AMCHAM SERBIA
A LEADER IN CHANGE

AmCham Health Care Committee

Key Challenges and Recommendations in the Health Care Sector

EXECUTIVE SUMMARY

Health care system in Serbia is one of the rare areas which has not undergone significant reforms in the past 10 years. Fiscal stabilization in the recent years has put significant additional pressure on the public health care system, putting delivery of health care services covered by mandatory insurance under significant strain. At the same time, the trend of growing out of pocket expenditures for health, currently assessed at the 40% of overall expenditures for health, mandate the opportunity to explore synergies between public and private health sector, aimed at improving health of the Serbian population.

With the objective to assist the authorities in improving allocative efficiencies of current health care budget, AmCham HCC has financed and managed a joint study with the Ministry of Health (the Study) during the 2015, which produced set of recommendations for increasing efficiency and financial sustainability of healthcare system in Serbia. The adopted recommendations create the basis for AmCham HCC's ongoing and future initiatives related to three key areas:

1. **Allowing faster access of new drugs and technologies**;
2. **Public private partnership** aimed at enabling full delivery of health care services to patients covered by mandatory insurance
3. **Optimization of public procurement processes** for delivering best overall value for money.

Acceleration of the access of new drugs and new technologies on the market of Serbia can be achieved through the mix of two main measures. The first would be dedicated increase of financial resources for innovative therapies, with the aim of approaching Serbia to Europe in allocating drugs for every citizen, as well as reducing significant backlog in availability of new modern therapies to the patients in Serbia. The second refers to compliance of existing regulations as well as their further improvement in terms of consistent implementation of existing regulations or their modifications, with the aim of greater availability of new medical technologies to citizens of Serbia. These recommendations mainly refer to the procedures of importing new technologies to the List of mandatory health insurance, issuing licenses for placing drugs and technologies in market, as well as the price determination.

As the Study shows, allocative synergy of public and private sector, as well as public sector contracting, should be based on purchasing per service system, so called DRG (Diagnostic Related Groups). As first steps have already been taken in remedying lack of capacity in the public hospital system in cooperation with the private sector (e.g. for waiting lists), it is necessary to allow quality based competition among the private sector without increasing costs to the NFIH (e.g. determine the price reimbursable by the NHIF, and allowing out-of-pocket participation). Furthermore, in order to properly allocate the capacities in the public primary care, it is recommended to allow private health care practitioners to be "chosen general practitioners". Such a measure would allow additional time of public health general practitioners to focus on the patients, instead of keeping administration of the private health care patients. Finally, as the backbone of every successful health care system is the efficient procurement system that allows for maximum competition among providers with the view of obtaining best care for the patients, it is essential to constantly review the system and its consequences. To that effect, it is necessary to start utilizing quality criteria in public procurements, strengthen reporting on the quality of procured goods and fine tune current procedures in order to ensure long term increase of competition among providers.

I. ACCELERATED ACCESS OF NEW DRUGS AND TECHNOLOGIES

While expenditure for medicines with 17% represents in relative terms not a small portion of total National Health Insurance Fund (NHIF) budget, in absolute amount of 53 euros per citizen, it is still at a lower end, especially in relation to European countries. This is particularly evident in the segment of innovative pharmaceutical products where Serbia reimburses significantly fewer new innovative products since 2007 when compared with referent and other EU countries. Even though at the end of 2016, 24 innovative medicines have been implemented on NHIF's Medicines List, discontinuity from 2012 to 2016 which has continued in 2017 and 2018, still results in extreme backlog in number of innovative medicines which are available to patients covered by mandatory health insurance in Serbia compared to Slovenia, Croatia, Bulgaria and Romania. In relation to countries which allocate comparable health assets per citizen, such as Bulgaria and Romania, it is evident that Serbia allocates significantly less percentage of this budget to medicines (17% in Serbia, compared to 25-30% in countries mentioned above).

AmCham Health Care Committee advocates for accelerated access of new drugs and medical devices since it has been proven that majority of new health technologies not only increase the life expectancy and productivity of population, but can also significantly reduce overall healthcare costs both in the short and in long run. On the other hand, this situation significantly threatens predictability in business of producer of pharmaceutical products and medical devices and limits the possibility for investments, which has already resulted in significant trend of reducing investments and withdrawal from Serbian market, which is not in the interest nor of state, nor of patients.

Challenge	*Suggestion of solution*	*Institution*
Dedicated increase of financial resources for innovative therapies and systematical approach		
❖ Serbia takes the last place in Europe as for the number and time frame needed for introducing innovative therapies. In Slovenia and Croatia, insured patients have available 3,5 times more innovative medicines than in Serbia, while in Bulgaria and Romania that difference is 2,5 times. ❖ Despite the annoucements, there is not systematical predictability in introducing new innovative therapies in health system of Serbia. From 2012 to 2018, there has been implementation of innovative medicines on the List of NHIF only in 2016.	✓ Implementation of mid term and long term systematical solution, which would make a significant long term improvement in availability of innovative medicines in Serbia and keep up the pace with European countries; ✓ Making budget plans for innovative medicines, in accordance with need and goals for improvement of the system of health care and related to that **the increase of budget for medicines and/or redistribution of available funds in health sector,** in order to improve the availability of innovative medicines.	NHIF and Ministry of Health

❖ Serbia invests the least amount of money for medicines in the region (53 EUR per capita, which is almost 40% less than Bulgaria and Romania and almost 60% less than Croatia and Slovenia);	✓ Active inclusion of pharmaceutical industry as partner in finding solution, as well as an investor in health care.	

Compliance with existing legal deadlines for issuing permits, renewal and further reduction of unnecessary administration

❖ Existing regulations are not enforced - NHIF is not resolving pending reimbursement applications in the time frames set in legislation. ❖ The criteria on the basis on which it is decided about priorities for reimbursement of the List are not clearly defined, so there is no predictability neither for patients, nor for the industry.	✓ Full respect of administrative procedure and the Directive about transparency EU by NHIF; Timely reply to all received applications. ✓ Introduce clear and transparent criteria for prioritization of reimbursement of the List in the Rulebook on Criteria and Procedure for Reimbursement; ✓ Increasing transparency of NHIF's and Ministry of Health's expert Committees;	NHIF
❖ The process of renewal and obtaining local Market Authorization for Drugs and Medical Devices by the Agency for Medicines and Medical devices, exceeds the legally prescribed deadlines. In average, delays for renewal of authorization for drugs between 2015 and 2018 were up to 5 months and 2,5 months for the new registrations. The increase of the Agency's tariffs has been done by the end of 2017, up to 60% in average, with no signs that compliance with deadlines will be done in parallel.	✓ Strict enforcement of legal deadlines for renewal and obtaining local Market Authorization for Drugs and Medical Devices. Reducing the administrative burden during the next amendments to the relevant regulation and minimizing it in the meantime. ✓ **Reducing administrative demands for delivering copies of documents in accordance with the Law on General Administrative Procedures –** establishing the database of general documents for every applicant (extract from the Agency for Business Registers, Ministry's decisions etc.) and implementing the rule of not asking for the copies of already delivered documents.	Agency for Medicines and Medical Devices

	✓ Considering amendments of relevant regulation in terms of implementing additionally simplified, shortened procedures for registration of drugs and medical devices, which have already been registered in EU. ✓ Implementation of permanent authorization for drugs, with the obligation of delivering all relevant information about important modifications.	
❖ Implementation of Managed Entry Agreements (MEAs) is limited only on two adopted models, not allowing risk sharing and protection of interest for both contracting parties (NHIF and producers).	✓ Improvement of Managed Entry Agreements (MEA) on risk sharing between NHIF and producers, as well as their further implementation in order to allow faster access for drugs with hard to predict budget impact and cost-effectiveness, but simultaneously continuing systemic innovation of the reimbursement list with medicines which completely meet prescribed criteria.	NHIF
❖ Burdensome procedure of determining prices on 3 levels - lack of alignment on pricing methodology by Ministry of Health and NHIF and parity for exchange rate not updated regularly	❖ Prices set by the Governemnt only for medicines reimbursed and procured by RHIF, process simplification in terms of notification by MAH based on the criteria of the Decree followed by Ministry of Health's Decision on maximum prices every 3 months, and revision of the exchange rate no later than in 3 months and following fluctuation on ± 3%;	Ministry of Health

II. PUBLIC-PRIVATE PARTNERSHIPS AIMED TO EFFECTIVE PROVISION OF HEALTH SERVICES TO INSURED PERSONS

Challenges	*Suggested measures*	*Institution*
Synergy between public and private sector in providing services within mandatory health insurance		
❖ Higher inclusion of the private sector for provision of services reimbursed by NHIF, as a way to shorten waiting lists in the public health care institutions.	✓ Expand existing collaboration with the private sector by increasing the number of services that can be provided by the private sector (AmCham`s and MoH`s Study from 2015 has shown private sector's price competitiveness, especially in the segment of tertiary services). ✓ Quality of service provided in the private sector can be assured by limiting eligibility for applying to accredited private health care institutions. Develop rulebook in order to set service quality criteria through accreditation and certification process; ✓ Further inclusion of private sector should not depend on listing the complete capacity of the private sector, rather than the needs of the public sector and the defined quality of the service to be provided on the one hand, and private providers that can provide these services in a given quality, on the other.	NHIF
❖ According to existing model of contracting services from the private sector, the full price is determined and refunded by NHIF and it is not possible for patient to make a co-payment.	✓ Determine the price of services which is reimbursed to patients bz NHIF and enable patients to make co-payments. This will increase the competitiveness of private providers of health services, both in terms of quality and price.	NHIF

The real choice of „chosen general practitioner“ and sector neutral possibility to prescribe NHIF reimbursable sick leave

❖ Private sector health care practitioners cannot be “chosen general practitioners” and cannot prescribe sick leave or direct the patient towards specialist institution. This results in public sector physicians being turned into “administration”. This results in duplicating expenses for providing the same medical services (once payed from the pocket, next time payed from mandatory health insurance), as well as converting public sector of chosen general practioners to pure administration, by which it additionally limits the access to primary health care protection to patients who are being taken care of by public sector.	✓ To draft instructions for implementing the Article 38 of the Rulebook on method and procedure of realizing the right from mandatory health insurance, by which it would be possible for doctors from private sector to be chosen practitioners and to prescribe sick leave on the burden of the employer. ✓ Abuses while prescribing sick leaves can be overseen by Health Inspection at Ministry of Health.	NHIF

Ban on formation of branches of private health institutions

❖ Lack of possibility to open branches of private health care institution at different locations which creates unnecessary administrative barrier to establishment, employment etc. Article 142 of Law on Health Care predicts possibility of organizing branches, depending on the type of services provied, number of employees, etc, but it does not precise if theritorrial dislocation of these organized units is allowed.	✓ Elaborate in the Law on Health Care and in the Rulebook on conditions and manner of internal organization of health institutions, so that health care institutions may establish branches outside of the seat of the institution.	Ministry of Health

Ban on provision of emergency medical assistance

❖ Effective ban of provision of emergency medical health by the private sector	✓ Harmonize Article 48 and Article 62 of the Law on Health Insurance	Ministry of Health

Burdensome and excessive requirements for registration of health institutions

❖ Burdensome and unnecessary requirements for registration of health care institutions (e.g. specialized gynecological hospital must have radiology services, biochemistry lab and employed pharmacist, while psychiatric hospital needs to have dentist service.)	✓ Harmonize the Rulebook on conditions for performing health care in the health care institutions and other health care facilities with the Law on Health Care	Ministry of Health

III. OPTIMIZATION OF PUBLIC PROCUREMENT PROCESSES AND STOCK MONITORING

Challenges	*Suggestion of measures*	*Institution*
Stocks management for medicines and medical supplies ih hospitals		
❖ Lack of information about stocks management for medicines and medical supplies in hospital creates surpluses in ones and shortages in others – IT system on stock control would improve overall supplies management	✓ Integrated software solution for stock management.	Ministry of Health
Criteria for tendering processes and reporting mechanisms		
❖ Exclusive focus on price only criteria in tendering processes for the procurement of medical supplies and devices, which results in great increase of supplies maintenance expenses, as well as secondary treatment expenses.	✓ **Inclusion of quality criteria in the public procurement process,** especially for medical supplies and devices. Additional education and help to contractors in defining criteria, and continuous consultation process with professional associations is needed. ✓ Unification of the practice of the competent authorities in assessing the acceptability of qualitative criteria and creating a database of tender documents (per procurement items) used in successful procurements based on qualitative criteria, which can be used as a model type. ✓ It is neccessary to adequately evaluate expenses of supply maintenance (and beyond the guaranteed deadline), in order to correctly evaluate total expenses of product's life cycle.	Ministry of Health Public Procurement Office Commision for Protection of Bidder's Rights Ministry of Finance

❖ Inadequate monitoring of the performance of the public procurement contract.	✓ Monitoring the performance of procured products by contracting and competent authorities should be strengthened - existing mechanisms for reporting to ALIMS on quality defects or adverse effects of medical devices by healthcare institutions are insufficiently used and controlled by ALIMS, but can provide important information about quality of purchased products in use. ✓ Introduce an obligation for contracting authorities to publish key aspects of contract performance on a website. This would speed up the monitoring of the execution of the contract and prevent the parallel ordering of several contracts with the same subject of procurement. The already prescribed internal audit function would be strengthened in this way. ✓ Expanding external control and contract performance linking mechanisms that exist with other state institutions (e.g. ALIMS reports in this case) and prescribing responsibilities to the contracting authority for incomplete reporting on this matter, would further strengthen the monitoring of the execution of the contract.	Ministry of Health Ministry of Finance