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Life Sciences Legal Update Q1 2022

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We have prepared for you a brief overview of selected legal and regulatory developments adopted in the Czech Republic and at the European Union level.

The first quarter of 2022 marked a legislative boom in the life sciences sector. The amendment to the Medicines Act came into force at the beginning of the year together with the amendment to the Addictive Substances Act. In addition to the rules for prescribing medicinal cannabis and the increase in the permitted dose of the active substance THC in industrial hemp and its products, the amendments also resulted in the regulation of websites offering medicines and the introduction of a central repository for vaccination records. There are also changes in the areas of veterinary medicinal products, the regulation of advertising of *in vitro* medical devices and in the labeling of food and food supplements.

Contacts:

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

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

Medical Devices

1. New legislation on the regulation of advertising of *in vitro* medical devices

The Chamber of Deputies is currently considering two bills to implement the new European Union regulation on *in vitro* diagnostic medical devices (IVDR)[1] and to unify the Czech legal system in this area[2].

The draft laws include a number of significant changes; the following are of particular interest:

- **Definition of an expert as a recipient of advertising**—an "expert recipient of advertising" for medical devices and *in vitro* diagnostic medical devices would also include health service providers (e.g. hospitals) and their employees (e.g. nurses).
- **Permissible content for catalogues and price lists**—these documents are currently not considered advertising so long as they do not include a description (characteristics) of the respective medical devices and *in vitro* diagnostic medical devices. Under the contemplated legislation changes, catalogues and price list would be permitted to include at least a basic description of the devices necessary for their identification.
- **Requirements for advertising aimed at professionals**—advertising of medical devices and *in vitro* diagnostic medical devices aimed at professionals would no longer have to include instruction for the device's use; this requirement proved impractical in the advertising sphere since the instructions were frequently several pages long.

The above bills are expected to take effect from May 26, 2022.

2. Amendment to the price regulation on the regulation of medical devices

With effect from February 1, 2022, the price regulation of the Ministry of Health on the regulation of prices of medical devices has been amended[3]. The price regulation regulates the year-on-year permissible increase in prices of the originator of medical devices. It is now possible to increase the originator price by a maximum of 4 percent (compared with the previous 3 percent).

3. *In vitro* diagnostic medical devices regulation—Transition Periods

EU Regulation 2017/746 on *in vitro* diagnostic medical devices (IVDR) will be effective from May 26, 2022. However, the obligation to place unique identifier carriers—which is part of the Unique Device Identification system (UDI system)[4]—will come into force for IVDs gradually, depending on their risk classification.

For class D (highest risk*) in vitro* medical devices, the obligation to carry a unique identifier applies from May 26, 2023; for class B and class C *in vitro* devices, this obligation applies from May 26, 2025, and for class A (lowest risk) *in vitro* devices, this begins to apply only from May 26, 2027.

4. Central repository of electronic vouchers launched

In accordance with the Medical Devices Act[5], the Ministry of Health launched a central repository of electronic vouchers on January 1, 2022. This will ensure the collection and storage of electronic vouchers, the collection and

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[1] Regulation (EU) 2017/746 of the European Parliament and of the Council of April 5, 2017 on *in vitro* diagnostic medical devices.
[2] See parliamentary print no. 167 and no. 168.
[3] Ministry of Health Price Regulation 2/2022/OLZP, dated January 7, 2022, amending Price Regulation 1/2019/CAU, dated May 22, 2019, on the regulation of prices of medical devices.
[4] The Unique Device Identification (UDI) system is a standardized system for identifying medical devices introduced by the Medical Devices Regulation (EU) 2017/745 and the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746. The aim of the UDI system is in particular to allow easier identification and traceability of medical devices. More information on the UDI system is available on the European Commission website.
[5] Act no. 89/2021 Coll., the Act on Medical Devices and on the amendment of Act No. 378/2007 Coll., on Medicinal Products and on Amendments to Certain Related Acts.

storage of records on the dispensing of medical devices on electronic vouchers as well as information relating to the handling of electronic vouchers.

Medicinal products

1. List of websites offering illegal medicines

With the entry into force of the amendment to the Medicinal Products Act[6], on January 1, 2022, SÚKL introduced a blacklist of websites with unlawful offers of medicines. The list includes websites offering both illegal and counterfeit medicines. The law obliges internet access providers to block access to these sites within 15 days from the date of their publication in the list. The first 22 sites were listed on March 10, 2022, and the list has gradually been growing.

Access to the complete list can be found on the SÚKL website (in Czech only).

2. Amendment to the Decree on Registration of Medicinal Products

An amendment to the Ordinance on the Registration of Medicinal Products[7] was adopted primarily to implement full adaptation of the Czech legal system in relation to the European Regulation on Medical Devices[8]. Important changes related to registration apply mainly to the area of summary product information, namely in the following areas:

- **Content and structure of the summary of product information** (Annex 3)
- **Content and structure of the package leaflet** (Annex 4)
- **Information to be provided on the packaging** (Annex 5)

The amendment entered into force on March 8, 2022, but it provides for a seven-year transition period for marketing authorization holders. During this time, it is sufficient to comply with the conditions set out in the pre-amended version of the law. However, from March 8, 2029, all holders must be in a full compliance with the new legislation.

3. New decrees – prices, prescription and good pharmacy practice

Prices and reimbursement of medicinal products and foods for special medical purposes (FSM)

The decree[9], which came into force on January 1, 2022, brings a number of changes. Particularly the following:

- Changes in the specification of administrative procedures,
- Unification of price discovery for medicinal products,
- Modification of the procedure for excluding price references with a pack size variation of more than 10 percent.
- Uniform introduction of an administrative fee of CZK 2,000 for accepting an application for setting or changing the maximum price or the amount and conditions for reimbursement of a medicinal product or food for special medical purposes[10], with effect from January 1, 2022.

[6] Act No. 378/2007 Coll., the Act on Medicinal Products and on Amendments to Certain Related Acts (the Medicinal Products Act).
[7] Decree No. 27/2022 Coll., amending Decree No. 228/2008 Coll., on the Registration of Medicinal Products, as amended.
[8] Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.
[9] Decree No. 525/2021 Coll., amending Decree No. 376/2011 Coll., implementing certain provisions of the Public Health Insurance Act. Available under link here.
[10] Decree No. 527/2021 Coll.

Prescription of medicinal products in the provision of health services[11], registration and documentation of addictive substances

Decree No. 522/2021 amending Decree No. 329/2019 Coll. on the prescription of medicinal products in the provision of health services, effective from 1 January 2022, has been published in the Collection of Laws. It is a reaction to the changes made in the amendment to the Act on Addictive Substances, especially in the area of:

- Prescribing of medicinal products containing addictive substances,
- Keeping records of vaccinations administered to patients using the existing electronic prescribing system,
- Keeping electronic records in the pharmacy also for certain medicinal products containing addictive substances.

Good pharmacy practice

Furthermore, the Decree on good pharmacy practice[12] was amended as a result of the adoption of the amendment to the Medicinal Products Act. However, this is only a legislative-technical change.

Amendment to the Act on addictive substances

Relaxed rules on cannabis cultivation

With effect as of January 1, 2022, the legal regulation[13] of the disposal of certain categories of cannabis has become more relaxed, and the market for medicinal cannabis has been liberalized.

The most significant changes introduced by the amendment particularly include:

- Increase in the legal THC content of technical hemp from 0.3 percent to 1.0 percent. Cultivation of technical hemp is, in principle, not subject to official authorization.
- End of the "monopoly" of one supplier on the cultivation of medical cannabis—anyone who now applies to the State Institute for Drug Control (SÚKL) and meets the conditions set out by the regulation can cultivate medical cannabis.

Veterinary medicinal products

1. Completely new legislation on veterinary medicinal products and medicated feed

On January 28, 2022, European regulations on veterinary medicinal products and medicated feed came into force. These regulations are as follows:

- Veterinary Medicinal Products Regulation[14]
- Regulation laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[15]
- Regulation on the manufacture, placing on the market and use of medicated feed[16]

A detailed transposition of the Veterinary Medicinal Products Regulation into the Czech legal system has not yet taken place; however, as of January, it introduces directly applicable rules for the authorization, labeling,

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[11] Decree No. 522/2021 amending Decree No. 329/2019 Coll., on the prescription of medicinal products in the provision of health services, effective from 1 January 2022.

[12] Decree No. 84/2008 Coll., on good pharmacy practice, detailed conditions for the handling of medicines in pharmacies, health care facilities and other operators and establishments dispensing medicinal products, as amended.

[13] Act no. 167/1988 Coll, Act on Addictive Substances.

[14] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

[15] Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018.

[16] Regulation (EU) 2019/4 on the manufacture, placing on the market and use of medicated feed.

manufacturing, distribution, control, use, pharmacovigilance and even advertising of veterinary medicinal products and medicated feed.

Food Supplements/Food

1. Amendment to the Decree on Sampling, Preparation and Testing Methods of Control Samples effective from April 1, 2022

- **Amendment to Decree No. 231/2016 Coll., On the collection, preparation and testing methods of control samples of food and tobacco products**

The main goal of the amendment is, in particular:

- Adaptation of Czech legislation to the Regulation on official controls[17] regarding sampling during official food controls,
- Addition of new rules and related annexes to this decree, which regulate the procedure for assessing the test result for the second expert opinion;
- Taking practical experience into account as regards the decree's application (e.g. the circumstances of transport of the sample to the laboratory).

2. National list of certain plants for use in the manufacture of food supplements

The Ministry of Agriculture has issued a National List of certain plants for use in the manufacture of food supplements. The document has a recommendatory nature and contains an open list of plants or their parts that may be used in the production of food supplements. For some plants, the list also specifies the conditions for their use.

The list contains only plants produced by traditional growing methods. The list does not affect the obligations of food business operators under applicable national and European legislation, in particular the obligation to place only food supplements on the market that are safe and do not pose a risk to human health.

The list is available here (with explanatory notes in Czech and in English, although the list itself is in Czech only).

3. Change in manufacturer's labeling

On January 1, 2022, an amendment to the Food and Tobacco Products Act[18] came into force, which newly established rules for labeling concerning the manufacturer when placing food and food supplements on the market.

When placing food on the market, information about its manufacturer may be provided by the word "manufacturer" or by a term having the same meaning for the consumer, provided that the name is followed by the name or business name and address of the food business operator who produced the food ("manufacturing" means the cleaning, sorting, conditioning, working and processing, including associated packaging, for the purpose of placing on the market, except for activities consisting only of a separate packaging process or slicing or other division of food, including their subsequent packaging).

If the food business operator's registered office and the place of business in which the food was manufactured are located in different countries, the name of the country in which the place of business is located, preceded by the words: "place of business" must also be stated on the package.

At the same time, the law sets out a transitional period. During this time foodstuffs placed on the market or labeled before the date of entry into force of the amendment may be sold until such stocks are exhausted.

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[17] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017.
[18] Act No. 110/1997 Coll., On Food and Tobacco products.

4. End of the transitional period for use of non-compliant trademarks

January 19, 2022 marks the end of the transitional period under the European Regulation on nutrition and health claims made on foods[19]. During this transitional period, products bearing a trademark or brand name that existed before January 1, 2005 and that did not comply with this regulation could be marketed until January 19, 2022. From that date on, all trademarks must comply with the rules for the use of nutrition and health claims set out under this regulation.

Reimbursements to the State Institute for Drug Control

In accordance with new legislation, the State Institute for Drug Control (SÚKL) is now obliged to collect reimbursements for its professional procedures or consultations[20]. The exact amount of these reimbursements is determined by the Ministry of Health, which has already adopted several implementing legal regulations in this regard:

1. Health Insurance

As of January 1, 2022, Decree No. 527/2021 Coll. determines the reimbursement amounts collected by SÚKL under the Public Health Insurance Act[21]. For example, for the preparation of an expert opinion on an application for determining the maximum price of a medicinal product, SÚKL will collect a reimbursement of CZK 9,900.

2. Addictive Substances

As of March 15, 2022, Decree No. 53/2022 Coll. sets forth the reimbursement amounts collected by SÚKL under the Addictive Substances Act[22]. For example, for actions performed in connection with an application for a license to cultivate cannabis plants for medicinal use, SÚKL may collect a maximum of CZK 52,200 in reimbursements.

We will keep you regularly informed about any legal updates via newsletters or LinkedIn social network.

[19] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of December 20, 2016.
[20] For example, Section 39f(14) of Act No. 48/1997 Coll., on Public Health Insurance and on Amendments and Additions to Certain Related Acts, as amended.
[21] Decree on determining the amount of reimbursement for professional acts and the method of determining the amount of reimbursement for professional consultations carried out by the State Institute for Drug Control under the Public Health Insurance Act.
[22] Decree on the determination of the amount of reimbursement of expenses for professional acts performed by the State Institute for Drug Control under the Act on Addictive Substances.

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

Blanka Crháková
Associate, Prague
D +420 236 082 256
blanka.crhakova@dentons.com
LinkedIn profile

Samuel Bodík
Associate, Prague
D +420 236 082 231
samuel.bodik@dentons.com
LinkedIn profile

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

Jan Petráš
Paralegal, Prague
D +420 236 082 483
jan.petras@dentons.com
LinkedIn profile

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