REFORMS FOR ECONOMIC GROWTH AND BUSINESS RESILIENCE 2022

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 ACCELERATING ADMINISTRATIVE PROCEDURES FOR MEDICINES

CHALLENGE: Uncertainties in the prescribed administrative procedures of issuance, renewal and variation of marketing authorisations and promotional materials 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 mean**s 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.**

RECOMMENDATIONS: 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:

- **Abolition of the obligation to submit a certificate of pharmaceutical product (CPP) for medicines approved in the EU under centralized, decentralized and mutual recognition procedures, as well as abolishing the requirement for submitting a sample of the drug except at the request of ALIMS.**
- **Introduction of simplification and shortening of the procedure for issuing authorizations for medicinal products under the accelerated procedure** for medicinal products approved by the centralized procedure of the European Medicines Agency (EMA) for the entire EU market.
- **Enable the approval of variations to a marketing authorization based on the European Public Assessment Report (EPAR)**, which provides an evaluation of a medicinal product authorized by a centralized procedure and includes all product information published on the European Medicines Agency's website, including data on approved variations.
- **Enabling systematic monitoring of the implementation of existing procedures and compliance with the prescribed legal deadlines for the implementation of procedures.**
- **Optimize the procedure for approving promotional material for medicines through the introduction of notification on the content of promotional material and ex post control of promotional material for the professional public.**

CHALLENGE: Complicated procedure for determining the **maximum price of medicines**, inconsistency of the methodology for determining prices by the Ministry of Health and the RHIF and irregular updating of the foreign exchange parity.

When determining the maximum price of a medicine, companies must request the approval of the Ministry of Health, which they have been waiting for an average of 2 to 3 months, although the criteria for setting the price are prescribed in detail. This procedure is further complicated by the fact that the maximum price is determined by a decision of the Ministry approved by the Government, which also unnecessarily prolongs the period in which such drugs cannot be placed on the market.

RECOMMENDATIONS: Amend the Law on Medicines, to allow:

- **Determining the maximum prices for the placement of medicines on the market by the marketing authorisation holder for medicines that are issued on the basis of prescription .**
- **Obligation of the competent authority to undertake periodical revisions of maximum prices of medicines and obligations of marketing authorization holders to inform the**

competent authority on the basis of the prescribed criteria about changes in the maximum prices of medicines.

- **Revision of maximum prices mechanism conducted by the MoH ex officio or initiated by MAH in the event that the fluctuation of the official exchange rate is ± 3%.**
- **Prescribe inspection oversight of compliance with these obligations.**

…BY ESTABLISHMENT OF AN ONLINE PLATFORM WHICH WILL ENABLE EFFICIENT AND TRANSPARENT PROCEDURES AND FILING OF APPLICATIONS AND ISSUANCE OF MARKETING AUTHORISATIONS FOR MEDICINES AND MEDICAL DEVICES

CHALLENGE: The online platform for administrative procedures for medicines is not yet fully operational, and it is crucial to help the efficiency of the implementation of procedures.

Additionally, the regulatory requirement for companies to provide physical documents after having submitted them online constitutes an onerous administrative practice and contributes to delays in bringing medicines and medical devices to the market.

As the ALIMS has developed an online platform for filing marketing authorisation applications for medical devices, and is finalising a similar system for medicines, and in view of the experience gained during the Covid-19 pandemic, the regulator ought to completely remove the requirements to provide physical documents in marketing authorisation procedures for both medicines and medical devices.

RECOMMENDATIONS:

- Establishment of an operational electronic platform for all administrative procedures for medicines, while enabling transparency to be provided to the applicant regarding the stage of his case and an assessment of the time required to complete the procedure.
- Admit scanned compliance statements for the registration procedures of medical devices;
- Admit all documents digitally signed by the marketing authorisation holder;
- Continue allowing variation applications to be made online but no longer return signed filing certificates and forms furnished with registration numbers to applicants;
- Continue admitting general correspondence/notifications/supplementary documentation sent by e-mail; and
- Eliminate the physical version of Form ZKM for control stickers and provide an appropriate online alternative.

…BY ADMINISTERING CLINICAL TRIALS MORE EFFICIENTLY

CHALLENGE: Significant exceeding of deadlines for clinical research approval procedures, increasing the total costs of the procedure, which is a significant negative incentive for investing in Serbia on this basis.

Average number of approved clinical trials in Serbia is 100 per year. Countries of comparable size and health service capacity are able to attract much larger numbers of clinical trials (Bulgaria has more than 200 per year, with more than 330 in Austria and over 350 in Hungary). As in recent years the average Serbian clinical trial was worth close to one million euros, it is clear how much potential to attract funding has been missed.

Coupled with the increase in overall trial costs (according to the current model of 'number of cases x number of centres x statutory fees'), these delays have proven to be a major deterrent to investment in Serbia in this field. Unless appropriate action is taken, these challenges will lead to pharmaceuticals firms staying away from research and development of new medicines at Serbian healthcare institutions and prevent Serbian health professionals from taking part in clinical trials.

RECOMMENDATIONS:

- **Amendments to the Law on Medicines and Medical Devices and the rulebook governing clinical trials to specify the duration of each individual phase of the procedure.**
- **Provide effective supervision** over the implementation of procedures and compliance with the prescribed deadlines for approval of clinical studies of ALIMS and the Ethics Committee of Serbia.
- **Provide transparent insight into the current status of the ongoing procedure** (initial surrenders or changes) at the level of EOS and ALIMS.
- **Modification of the calculation of administrative fees** to reduce the costs of administrative procedures related to clinical trials.

…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 ABOLITION OF 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 MESSAGE TO PHARMA COMPANIES THAT SERBIA VALUES INNOVATION AND WELCOMES THEIR R&D

CHALLENGE: With its long-standing practices for reimbursable medicines on one hand and recent government initiatives to leapfrog in the area of life sciences R&D, **Serbia sends mixed message to pharmaceutical companies**. Government initiatives related to digitalization of health as well as development of BIO4 campus are highly commendable, and we hope that the next Government will continue the course. By making infrastructural projects such as BIO4 Campus, engaging local and foreign knowledge, setting up internationally compliant still attractive regulatory environment for R&D and building necessary databases, *Serbia is **sending a message that it wants to be a life sciences R&D hub***. On the other hand, according to the EFPIA W.A.I.T. Indicator Serbia is for a number of years near the bottom of the ladder for the new drugs availability in Europe[1]. Regularity of the renewal of the reimbursement list with new innovative medicines

[1] EFPIA Patients W.A.I.T. Indicator 2021 study looks at drugs that have been registered in the EU in the last 4 years (2017-2020) and the number of those drugs that are available in a given country. Serbia is among the countries with the worst new drugs availability in Europe with 17 drugs available on the Drug List compared to 160 registered drugs. According to this indicator, Bosnia and Herzegovina, Northern Macedonia, Malta, Kazakhstan, and Albania are below Serbia. Other countries in the region record

does not exist as it is done on an *ad hoc* basis, effecting entrance of the new innovative drugs on the list approximately once in two years and creating long-run predictability issue for large generic companies which employ in Serbia thousands of people. This burdens business planning for generic and innovative pharma companies present in Serbia, ***sending the message, to the same companies it expects R&D from, that it is not the market that values innovation.***

RECOMMENDATIONS: It is necessary to start sending coherent message to the big pharmaceutical MNCs and AmCham is ready to assist in sending and enhancing the favourable message. Below are some of the key steps that need to be undertaken:

- Ensure annual renewal of the reimbursement list with the 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.
- Introduce clear and transparent criteria for prioritising medicines for entering the Reimbursable List Regulation as well as for the criteria for exiting the list.
- Enhance transparency of the work of expert committees at the HIF and the MoH.
- Increase the number of Managed Entry Agreement (MEA) models to broader risk-sharing, and protection of interests of both parties (the 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: Amendment to the Law on Medicines and Medical Devices should include changes to rules on the sales channels for sales of medicines which are sold Over the Counter (OTC medicines). 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) the inspection bodies react only upon the report, and not ex officio. Also, the capacity of the inspection to monitor internet trade does not exist, which also speaks of the need to change the existing regulatory framework as well as the method of supervision.

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 medication is 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 exchange of laboratory and medical reports of patients through a digital health project and a single electronic health file.

RECOMMENDATION: Continuation of the implementation of the digital health project according to the adopted Action Plan, with special emphasis on the early publication of technical specifications for data exchange between private and public health institutions.

significantly better availability of medicines, Croatia with 35 out of 160 registered medicines, Romania 38/160, Bulgaria 49/160, Hungary 65/160, as well as Slovenia with 78 out of 160 registered medicines.

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: The health system of Serbia, unlike examples in many EU countries, **does not allow pharmacies to extend their services to some basic primary health services** (measuring blood pressure, cholesterol, blood sugar, etc).

> **RECOMMENDATION**: Amendments to the Law and other regulations on health care to expand the scope of primary health services provided in pharmacies. In this way, access to preventive care will be facilitated, which will improve the health of citizens, save costs, and ensure that doctors and nurses have more time to dedicate to other health services that require special knowledge and experience.

… THROUGH ENABLING HEALTHCARE INSTITUTIONS TO PROPERLY MANAGE THEIR BUSINESS OPERATIONS

CHALLENGE: Since 2019, the new Law on Healthcare Protection introduces certain new forms of health care institutions, however, their establishment in practice is not legally possible due to the lack of an adequate by-law to set out necessary conditions and requirements for such new forms (e.g. policlinics, laboratory diagnostics institute, occupational healthcare institute, etc). The new amended rulebook from 2022 is with limited effect since it does not fully correspond to the applicable Law on Healthcare Protection. Additionally, the lack of adequate regulatory framework restrains healthcare institutions from establishing smaller

organizational units (i.e. branches) for certain forms of healthcare institutions, and therefore, does not enable them to optimize their business operations, costs, and management.

> **RECOMMENDATION:** Adoption of a new Rulebook on conditions for performing healthcare activities in healthcare institutions and other forms of healthcare services, which will enable business consolidation, costs optimization, and other business management activities.

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 treatment costs. Existing mechanisms available to healthcare institutions for notifying the ALIMS 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 web sites 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 utilization period 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.