Medicine shortages in CEE & SEE

Life Sciences & Healthcare

Wolf Theiss

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This 2024 Wolf Theiss Guide is intended as a practical guide to the general principles and features of the basic legislation and procedures in countries included in the publication.

While every effort has been made to ensure that the content is accurate when finalised, it should be used only as a general reference guide and should not be relied upon as definitive for planning or making definitive legal decisions. In these rapidly changing legal markets, the laws and regulations are frequently revised, either by amended legislation or by administrative interpretation.

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Introduction

Medicine shortages in Europe have reached unprecedented levels as a result of the COVID-19 pandemic. While this topic has been a concern for stakeholders and regulators for decades, the post-pandemic crisis necessitated urgent legislative reforms by individual countries and the European Union to meet pressing demands.

The CEE & SEE region, which has traditionally faced high levels of medicine shortages, has implemented various protectionist measures in the healthcare and pharmaceutical sectors. These measures aim to address the specific aspects of the region's supply and distribution models, along with regulatory strategies to maintain sufficient stocks.

This guide on Medicine Shortages in the CEE & SEE highlights the key elements of these measures across 10 countries in the region, outlining regional and country-specific practices. It provides insight into potential reasons for medicine shortages in the CEE & SEE region and describes planned legislative actions and procedures to address them. Furthermore the guide also explains how companies can use internal policies, rules and distribution strategies to manage the supply of certain medicines nationally, and examines the region's adherence to and application of the EU/EMA medicine shortages catalogue.

Hristina Dzhevlekova and Zuzana Hodoňová

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Austria

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1. What are the main reasons and relevant factors causing medicine shortages in your country?

Exemplary reasons

	Description
X	General business/marketing reasons.
	Termination/cancellation/change of a marketing authorisation - in other words product withdrawal. Manufacturers decide to withdraw pharmaceutical products from the market because in certain conditions they are no longer profitable; this is more and more common throughout Europe – especially for generics.
X	Delays in delivery/distribution.
	Deficiencies in production planning - most medicines and substances are produced outside the European Union in production facilities that produce materials for different pharmaceutical companies. Production is planned up to a year in advance, when specific volumes and delivery dates need to be contracted; any subsequent changes are almost impossible due to logistics.
X	Globalisation - production is highly globalised. Half of the medicines used in Europe are produced in just five or fewer factories worldwide. From a global point of view, Asia plays a major role, where two-thirds of the world's production of pharmaceuticals takes place.
	EU production is not competitive - competing with Chinese and Indian prices is impossible for European manufacturers. Both because of the cost of labour, environmental conditions for production and buildings, or even due to tax and price regulations.
X	Insufficient production capacity for active substances, which does not allow for an immediate increase in production volume.
X	Increased demand/sales (e.g. increased demand and consumption of medicines due to increased incidence of respiratory infections following the covid-19 pandemic).
	Low reimbursement/maximum price – reimbursements are set so low in CEE/SEE that global producers prefer to supply medicines to other countries. In practice, for some medicines, manufacturers are already exceeding the statutory maximum price/ reimbursement with the production price and it will not be possible for them to market the medicines further.

	Quotas imposed by manufacturers for certain countries.
X	Parallel trade/export - if products from countries with low drug prices are exported in large quantities to countries with higher prices, supply bottlenecks may occur in some cases in countries with lower prices.
	Geopolitical situation - a shortage of aluminium for the production of blisters, a shortage of packaging material for medicines, but also a shortage of glass for glass vials, ampoules and jars due to the war in Ukraine.
	Decline in the number of alternative medicines.
	Stockpiling - purchase of medicines by patients and pharmacies for stockpiling.
	Other.

According to a current report of the Austrian Agency for Health and Food Safety (AGES) and to the "Shortage Catalogue" of the Federal Office for Safety in Health Care (*Bundesamt für Sicherheit im Gesundheitswesen – BASG*), some reasons for temporary or permanent shortages of pharmaceutical products are as follows:

- **Parallel export:** Comparatively cheap medicines prices compared to other EU countries, which make the Austrian market unattractive for pharmaceutical companies in some cases. Consequently, the supply of medicines from Austria to other countries with higher price levels, such as Germany or Switzerland, might be prioritised leading to supply bottlenecks in Austria. To this end, BASG is entitled to issue a parallel export ban on specific medicinal products for reasons of public health protection.

- **Production reasons,** e.g., capacity shortages in production, delays in production, shortage of active and inactive ingredients , delays in delivery.

- **Increased additional demand:** As a result of outbreaks (such as COVID-19 or influenza), the additional demand for medicines cannot be covered in the short-term.

- **Outsourced production:** Active pharmaceutical ingredients are increasingly being manufactured in low-wage countries for cost reasons. The long transport route, often from Asia to Europe, and sometimes quality deficiencies in those countries increase the risk of delivery complications.

In 2023, BASG was provided with 1,515 reports of medicinal products that were not or not sufficiently available. However, no case was reported in which a patient was harmed due to drug supply shortages.

2. Has your country adopted legislation dealing specifically with medicine shortages and if so, what are the envisaged statutory measures and procedures?

Securing the supply of medicines is covered in Section 57a of the Austrian Medicinal Products Act (*Arzneimittelgesetz*– ***AMG***) and the Ordinance for Securing Supply with Medicinal Products (*Verordnung über die Sicherstellung der Arzneimittelversorgung*) based thereon.

Generally, marketing authorisation holders and wholesalers must ensure an adequate and continuous supply of the medicinal product in order to meet the needs of patients in Austria. In the event of any limitation related to the ability to distribute a prescription-only medicines in Austria, marketing authorisation holders must immediately notify the BASG. These electronically submitted notifications are automatically published in the "Shortage Catalogue" (*Liste der Meldungen zu Vertriebseinschränkungen von Arzneispezialitäten*) on the day following the actual start of the distribution limitation.

In addition, the BASG may impose a temporary export ban on certain products (parallel export ban) for reasons of public health protection. This instrument was implemented in 2020 during the course of the COVID-19 pandemic and regularly applied to around 200-400 medicinal products listed for export ban. In assessing the necessity of a ban, BASG takes into account the size of the population affected by a shortage, market share, market sales volume, calculated patient need, available stock and availability of potential alternative medicinal products.

Failure to comply with the above-mentioned obligations is punishable with administrative fines of up to EUR 25,000, or up to EUR 50,000 in cases of repeat offenses, which are imposed upon the responsible individuals (managing directors). In addition, competitors and market / consumer protection organisations could potentially file an injunction and / or claim damages under the laws on unfair competition.

Moreover, the recent conclusion of an agreement between the Association of Austrian Wholesalers of Pharmaceuticals (PHAGO) and the Austrian Federal Government, on the creation of an active ingredient warehouse, is aimed at preventing shortages during peak periods. Stock has been built up for the first time in late 2023 and includes the necessary ingredients for common antibiotics and medicines for cold symptoms. In periods of high demand, these can be called up by pharmacies for the production of magistral preparations.

3. Any applicable "soft law" measures?

Currently, there are no specific soft law measures dealing with drug shortages.

4. In addition to the above, what can companies do via internal policies, rules, distribution strategy etc. to regulate the supply of certain medicines within the national territory?

Marketing authorisation holders and pharmaceutical wholesalers who distribute medicines actually placed on the market must, within the scope of their respective responsibilities, ensure an adequate and continuous supply of said medicines to meet the needs of patients in Austria.

Generally, the risk of shortages should best be addressed in a coordinated manner including all parts of the supply chain. On the individual company level, observing developments in demand from previous years and adapting production and / or warehousing as well as coordinating with other market players such as pharmacies and physicians are advisable. In most cases, shortages of specific products can be dealt with at short-notice by coordinating supply at other levels of the chain or by substituting the product with similar ones, or by using different package sizes or active-substance levels. In addition, one of the more long-term solutions might be to move the production of medicinal products closer to the EU geographically.

5. Does your country treat OTC and prescription medicine differently in terms of possible shortages and measures?

The above-mentioned notification requirements and possible export bans only pertain to prescription drugs. However, market authorisation holders and wholesalers must ensure an adequate and continuous supply of all medicinal products.

6. To what extent does your country follow and apply the EU/EMA medicine shortages catalogue and are there any specific measures introduced in this regard?

No, there are no specific provisions in Austrian legislation aimed at the EU/EMA medicines shortages catalogue. BASG is an active member of the "Medicine Shortages Single Point of Contact (SPOC) Working Party" and communicates with other national regulatory authorities and EMA in the event of supply shortages that are classified as critical in at least one country.

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Medicine shortages in CEE & SEE

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Bulgaria

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1. What are the main reasons and relevant factors causing medicine shortages in your country?

Exemplary reasons

	Description
X	General business/marketing reasons.
X	Termination/cancellation/change of a marketing authorisation - in other words product withdrawal. Manufacturers decide to withdraw pharmaceutical products from the market because in certain conditions they are no longer profitable; this is more and more common throughout Europe – especially for generics.
	Delays in delivery/distribution.
	Deficiencies in production planning - most medicines and substances are produced outside the European Union in production facilities that produce materials for different pharmaceutical companies. Production is planned up to a year in advance, when specific volumes and delivery dates need to be contracted; any subsequent changes are almost impossible due to logistics.
	Globalisation - production is highly globalised. Half of the medicines used in Europe are produced in just five or fewer factories worldwide. From a global point of view, Asia plays a major role, where two-thirds of the world's production of pharmaceuticals takes place.
	EU production is not competitive - competing with Chinese and Indian prices is impossible for European manufacturers. Both because of the cost of labour, environmental conditions for production and buildings, or even due to tax and price regulations.
	Insufficient production capacity for active substances, which does not allow for an immediate increase in production volume.
	Increased demand/sales (e.g. increased demand and consumption of medicines due to increased incidence of respiratory infections following the covid-19 pandemic).
X	Low reimbursement/maximum price – reimbursements are set so low in CEE/SEE that global producers prefer to supply medicines to other countries. In practice, for some medicines, manufacturers are already exceeding the statutory maximum price/ reimbursement with the production price, and it will not be possible for them to market the medicines further.

	Quotas imposed by manufacturers for certain countries.
X	Parallel trade/export - if products from countries with low drug prices are exported in large quantities to countries with higher prices, supply bottlenecks may occur in some cases in countries with lower prices.
	Geopolitical situation - a shortage of aluminium for the production of blisters, a shortage of packaging material for medicines, but also a shortage of glass for glass vials, ampoules and jars due to the war in Ukraine.
	Decline in the number of alternative medicines.
X	Stockpiling - purchase of medicines by patients and pharmacies for stockpiling.
	Other.

According to the annual report of the Bulgarian Drug Agency for 2022 (2023 data is not yet available), the main reasons for temporary or permanent shortages of medicinal products identified by marketing authorisation holders **("MAH")** are as follows:

- **parallel export –** the main reason for Bulgaria's struggles with drug shortages is often cited as the significant parallel export of medical products to Western Europe (high-price countries). Exported quantities often disturb the supplies of medicinal products in the Bulgarian market. Various measures regarding how exports can be "controlled" without any breach of EU regulations and competition law are under discussion;
- **production reasons -** changes in the production cycle, insufficient production, delays in relation to raw materials or exhaustion of raw materials, problems with the supply of packaging materials;
- **marketing/commercial reasons -** change in the portfolio of the MAH, lack/reduced sales of the particular medicinal product (mainly due to the low prices charged for medicinal products in Bulgaria, low rates for reimbursement and claw back mechanics/ additional mandatory discounts);
- **increased demand of the medicinal product** and the inability to adapt supply/ production according to said demand (because of the above reasons, the Bulgarian drug market is often finds itself in unpredictable imbalances which pharmaceutical companies/MAHs are not able to quickly remedy via additional supplies due to their long supply cycles and forecasts).

2. Has your country adopted legislation dealing specifically with medicine shortages and if so, what are the envisaged statutory measures and procedures?

The matter of drug shortages is specifically addressed in Chapter 9 of the Bulgarian Medicinal Products in Human Medicine Act (**"MPHMA"**). The Act establishes a Specialised Electronic System for Tracking and Analysis of Medicinal Products (**"SESTAMP"**) which is operational since 2020. The purpose of the SESTAMP is to monitor the availability and stock of medicinal products included in the National Reimbursement List[1] based on information regarding sales and supply that is submitted by MAH/wholesalers/retailers of medicinal products and thus, limiting the risk of potential shortages.

Based on the submitted information and a statutory defined algorithm, the SESTAMP generates a medicine shortages catalogue on a weekly basis. Medicinal products included in the national shortages catalogue shall be deemed subject to an export ban.

In addition, in December 2023 a draft bill for an amendment to the MPHMA (**"Draft Bill"**) was submitted to the Bulgarian Parliament with the purpose of introducing further measures to address drug shortages. The proposed measures include, inter alia, an obligation for parallel distributors to notify the Bulgarian Drug Agency 3 months in advance of any (temporary or permanent) suspension of sales; adjustment of the algorithm for calculating medicine shortages; introduction of an expedited administrative procedure for authorising parallel imports during identified shortages, etc.

3. Any applicable "soft law" measures?

Currently there are no specific soft law measures (e.g., guidelines, industry codes, etc.) that deal with drug shortages in Bulgaria.

Certain general principles relating to drug shortages are included in the Code of Good Distribution Practice of the Bulgarian Association of Wholesalers of Medicinal Products (**"Code"**). For example, the Code provides that wholesalers of medicinal products should maintain a constant availability of prescription and over-the-counter (OTC) products that are needed by Bulgarian society to ensure the timely supply of medicines within the Bulgarian market. The Code further states that in the event of an emergency recall of medicines by the manufacturer and/or the Bulgarian Ministry of Health, wholesalers shall immediately inform all their customers on-line, by telephone or in person.

1 The National Reimbursement List indicates all medicinal products eligible for full/partial reimbursement with public funds. Under Bulgarian law only prescription (and not OTC) medicinal products are eligible for reimbursement

4. In addition to the above, what can companies do via internal policies, rules, distribution strategy etc. to regulate the supply of certain medicines within the national territory?

In addition to the measures under the MPHMA and the soft law sources outlined above, Bulgarian legislation also envisages an explicit obligation for MAHs and wholesalers to supply/maintain sufficient stock of medicinal products to meet domestic market demand. This regulatory obligation encourages companies to be active in considering possible internal measures to deal with reported drug shortages. The penalty for non-compliance is an administrative fine for the wholesaler in the amount of up to BGN 5,000 (EUR 2,500) for the first breach, and– up to BGN 100,000 (EUR 50,000) for the MAH for the first breach.

In practice, companies may have several contractual/commercial options to influence the supply and distribution of their medicinal products and to the extent possible, minimise the risk of possible shortages. Common practice involves the implementation of a direct-to-hospital (DTH) or direct-to-patient (DTP) distribution model, adjusting the distribution system to exclusive or selective distribution (whichever model might work better for the medicinal product's distribution), accommodating supply quotas as pursuant to domestic demand and additional margin, or even directly participating in public tenders, where feasible, etc. Implementing emergency supply systems for specific drugs is also possible, especially where the timing of the application of the drug is of the essence.

5. Does your country treat over-the-counter (OTC) and prescription medicines differently in terms of possible shortages and measures?

The measures envisaged in the MPHMA (see Q2 above) apply only with respect to prescription drugs, and not to OTC medicinal products.

As noted above, the SESTAMP collects information regarding the availability and possible shortages of medicinal products included in the National Reimbursement List only, which only covers prescription, but not OTC drugs.

6. To what extent does your country follow and apply the EU/EMA medicine shortages catalogue and are there any specific measures introduced in this regard?

Current Bulgarian legislation does not specifically address the EU/EMA medicines shortages catalogue. However, certain measures in that respect are envisaged under the Draft Bill currently pending before the Bulgarian Parliament.

Namely, the Draft Bill provides that medicinal products identified in the shortages catalogue of the European Medicines Agency, which are also covered under the National Reimbursement List, shall also be included in the national medicine shortages catalogue and be subject to an export ban.

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Medicine shortages in CEE & SEE

Life Sciences & Healthcare

Croatia

Wolf Theiss

1. What are the main reasons and relevant factors causing medicine shortages in your country?

Exemplary reasons

	Description
X	General business/marketing reasons.
X	Termination/cancellation/change of a marketing authorisation - in other words product withdrawal. Manufacturers decide to withdraw pharmaceutical products from the market because in certain conditions they are no longer profitable; this is more and more common throughout Europe – especially for generics.
	Delays in delivery/distribution.
X	Deficiencies in production planning - most medicines and substances are produced outside the European Union in production facilities that produce materials for different pharmaceutical companies. Production is planned up to a year in advance, when specific volumes and delivery dates need to be contracted; any subsequent changes are almost impossible due to logistics.
X	Globalisation - production is highly globalised. Half of the medicines used in Europe are produced in just five or fewer factories worldwide. From a global point of view, Asia plays a major role, where two-thirds of the world's production of pharmaceuticals takes place.
	EU production is not competitive - competing with Chinese and Indian prices is impossible for European manufacturers. Both because of the cost of labour, environmental conditions for production and buildings, or even due to tax and price regulations.
	Insufficient production capacity for active substances, which does not allow for an immediate increase in production volume.
X	Increased demand/sales (e.g., increased demand and consumption of medicines due to increased incidence of respiratory infections following the covid-19 pandemic).
X	Low reimbursement/maximum price – reimbursements are set so low in CEE/SEE that global producers prefer to supply medicines to other countries. In practice, for some medicines, manufacturers are already exceeding the statutory maximum price/ reimbursement with the production price, and it will not be possible for them to market the medicines further.

	Quotas imposed by manufacturers for certain countries.
	Parallel trade/export - if products from countries with low drug prices are exported in large quantities to countries with higher prices, supply bottlenecks may occur in some cases in countries with lower prices.
	Geopolitical situation - a shortage of aluminium for the production of blisters, a shortage of packaging material for medicines, but also a shortage of glass for glass vials, ampoules and jars due to the war in Ukraine.
	Decline in the number of alternative medicines.
	Stockpiling - purchase of medicines by patients and pharmacies for stockpiling
X	Other – the public procurement system for hospitals in Croatia, which operates in a manner where yearly tenders are awarded to only one supplier for certain medicines. This practice occasionally results in the withdrawal of other suppliers from the market due to significant financial losses incurred from excess inventory. Conversely, winning suppliers may encounter challenges in fulfilling the required quantities, leading to shortages of essential drugs in hospitals.

According to the information available on the Croatian Agency for Medicinal Products and Medical Devices (**HALMED**) website, the primary reasons for temporary or permanent shortages of medicinal products identified by marketing authorisation holders (**MAHs**) include:

- production issues;
- marketing or commercial reasons;
- increased demand for a medicinal product and the inability to adjust supply or production accordingly to meet said demand.

2. Has your country adopted legislation dealing specifically with medicine shortages and if so, what are the envisaged statutory measures and procedures?

In Croatia, under the Medicinal Products Act (which was promulgated in 2013 with the aim of harmonising Croatian legislation with European Union law and has undergone further amendments), MAHs and wholesalers operating within Croatian territory are obligated to ensure a consistent and uninterrupted supply of medicinal products to the general public.

MAHs are required to promptly notify HALMED, the Ministry of Health, and in the case of reimbursed products, also the Croatian Institute for Health Insurance (HZZO), in writing and without delay concerning circumstances that may lead to interruptions in supply or shortages of medicinal products in the Croatian market. The relevant reason must be specified.

Additionally, MAHs are also obligated to inform HALMED, at least two months in advance before discontinuing the supply, of their decision:

i) to discontinue placing or to withdraw the medicinal product from the market prior to the expiry of the marketing authorisation, regardless of whether this will be temporary or permanent,

ii) to submit an application for the revocation of the marketing authorisation, or

iii) not to submit an application for the renewal of said authorisation.

In their notification, MAHs must specify the reason for their decision, unless it concerns an urgent withdrawal or other extraordinary circumstances.

HALMED, based on notifications from MAHs, maintains and updates a publicly available national medicine shortages catalogue (list of drug shortages, available at hyperlink: https://www.halmed.hr/en/Promet-proizvodnja-i-inspekcija/Promet/Prekid-opskrbe-trzista-lijekom-i-nestasice/), as well as a list of interchangeable medicines that can be directly substituted at the pharmacy level without the need for consultation with a physician.

During drug shortages, if substitute medicines are unavailable on the Croatian market, HALMED may also authorise the following measures: (i) exceptional entry or import approval for substitute medicinal products not approved in Croatia but authorised in another EU member state or a third country, and/or (ii) approvals for the entry or import of medicinal products not labelled in Croatian, wherein the same approved medicinal product is made available on the Croatian market but labelled in a foreign language used by another EU Member State.

Croatian legislation does not currently include any additional specific restrictive measures, such as export bans or minimum stock requirements, to tackle drug shortages.

Furthermore, there are no imminent legislative changes anticipated in Croatia concerning drug shortages. However, efforts are underway to implement a new monitoring and prevention system designed to address shortages. This system is intended to offer automatic real-time information regarding available quantities of drugs and is projected to be operational by 2025.

3. Any applicable "soft law" measures?

Currently in Croatia, there are no specific soft law measures addressing drug shortages.

4. In addition to the above, what can companies do via internal policies, rules, distribution strategy etc. to regulate the supply of certain medicines within the national territory?

In Croatia, legislation mandates MAHs and wholesalers guarantee timely, continuous, and sufficient supplies of medicinal products. Monetary fines ranging from approx. EUR 13,000 to EUR 20,000 are prescribed for non-compliance with this obligation. Although such fines are generally not imposed in practice, this regulatory obligation prompts companies to proactively devise and implement internal measures aimed at preventing and managing drug shortages.

In practice, companies often institute shortage prevention and management plans. These plans typically involve identifying and mitigating vulnerabilities and risks throughout the supply chain, adjusting supply quotas based on demand forecasts and maintaining ample contingency stocks when justified.

Companies may pursue various contractual and commercial strategies to influence the supply and distribution of their medicinal products and, wherever feasible, minimise the risk of potential shortages. Common approaches include implementing a direct-to-hospital (DTH) or direct-to-patient (DTP) distribution model, adapting the distribution system to exclusive or selective distribution (whichever is more suitable for the medicinal product's distribution), adjusting supply quotas in accordance with national demand and additional margin considerations, and even participating directly in public tenders, where applicable.

5. Does your country treat over-the-counter (OTC) and prescription medicines differently in terms of possible shortages and measures?

The measures authorised by HALMED to address drug shortages (refer to Q2 above) are specifically designed for prescription drugs and do not encompass OTC drugs.

6. To what extent does your country follow and apply the EU/EMA medicine shortages catalogue and are there any specific measures introduced in this regard?

Current legislation in Croatia does not specifically address the EU/EMA medicine shortages catalogue, and no specific measures have been introduced in this regard. Medicinal products listed or identified in the EU/EMA shortages catalogue are not automatically included in the national medicine shortages catalogue.

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Medicine shortages in CEE & SEE

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Czech Republic

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1. What are the main reasons and relevant factors causing medicine shortages in your country?

Exemplary reasons

	Description
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X	Geopolitical situation - a shortage of aluminium for the production of blisters, a shortage of packaging material for medicines, but also a shortage of glass for glass vials, ampoules and jars due to the war in Ukraine.
X	Decline in the number of alternative medicines.
X	Stockpiling - purchase of medicines by patients and pharmacies for stockpiling.
	Other.

Following the covid-19 pandemic, like the rest of Europe, the Czech Republic has experienced a heightened occurrence of drug shortages.

The reasons behind these shortages include the lack of active substances or packaging, production discontinuations or insufficient planning by manufacturers, many of whom refer to the comparatively low prices in the Czech Republic.

Common reasons for supply interruptions are usually linked to production, logistics or regulatory problems, including:

- delayed or limited supply of active substances, raw materials or packaging materials;
- deficiencies in production planning and production capacity;
- pricing pressure on the low price of medicinal products;
- lack of alternative medicines;
- export to other countries with a higher price level;
- increased patient demand and stockpiling;

A prevailing viewpoint suggests that many of the factors contributing to drug shortages are attributable to national regulations, which limit the flexibility and attractiveness of the Czech market. Medicine prices in the Czech Republic are relatively lower compared to other EU Member States, resulting in the provision of medicines to the Czech Republic not being a high business priority for suppliers.

2. Has your country adopted legislation dealing specifically with medicine shortages and if so, what are the envisaged statutory measures and procedures?

In response to the prevalent drug shortages in the Czech Republic, the Ministry of Health introduced a so called "safety stocks" amendment to the Medicinal Products Act effective as of 2024.

The revised Medicinal Products Act imposes new responsibilities on stakeholders in the pharmaceutical market. A key change is the obligation placed on Marketing Authorization Holders (MAHs) to ensure medicine supplies for patients in the Czech Republic for 1-2 months following the notification of a disruption or termination of the supply, depending on whether the medicinal product in question has been consistently available or experienced interruptions over the past 2 years. The obligation to guarantee the ongoing supply of the medicinal product has a delayed effect. It will be applicable to MAHs from June 1, 2024, but only half the range. The full range will not come into effect until January 1, 2025.

The Amendment allows MAHs to secure the necessary one/two-month supply of medicines, even from foreign-language batches, that is, by utilising supplies initially designated for other countries.

The updated Medicinal Products Act introduces the possibility to designate a product as having "limited availability". Such a product may not be exported outside the Czech Republic, and pharmacies are subject to specific restrictions on ordering (limits to prevent stockpiling), while distributors are obligated to supply the product within two working days.

All links in the supply chain, from the MAH to the final pharmacy are mandated to furnish the State Institute for Drug Control (SUKL) with updates on the current stock of medicinal products facing limited availability, enabling the Ministry of Health to precisely gauge the available stock for delivery to pharmacies versus the stock still present in pharmacies.

Doctors and pharmacies can utilise the ePrescription system to provide patients with information about the current availability of products with limited availability.

The Ministry of Health will monitor if the medicine supply aligns with the expected demand from Czech patients. If a potential shortage is identified, the Ministry will incorporate the medicine into the reserve stock system. Wholesalers will then be automatically required to maintain a stock of that medicine, equivalent to the average monthly demand.

The powers of the SUKL and the Ministry of Health have also been strengthened, as reflected in the updated Public Health Insurance Act. SUKL will have the authority to issue a decision temporarily setting or changing the maximum price, as well as the amount and conditions of reimbursement for a medicine at risk of unavailability or deemed important for public health protection. For medicinal products not yet reimbursed in the Czech Republic but serving as substitutes for unavailable reimbursed medicinal products, SUKL shall establish the maximum price, either at the agreed-upon level with the health insurer or at the price at which it can be procured for distribution in the Czech Republic.

Due to the Amendment, costs and administrative burdens for MAHs, wholesalers and pharmacies will significantly increase. Critics argue that the state is transferring its responsibility for ensuring effective control over medicine stocks to private stakeholders. The need to maintain a monthly or bi-monthly stock of most prescription medicines available on the Czech market may seem inadequate.

3. Any applicable "soft law" measures?

Alongside the revision of the Medicinal Products Act, amendments to the related decrees were also adopted. These amendments provide more detailed regulations concerning the obligations related to the introduction of the "safety stocks" system, including a list of medicinal products exempt from the obligation to maintain "safety stocks.".

However, in terms of informal regulations (soft law), corresponding documents are currently lacking. It is expected that SUKL will create new methodologies and guidelines in the following months. SUKL has published a presentation and a Q&A section related to the amendment of the Medicinal Products Act which may help to clarify potential initial queries.

4. In addition to the above, what can companies do via internal policies, rules, distribution strategy etc. to regulate the supply of certain medicines within the national territory?

Given the risk of re-export of medicinal products to other countries, the direct-to-pharmacy/direct-to hospital channels (DTP/DTH) are commonly used for the distribution of innovative, oncology or biological products. The Czech Competition Office completed in 2023 a sector inquiry into the distribution of medicinal products, with a focus on DTP/DTH systems. The inquiry found that the public interest in ensuring the supply of medicines to domestic patients outweighs any potential disadvantages in terms of restricting competition.

Following the Amendment, it can be assumed that MAHs will report shortages earlier, even if products are still available on the market. As a consequence, MAHs are considering how to use the remaining stocks after reporting a shortage, possibly through their own communication channels.

In the event of restricted supplies for the whole EU market, MAHs may contemplate withdrawing from the Czech market where mandatory one/two-month deliveries are required, in favour of larger markets or markets with higher prices.

5. Does your country treat over-the-counter (OTC) and prescription medicines differently in terms of possible shortages and measures?

The newly introduced measures for addressing shortages apply to prescription (Rx) products. An exception is the possibility of permitting the import of foreign-language batches, even for (OTC) medicines. Some of the OTC products have recently been unavailable in the Czech market, and their provision for the needs of Czech patients was challenging to address under the current regulation.

6. To what extent does your country follow and apply the EU/EMA medicine shortages catalogue and are there any specific measures introduced in this regard?

SUKL maintains its own list of medicine shortages, where MAHs report the suspension or termination of supplies. This catalogue is included among the list of national registers of shortages set out on the EMA's website.

While the EMA shortages catalogue offers a comprehensive overview of drug shortages across the entire European market, the list maintained by SUKL, specifically capturing shortages at the local level for the Czech pharmaceutical market, holds greater significance.

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Medicine shortages in CEE & SEE

Life Sciences & Healthcare

Hungary

Wolf Theiss

1. What are the main reasons and relevant factors causing medicine shortages in your country?

Exemplary reasons

	Description
X	General business/marketing reasons.
	Termination/cancellation/change of a marketing authorisation - in other words product withdrawal. Manufacturers decide to withdraw pharmaceutical products from the market because in certain conditions they are no longer profitable; this is more and more common throughout Europe – especially for generics.
X	Delays in delivery/distribution.
	Deficiencies in production planning - most medicines and substances are produced outside the European Union in production facilities that produce materials for different pharmaceutical companies. Production is planned up to a year in advance, when specific volumes and delivery dates need to be contracted; any subsequent changes are almost impossible due to logistics.
X	Globalisation - production is highly globalised. Half of the medicines used in Europe are produced in just five or fewer factories worldwide. From a global point of view, Asia plays a major role, where two-thirds of the world's production of pharmaceuticals takes place.
	EU production is not competitive - competing with Chinese and Indian prices is impossible for European manufacturers. Both because of the cost of labour, environmental conditions for production and buildings, or even due to tax and price regulations.
X	Insufficient production capacity for active substances, which does not allow for an immediate increase in production volume.
X	Increased demand/sales (e.g. increased demand and consumption of medicines due to increased incidence of respiratory infections following the covid-19 pandemic).
X	Low reimbursement/maximum price – reimbursements are set so low in CEE/SEE that global producers prefer to supply medicines to other countries. In practice, for some medicines, manufacturers are already exceeding the statutory maximum price/ reimbursement with the production price, and it will not be possible for them to market the medicines further.

	Quotas imposed by manufacturers for certain countries.
	Parallel trade/export - if products from countries with low drug prices are exported in large quantities to countries with higher prices, supply bottlenecks may occur in some cases in countries with lower prices.
X	Geopolitical situation - a shortage of aluminium for the production of blisters, a shortage of packaging material for medicines, but also a shortage of glass for glass vials, ampoules and jars due to the war in Ukraine.
	Decline in the number of alternative medicines.
X	Stockpiling - purchase of medicines by patients and pharmacies for stockpiling.
X	Other – delays with registration or re-registration.

According to the shortage list published and constantly updated by the Hungarian National Center for Public Health and Pharmacy (**"NNGYK"**), some reasons for temporary or permanent shortages of medicinal products identified are as follows:

- transfer or storage complications (e.g. lack of warehousing/storage capacities);
- issues with the supply of active substance and other ingredients;
- limited supply;
- discontinuation of production;
- administrative reasons (i.e., compliance inadequacy);
- commercial reasons (e.g. pricing, marketing strategies).

The following circumstances also play a significant role for the emerging shortage of medicinal products in Hungary:

- due to Hungarian pricing regulations, companies are forced to sell their products on the Hungarian market at a price lower than in most of the neighbouring countries, therefore they tend to favour markets where they are able to realise the desired prices;
- supply chain issues due to the war in Ukraine: for example basic packaging materials such as paper and cardboard are unavailable;

- more and more medicinal products are being removed from the social security system in order to allow manufacturers to price freely and avoid tax burdens, as well as to get rid of unpredictable legal regulations;
- at the beginning of 2024, an extra profit tax was imposed on pharmaceutical manufacturers, which exists alongside the special tax applied since 2022;
- economic factors such as high inflation rate, increased energy prices, increase in raw material purchase prices.

2. Has your country adopted legislation dealing specifically with medicine shortages and if so, what are the envisaged statutory measures and procedures?

a) **Obligations of the market players**

With respect to the market players' distribution obligation in Hungary, Act XCV of 2005 on *Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products* (**"Medicines Act"**), as well as *Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products* ("**Medicines Thrift Act**") set forth that:

- **With regard to wholesalers:**
  - the wholesaler is obligated to obtain and distribute the medicinal products for which it has been granted a wholesale license and shall, apart from the balanced satisfaction of orders in the framework of the ordinary course of business, take into account patient care requirements. To that end, the wholesaler is required to maintain a purchase and inventory management system with facilities to ensure the transparency and controllability of the distribution and supply.
- **With regard to marketing authorisation holders:**
  - the marketing authorisation holder must ensure that wholesalers that are authorised in Hungary collectively maintain a continuous supply of the active pharmaceutical ingredients and their required quantities specified in the law.
  - the marketing authorisation holder shall also ensure that any wholesaler that is authorised in Hungary shall be given the opportunity to distribute the marketing authorisation holder's medicinal products, provided the wholesaler makes a statement specifically indicating that the product is requested for the purpose of satisfying patient care requirements in Hungary.

However, should a marketing authorisation holder (or in their absence, the "contracted" wholesaler) be unable to ensure the continuous supply of a medicinal product in Hungary, or either temporarily or permanently ceases its distribution, it (or in their absence, the "contracted" wholesaler) must immediately inform:

i) its contracted wholesale partners and the NNGYK,

ii) in the case of medicinal products eligible for social security reimbursement, the National Health Insurance Fund (**"NEAK"**)

of such a shortage, including the duration of the shortage and the available quantities of the medicinal product. Based on said information, the NNGYK determines whether there is an actual shortage or the risk of a shortage regarding the concerned medicinal product.

As a result of the investigation, the NNGYK may impose the following obligations on the marketing authorisation holder (and/or the "contracted" wholesaler) in order to remedy the shortage or its risk:

- The NNGYK may compel the marketing authorisation holder to obtain a substitute for the medicinal product affected by the shortage and to ensure the product information and packaging is in Hungarian;
- In the event that the shortage cannot be remedied in any other way, the NNGYK may – at the request of a wholesaler – authorise the supply of a medicinal product that may be used instead of the product of which there is a shortage;
- The NNGYK may introduce a ban on the export of a medicinal product intended for supply to the general public for a period that is necessary to guarantee security of supply, but for no longer than one year. (Note: There were many examples of this rule during the Covid-19 epidemic.)

In addition to the above, where the marketing authorisation holder of medicinal products reimbursed by the social security system intends to discontinue or is unable to continue the marketing of such a product that is already in circulation, temporarily or for any extended duration:

i) if being deprived of the medicinal product in question is likely to result in severe or persistent disability for the patients treated with such products; and

ii) there is no other medicinal product of similar active ingredients, pharmaceutical form and strength available in the territory of Hungary,

the administrator of state healthcare, emergency and safety reserves shall have powers to purchase the medicinal products in question from any legal entity that is authorised for wholesale or retail in a State other than Hungary.

b) **Authorisations granted to public bodies**

With respect to product shortages, the NNGYK was granted further authority with the Decree of the Minister responsible for Health, Social and Family Affairs No. 44/2004 (IV.28.) on the prescription and dispensing of medicinal products for humans.

If it is deemed necessary by the NNGYK to prevent and manage drug shortages, it

i) may impose certain reporting obligations on marketing authorisation holders, wholesalers, and hospitals regarding the available quantities of medicinal products or active substances that are at risk of shortage or may be used instead;

ii) may make the characteristics of the affected medicinal products, the duration of the shortage and their possible substitutes available on its website;

iii) may coordinate the supply of the medicinal products among hospitals (applied exceptionally) and work together with wholesalers to determine the quantities to be supplied to hospital pharmacies;

iv) it may, upon request, if required to meet domestic needs, authorise the wholesaler to obtain a medicinal product that may be used instead of a medicinal product in shortage (this is the so-called "contingent authorisation"). A contingent authorisation is issued for the import from abroad of a medicinal product not authorised for marketing in Hungary or of a medicinal product authorised for marketing but placed on the market in another country.

The NNGYK may also carry out an ex officio marketing authorisation procedure and issue parallel import authorisations to remedy a long-term shortage of medicines.

Finally, an individual method to handle the shortage is the so-called "individual import license" which can be requested by the attending physician only. The individual supply may be issued for a medicinal product which has a marketing authorisation in the European Economic Area ("EEA") or in a country who is party to the EEA Agreement, or which is authorised in Hungary but is temporally unavailable.

c) **Obligations related to reimbursed medicinal products**

Pursuant to the Medicines Thrift Act, the NEAK may state conditions during the procedure for a medicinal product to be admitted into the social security system, such as an obligation to distribute the reimbursed medicinal product for at least 3 years and a specific stockholding obligation to always ensure an adequate and sufficient supply.

d) **Implementation of a strategic list of medicinal products**

On 11 March 2023, the Minister of Interior issued a decree on the implementation of a strategic list of medicinal products. In its annex, 312 strategic pharmaceutical active substances are listed that are necessary to maintain safe patient care in Hungary.

Under this new decree, wholesalers must maintain a continuous stock of products containing these strategic active substances, equal to 1/12th of the quantity sold in the previous 12 months.

The NNGYK will have to publish on its website the list of medicinal products including these active substances which are on the Hungarian market. Medicinal products manufactured in Hungary must be marked with the "SH" symbol, and medicinal products manufactured by manufacturers with a manufacturing site in Hungary must be marked with the "S" symbol.

The decree in question will enter into force on the 60th day after its publication, and the notice issued by the NNGYK must appear on the first day of the month following the entry into force of the decree.

3. Any applicable "soft law" measures?

Currently, there are no specific soft law measures (e.g., guidelines, industry codes, etc.) dealing with drug shortages from a company perspective.

4. In addition to the above, what can companies do via internal policies, rules, distribution strategy etc. to regulate the supply of certain medicines within the national territory?

Companies can deal with product shortages in various ways, such as:

i) developing a stock allocation system for the region and within that framework, applying individualised quotas for different parts of the supply chain;

ii) moving to a direct-to-pharmacy model, when the company supplies the pharmacies and healthcare providers directly, without the involvement of an additional wholesaler;

iii) directly applying on public tenders;

iv) minimising the number of wholesalers with whom the company is in a contractual relationship or appointing a selective distributor;

v) allocating alternative products or offering different package sizes, if available, etc.

5. Does your country treat over-the-counter (OTC) and prescription medicines differently in terms of possible shortages and measures?

The measures envisaged in the Medicines Act (see Q2 above) apply with respect to both prescription-only as well as OTC medicinal products.

However, the Medicines Act contains stricter rules for medicinal products eligible for social security reimbursement (see Q4 above).

6. To what extent does your country follow and apply the EU/EMA medicine shortages catalogue and are there any specific measures introduced in this regard?

No changes have yet been made or are in the process of being made specifically in relation to the EU/EMA medicine shortage catalogue, but the NNGYK will take into account the practice of the EMA in developing its recommendations.

Disclaimer: Associates appearing under the professional supervision of their relevant partners at Wolf Theiss.

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Medicine shortages in CEE & SEE

Life Sciences & Healthcare

Poland

Wolf Theiss

1. What are the main reasons and relevant factors causing medicine shortages in your country?

Exemplary reasons

	Description
X	General business/marketing reasons.
X	Termination/cancellation/change of a marketing authorisation - in other words product withdrawal. Manufacturers decide to withdraw pharmaceutical products from the market because in certain conditions they are no longer profitable; this is more and more common throughout Europe – especially for generics.
	Delays in delivery/distribution.
	Deficiencies in production planning - most medicines and substances are produced outside the European Union in production facilities that produce materials for different pharmaceutical companies. Production is planned up to a year in advance, when specific volumes and delivery dates need to be contracted; any subsequent changes are almost impossible due to logistics.
	Globalisation - production is highly globalised. Half of the medicines used in Europe are produced in just five or fewer factories worldwide. From a global point of view, Asia plays a major role, where two-thirds of the world's production of pharmaceuticals takes place.
	EU production is not competitive - competing with Chinese and Indian prices is impossible for European manufacturers. Both because of the cost of labour, environmental conditions for production and buildings, or even due to tax and price regulations.
X	Insufficient production capacity for active substances, which does not allow for an immediate increase in production volume.
X	Increased demand/sales.
X	Low reimbursement/maximum price – reimbursements are set so low in CEE/SEE that global producers prefer to supply medicines to other countries. In practice, for some medicines, manufacturers are already exceeding the statutory maximum price/ reimbursement with the production price, and it will not be possible for them to market the medicines further.

	Quotas imposed by manufacturers for certain countries.
X	Parallel trade/export - if products from countries with low drug prices are exported in large quantities to countries with higher prices, supply bottlenecks may occur in some cases in countries with lower prices.
	Geopolitical situation - a shortage of aluminium for the production of blisters, a shortage of packaging material for medicines, but also a shortage of glass for glass vials, ampoules and jars due to the war in Ukraine.
	Decline in the number of alternative medicines.
X	Stockpiling - purchase of medicines by patients and pharmacies for stockpiling.
	Other.

According to the publicly available reports of the Supreme Audit Office and statements of the Polish Ministry of Health's officials, the main reasons for temporary or permanent shortages of medicinal products are as follows:

- **Low reimbursement/maximum prices -** in Poland, the prices of reimbursed medicinal products are low, and in some categories of products (e.g., generic drugs), they are the lowest in the European Union. This makes Poland an important reference country for the purpose of benchmarking the pricing of reimbursed medicines in other EU countries. As a result, even minimal price reductions of already low prices of individual medicines in Poland may trigger an avalanche of price decreases of medicines in other European countries. In practice, this either leads to delayed access to new medicinal products for Polish patients (as the pharmaceutical companies prefer to firstly launch the product in more profitable markets), or a pharmaceutical company abandoning the sale of a given medicine in Poland entirely, in order to protect its global profits.
- **Parallel export –** low prices of medicinal products encourage activities aimed at transferring medicinal products to other, more profitable markets by way of parallel export. Although the exported quantities can occasionally disturb the supplies of medicinal products to the Polish market, it is mainly the illegal form of exports, a so-called reverse distribution, that causes drug shortages in Poland.
- **Reverse distribution in supply chain –** in a typical reverse distribution mechanism, a medicinal product at the pharmacy, this being a stage immediately preceding the retail sale to the patient, does not reach the patient. Instead, it becomes the object of the wholesale trade again, to be finally disposed of abroad by a pharmaceutical wholesaler.

The operation of the reverse transfer of medicinal products is usually carried out under the false pretence of legitimacy, for example, returns due to alleged defectiveness or the use of brokering by entities conducting medicinal activity (clinics, hospitals etc.). It is the 'reversal' of the distribution chain that has underpinned the legislative changes aimed at criminalising it and preventing drug shortages in Poland.

- **Increased demand and the inability to adapt supply/production according to said demand –** shortages of specific medicinal products are frequently regional and occur due to temporary demand peaks. Manufacturing sites and supply chains may not adapt quickly enough to handle these fluctuations, leading to temporary shortages on the market.
- **Geopolitical situation –** drug distribution chains remain disrupted due to the war in Ukraine, leading to increased transportation costs for many products and, consequently, drug shortages.
- **Insufficient production capacity for active substances –** Like other EU countries, Poland imports most active pharmaceutical ingredients (APIs) from Asia, mainly China and India. Any disruptions in the supply chains from Asia make the entire EU, including Poland, vulnerable to drug shortages.

2. Has your country adopted legislation dealing specifically with medicine shortages and if so, what are the envisaged statutory measures and procedures?

A growing prevalence of reverse distribution in Poland (for details, please refer to Q1) and its impact on drug supplies prompted stricter legislative changes and controls over medicine supplies, addressed to different stakeholders. Namely:

- an **Integrated System for the Monitoring of Trade in Medicinal Products ("ZSMPOL")** was launched in 2019 as part of an "anti-export" package of amendments to the Pharmaceutical Law. ZSMPOL is an IT system populated daily with data, including stock levels, planned deliveries, reported shortages, etc. It is used by authorities like the Minister of Health and the Main Pharmaceutical Inspectorate ("MPI") for the purposes of monitoring of drug circulation and shortage management.
- based on ZSMPOL data, a bi-monthly **anti-export list of shortage medicines** is created. Listed products are subject to export control - exporters must notify the MPI of their intention to sell and export them outside Poland. The MPI may object within 30 days. Disposing of medicines without prior notification or against an objection is

illegal and leads to the mandatory withdrawal of the wholesale permit.

- the export of drugs included on the anti-export list requires notification in the **"SENT" system,** which monitors the transport of certain groups of goods and is supervised by the Head of the National Tax Administration. SENT collects data collected from export declarations and the geolocation data of transport vehicles. The MPI has been given the power to use and process the data collected in the SENT register for the purpose of supervising the medicinal products trade.
- **rules on medicine distribution direction in the supply chain were further clarified.** Supplying directly to the public was specified as the sole purpose of pharmacy operations, and a closed list of entities where pharmaceutical wholesalers could obtain medicines was introduced. Additionally, businesses involved in healthcare were prohibited from purchasing medicines for purposes unrelated to patient care and selling them. Any violation of the above rules is punishable by imprisonment from 3 months to 10 years (depending on the gravity of the offence).
- a **weekly summary of medicine availability analysis** is to be prepared by the Main Pharmaceutical Inspectorate and distributed to the Medical and the Pharmaceutical Chambers. This is in response to the need for cooperation between public administration and healthcare practitioners for effective medicine availability management. However, pharmacists emphasise the limited usefulness of these lists, as they are outdated by the time they reach district chambers, pharmacies, and doctors.
- **marketing authorisation holders (MAHs)** also face additional obligations to prevent drug shortages. They must notify the Office for Registration of Medicinal Products at least two months in advance of any planned discontinuation of distribution. In cases of sudden discontinuation due to unforeseen circumstances, immediate notification is required.
- a major amendment to the Reimbursement Act, mandates that **manufacturers must supply a minimum of ten wholesalers in the ambulatory pharmacy market** on an equal basis, with regard to those reimbursed products identified as being under threat of unavailability in Poland. While the Minister of Health is responsible for publishing a list of the ten largest full-line pharma wholesalers, the list remains unavailable at the time of this writing.

3. Any applicable "soft law" measures?

In Poland, there are currently no specific soft law measures (e.g., guidelines, industry codes,

etc.) dealing with drug shortages.

4. In addition to the above, what can companies do via internal policies, rules, distribution strategy etc. to regulate the supply of certain medicines within the national territory?

Polish legislation explicitly provides for MAHs' and wholesalers' obligation to supply/maintain sufficient stock of medicinal products, in order to meet domestic demand. This applies particularly to reimbursed products, where failing to ensure continuous supply carries significant consequences. MAHs that fail to meet demand face financial penalties from the National Health Fund (the only public payer in Poland) equalling the number of undelivered packs multiplied by their official net sales price (except for force majeure cases). Wholesalers face license revocation for non-compliance.

MAHs often influence the supply of their medicinal products using specific distribution models, like direct-to-hospital (DTH) and direct-to-pharmacy (DTP) distribution models. In these models, a pharmaceutical wholesaler belonging to the capital group of the MAH sells directly to those who supply patients (pharmacies, healthcare providers, hospitals etc.). However, according to officials, the "direct distribution" model contributes to acute regional drug shortages. According to the Pharmaceutical Chamber, many small and independent pharmacies face discriminatory practices from MAHs resulting in an uneven supply of products throughout the country based on a pharmacy's size, order and payment history; or a preference for a chain over individual pharmacies. Such regional shortages of medicinal products were the main reason for introducing an obligation to supply a minimum of ten wholesalers in the ambulatory pharmacy market on an equal basis under the Reimbursement Act (for details, please refer to Q2).

5. Does your country treat over-the-counter (OTC) and prescription medicines differently in terms of possible shortages and measures?

The measures imposing stricter controls over medicinal products' supply (for details, please refer to Q2) apply to all medicinal products, including over the counter (OTC) drugs. ZSMPOL collects information concerning the distribution of all medicinal products. Based on this data, an anti-export list is created, which includes products from any category at risk of shortage. Additionally, transport of products included in the anti-export list is reported and tracked through the SENT system. However, pharmacies are only required

to report shortages of prescription drugs and reimbursed drugs to the local MPI branch within 24 hours.

6. To what extent does your country follow and apply the EU/EMA medicine shortages catalogue and are there any specific measures introduced in this regard?

While Polish legislation does not specifically reference the EU/EMA medicines shortages catalogue, the Main Pharmaceutical Inspectorate (MPI) actively monitors drug shortages and maintains regular communication with Marketing Authorization Holders (MAHs) and the European Medicines Agency's dedicated Medicine Shortages Single Point of Contact (SPOC) expert group.

Poland

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Medicine shortages in CEE & SEE

Life Sciences & Healthcare

Serbia

Wolf Theiss

1. What are the main reasons and relevant factors causing medicine shortages in your country?

Exemplary reasons

	Description
X	General business/marketing reasons.
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X	Delays in delivery/distribution.
	Deficiencies in production planning - most medicines and substances are produced outside the European Union in production facilities that produce materials for different pharmaceutical companies. Production is planned up to a year in advance, when specific volumes and delivery dates need to be contracted; any subsequent changes are almost impossible due to logistics.
	Globalisation - production is highly globalised. Half of the medicines used in Europe are produced in just five or fewer factories worldwide. From a global point of view, Asia plays a major role, where two-thirds of the world's production of pharmaceuticals takes place.
	EU production is not competitive - competing with Chinese and Indian prices is impossible for European manufacturers. Both because of the cost of labour, environmental conditions for production and buildings, or even due to tax and price regulations.
	Insufficient production capacity for active substances, which does not allow for an immediate increase in production volume.
X	Increased demand/sales (e.g., increased demand and consumption of medicines due to increased incidence of respiratory infections following the covid-19 pandemic).
X	Low reimbursement/maximum price – reimbursements are set so low in CEE/SEE that global producers prefer to supply medicines to other countries. In practice, for some medicines, manufacturers are already exceeding the statutory maximum price/ reimbursement with the production price, and it will not be possible for them to market the medicines further.

	Quotas imposed by manufacturers for certain countries.
	Parallel trade/export - if products from countries with low drug prices are exported in large quantities to countries with higher prices, supply bottlenecks may occur in some cases in countries with lower prices.
X	Geopolitical situation - a shortage of aluminium for the production of blisters, a shortage of packaging material for medicines, but also a shortage of glass for glass vials, ampoules and jars due to the war in Ukraine.
	Decline in the number of alternative medicines.
X	Stockpiling - purchase of medicines by patients and pharmacies for stockpiling.
X	Other – delays with registration or re-registration.

There are no official public reports on drug shortages. According to the statements from the Ministry of Health, National Health Insurance Fund and different associations of pharmacists, the main reasons for temporary or permanent shortages of medicinal products are as follows:

- production reasons - changes in the production cycle, insufficient production, supply chain delays or exhaustion of raw materials, problems with the supply of packaging materials;
- marketing/commercial reasons - changes to the portfolio of the MAH, lack/reduced sales of the particular medicinal product (mainly due to the low prices charged for medicinal products in Serbia, and low rates for reimbursement);
- occasional delays with registration or re-registration, or problems with quality control tests;
- increased demand of the medicinal product and the inability to adapt supply/production according to said demand in a short period of time.

2. Has your country adopted legislation dealing specifically with medicine shortages and if so, what are the envisaged statutory measures and procedures?

There are no explicit provisions dealing with drug shortages adopted in legislation. However, certain provisions of the Serbian Law on Medicines and Medical Devices **(Law)** and its bylaws are of relevance here:

i) **Law on Medicines and Medical** Devices prescribes the obligation for both the MAH and the wholesaler to provide a continuous supply to the market. Specifically for the wholesaler, the Law prescribes that the legal entity that carries out the wholesale of medicines must ensure the continuous supply of medicines to the market, in accordance with the licence for the wholesale of medicines. Such legal entity must deliver, at the request of the health institution and private practice or veterinary institution, the medicine for which it has obtained a wholesale license in the shortest possible time, and in a way that does not endanger the life and health of people or animals. A wholesaler must keep necessary stocks of medicines, for which the wholesaler has received a licence, for the sake of the continuous supply of medicines to the market. This pertains to initiating procurement, importing and obtaining the certificates of analysis issued by the Serbian Agency for Medicines and Medical Devices (**ALIMS**) in a timely manner, so as to not to have an interruption in the market supply of medicines for which the wholesaler is responsible.

The Law further prescribes that the MAH must enter into a written supply agreement with any entity that is carrying out the wholesale of medicines for that MAH, as well as to submit a list of those legal entities at the request of the competent ministry as well as that, the wholesaler must inform the competent ministry, without delay, on any problem with ensuring the continuous supply of the drug to the market.

Finally, should the MAH decide to stop supplying the Serbian market, it must inform the Serbian Ministry of Health and ALIMS thereof, 12 months prior to the intended date of cessation of circulation of the medicinal product.

ii) **Rulebook on the Conditions for Wholesale of Medicines and Medical Devices, Information to be Entered in the Register of Licences Issued for the Wholesale of Medicines and Medical Devices, as well as the Method of Entry (Rulebook)** also prescribes the obligation of the wholesaler to continuously supply the market. Namely, the wholesaler has the obligation to supply medicines and medical devices:

- within the entire territory of the Republic of Serbia or a certain part of the territory of the Republic of Serbia for which it has received a wholesale license for medicines and medical devices;
- of certain type, that is, groups of medicines, as well as certain classes and categories of medical devices, in accordance with the license for the wholesale of medicines and medical devices;
- those that ALIMS has approved the import of, but for which a license was not issued. The wholesaler must deliver the necessary medicines and medical devices in cases of emergency, at the request of health institutions and private practices or veterinary organisations, in the shortest possible time that does not endanger the

life and health of people or animals. The wholesaler must maintain the necessary supplies of medicines and medical devices for which it has received a license from the competent ministry. This pertains to initiating procurement, importing and obtaining the certificates of analysis issued by the ALIMS, etc.

- Special obligations on informing the National Health Insurance Fund are prescribed for MAH in the **Rulebook on the Criteria, Method and Conditions for Including Medicines on the List of Medicines and Removing Medicines from the List of Medicines (National Reimbursement List[1] Rulebook),** among other: to inform the National Health Insurance Fund no later than six months before withdrawing the medicine that is on the National Reimbursement List from circulation; to inform the National Health Insurance Fund in case it cannot fulfil the obligation of continuous supply of the medicine that is on the National Reimbursement List, at the latest by the time it reaches a three month supplies as well as the timeframe in which continuous supply of that medicine will be provided again etc. If MAH does not fulfil the above requirements, the conditions for removing the medicine from the National Reimbursement List are met.

iii) Moreover, the National Health Insurance Fund monitors the availability and stock of medicinal products included **in the National Reimbursement List** as well as raw materials, based on information submitted by MAH/wholesalers/retailers of medicinal products, to prevent the risk of potential shortages.

iv) On the **official website of the National Health Insurance Fund i**t is possible to find information on the dates when the pharmacies listed therein received a supply of deficient medicines and to report a problem in the availability of medicines listed in the National Reimbursement List.

Additional measures for prevention of shortages include expanding the National Reimbursement List to add more generic drugs on the list, in order to increase competitiveness and provide more opportunities for a safer supply of medicines from a larger number of different manufacturers; enabling the off-label use of medicines included in the National Reimbursement List and changing the status of deficient medicinal products to prescription only (as seen recently with shortages of the diabetes drug Ozempic).

v) Lastly, **a temporary export ban** by the Serbian Government on the export of medicinal products is a restrictively used measure. It was last introduced in 2020, during the Covid pandemic, and it lasted 30 days.

1 The National Reimbursement List indicates all medicinal products eligible for reimbursement with public funds.

3. Any applicable "soft law" measures?

In Serbia there are currently no specific soft law measures (e.g., guidelines, industry codes, etc.) dealing with drug shortages.

Certain general principles relating to drug shortages are included in the Code of Good Distribution Practice of Wholesalers of Medicinal Products ("Code") adopted in 2016. Namely, the Code defines the public service obligation for wholesalers to continuously and adequately supply the range of medicines for which it has been issued a license, meet the requirements of a special geographical area and deliver the required medicines in a short period of time to the entire territory covered by the wholesale license. As seen above (in Q2), the same obligation is prescribed in more detail in the aforementioned Law and Rulebook.

4. In addition to the above, what can companies do via internal policies, rules, distribution strategy etc. to regulate the supply of certain medicines within the national territory?

The regulatory obligation for MAHs and wholesalers to supply/maintain sufficient stock of medicinal products to meet domestic market demand encourages companies to be active in considering possible internal measures to deal with reported drug shortages. The Law prescribes that the Ministry of Health may revoke the licence issued to a wholesaler, when the wholesaler does not perform its obligation to continuously supply the market. In addition, non-compliance with this obligation exposes the wholesaler and its responsible person/s to monetary fines in the amount of approx. EUR 8,500 to approx. EUR 25,500 and approx. EUR 850 to approx. EUR 1,700, respectively. Furthermore, the protective measure of prohibition of performing business activities for a period of three to ten years may be imposed. With respect to MAHs, given that they have a general obligation to continually supply the market, ALIMS will revoke marketing authorisations in cases where the medicine was not in circulation, in other words on the market of the territory of Republic of Serbia for three years since the marketing authorisation was first issued, or three years since it was last placed on the market.

In practice, companies may have several contractual/commercial options to influence the supply and distribution of their medicinal products, and to the extent possible, minimise the risk of possible shortages. The most common practice is to adjust the distribution system to exclusive or selective distribution (whichever model might work better for the medicinal products' distribution), accommodating supply quotas as per the country demand and additional margin, or directly participating in public tenders, where feasible, etc.

5. Does your country treat over-the-counter (OTC) and prescription medicines differently in terms of possible shortages and measures?

Yes, the National Reimbursement List only contains prescription medicines, and not OTC drugs. All measures taken by the National Health Insurance Fund (described in Q2 above) apply only with respect to prescription drugs, and not to OTC medicinal products.

6. To what extent does your country follow and apply the EU/EMA medicine shortages catalogue and are there any specific measures introduced in this regard?

Given that Serbia is not an EU Member State, Serbian legislation does not specifically address the EU/EMA medicines shortages catalogue.

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Medicine shortages in CEE & SEE

Life Sciences & Healthcare

Slovak Republic

Wolf Theiss

1. What are the main reasons and relevant factors causing medicine shortages in your country?

Exemplary reasons

	Description
X	General business/marketing reasons.
X	Termination/cancellation/change of a marketing authorisation - in other words product withdrawal. Manufacturers decide to withdraw pharmaceutical products from the market because in certain conditions they are no longer profitable; this is more and more common throughout Europe – especially for generics.
	Delays in delivery/distribution.
	Deficiencies in production planning - most medicines and substances are produced outside the European Union in production facilities that produce materials for different pharmaceutical companies. Production is planned up to a year in advance, when specific volumes and delivery dates need to be contracted; any subsequent changes are almost impossible due to logistics.
	Globalisation - production is highly globalised. Half of the medicines used in Europe are produced in just five or fewer factories worldwide. From a global point of view, Asia plays a major role, where two-thirds of the world's production of pharmaceuticals takes place.
	EU production is not competitive - competing with Chinese and Indian prices is impossible for European manufacturers. Both because of the cost of labour, environmental conditions for production and buildings, or even due to tax and price regulations.
	Insufficient production capacity for active substances, which does not allow for an immediate increase in production volume.
	Increased demand/sales (e.g., increased demand and consumption of medicines due to increased incidence of respiratory infections following the covid-19 pandemic).
	Low reimbursement/maximum price – reimbursements are set so low in CEE/SEE that global producers prefer to supply medicines to other countries. In practice, for some medicines, manufacturers are already exceeding the statutory maximum price/ reimbursement with the production price, and it will not be possible for them to market the medicines further.

	Quotas imposed by manufacturers for certain countries.
X	Parallel trade/export - if products from countries with low drug prices are exported in large quantities to countries with higher prices, supply bottlenecks may occur in some cases in countries with lower prices.
	Geopolitical situation - a shortage of aluminium for the production of blisters, a shortage of packaging material for medicines, but also a shortage of glass for glass vials, ampoules and jars due to the war in Ukraine.
	Decline in the number of alternative medicines.
X	Stockpiling - purchase of medicines by patients and pharmacies for stockpiling.
	Other.

According to the position of the State Institute for Drug Control regarding the drug shortages from August 2022 (2023 data not yet available), causes of long-term or short-term drug shortages include:

- **manufacturing reasons -** insufficient capacity, changes in production processes, staff shortages, identified deficiencies in quality,
- **logistical reasons -** delays in deliveries of incoming raw materials including active substances, logistical and distribution constraints,
- **parallel export -** export of medicines to other countries,
- **emergency situations -** for example, the COVID-19 pandemic or the military conflict in Ukraine, which have led to an increased demand for certain medicines, and at the same time cause restrictions to the distribution of medicines as well as staff shortages due to sick leave,
- **commercial reasons -** unnecessary stockpiling of medicines by patients, surges in the increased demand for certain types of medicines, for example at times of increased incidence of respiratory diseases or when competing products are out of stock.

According to a Ministry of Health press release from May 2023, additional problems include unnecessary overprescribing of medicines to patients, non-functioning and unmanaged delegated prescribing and insufficiently utilised extemporaneous preparation of medicines.

2. Has your country adopted legislation dealing specifically with medicine shortages and if so, what are the envisaged statutory measures and procedures?

This issue is indirectly affected by the specific obligations for Marketing Authorisation Holders (MAHs) and wholesalers and also by the legislation in relation to pharmacies. Specifically, the following:

- **The Emergency System** was introduced in Slovak legislation effective 1 January 2017. It is an information system for the emergency ordering of medicines. The Emergency System must be created by every MAH and must be available to pharmacies online. Through the Emergency System, pharmacies will order the medicine for the patient directly from the MAH if it is not possible to secure it directly from a wholesaler. The Emergency System is intended exclusively for situations where the supply of the medicinal product requested by the patient, on the basis of a submitted prescription, cannot be secured from a wholesaler and applies only to medicinal products for human use which are included in the list of categorised medicinal products.
- **The MAH of a medicinal product included in the list of categorised medicinal products is obligated to ensure that the medicinal product is available on the market in sufficient quantities** for the entire duration of the inclusion of the medicinal product in the categorised medicinal products list. If the medicinal product is not available on the market in sufficient quantities for 60 consecutive days, the Ministry may decide to remove the medicinal product from the list of categorised medicinal products. In addition, the MAH is obligated to notify the State Institute of any interruption or cancellation in the supply of a medicinal product for human use in the Slovak market, by stating the reasons before the interruption or cancellation of the supply; planned interruption or cancellation of the supply of a medicinal product for human use in the Slovak market is to be notified by the MAH to the State Institute for Drug Control at least two months in advance.
- **Ban on export of medicines.** According to the legislation in effect until 31 December 2016, wholesalers were obligated to inform the State Institute in writing of the intention to export human medicines 30 days prior to the commencement of the export of the human medicine. The State Institute for Drugs Control was authorised to issue an export ban if there was a shortage of the relevant medicine in the Slovak Republic. However, this power was challenged by the European Commission and, effective 1 January 2017, it was removed from the legislation. Under the current legislation, the Ministry of Health may issue a decision in crisis/emergency situations for the purpose

of introducing bans – to the necessary extent and for a necessary period of time – on the exportation of OTC medicinal products. During the COVID-19 pandemic, the Ministry of Health issued a decision prohibiting the exports of medicines containing paracetamol (acetaminophen), ibuprofen and acetylsalicylic acid.

- **Export restrictions** according to the status in effect as of 1 January 2017, a medicinal product included into the list of categorised medicinal products may only be exported by the manufacturer, MAH or wholesaler, provided that the MAH has empowered the manufacturer in writing to export the medicinal product. In the case of the export of a medicinal product included in the list of categorised medicinal products, the MAH is obligated to notify the State Institute for Drug Control of the export of the medicinal product no later than seven days after the export of said medicinal product. The aim is to monitor the export of a medicinal product for human use, while, according to the wording of the law effective 1 January 2017, the State Institute for Drug Control, can no longer prohibit the export of a medicinal product for human use that is included in the list of categorised medicinal products.

3. Any applicable "soft law" measures?

Currently there are no specific soft law measures (e.g., guidelines, industry codes, etc.) dealing with drug shortages.

4. In addition to the above, what can companies do via internal policies, rules, distribution strategy etc. to regulate the supply of certain medicines within the national territory?

Slovak legislation explicitly states that the MAH included in the list of categorised medicinal products is obligated to ensure that the medicinal product is available on the market in sufficient quantities while the relevant product is included in the list of categorised medicinal products. If the medicinal product is not available on the market in sufficient quantities for 60 consecutive days, the Ministry of Health may decide to remove it from the list of categorised medicinal products.

MAHs often influence the supply of their medicinal products using specific distribution models, such as direct-to-hospital (DTH) and direct-to-pharmacy (DTP) distribution models. In these models, a pharmaceutical wholesaler belonging to the capital group of the MAH sells directly to those who supply patients (pharmacies, healthcare institutions, hospitals etc.) and therefore the MAH has a better control over the flow of the product.

5. Does your country treat over-the-counter (OTC) and prescription medicines differently in terms of possible shortages and measures?

Legislation against drug shortages (see Q2 above) apply only with respect to prescription drugs, and not to OTC medicinal products. However, the Ministry of Health may issue a decision in crisis/emergency situations introducing bans – to the necessary extent and for a necessary period of time – on exportation of OTC medicinal products. During the COVID-19 pandemic, the Ministry of Health issued a decision prohibiting the exports of medicines containing paracetamol (acetaminophen), ibuprofen and acetylsalicylic acid.

6. To what extent does your country follow and apply the EU/EMA medicine shortages catalogue and are there any specific measures introduced in this regard?

Current Slovak legislation does not specifically address the EU/EMA medicines shortages catalogue. The EMA list of critical medicines is referred to by the State Institute for Drug Control on its website.

The State Institute for Drug Control publishes updated information based on notifications received from MAHs regarding the temporary or permanent discontinuation of supply of medicines in Slovakia.

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Medicine shortages in CEE & SEE

Life Sciences & Healthcare

Slovenia

Wolf Theiss

1. What are the main reasons and relevant factors causing medicine shortages in your country?

Exemplary reasons

	Description
X	General business/marketing reasons.
	Termination/cancellation/change of a marketing authorisation - in other words product withdrawal. Manufacturers decide to withdraw pharmaceutical products from the market because in certain conditions they are no longer profitable; this is more and more common throughout Europe – especially for generics.
	Delays in delivery/distribution.
	Deficiencies in production planning - most medicines and substances are produced outside the European Union in production facilities that produce materials for different pharmaceutical companies. Production is planned up to a year in advance, when specific volumes and delivery dates need to be contracted; any subsequent changes are almost impossible due to logistics.
X	Globalisation - production is highly globalised. Half of the medicines used in Europe are produced in just five or fewer factories worldwide. From a global point of view, Asia plays a major role, where two-thirds of the world's production of pharmaceuticals takes place.
	EU production is not competitive - competing with Chinese and Indian prices is impossible for European manufacturers. Both because of the cost of labour, environmental conditions for production and buildings, or even due to tax and price regulations.
X	Insufficient production capacity for active substances, which does not allow for an immediate increase in production volume.
X	Increased demand/sales (e.g. increased demand and consumption of medicines due to increased incidence of respiratory infections following the covid-19 pandemic).
	Low reimbursement/maximum price – reimbursements are set so low in CEE/SEE that global producers prefer to supply medicines to other countries. In practice, for some medicines, manufacturers are already exceeding the statutory maximum price/ reimbursement with the production price, and it will not be possible for them to market the medicines further.

	Quotas imposed by manufacturers for certain countries.
X	Parallel trade/export - if products from countries with low drug prices are exported in large quantities to countries with higher prices, supply bottlenecks may occur in some cases in countries with lower prices.
	Geopolitical situation - a shortage of aluminium for the production of blisters, a shortage of packaging material for medicines, but also a shortage of glass for glass vials, ampoules and jars due to the war in Ukraine.
	Decline in the number of alternative medicines.
	Stockpiling - purchase of medicines by patients and pharmacies for stockpiling.
X	Other. Delays in supply of medicines due to suboptimal public procurement procedures which are used by public pharmacy institutions (such as public pharmacies), which may cause delays in the supply of drugs.

According to the statements of the Slovene Chamber of Pharmacy and publicly available data, key reasons for the shortage of pharmaceutical products are following:

- **Parallel trade/export:** In Slovenia, drug prices are regulated, with authorities having the power to establish minimum pricing. This regulation can make the Slovenian drug market less appealing for higher-priced sales, influencing the attractiveness and profitability for Market Authorisation Holders (MAH) and potentially impacting the supply of medicinal products;
- **Production reasons:** Shortages in active ingredients on a global level as well as many medicinal products being produced outside the European Union, which affects longer and more expensive transport and, as a result, not keeping up with the demand for medicinal producs in Slovenia;
- **Market position in Slovenia:** Slovenia has a relatively small medicinal product market, which is why it largely depends on the demand and supply of producers in larger markets (e.g. France, Germany);
- **Suboptimal procurement procedures:** Medicinal product supply delays in Slovenia can also stem from protracted and inefficient procurement processes. However, the situation has seen improvement in the prescription drug sector due to the introduction of additional regulations, while over-the-counter (OTC) drugs continue to be subjected to public procurement procedures.

2. Has your country adopted legislation dealing specifically with medicine shortages and if so, what are the envisaged statutory measures and procedures?

In July 2023, Slovenia adopted the Intervention Act on measures to ensure the supply of medicines (*Zakon o nujnih ukrepih za zagotavljanje nemotene nabave zdravil za leti 2023 in 2024 – **ZNUZNNZ***), which establishes temporary measures to ensure a safe, constant, steady and high-quality supply of medicinal products in public pharmacy institutions for 2023 and 2024.

ZNUZNNZ stipulates that the provisions governing public procurement shall not apply to the supply of Rx, which must be, under existing legislation, provided by public pharmacy institutions within 24 hours of the order or the next working day at the latest.

Due to the strict requirements set by the public procurement legislation applicable to public pharmacy institutions, public procurement of medicinal products is often very complex, time-consuming and even unsuccessful, which can result in drug shortages in pharmacies. Therefore, the aim of the ZNUZNNZ is to relieve the burden on public pharmacy institutions.

Accordingly, under ZNUZNNZ, in cases of Rx shortages, the public pharmacy institution can bypass the public procurement law and order the Rx from a wholesaler (who, at the time of ordering, has a sufficient supply of requested Rx) in a transparent manner and in a way that does not unjustifiably limit competition between wholesalers. The pharmacy institution willissue an order to the wholesaler, sign the wholesaler's delivery note when taking over the Rx, hand the Rx to the patient and issue an invoice to the Institute for Health Insurance of Slovenia (*Zavod za zdravstveno zavarovanje Slovenije*). This procedure can also result in the public pharmacy institution purchasing the medicinal product at a price that is higher than the maximum allowed price, determined by the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (*Javna agencija Republike Slovenije za zdravila in medicinske pripomočke* - ***JAZMP***) at the national level. The mentioned order of the Rx can be issued to a wholesaler for the period up to 31 December 2024.

Private pharmacies, which represent a smaller share of pharmacies at the primary level, procure medicinal products freely (meaning they do not have to respect public procurement laws), even if the medicinal product dispensed in private pharmacies is paid for by the same entity as in cases involving public pharmacy institutions (i.e., Institute for Health Insurance of Slovenia, insurance companies or end users).

There is no specific legislation adopted to facilitate the provision of medicinal products to private pharmacies.

3. Any applicable "soft law" measures?

At the moment, Slovenia has not implemented any specific soft law approaches to tackle the issue of drug shortages.

Nevertheless, in October 2023, representatives from the pharmaceutical industry, pharmaceutical wholesalers, the Medical Chamber of Slovenia, the Slovene Chamber of Pharmacy, the Institute for Health Insurance of Slovenia, and the Ministry of Health, at the initiative of JAZMP, met and agreed on some additional voluntary measures to better manage drug shortages, namely:

i) MAHH, representatives of MAH in Slovenia, and wholesalers must inform JAZMP within an agreed timeframe about the drug shortage (i. e. 3 months before the temporary or permanent cessation of distribution or supply disruptions of a medicinal product);

ii) In case there is a need to import a substitute medicinal product, a call detailing the requirement will be published on JAZMP's website;

iii) The Medical Chamber of Slovenia or the Slovene Chamber of Pharmacy will submit to JAZMP their opinions on alternative therapies when the original medicinal product is not available.

4. In addition to the above, what can companies do via internal policies, rules, distribution strategy etc. to regulate the supply of certain medicines within the national territory?

According to the Medicinal Products Act, MAH (usually wholesalers or pharmaceutical producers) are required to inform JAZMP of the actual initiation of marketing of the medicinal product in the Republic of Slovenia, any temporary or permanent discontinuation of its marketing, or any disruptions in its supply. Should there be a temporary or permanent halt in the distribution of a medicinal product, or any interruption in its supply, JAZMP must be informed at least two months prior to the anticipated stoppage or disruption, except in instances of force majeure. Through this mechanism, JAZMP not only tracks the uninterrupted supply of medicinal products in Slovenia but also facilitates their substitution with suitable alternatives (alternative drug / medications) when necessary.

Consequently, JAZMP keeps a regularly updated list of medicinal products on its website, which includes special annotations for each individual medicinal product if its supply is disrupted.

Nevertheless, under the existing Slovenian legislation, neither suppliers (wholesalers) nor pharmacy institutions are required to maintain specific quotas or stocks of certain medicinal products.

In practical terms, this implies that each public pharmacy institution independently ensures the procurement of medicinal products in the event of shortages (for example with a purchase from another wholesaler) and in line with available measures such as ordering prescription drugs outside of public procurement procedures.

Generally, the risk of shortages should best be addressed in a coordinated manner including all parts of the supply chain. On the level of the individual company, observing developments in demand of previous years and adapting production and / or warehousing as well as coordinating with other market players such as pharmacies can be advisable.

5. Does your country treat over-the-counter (OTC) and prescription medicines differently in terms of possible shortages and measures?

Measures against medicinal product shortages are currently aimed at Rx (like the adopted ZNUZNNZ above).

6. To what extent your country follows and applies the EU/EMA medicine shortages catalogue and are there any specific measures introduced in this regard?

Apart from the abovementioned reporting by MAH to JAZMP on any disruptions in the supply of medicinal products, Slovenian legislation does not include specific measures targeting the EU/EMA catalogue of medicine shortages. However, JAZMP's appointed officials are active members within the working party that provides recommendations to EMA, "Medicine Shortages Single Point of Contact (SPOC)".

Additionally, JAZMP acts as a leader of Work Package 6: "Identification of best practices to address medicines shortages" within the EU project "Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network (CHESSMEN)" and tries to identify best practices to support the process of monitoring, reporting and managing medicinal product shortages. JAZMP's task is to prepare a common protocol to mitigate shortages in Member States. It is anticipated that these guidelines will be established in the second half of 2025. More information on the project is available at: "Chessmen – JAZMP".

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Medicine shortages in CEE & SEE

Life Sciences & Healthcare

Ukraine

Wolf Theiss

1. What are the main reasons and relevant factors causing medicine shortages in your country?

Exemplary reasons

	Description
X	General business/marketing reasons.
X	Termination/cancellation/change of a marketing authorisation - in other words product withdrawal. Manufacturers decide to withdraw pharmaceutical products from the market because in certain conditions they are no longer profitable; this is more and more common throughout Europe – especially for generics.
X	Delays in delivery/distribution.
	Deficiencies in production planning - most medicines and substances are produced outside the European Union in production facilities that produce materials for different pharmaceutical companies. Production is planned up to a year in advance, when specific volumes and delivery dates need to be contracted; any subsequent changes are almost impossible due to logistics.
	Globalisation - production is highly globalised. Half of the medicines used in Europe are produced in just five or fewer factories worldwide. From a global point of view, Asia plays a major role, where two-thirds of the world's production of pharmaceuticals takes place.
	EU production is not competitive - competing with Chinese and Indian prices is impossible for European manufacturers. Both because of the cost of labour, environmental conditions for production and buildings, or even due to tax and price regulations.
	Insufficient production capacity for active substances, which does not allow for an immediate increase in production volume.
X	Increased demand/sales (e.g. increased demand and consumption of medicines due to increased incidence of respiratory infections following the covid-19 pandemic).
	Low reimbursement/maximum price – reimbursements are set so low in CEE/SEE that global producers prefer to supply medicines to other countries. In practice, for some medicines, manufacturers are already exceeding the statutory maximum price/ reimbursement with the production price, and it will not be possible for them to market the medicines further.

	Quotas imposed by manufacturers for certain countries.
	Parallel trade/export - if products from countries with low drug prices are exported in large quantities to countries with higher prices, supply bottlenecks may occur in some cases in countries with lower prices.
	Geopolitical situation - a shortage of aluminium for the production of blisters, a shortage of packaging material for medicines, but also a shortage of glass for glass vials, ampoules and jars due to the war in Ukraine.
	Decline in the number of alternative medicines.
X	Stockpiling - purchase of medicines by patients and pharmacies for stockpiling.
X	Other – (i) continuation of active hostilities in Ukraine, (ii) delays with re-registration of medicines.

According to public information, the reasons for a temporary or permanent shortage of medicinal products in Ukraine are the following:

- the full-scale invasion resulted in decrease of medicines import in 2022 inter alia due to low demand and a large inflow of humanitarian medical aid into the country. Import of medicines from Belarus and Russia was banned. 2023 demonstrated a steady recovery of imports;
- certain production capacities and warehouse premises suffered physical damage; there are also premises within the territories that are now controlled by Russia;
- the fluctuations in the market during the first months of the war were caused by a sharply decreased demand for dietary supplements, anti-covid and prophylactic drugs resulting in a stock surplus, while demand for certain categories increased rapidly, leading to their shortage;
- an imperfect procurement system for the supply of medicines in 2022 resulted in a shortage of certain drugs included in national programs (such as certain cancer drugs). The reason for the delays in the delivery of medicines was not only due to the war, but also due to the irregularity of procurement processes conducted by the State Enterprise "Medical Procurement of Ukraine" (the national agency for the centralised procurement of medicines and medical goods (the **"Medical Procurement"**);
- delays with re-registration of certain medicines.

2. Has your country adopted legislation dealing specifically with medicine shortages and if so, what are the envisaged statutory measures and procedures?

The Law of Ukraine "On Medicines" dated 28 July 2022 specifically addresses the matter of drug shortages, providing for a public service obligation for wholesalers that requires ensuring the constant availability of the necessary assortment of medicinal products to meet the needs of the population of a certain administrative territory, and in the possibility to deliver the necessary volume of medicines in a short period of time to the relevant territory. However, this statutory act will become operational after the termination of martial law in Ukraine. In the meantime, there are certain provisions in Ukrainian effective laws and regulations aimed at filling this gap, as indicated below.

Under the effective laws:

- during the period of martial law in Ukraine, the Cabinet of Ministers of Ukraine, at the request of the Ministry of Health of Ukraine (the **"MHU"**), may temporarily stop the export of medicinal products in the event of their shortage in the Ukrainian health care system. No export ban has been imposed since the beginning of military aggression against Ukraine.
- Article 54 of the Fundamentals of Ukrainian Health Care Legislation introduces the general statutory obligation for health care institutions, (e.g. hospitals), to maintain a mandatory assortment of medicines and immunobiological products, including the necessary stock in case of epidemic diseases, natural hazards and disasters. In order to comply with this statutory provision, the MHU conducts distribution (and re-distribution, if necessary) and transfer of immunobiologicals (vaccines), medicinal products for persons suffering from infectious diseases and medical goods used for preventive vaccinations to health care institutions such as hospitals, which have entered into an agreement for the medical care of the population under the medical guarantee program with the National Health Services of Ukraine (the central executive body that implements state policy in the field of state financial guarantees for health care servicing of the population, (the **"NHSU"**)). The MHU is also obligated to maintain a stock of the mentioned products (at budget cost and within warehouses of state-owned entities) in the amount of 25 percent of their annual need for their continuous supply. Health care institutions report on the balance of products, their expiration dates and provide other information on a regular basis.
- under the agreement for medical care of the population with the NHSU, a health care institution as a medical services provider, is obligated to provide its services fully and in a timely manner. This requires them to promptly conduct the procurement of the required medicinal products.

- pharmacies participating in the "Affordable Medicines" reimbursement program[1] (i.e. the governmental program providing for a full/partial reimbursement of the cost of certain medicinal products to pharmacies), are obligated to ensure the continuous availability of the medicinal products provided for in the related agreements.
- an information and analytical system, MedData, has been established for the exchange of information that precedes the procurement process, the collection of applications, information on the remaining amount of medicines and medical goods. The MedData system is available to health care institutions and private medical professionals licensed to conduct medical practice, and having entered into an agreement with NHSU, they can submit applications for the purchase of goods and services via the MedData system as well as provide information on procurement, the use and balance of medicines and goods.

By means of a governmental resolution in July 2023, the MHU was authorised to determine, if necessary, the minimum and maximum level of the balance of medicinal products for the stable and continuous supply to patients, including at the level of administrative-territorial units and subordinate institutions. Medical Procurement, as an administrator of MedData, carries out a monitoring of the level of provision of goods, in order to conduct timely procurements aimed at preventing shortages.

3. Any applicable "soft law" measures – (e.g. guidelines, industry association' codes, self-regulations)? If possible, please give examples.

There are currently no specific soft law measures (e.g., guidelines, industry codes, etc.) that deal with drug shortages.

A general obligation is provided in the Standard of the MHU Instruction "Medicines. Good distribution practices. ST-N MOZU 42-5.0:2014", which corresponds to the Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01), setting forth a general obligation for distributors to maintain a sufficient stock of medicines necessary to meet the needs of the population of their geographic area. However, it is not a statutory obligation and it lacks further details for its implementation. Thus, it is rather seen as a kind of recommendation.

1 Based on the Register of Medicinal Products Subject to Reimbursement under the program of state guarantees of medical care available at the MHU's website, which continues to expand despite the war. Under Ukrainian law only prescription (and not OTC) medicinal products are eligible for reimbursement. Under this program, patients may receive medicinal products at no or reduced cost at the pharmacies participating in the program.

4. In addition to the above, what can companies do via internal policies, rules, distribution strategy etc. to regulate the supply of certain medicines within the national territory?

Overall, hospitals that have entered into agreements with the NHSU, as indicated in answer to Q2 above, are required to monitor and report on the balance of the medicinal products to MedData. The pharmacies participating in the "Affordable Medicines" reimbursement program of the NHSU have a contractual obligation to ensure a continuous supply of their services. The NHSU monitors the contractual performance and may apply penalties, such as an agreement termination.

Health care institutions that do not enter into an agreement with the NHSU (private clinics and individual medical practitioners) and as such are not subject to the respective regulatory and contractual obligations, are still well driven to ensure a continuous supply of their services. Unlike the state and municipal health care institutions that are mostly financed by the NHSU based on the agreements for the medical care of the population under the state-guaranteed programs, and which are dependent on the timely financing from NHSU, private clinics can afford to stockpile drugs at higher prices and make them immediately available.

5. Does your country treat over-the-counter (OTC) and prescription medicines differently in terms of possible shortages and measures?

The measures aimed at preventing a possible shortage (see answer to Q2 above) apply with respect to reimbursed medicinal products that are provided only by prescription. No shortage measures are currently set forth for OTC medicinal products.

6. To what extent does your country follow and apply the EU/EMA medicine shortages catalogue and are there any specific measures introduced in this regard?

Effective Ukrainian laws do not specifically address the EU/EMA medicine shortages catalogue.

Certain measures aimed at medicine shortages prevention are envisaged under a new Draft Bill recently submitted to the Ukrainian Parliament but not voted on yet. Specifically, the new draft Bill proposes to impose an obligation on wholesalers to have a constant availability of a mandatory minimum assortment of drugs (socially orientated drugs) according to the list that is to be determined by the MHU.

Furthermore, the MHU and Medical Procurement recently launched an e-Stock system as a pilot project. This is an electronic system for managing stocks of medicines and medical products. As claimed by the MHU, it will contain a full cycle of data on the circulation of medical products and will aggregate information related to needs, delivery, availability of drugs in hospitals, their use, disposal, etc.

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