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Life Sciences Legal Update

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Dear Readers,

We are pleased to bring you a new edition of *Life Science Legal Update*, our regular newsletter that focuses on key legal issues and innovations in pharmaceuticals and life sciences. In this edition, we focus on several recent developments and topics that may be relevant or of interest to you.

We look at the most recent legislative developments affecting the amendments to the Medicines Act and Health Services Act. We also inform you about fines recently imposed by the Office for the Protection of Competition and the State Institute for Drug Control, the decree regarding new requirements for the sale of coffee, tea and coffee products as well as the ban on the sale of distinctive flavors in heated tobacco products.

And as always, we wish you pleasant reading.

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Medicines Act amendment headed for third reading in lower house of Parliament

The amendment to the Medicines Act, which we wrote about in last quarter's edition of our newsletter, has passed the general and detailed debate in the Chamber of Deputies and will now go to its third reading, where it is expected to be approved by the deputies.[1]

The amendment to the Medicines Act is intended to limit shortages of medicines on the market by imposing obligations on manufacturers, distributors, pharmacies as well as state authorities. For example, it requires manufacturers to keep at least one or two months' supply of medicines in stock at any given time. At the same time, the new obligations on drug distributors, pharmacies and state authorities include, for example, requirements on drug manufacturers to continue to supply medicines for one-to-two months after reporting an outage, with the period depending on the reliability of supply in the previous period, or obligations for manufacturers to keep medicines in stock in a volume covering one or two months' supply. Distributors, on the other hand, will not be allowed to favor any pharmacies in the supply of medicines, which should reduce the occurrence of local unavailability. Pharmacies will also be obliged to report the current stock level of a medicine with limited availability and at the same time be able to order only in the quantity usual for that pharmacy.

The Chamber of Deputies is also currently discussing another change to Medicines Act[2] that would allow the sale of non-prescription (OTC) medicines through automated vending machines. For the time being, it is envisaged that only licensed pharmacies would operate these machines.

We will soon publish a more in-depth look at the proposed amendment to the Medicines Act, where we will analyze the changes in detail, with insights on how it will likely affect current practices in the Czech market and a comparison of how other EU countries have dealt with drug shortages.

ÚOHOS fines animal feed producers for price fixing practices

The Office for the Protection of Competition (ÚOHS), in connection with a series of local investigations carried out in 2021, recently fined three companies in the pet feed and pet goods sector for resale price maintenance (RPM) practices. All three companies had monitored retailers' compliance with recommended retail prices and urged them to adjust these prices according to their guidelines.

In the case of TENESCO s.r.o., ÚOHS imposed a fine of CZK 307,000 (approx. €12,500). In this case, ÚOHS took into account the relatively small annual turnover of the company and significantly reduced the fine, as it terminated its anti-competitive practices immediately following the local investigation. It also took into consideration the company's introduction of a new competition compliance program. Another factor contributing to the reduction in the fine was that TENESCO agreed to a settlement procedure, thereby speeding up the evidential and administrative proceedings before ÚOHS.[3]

In the other two cases of sanctions for RPM practices, ÚOHS fined EUROBEN, s.r.o. CZK 1.07 million (approx. €69,000)[4], while the highest fine, approx. CZK 48 million (approx. €2 million) was imposed on NOVIKO s.r.o. Generally speaking, this fine can be considered one of the highest fines imposed for RPM practices in the Czech Republic. On the other hand, ÚOHS considered NOVIKO's above-standard cooperation in the administrative proceedings and the improvement of its competition compliance program as a mitigating factor.

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[1] Chamber of Deputies, Chamber print 476 (psp.cz)
[2] Amendment No. 3355 to Parliamentary Draft No. 476, available here (in Czech only): Chamber of Deputies, Chamber print 476 (psp.cz)
[3] OPC fined animal feed suppliers, but reduced penalty for above-standard cooperation (uohs.cz) (in Czech only)
[4] Another fine for anti-competitive behavior in the pet food sector, EUROBEN to pay CZK 1 million (uohs.cz) (in Czech only)

No appeal was filed against ÚOHS's decision in any of the above cases; thus, the decisions are final.[5]

It would appear that the introduction of the compliance program is already being regularly rewarded by ÚOHS with a discount on its fine. With this in mind, companies that sell goods through distributors are encouraged to set clear internal rules for the negotiation of distribution contracts and safe communication with customer.

SÚKL issues record number of fines for ad violations

This year, the State Institute for Drug Control (SÚKL) issued a record number of final fines for violations of the Act on Advertising Regulation[6], amounting in total to CZK 4.5 million (approx. €180,000)—comparable to the total amount of fines issued in the previous three years combined. The fines mostly concerned advertisements for vitamin C injections, which can only be provided by prescription. The above can be seen from the summary of fines published on the SÚKL website.[7] The highest sanction imposed for this offence was CZK 810,000 (approx. €33,000).

Failing to comply with content requirements under the Act on Advertising Regulation was the most frequent violation, wherein the information provided in the product information summary was noncompliant. The summary of product characteristics should be aimed at professionals and include key information about the medicine, such as effects, dosage and side effects.

The Act on Advertising Regulation prohibits the advertising of prescription medicines aimed at the general public. For over-the-counter medicines, the Act sets out specific conditions that the advertising must meet. According to the statistics, SÚKL issued fines totaling CZK 3.9 million (approx. €158,000) for breaches of the Advertising Regulation Act in 2019. In 2020, fines were issued for almost CZK 1.1 million (approx. €45,000), in 2021 for CZK 1.33 million (approx. €54,000) and in 2022 for CZK 2.38 million (approx. €97,000).

Amendment to the Health Services Act – "electronization" of healthcare

The committees of the Chamber of Deputies are currently discussing a bill on health services, which the government adopted in mid-July.[8] The amendment introduces the concept of telemedicine into the Czech legal system. This is the first time that telemedicine tools have received legal support in the Czech Republic, enabling communication, investigation and potentially even the determination of treatment of patients at a distance. The amendment stipulates that health services may be provided remotely via telecommunications and information technologies, but only under precisely defined conditions specified in the law and in compliance with technical standards regarding the quality and security of communication. In the opinion of the Ministry of Health, the amendment aims, among other things, to ensure legal certainty for health service providers and patients themselves.[9]

At the same time, the amendment to the Health Services Act regulates the possibility of storing health records in electronic form, not only in hard copy. This measure aims not only to facilitate communication between health providers and patients, but also to create the basis for the full digitization of healthcare, which will be required by European legislation in the future.

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[5] Suppliers must not set fixed retail prices, NOVIKO will pay a fine of almost CZK 48 million (uohs.cz) (in Czech only)
[6] Act No 40/1995 Coll., on Advertising Regulation
[7] Sanctions imposed under the Advertising Regulation Act - year 2023, State Institute for Drug Control (sukl.cz)
[8] VeKLEP - Government Bill amending Act No 372/2011 Coll., on Health Services and Conditions of their Provision (Health Services Act), as amended (in Czech only)
[9] Government approves amendment to the Health Services Act - Ministry of Health (mzcr.cz) (in Czech only)

Decree on requirements for tea, coffee and coffee products

In July this year, on 1 July 2023 to be precise, the Decree on requirements for tea, coffee and coffee products entered into force.[10] One of the main reasons for adopting this Decree is to harmonize the production of tea, coffee and coffee products to directly applicable EU regulations.[11]

The Decree primarily regulates the method of providing information about tea, coffee and coffee products, as well as the types of tea, coffee and coffee products and their division into groups and subgroups. It then sets out, in annexes, the sensory, physical and chemical quality requirements applicable to certain types of tea, coffee and coffee products, as well as the permissibility of negative weight variations in packaging. Finally, it also lays down minimum technological requirements. For example, the Decree sets out the conditions for labeling a product as "matcha tea" or "civet coffee."

According to the explanatory memorandum, the reason for dividing teas, coffees and coffee products into groups and subgroups is primarily to prevent consumers from being misled about the nature of the product and its quality. The labeling will now indicate, for example, the serving size, the period of use and the persons for whom the product is intended, or, conversely, a list of persons who must not consume the product.[12]

Products labeled according to the previous Decree No. 330/1997 may be produced and marketed until 1 July 2024. After this transitional period, teas, coffees and coffee products that have already been labeled and marketed before the entry into force of the new Decree may be sold until stocks run out.

Ban on the sale of distinctive flavors in heated tobacco products

On 23 October 2023, the Amendment to the Food and Tobacco Products Act brought important changes to the sale of flavored heated tobacco in the Czech Republic. This legislation is based on the transposition of a European Directive[13] that abolishes certain exemptions for heated tobacco products.

Due to the increase in sales of these products and the increased interest in heated tobacco at the retail level, the sale of heated tobacco with a distinctive flavor is now prohibited.

The amendment defines heated tobacco as a product that produces nicotine and other chemicals and is inhaled. Flavored tobacco products can no longer be placed on the market from the above date, and heated tobacco products can no longer contain any flavoring in any of their ingredients. Any infringements of this prohibition will be punishable by fines of up to CZK 10 million (approx. €406,000).

This legislative change reflects a growing drive to regulate the tobacco industry and protect public health. It also aims to reduce the attractiveness of these products, particularly to young people, while reducing the health risks associated with their use. The legislator has not allowed any transitional period for the resale of products that have already been placed on the market, which will certainly have a significant impact on sellers and manufacturers of heated tobacco products in the Czech Republic.

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[10] Decree 187/2023 Coll., on requirements for tea, coffee and coffee products full and current version | ASPI | Wolters Kluwer ČR, a. s. (in Czech only)

[11] The Decree transposes Directive 1999/4/EC on coffee and chicory extracts and at the same time links to a large number of European regulations, such as European Regulation No. 1669/2011 on the provision of food information to consumers; European Regulation No. 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in relation to food safety. It also links to European Regulation No. 852/2004 on food hygiene and European Regulation No. 1308/2013 establishing a common organization of the markets in agricultural products.

[12] Explanatory memorandum of Decree No. 187/2023 Coll., on requirements for tea, coffee and coffee products

[13] Commission Delegated Directive (EU) 2022/2100 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the repeal of certain exemptions relating to heated tobacco products

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