PHARMACEUTICAL INDUSTRY

1.65

WHITE BOOK BALANCE SCORE CARD

Recommendations:	Introduced in the WB:	Significant progress	Certain progress	No progress
ALIMS should:				
Respect the existing timelines prescribed by the Law on Medicines regarding new registrations, renewals and variations of the Marketing Authorization	2017		√	
Adopt a digitalization strategy to enable the electronic submission of all requests that currently involve extensive unnecessary paperwork	2017		√	
Expand the list of medicines that can be issued without a prescription (in accordance with practices in the EU), while removing these drugs from the reimbursement list	2017			√
The Government should:				
Ensure the stable financing of medicine procurement through special-purpose transfers of budget funds to the NHIF, thereby covering the obvious shortage of funds in the NHIF's financial plan	2018			√
Ensure the harmonization of the legal framework with the EU acquis; transparency, predictability and legal security are the basic prerequisites for the sustainable functioning of the pharmaceutical industry in Serbia. Representatives of the pharmaceutical industry should be included in the consultative process when any legislative act is drafted	2013	√		
Take a stand regarding the future of its health institutions, primarily pharmacies. If state-owned pharmacies do have a future in their present status, the strong recommendation is that their entrustment to private partners should be conducted according to the law, where private-public partnerships are crucial. They guarantee legality, transparency and maximize the benefits for everyone involved	2017		√	
Urgently address the issue of settling debts of state-owned healthcare institutions towards wholesalers for supplied medicines and medical devices to ensure regular supply to these institutions	2017	√		
The NHIF should:				
Determine the amount of funds necessary for the introduction of new medicines to the reimbursement list	2018	√		
Ensure the predictability of the decision-making process, with clear time frames and a transparent consultations process with the representatives of the industry	2013		√	
Ensure more flexibility with respect to the models of specific contracts (since each product has its own specifics that need to be incorporated in the contract). Maybe the most important first step should be the introduction of a MEA model which would enable the market authorization holder to commit to lower the price of the drug in the tender process without changing the "visible" price on the reimbursement list	2017		√	
Continue improving the process of pricing medicines and including them in the reimbursement list. This process should be transparent, with clear rules, mandatory statement of reasons for the final decision and the right to legal remedy	2013			√

Recommendations:	Introduced in the WB:	Significant progress	Certain progress	No progress
The Ministry of Health should:				
File a request with the Ministry of Finance for the special-purpose transfer of funds to the NHIF for the procurement of new medicines (based on the information received from NHIF)	2018	√		
Abolish the practice of determining medicines' maximum wholesale price	2017			√
Reduce deadlines for issuing licenses for manufacturing and traffic of psychoactive substances in the Republic of Serbia and harmonize them with regulatory practices in the region	2013			√
The Ministry of Finance should:				
Take a positive decision on a reasoned request by the Ministry of Health for a special-purpose transfer of funds to the NHIF for new medicines	2018			√
Equalize custom duties for finished medicinal products and raw materials for medicines' production	2013			√
Ensure the same tax treatment of the whole pharmaceutical sector, in the field of import of finished products and raw material	2014			√
Adjust the VAT rate for raw materials to the rate applied to finished medicinal products	2013			√
Abolish VAT on donations of medicines and medical devices to health institutions;	2014			√
The NHIF should define reference prices for all medicines on the reimbursement list and the difference in price should be paid by the insured persons for medicines on the A1 list. The NHIF should not limit the level of co-payment for the A1 list drugs, as this is not an additional financial burden on the NHIF budget. This should ensure improved access to original and branded generic drugs by patients	2014			√

CURRENT SITUATION

The health of the nation is one of the key factors, if not the most important factor, of productivity and economic growth in society, directly related to investments into the healthcare system. At the same time, ensuring the supply of medicines and the availability of the latest therapies are among the key preconditions for positive results of the healthcare system of any country. In addition to the unhampered supply of medicines and availability of the latest therapies, the normal functioning of a healthcare system requires a systematically regulated and functionally efficient link between the three pillars supporting the medical treatment of the population: manufacturers, pharmaceutical wholesalers and healthcare institutions (private and state-owned).

The share of healthcare in the distribution of the gross national product in Serbia stands at approximately 10%. It is important to note that state/public resources account for only 60% of this amount (the National Health Insurance Fund (NHIF), the Ministry of Health and local governments), while the remaining 40% are private payments by citizens (the so-called out-of-pocket payments). This means that a significant burden of financing healthcare has been shifted to the patients. This is certainly not a positive attribute, having in mind the importance of the social role of the state in the provision of healthcare services. By comparison, in the European Union (EU), Member States finance between 70 and 80% of the total healthcare needs of the population from public sources.

Of the total public healthcare budget, 18% is allocated for medicines. Despite considerable steps forward in improving the availability of advanced therapies compared to the preceding period, this progress is not sufficient. Further strategic thinking and actions regarding the management of funds in the healthcare budget are important, having in mind the degree and character of the vulnerability of the health of the

population, i.e. the need for modern therapies for all, even the most severe diseases. The overall population mortality rate is approximately 46% higher than the EU average (14.2/1000 compared to 9.7/1000). The average life expectancy in Serbia is also considerably below the EU average (74.7 compared to 80.2). The greatest risks for the health and life of the population of Serbia are caused by coronary and vascular system diseases, malignant diseases, diabetes and chronic obstructive pulmonary diseases. For example, the gravity and complexity of this problem is best illustrated by the discrepancy between the cancer incidence rate, where Serbia is 18th in Europe, and cancer mortality rate, where it holds 2nd place. Bearing in mind the discrepancy in the cancer incidence rate and mortality rate in Serbia and the EU, the availability of oncological, as well as innovative medicines from other fields of therapy is clearly insufficient, while at the same time being crucial for reducing the high mortality rate of the population.

Achieving this goal requires further progress in the adoption of the legal framework, which is still incomplete and not fully harmonized with the EU acquis, consequently making decision-making procedures at various levels insufficiently transparent, including Government and NHIF decisions, and the laws difficult to apply in practice. Another problem is that time frames for important decisions are often too long and, even so, typically not observed. Furthermore, because their nature differs so much from other goods on the market, medicines, as the subject of various regulations and procedures, must be treated separately (example: the Law on Public Procurement). The participation of representatives of the pharmaceutical sector in the drafting of all relevant acts is necessary, and significant progress can already be seen in this field.

POSITIVE DEVELOPMENTS

1. The positive trend of negotiations and the signing of special agreements between the NHIF and pharmaceutical companies has continued in 2018 and the first half of 2019. However, the budget allocated for these purposes is significantly lower compared to 2016 (13 new innovative medicines have been placed on the Reimbursement List through the above process).

2. An important step forward was made regarding the quantification of funds required to place new medicines on the Reimbursement List. Namely, a common list of priorities was produced, covering all areas of therapy by the Central Medicines Commission, and/or competent national expert commissions. Based on this, the NHIF has produced an assessment of the funds required for this purpose, amounting to approximately EUR 80 million, with the calculation including significant concessions that pharmaceutical companies with prioritized medicines would commit to. The entire process unfolded with the support of the Ministry of Health and the Ministry of Finance, whose representatives in multiple meetings clearly expressed the position that the availability of medicines is one of the key priorities for both ministries, emphasizing that they will invest maximum effort to continuously allocate significant funds for this purpose.

3. Considerable improvements have been made in the communication and joint work of industry representatives (The Chamber of Commerce, Inovia and Genezis) and the Ministry of Health in drafting regulations of importance for doing business. The procedure for issuing licences under the remit of the Ministry of Health has also been accelerated.

4. Important improvements can be noticed in a part of the process of the normative resolution of the issue of debts owed by part of the state institutions, i.e. the definition of the time frame and the payer, as well as the introduction of direct payment for medicines to suppliers as per the Central Public Procurement by the NHIF, thus preventing the creation of new debts by hospitals and health centres and ensuring a continuous supply of medicines.

5. The Law on Medical Devices was adopted in December 2018, followed by the adoption of by-laws. The system for the electronic submission of documentation for medical devices has also been introduced by the Medicines and Medical Devices Agency of Serbia (ALIMS).

6. Amendments were adopted to the Rulebook on registration, in order to implement the provision of the applicable Law on Medicines introducing the issuance of permanent Marketing Authorizations (MAs) for medicines.

7. The procedure of determining the maximum price of medicines was made significantly shorter, with the option of continuous communication with representatives of the Ministry of Health and the Ministry of Trade throughout the process.

REMAINING ISSUES

1. Shortcomings in the process of including medicines on the NHIF Reimbursement List

The Rulebook on criteria for including/removing medicines from the Reimbursement List, as a key by-law in this area, needs to be amended to include clearer and more detailed criteria for the selection of medicines covered by the mandatory health insurance system. Although certain progress is already visible, each individual procedure for the placement of a medicine on the Reimbursement List should be even more transparent and with a mandatory explanation of the final decision, and the right to appeal.

2. The "duality" of medicine prices

The pricing of medicines is subject to strict administrative control, and involves a two-tier pricing procedure, by the Ministry of Health and by the NHIF.

Article 30 of the Rulebook on criteria for the inclusion of medicines on the Reimbursement List from April 2014 envisages that the difference in price between the original and generic A-list medicine with the same or similar pharmaceutical properties and in the same dosage may not exceed 30%, which is co-paid by patients. This limits the availability of medicines, primarily of original and branded generic medicines, as they often cannot fit into such a limited price range, and thus cannot be found on the Reimbursement List. Given that this difference in price does not represent a financial burden for the NHIF, an option allowing a price difference up to the maximum approved price would ensure a better availability of original and branded generic medicines.

3. Illiquidity of state healthcare institutions

Private healthcare institutions are successful, liquid and more or less profitable hospitals, health centres and pharmacies. However, the majority of healthcare institutions are state-owned, with a far more unfavourable financial performance, a total public procurement debt of RSD 12 billion, and a due debt towards pharmaceutical wholesalers of over RSD 4.4 billion that they cannot pay off on their own. The debts of hospitals that were partially resolved during the past period are once again a current issue. All of the above poses a serious threat to the liquidity of pharmaceutical wholesalers and the continuous supply of medicines to state healthcare institutions.

The lack of a systemic solution for the sustainability of state-owned pharmacies is a specific and burning issue that affects all beneficiaries of the healthcare system and affects both the manufacturers of medicines, as well as pharmaceutical wholesalers and pharmacies. In this regard, 12% retail margins for medicines are unsustainably low. This is far below the comparable margins and fees for issuing medicines in pharmacies in other countries, and there is no business acumen that can make up for this.

The pharmaceutical wholesalers' claims from state-owned public health institutions under public contracts for the supply of medicines and medical devices are in excess of EUR 36 million (of which approximately EUR 22 million is owed by pharmacies and health centres). State-owned public health institutions are not capable of repaying this debt, or even the smallest fraction of it, since total claims of wholesalers from state public health institutions currently exceed RSD 100 million.

The burden sustained by pharmaceutical wholesalers and other drug suppliers in financing the state healthcare system debts is enormous, limiting their ability to regularly supply pharmacies and hospitals in the future. This situation is not sustainable, and if the liquidity of pharmaceutical wholesalers is endangered, there will be consequences for all other participants in the pharmaceutical sector - medicine manufacturers, importers, and, ultimately, healthcare institutions and the healthcare system.

4. Administrative procedures and the issuing of MAs for medicines

ALIMS is still not adhering to the time frames prescribed by the Law on Medicines and Medical Devices and is slow to issue MAs, which are important for business.

ALIMS had an extremely large number of delays in 2018 in issuing renewed MAs for medicines, leading to an interruption in the continuity of the market supply for many medicines. Average delays were around 6 months after the expiry of the MA for a medicine, with the situation only stabilizing in October 2018 after the adoption of an amendment to the Rulebook on issuing a MA for a medicine which extended the validity of a MA for a 6-month period. The time frames for issuing renewals were reduced during Q1 2019, although the time frames prescribed by the Law on Medicines and Medical Devices are still not being adhered to.

ALIMS is applying new, significantly higher fees for its services as of 1 January 2018, thus the costs of acquiring new MAs, their renewal and amendments (variations), and the

newly introduced pharmacovigilance fees, have led to a doubling in the regulatory expenses for MAHs of medicine , creating a further burden on the pharmaceutical industry. However, this has not led to increased efficiency in the work of the ALIMS regarding adherence to time frames, since no additional staff has been hired for the relevant jobs. The price of certain other services, such as the documentation quality control for a imported batched medicines has been increased 3-5 times, even though such a service requires no additional use of materials or equipment by the National Control Laboratory in ALIMS (since the work is document-based, not laboratory-based), yet it represents a significant increase in the expenses of importers of foreign medicines, since it does not apply to domestic manufacturers of medicines.

In addition to new registrations and MAs renewals, ALIMS is still considerably tardy when it comes to approving amendments to licences (variations). Such delays regarding new indications and variations in medicine safety have a considerable impact on the availability of the latest information on medicines both for the health care professionals and for patients.

FIC RECOMMENDATIONS

- ALIMS should:
  - Adhere to the existing time frames established by the Law on Medicines regarding new registrations, renewals and variations of MAs.
  - Simplify procedures, so that ALIMS would complete regulatory activities within the time frames prescribed by the Law on Medicines and Medical Devices.
  - Provide for electronic submissions of all submissions for medicines (new registrations, renewals and variations).
  - Revise and harmonize the amount of certain tariffs; PV tariffs based on the INN; reduce the amount of tariff for the documentation of quality control for each imported batches of a medicine.
- The Government should:
  - Provide steady funding for innovative medicines and generic medicines while expanding the indications through a special-purpose transfer of budget funds to NHIF, thus compensating for the clear lack thereof in the financial plan of NHIF.
  - Take a position regarding the future of its healthcare institutions, primarily pharmacies. If state pharmacies have a future as such, a strong recommendation is to entrust them to a private partner in accordance with the law, with the key law being that on public-private partnership, and in accordance with the model respecting the specifics originating from the status and business operations of publicly-owned pharmacies undergoing PPPs. This guarantees the legality of the procedure, transparency and the maximization of benefit for everyone involved.
  - Urgently start resolving the issue of settling old debts of state healthcare institutions towards pharmaceutical wholesalers for already delivered medicines and medical devices, to ensure further continued supply for the institutions.
- The NHIF should:
  - Ensure the acquisition of the funds required from the central budget for introducing new medicines on the Reimbursement List.

- Continue the positive trend of ensuring the predictability of the decision-making process, with clear time frames and a transparent consultation process with industry representatives.

- Ensure greater flexibility regarding models for specific agreements, since every medicine has its own specific details that need to be incorporated into the agreement. Perhaps most importantly, and as a first step, it is necessary to introduce a model of a special agreement that would make it possible for the MAH of a medicine to commit to reducing the price of a medicine in a public procurement procedure, without changing the "visible" or published price on the Reimbursement List of NHIF.

- The Ministry of Health should:

  - Work continuously, together with the Ministry of Finance and the NHIF, on securing additional funds from the budget of the Republic of Serbia with the aim of including new therapies on the NHIF Reimbursement List.

  - With the aim of accelerating patients' access to medicines, allow the submission of required documentation for obtaining the highest price of medicines for use in human medicine to competent ministries as of the moment the MAH receives a Report from ALIMS following a session of the Commission for the Placement of Human Medicines on the Market. Enabling parallel processes for finalizing the licensing procedure for a medicine and for obtaining its maximum price would considerably reduce the time frame for placing each individual medicine on the market. Therefore, the proposal is to enable two processes to take place in parallel: obtaining a MA from ALIMS for placing a medicine on the market, and obtaining published maximum price of the medicine in a Decision on the highest prices of medicines for use in human medicine from the Ministry of Health.

  - Urgently draft a new Law on Medicines in cooperation with industry representatives.

  - Eliminate from the new Law on Medicines the issuing of permissions by ALIMS for the use of promotional materials and other documentation regarding the advertising of Prescription only medicines and/or promotional materials and other documentation intended for the health care professionals.

- The Ministry of Finance should:

  - Make a positive decision on a reasoned request by the Ministry of Health for a special-purpose transfer of NHIF funds for new medicines.

  - Ensure an equal tax and customs treatment of raw materials and finished medicines.

  - Abolish VAT on donations of medicines and medical devices to health institutions.