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Life Sciences Legal Update

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December is here, and that means another Legal Update full of Pharmaceuticals & Life Sciences news. We'll start with positive news, including a decision by the State Institute for Drug Control (SÚKL) on new reimbursement options for orphan drugs and the long-awaited law on single-use plastics, which aims to significantly lighten the burden on the environment. The Pharmaceuticals Act and the amendment to the Advertising Regulation Act have not escaped further updates. More clear rules for the production and trade of cannabis are provided by the implementing legislation for the Addictive Substances Act. Last but not least, you can read about the planned changes being discussed in the Chamber of Deputies, which are expected to affect the Advertising Regulation Act as well as the Public Health Protection Act.

We wish you pleasant reading.

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Health insurance companies

1. Decision of SÚKL on first-ever reimbursement for orphan drug

The amendment to the Public Health Insurance Act[1], which became effective on 1 January 2022, brought an additional way for patients to obtain pricing and reimbursement from SÚKL for orphan drugs. This is by approaching the health insurance company directly, with the medicine subsequently going through a special type of administrative procedure. Specifically, SÚKL decided on 15 September 2022, on the first-ever reimbursement of an orphan drug—in this case for spinal muscular atrophy (SMA).

As the Director of SÚKL, Irena Storová, said, "*The decision of SÚKL on the reimbursement of medicines for rare diseases will always mean a greater degree of certainty for patients. Thanks to this decision, the medicine they need will have a fixed reimbursement for several years.*"

The application for reimbursement of the drug for SMA was submitted on 10 January 2022; it took about nine months for the decision to be issued, including a review by a new committee of the Ministry of Health of the Czech Republic with patients and expert doctors. Unlike the previous "hard" way of assessing (for example, using cost-effectiveness), the change in legislation now allows for "softer" criteria to be taken into account, such as the severity of the disease or its impact on family and caretakers. The inclusion of patient organizations and professional societies as parties to the procedure is also an important pro-patient step.

Learn more about the SÚKL decision here (*in Czech only*).

2. Supreme Administrative Court confirms record fines on seven insurers

A total of **CZK 1.79 million** in fines imposed by the Czech Office for the Protection of Competition (ÚOHS) on seven health insurance companies were confirmed by the Supreme Administrative Court (SAC) in Brno. ÚOHS imposed the fines on each of the seven insurers for an offense committed during the procurement of the above-limit public contract: "*Ensuring comprehensive supply and distribution of pharmaceuticals containing vaccines for regular vaccinations from 2018 to 2021*".

According to ÚOHS, the insurers needed to show proof of at least two reference contracts with an aggregate value of at least CZK 300 million where at least one had to be for at least CZK 25 million. However, these references presented were limited to contracts involving the direct supply of medicines to GP surgeries or vaccination centers. The insurers were fined for setting the tender conditions in breach of the Public Procurement Act (PPA)[2] by failing to set the minimum level of technical qualification required by the PPA[3], as specified in the tender documents, in a manner appropriate to the complexity and scope of the subject matter of the contract.

The health insurers fined included, for example, the General Health Insurance Company of the Czech Republic, the Czech Industrial Health Insurance Company, and the Military Health Insurance Company of the Czech Republic.

The complete Supreme Administrative Court decision of 20 September 2022 in Case No. 5 As 65/2021 can be found here (*in Czech only*).

What is new in the law on single-use plastics?

We have a new law[4] that bans the production and sale of selected single-use plastics in the Czech Republic with effect from 1 October 2022. The law on the reduction of the environmental impact of selected plastic products

[1] Act No. 48/1997 Coll. on Public Health Insurance.
[2] Act No. 134/2016 Coll. - on public procurement (PPA), Section 73(6)(b) in conjunction with Section 6(1) and (2) PPA.
[3] pursuant to Section 79(2)(b) PPA.
[4] Act No. 243/2022 Coll. on limiting the environmental impact of selected plastic products (Disposable Plastics Act).

transposing the EU directive (SUP Directive)[5] includes several types of measures—from a complete ban on products to restrictions on their consumption, to mandatory contributions from producers to clean up municipalities and cities.

Politicians hope that the new law on single-use plastics will reduce the amount of waste that ends up in landfills today. There are already several alternatives to banned plastic products that can provide significant environmental relief in terms of material savings (up to 1.77 billion units per year), while some products can be reused (e.g., reusable drinks cups) or will use more recycled materials in their manufacture.

In addition, the law also helps municipalities, which will be entitled to a contribution towards the cleaning of public spaces. Under the so-called extended responsibility, some manufacturers (e.g., manufacturers of filtered tobacco products) will be obliged to contribute to the cleaning of their products' waste in municipalities. At the same time, manufacturers are obliged to inform purchasers about the correct handling of waste and to label the plastic product with its appropriate plastic category.

Medicinal products

3. Amendment to the Medicines Act – Purchases of medicines and their availability in crisis situations

The amendment to the Medicines Act[6], effective from 1 December 2022, is a much-debated topic, especially regarding the availability of medicines in crisis situations. The amendment was prompted primarily by frequent shortages in the supply of medicines in the EU market. This should be prevented by closer cooperation between the Ministry of Health of the Czech Republic (the Ministry) and SÚKL. The amendment also provides the Ministry with **considerable powers in purchasing (pricing) and distributing medicines**. Among other things, the Ministry will now have the power to:

- Purchase or distribute medicinal products;
- Temporarily fix, through an emergency measure, a medicine's reimbursement conditions or price to the final consumer;
- Derogate from the Medicinal Products Act when providing for the purchase or distribution in a state of emergency (local or national) or state of war;
- Maintain a list of medicinal products which are essential to the population and whose distribution abroad is subject to an obligation of distributors to report to SÚK;
- Restrict or prohibit the redistribution abroad of medicinal products (those on the aforementioned list).

4. The blocking of illegal websites continues

In our first issue of this year's Life Sciences Legal Update, we mentioned a list of websites offering illegal medicines in violation of the Pharmaceuticals Act (as of 1 January 2022). SÚKL has decided to inform the general public about these websites and warn them against purchasing unapproved products. Based on this list, the Medicinal Products Act obliges Internet access providers in the Czech Republic to prevent access to the websites listed in this list within 15 days from the date of publication.

On 1 October 2022, a law[7] came into force that empowers the State Agricultural and Food Inspection Authority (SZPI) to create and maintain another list of blocked websites. From 1 October 2022, SZPI maintains a list of

[5] Directive (EU) 2019/904 to reduce plastic waste in the seas and oceans and promote the circular economy.
[6] Act No. 378/2007 Coll., the Act on Medicinal Products and on Amendments to Certain Related Acts (the Act on Medicinal Products), as amended, see Parliamentary Print No. 73 under the link: Sněmovní tisk 73/0 (psp.cz).
[7] Act No. 247/2022 Coll. amending Act No. 242/2000 Coll., on organic farming and amending Act No. 368/1992 Coll., on administrative fees, as amended, as amended, and Act No. 146/2002 Coll., on the State Agricultural and Food Inspection and amending certain related acts, as amended.

websites that offer unsafe food products or whose content seriously violates the requirements set out in legislation, which SZPI is responsible for monitoring.

The complete list of blocked websites by SZPI available here (*in Czech only*).

Medical devices

5. A forthcoming amendment to the Advertising Regulation Act could clarify the distinction between advertising and commercial communications

The current regulation in the Advertising Regulation Act[8] can hardly be described as sufficient. Its current wording limits how pharmaceutical companies and medical device manufacturers can communicate about their products, both to the general public and to professionals.

One particular sticking point in recent years involves a lack of clarity in what is considered a "provision of information" (commercial communication) versus "advertising communication." Not even Czech case law offers much clarity to the blurred distinction between these concepts, despite some attempts[9]. Section 2(f) of Act No. 480/2004 Coll., on Certain Information Society Services defines commercial communication as all forms of communication, including advertising and encouragements to visit websites that are intended to promote, directly or indirectly, the goods or services or the image of the undertaking of a person who is an entrepreneur or who carries out a regulated activity. Commercial communication is therefore a broader concept than advertising. According to the case law, every advertisement is a commercial communication, but not every commercial communication is automatically an advertisement.

Although this provision defines commercial communication only for the purposes of the Act on Certain Information Society Services, this definition is also fully consistent with the logic of the Act on Advertising Regulation. A different understanding of commercial communication would make no sense for the Advertising Regulation Act to separately regulate advertising and commercial communication in sections 3(1) and (2).

Therefore, the Ministry of Industry and Trade (MIT), which oversees the newly drafted amendment, has established an expert commission that will, among other things, deal with the regulation of the advertising of pharmaceutical products. The MIT promises to submit to the government a substantive plan of the amendment by the end of next year. Therefore, it is not yet possible to talk about the specifics of the forthcoming amendment.

Implementing regulations to the Addictive Substances Act

6. Clearer regulations on the production and trade of medicinal cannabis

As we informed you in the first issue of the Life Sciences Legal Update, as of 1 January 2022, an amendment to the Addictive Substances Act introduced relaxed rules for cannabis cultivation. Until recently, the implementing legislation setting out specific rules still needed to be passed.

In the third quarter of this year, the amendment was implemented by a number of sublegislative regulations:

[8] Act No. 40/1995 Coll. on the regulation of advertising and on amending and supplementing Act No. 468/1991 Coll. on the operation of radio and television broadcasting, as amended.
[9] Cf. e.g., the judgment of the SAC of 16 April 2020, No.10 As 413/2019-49.

- On 10 August 2022, Decree No. 219/2022 Coll.[10] entered into force, which primarily regulates the limits for the concentration of cannabis in medicinal products—for example, for a hospitalized patient, the amount of cannabis is now limited to a maximum of 6 g of dried plant or 6/7 g of extract.
- On 1 July 2022, Decree No. 168/2022 Coll.[11] updated the list of medicinal and auxiliary substances used in the preparation of medicinal products by adding extracts of Indian hemp, cannabis and THC to the list.
- On 1 July 2022, Government Regulation No. 159/2022 Coll.[12] amended the list of addictive substances by adding cannabis extract for medicinal use and cannabis intermediate for medicinal use to the list.
- On 1 July 2022, Decree No. 174/2022 Coll.[13] and Decree No. 187/2022 Coll.[14] entered into force, which sets standards for:
    - the application for a permit to handle addictive substances and products,
    - the authorization to export or import addictive substances and products,
    - fulfilment of the obligation to report to the General Directorate of Customs, and
    - reporting to the local customs office.
- On 1 July 2022, the price regulation of the Ministry of Foreign Affairs No. 3/2022/OLZP[15] came into force, which set the maximum price at CZK 143.75 per 1 g of cannabis for medicinal use, or CZK 1006.25 per 1 g of cannabis extract.
- On 27 August 2022, Decree No. 235/2022 Coll.[16], entered into force, laying down rules for the cultivation of cannabis plants for medicinal use, their storage and security, and the manner and extent of logging and recording of cultivation-related activities.

The rules for the cultivation and trade in medicinal cannabis are thus gradually becoming clearer, and legal certainty is being given to producers and other members of the distribution chain.

Tobacco industry

7. The end of the sale of nicotine sachets to children is approaching

The Czech Chamber of Deputies is currently debating an amendment to the Act on the Protection of Health from the Harmful Effects of Addictive Substances (*in Czech only*), which will result in regulating the sale and use of nicotine sachets—small pouches of nicotine and tabaco that is used orally. According to the explanatory memorandum to the amendment, the regulation is being introduced primarily due the use of nicotine sachets by children and adolescents (nicotine is described as a highly addictive substance with negative health effects). The exact wording of the amendment is not yet known, but it is clear that the sale of nicotine sachets to persons under 18 is likely to be discontinued. The amendment should enter into force on 1 January 2023.

The Ministry of Health also presented a draft decree on nicotine sachets. The decree regulates the requirements for the composition, appearance, quality and characteristics of tobacco-free nicotine sachets and their labeling. The draft decree will now be examined by a working committee of the Legislative Council of the Government. The Decree is expected to enter into force in July 2023.

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[10] Decree amending Decree No. 236/2015 Coll., laying down conditions for the prescription, preparation, distribution, dispensing and use of individually prepared medicinal products containing cannabis for medicinal use, as amended by Decree No. 307/2020 Coll.
[11] Decree amending Decree No. 85/2008 Coll., on the determination of the list of medicinal substances and excipients that may be used for the preparation of medicinal products, as amended by Decree No. 270/2013 Coll.
[12] Government Regulation amending Government Regulation No. 463/2013 Coll., on lists of addictive substances, as amended.
[13] Decree amending Decree No. 53/2014 Coll., on the forms of forms under the Addictive Substances Act.
[14] Decree amending Decree No 151/2005 Coll., laying down model forms for the reporting of persons growing poppy or hemp and the method of filling in and handling these forms.
[15] Price Regulation of the Ministry of Health No. 3/2022/OLZP of 12 May 2022 on the regulation of prices of individually prepared medicinal products containing cannabis for medicinal use.
[16] Decree on the cultivation and processing of cannabis plants for medicinal use.

8. Excise duty on tobacco products to rise, e-cigarettes and nicotine sachets to be taxed

National Drug Coordinator Jindřich Vobořil has presented the government with a new action plan on addiction until 2025. According to the media, the plan should include a significant increase in the excise duty on tobacco products (expected in early 2024) and the introduction of an excise duty on e-cigarettes and nicotine sachets (expected in mid-2023). The excise duty on alternative products, including e-cigarettes and nicotine sachets, is expected to be about one-third lower than the excise duty on tobacco products.

Constitutional Court rejects MP's proposal to repeal several parts of the Pandemic Act

In its motion to repeal the amendment, the opposition criticized the fact that the norm was discussed in a state of legislative emergency, claiming however that there was no reason for it. Also, the possibility of ordering quarantine of people suspected of being infected with COVID-19 remotely, for example by telephone or SMS, was described as unconstitutional. The motion also referred to the interruption of a five-hour speech by SPD leader Tomio Okamura.

However, the Constitutional Court concluded that "*[t]he legislative emergency was not [...] misused to suppress the rights of the parliamentary minority,*" as stated by the judge rapporteur Jaromír Jirsa. In his view, this was a proper legislative process. He pointed out that there were hundreds of thousands of people infected with the coronavirus in the Czech Republic at the time the amendment was discussed.

Jirsa also pointed out the absurdity of not using modern means of communication in relation to its citizens, which in this case proved to be fast and effective.

The Constitutional Court thus unanimously rejected the opposition motion, without dissenting opinions. The ruling is available on the website of the Constitutional Court here (*in Czech only*).

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