HEALTHCARE COMMITTEE

OBJECTIVE 1: FACILITATE ACCESS TO NEW MEDICINES AND MEDICAL TECHNOLOGIES

…BY ACCELERATING ADMINISTRATIVE PROCEDURES FOR MEDICINES

CHALLENGE: There have been major delays with the issuance and renewal of marketing authorisations and approval of variations and promotional material.

Statutory time limits for granting and renewal of marketing authorisations and approval of variations and promotional material for medicines by the regulator, the Serbian Medicines and Medical Devices Agency (ALIMS), are on average exceeded by several months. 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.** Delays in approving variations (changes to the terms of marketing authorisations) **prevent the marketing of products subject to those variations, limiting opportunities for adjusting treatments to suit patients' needs** (with some companies even opting not to apply for variation approval due to the length of the procedure). Finally, delays with approving promotional material **prevent the delivery of appropriate training for doctors and other practitioners and stop pharmaceutical companies from responding to the urgent needs of healthcare providers** (such as during the Covid-19 pandemic), thereby significantly reducing the number of applications for approval of promotional material and adversely affecting the uptake of products by the market. Poor compliance by the regulator with statutory time limits has been a regular occurrence for years, and, in spite of some improvements, urgent action is needed to make procedures more efficient and ensure patients can access medicines quickly.

RECOMMENDATIONS: Optimise the regulator's procedures and monitor its compliance with statutory time limits.

- **Allow all medicines to be subject to time-unlimited marketing authorisations.** This would entail prescribing a simplified procedure for granting **unlimited marketing authorisations for 'old' medicines** (those marketed in Serbia since before 2011) on the EU pattern, with documentation requirements limited to Models 1 and 2. As the effects of these medicines are already known in Serbia, authorisations that do not expire would reduce the administrative burden on marketing authorisation holders and allow the ALIMS to focus its regulatory capacity on compliance with statutory time limits in other procedures.
- **Optimise procedure for approval of promotional material for medicines.** Follow the lead of some EU Member States by introducing **ex-post approval of promotional material aimed at health professionals,** whilst retaining **prior approval only for material intended for the general public.**
- **Allow variations to be approved based on European Public Assessment Reports (EPARs),** which describe the evaluation of medicines authorised via the centralised authorisation procedure and include product information, including on approved variations, published online by the European Medicines Agency. Adjust internal procedures so that, if multiple variations have been submitted for a medicine, approval of the latest variation also means approval of all previous ones. Make up-to-date product information, including approved variations, available on the ALIMS web site, in contrast to the current practice whereby information is available only after initial or renewed authorisation.
- **Monitor compliance with procedures and statutory time limits.**

CHALLENGE: Current three-tier procedures for setting maximum prices of medicines are unwieldy; pricing methodologies of the Ministry of Health (MoH) and the National Health Insurance Fund (HIF) are poorly aligned; foreign exchange rates are not updated regularly.

> **RECOMMENDATIONS:** Ensure the Serbian Government sets maximum prices only for medicines whose cost is covered by the HIF (i.e. that are included in the official Reimbursable List). Require marketing authorisation holders to notify the appropriate authority of any upward or downward adjustment to the maximum price exceeding 3 percent, based on criteria set out in the Government's Medicines Pricing Order and changes to the exchange rate, at least once every three months. Mandate oversight of compliance by the appropriate inspection body.

…BY PERMITTING ONLINE FILING OF APPLICATIONS AND ISSUANCE OF MARKETING AUTHORISATIONS FOR MEDICINES AND MEDICAL DEVICES

CHALLENGE: 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.

> **RECOMMENDATIONS:** 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. To this end, the regulator should:
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> - Admit scanned compliance statements;
> - 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: Only 20 clinical trials were approved between 1 January and 15 June 2020, in contrast to more than one hundred such trials approved annually in previous years. 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. Even though procedural amendments enacted in 2019 have accelerated clinical trials, 2020 has seen major breaches of time limits for trial approval. 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:** Ensure effective oversight of compliance with procedures and time limits for trial approvals and reduce administrative fees payable to the Serbian Medical Ethics Committee.
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> **Effective oversight of the trial approval process** would entail providing support to the Medical Ethics Committee and the ALIMS to allow them to efficiently discharge their duties and achieve closer co-ordination, as well as making sure procedures are completed within the statutory time limits. In addition, start-up periods (from application filing to establishment of first trial centre) should not exceed three months, which can be achieved by running procedures to approve the import of trial

drugs and equipment and export of biological samples in parallel with clinical trial approval processes. Lastly, stakeholders ought to be permitted better access to information on the status of their cases (regardless of whether these are initial filings or amendments) under consideration by the Medical Ethics Committee and the ALIMS.

The current model for **assessing administrative fees** should be replaced by one in which the number of centres is multiplied by the amount of the statutory fee. In addition, the practice should be abandoned whereby trial amendments are charged by trial centre (for instance, charges for amendments to trial protocols that are identical for all centres are based on the number of centres, although they are reviewed only once and there are no differences between centres) because this unduly increases costs for trial sponsors.

…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. 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 ELIMINATING 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 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 in spreadsheet format but without pricing data. Alternatively, assign sub-codes to distributors to allow them to access the ALIMS system and directly input prices.

…BY INCREASING TRANSPARENCY AND EFFICIENCY IN INTRODUCING INNOVATIVE TREATMENTS

CHALLENGE: The HIF breaches statutory time limits for ruling on applications for inclusion of medicines in the official Reimbursable List; in addition, criteria employed when prioritising medicines for inclusion are unpredictable, resulting in no clarity as to how scarce resources are directed at innovative and effective treatments.

RECOMMENDATIONS:

- Ensure each application for inclusion in the Reimbursable List is ruled on within the statutory time limit and monitor compliance.
- Introduce clear and transparent criteria for prioritising medicines in the Reimbursable List Regulation and enhance transparency of expert committees at the HIF and the MoH.
- Increase the number of Managed Entry Agreement (MEA) models. Only three models are currently approved for use, which restricts opportunities for improving financial performance and predictability for the HIF, risk-sharing, and protection of interests of both parties (the HIF and manufacturers).

- Introduce separate funding lines for innovative medicines. The additional funds this would require can be raised by increasing the rate of tax on medicines and medical devices covered by the HIF.

…BY INTRODUCING ADVANCED OPTIONS FOR SELLING MEDICINES AND MEDICAL DEVICES

CHALLENGE: The current Medicines Law 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 no inspection body appropriately controls compliance, which increases risks to the Serbian population.

> **RECOMMENDATION:** Repeal the ban on selling 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 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: 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 glorified 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.

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.
- Aligne 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 enter into 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 useful lives 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 enters into 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.