a digital certificate, a paper application for registration can be submitted to the JAZMP, using the paper form for the registration of economic operators established in the Republic of Slovenia.

Q10

CIT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of advertisement costs for income tax purposes, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

According to Slovenian CIT legislation, there are no special restrictions with respect to deductibility of advertisement costs. In practice, tax authorities may request some documents or proof and, depending on the facts of the case, try questioning the type of the costs based on other binding restrictions concerning deductibility.

The general regulation for tax-deductible expenditures, under Article 29(1) of the Slovenian CIT Act-2, is that the expenditures required to acquire revenues which are taxable under the CIT Act, shall be recognized for CIT purposes; Paragraph 2 of the same Article defines expenditures that are not required to acquire revenue, i.e. when expenditures are not a direct condition for performing activities and are not a consequence of performing activities, are of a private nature, or does not conform to normal business practice.

Q11

VAT | Are there any restrictions (resulting either from tax law or tax authorities' practice) with respect to deductibility of input VAT on advertisement costs, e.g. when the advertisement is questioned by the regulatory authorities or the regulatory authorities impose sanctions for violating the advertisement regulations?

Please note that Slovenian VAT legislation does not prescribe any specific restrictions in respect of input VAT deductibility for advertisement of medical devices.

Therefore, general rules on the right to deduct VAT apply. According to the Slovenian VAT Act (Article 63), a taxable person has the right to deduct from the VAT due the VAT they have paid or shall pay in relation to the purchase of goods or services, provided that those goods or services are used or will be used for the purposes of their taxed transactions.

Offices and contacts in CEE Region

Bulgaria

Juliana Mateeva
Partner
E: jmateeva@kpmg.com
Emil Evtimov
Director
E: eevtimov@kpmg.com
KPMG Bulgaria OOD
45A Bulgaria blvd. Sofia,
1404 Bulgaria

Croatia

Paul Suchar
Partner
E: psuchar@kpmg.com
Suzana Delija
Senior Manager
E: sdelija@kpmg.com
KPMG Legal s.r.o.,
advokátní kancelář -
Podružnica Zagreb;
Ul. Ivana Lučića 2,
10000, Zagreb, Croatia

Czech Republic

Martin Hrdlik
Partner
E: mhrdlik@kpmg.com
Ladislav Karas
Legal Manager
E: lkaras@kpmg.com
KPMG Legal s.r.o.,
advokátní kancelář;
Pobřežní 648/1a
186 00 Praha 8,
Czech Republic

Estonia

Karin Oras
Director
E: karin.oras@kpmglaw.ee
Rauno Klemm
Manager
E: rauno.klemm@kpmglaw.ee
Advokaadibüroo
KPMG Law OÜ,
Narva road 5,
Tallinn 10117, Estonia

Hungary

Bálint Tóásó
Partner
E: balint.toaso@kpmg.hu
Fanni Márkus
Associate
E: fanni.markus@kpmg.hu
KPMG Legal Tóásó
Ügyvédi Iroda,
31 Váci út,
Budapest 1134,
Hungary

Latvia

Una Petrauska
Managing Partner
E: upetrauska@kpmglaw.lv
KPMG Law ZAB
SIA, Roberta Hirša
iela 1, Vidzemes
priekšpilsēta, Rīga,
LV-1045, Latvia

Poland

Sabina Samplawska
Partner
E: ssamplawska@kpmg.pl
Michał Komar
Senior Associate
E: mkomar@kpmg.pl
KPMG Law Bajno Stopyra sp.k.
& KPMG Tax M. Michna sp.k.
ul. Inflancka 4A
00-189 Warszawa
Poland

Romania

Laura Toncescu
Partner
E: ltoncescu@kpmg.com
George Manea
Senior Manager
E: georgemanea@kpmg.com
Toncescu si Asociatii
SPARL, Bucharest-
Ploiesti road no 89A,
district 1 Bucharest,
Romania

Slovakia

Marian Dzuroska
Associate Partner
E: mdzuroska@kpmg.sk
Cyril Hric
Senior Manager
E: chric@kpmg.sk
KPMG Legal s.r.o.,
Dvořákovo nábřežie 10,
811 02 Bratislava,
Slovakia

Slovenia

Matic Kramar
Director
E: matic.kramar@kpmg.si
Gregor Drnovsek
Director
E: gregor.drnovsek@kpmg.si
KPMG poslovno
svetovanje, d.o.o.,
Železna cesta 8a
Ljubljana, SI-1000,
Slovenia

Contact in Poland



KPMG Poland

Sabina Samplawska

Partner, Tax, Head of Life Sciences,
KPMG in Poland

E: ssamplawska@kpmg.pl

Michał Komar

Senior Associate
KPMG Law

E: mkomar@kpmg.pl

KPMG.pl

KPMG offices in Poland

Warsaw

ul. Inflancka 4A
00-189 Warszawa
T: +48 22 528 11 00
E: kpmg@kpmg.pl

Cracow

ul. Opolska 114
31-323 Kraków
T: +48 12 424 94 00
E: Cracow@kpmg.pl

Poznań

ul. Roosevelta 22
60-829 Poznań
T: +48 61 845 46 00
E: poznan@kpmg.pl

Wrocław

ul. Szczytnicka 11
50-382 Wrocław
T: +48 71 370 49 00
E: wroclaw@kpmg.pl

Gdańsk

al. Zwycięstwa 13A
80-219 Gdańsk
T: +48 58 772 95 00
E: gdausk@kpmg.pl

Katowice

ul. Francuska 36
40-028 Katowice
T: +48 32 778 88 00
E: katowice@kpmg.pl

Łódź

ul. Kopcińskiego 62d
90-032 Łódź
T: +48 42 232 77 00
E: lodz@kpmg.pl

©2023 KPMG Law Bajno Stopyra sp.k. is a law firm associated with KPMG in Poland.

©2023 KPMG Tax M.Michna sp.k., a Polish limited partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee. All rights reserved.

The KPMG name and logo are trademarks used under license by the independent member firms of the KPMG global organization.

The information contained herein is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavour to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

Document Classification: KPMG Public