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CEE Legal Alert

news in Pharmaceutical Industry

Czech Republic

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PROPOSAL TO REGULATE ADVERTISEMENT OF MEDICAL DEVICES IN THE CZECH REPUBLIC

In relation to the adaptation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ("**MDR**") the Czech government has proposed various amendments to the regulation of medical devices in order to ensure compliance with EU law. Within these amendments, the Czech government also envisages explicitly regulating the advertising of medical devices and enacting stricter and more detailed regulation of advertising of medical devices than required by the MDR.

Current regulation of advertising of medical devices

Currently, advertising of medical devices is not specifically regulated in the Czech Republic. If it is carried out, it must comply in particular with the general requirements of Act No 40/1995 Coll., on Advertising Regulation. The supervision of compliance with the general requirements of the Act in case of advertising, including advertising of medical devices, is performed by regional trade licensing authorities.

Under the general requirements, in particular advertising in violation of legal regulations, including competition law, deceptive advertising as well as advertising contrary to good morals or promoting behaviour prejudicial to the health or safety of persons or property is forbidden. Comparative advertising is allowed only under specific conditions.

Governmental proposal

The governmental proposal envisages introducing regulation of advertising of medical devices (both general medical devices and in vitro diagnostic medical devices), that is in various respects inspired by the regulation of advertising of medicinal products. Only a medical device that can be placed on the market according to the applicable legal regulations shall be allowed to be the subject of an advertisement (an exception is envisaged for advertising at congresses if the device is labelled accordingly). Special rules shall apply depending on whether the advertising is directed at professionals or at the general public.

Advertising directed at **professionals** shall only be disseminated through communication channels intended mainly for professionals, and shall fulfil specific content requirements such as information that will allow experts to form their own opinion and basic information contained in the instructions for use of the medical device. It shall be forbidden to provide gifts to professionals in connection with advertising and any hospitality or accommodation provided to professionals at professional meetings or congresses shall be adequate.

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Advertising directed at the **general public** shall fulfil specific content requirements such as name of the device, invitation to carefully read the instructions for use, and it shall not promote medical devices which, in accordance with the manufacturer's instructions, are intended for use by a healthcare professional only, or which may be issued only on a voucher or request issued by a doctor. Various other partial bans shall be introduced in this area, along the lines of the regulation of the advertising of medicinal products, such as the prohibition of references to the recommendations of scientists, health professionals or celebrities.

Supervision of advertising of medical devices is to be entrusted to the State Institute for Drug Control.

Current status of the proposal

The government submitted its proposal to the Chamber of Deputies, the Lower House, in January 2020. However, due to the Covid-19 crisis, the hearings regarding the proposal were interrupted and the proposal is subject to further discussions in November 2020. If the proposal is approved by the Chamber of Deputies as well as the Senate, the Upper House, and signed by the President, it will become effective on the first day of the calendar month following its publication in the Collection of Laws.

This proposal is not the first governmental attempt to reintroduce specific regulation of advertising of medicinal products, which was regulated until January 2006, into the Czech legal system. In 2013 the legislative attempt to incorporate regulation of advertising of medical devices was unsuccessful. In October 2020, a member of the Chamber of Deputies proposed the removal of the regulation of advertising of medical devices from the proposal as a whole. It therefore remains to be seen whether this proposed regulation of advertising of medical devices will be approved by the Czech Parliament.

THE EFPIA MEMBER ASSOCIATION IN THE CZECH REPUBLIC HAS INTRODUCED THE NEW CODE OF PRACTICE

Following the adoption of the new *EFPIA Code of Practice* in 2019, the Czech EFPIA member association, the Association of Innovative Pharmaceutical Industry ("**AIFP**"), has this year introduced the new *AIFP Code of Practice* ("**Code**").

The time and subject-matter scope of the Code

The Code was adopted by the *AIFP Board* on 23 March 2020 and approved by the *AIFP General Assembly* on 16 April 2020. With effect as of the 1 January 2021, when the *Code* comes into force, the *Code* replaces the currently applicable AIFP ethical regulations, in particular the *AIFP Code on Conduct*, *AIFP Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations*, and *AIFP Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations*. In line with the *EFPIA Code of Practice*, the *Code* consolidates and clarifies the ethical rules concerning the advertising of prescription-only medicinal products ("**Products**"), interactions between pharmaceutical companies and healthcare professionals ("**HCP**"), healthcare organizations ("**HCO**") and patient organizations ("**PO**"), as well as disclosure of transfers of value provided by pharmaceutical companies to HCPs, HCOs and POs, taking into account also the current status of the local legal regulation of advertising and interpretation thereof by the competent regulatory authorities, namely the *State Institute for Drug Control*.

The *Code* covers a wide range of matters from distribution of promotional and educational materials, medical samples and items of medical utility to HCPs, through supporting the attendance of HCPs at educational events and congresses and providing gifts, donations and grants to HCPs and/or HCOs, to contracting HCPs, HCOs, POs and POs' representatives as service providers of a pharmaceutical company.

The selected new rules introduced in the Code

With respect to the foregoing, please find below only the key selected new rules which the Code introduces in addition to the ethical rules already contained in the currently applicable AIFP ethical regulations and which might be of particular interest to AIFP member companies.

Prohibition of advertising of non-registered Products and off-label advertising

In compliance with Czech law, the Code prohibits the advertising of any non-registered Product or off-label advertising of a registered Product. The Code further clarifies that any promotional information including a reference to a Product (or its use) which is not registered in the Czech Republic or which is registered locally under different conditions must not be disseminated vis-à-vis participants also at an international event organized in the Czech Republic, even if a pharmaceutical company makes it clear that the Product (or its use) is not registered in the Czech Republic and the promotional material indicates the countries in which the Product is registered and/or explains that registration conditions differ country-to-country.

Distribution of product-specific educational materials to patients

The Code indicates that in addition to non-promotional information relating to human health and disease, it might be permissible under *certain specific circumstances* to provide patients with educational materials, even if they include a reference to a generic or brand name of a Product, provided that the educational materials (i) include at the very beginning the information that they are designated only for patients using the relevant Product, and (ii) are provided only to patients using the relevant Product and only by medical persons or pharmacists. Notwithstanding the foregoing, please note that Czech law prohibits the advertising of prescription-only Products to the general public and does not specify whether and under which circumstances the distribution of the above-referred materials would be considered as non-promotional and as such permissible. Thus, the distribution of said materials is quite risky and the permissibility thereof must be carefully evaluated on a case-by-case basis.

Exception from rules on contracting with HCPs, HCOs' members and POs' representatives

Pursuant to the Code, a pharmaceutical company may engage an HCP or a PO's representative as its consultant subject to meeting the conditions under the Code only on the basis of a prior written contract, specifying the nature of provided services and the remuneration for and possibly the compensation of expenses incurred in relation to such services. In accordance with the new Code, the requirements for engaging consultants will not apply in case the consultation is part of a limited market research, such as a one-time phone interview, if the HCP, HCO's member or PO's representative is not consulted repeatedly (either in relation to the same research or generally) and if the remuneration is minimal. In such a case, the service and remuneration may be provided even in the absence of the above-referred prior written contract.

The (non-)binding nature of the Code

The Code does not constitute a generally binding legal regulation, but a pharmaceutical industry-specific self-regulatory tool implemented by the AIFP to promote a high level of integrity and transparency of relationships between pharmaceutical companies and relevant stakeholders in the area of healthcare. The Code is binding on and may be enforced by the competent AIFP bodies against AIFP member companies only.

The Code comes into effect as of 1 January 2021 and the AIFP member companies are expected to ensure compliance therewith as of that day. Please do not hesitate to contact us should you have any questions about the Code. Upon your preference, we would of course be pleased to assist you with updating your company's internal regulations with respect to the Code or to prepare training about the Code for the relevant stakeholders at your company.

We will be happy to answer any follow-up questions relating to the regulation of advertisement of medical devices and its development, as well as any other queries you might have with regard to Czech law. Although this legal alert concerns Czech law, please feel free to contact us with questions relating to any other jurisdiction.

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NEW REGULATION ON HEALTHCARE SERVICE RELATIONSHIP

On October 14, 2020 the Hungarian Parliament adopted Act C of 2020 on Healthcare Service Relationship ("**Act**") which fundamentally transforms the employment relationships at State-owned healthcare service providers. The Act envisages substantial increase in the statutory wages of physicians depending on seniority over the coming three years.

A key point of the Act that may be of interest to the pharmaceutical industry is the set of conflict of interest rules to be applicable to physicians that want to engage in activities (e.g. private practice or other professional services) beyond the healthcare service relationship regulated by the Act.

The Act requires the prior authorization of a body to be designated by the Government for any further employment relationship or remunerated activity of physicians with the exception of scientific, educational, artistic, readership, editorial work or intellectual activity falling under legal protection.

This provision may have an impact on professional services agreements that pharmaceutical companies conclude with HCPs for advisory, speaker or other services.

Companies should assess if the professional services to be provided by the HCPs fall under the above statutory exceptions. If the services do not fall under any of the above exceptions, the physician will have to obtain the prior authorization of a Governmental body.

The prior authorization of the body to be designated by the Government will always be necessary in case the duration of the professional services mandated by a pharmaceutical company overlaps with the working time of the physician under the healthcare service relationship regulated by the Act.

Further, physicians may not conduct healthcare activity (beyond their statutory healthcare service relationship) at the seat or premises of the healthcare service provider employing them. This conflict of interest provision may impact clinical trial contracts as investigators usually conduct clinical trial activities at their own institutions which also often have a contract with the sponsor for conducting the clinical trial.

In case of failure to comply with the above provisions of the Act, the healthcare service relationship of the physician shall be terminated with immediate effect.

We await the implementing decrees of the Act and hope they will contain guidance on the interpretation of the above provisions of the Act as well.

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THE HUNGARIAN REGULATORY AUTHORITY ISSUED NEW DECISIONS ON PROMOTIONAL ACTIVITIES OF PHARMACEUTICAL COMPANIES

The National Institute of Pharmacy and Nutrition ("**OGYÉI**") published new decisions on its webpage concerning pharmaceutical promotional activities and interactions with HCPs. The OGYÉI investigated the commercial practices of Aramis Pharma Kft., Lilly Hungária Kft. and Sager Pharma Kft. and imposed fines due to alleged infringements. The key findings of the decisions are the followings:

Several types of contracts concluded with HCPs for professional services were considered as unlawful commercial practices

Contracts for services not related to the healthcare activities of HCPs

The OGYÉI objected contracts based on which the HCPs were mandated to hold professional trainings for medical sales representatives of a pharmaceutical company. The role of the HCPs was to "host" the medical sales representatives within a professional role play and later to comment on the performance of the same medical sales representatives.

According to the OGYÉI, the professional role play is not directly related to the healthcare activities of the HCPs participating in the simulation. Contracts concluded with HCPs for providing professional services shall only be concluded for the provision of services closely related to the professional activity of the HCPs and shall not serve promotional purposes. The OGYÉI concluded that the objected contracts had a promotional character, therefore, payments made under such agreements were unlawful.

Contracts for holding professional presentations with promotional content

The OGYÉI objected contracts based on which HCPs held presentations at roundtable events organized by a pharmaceutical company because the presentations had promotional nature as medicinal products of the company were easily identifiable. The OGYÉI found that the aim of these contracts was to facilitate the commercial practice and promotion of medicinal products of the pharmaceutical company under investigation.

As it was already laid down in former case-law, the OGYÉI highlighted that while performing contracts concluded with HCPs for professional speaker services, the use of company-branded presentation materials and backgrounds shall be avoided and the presentation shall not contain either the name of the company, its products, or the company logo or image. Therefore, payment for such professional presentations were also considered as unlawful financial benefit.

Contracts for drafting professional articles published in company branded publications

The OGYÉI objected processional services agreements based on which HCPs were mandated to draft professional articles or case reviews to be published in the pharmaceutical company's own professional publication. The OGYÉI found that the publications were of promotional nature for the following reasons: (i) they were branded; i.e. it was clear from the outset that it is the publication of the pharmaceutical company under investigation; (ii) the articles focused on a product of the company and trials related to that product; and (iii) the publication was distributed by medical sales representatives and at stands or booths of the pharmaceutical company at professional events.

In the OGYÉI's view, these contractual relationships went beyond the healthcare activity and the sharing of professional experience of the HCPs as the performance of these contracts was meant to facilitate the promotional activity of the company.

Speaker services to subordinates of the speaker and presentations overlapping with professional work duties of HCPs

The OGYÉI considered the speakers' fees paid for presentations held by HCPs in front of an audience which predominantly comprised of their own subordinates who work at the same department/institution and whom they have daily contact with as prohibited financial benefit. The remuneration provided for holding these presentations at hospitals was capable of motivating HCPs to discuss products of the pharmaceutical company at forums where their subordinates are dutifully present whereby inducing them to follow the recommendations of seniors and apply the presented products in their healthcare practice.

In addition to that, the OGYÉI objected speaker agreements in cases where HCPs had a duty, based on their job description with the hospital, to hold similar presentations at the internal meetings of the hospital (typically so-called referral meetings).

Group detailing versus events

In one of the OGYÉI decisions, the OGYÉI noted that in case hospitality is being provided at the events typically called "referral meetings, business meetings or business referrals", the events shall not be qualified as group detailing activities. This is because on the one hand, HCPs were participating in the events, on the other hand they were organized or their organization was actively facilitated by the pharmaceutical company or its medical sales representatives. The OGYÉI shall be notified of such events 15 days in advance.

Establishment and operation of a scientific organizational unit within the company for the management of commercial communication activities

The OGYÉI highlighted that the task the scientific organizational units is to ensure the delivery of professionally verifiable, substantively accurate information during communication with HCPs. The OGYÉI expects that such an organizational unit should operate at each pharmaceutical company under the direct supervision of the management. In the OGYÉI's view, if such department does not exist at a pharmaceutical company, the efficient control of commercial communication will be undermined that may result in poor quality of communication.

Sponsorship provided for attending conferences abroad

The OGYÉI highlighted in one of its decisions that pharma companies may only sponsor the participation of HCPs at conferences abroad if the participation at the conference is justifiable. Pharma companies are therefore expected to assess if the resources required for the subject-matter of the event or the necessary expertise are available only abroad, at the location of the event, and the costs of organizing such event at a location closer to the workplace of the participants would be disproportionately higher.

The pharmaceutical company under investigation sponsored the participation of an HCP in the Singapore conference of the European Society for Medical Oncology ("**ESMO**").

The OGYÉI found the sponsorship was unreasonable and unlawful given that there was another ESMO conference organized in Europe presenting essentially the same topics at the same time as the Singapore conference.

Compliance recommendations

In one of the decisions, the OGYÉI made recommendations on commercial practices of the pharmaceutical company under investigation.

One of the recommendation refers to sponsoring accommodation at domestic professional events and states that it would be practical to ask for justification from the participants in the application form concerning the sponsorship of accommodation in domestic professional events.

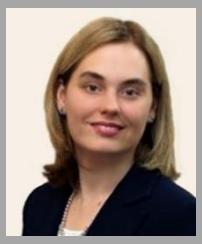
In the other recommendation the OGYÉI repeatedly draws attention to the fact that business meals offered to HCPs by company employees are not related to the healthcare activity of HCPs, therefore they shall qualify as prohibited benefit.

The extracts of the OGYÉI decisions are available in Hungarian language at the following links:

> **https://www.ogyei.gov.hu/ogyei314462020__aramis_pharma_gyogyszermarketing_kereskedelmi_es_szolgaltato_kft**
>
> **https://www.ogyei.gov.hu/ogyei732102019__sager_pharma_szolgaltato_kft**
>
> **https://www.ogyei.gov.hu/ogyei137872020__lilly_hungaria_gyogyszer__allategeszsegugyi_es__orvosi_berendezeseket_gyarto_es_ertekesito_kft**

The OGYÉI's findings in the above-mentioned decisions are useful as pharmaceutical companies may incorporate them into their daily practice, thereby reducing the chance of legal consequences and sanctions such as a fine to be imposed in a potential investigation of the OGYÉI.

Contacts



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NEW REIMBURSEMENT REGULATIONS

On November 26, 2020 the Act of 7 October 2020 on Medical Fund (the "**Act**") will come into force. The Act assumes, *inter alia*, that:

- **additional funds of up to PLN 4,2 billion** (currently approximately **EUR 920 million**) annually will be spent between **2021 and 2029** (in 2020 it should be PLN 2 billion) for financing seven areas, including the reimbursement of innovative therapies;

- the **maximum amount for reimbursement of innovative therapies** may not exceed **5% of the total annual budget** of the National Health Fund dedicated **for the reimbursement** in Poland - in 2020 this budget amounts to ~PLN 14 billion (~EUR 3,1 billion), **i.e. up to PLN 700 million (~EUR 155,5 million)** could be allocated each year for this area (based on current reimbursement budget, which is floating).

Proper implementation of the idea standing behind **this Act required certain amendments to the Polish Reimbursement Law of 2011** that may be important from your perspective. Below please see the brief summary of the key changes.

New categories of medicinal technologies

The Act assumes that the **additional funds will be dedicated for financing two new medicinal technologies** that will also become defined in the Reimbursement Law in a following way (currently, the Reimbursement Law contains only a definition of a "medicinal product" which covers all of the products):

- **Medicinal technology of high clinical value** ("**MTHCV**") - medicinal technology that has obtained marketing authorization ("**MA**") in the "centralized procedure" after 1 January 2017, which fulfils the following conditions: (i) it has not yet been publicly funded; and (ii) it was included in the list of MTHCV published by the Agency for Health Technology Assessment and Tariff System ("**AHTATS**").

- **Highly innovative medicinal technology** ("**HIMT**") - medicinal technology used in oncology or rare diseases that has obtained MA in the "centralized procedure" and which has been included in the list of highly innovative drug technologies published by AHTATS.

HIMT variations

At least once a year, AHTATS will be establishing the level of innovation of drug technologies used in oncology and rare diseases and the principles for establishing **the HIMT list**, taking into account, in particular: the expected health effects, strength of the intervention, the quality of scientific data, the unmet health need, the size of the target population and health priorities.

The Minister of Health ("**MoH**") will publish the HIMT list and inform the marketing authorization holders ("**MAH**"), whose technologies are included on this list, about the possibility of applying for the reimbursement.

The first list - will be prepared and presented to the MoH no later than **3 months** from the date of entry into force of the Act and include medicinal **products registered after 1 January 2020**.

The efficiency and potential adverse effects of reimbursed HIMT will be analyzed in real-time an compared with alternative medicinal technologies. 90 days before the end of the reimbursement period AHTATS will publish an evaluation report on the effectiveness and quality of treatment based on data from medical records.

MTHCV variations

Publication of the MTHCV list along with establishment of indicators to assess the effectiveness of the therapy and the expected health benefits **will be made by AHTATS only once**. The list will be created analogically to the HIMT list and should be presented to the MoH within the period of **9 months following the Act's entry into force**.

HIMT *ex officio* reimbursement

What seems to be extremely important is the MoH's right to issue reimbursement decisions with respect to HIMT *ex officio*. It could happen in cases where MAH (or its representative) has not submitted the reimbursement application despite the fact it has been informed by the MoH that its HIMT has been included on the HIMT list. The key problem is that the procedure of the *ex officio* reimbursement has not been regulated in the Act. Consequently, we are unable to describe how this could look like.

Some companies may not plan to have their products reimbursed in Poland or may not be yet prepared for supplies. In such *ex officio* procedure MAH will be practically excluded from the proceedings despite the fact it will pertain its products.

Under the current wording of the Reimbursement Law, the *ex officio* procedure is envisaged for off-label indications. However, the off-label reimbursement is in practice additional to the existing reimbursement of on-label indications and copies the conditions of the on-label reimbursement decision.

Differences in the reimbursement applications and the negotiations process

The most important differences in the process of application for reimbursement, as compared to standard reimbursement application currently used for all the therapies, pertain to HIMT (in case of MTHCV the only difference is that the rationalization analysis does not need to be filed with the application).

The abovementioned key variations are as follows:

- the **application for HIMT reimbursement** can be called as **"simplified"**, because the scope of the analyses submitted with it is includes **only a budget impact analysis**;

- the **application will not be submitted to the AHTATS** for preparation of the verification analysis, the position of the Transparency Board and the AHTATS recommendation;

- application should be considered by the MoH (in other words - the reimbursement decision should be issued) within **60 days** (not standard 180 days).

Changes to the standard rules of conducting negotiations are as follows:

- in case of HIMT reimbursement application the Economic Commission (body responsible for supporting the MoH in the negotiations process; "**EC**") will be obliged to **invite the applicant for negotiations within 1 month** from the day the EC receives the application;

- during the negotiations of HIMT reimbursement clinically relevant endpoints will be identified and risk sharing mechanisms based on clinical outcomes will be established;

- the **negotiations of both HIMT and MTHCV will last no longer than 30 days** from the first day of the negotiations, divided into a maximum of 3 rounds - in particularly justified cases, the EC will be able to adopt a resolution on conducting one additional round of negotiations;

- **in case of disagreement** with the applicant, the EC will adopt a negative resolution, and the **result of the negotiations** together with their course (excluding business secrets) will be **published on the MoH's website**.

Financing of the treatment continuation

The most controversial regulation assumes that in case of HIMT and MTHCV used in a drug programme, with respect to which: (i) the reimbursement decision has been revoked or (ii) no decision on continuation has been issued, the decision holder will be **obliged to provide free continuation of treatment for patients who started treatment before the date of revocation or expiry of the reimbursement decision**.

It should be noted that in some cases the reimbursement decisions may expire for the reasons not attributable to the decision holder (e.g. the MoH does not agree for the new price in the "continuation" proceedings) and then it will still be obliged to finance the continuation. This may be particularly important for companies having reimbursed HIMT/MTHCV used in chronic diseases, where the treatment lasts for years.

NEW LAW ON MEDICAL DEVICES

Polish Government continues works on the new Act on Medical Devices that should basically only technically implement the directly applicable EU regulations however, it is an extremely elaborate document.

Advertising

In general, the advertising of the product may not infringe the bans set forth in the Article 7 of the Regulation 2017/745 and of the Regulation 2017/746 and must be formulated in a way that can be understood by the average user. This requirement also pertains to medical and scientific expressions and references to scientific research, opinions, literature, studies and other materials dedicated for professionals.

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Current version proposes two public advertising bans: (i) prohibiting the use of the image of HCPs or suggesting the use of such image and (ii) calling children to purchase the devices or convince parents or other adults to do so.

Also, advertising that is misleading with regard to the terms and conditions of maintenance and other activities related to, inter alia, servicing, maintenance, software updates or safety checks, will be prohibited. The bill assumes that advertising may be conducted by all "business entities" and other entities with the consent of such entity. The new version of the bill includes a catalogue of the following activities, subject to advertising provisions:

1. advertising of activities in which a device is used to provide services;
2. presentation of a device during promotional meetings;
3. paid public opinions of users;
4. visiting HCPs for promotional purposes;
5. sponsoring various types of events and presenting devices at them.

The supervision over the advertising of the devices indicated in point 1 will be exercised by the Minister of Health in the scope of medical entities, and the Chief Sanitary Inspectorate (*Główny Inspektor Sanitarny; "GIS"*), in the remaining scope. Activities under points 2-5 will be supervised by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (*Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych*; "President of the Office").

Also, if the President of the Office finds that Article 7 of the Regulation 2017/745 or Regulation 2017/746, as regards advertising, has been infringed, it will order, by way of administrative decision to (i) remedy the infringements found, (ii) cease the publication, appearance or conduct of the advertisement concerned, or (iii) publish the issued decision in places or media where a given advertisement has appeared.

Advertising of the product shall be carried out in audio-visual, audio-visual or visual. The bill provides only a general directive that the advertisement of the device shall include at least the name or trade name of the product and the intended use of the product. The remaining requirements will be determined by the Minister of Health in the regulation covering the necessary data to be included in the advertisement and the way in which advertising is communicated, having regard to the need for objective presentation of the product, the safety of its use and the state of the art of product users.

The entity advertising the product will be obliged to keep the advertisement patterns and information on where it has been distributed for 2 years from the end of the calendar year in which the advertisement was distributed. It will be also obliged to provide the President of the Office, at request, a specimen of each advertisement addressed to the public, together with information on how and when to disseminate it.

Please note that the new advertising rules will apply as of 1 January 2022.

Administrative fines

The issue that evokes the emotions is a very broad catalogue of administrative fines. In some cases, a fine may amount to as much as PLN 5 million (~over EUR 1,1 million), e.g. for illegal marketing or use of medical devices, or the introduction of devices that do not meet safety and performance requirements, or the use of, inter alia, texts, names or trademarks that may mislead the user as to the intended use, safety and performance of the device. With the exception of the fine for misleading advertising of an activity in which the device is used to provide services, which will be imposed by the GIS, the President of the Office will impose all fines on the basis of an administrative decision. The original version of the bill included the creation of a public list of medical devices. The new version additionally foresees the creation of a list of distributors who, having obtained an access code and password to this list, will enter the Basic UDI-DI code of the device, its type and trade name, as well as information about each device imported for the first time in Poland. Failure to comply with these obligations will be subject to a fine of up to PLN 200,000 (~EUR 45.000). Additionally, manufacturers of custom-made devices and their authorized representatives based in Poland will be obliged to submit an application to the President of the Office for registration of the activity before the first marketing or submission for evaluation of the activity. Failure to do so will also be subject to a fine of up to PLN 200,000.

The new version maintains the acceptability of reprocessing single use medical devices while prohibiting their disclosure or further use. Violation of this prohibition will be subject to a fine of up to PLN 500,000 (~over EUR 110.000).

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SLOVAKIA REVISES SOCIAL ASPECTS OF ITS PHARMACEUTICAL REIMBURSEMENT POLICY

A new piece of draft legislation is going through the early stages of legislative proceedings in Slovakia in an effort to improve the economic situation of patients from socially vulnerable groups. The draft aims at reduction of supplementary payments by the said groups of patients for pharmaceuticals, medical devices and dietetic food, which are reimbursed from the public health system.

The affected groups of patients are in particular children under six years of age, recipients of old age pensions and disability pensions and persons with severe health disabilities. The legislative change should in fact provide better access to healthcare for these patients. Enactment of the law is anticipated by the Slovak Government's Program Statement for 2020 – 2024.

From a technical legislative perspective, the draft law is an amendment to Act No. 363/2011 Z. z. on the Scope and Conditions of Reimbursement of Pharmaceuticals, Medical Devices and Dietetic Food on the Basis of Public Health Insurance and on Amendment of Certain Other Acts. The originally proposed effective date is 1 January 2021.

The draft law has already gone through the Inter-Ministerial Comment Procedure, which is an early stage of legislative proceedings in Slovakia. The Ministry of Health is currently evaluating the comments obtained and it can be expected that it will soon submit the draft to the Slovak National Council. However, it is very probable that the originally expected effective date will have to be postponed as the legislative procedure will likely not come to an end before 2021.

POSSIBLE EXTENSION OF MAHS OBLIGATIONS WITH RESPECT TO PHARMACOECONOMIC ANALYSIS

The Ministry of Health of Slovakia is working on an amendment to its Decree No. 422/2011 Z. z., on Details of Pharmacoeconomic Analysis of Pharmaceuticals ("Decree"). The amendment should introduce a new obligation of MAHs to submit a pharmaceutical's interactive pharmacoeconomic model as an integral part of a pharmacoeconomic analysis.

Under the current wording of the Decree, MAHs may freely decide whether or not to provide the regulator with the interactive model, which creates a rather low standard level of verifiability of provided information about the assessed pharmaceuticals, which information forms the basis for the regulator's decision on reimbursement of the respective pharmaceuticals.

By obliging MAHs to provide the interactive model within the framework of pharmacoeconomic analysis, the amendment to the Decree aims at ensuring good reliability of input data, which will enable the regulator to make well-informed decisions. As a result, the Ministry of Health hopes to increase the efficiency of public resource spending on pharmaceuticals via reimbursements.

The preliminary phase of the legislative procedure has already been finished and we are monitoring further developments.

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