DENTONS

Life Sciences Legal Update

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Dear Readers,

We bring you the first 2024 edition of the quarterly Life Science Legal Update, in which we regularly cover key legal aspects and innovations in the Pharmaceuticals and Life Sciences sectors. The first quarter of 2024 is full of news in the pharmaceutical, healthcare services and food sectors. For instance, there has been much discussion about limiting the availability of HHC substances to consumers; in addition, several implementing regulations for the amendment to the Medicines Act have come into force as well as a new pricing regulation under which health insurers will now be able to request a maximum price for a specific medicinal product as part of an exceptional reimbursement regime. The EU is about to negotiate the draft pharmaceutical package presented by the European Commission. Last but not least, the major amendment to the Significant Market Power Act which has been newly effected, and which largely affects buyer-supplier relationships in the supply of food, agricultural products and other related services.

We wish you pleasant reading.

Contacts:

Tomáš Bílek
Partner, Prague
M +420 602 386 146
tomas.bilek@dentons.com
LinkedIn profil

Adam Přerovský
Senior Associate, Prague
M +420 725 004 238
adam.prerovsky@dentons.com
LinkedIn profil

Anna Urbanová
Associate, Prague
D +420 236 082 289
anna.urbanova@dentons.com
LinkedIn profile

Election of the new head of State Institute for Drug Control is again on the agenda

The Czech State Institute for Drug Control (SÚKL) is looking for a new head once again. The previous director, Kateřina Podrazilová, was appointed only last September. According to the health minister, the reason for her dismissal after less than three months was dissatisfaction with the management of SÚKL. A new selection procedure was announced at the beginning of 2024, with the new appointment to be made in late March/early April 2024.

Implementing regulations for the amendment to the Medicines Act

At the end of last year, the Parliament prepared a significant amendment to the Medicines Act. The amendment, which has a staggered effectiveness from the beginning of 2024, brought new obligations. We covered these in past editions of Life Science Legal Update and, specifically, in an article for the Czech journal, Právní Prostor[1]. The rest of the provisions related to the amendment will come into force on 1 June. Parliament has also prepared a number of amendments to the implementing legislation.

One of the main obligations of holders of a registration decision—which the amendment to the Medicines Act will introduce from 1 June 2024—is to ensure additional supplies of medicinal products whose supply will be interrupted or terminated for a statutory period of time. However, the obligation does not cover all medicinal products; *Decree No 457/2023 Coll*. of the Ministry of Health specifies the exemptions: the obligation will not apply, for example, to influenza and COVID-19 vaccines, diagnostic and therapeutic radiopharmaceuticals and other medicines listed in *Decree No 457/2023 Coll.*

In relation to the obligation to provide information, *Decree No. 461/2023 Coll.*, effective from 1 January 2024, sets a shorter deadline for distributors to provide information on the volume of medicinal products distributed to pharmacies and other healthcare providers, and/or to other distributors or sellers of reserved medicines. This must now be provided by the fifth day of the calendar month following the calendar month the report covers. In addition to shortening the deadline for providing information, the requirements for distributor reporting are also expanded to include identification of the person to whom the medicinal product was supplied, the type of purchaser facility, the person's identification number and the facility identification code, which is now assigned to each individual facility, such as each specific pharmacy. *Decree No. 461/2023 Coll.* establishes an obligation for distributors to provide SÚKL with information about the quantity of medicinal products designated as a "limited availability" product within one working day from the date of the marking as such, and always at the end of each working day for the duration of the marking with this designation.

Furthermore, *Decree No. 460/2023* Coll. sets the deadline for the reporting of holders of a registration decision to 5 days. It also expands the groups of reserved medicinal products and makes minor changes to their registration process.

The amendment to the Decree on Good Pharmacy Practice is addressed in *Decree No. 459/2023 Coll*. One change involves the amount of medicine to be dispensed. If the prescribed medicinal product does not come in the required quantity, according to the dosage form, the pharmacy is obliged to dispense the medicinal product in the nearest pack size with regard to the expected duration of therapy.

Finally, *Decree No. 458/2023 Coll*. restricts the use of prescriptions for so-called repeat prescriptions for medicinal products that have been designated with "limited availability."

[1] Novela zákona o léčivech – naděje, nebo boj s větrnými mlýny? (Amendment to the Medicines Act – hope or a fight with windmills?) | Právní Prostor (pravniprostor.cz)

New price regulation

On 1 January 2024, a new price regulation for medicinal products and food for special medical purposes also came into force.

Under the new regulation, health insurance companies will be able to request to set the maximum price for a medicinal product or special foods for medical purposes, which, according to *Section 16 of Act No.48/1997 Coll.,* on Public Health Insurance, are generally not reimbursed by health insurance. However, the insured person may exceptionally request the health insurer to reimburse them on the basis that that medicine is the only option in terms of the insured person's condition. In that case, not only the products covered under the aforementioned Section 16 but also the commercial surcharge will be subject to price regulation.

Another amendment divides the trade surcharge between distributors and pharmacies according to fixed percentages, whereby the last distributor supplying a pharmacy must always receive at least CZK 1.50, excluding VAT.

Amendment to the Decree on food supplements

The Ministry of Agriculture has submitted to the Parliament an amendment to the Decree on food supplements and food composition. The draft amendment has already been subject to the comment procedure. The amendment sets the effective date at 1 July 2024, but thanks to a transitional provision, foods labeled and marketed before the effective date can still be sold until stocks run out.

This amendment also proposes to extend the list of substances that cannot be included in food products. The ban would apply not only to the addition of these substances but also to their natural presence in the food. In other words, foods that have such substances in them by nature are also prohibited. In particular, list now includes kratom plant (Mitragyna speciosa), kratom extract and HHC (hexahydrocannabinol).

Kratom was added to the list primarily to protect consumers, as it is a substance with the potential to become addictive, a negative impact on human health and it carries a potential risk of being consumed by children or adolescents. Some substances, such as melatonin, will be removed from the list of banned substances.

Amendment to the government regulation on lists of addictive substances

Following a number of reports of HHC overdoses in the media, the substances hexahydrocannabinol (HHC), hexahydrocannabinol-O-acetate (HHC-O) and tetrahydrocannabinol diphosphate (THCP) were added to the list of psychotropic substances as part of Government Regulation No. 463/2013 Coll. in its Annex 4. The amendment to the government regulation came into force on 6 March 2024. At the same time, the regulation does not provide for any transitional period that would delay its application and enforcement in practice. Thus, from 6 March 2024, HHC should become unavailable to ordinary consumers. However, this is essentially only a temporary ban, which is expected to end on 1 January 2025, when the forthcoming amendment to the Addictive Substances Act, discussed below in this newsletter, is expected to come into force.

EU pharmaceutical package

In the autumn of 2023, the Senate adopted a resolution on the European Union's revised package of pharmaceutical legislation, which aims to ensure timely access to high-quality, safe and effective modern medicinal products, while maintaining both the affordability of these products and the competitiveness of the European pharmaceutical industry. Another objective of the pharmaceutical package is to reduce inequalities among EU citizens in the ability to access the medicinal products. In addition, the resolution stresses the need to ensure intellectual property protection, which goes hand in hand with a predictable and stable regulatory framework.[2]

The pharmaceutical package brings the possibility of central purchasing of new (and therefore expensive) medicines. For example, during the pandemic vaccines against COVID-19 were purchased in a similar way. The aim here is to reduce the price of these innovative medicines and thus make them more accessible to all EU citizens. Another point that appears in the package is an attempt to reduce the administrative burden related to registering new medicines. In this respect, the provision concerning data protection is somewhat unwelcome, as there are certain concerns about weakening intellectual property protection, thereby potentially discouraging investors and reducing the attractiveness of the European pharmaceutical market.

The pharmaceutical package as a proposal from the European Commission will now be discussed at the EU level, and each member state will have its opinion—which is likely to lead to numerous changes. Therefore, negotiations will most likely continue for several months before a final proposal is drawn up. How various member states are approaching the package is also problematic for its passing; some of them more or less support the idea of protecting patients, while others focus more on protecting manufacturers and the pharmaceutical industry.

As for the pharmaceutical package, it is clear at this point that the current composition of the European Parliament will not be able to approve it before the elections this June. A thorough analysis of the proposal and a vote will therefore have to wait for the new legislature, which first convenes on 16 July.

Amendment to the Addictive Substances Act

The amendment to the Addictive Substances Act introduces two categories of psychoactive substances: "psychomodulants" and "new psychoactive substances." One of the aims of this amendment is to protect consumers and to prevent the sale of certain substances to minors by addressing concerns regarding the so-called grey zone, where the Czech Republic lacks regulation. These are substances that are psychoactive but have low social and health risks and are therefore not controlled as narcotic or psychotropic substances. To give an idea of the substances that will likely be affected by the amendment, we include, for example, kratom and low-potency cannabis.

Therefore, under the amendment the marketing or handling of substances categorized as psychomodulants would be subject to strict conditions. The amendment defines psychomodulants as substances that present a low risk of negative health and social impacts on individuals and society and that, when used in an informed manner, contain an acceptable risk of dependence for an adult. In view of this general definition, it is envisaged that the list of psychomodulatory substances will be extended in the future and that implementing regulations will be introduced, probably for individual psychomodulatory substances, setting the maximum permitted amount or maximum concentration of the active substance, together with other parameters.

Another category introduced by the amendment is psychoactive substances. These are substances that are psychoactive but their impact on health is unknown. It will be possible to handle these substances in the context of research, but it will not be possible to place them on the market. An example is the substance HHC, which has been mentioned in the media in recent months.

[2] 290th resolution of the Senate of the 18th meeting held on 8 November 2023.

At this point, an amendment to the bill submitted by the Ministry of Health should be ready. According to Health Minister Válek, he would like to have the amendment approved by the end of spring. Once approved, the law will need to be notified to the Commission, as the law will interfere with the free movement of goods within the EU internal market.

Health insurance amendment reopens possibility of above-standard healthcare coverage

Health Minister Vlastimil Válek plans to submit a draft amendment to the Public Health Insurance Act by the end of the first half of 2024. One of the main objectives of the amendment is to motivate people to take care of their health in a more responsible manner.

The amendment talks about the possibility in the future of a "personal account" where people would collect points if they take care of their health, for example by going for preventive checkups. These points could then be used to earn rewards or allowances for spas, dental cleanings and other similar services. Furthermore, the amendment emphasizes physical activities, through which the minister aims to motivate citizens and even include them in the treatment process.

Another of the many proposals is to reintroduce, for a higher payment, a "premium healthcare policy," which would cover additional healthcare services. So far, there has been talk of possibly adding coverage for various dental procedures, such as for prostheses, or for access to a doctor and care in a nursing home. Patients who pay for the premium coverage would not have to pay for the currently unreimbursed services themselves. Finally, the amendment also aims to deal with access to healthcare, where the main point is systemic change; in this respect the amendment increases the competence of insurance companies in this area.

Despite the suggested fixes, critics cite as the main inconvenience the fear of deepening social inequality and the impact on the health of socially vulnerable citizens who, for example, cannot afford to request time off work to undergo preventive checkups due to their time-consuming jobs.

Significant Market Power Act expands who is considered to have market power

On 1 January 2024, the amendment to the Significant Market Power Act (the Act) came into full force. In particular, the amendment transposed into national legislation EU Directive 2019/633 on unfair commercial practices between undertakings in the agricultural and food supply chain. The key new element, which affects a wide range of addressees, was the extension of the concept of significant market power to the entire supply and supply chain. With this amendment, any customer in the chain has market power if its turnover exceeds €2 million and at that turnover exceeds that of the supplier.

It is therefore important to bear in mind that the Act will apply to the entire customer-supplier chain from the entry into force of this amendment. An important consequence of this is that contracts concluded in the past must be adjusted in connection with the amendment to the Act; for example, it is crucial to be transparent in any negotiations on discounts. Specifically, this means specifying in advance the amount of the discount or the way it is determined.

At the end of 2023, informal discussions with the Office for the Protection of Competition (ÚOHS) revealed that it would focus its investigative activities on the enforcement of the new rules arising from the Act. ÚOHS lived up to its words; at the beginning of 2024 it launched administrative proceedings in connection with Act against Košík.cz s.r.o. and Heineken Česká republika, a.s.

Commission report on active competition enforcement in the pharma sector

At the end of January 2024, the European Commission published the Report on active competition enforcement in the pharmaceutical sector. The Commission's report provides an overview of the application of EU antitrust rules and merger control in the pharmaceutical sector from 2018 to 2022, both by the Commission and by national competition authorities. The Report shows that over the period, the Commission and the national competition authorities investigated more than 70 cases affecting the pharmaceutical sector. Of these 40 were able to be closed by the time of the Report's release.

In 26 cases, fines totaling more than €780 million were imposed. In half of these 26 decisions, the competitor was found to have abused its dominant position. The remaining decisions concerned hard cartels (31 percent), vertical agreements (11 percent) or agreements between originator and generic manufacturers not to enter the market (pay-for-delay agreements) (8 percent). These figures can be contrasted with the results of a similar report covering 2009–2017, where abuse of dominance accounted for 45 percent of all fined cases, pay-for-delay agreements (31 percent), direct cartels (17 percent) and vertical agreements (17 percent). Thus, a declining trend of investigations by the Commission and national authorities regarding pay-for-delay agreements can be observed.

As regards merger control, the Report notes that the Commission has reviewed more than 30 mergers in the pharmaceutical sector and found in five cases that they could increase prices, jeopardize the availability of certain medicines to patients and/or undermine innovation efforts in the field of new medicines. Four of the mergers examined were eventually cleared after the companies concerned submitted remedies that would maintain the existing level of competition. The Commission's initial competition concerns regarding one merger led to it being abandoned.

No more bonus gifts for cigarettes and alcohol purchases

The consolidation package, effective from the beginning of this year, includes the seemingly inconspicuous innovation of a ban on adding "gifts" to the purchase of tobacco products, electronic cigarettes, nicotine sachets and other listed products. Until now, it has been a relatively common practice for retailers to add lighters, chewing gum and alcoholic beverages, including hard alcohol, to the purchase of typically larger quantities of cigarettes. The explanatory memorandum to this amendment highlights that the combination of alcohol and nicotine prompted the legislative change.

In addition to adding gifts to the purchase of nicotine and similar products, it is now also prohibited to add these products as "gifts" in connection with the sale of any goods and services. For example, the formerly common practice of adding free nicotine sachets to the purchase of cigarettes is no longer allowed.

Life Sciences team Prague

Tomáš Bílek
Partner, Prague
D +420 236 082 226
tomas.bilek@dentons.com
LinkedIn profile

Adam Přerovský
Senior Associate, Prague
D +420 236 082 241
adam.prerovsky@dentons.com
LinkedIn profile

Ivana Štorková
Senior Associate, Prague
D +420 236 082 111
ivana.storkova@dentons.com
LinkedIn profile

Jitka Soldado
Senior Associate, Prague
D +420 236 082 233
jitka.soldado@dentons.com
LinkedIn profile

Anna Urbanová
Associate, Prague
D +420 236 082 289
anna.urbanova@dentons.com
LinkedIn profile

Vladimír Kreiža
Junior Associate, Prague
D +420 236 082 279
vladimir.kreiza@dentons.com
LinkedIn profile

Tomáš Jonáš
Junior Associate, Prague
D +420 236 082 260
tomas.jonas@dentons.com
LinkedIn profile

Robert Květoň
Junior Associate, Prague
D +420 236 082 263
robert.kveton@dentons.com
LinkedIn profile

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