PHARMACEUTICAL INDUSTRY

1.70

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 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			√
NHIF should:				
Ensure the acquisition of the funds required from the central budget for introducing new medicines on the Reimbursement List.	2018		√	
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.	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		√	
Timely payment.	2020	√		
Ensure 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		√	
Provide for electronic submissions of all requests for medicines (new registrations, renewals and variations).	2017	√		
Revise and harmonize the amount of certain tariffs; PV 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 huge 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 (74,7 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, with increased preventive examinations and raising the awareness of patients about 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. Over the last seven years, from 2017 to today, 80 innovative drugs for various conditions (oncological and haematological diseases, multiple sclerosis, psoriasis, hepatitis C, heart failure, diabetes) have been added to the Reimbursement List, with 26 of them added in 2022, for which about 5.8 billion dinars were allocated. This trend is encouraging, but introducing innovative medicines to the list should not be a one-time investment; it is necessary to secure funds for therapies continuously every year and to apply a similar model for innovative medical devices. In 2023, off-label use of drugs was permitted, allowing the NHIF to cover treatments for conditions for which the drug is not officially registered but has proven to be effective and safe in practice, increasing the number of therapeutic options for various diseases.

2. 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.

3. ALIMS continues with the digital transformation of regulatory processes in the field of medicines by introducing and implementing the Regulatory Information Management System (RIMS), which is already operational for registration processes, expert opinions, clinical trial requests, and approval of control stamps. For the implementation of this system, ALIMS established a best practice pilot project in collaboration with and through testing with marketing authorization holders.

4. In the past period communication and joint efforts between representatives of the pharmaceutical industry and the Ministry of Health/NHIF continued, focusing on all business-related issues, particularly addressing challenges related to drug shortages and ensuring regular supply.

REMAINING ISSUES

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

As noted, there is a positive trend in the availability of innovative drugs, which should also apply to innovative medical devices. 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 an update to the Reimbursement List with new generic (non-budget) drugs by the end of 2022 or at the latest in the first quarter of 2023, this has not occurred as of September 2024. 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, coupled with the resulting economic crisis and inflation, are having a significant and negative impact on the pharmaceutical industry. As a result, pharmaceutical products prices have been subject to fluctuations, i. e. increases due to increased transportation costs, limited access and rising prices of raw materials, increased production costs and geopolitical uncertainty. All the above has a major impact on the continuous supply and availability of medicines, which has been reflected in global shortages of a significant number of medicines.

The challenges in medicine supply and potential market withdrawals have also been recognized by the European Commission, which addressed these issues in its proposed new Pharmaceutical Directive in April 2023. The proposal calls for cooperation between institutions and industry at the EU member state level, as well as timely notifications of shortages and potential market exits. As an example, the Government of the Federal Republic of Germany increased drug prices in 2023 to ensure supply stability and prevent further shortages.

In Serbia, introducing Greece as a reference country for drug pricing, alongside Italy and Slovenia, is expected to reduce drug prices, but the concrete effects will only be known once new prices are published. Wholesale distributors, whose distribution costs are included in the price of medicines, are particularly burdened by the rising costs of fuel, other energy sources, and increased operational expenses that are essential for regular and safe supply. Given the specific circumstances and challenges facing the pharmaceutical industry in Serbia, it is necessary to involve all relevant stakeholders in the decision-making process to ensure stable and continuous medicine supply in the Republic of Serbia in the coming period.

4. Resolving of remaining debt of state healthcare institutions to wholesalers and suppliers

It is necessary to continue with activities regarding settlement of remaining debts and payments of healthcare insti-

tutions 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.

5. Administrative procedures and the issuing of licences for medicines

In addition to new registrations and licence renewals, ALIMS is still considerably tardy when it comes to approving amendments to licences (variations). Variations approval and licences renewal are being waited for years, in case of permanent medicine licence, since there are no more renewals after 5 years, deadlines do not exist in practice. Such delays, despite ALIMS undertaking a series of activities and measures since the beginning of the year to expedite procedures within legal deadlines concerning new indications and variations related to drug safety, significantly affect the availability of the latest information regarding drug use for both healthcare professionals and patients, as well as the availability of the drugs themselves in 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.
- 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.

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 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.

- 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.

NHIF should:

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

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.
- 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.