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Life Sciences Legal Update Q2 2022

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We bring you the summer edition of our regular Life Sciences legal news.

While everyone is on vacation, we've prepared a summer edition full of hot news from the Pharmaceuticals and Life Sciences sectors. Whether you're chilling on the beach or on your way to a summer festival, you now have the perfect opportunity to flick through our roundup of the most important legal developments in the industry.

July 1 marks the first day of the holiday season as well as the start of the Czech Presidency of the European Council, which includes the healthcare sector among its priorities. The European Commission is preparing a revision of EU pharmaceuticals legislation, a decision of the Ministry of Health helps to clarify a recent amendment concerning prices and reimbursements of medicinal products, and legislation on medical devices was not left out of the news. And those who read to the end will discover upcoming changes to pharma's blockchain trials.

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Czech Presidency of the European Council—Healthcare is a priority

The Czech Republic has assumed its second EU presidency (the first being in 2009), which will run from July 1, 2022 to December 31, 2022. The priorities of the presidency are largely influenced by the war in Ukraine, thus the primarily focus is on the strategic resilience of the European economy, managing the refugee crisis, energy security, strengthening European defense capabilities and post-war reconstruction in Ukraine. However, priorities in healthcare have also been given a place, including the following areas:

- Oncology
- Availability of treatment for rare diseases
- Vaccination
- Strengthening the EU's global role in health

What can we expect from these priorities? In this respect, the Czech Republic plans to submit (i) proposals for a regulation on the European Health Data Space (EHDS), (ii) revisions to the Blood Directive and the Tissue and Cell Directive[1], and (iii) a proposal for a regulation on European Medicines Agency (EMA) fees. We would also like to bring to your attention the progress report to be presented at the December Employment, Social Policy, Health and Consumer Affairs Council (EPSCO).

Medicinal products

1. Upcoming revision of European medicinal legislation

All indications are that a major revision of rules at the EU level for the functioning of the European pharmaceutical market is imminent. The revision was the subject of the June "Pharmaceutical Strategy for Europe" conference organized by the Senate of the Parliament of the Czech Republic in cooperation with the Czech Association of Innovative Pharmaceutical Industry (AIFP). In particular, both Directive 2001/83/EC on the Community code relating to medicinal products for human use, and Regulation 726/2004, which lays down the procedures for the authorization and supervision of medicinal products, will likely be affected by the revision. In addition to a number of new rules aimed at ensuring the quality, efficacy and safety of medicines, the expert community also expects the revision to place a major emphasis on research and innovation in the pharmaceutical system as a means of making it more competitive and crisis-proof. Last but not least, European legislators aim to ensure faster and easier access to (not only) innovative medicines. After such medicines are first registered in a member state, they tend to take a long time to reach patients from economically weaker countries. However, we will have to wait for the actual content of this series of amendments, which the European Commission plans to present towards the end of this year.

2. Czech Ministry of Health decision clarifies interpretation of amendment to Public Health Insurance Act[2] regarding prices and reimbursement of medicinal products

The amendment to the Public Health Insurance Act came into force in January this year, and it has raised many issues, especially related to the so-called "third route" for highly innovative medicines (such as orphan drugs), especially in terms of the availability of these medicines. In this respect, the decision of the Ministry of Health in the case of the medicinal product KYPROLIS has shed more light on the definition of the indication and the overall management of the procedure under Section 39da of the Public Health Insurance Act. This decision shows that if a medicinal product designed to be an orphan drug has multiple indications (as is the case with KYPROLIS), this is

[1] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
[2] Act No. 48/1997 Coll. on Public Health Insurance and on Amendments and Supplements to Certain Related Acts.

not an obstacle to its reimbursement from the public health insurance. In fact, the provision of Section 39d of the Public Health Insurance Act, according to which reimbursement is determined for highly innovative medicinal products, does not include the same condition as the provision of Section 39da, i.e. that the application must not be submitted for the same indication. According to Section 39d of the Public Health Insurance Act, a highly innovative medicinal product may also be granted reimbursement for use in a specific therapeutic regimen if its benefit for the treatment of a severe disease has been sufficiently substantiated on the basis of available data.

3. European Commission opens investigation into possible anticompetitive product disparagement in the pharmaceutical sector

The Commission has opened an investigation into Vifor Pharma's conduct aimed at restricting competition by illegally denigrating Monofer, a product manufactured by Pharmacosmos—Vifor Pharma's direct (in fact only) competitor on the European market for intravenous iron therapy. Vifor Pharma is alleged to have disseminated misleading information about the safety of Monofer over a period of several years in order to favor of its own, highly successful, product Ferinject.

The Commission's press release is available at here.

Provision of healthcare services

4. Czech Constitutional Court rejects "complaint for everything"

A proposal by a group of 48 senators to annul selected provisions of the Public Health Insurance Act (in particular provisions related to setting reimbursements) and the Health Services Act (and certain decrees) was rejected by the Czech Constitutional Court[3]. The complaint was so broad that it was aimed at changing the de facto entire system of healthcare financing (which in its current form was described as completely misconceived, unethical and non-transparent) and earned the working title "complaint for everything." Although the Czech Constitutional Court has admitted that some mechanisms may be ill-conceived, and has not even ruled out future constitutional review, it has been clear about its role, which is not intended to be the formulation of state health policy.

5. Amendment to Decree on method of valuation of costs of healthcare services

A new decree on the method of valuating costs of healthcare services for the purposes of redistribution of premiums from public health insurance has been published in the Collection of Laws. The decree aims primarily to amend the established system of valuation of individual healthcare services for health insurance companies, which subsequently reimburse these (reimbursed) costs of healthcare services from public health insurance. For example, the Decree differentiates the costs of health services according to whether they were reported by providers of outpatient care, acute inpatient care, long-term inpatient care or health services reported by providers of emergency medical services. This decree became effective on 30 April 2022.

Medical devices

6. Decree implementing certain provisions of the Medical Devices Act relating to electronic prescriptions

The Decree[4] of the Ministry of Health regulates in detail the procedure and conditions for communication of prescribers and dispensers with the electronic prescription (eRecipe) system, in particular:

- The form of the electronic prescription identifier;

[3] The ruling of the Constitutional Court Pl. ÚS 49/18 available here (in Czech only).
[4] Decree No. 98/2022 Coll., on the method of valuation of costs of health services for the purpose of redistribution of public health insurance premiums.

- The method of sending requests for the creation, modification and cancellation of an electronic prescription by prescribers;
- The scope of the data required for the creation, modification and cancellation of an electronic prescription and related details; and
- The way the identification data of the person authorized to prescribe or dispense the device must be communicated to the State Institute for Drug Control.

The Ministry further briefly states that the Decree was prepared to implement new, enabling provisions contained in the Medical Devices Act relating to a voluntary use of electronic prescriptions for medical devices.

Teaser

7. ‘Blockchain and pharma’ is no longer just an echo from the future—PharmaLedger platform

PharmaLedger is an ambitious blockchain project, supported by the EU and the Innovative Medicine Initiative—a European PPP—and in collaboration with pharmaceutical companies and blockchain developers, which in its first phase aims to resolve several pressing problems in the pharmaceutical industry, including the possibility of implementing electronic package inserts.

We will look at how the whole project is supposed to work, what exactly the connection between blockchain and the pharmaceutical industry means, as well as what adjustments will need to be made to current legislation to make the whole project possible—in a separate post. Stay tuned!

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