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 third 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) 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:

- Allowing faster access of new drugs and technologies;
- Public private partnership aimed at:
  - enabling full delivery of health care services to patients as covered by mandatory insurance (reduction of waiting lists) and
  - shifting focus from curative to preventive medicine;
- Optimization of public procurement processes (tendering and stock monitoring) 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 three main measures. The first would be simply consistent application of the existing laws and regulations (especially regarding timely answer to the applications). The second would be creating a clear and transparent list of criteria for innovating the reimbursement list, and list review in a predictable time intervals (e.g. semi-annually), in accordance with the clearly set budget. The third would be review and simplification of the pricing mechanism, as it is too burdensome for the private sector, overwhelming for the scarce state capacities to administer, while providing no benefits to the patients.

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. 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.

In addition, as shifting the focus from curative to preventive medicine is necessary for long term sustainability of the Serbian health care system, different forms of public-private partnerships with private providers, pharmaceutical and medical devices companies will be offered in order to increase access to new technologies and medicines, which would increase efficiency of our healthcare system, decrease downtime and costs of overall treatment.

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.
While expenditure for medicines with 20% represents in relative terms not a small portion of total National Health Insurance Fund (NHIF) budget, in absolute amount it is still at a lower end in relation to comparative 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. Serbia has almost 9 times less new innovative drugs on the reimbursement list compared to Italy, Slovenia, Croatia and Bulgaria, with the gap increasing year on year since NHIF didn’t reimburse new innovative products for more than 3 years now. While the current legislation defines criteria and sets minimum once a year requirement for reimbursement of new drugs, the NHIF does not observe the general administrative procedure and reimbursement legislation. In respect of medical devices the legislative framework is even not yet provided for reimbursement procedure and criteria of new health technologies.

AmCham Health Care Committee calls for systemic support to accelerated access of new medicines 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 side, it will allow producers of pharmaceutical products and medical devices more business predictability and opportunities for increasing their investments, at the same time shifting the trend of decreasing investments and withdrawing from Serbian market, together with reducing future opportunities and access to therapy by patients in Serbia.
1. Procedural Fairness and Transparency

**Issue:**

- WAIT indicator for Serbia (time to access of new treatments) is negatively assessed due to the length of waiting time for the approval and market entry of drugs.

- Existing regulations are not enforced—NHIF is not resolving pending reimbursement applications for years, no new INNs have been reimbursed for more than 3 years.

- Implementation of Managed Entry Agreements (MEAs) prolonged, not allowing risk sharing and protection of interest for both contracting parties (NHIF and producers).

- Representatives of private healthcare sector (producers, providers, insurers) not recognized as a trusted partner and relevant stakeholder.

- The process of obtaining local Marketing Authorization for drugs already registered in EU by the Central Procedure (CP) and Medical Devices often lasts longer than defined by the Law on Drugs and Medical Devices due to slow administration.

**Proposed Measures:**

- Full respect of Administrative Procedure and EU Transparency Directive by the NHIF;

- Enforce timeframes based on the Laws and regulations, including penalties and remedies;

- Introduce MEAs for accelerating access of drugs with hard to predict budget impact and cost-effectiveness, while still allowing regular reimbursement for drugs that fully meet criteria for reimbursement;

- Allow public access to NHIF’s and Ministry of Health’s Committees structure and meetings, NHIF financial plans and expenditure per drug list;

- Introduce clear and transparent criteria for prioritization in the Rulebook on Criteria and Procedure for Reimbursement;

- Amendments to the Rulebook on Criteria and Procedure for Reimbursement;

- Include private sector as relevant stakeholder in drafting and amending regulations;

- Introducing simplified procedure for drugs and medical devices already registered in the EU.

**Regulation:**

- Law on Medicines and Medical Devices

- Rulebook on Criteria and Procedure for Reimbursement

- Administrative Procedure Act
The main issue for the industry is lack of enforcement for existing rules and regulations, procedural fairness, transparency and implementation of deadlines already defined by the Government and relevant institutions. Existing regulations are not enforced, which is directly breaching the EU Transparency Directive. It would be necessary to secure enforcement of the timeframes set in the Laws and by-laws in practice, meaning that RHIF should be obliged to issue official Decision for every reimbursement application within the set timeframe (120 days for new molecules, 90 days for generics) and send it to Marketing Authorization Holder (MAH). In case of negative decisions, they should be accompanied with relevant rationale;

By the same token the process of obtaining local Marketing Authorization for Drugs already registered in EU by the Central Procedure (CP) and Medical Devices often lasts longer than defined by the Law on Drugs and Medical Devices due to slow administration. In addition to complying with timelines already set by the Law on Drugs and Medical Devices, also simplified procedure needed for drugs registered by the European Medicines Agency CP (no longer than 60 days) as well as for Medical Devices already registered in the EU (no longer than 30 days).

Therefore, the articles addressing procedural transparency and compliance with set timeframes should be reinforced in existing and new regulations, including penalties and remedies for breaching defined requirements from both parties (MAH as well as Governmental bodies);

Increased access of new technologies would have almost instant positive influence on the financial sustainability of the healthcare system in Serbia by decreasing other healthcare expenditures such as: waiting lists/hospitalization costs; costs of complications and side effects therapy; costs of sick leave of patients and other; There should be systemic mechanisms planning for introduction of new technologies. While we understand and support the use of Managed Entry Agreements (MEA) as a special form of contracting that should allow share of risks between the RHIF, we believe that they cannot be a substitute for a systemic innovation of the reimbursement list. Although MEAs are common practice in all developed healthcare systems, their purpose is to allow faster access for drugs with hard to predict budget impact and cost-effectiveness. Here, we are proposing that clear and transparent criteria for prioritization should be introduced in the Rulebook for reimbursement, enabling implementation of a decision making process when expected budget impact for new reimbursement entries is overcoming system capacities, and secondly that more flexibility in defining terms and conditions of MEAs is allowed, providing full benefit in terms of access, predictability, cost and risk minimization;

While respecting confidentiality where it’s needed, we believe that increased transparency in all segments of making regulations and their enforcement, which are in line with the EU practices, should be introduced ASAP. That means publication and active interaction with the private sector on amendments of health related regulations, transparency of planning and decision making process for entering reimbursement lists, including rationale, criteria and Committees structures. We believe that it would be a strong anti-corruption signal, and would allow exchange of information to the decision makers, which is crucial for obtaining the best possible care for insured persons, within the set budgetary limits.
## 2. Reimbursement Procedure

### Issue:

- New INNs allowed to be submitted for reimbursement only once a year (March 1st-31st) going directly against free market principles and European Competition rules
- NHIF determines the price of drugs where Government covers only the portion of costs (A1 List)
- No clear criteria for setting co-pay for A1 List
- Biosimilars while recognized as a specific category of drugs in Ministry of Health’s laws and regulations, not introduced in NHIF’s Rulebook on Criteria and Procedure for Reimbursement
- Reimbursement list as part of NHIF’s Rulebook on Reimbursement List

### Proposed Measures:

- At least one more timeslot to be allowed (e.g. September) for submitting reimbursement application for new INNs;
- Allowing free pricing on A1 List, within the provided maximum price;
- Introducing transparent criteria for determining level of co-pay;
- Include Biosimilars as a category in the Rulebook as non-interchangeable medicines (marked with suffix) and with different pricing methodology versus generics, following example from surrounding EU markets;
- Procurement of all non-interchangeable medicines within the same INN;
- NHIF to follow Ministry of Health’s pricing methodology for reimbursement purposes and non-visible prices (MEA)
- Reimbursement list separated from the Rulebook.

### Regulation:

- Law on Medicines and Medical Devices
- Rulebook on Criteria and Procedure for Reimbursement
- Decree on Determining Prices of Prescription Medicines
- Administrative Procedure Act
Current Rulebook on Criteria and Procedure for Reimbursement is setting only 1 timeframe annually for submitting reimbursement application for new INN (March 1st-31st) which is, although explained by the purpose of better planning. Based on the comparative practices, it is necessary to allow at least semi-annual applications for the purpose of allowing new lifesaving medicines to get faster access to patients.

For drugs where Government covers only the portion of costs (A1 List) free pricing mechanism should be allowed in a way that NHIF determines the costs instead of the price. This means that NHIF should determine the amount within each INN which they accept to reimburse, while the absolute price and co-pay level by the patient would be up to the MAH to set. As a result, by increasing competitiveness and price flexibility, NHIF would control its expenditures per INN/therapeutic areas more efficiently and even achieve additional savings in the procedure of public procurement.

Also, criteria for setting co-pay for A1 List should be made transparent, since in current situation without official methodology it could be evaluated as inconsistent and arbitrary;

Biosimilars should be included as a category in the Rulebook with different pricing methodology versus generics, following example from surrounding EU markets – 15% lower versus Referent drug for the 1st entrant, followed by additional 5% price decrease for up to 4th entrée within the same INN;

Although NHIF has no formal competence to regulate pricing of drugs, it does so de facto through Rulebook on Reimbursement List. At the same time, Reimbursement list is part of this Rulebook, which is isolated case in Serbia, additionally complicating and prolonging its updating process with negative impact on NHIF budget and patient’s access to new drugs. NHIF should follow Ministry of Health’s pricing methodology for reimbursement purposes and non-visible prices (MEA), including the same IRP sources, parities and the same drug categories (Referent/Innovative, Generic and Biosimilar). Reimbursement list should be separated from the Rulebook allowing more frequent updates, minimum once per year for introducing new INNs (as already prescribed by the regulations but not seen in practice) following IRP revision and Exchange Rate alignment, which would also allow additional savings;

Since all INNs are subject to public procurement on national level, Rulebook on Reimbursement should also define non-interchangeable medicines and propose marking of these drugs with suffix in order to allow procurement of all non-interchangeable medicines within the same INN;

At the same time, prices negotiated through procurement process should remain confidential, while cost-effectiveness approach with quality criteria in addition to price should be included in procurement process.
### 3. Improvement and Simplification in Drug Pricing Mechanisms

#### Issue:

- Burdensome procedure of determining prices on 3 levels
- Lack of alignment on pricing methodology by Ministry of Health and NHIF
- Parity for exchange rate not updated regularly

#### Proposed Measures:

- Prices set by the Government only for medicines reimbursed and procured by RHIF, or
- Max prices set by Ministry of Health only at first entry of a new drug;
- Process simplification - Notification by MAH based on the criteria of the Decree followed by Ministry of Health’s Decision on maximum prices every 3 months;
- Revision of the exchange rate no later than in 3 months and following fluctuation on ± 3%;

#### Regulation:

- Decree on Determining Prices of Prescription Medicines
- Decision of the Highest Prices of Medicines for Human Use, Issued on Prescription
Current practice of determining prices on 3 levels (Ministry of Health for all products entering the market; Republic Health Insurance Fund for reimbursed medicines; trough tendering procedures for all drugs procured by NHIF) is too complicated, inefficient, burdensome and against free market principles;

Our position is that Government should set the prices only for medicines reimbursed and procured by NHIF, while for all the others free pricing mechanism should be introduced;

In case this is not acceptable for the Government, drug pricing should be facilitated, conducted by Ministry of Health only once at the point of new drug entry to the market, and followed by the same procedure from NHIF for reimbursement purposes;

The process and methodology should also be simplified:

a) prices should be calculated based on IRP (the average in the basket of Italy, Croatia and Slovenia) without additional parities and the same for all drug categories (Referent/Innovative, Generic and Biosimilar)

b) Market Authorization Holder (MAH) would send Ministry of Health Notification letter on the price for the new product after receiving Market Authorization, with the simple calculation instead of current full Price File, followed by Ministry of Health officially publishing new Decision on maximum prices every 3 months;

While the Decree on setting prices of prescription medicines includes the parity for exchange rate, Price list is not updated regularly creating additional price difference covered by the industry. Therefore, Decree requires additional article guaranteeing automatic exchange rate update every 3 months and following oscillations ± 3%;
II. PPP ON EFFICIENT PROVISION OF HEALTH CARE SERVICES TO THE INSURED PERSONS

1. Synergy between public and private sector in providing services within mandatory health insurance

**Issue:**

- Higher inclusion of the private sector for provision of services reimbursed by NHIF, as a means to shorten waiting lists in the public health care institutions.
- Quality of service provided in the private sector can be assured by limiting eligibility for applying to accredited private health care institutions, and allowing co-payment by the beneficiary. In such a way competition between private health care providers will be enhanced, on the quality and as well as price.

**Proposed Measures:**

- Develop rulebook in order to set service quality criteria through accreditation and certification process;
- Prescribe possibility of co-payment by the beneficiary of service.

**Regulation:**

- Regulation does not need to be changed.
- Applicable regulations:
  - Law on Health Care
  - Rulebook on the conditions and criteria for contracting providers of health services and determining their remuneration

1. Synergy between public and private sector in providing services within mandatory health insurance – more info

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. hemodialysis, IVF, and for certain ophthalmological operations), it is important to expand the trend with simply fine tuning the existing models. Namely, it is necessary to allow quality based competition among the private sector without increasing costs to the NHIF. One mechanism that the state already has operating is certification and accreditation mechanisms which guarantees certain level of overall service quality equal in the public and private sector. The other mechanism that would increase choice to the patients and could increase the quality of the services provided, is determining the price reimbursable by the NHIF, and allowing co-payment, thus introducing more choice to the patients.

Similar practice is already being used in other areas of state health care system, e.g. patient’s participation on drugs that are partly reimbursable by the NHIF.
2. The real choice of „chosen general practitioner“ and sector neutral possibility to prescribe NHIF reimbursable sick leave

**Issue:**

- 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”.

**Proposed Measures:**

- Draft instructions for implementing the Rulebook

**Regulation:**

- Regulation does not need to be changed.
- Applicable regulations:
  - Law on Health Insurance
  - Rulebook on the manner and procedure for realizing rights from mandatory health insurance (Articles 38 a-38 d) provides for opportunity of chosen doctor in the private practice

2. The real choice of „chosen general practitioner“ and sector neutral possibility to prescribe reimbursable sick leave – more info

Although the Law on Health Care does not explicitly ban the choice of general practitioner from the private sector, lack of by-laws (Instruction on implementing Article 38 a-d of the Rulebook on manner and procedure for realizing rights from mandatory health insurance) and practice of the NHIF not to contract health institutions in the private sector for providing such services, de facto precludes patients from real, sector neutral, choice of their general practitioner.

This results in duplication of costs for providing the same health service (once paid out of pocket, the other paid out of mandatory health insurance), and in turning public sector „chosen GPs“ into pure administration, thus further limiting access to primary health care to patients catered for solely by the public sector.

As the passing of the Law on Evidences in Health Care laid the grounds for unification of the patient’s documentation in the public and the private sector, and first steps are taken in the public sector in introducing electronic files, there is a little rationale to maintain this restriction of choice for the private health institutions that fulfil the same criteria public sector does.

The mechanism of accreditation and certification of the private health institutions, can serve as the entry requirement for contracting services and can be used as a mechanism of control against malpractice.
3. Ban on formation of branches of private health institutions

**Issue:**
- Lack of possibility to open branch of private health care institution at different locations which creates unnecessary administrative barrier to establishment, employment etc.

**Proposed Measures:**
- Elaborate in the Law on Health Care and in the Rulebook on conditions and manner of internal organization of health institutions, that health care institutions may establish branches outside of the seat of the institution

**Regulation:**
- Necessary change to the Law on Health Care
- Rulebook on conditions and manner of internal organization of health institutions

3. Ban on formation of branches of private health institutions – more info

Article 142 of the Law on Health Care provides for possibility to organize branches depending on the type of services rendered, number of employees etc, but does not specify whether territorial dislocation of such organization units is allowed. This ambiguity should be rectified in the Amendments to the Law on Health Care, as it significantly hampers the development of the private health sector.
4. Ban on provision of emergency medical assistance

**Issue:**

- Effective ban of provision of emergency medical health by the private sector

**Proposed Measures:**

- Harmonize Article 48 and Article 62 of the Law on Health Insurance;
- If quality of service is the concern for such a ban, develop quality related indicators. In the interim, allow certified and accredited institutions provision of such services;

**Regulation:**

- Law on Health Care, Article 48, Paragraph 3 and Article 62

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4. Ban on provision of emergency medical assistance – more info

It is necessary to harmonize Art. 48 of the law on Health Care which provides that only public health institutions may provide emergency medical assistance, while Art. 62 provides for obligation for provision of such service with the penalty for breach from RSD 100.000 – 500.000.
### 5. Burdensome and excessive requirements for registration of health institutions

#### Issue:
- 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.

#### Proposed Measures:
- 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

#### Regulation:
- Rulebook on Conditions for Performing Health Care in the Health Care Institutions and Other Health Care Facilities

There is a need to review in detail the conditions for granting the provision of health care services, as the current ones were drafted having primarily in mind large state health care institutions, and need to be updated regarding the use of modern technical equipment.

Currently prescribed conditions may be burdensome in some cases (as e.g. specialist psychiatric hospital needs to have X-ray, full biochemical lab, dentist service and a portable stove „rešo“), while not contributing in any way to the increase of quality of service provided.

Significant issue is also the fact that there are state health care institutions, which provide services to the patients and are reimbursed by the NHIF, which do not fulfill criteria mandated by the Law on Health Care and the relevant Rulebook on conditions for provision of health services in health institutions and other health care practices.

This all calls for a thorough review of conditions necessary for quality provision of service to the patients provided in the mentioned regulations.
III. PPP IN SHIFTING FOCUS FROM CURATIVE TO PREVENTIVE MEDICINE

Problem:

- The accent in Serbian healthcare services is still on the curative, rather than preventive services

Proposed Measures:

Public-Private Partnerships (PPP) with:

- Pharmaceutical and medical devices companies for raising awareness on the importance of screening in general population
- Private healthcare providers for outsourcing part of the services on primary care level
- Private health insurance companies for higher inclusion of preventive measures in healthcare package

Regulation:

- Law on Health Insurance
- Law on Health Care

1. Shifting focus from curative to preventive medicine – more info

While the number of preventive examinations has increased during the last decade, they are still below EU average. Diagnosis and treatment examinations are still more often than preventive ones which is especially visible in the case of preventive screenings for malignant diseases (breast cancer, cervical cancer, colorectal cancer) and chronic non-communicable diseases (cardiovascular, metabolic, respiratory...). Capitation as a model for paying earnings in primary health care does take into account the number of provided preventive examinations and screening tests with 30% in the total rating, but still performance-based part of earnings is significantly smaller and does not really reward providers for delivering better quality;

Low level of preventive comparing to curative services has significant negative effect on long-term financial sustainability of the system. Building up the quality of primary and preventive care through better screening and timely treatment of chronic diseases, as well as promotion of healthier lifestyle will reduce healthcare costs in the mid-to long term.

Efficiency in primary care should be stimulated by raising awareness in general population on the importance of screening and preventive examinations, where public-private partnership with pharmaceutical and medical devices companies should be considered in areas of common interest. In order to boost this type of services, government and NHIF need to consider outsourcing part of the services on primary care level, where patients should also have the option to choose general practitioner from private Healthcare Institutions. Also additional private health insurance should be considered for partnering as it often has higher standard of healthcare and wider scope of coverages, with higher inclusion of preventive measures.
### IV. OPTIMIZATION OF PUBLIC PROCUREMENT PROCESSES AND STOCK MONITORING

#### 1. Stocks management for medicines and medical supplies in hospitals

- **Issue:**
  - Lack of information about stocks management for medicines and medical supplies in hospital creates surpluses in one and shortages in others – IT system on stock control would improve overall supplies management

- **Proposed Measures:**
  - Integrated software solution for stock management

**Regulation:**
- Regulation does not need to be changed.

#### 2. Criteria for tendering processes and reporting mechanisms

- **Issue:**
  - Abandon price only criteria for tendering processes and introduce quality based criteria, as low quality material and equipment may significantly increase secondary costs of treatment and save lives
  - Develop stricter reporting mechanisms for health care institutions focusing on quality of procured material in exploitation

- **Proposed Measures:**
  - Inclusion of quality criteria in the public procurement process, especially for medical supplies and devices.
  - Develop efficient HTA mechanism.
  - Ministry of Health and Public Procurement Office to develop models for specific frequent supplies with quality based criteria, that can be replicated
  - Further develop reporting mechanism of unwanted outcomes in exploitation of public procurement goods. Create black lists for providers.

**Regulation:**
- Regulation does not need to be changed.
NHIF conducts in the name and for the account of Healthcare institutions in their network centralized public procurement, but there is an increasing trend of unsettled liabilities of healthcare institutions. The main reason for growing concern is poor management of public procurement process and supplies. Therefore, there is a strong need for establishing integrated software solution for stock management, and optimization of procurement of medicines and medical supplies.

In order to protect quality of patient health services, it is essential to balance the public procurement process and ensure that lowest price cannot be the only decision driver. Quality, technical specifications, life cycle costs and additional services should play a significant role in making selection criteria.

Introduction of stricter system of reporting on quality of procured goods in performance would allow for "learning" within a system and focus on affordable quality.