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Legal Update

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Czech Republic: Proposed new medicinal product supply obligations and mandatory stock requirements

Draft amendment to the Act on Medicinal Products and the Act on Public Health Insurance

In brief

Progress in legislative process and summary of key proposed changes under the draft amendment to the Act on Medicinal Products and the Act on Public Health Insurance

In depth

As many other countries in the EU, the Czech Republic has repeatedly experienced shortages in the supply of medicinal products for human use ("**Medicinal Products**"). In response to this unfavorable situation, the Government of the Czech Republic prepared and submitted for discussion to the Parliament of the Czech Republic a draft amendment to Act No. 378/2007 Sb. on Medicinal Products and on Changes to Some Related Acts, as amended ("**Act on Medicinal Products**"). This draft aims to implement new tools and obligations meant to improve the availability of Medicinal Products for patients in the Czech Republic, which will affect practically all links of the distribution chain. During the consideration process before the Chamber of Deputies of the Parliament of the Czech Republic, a number of legislative riders were introduced (such as the widely discussed comprehensive legislative rider originating with the Ministry of Health of the Czech Republic ("**Ministry**")), including the proposed amendments to Act No. 48/1997 Sb., on Public Health Insurance on Changes and Supplements to Some Related Acts, as amended ("**Act on Public Health Insurance**").

On 15 November 2023, the respective draft amendment to the Act on Medicinal Products and the Act on Public Health Insurance (including some of these legislative riders) ("**Amendment**") was approved by the Chamber of Deputies of the Parliament of the Czech Republic and will now be submitted to the Senate of the Parliament of the Czech Republic for discussion.

Although the legislative process for the Amendment has not been completed yet, and the Amendment wording cannot, therefore, be considered final, we would like to provide an overview of the proposed legislative changes most relevant for Medicinal Product distributors and marketing authorization holders (MAH).

I. Summary of key proposed changes

A. Measures to ensure the availability of scarce Medicinal Products with the "limited availability" flag

Among other things, the Amendment authorizes the State Institute for Drug Control ("**Institute**") to identify certain Medicinal Products as having the "limited availability" flag. This concept comes into play in the context of an interruption or termination of marketing of a Medicinal Product, provided that the following conditions have been met:

a. The relevant Medicinal Product is one (i) that is subject to the determined reimbursement from public health insurance or maximum price, (ii) that is not subject to an exemption from this duty according to the relevant implementing regulation (which is expected to enlist Medicinal Products that are difficult to stock in practice, such as seasonal vaccines or radiopharmaceuticals) and (iii) for which the interruption/termination of its marketing has been notified.

b. The Institute determines that the needs of patients in the Czech Republic cannot be sufficiently covered by the quantity of the above Medicinal Product currently available or the corresponding quantity of another substitute Medicinal Product with corresponding therapeutic properties.

If the above conditions have been met, the Institute will assign the "limited availability" flag to the respective Medicinal Product as well as the substitute Medicinal Product. This will trigger a number of special **measures aimed at ensuring the availability of the Medicinal Product with the "limited availability" flag on the market**, including at the level of the individual links within the distribution chain. For example:

- **The MAH** will be obligated to publish — through a publicly accessible professional information service — a list of the distributor(s) distributing the Medicinal Products with the "limited availability" flag on the Czech market (which should allow pharmacies to know where to buy the Medicinal Product).
- **Pharmacies** will only be allowed to order Medicinal Products with the "limited availability" flag from distributors on a limited basis (i.e., within the limits prescribed in order to prevent panic buying and pharmacies overstocking).

  In this regard, the Amendment provides a number of detailed rules defining the respective order quantity limits. For example, a pharmacy operator can only order the Medicinal Product so that its quantity in the pharmacy does not exceed the usual number of its packages dispensed in one calendar week over the last 12 calendar months; if no package was dispensed within this period, the Medicinal Product can be ordered in the quantity prescribed on a particular prescription. Special rules apply in relation to pharmacies supplying in-patient hospitals.
- **A distributor** will be obligated (i) not to distribute any Medicinal Product with the "limited availability" flag that has been intended for the Czech market by the MAH outside the Czech Republic and (ii) to deliver the Medicinal Product with the "limited availability" flag ordered by a pharmacy in line with the prescribed limits to that pharmacy within two business days from receiving the order.

  In practice, whether a pharmacy order was made in line with the prescribed limits (as described above) can be difficult to verify for a distributor, particularly if the distributor does not have access to up-to-date data about the stock and dispensation of Medicinal Products in the particular pharmacy, and considering that the pharmacy can order from multiple distributors at the same time. Thus, it remains to be seen whether and to what extent the supply obligation under point (ii) can be satisfied by (or enforced against) a distributor.

The Amendment also regulates a **number of notification and information duties for individual market entities** in this respect, particularly with regard to the data that should enable the Institute to maintain an overview of the developments in the Medicinal Products' stock on the market.

In addition, based on a legislative rider, the Amendment now provides that, in relation to Medicinal Products with the "limited availability" flag, the Institute will make the following information available through the eRecept system:

a. To pharmacies: information about the quantity of the Medicinal Product, as reported by distributors, and data on the distributors that have it available.
b. To prescribing medical doctors: information about the quantity of the Medicinal Product, as reported by pharmacies and the pharmacies that have it available (this data will also be accessible to a patient to whom the Medicinal Product was prescribed through the relevant patient application).

B. Changes in duties to ensure the supply of Medicinal Products to the market in the Czech Republic

The Amendment proposes **abolishing regulation of the so-called protected distribution system** (including the concept of a privileged distributor and the duty of the MAH to supply the privileged distributor so that the Medicinal Product is available to it in a quantity corresponding to at least the so-called two-week average demand), which was embedded in the Act on Medicinal Products by the lex Pawlas amendment in 2019. The enforceability of the protected distribution system has been contested since its being established.

Instead, the Amendment imposes new duties on both MAHs and distributors. These duties are to ensure the availability of Medicinal Products in the Czech market. A brief description of these duties is provided below.

B.1 Key duties of MAHs to supply Medicinal Products to the market

The Act on Medicinal Products preserves the **general availability duty of a MAH**, i.e., the duty to ensure the availability of Medicinal Products for the needs of patients in the Czech Republic by supplying them to the market in appropriate quantities and at appropriate time intervals.

In addition, the Amendment introduces a **new supply obligation of the MAH, which is applicable in the event of an interruption/termination of marketing of certain Medicinal Products**, namely where the Medicinal Product meets all of the following conditions:

a. It is subject to the determined reimbursement from public health insurance or the determined maximum price.

b. No exemption from this duty is provided for by the implementing legislation.

c. Twelve months have not yet elapsed since its placement on the market.

In this case, the MAH will be obligated to ensure that — without any undue delay after notification of the interruption/termination of the marketing of the respective Medicinal Product — the Medicinal Product (or a substitute Medicinal Product with the determined reimbursement from public health insurance or maximum price) will be supplied to the Czech market in a prescribed quantity, i.e., in a quantity corresponding to at least:

a. Twice the average monthly supply of the Medicinal Product (unless the conditions under point (b) are met).

b. One average monthly supply of the Medicinal Product, provided that in the two years prior to such notification, the Medicinal Product was being supplied to the Czech market without any interruption, totaling more than 20 days.

Based on a legislative rider, the Amendment also introduces the possibility for the MAH to meet this supply obligation by importing a foreign language batch of the Medicinal Product if the Institute allows it. However, if the Institute rejects the request to import a foreign language batch of the Medicinal Product, even though the MAH has offered to provide the Medicinal Product with a label including its Czech name and the Czech patient information leaflet attached to its outer packaging, the MAH will not be obligated to supply the Medicinal Product to the extent corresponding to the quantity of the Medicinal Product specified in the MAH's request.

B.2 Key duties of the distributor to supply Medicinal Products to the market

The Act on Medicinal Products preserves the **general availability duty of a distributor**, i.e., the duty to ensure the supply of Medicinal Products to operators authorized to dispense Medicinal Products (pharmacies) in quantities and at intervals corresponding to the needs of patients in the Czech Republic. This duty is now also explicitly stipulated in relation to supplies to military health service providers for the needs of patients — soldiers on active duty.

In addition to the new duties relating to Medicinal Products with the "limited availability" flag (as described in section A above), the Amendment imposes an explicit **prohibition on distributors from favoring a particular operator authorized to dispense Medicinal Products (a pharmacy) or a military distributor of medicinal products when ordering any Medicinal Product**.

In this regard, the Amendment does not further specify which conduct shall be considered as favoring conduct or whether and in which cases such favoring conduct would be permissible from the perspective of the Act on Medicinal Products. The Amendment-related Explanatory Report suggests that there might be some reasons justifying favoring conduct, but the guidance is very unclear and hard to align with the wording of the provision without making it obsolete. Thus, the provision is expected to be a source of interpretation difficulties and potential quarreling between pharmacies and distributors.

C. New duties of a distributor relating to the stock reserve system

According to the Amendment, the Ministry will be authorized to temporarily include a Medicinal Product that is important for the provision of health services in the Czech Republic in the so-called reserve stock system, provided that the planned volume of supplies of the Medicinal Product on the Czech market does not correspond to the predicted need for it.

Including a Medicinal Product in the reserve stock system will trigger a number of duties newly imposed on distributors. In particular, a distributor will be obligated **to create and maintain a stock of the Medicinal Product** in a quantity corresponding to the average monthly volume of the Medicinal Product it distributes. Subsequently, if the Ministry concludes that the volume of the respective Medicinal Product no longer sufficiently covers the current needs of patients in the Czech Republic, it can impose the duty on the distributor **to release the stock of that Medicinal Product for distribution to operators authorized to dispense Medicinal Products** (pharmacies).

As the Amendment provides that the above mechanism will be triggered in the situation of an imminent or actual shortage of a Medicinal Product on the market, it is questionable whether, in such a situation, it will be within the distributor's capabilities to procure the Medicinal Product to create reserve stocks in the required quantities and to meet the relevant duty. Since it cannot be excluded that a withdrawal of the Medicinal Product from circulation into these stocks might contribute to the potential unavailability of the Medicinal Product for patients in the Czech Republic (instead of curing it), the measure may prove to be counterproductive in practice.

D. Other selected news

On the basis of the approved legislative riders, the Amendment introduces additional measures, such as the following:

- For pharmacies, the eRecept system will provide the ability to view the electronic prescription that a pharmacy may use to inform a patient to whom a specific Medicinal Product has been prescribed about the availability of the Medicinal Product in its stock.
- Subject to prescribed conditions, it will be possible to apply for approval to also import a foreign language batch in relation to over-the-counter Medicinal Products.
- In the case of a threat to the availability of a Medicinal Product that is important for the provision of health services, the Ministry will be authorized to regulate (in the form of a measure of a general nature) the conditions for its distribution, prescription, and dispensation.
- To ensure the availability of a Medicinal Product that is important for the provision of health services, the Ministry will be authorized to issue a decision ordering a health insurance company to reimburse a Medicinal Product that is distributed in the Czech Republic under a special regime (on the basis of a special decision on temporary authorization to distribute, dispense and use the Medicinal Product pursuant to Sec. 8 (6) of the Act on Medicinal Products or within the framework of an approved specific treatment program pursuant to Sec. 49 (3) of the Act on Medicinal Products) and that is a substitute of a Medicinal Product with the "limited availability" flag.
- To maintain the availability of reimbursed services for the insured, the Institute will be authorized to issue a decision determining or changing the maximum price or the amount and conditions of reimbursement for a Medicinal Product that is important for the provision of health services, whose availability is endangered or which has become unavailable, or for a Medicinal Product important in terms of public health protection.

On the other hand, the Chamber of Deputies of the Parliament of the Czech Republic did not support certain legislative riders. Therefore, the Amendment does not contain the following, for example:

- The rules on the creation of a Medicinal Product strategic national stock to protect public health and prevent shortages of critically important medicinal products within the prescribed terms;
- The option to sell Medicinal Products without a prescription through automated boxes.

II. Further legislative process and the Amendment's effective date

For the Amendment to become a law, it needs to be discussed by the Senate of the Parliament of the Czech Republic, submitted to the president of the Czech Republic for signature, and published in the Collection of Acts. It is stipulated that the Amendment is to come into force on the first day of the month following its publication in the Collection of Acts (with the exception of the measures for which it is necessary to give the obliged entities time to prepare, which will become effective on the first day of the sixth month following the date of publication in the Collection of Acts). Given the legislative process's progress, the Amendment is expected to come into force at the beginning of 2024. For your convenience, we will, of course, monitor any further developments in the legislative process.

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We will be pleased to provide further information about the Amendment and assess its impact on your company's operation and distribution system. Please do not hesitate to contact us if you have any questions or should you need any assistance.

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