PHARMACEUTICAL INDUSTRY

1.55

WHITE BOOK BALANCE SCORE CARD

Recommendations:	Introduced in the WB:	Significant progress	Certain progress	No progress
The Government should:				
Provide steady funding for innovative medicines/ medical devices 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.	2018		√	
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.	2017			√
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.	2018		√	
With the aim of accelerating patients' access to medicines, allow the submission of documentation for obtaining the highest price of medicines for use in human medicine to competent ministries as of the moment the holder of the licence for the medicine 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: the final part of the process of obtaining a licence for placing a medicine on the market from ALIMS, and the process of publishing the maximum price of the medicine in a Decision on the highest prices of medicines for use in human medicine by the Ministry of Health.	2019			√
Urgently draft a new Law on Medicines in cooperation with industry representatives.	2019			√
Eliminate from the new Law on Medicines the issuing of approvals by ALIMS for the use of promotional materials and other documentation regarding the advertising of prescription medicines and/or promotional materials and other documentation intended for the professional public.	2019			√
Amend the Law on the Protection of the Population from Infectious Diseases and the accompanying Rulebook on the Training Program so that employers can conduct training for employees in the medicines production, trade and dispensing, as it is already regulated by other regulations.	2023			√
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.	2018		√	

Recommendations:	Introduced in the WB:	Significant progress	Certain progress	No progress
Ensure an equal tax and customs treatment of raw materials and finished medicines.	2013			√
Abolish VAT on donations of medicines and medical devices to health care institutions.	2014			√
To provide wholesalers with more favourable conditions for fuel procurement for the transportation of medicines.	2024			√
NHIF should:				
Ensure the acquisition of the funds required from the central budget for introducing new medicines on the Reimbursement List.	2018		√	
To enhance the process of ensuring predictability in decision-making, with clear timelines and a transparent consultation process with industry representatives.	2013		√	
Ensure greater flexibility regarding models for specific agreements, since every medicine has its own specific details that need to be incorporated into the agreement.	2017		√	
Enable the electronic submission of introducing new medicines on the Reimbursement List, without submitting paper documentation.	2020			√
Additionally improve full functionality of its information systems SAP and Finance Portal with SEF of the Ministry of Finance, in order to ensure timely, accurate and correct monitoring, control and payment of invoices issued for delivered drugs and medical devices.	2023		√	
ALIMS should:				
Adhere to the existing time frames established by the Law on Medicines regarding new registrations, renewals and variations of licences.	2017		√	
To promptly activate the procedure for variations and renewals of licenses through RIMS.	2024		√	
Revise and harmonize the amount of certain tariffs; pharmacovigilance tariffs based on the INN; reduce the amount of tariff for the documentation control for each imported series of a medicine.	2019			√
An additional number of professional executors should be hired in order to resolve cases faster within the legally prescribed deadlines and reduce delays, especially in resolving accumulated variations for medicines.	2021	√		

CURRENT SITUATION

The health of a nation is one of the fundamental pillars of stability and prosperity for any society. A healthy population is crucial for economic growth and development as it directly influences workforce productivity, reduces healthcare costs, and improves the quality of life. Quality healthcare allows people to work more efficiently, take fewer sick days, and contributes to greater overall productivity. On the other hand, inadequate healthcare can significantly burden the national health system, increase healthcare costs in the long run, and reduce the nation's working potential.

The economy of a country is closely linked to the health of its population. Various illnesses and health challenges can lead to a reduction in the available workforce, increase disability rates, and cause premature mortality, all of which collectively hinder economic growth. A healthy population not only contributes to higher economic output but also eases the strain on public finances by reducing expenses on treatment and rehabilitation.

Investing in healthcare is not just a moral obligation but also a strategic economic decision that can bring significant benefits to society. Therefore, developing effective health policies and ensuring access to healthcare and modern therapeutic options for all citizens should be a priority for any Government striving for sustainable economic development and social well-being.

An essential and extremely important part of the healthcare system is the regular supply of medicines and the availability of the most advanced therapies, which are a basic prerequisite for positive outcomes in the healthcare system of any country. For the healthcare system to function optimally, in addition to uninterrupted supply of medicines and access to the latest therapies, there needs to be a systematic and efficient connection among the three pillars on which the entire pharmaceutical market rests: manufacturers, wholesalers, and healthcare institutions (private and public).

According to the Health Insurance Law, mandatory health insurance covers illness and injury cases, early disease detection, medical examination, treatment, rehabilitation, medications, medical aids, and supplies. However, some analyses and certain medicines are not covered by the National Health Insurance Fund (NHIF), which forces patients to turn to the private sector and pay for treatment out of their own pockets. This has led to a rapid growth of the private healthcare sector in the past decade. In the previous period significant progress has been made in improving the availability of the most advanced therapies. The next step would involve establishing a regular annual allocation of funds from the central budget to the NHIF specifically for financing new therapies.

The average life expectancy in Serbia is considerably below the EU average (74,8 compared to 81,4). 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 issue are best illustrated by the disparity between the incidence rate of oncological diseases and the corresponding mortality rate. In Serbia, the mortality rate is significantly higher than in several European countries that report even greater incidence rates. Bearing in mind it is evident that the availability of oncological treatments, as well as innovative medicines across other therapeutic areas, remains insufficient. At the same time, such access is essential for reducing the high mortality rate among the population, alongside enhanced preventive screenings and increased patient awareness of their importance.

It is completely clear that the NHIF, even with the assumption of the best resource management, is not able to adequately respond to all patients' needs for drug therapies from its own income. For that reason, purposeful and continuous intervention from the central budget is necessary, in addition to the existing allocations of the NHIF for medicines.

It is very important for stable pharmaceutical market functioning to continue the harmonization of the domestic legal framework with EU acquis, primarily through the Law on Medicines, whose adoption has been postponed for several years. That way the practice inapplicability in some of its provisions and non-transparency in certain procedures should be eliminated.

Another problem is that time frames for important decisions are often too long and, even so, typically not observed. 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 adoption of the Law on health documentation and records in the field of health continues the efforts towards digitalization in healthcare and the establishment of the Republic Integrated Health Information System, which will integrate data about all healthcare resources alongside electronic services for healthcare institutions and patients, significantly improving the efficiency of the healthcare system and decision-making processes. The development of the electronic health record, a centralized digital system is currently underway, aiming to provide faster and more accurate access to each patient's medical history, reduce administrative burdens, improve coordination among healthcare institutions and professionals, enable data analytics, etc.

2. ALIMS is actively continuing the digital transformation of regulatory processes in the pharmaceutical sector through the implementation and operationalization of the Regulatory Information Management System (RIMS). The system is already functional for procedures related to marketing authorization, issuance of

various expert opinions, clinical trial applications, and approval of control stamps. In connection with the rollout of RIMS and newly introduced functionalities, ALIMS has established a good practice model through pilot projects involving system testing with marketing authorization holders, as well as dedicated training sessions. The introduction of additional functionalities particularly those related to renewals and variations is expected soon.

3. In the past period, communication continued between representatives of the pharmaceutical industry and the Ministry of Health/NHIF regarding the submission of data on potential upcoming, known, current, or prolonged medicine shortages. A proposal for future practice is for the RFZO to compile relevant data and regularly publish public reports on medicine shortages, ensuring their availability to the professional community.

REMAINING ISSUES

1. A lack of a systemic solution for financing the introduction of New Drugs on the Reimbursement List

Despite a recorded positive trend in the availability of innovative medicines, the List of Medicines featuring innovative therapies has not been published in the past two years. To enable the continuous introduction of new drugs to the Reimbursement List requires an annual allocation of targeted funds from the central budget to the NHIF. Before this, all relevant medical commissions within the Ministry of Health/NHIF should evaluate all submitted requests for listing drugs/medical devices on the Reimbursement List and determine the exact amount needed to meet the needs of patients across all therapeutic areas.

2. 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.

Although the NHIF announced amendments to the List of Medicines by including new medicines with no impact on the budget (non-budget), this had not occurred by October 2025. For the sake of business predictability, as well as ensuring the stability of supply and the availability of essential therapies, it is necessary for the NHIF to establish clear deadlines, timelines, and a process for updating the Reimbursement List.

3. Policy of medicine prices and distribution costs

The ongoing global conflicts, followed by the economic crisis and inflation, have had a strong and negative impact on the pharmaceutical industry. This impact has affected both the production of medicines and the distribution chain through increased transportation and storage costs, rising prices of raw materials, higher manufacturing expenses, and growing geopolitical uncertainty. Wholesalers, whose distribution costs are embedded in the price of medicines, have been particularly burdened by rising fuel and energy prices, as well as other increased operational expenses that are essential for regular and safe supply. It is also important to note that regulatory fees, which are mandatory for compliance with regulatory authorities, continue to follow the upward trend of prices and inflation.

Over the past year, the National Health Insurance Fund (NHIF) implemented price adjustments for a number of generic medicines. This measure represents an important step toward enhancing the sustainability of the pharmaceutical market and preserving patient access to essential therapies.

This decision represents a positive signal, as previously unrealistically low medicine prices often posed serious challenges for manufacturers, leading to the risk of certain products being withdrawn from the market. For all the reasons outlined above, price correction serves as a necessary instrument for ensuring stable supply and continuous availability of therapies for patients in Serbia. Given the specific circumstances and challenges faced by the pharmaceutical industry in Serbia, it is essential to involve all relevant stakeholders in the decision-making process to secure stable and uninterrupted access to medicines in the Republic of Serbia moving forward.

4. Resolving of remaining debt of state healthcare institutions to wholesalers and suppliers and timely payments for delivered medicines

It is necessary to continue with activities regarding settlement of remaining debts and payments of healthcare institutions for delivered medicines, medical devices, which refer to procurements that are not subject to the CJN of the NHIF, i. e. subject to direct payment.

A prerequisite for the regular supply of the healthcare system and patients is the timely payment for medicines delivered through centralized public procurement to suppliers, as well as to pharmacies for dispensed medicines.

5. Administrative procedures and the issuing of licences for medicines

ALIMS is still experiencing delays when it comes to approving amendments to licences (variations). They have undertaken a series of activities and measures to accelerate procedures, which significantly affect the availability of the latest information regarding medicine use for both healthcare professionals and patients, as well as the availability of the medicines themselves on the market.

6. Regulations effecting business

Despite the fact that the adoption of the new Law on Medicines has been in the Work Plan of the Ministry of Health for 6 years, no progress has been made in preparation of this regulation.

It is necessary to amend the Law on the Protection of the Population from Infectious Diseases in the part of the provisions on training for the acquisition of basic knowledge of personal hygiene for employees in the production, distribution and dispensing of medicines organized and conducted by the Ministry of Health, with the payment of the prescribed fee because of the adoption of this Law and the accompanying Rulebook on the training program, it was not taken into account that the obligations and responsibilities of drug manufacturers, wholesalers and pharmacies in the part of hygiene training are already regulated by special regulations as well as the strict requirements of the Good Manufacturing Practices Guidelines (GMP) and the Good Practices Guidelines in distribution (GDP).

FIC RECOMMENDATIONS

The Government should:

- Provide steady funding for innovative medicines/ medical devices 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.

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.
- Together with the Ministry of Domestic and Foreign Trade, with the aim of accelerating patients' access to medicines, allow the submission of documentation for obtaining the highest price of medicines for use in human medicine to marketing authorization holder as of the moment the holder of the licence for the medicine 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: the final part of the process of obtaining a licence for placing a medicine on the market from ALIMS, and the process of publishing the maximum price of the medicine in a Decision on the highest prices of medicines for use in human medicine by 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 approvals by ALIMS for the use of promotional materials and other documentation regarding the advertising of prescription medicines and/or promotional materials and other documentation intended for the professional public.

- Amend the Law on the Protection of the Population from Infectious Diseases and the accompanying Rulebook on the Training Program so that employers can conduct training for employees in the medicines production, trade and dispensing, as it is already regulated by other regulations.

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 care institutions.

- To provide wholesalers with more favourable conditions for fuel procurement for the transportation of medicines and medical devices.

NHIF should:

- Ensure the acquisition of the funds required from the central budget for introducing new medicines on the Reimbursement List.

- Enhance the process of ensuring predictability in decision-making, with clear timelines 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.

- Enable the electronic submission of introducing new medicines on the Reimbursement List, without submitting paper documentation.

- Ensure timely payment for delivered or dispensed prescription medicines, in accordance with signed contracts.

ALIMS should:

- Adhere to the existing time frames established by the Law on Medicines regarding new registrations, renewals and variations of licences.

- To promptly activate the procedure for variations and renewals of licenses through RIMS.

- Revise and harmonize the amount of certain tariffs; pharmacovigilance tariffs based on the INN; reduce the amount of tariff for the documentation control for each imported series of a medicine.