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Life Sciences Legal Update

Q1 2023

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Welcome to our regular quarterly edition of the Life Sciences Legal Update, which focuses on key news and events in the life sciences sector in the first quarter of 2023. Find out what new regulations, court decisions and trends are impacting the pharmaceutical and healthcare law landscape in the Czech Republic, and what implications this may have for your business.

We wish you pleasant reading.

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Medical devices

1. New Act on medical devices and new developments in the field of *in vitro* diagnostic medical devices

Following the European *In Vitro* Diagnostic Medical Devices Regulation (**IVDR**)[1], the Czech Republic adopted a completely new Act on Medical Devices and *In Vitro* Diagnostic Medical Devices (**Medical Devices Act**)[2], which entered into force on 22 December 2022. The adoption of the new Medical Devices Act has consolidated fragmented national legislation in the field of medical devices.[3] The original acts, 89/2021 Coll. (**Act on Medicinal Products**) and 268/2014 Coll. (**Act on *In Vitro* Diagnostic Medical Devices**), were effectively repealed and replaced by the new Medical Devices Act.

Changes brought by the Medical Devices Act

- **New legal concept—ex officio proceedings to annul prior decisions on a boarderline product**
- **Registration of medical devices at the Europe level**
- **Prohibition on supplying medical devices to non-professionals**
- **New developments in the area of instruction-deletion of authorized representatives**
- **New archiving obligation for distributors of spare parts**

A change has occurred in connection with boarderline products in the form of a new concept: ex officio proceedings for the annulment of a decision. The European Commission can now decide on the nature of a product or group of products by means of implementing acts. In the event of a conflict between a decision of the European Commission and an already-issued decision of the State Institute for Drug Control (**SÚKL**), SÚKL will be obliged to cancel the issued decision in an ex officio procedure.

Another addition is the registration of medical devices, which will take place exclusively at the European level, with medical devices being registered exclusively by manufacturers in the European Database of Medical Devices. Distributors remain obliged to report medical devices distributed by them under the Medical Devices Act, but only to a limited extent (distributors are obliged to report the primary model identifier and the purpose of the medical device).

The Medical Devices Act contains a provision that prohibits the delivery of medical devices intended for diagnosis and also devices that are tied to the so-called safety voucher to non-professionals. This prohibition does not apply to diagnostic medical devices of risk class A and devices intended for self-testing by the manufacturer. In this context, a layperson is defined in Article 2(31) of the IVDR as "*an individual who has no formal training in the relevant health care or medical field.*"

Regarding who has the right to provide instruction, authorized representatives have been removed from the list of persons who can instruct or authorize training centers to train instructors. As a result, authorized representatives will only be able to instruct if first authorized by the manufacturer.

Last but not least, the Medical Devices Act includes an obligation for distributors of medical device components to archive documentation for 10 years from the date on which they supplied the components.

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[1] Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices
[2] Act No. 375/2022 Coll., on medical devices and *in vitro* diagnostic medical devices
[3] Originally regulated separately by Act No. 89/2021 Coll., on medical devices; *in vitro* diagnostic medical devices were regulated by Act No. 268/2014 Coll., on *in vitro* diagnostic medical devices

2. News on the regulation of advertising of medical devices and *in vitro* diagnostic medical devices

With effect from 22 December 2022, an amendment to the Advertising Regulation Act[4] brought about a loosening of certain requirements for promoting medical devices and *in vitro* diagnostic medical devices. Specifically, the following innovations:

- **Catalogue and price list as a form of advertising for medical devices**
- **Change in the requirement to provide basic information regarding approved instructions for use**
- **Modification of target group for advertising**
- **Change in the indication of a medical device's purpose**

Under the previous version of the Advertising Regulation Act, in order for a catalogue or price list not to be considered an advertisement, it could not include any descriptions of the characteristics of the medical devices. The amended version of the law relaxes this restriction and allows price lists and catalogues to include at least a basic description of the devices' characteristics, i.e., necessary for their identification.

Before the amendment went into effect, the advertising of medical devices to professionals had to include basic information on how the device is used. But this requirement has proved problematic: Depending on the medical device, the instructions for use can be dozens of pages long, making the inclusion of "basic information" in the advertisement unfeasible. Thus, this formal requirement has now been deleted altogether, which will help simplify the process of advertising medical devices to professionals.

The amendment also expands the target group of advertising for medical devices to include employees of healthcare providers who previously were not categorized as healthcare professionals. This change recognizes that the use of medical devices in the context of providing health services is highly variable and includes not only doctors but also nurses, biomedical engineers and other employees of the healthcare provider.

Under the previously effective Advertising Regulation Act, advertisements for medical devices to the general public had to state the specific purpose for which the devices were intended. The amendment has slightly modified this obligation so that it is sufficient to state only the main purpose of the medical device. This measure provides more flexibility in advertising campaigns while still maintaining a high level of consumer protection.

Health insurance companies

1. Supreme Administrative Court: Health insurance companies must better justify failure to provide exceptional reimbursement

The Supreme Administrative Court (**the Court**) overturned[5] the decision of the Municipal Court in Prague, which dismissed a lawsuit against a decision of the General Health Insurance Company (VZP). The insurer had refused to reimburse a patient undergoing treatment for cancer of the nasopharynx for the medicinal product Opdivo with the active ingredient nivolumab. The patient had requested reimbursement for a given medical service otherwise not covered by health insurance, in accordance with Section 16 of the Public Health Insurance Act.[6]

According to this provision, the insurance company covers a health service not otherwise covered by health insurance provided the following conditions are cumulatively met: It is a health service not otherwise covered, it is the only option in terms of the patient's health condition and the case is exceptional. In this case, the reason for the reimbursement request for the alternative treatment with the drug Opdivo was because the normally covered treatment, chemotherapy, resulted in toxicity. However, according to the insurance company, toxicity is not

[4] Amendment to Act No. 40/1995 Coll., on the regulation of advertising, in connection with Act No. 376/2022 Coll., amending certain acts in connection with the adoption of the Act on medical devices and *in vitro* diagnostic medical devices
[5] Judgment of the Supreme Administrative Court No. 10 Ads 334/2022 - 41 of 31 January 2023
[6] Act No. 48/1997 Coll. on Public Health Insurance and on Amendments and Supplements to Certain Related Acts

an exceptional manifestation of chemotherapy, and furthermore, studies allegedly indicated that Opdivo was not more effective than chemotherapy.

According to the Court, the insurance company dealt only in a very general way with the question of whether the statutory conditions for exceptional reimbursement were met and did not sufficiently explain whether the requested alternative treatment was safer or not, as a mere reference to a study was not sufficient. In the subsequent proceedings (and, given the general binding nature of the opinion of the Court in similar cases), the exceptional nature of the case and whether the requested treatment is the only option in view of the patient's state of health must be professionally and individually substantiated.

Medicinal products

1. Amendment to the Medicines Act and possible repercussions

The amendment to the Medicines Act[7], which is currently under the government commentary procedure in Parliament, should speed up and simplify the process of registering medicines. The aim of the amendment is primarily to encourage the development of new medicines for patients with incurable diseases and to improve the availability of medicines on the market. Reducing the requirements for clinical trials is one of the main changes introduced by the amendment. This can be seen mainly as an effort to reduce the administrative burden on researchers and pharmaceutical companies.

There have also been negative responses to this proposed amendment. Critics (such as the Association of Innovative Pharmaceutical Industry) fear that a reduction in the requirements for clinical trials could lead to more drugs appearing on the market with lower efficacy and safety for patients. Such drugs could be ineffective or even dangerous for patients, which could lead to a risk of deterioration in their health. It is therefore important that the new rules have the aim of protecting patients' health and that they comply with the highest standards of quality and safety of medicines.

2. The Competition Office has completed sector inquiry into the distribution of pharmaceuticals and issues recommendations

The Office for the Protection of Competition (**the Office**) has completed its sector inquiry into the distribution of medicines, which ran from 2021 to 2022. In view of its findings, the Office has issued several recommendations addressed to regulators, marketing authorization holders (**MAH**) and consumers.

The investigation focused in particular on the impact and effects of distribution models on competition in the wholesale and retail markets for pharmaceuticals. It paid particular attention to so-called direct-to-pharmacy (DTP/DTH) models, which are generally used in the distribution of specialty, higher-priced medicines.

Recommendations to MAHs:

- **Having multiple distributors**
- **At the retail level, correctly setting withdrawal limits and distribution surcharges for pharmacies**
- **No "hard caps" in distribution contracts**
- **Distribution agreements that do not seek to restrict or exclude parallel trade**
- **Communications on retail prices being as recommendatory as possible**
- **Negotiating "business representation" at the wholesale level**
- **When choosing an exclusive distribution model, implementing regular and transparent selection procedures**

[7] Act No. 378/2007 Coll., on pharmaceuticals and on amendments to some related acts, link to the amendment here: ODok Portál - VeKLEP - Návrh zákona, kterým se mění zákon č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů

3. SÚKL has published[8] an opinion on the amendment to the Public Health Insurance Act[9] regarding the provision of discounts and bonuses.

Due to the interpretative ambiguities regarding the provision of discounts on the dispensing of medicinal products covered by public health insurance, which are currently regulated by the amendment to the Public Health Insurance Act[10], SÚKL has published an opinion on this issue.

The only permissible form of advantageous dispensing of a medicinal product covered by public health insurance is a reduction of its final price at the time of dispensing, whether in the form of an across-the-board discount, a discount on a specific item or a discount on the copayment.

Other forms of benefits (e.g., loading rewards-points on loyalty cards, vouchers and discounts for the next purchase, accumulation of discounts for previous purchases, conditioning the amount of the discount on the quantity of dispensed medicines, providing discounts on other assortments, etc.) are considered by SÚKL as activities that are contrary to the Public Health Insurance Act.[11]

The opinion also includes answers to frequently asked questions on the subject.

4. SÚKL has launched new drug database providing comprehensive information for patients and healthcare professionals.

SÚKL has launched a new database of medicines called "Medicinal Products in the Czech Republic." This database provides access to comprehensive information on registered medicines in the Czech Republic. As a result, patients and healthcare professionals will have an overview of the composition of medicines, contraindications, adverse effects, and interactions with other medicines. The database also includes information on packaging and prices of medicines.

The database will be particularly useful for doctors and pharmacists, who will be able to quickly and easily navigate available medicines and compare their effectiveness and cost. At the same time, the database will provide greater transparency in the pharmaceutical market and enable patients to obtain better information about the medicines they are taking. The "Medicinal Products in the Czech Republic" database is freely accessible on the SÚKL website[12] and will be continuously updated.

Dietary supplements/foods

1. New regulation of nicotine pouches: Even stricter rules

In the Czech Republic, the market for nicotine pouches—a new category of tobacco-free nicotine products—is already relatively well-developed. Despite this, there has been no legal regulation of their sale in the country and, unlike tobacco products and electronic cigarettes, no decree specifying the requirements for nicotine pouches, their labelling and notification to regulators. This is now changing.

Before a decree on nicotine pouches[13] is realized, the amendment to the so-called anti-smoking law[14] will likely come into force. The legislative process for its adoption has already been duly completed and will result in a ban on the sale of nicotine pouches to persons under 18 years of age, i.e., it introduces the same rules on them as for other

[8] Amendment to the Public Health Insurance Act—provision of discounts and bonuses, State Institute for Drug Control (sukl.cz)
[9] Act No. 48/1997 Coll., on public health insurance and on amendment and supplementation of some related acts
[10] § 32 of the amendment to the Public Health Insurance Act
[11] § 32 (4) of the Public Health Insurance Act
[12] The complete list can be found here: SÚKL - Přehled léčiv (sukl.cz)
[13] The text of the draft decree is available here. https://odok.cz/portal/veklep/material/ALBSCGFATQG6/
[14] The amendment can be found here: https://www.psp.cz/sqw/text/orig2.sqw?idd=218884

nicotine products. This step is generally uncontroversial since, even before the amendment, some distributors were contractually obliging retailers to sell only to adults.

In the case of the nicotine pouches decree, the situation is not so clear. Among other things, the decree limits the amount of nicotine in a single pouch to 12 mg, which is approximately medium in terms of current market supply. It is therefore possible that some adult smokers may find the nicotine intensity too low and revert to smoking conventional cigarettes. With nicotine pouches, the amount of nicotine in the pouch is not equal to the amount of nicotine ingested by the user.

Although nicotine pouches are not a smoking cessation product, they can realistically replace cigarettes for some smokers, competing with smoking cessation products such as nicotine gum, sprays, etc. The new regulation thus appears to ultimately benefit the manufacturers of these products.

Healthcare

1. Draft amendment to the Health Services Act refines rules for the provision of telemedicine

The comment procedure for the amendment to the Health Services Act[15], as amended, has been completed and the bill is now heading to the Chamber of Deputies; the amendment should be effective from 1 July 2023.

The Ministry of Health, which is backing the proposal, wants to anchor the definition of telemedicine, which has so far been lacking in the legislation. This significantly complicates the provision of telemedicine services; among other things, there is confusion as to whether a telemedicine service is a reimbursable health service.

Currently, health services can only be provided in a healthcare facility or, in certain circumstances, in the client's home environment. The amendment would allow health services to be provided outside the healthcare facility if the use of information technology without the patient's participation is involved or if the service consists of sending data on the patient's health status. When providing telemedicine, "technical requirements for the quality and security of communication" must be met, to be further defined in an implementing decree.

2. How to get patient consent right: Supreme Court issues key decision for doctors

Recently, The Supreme Court issued a decision[16] that specifies the procedure by which a patient's consent to a procedure must be obtained. According to this decision, the doctor must conduct a proper oral interview with the patient prior to the procedure and explain all relevant information about the planned procedure, including the risks and possible consequences. If the patient agrees, the doctor should record this information in the patient's medical records.

This decision is of great importance for medical practice in the Czech Republic. There has often been confusion as to how patient consent to a procedure should be obtained. It is now clear that the oral interview between the doctor and patient is a key part of this process.

The Supreme Court further emphasized that the patient must be able to fully understand all information communicated to him by the physician. If the patient expresses an interest, the doctor should explain the information to the patient repeatedly and ascertain whether the patient is actually capable of giving his or her consent. If the doctor records the patient's consent in the patient's medical record, this record should be accurate and comprehensive and should include the date and time consent was obtained. It is therefore essential that the patient does not simply sign documents without knowing what they are signing.

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[15] Amendment to Act No. 372/2011 Coll., on Health Services and Conditions of their Provision (Health Services Act), (available here: ODok Portál - VeKLEP - Návrh zákona, kterým se mění zákon č. 372/2011 Sb., o zdravotních službách a podmínkách jejich poskytování (zákon o zdravotních službách), ve znění pozdějších předpisů)

[16] Source: Nejvyšší soud vyložil, jak má vypadat souhlas pacienta se zákrokem. Klíčový je ústní pohovor - Česká justice (ceska-justice.cz)

It is important to understand that properly obtained patient consent for a planned procedure is a necessary condition for the provision of quality healthcare. Patient consent is important not only from an ethical and moral point of view, but also from a legal point of view. The patient has the right to be informed about his or her health and the procedure to be carried out, and the right to refuse the procedure if he or she does not agree to it.

Doctors should also be cautious when explaining the risks and complications associated with the planned procedure. They must be able to convey this information to the patient in an understandable way and answer all their questions. If doctors do not show sufficient care and attention in obtaining the patient's consent, they may face potential litigation.

In summary, the Supreme Court's decision therefore fundamentally strengthens the right of patients to be informed about their health and to be able to decide their health fate in full knowledge of all circumstances. At the same time, however, it places the emphasis on doctors to obtain the patient's consent in the correct manner and to carefully record all relevant information in the patient's medical records.

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