# PHARMACEUTICAL INDUSTRY

1.64

## WHITE BOOK BALANCE SCORE CARD

| Recommendations: | Introduced in the WB: | Significant progress | Certain progress | No progress |
|---|---|---|---|---|
| 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 | | √ | |
| 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 | | | √ |
| Ensure the settlement of the remaining outstanding debt of state healthcare institutions towards pharmaceutical wholesalers and suppliers for delivered medicines and medical devices, in order to ensure further continued supply for the institutions. | 2017 | | √ | |
| The 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 | | √ | |
| Ensures timely direct payment to suppliers for delivered drugs and medical devices, as well as timely payment to pharmacies for prescription drugs. | 2020 | √ | | |

| Recommendations: | Introduced in the WB: | Significant progress | Certain progress | No progress |
|---|---|---|---|---|
| Ensure control of health institutions in the part of dedicated spending of funds for medicines, for obligations that health institutions settle themselves, i.e. which are not subject to direct payment - Claims according to Article 9 of the Rulebook on the content and scope of the right to health care from compulsory health insurance and on participation. Determine clear criteria when potentially the price from the framework agreement/ public procurement contract can be increased or decreased, taking into account the numerous factors that influence cost increases. | 2022 | | | √ |
| 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 Rulebook for acquiring basic knowledge about personal hygiene 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. | 2020 | | | √ |
| 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 | | √ | |
| 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 | | | √ |
| Amend the Law on Fees for the Use of Public Goods in the part of fees for medicines that remain in possession after the expiration date and are collected from citizens, so that compensation basis is determined by the amount of medicines collected from citizens, which needs to be disposed of as pharmaceutical waste and precisely determine the taxpayer. | 2020 | √ | | |

## 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 62% of this amount (the National Health Insurance Fund (NHIF), the Ministry of Health and local governments), while the remaining 38% 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, 22% 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 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.

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, which should be adopted. 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

- In the middle of 2021, the NHIF, in coordination with the Ministry of Finance, provided an extremely high amount of budget funds for the increased availability of new drugs (RSD 5.8 billion). After that, a complex prioritization procedure was carried out among all submitted requests for placing the drug on the NHIF drug list, which is the responsibility of the medical commissions of the Ministry of Health and the NHIF. All these activities, along with the implied negotiations and the conclusion of special contracts between drug license holders and the NHIF on the conditions for financing prioritized drugs, resulted in the inclusion of 26 new drugs from a wide range of therapeutic areas on the Drug List (starting in 2022). By far the largest part of the above-mentioned budget it is aimed at financing the most modern drugs for the treatment of diabetes patients, and in addition, significant funds are also intended for the financing of medical therapies for oncology patients, as well as for patients with certain forms of multiple sclerosis, psoriasis, leukemia and hemophilia.

- NHIF announced the adoption of amendments to the NHIF Reimbursement List, which would include new drugs that would be available to patients at no additional cost to NHIF, by the end of 2022 or in the first quarter of 2023 at the latest. That has not happened even as of this writing (July 2023).

- A new model of a special contract was agreed which was/will continue to be used as a basis for placing new drugs on the List of Drugs A/A1.

- Past period brought considerable improvement in the communication and joint work of industry representatives and the NHIF/Ministry of Health regarding doing business, but big step back was made by NHIF introducing new reference countries for the formation of drug prices, without any prior consultation with any pharmaceutical association.

- During the 2022 direct payment for medicines to suppliers as per the CPP by the NHIF continued.

- In addition to the introduction of the Electronic Invoice System by the Ministry of Finance, NHIF implemented SAP and the Finance Portal with the aim of establishing monitoring and control of contracting and execution of contracts for centralized public procurement, which all contributed to the further digitization of wholesale drugstore operations.

- The Ministry of Finance has observed that the provisions of the Law on Charges for the Use of Public Goods regarding the obligation to pay a fee for products that after use become special waste streams for medicines that are collected from citizens through pharmacies cannot be applied, i.e. that their application would cause disruptions on the market, and these provisions were deleted through amendments to the Law.

## REMAINING ISSUES

1. **A lack of a systemic solution for financing the introduction of new drugs on the Reimbursement List.**

It is necessary to provide assigned funds transfer from the central budget to the NHIF every year, to maintain the continuity of the new drug introduction on the Reimbursement List. This should be preceded by a statement of all competent medical commissions within the MoH / NHIF, after which evaluating all submitted requests for placing drugs on the Reimbursement List would determine the exact amount that has to be transferred to meet the needs of patients in 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.

3. **Policy of medicine prices**

Conflict in Ukraine, following economic crisis and inflation have strong, negative effect on pharmaceutical industry. The negative impact was reflected both on the production of medicines and on the distribution chain. 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 of the above has and may have an even greater impact in the near future on the continuous supply and availability of medicines. The pharmaceutical industry is facing its biggest challenges in the last few years.

The challenge in the supply of drugs and potential withdrawals from the market is also recognized by the European Commission, which in its proposal for Pharmaceutical Legislation from April of this year significantly highlighted these allegations and therefore requires an increase in the supply of key drugs at the level of the European Union countries, as well as timely notification of potential exit from the market.

Also, we cite the example of Germany, which, due to a significant crisis and its impact on the pharmaceutical industry, raised the prices of medicines in order to ensure stability and prevent drug shortages.

In Serbia, the amendment of the Rulebook on the criteria, method and conditions for placing medicines on the List of Medicines, i.e. for removing medicines from the List of Medicines in the part related to - comparable countries and comparable wholesale prices in comparable countries, which can have a strong impact on the operations of the pharmaceutical industry in Serbia, above all in the case of a significant reduced price. The rulebook on the criteria, method and conditions for putting medicines on the List of Medicines, i.e. for removing medicines from the List of Medicines ("Official Gazette of the RS", number 45/22) stipulates that comparable countries, in the sense of this rulebook, are: Republic of Slovenia, Republic of Croatia and the Republic of Italy. The problem in the implementation of the Rulebook in question arose when the Republic of Croatia decided that the prices of medicines would no longer be publicly available. The reference country that will replace Croatia is currently being decided.

Considering the specificity of the situation and the challenges faced by the pharmaceutical industry in Serbia, it is necessary to involve all interested parties in making this and similar key decisions in order to ensure a stable and continuous supply of medicines 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 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.

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 are not existing in practice. Such delays regarding new indications and variations in medicine safety have a considerable impact on the availability of the latest information on the use of medicines both for doctors and for patients.

In addition to the fact that the Agency applies significantly higher tariffs for its services from 1 January 2018, which led to the duplication of regulatory costs of the pharmaceutical industry, this did not lead to a more efficient work of the Agency in terms of meeting deadlines. Fees for medicines are enormous, every activity that the Agency needs to perform is invoiced, even those that were not done before. Due to such high costs, companies give up new registrations, and also cancel existing ones, which is why patients suffer the consequences.

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 the drafting of this, for the pharmaceutical industry, the most important legal act.

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. During 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

ALIMS should:

- Adhere to the existing time frames established by the Law on Medicines regarding new registrations, renewals and variations of licences.
- Provide for electronic submissions of all requests 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 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 huge delays, especially in resolving accumulated variations for medicines.

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.

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

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.