

REFORMS FOR ECONOMIC GROWTH AND BUSINESS RESILIENCE 2025

HEALTH CARE COMMITTEE



AMCHAM SERBIA
A LEADER IN CHANGE

HEALTHCARE COMMITTEE

OBJECTIVE 1: FACILITATE ACCESS TO NEW MEDICINES, MEDICAL TECHNOLOGIES AND BECOME R&D HUB FOR LIFE SCIENCES

...BY IMPROVING ADMINISTRATIVE PROCEDURES FOR MEDICINES

CHALLENGE 1: Unclear administrative procedures for issuance, renewal, and variation of marketing authorisations and promotional material and multiple breaches of statutory deadlines for their implementation.

The Serbian Medicines and Medical Devices Agency (ALIMS) repeatedly breaches statutory time limits for granting and renewal of marketing authorisations and approval of variations and promotional material for medicines. Delays with marketing authorisations means patients face unduly lengthy waiting times for new treatments, interruptions to the supply of medicines, and additional costs due to failed bids in public procurement tenders. In 2024, the ALIMS optimised its internal procedures and reorganised its operational structure, thereby making progress in improving efficiency in issuing and extending marketing authorisations and approving variations and since 2025, the Regulatory Information Management System (RIMS) has been launched to digitalize procedures for issuing marketing authorizations for medicines, with further expansion of RIMS expected in the coming period to cover variation procedures and license renewals. However, given the volume of backlogged regulatory applications and the agency's internal arrangements and case clearance rates, the ALIMS is expected to return to full compliance with statutory time limits in the following years.

In addition to these delays, the regulatory framework also imposes restrictions hindering the improvement of some procedures. For instance, a medicine may not be promoted to professional audiences whilst its Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) are awaiting variation approval (Art. 29(1) of the Rulebook on Advertising of Medicines and Medical Devices). As currently interpreted, this provision means holders of marketing authorisation may not give out promotional material to professional audiences or seek approval of promotional material for medicines from the ALIMS even though this material complies with previously approved variations. This also means that marketing authorisation holders will remain unable to promote even medicines that are placed on the market, pursuant to approved variations, until ongoing SmPC and PIL variation procedures are complete.

Moreover, rules governing issuance of marketing authorisations do not foresee simplified procedures for assessing documentation for medicines which have previously obtained authorisations through decentralised procedure (DCP) in an EU member state. The law and the marketing authorisation rules do, however, envisage expedited local authorisation procedure for medicines authorised by the European Medicines Agency (EMA) following centralised procedure (CP), including expedited documentation assessment. DCP medicines undergo examination procedures in the EU that are aligned with EU quality, safety, and efficacy standards, however Serbian rules prevent these medicines from accessing expedited procedures. This means the ALIMS is unable to enhance its efficiency in this regard.

RECOMMENDATION: Amend the Law on Medicines in order to optimise the regulator's procedures and monitor its compliance with statutory time limits. The key suggested improvements encompass:

- **Abolish the requirement to submit a Certificate of Pharmaceutical Product (CPP) for medicines authorized in the EU through centralized, decentralized, or mutual recognition procedures, as well as for marketing authorization renewal procedures.**
- **Abolish the requirement to submit a product sample, except upon specific request by ALIMS.**
- **Introduce a simplified and expedited marketing authorization procedure for medicines approved through the European Medicines Agency's (EMA) centralized procedure for the entire EU market,**

as well as procedural simplifications for medicines authorized via the decentralized procedure in EU countries.

- Enable systematic monitoring of existing procedures and compliance with legally prescribed timelines for processing applications through the RIMS (Regulatory Information Management System).
- Allow the promotion of medicines undergoing SmPC and PIL variation procedures, provided that the promotional material aligns with previously approved variations for that medicine.
- Optimize the approval procedure for promotional materials by introducing a notification system for promotional content and enabling ex post control of materials intended for healthcare professionals.

CHALLENGE 2: Complicated procedure for determining the **maximum price of medicines**, inconsistency of pricing methodology used by the Ministry of Health (MoH) and the national health insurance fund (HIF), and intermittent updating of foreign exchange rates.

When determining maximum prices of medicines, companies must seek approval from the MoH, which takes on average between two and three months, although pricing criteria are prescribed in detail. This procedure is further complicated by the fact that the MoH's maximum price decision must be approved by the Government, which also unnecessarily extends the time during which such drugs cannot be marketed.

RECOMMENDATIONS:

- Allow marketing authorisation holders to set the maximum prices of prescription-only medicines.
- Mandate the competent authority to periodically revise maximum prices of medicines and require marketing authorisation holders to notify the competent authority, based on prescribed criteria, about changes to these maximum prices.
- Stipulate that the MoH may review maximum prices either automatically or when sought by the marketing authorisation holder if the exchange rate fluctuates by more than $\pm 3\%$.
- Prescribe inspection oversight to assess compliance with these obligations.

.....THROUGH THE IMPLEMENTATION OF THE RIMS ELECTRONIC PLATFORM FOR ALL MEDICINE-RELATED PROCEDURES, WHICH WILL ENABLE EFFICIENT AND TRANSPARENT PROCESSES, INCLUDING DOCUMENT SUBMISSION AND ISSUANCE OF DECISIONS IN ELECTRONIC FORM

CHALLENGE: The RIMS system became operational on January 1, 2025, with the goal of enabling electronic submission and retrieval of documentation for marketing authorization procedures before ALIMS. However, the platform still does not cover procedures for variations and renewals of marketing authorizations, which are expected to be integrated in the coming period.

RECOMMENDATIONS:

- Once technical conditions are met, integrate variation approvals and renewal procedures into the RIMS platform;
- Ensure transparency for applicants regarding the current stage of their application and provide estimated processing times;
- Continue to accept general correspondence/notifications/additional documentation via email for procedures that are not yet digitized.

...BY REDUCING FEES NOT LINKED TO PUBLIC SERVICE DELIVERY (SUCH AS THE MEDICAL DEVICE VIGILANCE FEE)

CHALLENGE: The medical device vigilance fee imposes huge costs on businesses (running to 30,000 euros annually for some firms), regardless of whether their products are affected or not; this charge is unknown in

either the EU or the region. Pharmacovigilance oversight is also no better developed than before the fee was introduced.

RECOMMENDATION:

- **Abolish the current vigilance fee** and introduce an annual medical device fee payable for each registration with the Medical Devices Register by category of medical device.

...BY ABOLISHING REQUIREMENTS TO PROVIDE INFORMATION NOT AVAILABLE TO MARKETING AUTHORISATION HOLDERS (SUCH AS DATA ON MEDICAL DEVICE SALES)

CHALLENGE: Providing data on medical device sales is time-consuming and requires much effort on the part of businesses: a marketing authorisation holder with more than 1,800 registered medical devices that uses distributors will find it almost impossible to input prices and quantities for each type of device into the regulator's information system. Marketing authorisation holders have agreements with large numbers of distributors, with information on retail prices often unavailable and confidential (as companies have rules in place preventing them from asking distributors for these data) and therefore unavailable. Finally, the Medical Devices Law does not require marketing authorisation holders to provide price information.

RECOMMENDATION:

- **Stipulate that all available information is submitted to the ALIMS but without pricing data.** Alternatively, assign codes to distributors to allow them to access the ALIMS system and directly input prices.

... BY SENDING THE MESSAGE TO PHARMACEUTICALS COMPANIES THAT SERBIA VALUES INNOVATION AND WELCOMES THEIR RESEARCH AND DEVELOPMENT

CHALLENGE: With its long-standing practices for reimbursable medicines at odds with recent government initiatives designed to make rapid progress in life sciences R&D, **Serbia has been sending a mixed message to pharmaceutical companies.** The government's healthcare digitalisation efforts and the BIO4 Campus are highly commendable, and AmCham hopes that the next government will continue on the same course. By developing infrastructure projects, such as the BIO4 Campus, engaging local and foreign knowledge, creating an internationally compliant yet attractive regulatory environment for R&D, and building the required databases, Serbia sends the message that it wants to be a life sciences R&D hub. On the other hand, as measured by the EFPIA W.A.I.T. Indicator, Serbia has for years recorded one of the lowest scores for new drug availability anywhere in Europe.¹ The reimbursement list is not regularly updated to include new medicines; rather, revisions are done on an ad hoc basis, with new innovative drugs placed on the list, which hinders long-term predictability for large generic pharmaceuticals companies that employ thousands of people in Serbia. This has been having a detrimental effect on business planning for generic and innovative pharma companies, **where the same companies Serbia looks to for R&D are in effect told the country is not a market that values innovation.**

RECOMMENDATIONS: Begin sending coherent messages to big multinational pharmaceutical companies. Below are some of the key steps that need to be taken:

- Ensure annual revision of the reimbursable list to include new innovative medicines.
- Ensure sustainable, credible, and predictable financial planning for innovative and generic drugs and technologies, which should aim to bridge the gap with the comparable EU countries.

¹ The EFPIA Patients W.A.I.T. Indicator 2022 study looked at drugs that have been registered in the EU in the previous 4 years (2018-2021) and the number of those drugs that are available in a given country. Serbia has one of the worst new drugs availability ratings in Europe, with 14 drugs available on the Drug List compared to 168 registered in the EU. According to this indicator, Serbia is ahead of Bosnia and Herzegovina, North Macedonia, Malta, Turkey, and Albania. Other countries in the region record significantly better availability of medicines, with Croatia scoring 46 out of 168 registered medicines, Romania 51/168, Bulgaria 56/168, Hungary 57/168, and Slovenia 72/168 registered medicines.

- Introduce clear and transparent criteria for prioritising medicines for entering the Reimbursable List Regulation as well as for criteria for exiting the list.
- Enhance transparency expert committees at the HIF and the MoH.
- Increase the number of Managed Entry Agreement (MEA) models to broaden risk-sharing and protect the interests of both parties (both HIF and manufacturers). Increase usage of existing MEA models to obtain non-budget impact status.

... BY INTRODUCING ADVANCED OPTIONS FOR SELLING MEDICINES AND MEDICAL DEVICES

CHALLENGE: Amendments to the Law on Medicines and Medical Devices should include changes to rules on how Over the Counter (OTC) medicines can be sold. The current Law on Medicines and Medical Devices explicitly prohibits selling medicines online, which is a huge obstacle to deploying advanced options for accessing medicines. The ban is widely circumvented (with counterfeit medicines and medicines not authorised for sale in Serbia frequently sold online), and inspections react only when notified, rather than on their own initiative. Inspection bodies are also unable to monitor online sales, suggesting the need to change both the existing regulatory framework as well as oversight arrangements.

RECOMMENDATION: Abolish the ban on selling OTC medicines online and regulate their sale following general principles applied in the EU. The solution should entail allowing online sales only by pharmacies that are registered as retailers of medicines and medical devices in Serbia and are duly certified by the MoH as meeting specific requirements for advertising, sale, and delivery of medicines. These requirements could include, for instance, having a suitable web platform that permits the display of prices and characteristics of medicines sold, ability to identify customers if/when prescription-only medicines are sold, having a licensed pharmacist on staff, delivery by registered delivery service in accordance with good distribution practice, etc.

OBJECTIVE 2: INCREASE HEALTHCARE AVAILABILITY

... BY PROMOTING SYNERGIES BETWEEN THE PUBLIC AND THE PRIVATE SECTOR

CHALLENGE: Enabling electronic sharing of patients' laboratory and medical reports by introducing the National Integrated Healthcare Information System (RIZIS) and a single electronic patient record.

RECOMMENDATION: Continue implementing the digital health project according to the new 2024-2025 Healthcare Digitalisation Action Plan, with special emphasis on the early publication of technical specifications for data sharing between private and public health institutions.

CHALLENGE: Doctors who work in the private sector cannot serve as 'selected GPs', issue sick leave notes, refer patients to specialists or for diagnostic examinations, or issue prescriptions for medicines on the HIF's Reimbursable List. In consequence, public-sector GPs have in effect become administrative staff, resulting in duplication of costs for the same healthcare services (once out-of-pocket, and once through health insurance) and additionally limiting access to primary healthcare for patients treated exclusively in the public sector.

RECOMMENDATION: Develop instructions on application of Article 38(a) to (d) of the Regulation on Access to Mandatory Health Insurance Rights to allow private-sector doctors to serve as 'selected GPs' and issue sick leave certificates, whilst ensuring oversight by the Ministry of Health. In parallel, the HIF should begin contracting with private healthcare providers as quickly as possible pursuant to Articles 38a and 38b of the Regulation.

CHALLENGE: Private clinics are not allowed to administer vaccines required under the National Programme of Immunisation against Infectious Diseases.

RECOMMENDATION: Ensure existing regulations are interpreted so as to allow vaccination at private clinics, whilst providing a mechanism for notifying the Batut Public Health Institute of all vaccinations, including mandatory ones. Experience with the Covid-19 pandemic shows that protection from infectious disease outbreaks is particularly important for public health and that a broader range of institutions ought to be involved in this process, provided they are closely overseen by the appropriate authorities and that there exists appropriate exchange of information.

CHALLENGE: Private capacities are under-utilised in the provision of services funded by the HIF, even though their greater involvement would reduce waiting lists at public healthcare facilities. In addition, the current model used to contract services from the private sector prescribes only full prices reimbursable by the HIF, and patients are not allowed to pay extra for elective services.

RECOMMENDATION: Expand the scope of co-operation with the private sector by broadening the range of services that can be provided by private healthcare providers. Research conducted jointly by AmCham and the MoH has revealed that the private sector is price-competitive, especially in the tertiary sector. Contracts should set only prices that the HIF would reimburse to patients whilst allowing patients to pay any differences out-of-pocket if interested. This would increase the competitiveness of private healthcare providers in terms of both quality and price.

CHALLENGE: Unlike many EU counterparts, **the Serbian health service does not allow pharmacies to provide some basic primary healthcare services** (such as measuring blood pressure, cholesterol, blood sugar, etc).

RECOMMENDATION: Amend the Healthcare Law and other relevant regulations to expand the scope of primary health services provided in pharmacies. This will facilitate access to preventive care, which will improve public health, save costs, and ensure that doctors and nurses have more time to dedicate to other health services that require specialist knowledge and experience.

...BY ALLOWING HEALTHCARE INSTITUTIONS TO PROPERLY MANAGE THEIR OPERATIONS

CHALLENGE: Healthcare Law has introduced new types of healthcare facilities (such as policlinics, laboratory diagnostics facilities, occupational healthcare facilities, and the like), but these are still unable to be legally constituted as the required statutory instruments are yet to be enacted. Regulation on Requirements for Provision of Healthcare Services is not fully aligned with the Healthcare Law. Additionally, the lack of an appropriate regulatory framework prevents some healthcare institutions from establishing branches and so hinders their efforts to optimise their operations, costs, and management.

RECOMMENDATION: Adopt a new Regulation on Requirements for Provision of Healthcare Services, which will allow healthcare providers to consolidate, optimise costs, and take other effective management decisions.

OBJECTIVE 3: ACHIEVE BEST VALUE FOR PATIENTS

... BY OPTIMISING PUBLIC PROCUREMENT AND TRACKING STOCKS

CHALLENGE: Exclusive focus on the lowest price criterion when purchasing medical devices and equipment has resulted in greatly increased maintenance and secondary costs of treatment. Existing mechanisms available to healthcare institutions for notifying the ALIMIS of issues with quality or adverse reactions to medical devices are under-utilised and poorly monitored, even though they could provide significant insights as to the quality and suitability of these products.

RECOMMENDATIONS:

- Emphasise quality in public procurement (by using the most economically advantageous tender, or MEAT, approach), especially for medical devices. Provide additional training and

support to contracting authorities to establish criteria and ensure constant consultations with professional associations.

- Align authorities' practices in assessing quality criteria; develop a database of contracting document files used in successful MEAT procurements arranged by type of product procured and use these files as templates.
- Enhance performance monitoring of procured products by both contracting authorities and relevant government bodies. Require contracting authorities to publish key contract performance information on their websites and enhance external oversight in this regard.

CHALLENGE: Healthcare institutions rarely conclude preventive and regular maintenance contracts for medical equipment. Regular maintenance is usually restricted to the manufacturer's warranty period, with repairs made as and when faults appear once the warranty has expired. This practice significantly reduces the service life of equipment, resulting in delays with treatment and lengthy waiting times. In the absence of service contracts, any procurement of spare parts and maintenance services constitutes unforeseen expenditure and must be specifically approved by the MoH.

RECOMMENDATION: Ensure multi-annual service contracts are in place, as well as that the MoH concludes umbrella contracts. Categorise health institutions into first-, second-, and third-priority facilities and initially sign umbrella contracts only for first-priority institutions, such as clinical centres, and later extend them to second- and third-priority entities. This would ensure substantial savings, allow costs to be planned at the annual level, and extend the useful lives of equipment.

CHALLENGE: Lack of information on stocks of medicines and medical devices available at hospitals leads to surpluses at some facilities and shortages at others.

RECOMMENDATION: Introduce a common information system to permit centralised management of stocks, costs, and other aspects of importance for planning.