1. ------IND- 2019 0484 CZ- EN- ------ 20191029 --- --- IMPACT

**Explanatory memorandum**

**I. General part**

**A.** **Explanation of the necessity of the proposed legislation, justification of its main principles and assessment of the existing provisions**

I.

In recent years, the Czech market in medicinal products has been facing threats of unavailability of certain medicinal products. In the case of some medicinal products, it becomes lucrative to divert them to other markets, especially in connection with the system of pricing and reimbursement of medicinal products in the Czech Republic, thanks to which the prices for Czech patients are lower than in other European Union countries. For this very reason, it is appropriate to take measures ensuring the availability of medicinal products to healthcare providers and, through them, to patients in the Czech Republic. The supplies of medicinal products intended and manufactured for the Czech market should primarily cover the needs of Czech patients. It is a basic responsibility of every EU Member State to protect public health and provide healthcare to its citizens. In the Czech Republic, this fundamental role of the State is laid down directly in constitutional law (the Charter of Fundamental Rights and Freedoms). In order to fulfil these essential functions of the State, the Czech Republic, as well as other EU Member States, has exclusive competences arising from the primary law of the European Union (in particular the Treaty on the Functioning of the European Union – TFEU) and competences that may, in justified cases, place restrictions on the basic pillars on which the EU stands, such as the free movement of goods and services (Article 36 TFEU).

Through Act No 66/2017, provisions were added to Czech legislation making it possible to adopt measures against undesired exports or distribution outside the Czech market of medicinal products intended for patients in the Czech Republic, together with provisions aimed at ensuring that the medicinal products are supplied to pharmacies. The essence of the provisions was to introduce the obligation of the distributor to supply a medicinal product ordered by the pharmacy within two working days and an obligation of marketing authorisation holders (i.e. the manufacturer or the supplying pharmaceutical company) to supply to the distributor who has reached out to them the requested medicinal product within the scope of the distributor’s market share.

However, these provisions did not fit the context of the Pharmaceuticals Act and contained a number of imperfections, which made it inapplicable and unenforceable. Even though the formulation ‘to ensure the availability of medicines on the market’ suggests that this should be a safeguard for cases where the marketing authorisation holder fails to fulfil his obligation to supply the market according to patients’ needs, it is also interpreted in the sense that the distributor can always request and the holder is always required to supply the medicinal product, even if the market needs are covered by the holder through other distributors. Nevertheless, this interpretation is not in line with EU law where, according to the Commission, it can be derived from Article 77 of Directive 2001/83/EC of the European Parliament and of the Council that marketing authorisation holders are free to decide whether they will distribute medicinal products themselves or through other distributors. The obligation of holders to supply medicinal products (within the scope of their market share) automatically would restrict the free movement of goods. Mandatory supplies to the extent of their market share are in clear contradiction with competition rules in that they lead to ‘chronic availability’ of medicines for a certain period and effectively prevent access to the market for medicinal products in the case of a new distributor entity.

According to the current wording of the Act, all medicinal products must be included in the market share, regardless of whether they are intended for the Czech market or not, or whether they are over-the-counter or prescription-only medicinal products. At the same time, the availability of over-the-counter medicines is not the issue – no one has brought it up as a problem – attention is focused on prescription medicines, which are, to a large extent, reimbursed from public health insurance. However, the obligation to apportion medicinal supplies according to market shares is not focused only on this category but, unnecessarily and artificially, on all medicines distributed in the Czech Republic. Hence, paradoxically, it is directed not only at over-the-counter medicines but, for instance, also at vaccines which are subject to a completely separate regime of direct supplies to physicians’ offices and where the obligation to supply all distributors in the Czech market to the extent of their market shares could completely paralyse the state-guaranteed system of regular and State-regulated vaccination of the population.

Moreover, the existing Act fails to make it clear how the market shares should be calculated, whether from the financial volume of the supplies, the number of packages or a conversion to the recommended daily doses – the shares of the entities will vary significantly depending on the methodology chosen. It is also unclear whether this concerns supplies to other distributors or supplies to pharmacies. The interpretation that it should be the market share of supplies to the market (i.e. including supplies to other distributors) and not to pharmacies would, paradoxically, mean that the marketing authorisation holder is required to also supply a medicinal product intended for the Czech market to distributors who never supply medicines to pharmacies, but only export (re-export) them. Even though it is very unlikely that this was the intention of the provisions, nothing in the Act suggests that it should be calculated from supplies to pharmacies.

Neither does the Act specify who should determine or calculate the market shares, what process and what data should be used for this purpose and whether the shares should be disclosed. The economic results of the individual entities are not public. Although data on medicinal supplies are available to the State Institute for Drug Control (the Institute), this is not the full scope of the data and, under the Pharmaceuticals Act, the Institute is prohibited from disclosing or making any of the data available in a manner making it possible to identify the entity which the data concern. Neither can the calculation of market shares be addressed in secondary legislation (an implementing decree) because there is no authorisation for the Ministry of Health in the current wording of the Act to define the absent process of calculating market shares in an implementing decree. Equally, none of the existing authorisations for issuing implementing decrees covers the possibility of defining market shares in any of the existing implementing decrees, which has been confirmed in opinions of the legislative departments of the Office of the Government and the Parliament’s Chamber of Deputies.

In some cases, the actual availability of reimbursed health services to patients insured in the Czech Republic is limited by the existing regulatory rules for pricing and reimbursement of medicinal products. The rules applied are relatively effective in exerting pressure on low maximum prices and in terms of control over public health insurance expenditure. Nevertheless, it is a relatively slow and administratively complex system which, in its current form, does not allow the State and the payers to respond to unexpected situations of acute need. Such situations include, for example, the unavailability of a medicinal product important for the provision of healthcare and, even though both the State and the payers would evaluate the situation as one that requires special/individual adjustment of the maximum price or reimbursement, the current system does not make such a measure possible, even if it were in the public interest. While the existing Pharmaceuticals Act contains the legal concepts allowing for targeted and relatively swift measures to make it possible to place on the market (in terms of market rules and restrictions) a medicinal product substituting the product that is currently unavailable, the actual availability of the product for treating patients is in many cases limited by the fact that the reimbursement of that product from health insurance has not been set or the co-payment is excessively high compared to the original product, or the regulated maximum price is so low that it is impossible to supply to the Czech market with the substitute product purchased abroad.

II.

In light of the shortcomings of the existing provisions, it is now proposed to modify the current wording of the Pharmaceuticals Act to achieve the desired state where patients have access to the necessary medicinal products that have been prescribed to them, while not distorting the market and the rules of competition beyond the level that is strictly necessary. The purpose of the present draft is to contribute to better availability of pharmaceuticals to Czech patients through **a combination of four** interrelated **measures.** In order to ensure comprehensively the availability of medicinal products, three measures at the level of the Pharmaceuticals Act and one measure at the level of the Public Health Insurance Act are being proposed.

The first measure involves positive **market interventions supporting non-standard channels for supplying medicines**, which are essential for the provision of healthcare in the Czech Republic and cannot be substituted, and the supply of which to Czech patients is in the public interest, even if these medicines do not meet the formal requirements under marketing authorisations or good manufacturing practice rules. This mechanism reflects the complicated situation in the European market, which is strictly bound by regulations that are far stricter than in most other countries. If a shortage of a medicinal product has been detected, the State should have mechanisms in place making it possible to import and use the product even if some of the formal requirements have not been duly met (§ 11 of the attached draft). Such mechanisms include, for example, authorisation for the use of a medicinal product with a defect of an administrative nature that does not affect the quality and safety of the medicinal product (e.g. inconsistency between the text on the packaging and the marketing authorisation dossier) or, in connection with Brexit, imports of medicinal products from Great Britain when it is no longer part of the EU and the production sites have lost the relevant good manufacturing practice (GMP) certificates, without which pharmaceuticals cannot be normally supplied to the European market.

The second measure involves negative market interventions, the purpose of which is to **prevent uncoordinated exports outside the Czech Republic** of a predefined, identifiable and justifiable group of medicines. The Ministry’s intention is to reduce unpredictable shortages of medicines caused by exports – the State will have full control over the scope of medicines that can be exported by specifying the medicinal products which are permitted to be exported based on objective and verifiable criteria. This should concern medicinal products that are reimbursed from public health insurance and dispensed on prescription. The fact that these medicinal products are reimbursed from health insurance under Act No 48/1997 shows in itself that their availability is in the public interest and is important for the provision of healthcare in the Czech Republic and that the State should – taking into account the whole range of consequences (e.g. the co-payment amount, the positive drug lists of health insurance companies, the inclusion of co-payments in co-payment limits) – ensure the availability of such medicines to Czech patients (§ 77c and § 77d of the attached draft).

The first two measures will ensure that medicinal products needed to ensure high-quality, safe and effective healthcare are available on the market and are not exported from the Czech market in quantities that could cause a shortage. The third measure will then ensure that medicines that are already available in the distribution chain are supplied to pharmacies effectively and without an undue regulatory burden distorting the market, in the situation where a patient enters the pharmacy with a valid prescription for a medicinal product and the pharmacy is unable to order the medicinal product through standard distribution channels. This mechanism is the ‘**emergency** medicine **ordering system**’, which should be compulsorily set up and operated by every manufacturer of a medicine reimbursed from public health insurance and dispensed on prescription and through which the manufacturer should be obliged to supply the medicinal product to the pharmacy within two working days if the pharmacy is unable to obtain the medicine otherwise (§ 33a to § 33c of the attached draft).

The obligation to supply the market should therefore be transferred from the distributors of pharmaceuticals to the shoulders of the manufacturer who is responsible for ensuring that the supplies meet the market needs. At the same time, the manner in which the medicines will be supplied to the pharmacy by the manufacturer (whether the manufacturers will do this themselves or in contractual cooperation with the distributor) does not need to be regulated by legislation, hence, we enable the marketing authorisation holder (manufacturer) to use all possibilities falling within the limits of competition rules.

The measure under the Public Health Insurance Act is directed at situations where a measure to ensure the availability of a product has been adopted under the Pharmaceuticals Act and, at the same time, in order to **ensure** **the actual (and financial) accessibility of the treatment**, the maximum price at which the medicinal product can be placed on the Czech market or the amount of reimbursement from health insurance need to be changed operatively for a limited period of time during which it is expected to be unavailable.

III.

The primary objective of the proposed legislation is to **ensure the availability of medicinal products to patients in pharmacies in the Czech Republic**. As mentioned above, this is mostly a combination of more effective regulation of re-exports of pharmaceuticals and creation of a system ensuring the availability of a prescribed medicinal product to a particular patient in the Czech Republic if the pharmacy is unable to source the medicinal product from the distribution network in the Czech Republic in the standard manner. Therefore, patients who have been prescribed a medicinal product should be able to collect it **at any pharmacy** of their choosing.

On the other hand, the proposed provisions also aim to respect as much as possible both the functioning mechanisms and the contractual relations between all parties in the supply chain – i.e. marketing authorisation holders, distributors and pharmacies – as well as respect the general market and economic realities.

In the case of some medicinal products, the justified interest in keeping the prices of medicines in the Czech Republic low, which is implemented through strict price regulation, leads to relatively significant differences between the prices at which they are marketed in the Czech Republic and those at which they are traded in economically stronger countries. As a result, these medicinal products become attractive articles for re-export, i.e. exports of packages intended for the Czech market to other countries. In the context of the free movement of goods within the EU, the distribution of medicinal products abroad is a lawful activity. The problem arises when, due to re-exports of packages intended for the Czech market, the availability of medicinal products to patients in the Czech Republic becomes restricted, as does the availability of healthcare.

The efforts of marketing authorisation holders to prevent uncontrolled outflow abroad of products intended for Czech patients lead to adopting various restrictive distribution models with the primary aim to limit the risk that, instead of being dispensed to the patients, the medicinal products are exported abroad. An undesirable consequence of the restrictive measures that are in place is that the medicinal product is not available in the normal distribution network and it may become difficult for the patient to obtain it in a pharmacy that does not normally dispense such a medicinal product.

The proposed regulation relating to ensuring supplies to pharmacies focuses exclusively **on ensuring the availability of authorised medicinal products prescribed to the patient and reimbursed from public health insurance when dispensed to the patient on prescription**, for the following reasons:

a) Only **reimbursed medicinal products are subject to price regulation**. Medicinal products for which no reimbursement from health insurance is specified may be sold by the marketing authorisation holder at any price and is not restricted by an officially set limit. This is not the case for reimbursed medicines – this is a category where both the manufacturer’s price and the mark-up of distributors and pharmacies are regulated. Hence the regulatory intervention concerns medicinal products, **whose availability is important** for the provision of healthcare and medicinal products important for the provision of healthcare, are generally reimbursed from health insurance in the Czech Republic. All reimbursed medicinal products are included in the List of Reimbursed Medicinal Products (SCAU), which is issued by the Institute every month.

b) The dispensation to a particular patient only applies to prescribed medicinal products. Medicinal products prescribed on request forms and reported as separately charged medicinal products (ZULP) when providing healthcare are ordered by healthcare facilities from pharmacies and subsequently used for patients when providing healthcare (the unavailability of these medicinal products is not caused by a failure to deliver it to a particular pharmacy). Moreover, neither the Ministry of Health nor the Institute have any knowledge of their unavailability to health service providers.

c) Electronic prescription is compulsory from 1 January 2018. Prescriptions may be issued in paper form only under the specified conditions, which by their very nature do not constitute grounds for regulating the availability of medicinal products (this concerns e.g. physicians who do not provide healthcare but are allowed to prescribe medicines for their family members). Thus, **prescription of the medicinal product in the context of the standard provision of health services** should be a condition for using the regulated (emergency) supplies. The combination of the situation where, in exceptional circumstances, a medicinal product which is not commonly available is prescribed in paper form and it needs to be ordered through the holder’s emergency system is unlikely and will very rarely occur in practice. Therefore, for orders in the emergency system, we want to focus on using the electronic prescription, which will make it possible to reduce significantly the administrative burden on both the pharmacy and the marketing authorisation holder.

d) The electronic form of the prescription will also make it possible to verify the existence of the prescription, which is the reason for using the ordering system. It appears that a suitable technical solution would be to create a universal service (available to all, i.e. pharmacies, distributors and marketing authorisation holders), which would verify whether the medicinal product is prescribed on the given electronic prescription after entering a combination of the electronic prescription identifier and the SÚKL code of the authorised medicinal product. If it has been prescribed, the service will send information about the number of prescribed packages. This information is completely anonymous, without any personal or sensitive data, for which the user needs to know the identifier and SÚKL code combination of the prescribed medicinal product. The service should be operated as part of the eRecept prescription system on the SÚKL website, which is always available online.

IV.

The proposed legislation involves the setting up of a **system to ensure that, in specific situations defined and within a time limit laid down by the Act, a particular medicinal product is supplied to a pharmacy where a particular medical prescription has been presented** if the pharmacy is unable to obtain the medicinal product via standard channels. The ‘emergency system’ will work as follows:

Holders of marketing authorisation for prescription medicinal products **reimbursed** from health insurance **will establish and operate an automated electronic information system for ordering prescribed** medicinal products for human use.

Hypertext links to information systems of the individual holders of marketing authorisation for the medicinal products **will be made available on the Institute’s website**.

The system will ensure **uninterrupted electronic receipt of orders** of medicinal products sent by pharmacies.

In the event of system downtime, the marketing authorisation holder will ensure the receipt and confirmation of orders in another demonstrable form, for example via email or by phone, which will be made available as an alternative solution on the Institute’s website.

As part of the information systems of the individual marketing authorisation holders, pharmacies will have access to information about the distributors to which the medicinal product has been supplied. If it is not possible to order the medicinal product by standard means, i.e. the pharmacy is unable to order the medicine from the distributor listed in the holder’s information system, and the medicine cannot be substituted with another available medicine under the applicable rules of generic substitution, the pharmacy will be **able to order** the prescribed medicinal product reimbursed from public health insurance through the emergency system, i.e. directly from the holder of the marketing authorisation for the given medicinal product. This will be a public service available to all pharmacies without distinction. The emergency system is not and must not be an instrument of competition, i.e. a means of putting certain groups of pharmacies (depending on ownership, location or financial condition) at an advantage. The costs of supplying the medicinal products ordered through the emergency system shall be borne by the marketing authorisation holders and even if supplied by an entity authorised for distribution and designated by the marketing authorisation holder, the mark-up applied by the distributor must not constitute a barrier to a fair contractual relationship and become an aggressive or competitive tactic of the distributor creating unequal or disadvantageous delivery conditions for different pharmacies. To this end, it appears appropriate for the regulated distributor’s mark-up to be shared or capped in order to give the pharmacy a mark-up guarantee. This should be ensured by issuing a pricing regulation of the Ministry of Health on the date of entry into force of the present draft.

The supply of medicinal products through the emergency system **must not become the only channel** through which medicinal products are supplied by the marketing authorisation holder supplies to the Czech Republic because the supplies through the emergency system will not constitute fulfilment of the obligation under point 3 of § 33(3)(g) – to ensure supplies covering the needs of patients in the Czech Republic at adequate quantities and appropriate time intervals. At the same time, the emergency system must not become the standard distribution channel. It is a complementary, exceptional channel for supplying pharmacies in extreme cases (if the standard distribution channel fails). The Slovak experience shows that 100 to 160 types of medicinal products are supplied to pharmacies through the emergency system every month and the supplies represent less than 1 % of total orders from pharmacies. The reality in the Czech Republic is not expected to differ fundamentally from the Slovak experience.

On the basis of an order, the holder of marketing authorisation for the medicinal product will be required to **supply** the product to the given pharmacy **within two working days** of the date of receiving the order. As regards setting the time limit, pursuant to the provisions of § 602 of the Civil Code governing the principles of counting time when an obligation is to be fulfilled or a right exercised on or by a certain date, the other party is not required to be available for this purpose for the entire day, but only for the part of it during which the obliged party can reasonably be expected to be available according to conventions or established practice between the parties. Typical opening hours also represent a normal part of the day. It is taken for granted that the parties may agree otherwise.

In addition to the details of the particular prescribed medicinal product, the pharmacy’s order will contain the identifier of the electronic prescription on which the medicinal product was prescribed to the patient. No patient data will be provided in the order. In order for the marketing authorisation holder or the distributor to be able to **verify that the electronic prescription exists**, a publicly accessible and free service will be available on the Institute’s website which, after entering the electronic prescription identifier in combination with the SÚKL code of the ordered product will, in an anonymised manner, confirm the existence of the prescription and return information about the number of packages of the prescribed medicinal product.

When ordering through the emergency system, the pharmacist will flag the electronic prescription in the central electronic prescription repository (CÚER), thereby temporarily ‘blocking’ the prescription to ensure that only one pharmacy can make an order using that prescription. At the same time, if necessary, the dispensing pharmacy can extend the validity of the prescription to twice the original period.

Exemptions from the holder’s obligation to supply the medicinal product through the emergency system, i.e. reasons for ‘vindication’, will be provided. For example, a duly reported shortage or termination of supplies to the market (the reasons for the shortage will also need to be taken into account –- these should be objective obstacles to supplying the Czech market). Nevertheless, an interruption in the supplies of a reimbursed medicinal product should not last longer than 120 days over the past 12 months in total. In the event the pharmacy has a past due debt with the distributor, the medicinal product will be delivered subject to payment of its price at the latest upon receipt.

If the pharmacy orders the medicinal product through the emergency system, it will then be required to **collect** **and** **dispense** the delivered medicinal product **to the patient**. If the medicinal product is not dispensed to the patient (e.g. the patient does not come to collect it), the pharmacy can return the medicinal product to the distributor who delivered it within two weeks. The distributor will be required to collect medicinal products that the pharmacy could not dispense to the patient and that are returned within this time limit.

**Penalties** are laid down **for misusing** the emergency system. In addition to pecuniary penalties, the possibility to withdraw the pharmacy’s licence (licence withdrawal initiated with the regional authority) for repeated breaches of the obligation should be provided.

V.

At present, marketing authorisation holders have no way of making sure that the packages of medicinal products they have supplied to the Czech market are in fact used for treatment and are not exported. Marketing authorisation holders are required to supply medicinal products to the market in quantities and at time intervals corresponding to Czech patients’ needs, but they have no way of ensuring that packages needed by Czech patients are not exported by another distributor.

In order to ensure the availability of medicinal products to Czech patients, a new wording of § 77c of the Pharmaceuticals Act has been proposed to replace the existing provisions concerning restrictions on the exports of medicinal products that are difficult to implement in practice.

In order to ensure that medicinal products supplied by the marketing authorisation holder to the Czech Republic are used primarily to cover the needs of our patients and not for exports without ensuring the availability of healthcare in the Czech Republic, medicinal products that are reimbursed from public health insurance if dispensed on prescription should now be subject to an **authorisation scheme**. In other words, it would only be possible to re-export reimbursed medicinal products that are on the **positive drug list issued and updated monthly by the Institute through a general measure**. The list would include only medicinal products for which there is a high degree of certainty, based on recent and current indicators, which are all objective and reviewable, that re-exports of those products in the following month will not make them unavailable to patients in the Czech Republic. The determining criteria for deciding whether to include a medicinal product in the list of drugs that can be re-exported are exhaustively listed in the Act and are based on an evaluation of the data obtained by SÚKL on the basis of reports from marketing authorisation holders, distributors and pharmacies. This eliminates the risk of subjective evaluation. At the same time, this solution provides for a scheme that is transparent and non-discriminatory toward distributors because the medicines included in the list issued in the form of a general measure can be re-exported by any distribution authorisation holder. Hence, the market will not be distorted and no part of the supply chain or specific entity or group of entities will have an advantage.

As mentioned above, these provisions should not affect all medicinal products – they will specifically concern reimbursed medicinal products (when dispensed on prescription) which, according to current experiences, are at risk of being re-exported. These should be medicinal products which are reimbursed from health insurance if dispensed on prescription. The importance of this group of medicines was described above. **The availability of reimbursed medicinal products is absolutely essential for the provision of healthcare.** Medicinal products reimbursed from public health insurance must meet a number of conditions laid down by Act No 48/1997 on public health insurance, as amended (§ 15, § 39b, etc.). One of the conditions is that their inclusion in the public health insurance system has to be consistent with public interest. If there is **public interest** in reimbursing them from public health insurance, logically, there has to be public interest in ensuring that they are readily available to patients.

Nevertheless, by entering the public health insurance system, these medicines become much more ‘vulnerable’ because reimbursement is automatically accompanied by price regulation and these medicinal products are thus subject to very strict price regulation rules (the setting of a maximum price, maximum mark-up, agreements with health insurance companies on price or reimbursement discounts, etc.) that ultimately lead to **medicines in the Czech Republic being among the cheapest in the European Union**. This benefits, in particular, Czech patients and the Czech public health insurance system administered by health insurance companies. However, as a by-product, this has also been of benefit to re-exporters in recent years – who take advantage of the low regulated prices of reimbursed medicines and the large difference when compared to the prices in other EU countries and buy medicines originally intended for Czech patients to resell them to other countries. The combination of minimal administrative barriers, a low degree of regulation in distribution and a large difference in prices and thus mark-ups makes re-exports a lucrative **business that does not bring any added value to the Czech healthcare system**; on the contrary, it threatens it with shortages in medicinal supplies to pharmacies and hospitals.

The Institute’s existing statistics clearly demonstrate that medicinal products reimbursed from public health insurance constitute the group of the most lucrative medicines that are most frequently exported from the Czech Republic. Unfortunately, cases where most of the stock of a medicinal product in Czech warehouses is re-exported are not an exception. In these situations, it is completely apparent that the availability of such medicines to patients in the Czech Republic is at risk.

At the same time, the existing method of regulating re-exports is inadequate as it does not make it possible to respond **flexibly** to the fast-changing situation in the European market. Prices of medicines in the EU are changing virtually every day and it is not in the capacity of the Institute or any other authority to estimate when and where it will be profitable to re-export a medicinal product. Hence, in some cases, a significant share of the stocks of a medicinal product in the Czech market may be re-exported practically within days or a few weeks after the re-exporter, in cooperation with foreign partners, obtains the information that, thanks to a relatively high margin, it could more lucrative to sell a medicinal product in another EU country. However, it is impossible to respond within such a short period of time with the measures described in the existing legislation.

Neither does the Act in its current form make it possible to **respond preventively** in a situation where the State can see indications of the imminent unavailability of a medicinal product and it wants to use all means to keep limited stocks within the Czech market. One example is a situation where manufacturing problems lead to a halt or a significant reduction in supplies of medicines to the market. If the manufacturer/marketing authorisation holder informs us about this fact, including information about the expected unavailability or reduced availability of medicines in the coming weeks or months, the current wording of the Act does not make it possible to ban re-exports preventively in such situations.

There can be many similar situations. Most of them have a common denominator – as already mentioned, medicinal products reimbursed from public health insurance are at the greatest risk because, in particular in the case of these medicines, due to optimisation of manufacturing and supplies and as a consequence of price pressures, the manufacturers supply the market only in quantities covering the needs of the local market, with zero or absolutely minimal reserve stocks. Even when there are reserve stocks (stocks above normal consumption), these are intended for the event the number of patients in the Czech Republic rises rather than for re-exports.

Table 1, which lists the 20 most re-exported packages **according to the number of defined daily doses** (DDD), shows that these are medicinal products that are reimbursed if dispensed on prescription; at the same time, it suggests that re-exports concern both medicinal products registered as ‘originals’ and generic medicinal products. Therefore, the measure concerns all medicinal products that are reimbursed if dispensed on prescription. In addition, as mentioned above, the fact that the medicinal products in question are reimbursed from public health insurance justifies the scope of regulation on re-exports as these are the products that are subject to price regulation (to the benefit of Czech patients and the public health insurance system). These are the products that need to be kept in the Czech market because they are important for the provision of healthcare in the Czech Republic (*a contrario* – as follows from § 15(6) of Act No 48/1997, products that have the nature of supportive or complementary medicines in therapy or products that do not meet the effective therapeutic intervention requirements are not reimbursed from public health insurance). These are products representing a category of medicines, the reimbursement of which from health insurance is in the public interest (§ 39b(2) of Act No 48/1997) and their potential unavailability would significantly jeopardise public health and the Czech patients’ access to healthcare.

*Table 1 – TOP 20 by the number of DDDs (source: SÚKL)*

|  |  |  |  |
| --- | --- | --- | --- |
| Abbreviated product name | DDD re-exports | DDD supplies to pharmacies | ATC7 name |
| BISOCARD | 7 621 125 | 927 450 | BISOPROLOL |
| CONTROLOC | 6 101 296 | 10 571 122 | PANTOPRAZOLE |
| TAFLOTAN | 4 954 590 | 2 224 890 | TAFLUPROST |
| CIPRALEX | 3 290 828 | 12 200 900 | ESCITALOPRAM |
| ZYRTEC | 2 569 170 | 6 009 202 | CETIRIZINE |
| CALCICHEW D | 2 076 780 | 9 583 630 | CALCIUM, COMBINATION WITH VITAMIN D AND/OR OTHER MEDICINAL PRODUCTS |
| FLUTIFORM | 2 068 200 | 5 345 790 | FORMOTEROL AND FLUTICASONE |
| GOPTEN | 1 969 702 | 6 776 203 | TRANDOLAPRIL |
| INHIBACE | 1 661 492 | 2 759 256 | CILAZAPRIL |
| ZOREM | 1 451 600 | 7 646 810 | AMLODIPINE |
| TELMISARTAN EGIS | 1 412 376 | 2 343 192 | TELMISARTAN |
| AERIUS | 1 256 340 | 8 991 240 | DESLORATADINE |
| LORISTA H | 1 244 012 | 5 546 408 | LOSARTAN AND DIURETICS |
| BETASERC | 1 146 940 | 6 221 063 | BETAHISTINE |
| VICTOZA | 1 083 870 | 787 560 | LIRAGLUTIDE |
| NOVORAPID FLEXPEN | 1 036 388 | 3 473 288 | INSULIN ASPART |
| OMEPRAZOLE STADA | 1 000 000 | 28 159 450 | OMEPRAZOLE |
| NOVORAPID PENFILL | 957 413 | 2 697 375 | INSULIN ASPART |
| PRESTARIUM NEO COMBI | 896 880 | 25 828 530 | PERINDOPRIL AND DIURETICS |
| VIPIDIA | 888 356 | 1 627 276 | ALOGLIPTIN |

In order to deal with emergency situations (e.g. threats to market availability due to a quality defect detected), the State should still be able to issue operative measures prohibiting or restricting exports of a particular non-reimbursed medicinal product abroad, regardless of the exporter.

Such a measure must always be justified by the fact that the availability of healthcare to Czech patients would be jeopardised if the packages were exported. In the current situation, where there is only a very limited number of production sites, in particular for certain active substances used for the manufacture of medicinal products, the entire or a significant part of the European market is put at risk if a defect is detected and it is obviously in the public interest to prevent medicinal products intended for the Czech market from being exported for financial reasons thereby jeopardising the availability of healthcare to Czech patients. In order to ensure that all potential operators who could export the products are impacted, the ban will be issued in the form of a general measure, which is a suitable form of imposing obligations addressing an indeterminate group of entities.

For the sake of ensuring a flexible response to such exceptional situations, a special procedural status is proposed for the general measures to be issued – this will be a single-stage process whereby the Institute will issue the measures on the basis of an assessment of all information available to it. The general measure will be issued without a drafting procedure and announced by means of a public notice on the official notice board of the Institute; it will enter into force on the date specified in the measure. Only this will provide a sufficiently responsive and flexible solution to the issue of availability of medicines in the Czech market.

VI.

In order for the legislative amendments aimed at ensuring availability of medicinal products to patients in the Czech Republic to be comprehensive, the aforementioned amendments to the Pharmaceuticals Act are complemented with amendments to the Public Health Insurance Act. It is proposed that, in order to **ensure the availability of reimbursed healthcare** to insured persons, the Institute can issue emergency measures temporarily amending or setting the maximum price for a medicinal product or the amount of and conditions for reimbursement of the product from health insurance in a situation where the Ministry or the Institute has issued a measure under the Pharmaceuticals Act to ensure the availability of a medicine by allowing the placing on the market of a product.

This extension of the existing system for setting maximum prices and the amount of and conditions for reimbursement from health insurance to include the possibility of issuing an emergency measure will enable the State to respond in an adequate and sufficiently flexible manner to price and reimbursement issues related to a shortage of a medicinal product important for the provision of health services so that the availability of reimbursed services to insured person is not at risk. The measure will apply for the period of the expected unavailability, but no longer than one year. The measure concerning reimbursement from health insurance will ensure that the co-payment paid by the patient for the substitute medicinal product matches that paid for the original medicinal product, hence, the financial costs incurred by the patient will not increase due to the shortage. At present, it is not possible to supply for the needs of Czech patients a medicinal product which, due to a shortage, is available only in foreign markets in a situation where the set maximum price for the product is significantly lower than the purchase price in another market. The new measure will also make it possible to set with sufficient promptness a temporary maximum price and reimbursement from health insurance for a substitute medicinal product not reimbursed in the Czech Republic.

The proposed measure cannot be claimed, nevertheless, it will be issued by the Institute in the public interest and in order to ensure the availability of reimbursed services. Therefore, the public interest, including the stability of public budgets, will be assessed before issuing the measure and if the increased reimbursement is not in the public interest, but there is another alternative for maintaining the availability of reimbursed services to patients, the measure will not be issued by the Institute. The Institute may issue the measure either ex officio or at the request of the person referred to in § 39f(2) (health insurance companies, marketing authorisation holders, submitters of specific therapeutic programmes) or distribution authorisation holders.

VII.

A final summary of the basic principles and objectives of the proposed legislation:

* No interference with the distribution relationships that are in place for most medicines in the market. No distortion of market and competition rules. If competition rules are breached, sufficient correction mechanisms exist in legislation; the Office for the Protection of Competition, not the Ministry of Health, is the competent authority.
* Regulate only the supplies of reimbursed medicinal products dispensed on prescription when not available in the regular distribution network. Over-the-counter drugs are generally always available in the market, and if not, this is because of production difficulties rather than inefficiencies in distribution or logistics. Medicines prescribed using the request form are generally always available to healthcare providers, hence, they consider the existing mechanisms of supply to these facilities to be sufficient.
* Impose on every marketing authorisation holder the obligation to ensure that the holder’s medicinal product is supplied, within the set time limit, to the pharmacy chosen by the patient to collect that product when that pharmacy is unable to order the product from the regular distribution network. Pharmacies do not need to go through the complicated process of finding the distributors that have the product in stock.
* Ensure that the medicinal products supplied to the pharmacy are used for dispensation to patients or providers of health services.
* Introduce measures ensuring that medicinal products placed on the Czech market are preferably used for patients in the Czech Republic and can be exported only if this does not jeopardise the availability of the medicinal product in the Czech market in a quantity appropriate to the needs of Czech patients.
* Introduce temporary extraordinary measures in the Public Health Insurance Act, which, in the public interest, will make it possible to set or modify the maximum price or the amount of and conditions for reimbursement.

**B. Assessment of compliance of the proposed legislation with the constitutional order, international treaties and the law of the European Union**

**1. Compatibility with the constitutional order of the Czech Republic**

The amendment to the Pharmaceuticals Act is compatible with the constitutional order of the Czech Republic. The proposed amendment governs the obligations of the individual entities in order to increase the availability of medicinal products to patients, thereby improving the quality and safety of the provided health services. The proposed changes are in the interest of protecting the life and health of patients and do not go beyond the framework of the Constitution of the Czech Republic nor of the Charter of Fundamental Rights and Freedoms. On the contrary, the proposed legislation strengthens the mechanisms ensuring the availability of healthcare and provides the State with additional means that it should use to fulfil the obligations placed on it by Article 31 of the Charter of Fundamental Rights and Freedoms in a better and more effective way.

In addition, this change will entail amendments to implementing legislation, specifically there will be partial changes in Implementing Decree No 228/2008 on production and distribution, as amended, and Implementing Decree No 84/2008 on good pharmacy practice, as amended.

The draft amendment to the Public Health Insurance Act is in compliance with the constitutional order of the Czech Republic. The proposed amendment introduces extraordinary measures to increase the availability of reimbursed services to patients, thereby improving the quality and safety of the provided healthcare. The proposed changes are in the interest of protecting the life and health of patients and do not go beyond the framework of the Constitution of the Czech Republic nor of the Charter of Fundamental Rights and Freedoms. On the contrary, the proposed legislation introduces a flexible mechanism ensuring the availability of healthcare and provides the State with additional means that it should use to fulfil the obligations placed on it by Article 31 of the Charter of Fundamental Rights and Freedoms in a better and more effective way.

**2. Compatibility with EU law and international treaties**

The proposed changes to the Pharmaceuticals Act are not in contravention with EU law and international treaties by which the Czech Republic is bound. The draft does not implement any law of the European Union into the legislation of the Czech Republic and is not in contravention with the law of the European Union.

The proposed amendment interferes with the rights and obligations of holders of marketing authorisations for medicinal products and distributors of pharmaceuticals. This legislation is partially harmonised with and governed in particular by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. The proposed provisions are compatible with this Directive and the mechanisms for ensuring the availability of medicines in the Czech market fully correspond to Article 81 of this Directive, which lays down that ‘*[t]he holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. The measures for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.*’ The submitters declare that the mechanisms proposed in the legislation only further refine the obligations already imposed on holders and distributors by Union law (see the provisions above) and Czech legislation (in particular § 33(3) of Act No 378/2007 on pharmaceuticals).

As regards the interference with the free movement of goods and services, the proposed legislation concerns the rights and obligations laid down in primary EU law, namely Article 35 of the Treaty on the Functioning of the European Union. The proposed mechanisms partially interfere with the free movement of goods, but only to the extent permitted by primary law on the basis of Article 36 of the Treaty on the Functioning of the European Union, which lays down that ‘*[t]he provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.*’ Given that the proposed provisions are not discriminatory, the restrictions on distribution of medicines are applied to an objectively defined group of medicines known in advance (prescription medicines reimbursed from public health insurance defined by the List of Reimbursed Medicinal Products (SCAU) issued by the Institute) and no distinction is made between holders and distributors depending on where in the European Union they are established and where their medicines are distributed, the submitters are of the opinion that the above provisions of Article 36 of the Treaty on the Functioning of the European Union are being fully complied with.

The draft act was formulated so that it is fully compliant with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, in particular with Article 81, pursuant to which the obligations imposed by national rules concerning the distribution of medicinal products upon distributors, whose authorisation has been granted by another Member State, should be comparable to those imposed upon domestic distributors, and ‘[t]he holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered’.

The proposed provisions also reflect the conclusions of the Court of Justice of the European Union, in particular the Judgment of the Court of 16 September 2008 in Joined Cases C‑468/06 to C‑478/06. It is clear from the Court’s judgment [75] that it is for the State (the competent national authority), not for the marketing authorisation holder, to resolve the situation where parallel trade leads to a shortage of medicinal products in a given domestic market by taking appropriate and proportionate steps consistent with national legislation and with the obligations stemming from Article 81 of Directive 2001/83/EEC.

It can be concluded that the proposed legislation also stems from the framework outlined by the European Commission in the document entitled ‘Paper on the obligation of continuous supply to tackle the problem of shortages of medicines. Agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018’, in which the Commission clearly confirmed that Member States are authorised to restrict parallel trade in medicines (exports of medicines to another Member State), if the reason is a concern about shortages in the domestic market, provided that a number of conditions (e.g. transparency, reviewability, revisions within a reasonable time period, non-discriminatory criteria that are known in advance) are met. All of these conditions were taken into account in the draft act.

The amendment to the Public Health Insurance Act is not in contravention with international treaties by which the Czech Republic is bound. The draft does not implement any law of the European Union into the legislation of the Czech Republic and is not in contravention with the law of the European Union. It is fully the responsibility of each Member State to ensure availability of reimbursed healthcare (under equal conditions).

**C. Expected economic and financial impact of the proposed legislation**

The stakeholders include:

* State Institute for Drug Control
* Ministry of Health
* Holders of marketing authorisations for reimbursed medicinal products
* Distributors of medicinal products
* Operators of pharmacies
* Health insurance companies

Impacts on the national budget

No extensive financial impacts are expected in relation to the amendment to the Pharmaceuticals Act. The impacts will include the costs of (i) ensuring publication of information about the emergency systems of individual holders of marketing authorisations for medicinal products, (ii) setting up (as part of the eRecept system) the service for verifying that the ordered medicinal products have been prescribed and (iii) ensuring control over compliance with the proposed legislation. The publication of information about emergency systems will be an administrative act involving the publication and updating of the relevant list on the Institute’s website, which is unlikely to require additional financial costs or human resources. The setting up of the service for verifying in the eRecept system that the ordered medicine has been prescribed is a one-off operation that will be performed in the context of maintenance of the eRecept information system. The relevant reports (Implementing Decree No 228/2008 – REG-13) will also be modified to include supplies to pharmacies through the emergency system, as will be the reports from pharmacies on medicinal products provided to another pharmacy (Implementing Decree No 84/2008). The issuing of the general measures referred to in § 77c and § 77d is an agenda already being dealt with at present by the Institute and the changed scope will not require any additional personnel or technical resources. Control over compliance with the new obligations should be carried out as part of the Institute’s existing supervisory activities. Hence, no additional costs to be covered from the national budget are expected. The affected administrative authorities, i.e. the Institute and the Ministry of Health, will cover the costs associated with the proposed legislation from their operating budgets.

Impacts on public health insurance resources are expected in connection with the amendment to the Public Health Insurance Act. Given the fact that this will concern measures in the event of an unforeseen shortage in supplies of medicinal products, it is not possible to estimate the amount in advance. Nor is it possible to quantify the nominal difference between the standard amount of reimbursement from health insurance and the amount of reimbursement to be determined by the measure, as this will depend on the prices abroad at that time. The measure will be issued only for the period of the expected shortage, which will vary. It should also be noted that the longer the expected period of shortage, the greater the likelihood that the existing rules will be applied (in particular the possibility to set the amount of reimbursement for a medicinal product in a specific therapeutic programme). The measures are expected to be applied in particular in the case of short-term shortages where it needs to be possible to adopt a swift solution.

The proposed measure cannot be claimed, nevertheless, it will be issued by the Institute in the public interest and in order to ensure the availability of reimbursed services. Therefore, the public interest, including the stability of public budgets, will be assessed before issuing the measure and if the increased reimbursement is not in the public interest, but there is another alternative for maintaining the availability of reimbursed services to patients, the measure will not be issued by the Ministry.

Impacts on the business sector

The amendment to the Pharmaceuticals Act is expected to have financial impacts especially on **marketing authorisation holders**; these will include costs of (i) creating the emergency system and (ii) ensuring its continuous operation, as well as (iii) costs of supplying the medicinal products ordered via the emergency system.

Given that the obligation to set up and operate an emergency system has already been imposed on marketing authorisation holders in Slovakia, the calculation of the costs can be based on data relating to the Slovak market. In the vast majority of cases, the emergency systems are not operated by the marketing authorisation holders themselves; instead, they use the services of wholesale distributors who have developed an electronic system satisfying the legal requirements, which the distributors offer and tailor to the individual marketing authorisation holders. This means that the marketing authorisation holders have designated a third party to fulfil their obligations, which is not prohibited under the Slovak or the proposed Czech legislation; still, the responsibility is always borne by the marketing authorisation holder himself (potential breaches of the obligations associated with penalties can then be regressively enforced by them against their contractual partners).

Since the wholesale distributors have developed an emergency system for dozens of marketing authorisation holders, the costs of developing the system were spread among all users. The higher the number of users, the lower the costs of introducing the emergency system. The costs of operating the system then depend on the portfolio of medicinal products covered by the emergency system, as well as on how ‘smooth’ the supplies to the Czech market are.

The system is designed so that if the needs of patients in the Czech Republic are sufficiently covered, a list of distributors through whom supplies are ensured by the holder will be published within the holder’s emergency system. The pharmacist will simply contact one of the distributors who will then supply the medicinal product to the pharmacist in the standard manner. The emergency system is intended only for cases where the medicinal product cannot be ordered in the standard manner in the regular distribution network. Therefore, if the supply of medicines is smooth and sufficient, the holders’ costs of operating the system will be minimal.

Given that both the wholesale distributors offering the service of operating the emergency system and the vast majority of marketing authorisation holders placing medicines on the Czech market also operate in the Slovak market, where the system and the related contractual relationships are already in place, it can be expected that in many cases this system will simply be extended to cover the Czech market and the costs could be significantly lower than was the case in Slovakia, where an entirely new system was created.

According to the data from Slovakia, the costs of introducing the emergency system incurred by holders who accepted the offer of a wholesale distributor were equivalent to CZK 80 thousand. However, as explained above, it can be expected that this amount will be significantly lower when the system is introduced in the Czech Republic.

Depending on the size of the portfolio, the monthly fee for operating the system varies between an equivalent of CZK 10 to 15 thousand.

The total costs also include a fee per supplied medicinal product that was prescribed and ordered through the emergency system (if the distributor contracted to operate the emergency system for the holder is also contracted to supply the ordered medicinal product to the pharmacy) amounting to approx. CZK 25 per package. These costs will vary significantly depending on the degree of utilisation of the emergency system for supplies.

There are currently around 270 marketing authorisation holders in the Czech Republic with a medicinal product reimbursed by health insurance if dispensed on prescription.

As regards the contractual arrangements between marketing authorisation holders and distributors who have been contracted to not only operate the emergency system, but in particular to supply the ordered medicines to pharmacies, the current situation in Slovakia is such that the stocks with contractual distributors are owned by the marketing authorisation holder of each medicinal product that is subject to regulation (or a company that is controlled by the holder and is part of a concern), which requires the creation of separate ‘micro-consignment’ warehouses for each holder with all the accompanying additional costs and administrative burden (GDP audits of the selected contractual distributor by the holder at the beginning of the process; creation of changes in the internal Enterprise Resource Planning (ERP) systems with the possibility of monitoring stocks on both the holder’s and the distributor’s side; violation of the FEFO principle – First Expire, First Out – in the logistics chain, where the medicines in the consignment warehouse are prone to ‘ageing’ unlike in normal distribution through distributors).

The proposed legislative objective is formulated (taking into account the Slovak experience) so that, on the basis of a contract between the relevant marketing authorisation holder and the selected contractual distributor, a predetermined portion of ordinary stocks owned by the distributor can be allocated in the Czech Republic for the needs of supply within the emergency system (if so contractually agreed between the holder and the distributor), which the distributor can supply to pharmacies only with the holder’s consent. These would not be fixed stocks, but stocks replenished through regular supplies, i.e. without breaching the FEFO principle. This means that a certain level would be set and, when stocks drop below this level, medicinal products will only be delivered through the emergency system.

**Distributors** who do not supply pharmacies on behalf of marketing authorisation holders in the context of the emergency system will not be affected by the proposed legislation. The costs of setting up and operating the emergency system incurred by the distributors who will supply pharmacies will be reimbursed by the marketing authorisation holder on the basis of a contract concluded between them. Wholesale distributors offering a full-scale service through their own automatic emergency system will have to invest in the development of a system or in the modification of the Slovak version. However, these costs will be subsequently spread among the marketing authorisation holders offering the distributor’s system (costs explained above). Therefore, from the perspective of the distributors, the draft is cost neutral in terms of setting up the emergency system or it could even generate additional revenue in the form of a new service that they could offer their clients – marketing authorisation holders.

In terms of measures restricting re-exports of pharmaceuticals, the impact of the proposed legislation lies in that it makes it impossible to distribute medicines abroad at one’s own discretion in the case of an objectively defined group of medicines that are reimbursed from public health insurance if dispensed on prescription, where there is public interest in protecting the population’s health by ensuring the availability of healthcare to Czech patients.

**Operators of pharmacies** will not be directly affected by the proposed legislation. It can be assumed that the modifications of the software for communication with distributors and the central repository of electronic prescriptions will be made as part of routine maintenance and servicing.

No significant impacts on businesses are expected with regard to the amendment to the Public Health Insurance Act. The only effect is that there will be a slightly greater chance for Czech distributors to supply the Czech market with medicinal products whose maximum price is currently significantly lower than the price at which they are available in foreign markets, which prevents trade in them at present.

**D. Assessment of impacts of the proposed policy in relation to the protection of privacy and personal data**

The proposed amendment to the Pharmaceuticals Act relating to the emergency medicine ordering system is designed so that no personal or special patient data are exchanged. The electronic prescription verification service (§ 81(1)(h)) will operate on a completely anonymous basis and no personal data will be used for this purpose.

As regards the disclosure of data related to pharmaceuticals, the data are further refined through the changes proposed in § 99; the State Institute for Drug Control already discloses the vast majority of them. The draft envisages disclosure of the data using an open machine-readable format, which should greatly contribute not only to the provision of information to the general public, but especially to the utilisation of statistically significant data, which can help many governmental and non-governmental projects optimising the national drug policy and the health policy in general. Data on medicinal products that are actually in the market or on shortages of medicines can contribute positively to the development of tools facilitating prescription by physicians (prescription of only those medicines that can be expected to be available to the patient in the pharmacy). Data on real prices of medicines are important for patients, especially in relation to the average co-payments that they can expect to pay in pharmacies – this data can also be communicated to the patient by the physician when making the eRecept prescription and, if appropriate, adapt the prescription accordingly (e.g. in terms of the size of packaging, etc.). Region-specific data on the prescription of specific drugs are key for comparing and evaluating prescription effectiveness and for projects concerning rationalisation of prescriptions (e.g. local differences in prescriptions of antibiotics and provision of feedback to physicians by health insurance companies as to whether their prescription rate corresponds to the average for that region). All disclosed data must be anonymised as regards patients and, in the vast majority of cases, also aggregated (without distinguishing between specific providers – the reporting entities). The data are left unaggregated only in selected cases where it is in the public interest to disclose the identity of the regulated entity – marketing authorisation holder, broker, distributor and his qualified person, pharmacy and its head pharmacist. In the vast majority of cases, these are legal entities. In the case of pharmacies, this could in some cases concern natural persons–entrepreneurs. Naturally, qualified persons and head pharmacists are natural persons. In all of these cases, these are persons who are legally bound by specific obligations and, with regard to the responsibility of these persons, it is necessary for the public to be informed about them and know who they can contact in the relevant situations.

Apart from the fact that the marketing authorisation holder, who is a legal entity in all currently known cases, will be implicitly identifiable from most of the reports under § 99(2) (e.g. pursuant to point (a), a list of all authorised medicinal products with the name of the marketing authorisation holder will be provided), in the vast majority of cases, these will be purely statistical and completely anonymised data.

This means that the data referred to under points (a) to (d) and (f) to (h) are completely anonymised not only as regards the patients, but also as regards the regulated entities, because these data will be published in such a manner that neither the distributor nor the pharmacy will be identifiable in the reports under these points. Even though, naturally, no patient data will be included in the data published under point (e) and points (i) to (k), it will be possible to identify the regulated reporting entity – the broker, distributor or pharmacy – from this information. These cases will generally concern legal entities, but, in certain cases, may include self-employed persons.

When formulating the changes to § 99 and creating the list of information to be disclosed, interest in protecting personal data of regulated entities was respected and measured against the public interest in providing the general public at least with the basic identifying information of these entities that is required should there be a need to enforce the public rights vis-à-vis these entities. In this case, the public interest in disclosing the data to the extent set out in § 99 outweighs the private interest of the regulated entities in protecting their personal data.

Even though a list of pharmacies and their operators in the National Register of Providers is available on the Ministry's website pursuant to § 74 of Act No 372/2011, it is also available to the Institute in the context of its official activities (the issuance of certificates of compliance with factual, technical and personnel requirements). The Institute has continuously had the competence to publish a list of pharmacies and it is even included in the existing Act (§ 99(1)(e), point 4). The fact that this is now explicitly laid down in the Pharmaceuticals Act and the scope of the information to be disclosed in a machine-readable format (open data) is now explicitly defined will make it possible to provide patients with more information and create new useful tools (e.g. a map of pharmacies in the Czech Republic as part of projects concerning the availability of pharmacy care, etc.). With the current method of disclosing information through the National Register of Providers, the statistical data can only be disclosed in an environment that is not user-friendly.

The amendment to the Public Health Insurance Act in the second part of the present draft act is not related to the protection of privacy or personal data.

**E. Assessment of corruption risks of the proposed policy (CIA)**

The proposed system does not entail any corruption risks; on the contrary, it introduces a transparent system to ensure the availability of medicinal products to patients in pharmacies. The extraordinary measures relating to maximum prices or reimbursement will be issued by the Institute in administrative proceedings and, as is the case in other proceedings, both the supporting documents for issuing the decision and the decision itself will be made public.

**F. Impacts on State security**

The proposed legislation has no effect on State security and defence.

**G. Impacts related to non-discrimination and gender equality**

No impacts related to non-discrimination and gender equality are expected.

**II. Special part**

**A. Draft act amending Act No 378/2007 on pharmaceuticals and on amendments to certain related acts (Pharmaceuticals Act), as amended**

**Re points 1 and 2 (§ 11)**

These provisions concern the responsibilities of the Ministry of Health in connection with the changes related to issuing the general measures referred to in § 77c and § 77d. The Ministry will continue to issue measures to facilitate the availability of medicinal products to Czech patients in terms of enabling the distribution, dispensation and use of medicinal products that do not meet all the requirements under the Act. These measures are aimed at situations where, in order to ensure the availability of treatment to patients, the risks and benefits are always assessed individually in light of the nature of the derogation and irreplaceability in the provision of health services to patients in the Czech Republic. The purpose of the measures laid down in § 11(g) and (h) is to issue only such measures that have a positive effect on the market, i.e. allow for imports, distribution, dispensation and use of medicinal products, which could otherwise not be marketed and used in the Czech Republic under standard circumstances, if they had to fulfil all other requirements under the Act. These measures do not aim to affect the market adversely, i.e. restrict distribution, imports or exports of medicinal products that can otherwise be handled without specific restrictions – these specific negative interventions regulating the free handling of medicines (distribution, imports, exports) can only be done through the measures described in § 77c or § 77d.

In the case of the proposed new wording of § 11(h), the Ministry was inspired by the wording of the same provisions that were in force until 30 November 2017, before the amendment through Act No 66/2017. The legislation then contained provisions requiring the Ministry of Health to take ‘measures to ensure the availability of medicinal products important for the provision of healthcare and adopt measures to promote research, development and availability of medicinal products for rare diseases and medicinal products that may be designated as such, as well as medicinal products for paediatric use.’ These provisions were amended through Act No 66/2017. However, the new legislation (Act No 66/2017) proved to be inadequate and incapable of enabling a flexible response to the changing situation in the market of medicinal products. Therefore, the present draft act aims to maximise the tools available to the State to ensure that the necessary medicinal products are available to patients in the Czech Republic. Through this measure, the Ministry could, for example, exceptionally and temporarily permit the distribution, dispensation and use of an unauthorised medicinal product, or the distribution, dispensation and use of an authorised medicinal product not placed on the market in accordance with marketing authorisation or good manufacturing practice rules.Given that § 11(g) and (h) contains the relatively broadly conceived provisions of the Act establishing the responsibility of the Ministry of Health to actively address situations involving shortages of essential medicines or the need to seek ways to source irreplaceable medicines for Czech patients even by extraordinary means, it would not be suitable to restrict the Ministry’s procedural processes. Hence, depending on the circumstances, both the issuance of a decision in administrative proceedings or the issuance of a general measure come into consideration.

It is also clear from the text of both provisions that they concern a broad range of situations where the ad hoc solution can either take the form of an individual normative administrative act allowing an entity to take a certain action that would otherwise not be allowed under standard circumstances due to the strict provisions of the Pharmaceuticals Act or, conversely, deal with the need to address an indeterminate group of recipients who will be allowed to use or dispense medicinal products in a manner that would otherwise contradict, for example, the marketing authorisation and the conditions of the authorisation. Therefore, the hands of the Ministry of Health are not being tied by laying down the specific form in which the measures referred to in § 11(g) and (h) should be implemented.

In addition, the powers of the Ministry of Health related to measures against re-exports of medicines, which are modified and transferred to the Institute under the draft, are being removed.

**Re points 3 to 5 (§ 13)**

The scope of competence of the Institute is extended to include the obligation to issue regular general measures pursuant to § 77c, which will contain a list of reimbursed medicinal products that can be distributed outside the Czech Republic.

The scope of competence of the Institute will also be extended to include the possibility to issue, in emergency situations (e.g. threats to market availability due to a quality defect detected in medicinal products with a significant share in consumption in the Czech Republic), measures pursuant to § 77d prohibiting or restricting exports of a particular medicinal product, regardless of the exporter. Such a measure must always be justified by the fact that the availability of healthcare to Czech patients would be jeopardised if the packages were exported. In order to ensure that all potential operators who could export the products are impacted, the ban will be issued in the form of a general measure.

For the sake of ensuring a flexible response to such exceptional situations, a specific procedural status is proposed for issuing the general measure – this will be a single-stage process where the general measure will be issued by the Institute on the basis of assessment of all information available to it.

In addition, the Institute will now provide access to a service for verifying the existence of the electronic prescription used by the pharmacy as the basis for making the order through the marketing authorisation holder’s emergency system.

The Institute will also publish specifications for a unified communication interface prescribing the technical parameters of automated communication between pharmacies and marketing authorisation holders through the emergency system.

**Re point 6 (§ 33(2))**

A new obligation is being imposed on marketing authorisation holders to supply the market with medicinal products, which are reimbursed from public health insurance if dispensed on prescription (hereinafter ‘reimbursed medicinal product’) and which, at the same time, the Institute found to be substitutable by another medicinal product when assessing the notifications of interruption, so as to avoid interruptions in supplies for a period longer than 120 days over the past 12 months in total. The main reason for introducing these provisions is the need to prevent the potential misuse of the interruption of supplies to the market and thus avoid the obligation to supply the relevant medicinal products through the emergency system.

This means that reimbursed medicinal products are medicinal products included in the List of Prices and Payments for Medicinal Products and Foods for Special Medical Purposes (SCAU), which is published by the Institute on the basis of its responsibilities under § 39n of Act No 48/1997 on public health insurance, as amended, and which reflects every month the relevant administrative proceedings to set, change or revoke maximum prices or the amounts of and conditions for reimbursement of medicines from public health insurance. These are medicinal products that are reimbursed if dispensed on prescription. In other words, these are not medicinal products that are reimbursed only when a medical procedure is performed and charged to the health insurance company together with the corresponding medical procedure as a separately charged product. Thus, the term ‘reimbursed medicinal product’ does not cover medicinal products that are referred to as ‘products used for treatment in centres’, products marked with the symbol ‘S’, etc.

The Institute is granted new powers allowing it to add to the published list of medicine shortages (created on the basis of notifications of interruption or discontinuation of the supply of medicines to the market) information as to whether the unavailable medicine can be substituted by another medicinal product and if so, which one. This is valuable information for both patients and the prescribing physicians; at the same time, this information will also be used as a source for creating the list of medicines that can be re-exported – distributed outside the Czech Republic (§ 77c). The medicinal products that are the substitutes for the unavailable medicines can either be indicated using their name (indication of the specific SÚKL codes) or – in the case of an easier substitution – by providing a reference to an entire ATC group (active substance), if many substitutes are available. Naturally, in cases where only one or a couple of specific substitutes (SÚKL codes) are indicated, these should be relevant for formulating the general measure allowing re-exports of medicines under § 77c; specifically, these should be removed from the list to ensure that these substitutes are available to Czech patients. On the other hand, in situations where an entire ATC group is considered to be an alternative, this information is not relevant for formulating the general measure pursuant to § 77c.

**Re point 7 (§ 33(3)(g), point 3)**

The emergency system is not intended to replace standard supplies of medicines to the Czech market, but to ensure the availability of a medicinal product to a particular patient in a situation where it cannot be sourced via standard channels. For the sake of certainty of all involved parties, the provisions are formulated so as to make it clear that the obligation to ensure supplies covering the needs of patients in the Czech Republic cannot be fulfilled by providing the supplies only through the emergency system.

**Re point 8 (§ 33a to § 33c)**

This point lays down the obligation for holders of marketing authorisation for reimbursed medicinal products (details concerning the definition of a reimbursed medicinal product are provided above in relation to § 33(2)) to set up and operate an emergency system as an information system for ordering and supplying medicinal products in the event these cannot be ordered in the standard manner. It is an automated electronic system, which must include a substitute non-automated system in the event the system is unavailable. The holders of marketing authorisation for all medicinal products which are reimbursed from health insurance if dispensed on prescription must set up the emergency system (or have it set up by another person). The Institute will make available a unified communication interface for the emergency systems so as to ensure their uniform appearance and thus facilitate access to and use of the system by pharmacists.

As regards the contractual arrangements between marketing authorisation holders and distributors who, on the basis of a contract, not only operate the emergency system, but especially supply the ordered medicines to pharmacies, the proposed legislative objective is formulated (taking into account the Slovak experience) so that, on the basis of a contract between the relevant holder and the selected contractual distributor, a predetermined portion of ordinary stocks owned by the distributor can be allocated in the Czech Republic for the needs of supplies within the emergency system (if so contractually agreed between the holder and the distributor), which the distributor can supply to pharmacies only with the holder’s consent. These would not be fixed stocks, but stocks replenished through regular supplies, i.e. without breaching the FEFO principle. This means that a certain level would be set and, when stocks drop below this level, medicinal products will only be delivered through the emergency system.

Hence, the obligation to set up an emergency system concerns medicinal products whose availability is important for the provision of healthcare, and such medicinal products are generally reimbursed from health insurance in the Czech Republic. All reimbursed medicinal products are subject to price regulation and are included in the SCAU List issued every month.

The holder of the marketing authorisation for a medicinal product reimbursed from health insurance will operate the emergency system for ordering prescribed medicinal products for human use continuously, either himself or through another person. Within the emergency system, the marketing authorisation holder is required to provide a list of distributors currently ensuring the regular supply of reimbursed medicinal products to the Czech market. If a pharmacy is unable to order the required medicinal product prescribed on an electronic prescription by contacting at least two of these distributors (or one, if only one is listed) and it is not possible to utilise ‘generic substitution’ as referred to in § 83(2) of the Act, it may use the emergency system to order the product. In addition to the code of the prescribed medicinal product, the electronic prescription identifier of the medicinal product will be entered in the order. This information combined will enable the marketing authorisation holder or distributor to verify the existence of the electronic prescription on the basis of which the order was placed in the emergency system. It will be verified through the publicly accessible and free CÚER service which will send back anonymous information about the number of packages of the medicinal product that have been prescribed.

Completeness is not specified as a prerequisite for validity of the order because it is not technically applicable. Logging in to the emergency system in itself implies prior registration and all the information needed for the subsequent orders of medicines to be considered complete is entered upon registration.

On the other hand, correctness concerns the details provided in the order, which must correspond to reality or the requirements of the Act. For example, if an order contains an invalid eRecept ID, it will be complete but incorrect and hence will not obligate the marketing authorisation holder to deliver the medicinal product on the basis of such an order.

The medicinal product ordered in this manner must be collected by the pharmacy operator and must not be used for a purpose other than dispensing it to the patient. If the pharmacy operator cannot dispense the medicinal product to the patient (e.g. because the patient does not come to collect it), it can be returned to the distributor who supplied it within two weeks. The distributor is required to accept the returned medicinal product.

The marketing authorisation holder will promptly acknowledge that the order has been received and ensure that the medicine is supplied to the pharmacy within two working days. It follows from the provisions of § 602 of the Civil Code governing the principles of counting time when an obligation is to be fulfilled or a right exercised on or by a certain date that the other party is not required to be available for this purpose for the entire day, but only for the part of it during which the obliged party can reasonably be expected to be available according to conventions or established practice between the parties. Typical opening hours also represent a normal part of the day. It is taken for granted that the parties may agree otherwise.

If the prescribed packaging of the medicinal product is not available to the holder, he shall supply the pharmacy with the corresponding quantity in the packaging of a different size that currently is available. It is possible to supply a smaller packaging or a number of packages where the total number of units of the pharmaceutical form is smaller than prescribed on the eRecept prescription (e.g. instead of two packages of 50 tablets each, one package of 30 tablets or 3 packages of 15 tablets each may be dispensed). Above the prescribed number of units of the pharmaceutical form, the total quantity can only be increased by up to 50 % (e.g. instead of one package of 14 tablets, one package of 21 tablets can be supplied). Given the specific and diverse situations that may occur, a flag will be added to the unified communication interface which can be checked by the ordering pharmacy to indicate whether delivery of the medicine in a packaging of a different size than that prescribed on the eRecept would be acceptable by the pharmacy (or the patient) or not. This may facilitate and speed up communication and prevent possible returns.

Holders are not required to fulfil the obligation to supply the product within two working days only if they have reported an interruption or discontinuation of supplies to the market (the decision to produce for another market does not absolve them of this obligation) or if there is a force majeure situation. In addition, an order does not have to be fulfilled if it contains incorrect information. The holder must inform the pharmacy of the reasons for not supplying the product.

The draft allows pharmacies to dispense a medicinal product that, for some reason, has not been collected by the original patient, to another patient who has also been prescribed the medicinal product in question.

Even though the pharmacy has the option to return the medicinal product, if it knows that the product can be used for another patient, then it is economically rational not to return the product.

Supplies under the emergency system are a public service available to all pharmacies without distinction. The emergency system is not and must not be used as an instrument of competition, favouring certain pharmacies over others or creating unequal or particularly disadvantageous conditions for supplying medicines to pharmacies. The emergency system is a special supplementary instrument that cannot replace the standard distribution channels and established supplier–customer relations. Hence, only a fraction of the supplies to pharmacies will take place through the emergency system.

The Institute’s website will make available hypertext links to the emergency systems of the individual marketing authorisation holders and the contact details for the substitute system in the event the system is unavailable. Marketing authorisation holders are required to report these details and any changes to them no later than two working days before implementing them.

Marketing authorisation holders will be required to keep records in electronic form of the distributors and pharmacies to which they have supplied medicinal products through the emergency system. By analogy with other documentation relating to medicinal products, the obligation to retain these records is limited to five years. The data relating to medicinal products supplied through the emergency system will be provided by the marketing authorisation holder to the Institute electronically. The method, form and interval of the reports in relation to other periodic reports provided by marketing authorisation holders will be laid down in the relevant implementing decree.

At the same time, marketing authorisation holders will be required to report to the Institute continuously in an electronic form all orders made through the emergency system, together with all order rejections, in a manner and form corresponding to the current DIS-13 reports. This information will be made public and the list of medicines ordered through the emergency system will be used as source information for drawing up the general measures permitting re-exports of medicines. If larger quantities of certain medicines are systematically ordered through the emergency system, it is appropriate to prohibit re-exports of such medicinal products as this is an indication of unavailability of the medicinal products in the distribution network or in the stocks held by pharmacies.

**Re point 10 (§ 77(1)(h))**

A distributor who enters into a contract with a holder for the supply of medicinal products through the emergency system is required to supply the medicinal product to the pharmacy within two working days of the order time, of which the holder is required to inform the distributor. If the pharmacy has a past due debt with the distributor, the product will be delivered subject to payment at the latest upon delivery.

**Re point 11 (§ 77(1)(q))**

If the Institute has issued a measure under § 77d prohibiting or restricting exports of a medicinal product or the Ministry of Health has taken another measure to ensure the availability of medicinal products under § 11(g) or (h), the distributor is required to act in accordance with that measure when distributing products. Naturally, reimbursed medicinal products not covered by a general measure issued under § 77c cannot be re-exported by distributors either.

 **Re point 12 (§ 77c)**

In order to ensure that medicinal products supplied by the marketing authorisation holder to the Czech Republic are primarily used to cover the needs of our patients and not for export without availability of healthcare in the Czech Republic being ensured, it is laid down that a reimbursed medicinal product that has been placed on the market may be supplied to another Member State or a third country only if it is included on the list issued by the Institute in the form of a general measure. These provisions do not affect all medicinal products, but specifically reimbursed medicinal products (details of the definition of a reimbursed medicinal product are provided above in relation to § 33(2)), the availability of which to patients in the Czech Republic is most jeopardised by re-exports based on past experiences. This regulation is justified in more detail in the general part of this explanatory memorandum.

The general measures containing the list of reimbursed medicinal products that can be distributed outside the Czech Republic (re-exported) in the following month will always be issued by the Institute at the beginning of the calendar month (the fifth day), i.e. one day after it has received fresh data on orders through emergency systems for the past month. It will be prohibited to re-export medicinal products not included in the list. This means that it is an authorisation scheme.

The list of medicines that may be re-exported will be issued by the Institute on the basis of objective, reviewable and transparent criteria exhaustively listed in paragraph (2). The situation where a medicinal product is ordered through the emergency system is a clear indication of reduced availability of the medicine in the distribution market, therefore, such medicines should not be re-exported and should not be included in the list. If the availability of the medicine was reduced over the past three months due to an interruption of supplies to the market, this may have a significant effect on the stocks available for distribution in the Czech Republic, therefore, it is in the interest of the availability of the medicine to Czech patients to prohibit re-exports temporarily and stabilise the stock levels. This also applies to reported interruptions in supplies expected to occur in the coming period after issuing the general measure – in such a case, it is a precaution to avoid losing the stocks that will be needed in the future. A similar justification applies to the reports on discontinuation of supplies to the market.

Pursuant to § 33(2), when an interruption or discontinuation of supplies to the market is reported, the information as to whether and which medicinal products can be used as a substitute is published by the Institute. It is entirely appropriate to protect the availability of healthcare to Czech patients by preventing re-exports of medicines, which are substitutes for unavailable medicines. When one medicine that can only be substituted by one or a couple of other medicines becomes unavailable, it is appropriate to ensure that these substitutes are retained primarily in the Czech market and not re-exported.

The last criterion, which is also objective and reviewable, is the level of re-exports of the medicinal product. It follows from other provisions of the Act that the marketing authorisation holder is required to supply medicinal products according to the needs of the patients in the given country. It can be assumed, and the information available to the Ministry of Health and the Institute confirms this, that registration holders fulfil this obligation economically and optimise production and supplies to the market so that they do not supply in quantities that are far greater than needed. This is also evidenced by the limited global production capacities and price pressures in individual countries, which lead holders to supply only the minimum quantity of the medicines whose prices are regulated. At the same time, production and logistical reasons do not favour large stocks as they cause the individual entities in the supply chain to have their cash uneconomically tied up and be unable to use it flexibly (cash flow).

Taking into account reserve stocks and past experience and observations of regulators, the 10 % threshold for re-exports still remains acceptable. This quantity of ‘lost’ stocks is still likely to be flexibly managed. Above this threshold, however, the marketing authorisation holders cannot always be expected to be able to manage without issue the manufacturing and logistics capacities. Hence, the 10 % threshold appears to be critical according to past experience with issuing general measures under the current version of the Act.

All the criteria set out in paragraph (2) were formulated and carefully evaluated so that the degree of interference with the right to free distribution of medicines is adequate and justified in relation to the need to ensure the availability of medicinal products to patients in the Czech Republic. The restriction on the free movement of goods laid down by the provisions of § 77c (and § 77d) is non-discriminatory, transparent and justifiable by the reasons referred to in Article 36 of the Treaty on the Functioning of the European Union (TFEU) and proportionate in light of how the desired objective is to be achieved.

**Re point 12 (§ 77d)**

As a precaution for unforeseeable emergency situations (e.g. threats to market availability due to a quality defect detected), the possibility for the State to operatively issue measures prohibiting or restricting exports of a particular medicinal product, regardless of who exports it, must be maintained. The issue of such a measure must always be justified by the fact that, if the packages are exported, the availability of healthcare to Czech patients will be jeopardised, and the protection of public health is a public interest.

In order to ensure that all potential operators who could export the products are impacted, the ban should be issued in the form of a general measure. A general measure is understood to be an administrative act blending a specifically defined subject matter with generally specified addressees, i.e. it is neither a legislative act nor an administrative decision. Given that, by definition, general measures have a specifically defined subject matter and abstractly defined addressees, it was chosen as the most suitable means to ensure a flexible response by the Institute to ensure the accessibility of healthcare to patients in the Czech Republic in exceptional cases that may occur if medicinal products are distributed outside the country. A single-stage process of issuing binding general measures has been proposed so that the Institute can act quickly and flexibly enough. The measure will be revoked as soon as the reasons for prohibiting distribution outside the country cease to exist.

**Re points 13 to 15 (§ 81)**

The electronic form of prescriptions will enable the marketing authorisation holder or distributor to verify the existence of the prescription on the basis of which the prescribed medicinal product is being ordered through the emergency system. The creation of a universal service (available to all, i.e. to pharmacies, distributors as well as marketing authorisation holders) is a suitable technical solution, as it will send back information as to whether the electronic prescription exists upon entering a combination of the electronic prescription identifier and the SÚKL code of the authorised medicinal product. If the response is positive, the service will send information about the number of prescribed packages. This information is completely anonymous, without any personal or sensitive data. In order to use the service, the user has to know the combination of the identifier and the SÚKL code. The service is provided by the Institute as part of the CÚER service and is always accessible online.

**Re point 16 (§ 81h)**

To ensure efficient ordering through the emergency system – i.e. obtaining the prescribed medicinal product for a particular patient – it needs to be ensured that a particular electronic prescription is used to place a single order. When ordering through the emergency system a medicinal product prescribed via electronic prescription, the pharmacist enters this information in the CÚER service, thereby ensuring that any other pharmacy can see that the prescribed medicine will be delivered to a different pharmacy via the emergency system and, therefore, it is not possible to initiate another dispensation process for the same prescription. If the original pharmacy receives information that the ordered medicinal product cannot be supplied through the emergency system, it will cancel this entry in the eRecept system.

**Re points 17 to 19 (§ 82(3) and (4))**

Since the provisions allowing, in exceptional cases, the receipt of medicines from another pharmacy get misused in practice for obtaining medicinal products in order to re-export them, the provisions have been reworded so that their purpose – to ensure the availability of special medicinal products that cannot be obtained from the distributor when needed – is formulated precisely. These are, in particular, special medicinal products, which are costly and unpredictable in terms of when and where they will be needed. Such medicinal products are kept at specialised or higher-level healthcare facilities from which they are delivered when needed to the hospital where the patient is hospitalised. This scheme applies especially to antidotes, certain anti-infectives and other medicinal products used in vital indications (e.g. gynaecology). Given the nature of these medicinal products, it is apparent that, when they are needed, the patient’s condition requires hospitalisation, therefore, these medicinal products can now only be transferred between pharmacies supplying providers of in-patient care and the medicinal product received must be used only for hospital patients. It is specified that deliveries from other pharmacies can only be taken by a pharmacy supplying in-patient facilities, while maintaining the condition that this may happen only if the pharmacy is unable to obtain the medicinal product in time from a distributor or if another (providing) pharmacy has unused stocks of that medicinal product. The receiving pharmacy may dispense the medicinal product only to a health service provider, which must use it in the provision of in-patient care. Thus, these provisions should make it possible to transfer unused stocks, but only for use by hospital patients.

At the same time, pursuant to the provisions, the providing pharmacy is required to pass to the Institute information about the medicinal products provided and the receiving pharmacy so that the Institute has control over possible misuse.

**Re points 20 to 25 (§ 99(1)(l))**

The data to be made available by the Institute are supplemented to include information about the emergency systems of marketing authorisation holders so that they are available to pharmacists at any time they need to use them.

**Re points 26 to 29 (§ 99(2) and (3) and § 99(6))**

These are technical modifications of the provisions relating to the disclosure of data by the Institute. In an effort to exercise state authority effectively and in order to reduce the administrative burden, the method of disclosing the data obtained by the Institute while performing its official activities is laid down. Hence, data made public in a way that allows remote access and in an open and machine-readable format – i.e. in the form of open data – will be made publicly available in the given format in a transparent manner and anyone will be able to use them. At the same time, this will reduce the administrative burden related to submitting requests for the provision of various data.

In the vast majority of cases, the scope of the disclosed data corresponds to the scope already defined under the existing legislation and only the form (open data) is being changed in these cases; in the interest of greater legal certainty for all involved parties, the level of detail is being refined for every set of data in favour of disclosing data in the broadest scope possible, having taken into account the proportionality between the interest in protecting personal or business data of entities that are subject to regulation and the public interest in knowing such data that directly affect the availability of medicines or pharmaceutical care, and protection of the interests of the Czech population – patients. Therefore, under some provisions (e.g. § 99(2)(e)), the details that should be provided in the case of the disclosed published data are being extended beyond the status quo. In addition to the overriding public interest, such disclosure will also contribute to market self-regulation and the application of self-regulatory instruments correcting distortions in the pharmaceuticals market.

When the provisions emphasise that the disclosed data should be anonymised (§ 99(2)(d), (f), (g), (h)), this means not only the provision of data in a manner ensuring that the patient to whom the medicinal product was prescribed or dispensed cannot be identified – deemed a given to the submitter of the draft– but also in a manner that makes it impossible to identify the entity handling the medicinal products in an appropriate manner (the distributor, pharmacy, prescribing physician, etc., regardless of whether this is a legal entity or a natural person).

When the provisions emphasise that the disclosed data should be aggregated (§ 99(2)(f) and g)), this means that the structure of the data processed and disclosed by the State Institute for Drug Control should not match that of the primary input data. For example, in the case of § 99(2)(f), it is clear that the primary data are data from the eRecept information system, where the data are structured according to the actual electronic prescriptions in the system (eRecept identifiers). Nevertheless, the objective is not to disclose data about eRecept prescriptions, but about the medicinal products prescribed on them, therefore, the Institute will have to process the data to create a different aggregate structure so that the data disclosed are not about how many eRecept prescriptions for a given medicinal product have been prescribed or dispensed, but about how many packages of medicinal product XY was prescribed and dispensed in total in the past month (further distinguished by individual districts).

**Re point 30 (§ 101(5))**

In connection with repeatedly penalised breaches committed by certain entities, where the imposition of pecuniary penalties does not appear to be sufficiently effective, it is proposed to grant a new power to the Institute – to submit to the competent administrative authority a proposal for withdrawal of authorisation to provide pharmaceutical care. Experience has shown that, for some entities, pecuniary penalties are not an obstacle to further breaching the Act, in particular in relation to re-exports of medicinal products.

**Re points 31 to 34 (§ 103(10))**

New infractions that could be committed by pharmacy operators in connection with the new provisions are being inserted. Pharmacy operators will commit an infraction if they ‘misuse’ the marketing authorisation holder’s emergency system by ordering a medicinal product even when the legal requirements for using it are not met (no attempt was made to order it via standard channels or use generic substitution). In addition, infractions that pharmacy operators could commit in relation to the exchange of medicinal products between pharmacies are being specified.

**Re points 35 to 37 (§ 105(2))**

Distributors will commit an infraction if they supply a reimbursed medicinal product abroad even though they have not been authorised to do so by the marketing authorisation holder or if they act at variance with the general measure referred to in § 77d or a measure issued by the Ministry of Health under § 11(g) or (h) of the Act. An infraction will also be committed by a distributor who fails to collect back a medicinal product supplied through the emergency system to a pharmacy that has not dispensed it within two weeks.

**Re point 38 (§ 105(5))**

Marketing authorisation holders will commit an infraction if they interrupt the supply of a non-substitutable reimbursed medicinal product to the market for a period totalling more than 120 days over the past 12 months.

**Re point 39 (§ 105(11))**

The provisions concern infractions committed by holders of marketing authorisation for reimbursed medicinal products by breaching obligations related to the emergency system. Marketing authorisation holders will commit an infraction, in particular, if they fail to set up and operate an emergency system in accordance with the legal requirements or supply a reimbursed medicinal product, or if they fail to comply with their registration, notification or information obligations related to operating the emergency system.

**Re points 40 to 43 (§ 107)**

The corresponding penalties to be imposed in relation to the newly introduced infractions are specified under this point.

**Re points 44 and 45 (§ 114)**

The list of provisions, for the implementation of which the central administrative authorities in the field of pharmaceuticals are authorised to issue implementing legislation, is being modified.

**Re transitional provisions**

Given the need to ensure the functioning of the whole system that is being newly set up, a transitional period needs to be provided for the stakeholders (the Institute and marketing authorisation holders) to prepare and implement the system successfully. First of all, the Institute needs to be given enough time to publish the specifications of the communication interface for the emergency systems of marketing authorisation holders. Second, marketing authorisation holders need to be given enough time after publication of the specifications of the communication interfaces in order to set up their emergency systems and notify the Institute about them. Finally, in order for the system to function, the Institute needs to be given enough time to publish the information about emergency systems of marketing authorisation holders.

**B. Draft act amending Act No 48/1977 on public health insurance and on amendments to certain related acts, as amended**

**Re Part Two:**

**Re § 39k(1)**

The Institute is provided with the possibility to issue a decision that will temporarily set or change the maximum price and the amount of and conditions for reimbursement of a medicinal product important for the provision of health services that is at risk of becoming or has become unavailable. The measure can be issued when preceded by a measure issued to ensure the availability of medicinal products under the Pharmaceuticals Act. Hence, it will concern medicinal products for which consent has been granted by the Ministry of Health for use within a specific therapeutic programme, medicinal products whose distribution, dispensation and use have been authorised under § 11(h) or (o) or ‘foreign language batches’ authorised by the Institute under § 38 of the Pharmaceuticals Act. In order for the measure to be issued, it must be in the public interest, an integral part of which is the interest in maintaining financial stability of the health insurance system and ensuring the availability of reimbursed services, as well as consideration of the financial burden on patients.

As the above clearly suggests, the possibility of influencing the maximum price and hence reimbursement from public health insurance for a medicinal product ‘important for the provision of health services where there is impending or existing unavailability’ cannot be looked at in a narrow sense and out of context, but always in relation to ‘extraordinary’ measures taken under the Pharmaceuticals Act. Thus, a deliberate influencing of the price or reimbursement of a medicine, for which measures have not been issued under the Pharmaceuticals Act due to an emergency situation, is out of question. Nevertheless, the existence in itself of such an emergency measure may still be insufficient. The modification of the price and reimbursement, as referred to in paragraph (2), must be in line with the public interest, which, in the context of the provisions of the Public Health Insurance Act and the established decision-making practice, means that, among other things, the availability of therapeutically interchangeable treatment needs to be considered. It will definitely not be in the public interest to increase the regulated price and reimbursement where there is a shortage in the supply of a medicine and its availability is jeopardised, but another therapeutically interchangeable medicine is available to patients.

It is also clear from this context that these types of proceedings entail no risk of a conflict of interest since the proceedings come into consideration only where neither the product subject to assessment nor a therapeutically interchangeable substitute are available, and thus participation of the marketing authorisation holder is unnecessary. Given that this is an extraordinary measure, breaches of the legitimate interests of marketing authorisation holders are out of the question since they always have unrestricted access to the mechanisms set out under § 39a § 39j, which fully reflect the requirements and entitlements introduced by Directive 89/105/EEC. Hence, the requirements of Directive 89/105/EEC – transparency, reviewability and objective criteria – are maintained, as is the time limit for inclusion of a medicinal product in the national public health insurance system – all of this is transposed into the provisions of § 39a to 39j. The provisions of § 39k are in no way related to those requirements of the Directive, since they are intended for situations that are quite different from the inclusion of a medicinal product in the system at the request of a marketing authorisation holder. Nevertheless, these provisions also fulfil the strict criteria under Articles 2, 3 and 6 of Directive 89/105/EEC.

**Re § 39k(2)**

These provisions lay down the rules for medicinal products that are not reimbursed in the Czech Republic, but can be a substitute for an unavailable medicinal product that is reimbursed. In such a case, the Institute will set the maximum price at an amount agreed with the health insurance company (the maximum price agreement) or an amount at which it can be purchased for distribution to the Czech Republic. The reimbursement for such a medicinal product will be set so that the patient’s co-payment (the difference between the maximum price and the reimbursed amount), taking into account the size of the package and the dosage, matches the co-payment for the original, currently unavailable, medicinal product. If necessary, the Institute will modify the conditions for reimbursement so that the substituting medicinal product is reimbursed only in indications where there is no other substitute. The Institute will lay down the measure for the expected period of the shortage, but for no longer than one year.

**Re § 39k(3)**

In the case of a medicinal product already reimbursed from health insurance (under Part Six of the Act), the Institute may change the maximum price to an amount agreed between health insurance companies and the applicant or an amount at which it can be purchased for distribution to the Czech Republic. The reimbursement for such a medicinal product will be changed so that the patient’s co-payment (the difference between the maximum price and the reimbursed amount), taking into account the size of the package and the dosage, matches that before the measure was adopted. If necessary, the Institute will modify the conditions for reimbursement so that the substituting medicinal product is reimbursed only in indications where there is no other substitute. The Institute will lay down the measure for the expected period of unavailability, but for no longer than one year. The enforceability of the original decision pursuant to § 39h is suspended during the period of application of the measure. However, the measure does not preclude conducting proceedings under § 39i or an in-depth or shortened revision; if a decision is issued, it will be enforceable for the given medicinal product after the measure expires.

**Re § 39k(4)**

The Institute may issue the measure ex officio or at the request of a health insurance company, marketing authorisation holder, importer or submitter of a specific therapeutic programme, or a distribution authorisation holder under the Pharmaceuticals Act. The request must contain identification of the applicant and the medicinal product, the indications for which reimbursement is requested, the proposed amount of reimbursement, the proposed maximum price, details of the differences in the summaries of product characteristics, a copy of the measures under the Pharmaceuticals Act, and documents providing proof of the purchase price of the medicinal product. The parties to the proceedings include the applicant and the persons referred to in § 39f(2).

**Re § 39k(5)**

If it is in the public interest, i.e. especially if there is no longer a risk of unavailability of reimbursed services, the Institute will decide to terminate the measure earlier than originally stipulated.

**Re § 39k(6)**

The first step in the proceedings of the measure is a request for comments on the supporting documents to be given within ten days (the deadline may be extended by the Institute). All documents are delivered in the form of a public notice. The measures will be enforceable by issuing them in the next update of the list pursuant to § 39n(1) after the time limit for appeal has expired.

**Re § 39k(7)**

An appeal may be filed against the measures, but, given that they are issued in the public interest, it will have no suspensory effect.

**Re § 39k(8)**

Pursuant to these provisions, the Institute is required to inform the Ministry of Health about the measures issued.

**Re Part Three:**

In light of the fact that the proposed system may fall within the scope of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, it is apparent that the proposed restrictions may fall under the definition of ‘other requirements’ within the meaning of Article 1 of the Directive, therefore, the draft act must be notified to the European Commission as a technical regulation.

**Re Part Four (entry into force):**

The provisions that govern ensuring the availability of medicinal products in the Czech Republic and, in particular, those concerning the emergency system are proposed to enter into force on …………, this means that there will be a transitional period of several months so that the obliged parties have sufficient time to set up their emergency systems and prepare for the functioning of the system. As regards Article I, point 9, the date of entry into force of this point needs to be postponed as it would not be fair to require the fulfilment of this obligation when the transitional provisions provide a six-month period for setting up and operating the emergency systems. Hence, the date of entry into force of these provisions needs to be postponed by that period.

In Prague, 26 August 2019

Prime Minister:

Ing. Andrej Babiš, m.p.

Minister for Health:

Mgr. et Mgr. Vojtěch, MHA, m.p.