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Life Sciences Legal Update

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Life Sciences Legal Update offers you insights into the most important legal changes and news in the **pharmaceuticals and life sciences** sector. In this issue, we look at the cancellation of the food worker's health cards, the new pharmaceutical strategy of the European Commission, and the current situation with regard to the ban on CBD sales.

We wish you pleasant reading.

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Revision of European medicines legislation

1. European Commission presents draft pharmaceutical regulations

On April 26, 2023, the European Commission proposed a review of pharmaceutical regulations.[1] The most extensive reform in the pharmaceutical sector in more than 20 years, it aims to make regulation more flexible and better adapted to the needs of individuals and players in the EU pharmaceutical industry. As the European Commission itself states in its press release[2], the revision will make medicines more accessible, available and affordable, support innovation and increase the competitiveness and attractiveness of the EU pharmaceutical industry.

The new legislation addresses the significant obsolescence of current legislation and the resulting problems in the sector, in particular the increasingly frequent critical shortages of medicines, as well as the significant inequalities in the availability of medicines across EU countries. It includes revised and simplified methods for the registration, monitoring, labelling and marketing of all medicines and their patent protection. Last but not least, the new rules, in compliance with the aims of the Green Deal for Europe, address the environmental impact of the production of pharmaceuticals - a topic covered in detail in this article.

However, certain passages of the new legislation have sparked public criticism, particularly, the proposed reduction of patent protection by two years. The European Commission claims this measure will help increase the availability of medicines by allowing generics to enter the market earlier. On the other hand, critics argue that this move will have a negative impact of the incentive for manufacturers of original medicines to invest in innovation, research and development.

We will keep you informed about the further fate of the proposals, which will now be presented and discussed by the European Parliament and the Council.

End of food worker's health cards

2. The amendment to the Public Health Protection Act cancelled so-called food worker's health card

People working in the food industry will no longer need a food worker's health card as a result of an amendment to the Public Health Protection Act[3], which came into force on July 1, 2023. The food worker's health card was cancelled by the legislators as an unnecessary administrative burden. They pointed out that doctors could issue the document indefinitely and with unlimited validity. Thus, a person who had obtained a card for the purpose of replenishing goods in a shop could use it several years later, for example, for work in the processing of raw meat. In addition, medical examinations to obtain the cards were often not very thorough, according to legislators.

The amendment also contains a modification of the Water Supply and Sewerage Act, which aims to improve the safety of drinking water. Water supply operators are now obliged to prepare a risk plan and solution covering the entire system from the water source to the customer's tap.

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[1] Reform of the EU pharmaceutical legislation (europa.eu).
[2] European Health Union: Commission proposes reform of medicines to make medicines more accessible, affordable and innovative (europa.eu).
[3] 167/2023 Coll. - Act amending Act No. 258/2000 Coll., on the protection of public health and on amending certain related acts, as amended, and other related acts (sbirka.cz)

Pharmacy

3. Czech government approves amendment to the Medicines Act

On June 14, 2023, the Czech government approved an amendment to the Medicines Act[4], to curb drug outages in the market. The bill sets out new obligations for drug manufacturers, distributors, pharmacies and state authorities. Among the most important obligations for manufacturers is the obligation to keep sufficient medicines in stock to cover one- or two-months' needs depending on the type of the medicine and the frequency of its shortages on the market.

The draft law introduces a new obligation for drug manufacturers to deliver medicines within one to two months after reporting an outage, with the period depending on the reliability of supply in the previous period. Distributors will now be obliged to inform the State Institute for Drug Control (**SIDC**) about how many packages of a medicine with limited availability they have in stock. This information will allow the Ministry and SIDC to have an overview of the quantity of the product in distribution and therefore available for supply to pharmacies.

The Minister of Health commented on the amendment: "*This amendment represents one of the biggest reforms of the pharmaceutical legislation in the last 15 years, significantly increasing the resilience of the Czech pharmaceutical market against outages and fundamentally strengthening the position of patients. It will enable the Ministry of Health to respond more effectively to drug supply outages and minimize their impact on citizens*."

The draft will now go to the Chamber of Deputies and then through the rest of the legislative process. Its final form is therefore not yet certain. We will keep you informed of any developments in the next edition of the Life Sciences Legal Update.

Tobacco industry and CBD

4. Ban on flavors of heated tobacco products

After the ban of menthol-flavored cigarettes (2020) and other flavors (2016), flavored heated tobacco products will be banned from October 23, 2023. The new regulation is the result of the transposition of Commission Directive 2022/2100[5]. Thus, in the future, flavors will only be allowed in electronic cigarettes and nicotine sachets without tobacco content.

The measures come at a time when taxation is increasing on all categories of nicotine products. The consolidation package, which amends the Excise Act to this end, is ahead of European regulation in terms of its scope. It can be concluded that the existing relatively friendly tax and regulatory policy towards new nicotine products is becoming noticeably stricter. This is true of the approach of both European and national institutions. Thus, it seems that the argument about the potentially lower risk of nicotine alternatives is no longer as strong as it was at the time of their introduction.

5. What about the ban on CBD sales?

In April of this year, the Ministry of Agriculture issued a report that the State Agricultural and Food Inspection Authority (**SAFIA**) was going to issue a measure to ban the marketing of products containing cannabidiol (CBD) and other cannabinoids. This news has aroused public interest and has been commented on by the Minister of Agriculture and the Prime Minister.

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[4] Draft amending Act No. 378/2007 Coll., on Medicinal Products and on Amendments to Certain Related Acts (the Medicinal Products Act), as amended, which on 14 June 2023

[5] B COMMISSION DIRECTIVE IN TRANSMITTED LEGISLATION (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the removal of certain exemptions for heated tobacco products

The Ministry of Agriculture did not come up with the CBD initiative on its own but referred to the European Commission. The European Commission issued a statement in February 2023 that it would, in simple terms, consider CBD products as so-called new food. New food is regulated by the Regulation No. 2015/2283 of the European Parliament and of the Council, on new food[6]. A new food is simplistically defined as a food that was not used to a significant extent for human consumption in the EU before May 15, 1997, and meets other characteristics. Placing such new food on the market is subject to inclusion in the Union list of authorized new food, following an application and assessment by the European Food Safety Authority. The Authority has issued a report which suggests that the inclusion of CBD on the Union list of authorized food will not be fast. The Authority lacks certain data on the potential health effects of CBD. However, the government has postponed a planned measure to regulate the sale of CBD (cannabidiol) in food. The announcement was made by Prime Minister Fiala, who also said a task force would be set up to find a suitable way to ensure that CBD products are not included in the planned ban.

One of the proposed solutions that is currently on the table is a proposal by the national anti-drug coordinator, Jindřich Vobořil, who serves as an advisor to Prime Minister Fiala. Vobořil proposes the creation of a special category of psychomodulatory substances, which would include not only CBD, but also cannabis HHC (a synthetic version of the psychotropic THC) and kratom. These substances would be regulated at a lower level than hard drugs.

The proposed law will precisely define the allowed concentration of these substances in products, and sellers would have to obtain a special license from the state. Sales would be allowed only in person and only to people over 18 years of age. Furthermore, these products would be subject to an excise duty, the amount of which is still under discussion.

[6] REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015 on new food, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (europa.eu)

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