Medicines Shortage Monitoring System

Zagreb, April 2025

Introduction

In February 2025, the Ministry of Health sent a notice to marketing authorization holders (MAHs) in Croatia regarding the implementation of an investment project NPOO C5.1. R4-I4 "Development of a medicines shortage monitoring and prevention system in Croatia" from the National Recovery and Resilience Plan (NRRP) 2021–2026. It also announced amendments to the Medicines Act and the introduction of a new ordinance that will establish obligations for the regular submission of data on medicines consumption, supplies, and shortages. Along with the letter, the documents *Documentation – Service Methods* and *List of Critical Medicines* have also been submitted.

First of all, we would like to draw attention to the fact that the amendments to the Medicines Act and the adoption of the new ordinance are not included in the Ministry of Health's 2025 Plan of Legislative Activities, even though they should have been, pursuant to Article 8 of the Act on Better Regulation Policy Instruments and Article 11, paragraph 5 of the Access to Information Act. In previous years, the Ministry of Health has established work groups for drafting new laws and ordinances, which included the relevant stakeholders of the healthcare system, which agreed on the contents of new regulations by reaching a consensus through dialog. We believe that the procedure of preparing a document that is important for the healthcare system should include all the stakeholders of that system from the very beginning, especially those directly affected by the new regulations.

Additionally, through public procurement, the Ministry of Health has already selected a provider for the development of the web service for the Medicine Shortage Monitoring and Prevention System (PPNL), and according to available information, the system has already been developed. In the mentioned web system, as seen in the document *Documentation – Service Methods,* the obligations of MAHs, wholesalers, and pharmacies regarding reporting to the PPNL system are described in great detail. This includes delivery plans, implementation of plans, stocks, outflows/sales, and the frequency and method of reporting. We consider it procedurally incorrect to first commission a software solution that thoroughly details the process of monitoring shortages, including extensive reporting obligations for reporting entities (MAHs, wholesalers, and pharmacies), and only then regulate these obligations through amendments to the law and an entirely new ordinance.

As we already stated, the reporting entities were not included in the working group for this project, which puts them at a disadvantage. This has prevented the interested parties to whom the regulation directly applies from actively participating in the dialog and contributing before the beginning of the public consultation process. Such an approach reduces the likelihood of finding a solution that would satisfy all involved parties and ensure the successful implementation of the project.

The process of monitoring medicine shortages in Croatia already exists through the procedure for reporting shortages by MAHs. MAHs are required to immediately notify the Agency for Medicinal Products and Medical Devices (HALMED) and the Ministry of Health of any circumstances that may lead to a medicine shortage. Additionally, for medicines included in the list of medicines of the Croatian Health Insurance Fund (HZZO), they must also inform the HZZO. Information on the start, reason, and expected resolution of shortages is already available to the healthcare administration.

Shortcomings of the Proposed New Shortage Monitoring System

Despite the absence of amendments to the Medicines Act and the new ordinance, the document *Documentation – Service Methods* defines the obligations and very detailed guidelines for reporting entities:

1. Reporting by wholesalers on medicine stocks
2. Reporting by wholesalers on medicine outflow
3. Reporting by pharmacies on medicine stocks
4. Reporting by pharmacies on medicine turnover
5. Marketing authorization holders' medicine delivery plans
6. Implementation of medicine delivery plans by marketing authorization holders
7. Reporting on unsuccessful medicine dispensing in pharmacies
8. Reporting by wholesalers on the inability to dispense medicines to pharmacies
9. Wholesaler's response to inquiries about stock levels

Does Croatia have a problem with medicine shortages?

HALMED regularly updates the list of shortages on its website in accordance with reports from MAHs. To better understand the extent of medicine shortages in Croatia, the list was analyzed based on two criteria: the availability of a medicine with the same active substance and strength (generic alternatives) and the availability of a replacement medicine. Of the total reported shortages, only **5% represent actual shortages for patients** (medicines without a generic alternative or replacement). Considering that nearly **10,000 medicines are available** in Croatia, thanks to the efforts of MAHs and a functional shortage monitoring system, it is clear that the **continuous and uninterrupted supply** to patients is ensured for **over 99% of medicines.** In conclusion, Croatia does not have a significant problem with medicines shortages.

Unclear project objective and methods of preventing shortages

The final objective of the medicine shortages monitoring and analysis system is not entirely clear. If the goal of the project is to develop a model for predicting and preventing shortages (DON, p. 72), we believe it is necessary to clarify further and validate how the project predicts and prevents shortages. If the goal of this project is to ensure a timely response process through **emergency input or import**, the question arises regarding the role of the Ministry of Health, HALMED, and the HZZO in initiating the procedure. It is important to emphasize that emergency input or import is already one of the successful options for preventing shortages implemented by MAHs.

The assumption that the system would provide "valuable pharmacoepidemiological data based on which medicine pricing policies could be created, medicines could be included in the list according to epidemiological parameters, and financial surges in consumption that could threaten the sustainability and elasticity of the healthcare system could be prevented" potentially overlooks and excludes the current pricing procedure for medicines in Croatia, which is regulated by existing legislation.

Also, the goal of preventing shortages by **including another manufacturer in the HZZO List of Medicines** is unclear unless this goal only pertains to generic and biosimilar medicines. In the context of innovative medicines, current regulations allow MAHs to have a medicine included on the HZZO List of Medicines, whereas this is not possible for parallel distributed medicines. Parallel distributors are not marketing authorization holders or manufacturers of medicines but only actors in the parallel supply chain of medicines. This topic is addressed in more detail in AmCham's position paper regarding the procurement of special groups of medicinal products at the national level. A related issue is the shortage reporting system in this type of distribution model, as the MAH is responsible for communication with HALMED, yet they may not even be aware of specific shortages.

In order to better regulate parallel distribution in Croatia, we believe that the amendments to the Medicines Act and the ordinance should explicitly state that parallel distributors have the same obligations as MAHs. In the case where the selected supplier in the public procurement process is a

wholesaler with business relations with a parallel distributor (for centrally approved medicine) and a parallel importer (for other medicines), the MAH cannot have plans for these deliveries. The MAH can still have delivery plans for hospitals that were not included in the centralized public procurement for state hospitals or if shortages occur in the distribution chain of the parallel distributor. However, they cannot have plans for a comprehensive supply of the Croatian market in accordance with previous annual consumption.

Parallel distribution chains should have the same obligation of public supply if they have the same right to take over the supply of all state hospitals during a single public procurement cycle. Furthermore, we believe that parallel distribution of medicines in Croatia should be better regulated, thus categorizing parallel distributors within the supply chain and consequently assigning them the same obligations as other economic entities within the same category. Currently, parallel distributors are wholesalers who, according to the proposal, are not required to report medicines sales to other wholesalers. If this remains the case, it raises the question of how the system would monitor stock levels in Croatia and anticipate potential shortages when an unregistered channel for medicines entering the market also exists. Parallel distribution of medicines is intrinsically linked to shortages and must be addressed in a way that ensures parallel distributors are subject to the same reporting obligations for medicine delivery plans and their implementation as other participants in the pharmaceutical supply chain.

Excessive use of commercially confidential information and technical barriers to reporting

As reporting entities, all stakeholders within the supply chain will have to submit data that, according to the Act on the Protection of Undisclosed Information with Market Value (ZZNITV), may be considered protected data with market value. We believe that this requirement by the regulator constitutes an excessive use of data that, for data owners, is considered commercially sensitive (annual delivery plans, stocks). The mechanisms for safeguarding and controlling the processing of such data and the responsibilities in the event of their misuse are dubious. The announced project, i.e., the requirements for extensive and frequent reporting, is contrary to the publicly declared strategic goal of the Government of the Republic of Croatia to reduce administrative burdens and additional requirements for businesses in Croatia.

There are nearly 10,000 medicinal products on the market in Croatia. The volume of data and the frequency of reporting for all reporting entities pose a significant challenge in terms of process adaptation, technical requirements, data access within the company, and the human resources needed for data implementation and oversight. Within that number, there is a large number of medicines whose patent protection has expired, resulting in multiple medicines on the market with the same active substance, and medicines that have different compositions but are interchangeable. **In the event of a shortage of such medicine, multiple generic or replacement medicines are available on the market**, allowing patients to start or continue their treatment without interruption. The purpose of collecting such a large volume of data is therefore questionable, especially for medicines whose shortage should not pose a problem for patients.

A functional shortage forecasting system assumes forecasting, analysis, and reporting based on historical data on medicine consumption. However, the entire system is difficult to analyze through linear trends due to the **frequent anomalies in medicine consumption**. For instance, the system would identify and factor in an unanticipated surge in demand for a specific medicine when a shortage of a clinical parallel or generic medicine is reported, incorporating this into the forecast for potential future shortages of that medicine. The documentation does not clearly define the procedure for handling a medicine with sporadic use, for example, a medicine that a wholesaler can procure in minimal quantities for a targeted patient (e.g., 1-2 pcs.). To clarify, if a medicine is not available on the Croatian market, the wholesaler has the option to procure it from another country (with an exemption from labeling in Croatian), thereby creating an obligation for the MAH to report the release of the medicine onto the market. After treating the patient in question, the MAH must immediately report the shortage. The question arises as to whether it is correct to define a minimum stock of the medicine in this case, as it is impossible to anticipate it in the future.

The same question applies to medicines with fluctuating demand due to their seasonality. It is important to emphasize that due to the relatively small number of patients, many medicines available in Croatia come in **multilingual packaging** to optimize production, which means that the

manufacturing and distribution of these medicines are planned for multiple countries that share the same packaging. By analyzing the medicines portfolios of pharmaceutical companies that are members of AmCham, we found that approximately **50-70%** of the medicines available in Croatia are in **multilingual packaging**. Reporting on deliveries of such medicines to Croatia for a one-year period is an impossible task, as the **redistribution of a medicine batch is carried out based on the current needs of each country** before the medicine is delivered to the countries sharing the same medicine. Additionally, pharmacies have a common practice of sending the same order to multiple wholesalers, which creates artificially increased demand for the medicine within the supply chain. In such cases, the system will receive a signal of incomplete implementation of plans.

It is unclear how the system will be linked to the current list of medicines for which HALMED has received a shortage report, as individual MAH may interpret the term differently. The start and the estimated end of the shortage are reported, but this date is subject to change within a month, which can lead to potentially inaccurate real-time data.

AmCham recommendation

Below are the recommendations for improving the project "Development of a medicines shortage monitoring and prevention system in Croatia":

1. ***Including all stakeholders in the drafting of the regulation****: Given the way the project was initiated, with already highly detailed obligations defined but without the inclusion of all system stakeholders (i.e., future reporting entities) in the project preparation, we believe that it is necessary to postpone the adoption of the proposed amendments to the Medicines Act and the new ordinance. We propose establishing a working group that includes all relevant stakeholders, including representatives of AmCham's Healthcare Committee, which will define the necessary amendments to the legislation and bylaws related to this project.*
2. ***Equalizing the obligations of parallel distributors with those of marketing authorization holders****: Given that parallel distributors operate in the Croatian pharmaceutical market and have not been able to ensure a continuous supply of medicines in the past, we believe that legislative amendments should clearly stipulate that parallel distributors are subject to the same obligations as MAHs in terms of reporting medicine delivery plans and their implementation.*
3. ***Reducing the frequency of reporting****: The currently proposed reporting frequency for obligated parties is not technically feasible, particularly the weekly reporting for wholesalers. Furthermore, given that MAHs do not have data on medicine delivery plans for a year in advance, and for medicines with multilingual packaging – which constitute the majority of the medicines from our members – they do not have the ability to allocate medicine batches to countries long before the actual delivery (based on current market needs), we believe that the expected frequency and scope of reporting are not technically feasible. We propose to reduce the obligation for MAHs to report on delivery plans to just one quarter, as this would provide the monitoring system with enough data to predict potential shortages.*
4. ***Limiting the list of critical medicines****: Given that nearly 10,000 medicinal products are available in Croatia, the obligation to report on all medicines would unnecessarily overwhelm the shortage monitoring system. We, therefore, believe that before the implementation of the project, and in collaboration with medical associations, it is necessary to define a list of critical medicines from the perspective of patients' right to healthcare, as is the case in other countries that have implemented similar systems. Alternatively, until the national list is established, interim reporting and monitoring should be related to the current* List of critical medicines in the EU.
5. ***Application of Multiwinning tenders****: Parallel with this project, we believe that medicines shortages in hospitals could be mitigated by introducing public procurement with multiple selected bidders. This would decrease the risk of other suppliers being excluded from the Croatian market for extended periods, thereby preventing disruptions in investments needed to maintain production and supply in Croatia.*

For additional information, please contact: American Chamber of Commerce in Croatia

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