Oncology Financing in Serbia
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ACRONYMS & ABBREVIATIONS

CDC Central Drug Committee
COVID-19 Respiratory illness caused by the SARS-CoV-2 virus
CPI Consumer Price Index
CT Computerized tomography
DALY Disability-adjusted life years
DRG Diagnosis related group
EU European Union
EUR Euro
Eurostat European Statistical Office
GDP Gross domestic product
HPV Human papillomavirus
HTA Health technology assessment
ICD-10 International Classification of Diseases, Tenth Revision
IMF International Monetary Fund
LINAC Medical linear accelerator
MOH Ministry of Health
MRI Magnetic resonance imaging
NCD Non-communicable disease
NHIF National Health Insurance Fund
NICE The National Institute for Health and Care Experience of the United Kingdom
OOP Out-of-pocket
PET Positron emission tomography
PPP Purchasing power parity
RSD Serbian dinar
USD United States dollar
WHO World Health Organization
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## EXECUTIVE SUMMARY

### Context
- Economic growth has been strong in Serbia in recent years, with a potentially positive impact on available resources for health. However, the anticipated economic crisis post-COVID could negatively impact overall resources for health.

- The Serbian health system is highly centralized, and is challenged by chronic administrative, management, and financing inefficiencies. The ‘command and control’ nature of the health system structure does not allow for much experimentation with innovative financing although some provider payment reforms are being tested in hospitals.

### Oncology Financing & Performance
- The oncology program is underfunded, as is the entire health system. Given the country’s epidemiological profile, investments are most needed for cancer prevention programs and early diagnosis. Fifty-two percent of cancer cases are diagnosed in late stage, substantially reducing the chances of a patient’s survival and increasing reliance on costly therapies.

- Serbia’s expenditure on drugs is low, and there is limited access to innovative therapies. Of the latest 43 innovative therapies approved in the EU, up until 2019 Serbia had included only one on the reimbursement list while Bulgaria had 21 and Croatia 18.

- The government endorsed the Cancer Management Plan 2020-2022, which defines targets for improving prevention, early diagnosis, and treatment, with no evident accountability mechanism for tracking their achievement.

- The government has made two ad hoc allocations from the national budget for sixteen innovative therapies – USD 50 million in 2020, and USD 35 million in 2021 – which included seven drugs for oncology. These funds are channeled through the National Health Insurance Fund, though without a commitment for future funding.

### Key Trends & Takeaways
- Serbia’s ability to improve the performance of its oncology program is hampered by limited financial information, fragmented and outdated data systems, and limited use of evidence-based approaches to support decision-making processes.

- Decision-making processes in the public health system are a result of political imperatives rather than evidence-based approaches. Optimal resource allocation is further constrained by centralized decision-making, and the fact that service providers and managers have a reactive as opposed to a strategic role in care provision and clinical decision-making.
INTRODUCTION

The global cancer burden is increasing, and countries are grappling with how to sustainably fund comprehensive and high-quality oncology care, including access to new technologies and therapies. An in-depth understanding of oncology funding flows and the systems and structures that influence them can enable targeted policy efforts to improve financing for national cancer programs.

This country profile is part of a compendium funded by MSD that analyzes how countries finance their oncology programs. It contains valuable information for all stakeholders interested in promoting sustainable and robust financing for oncology care programs and illustrates a variety of ways to engage in realizing this outcome.

This country profile analyzes the situation of oncology financing in Serbia, with a particular focus on its organization, its opportunities, and the possible solutions for its current challenges. With an already large and projected increase in cancer burden, oncology care costs are being brought into sharper focus given the challenges they present to Serbia’s tax-funded health system.
MACROECONOMIC, DEMOGRAPHIC & CANCER BURDEN SITUATION

MACROECONOMIC & DEMOGRAPHIC OUTLOOK

The Serbian economy has not been as severely impacted by the COVID-19 crisis as other countries in the region and is expected to recover more quickly than other economies. In 2019, the Serbian gross domestic product (GDP) grew by 4.2%, with a smaller contraction in 2020 compared with the rest of Europe, at around -2.5%. Serbia was impacted less severely because of an already high level of growth before the crisis (5.2% in Q1 of 2020); low reliance on high contact sectors such as tourism; stringent containment measures; and a large package of fiscal and monetary policies that preserved jobs, boosted consumer and health care spending, and injected liquidity into the banking system.

Despite relatively strong macroeconomic performance, Serbia’s GDP per capita remains low at $7,400 per year. In purchasing power parity (PPP) terms, Serbia’s GDP per capita in 2019 was USD 19,000, while Bulgaria’s was 30% higher at USD 24,800 and Croatia’s 58% higher at USD 30,100.

The Serbian population is aging rapidly, and fertility is declining. Serbia’s population is 6.9 million people, with negative growth rates documented starting in the mid-1990s. At these rates, the World Bank estimates that the population will decline to 5.5 million people by 2050. The share of the population over 65 has increased from 13.5% in 2000 to 18.7% in 2019 (Figure 1) and is projected to increase to 26.5% of the population by 2050.

The disease burden currently shows an increase in non-communicable diseases (NCDs). The share of NCDs in total disability-adjusted life years (DALYs) is moving in the same direction; it has increased from 78% in 1990 to 87% in 2010 to 88% in 2018 (IHME 2020).

CANCER BURDEN

The leading causes of death are cardiovascular diseases (51.8%) and malignant tumors (21.3%) (IHME 2018). The share of malignant tumors has increased from 20.2% to 21.3% over the last decade. Over 60% of malignant tumors affect people above the age of 65. Given population trends, the cancer burden in the country will increase by 70% by 2040, thus substantially increasing the costs of care.
With the second highest cancer mortality rate in Europe, Serbia is classified as a high-risk country. Cancer mortality is not only the second highest in Europe, but also above any other regional or socio-economic cluster average in the world. Though cancer mortality is high, cancer incidence is moderate. Serbia ranks 12th in Europe with over 300 annual new cases per 100,000 people (Figure 2. Cancer Burden in Serbia).

Almost 600,000 disability-adjusted-life-years (DALYs) are lost due to cancer every year, with males accounting for 56.3% of the total.

The key risk factors for cancer in Serbia are inadequate diet, high blood pressure, tobacco, and alcohol use, and increasingly, air pollution. One in three people in Serbia report smoking cigarettes (34.7%), compared to a European average of 26% and global rate of 20%. Alcohol consumption per capita is 11.1 liters annually, above the WHO recommended amount of 9.9 liters (WHO 2020).

**HEALTH SYSTEM STRUCTURE & HEALTH FINANCING**

Serbia’s health system is highly centralized, and access to health care is a guaranteed constitutional right for all citizens. The Ministry of Health (MOH) and the National Health Insurance Fund (NHIF) are the key entities in the Serbian health system, with distinct roles and responsibilities independent of one another. The MOH is responsible for developing and implementing national health policy and it owns and regulates the public healthcare provider network, which consists of 355 institutions and over 100,000 employees. The NHIF is the main purchaser of public health services and pharmaceuticals.

Serbia has universal health coverage, with a comprehensive defined benefits package (Box 1). Based on the principle of solidarity, citizens – formal sector workers, self-employed, farmers, and their

**Box 1. Serbian Health Insurance Benefits Package**

A remnant of the previous socialist regime, the benefits package in Serbia covered by the compulsory National Health Insurance includes all services provided in public health facilities. Over the last five years, cosmetic surgery, dental care, and medical care received out of the country have been excluded from the benefits package in an effort to contain costs and better prioritize care. The public health system is responsible for providing virtually all oncology-related services, and the NHIF covers all anti-cancer drugs and innovative therapies that are included on the reimbursement list. Inclusion in the benefits package does not translate to access given funding insufficiency in the system.
respective dependents – contribute a share of their incomes and are thus entitled to use as much health care as needed.

While on paper the structure of the public health system in Serbia is sound; in practice, it is underfunded and ridden with inefficiencies. The World Bank’s cross-country comparison of health expenditure and health outcomes suggests that Serbia’s expenditure versus health outcome ratio is well below neighboring countries, indicating that there is room for efficiency improvements. In this highly centralized system, the budget is allocated based on historic trends rather than evidence-based needs assessments. Moreover, the health system increasingly relies on OOP to finance health care, which contributes to growing inequities in access and outcomes (Figure 3). Health system performance is suboptimal; patients face long wait times and the NHIF uses many ad hoc cost containment mechanisms that lead to access and equity problems.

![Figure 3. Health Expenditures in Serbia, 2018](image)

Source: World Development Indicators 2020

Relative to the countries in the region (Figure 4), health expenditure in Serbia appears on par or even higher in relative terms (as % of GDP and government health expenditure), although it is lower in absolute terms (USD and PPP). Government health expenditure accounts for 12% of total government expenditures, and 5% of the GDP when private spending is excluded. Government spending per capita in Serbia amounts to USD 748 (PPP), compared to USD 874 in Bulgaria, USD 1468 in Croatia and USD 2126 in Slovenia.

Through it has a generous social health insurance benefits package, Serbia has the second highest share of private spending on health in the region, after Bulgaria. Almost 90% of OOP spending goes directly to the private sector, bypassing the public health sector. In 2018, OOP expenditure accounted for almost 96% of all private spending, while the voluntary private health insurance accounted for just 2% of private expenditures. Out-of-pocket spending in Serbia is disproportionately high when benchmarked against the neighboring countries; it has the lowest GDP per capita in PPP yet the third highest level of OOP.
Oncology care is still largely the responsibility of the government, with an ever-increasing share of OOP payments for diagnosis and related out-patient services in private clinics. The NHIF does not reimburse private providers for the provision of oncology services. Voluntary and supplementary private insurance represents 2% of the total health expenditure and plays a negligible role in oncology financing. Several private insurers now offer supplementary insurance for major NCDs including oncology and cardiovascular diseases for treatment abroad. These insurance policies cover treatment costs of up to USD 2 million, limited to cancers detected in early stages before metastasis.

**THE NATIONAL CANCER PROGRAM**

**PROGRAM SNAPSHOT**

The Serbia government adopted the Program for Improving Cancer Management 2020 – 2022, which sets clear targets for improvements along the entire continuum of cancer care, and particularly prevention. The program introduced an expert working group for prevention and control of cancer, responsible for planning prevention activities, and coordinating their implementation. It contains targets for reducing risky behavior (smoking, unhealthy eating habits, and alcohol consumption). Serbia Against Cancer 2010 - 2015 was the only national cancer program that preceded the current one.

The Serbian Public Health Strategy 2018-2026 – a multi-sectoral collaboration between the Ministries of Health, Education, and Sports and Youth – identifies cardiovascular diseases and malignant tumors are the leading causes of death in the country. Risky behaviors are a common root cause, and the government’s strategy explicitly focuses on the promotion of healthy living and behavior changes. The strategy commits to implementing policies to reduce alcohol and tobacco consumption by 10%, and increasing healthy diets and physical activity practices by 10% by 2026.
The government’s commitment to fighting cancer is also evident through collaboration with the World Bank. The government sought targeted assistance in 2018 from the World Bank for improving the quality of oncology care and strengthening governance. Advances are evident in the efforts to strengthen the national cancer registry system and increase the coverage of diagnosis and radiation therapy. The MOH invested almost 70% of additional financing for the World Bank’s Second Health Project (USD 21 million) in radiology infrastructure for improving cancer diagnosis and treatment.¹

To execute the National Program for Improving Cancer Management, the MOH committed additional USD 29 million for the period 2020-22. These funds will be provided from the national budget and distributed in the following manner: USD 2 million in 2020, USD 16.2 million in 2021 and USD 10.4 million in 2022. The MOH will thereafter finance the activities for improving cancer prevention, early diagnoses and treatment, mainly through the Institute of Public Health “Batut”.

CANCER CARE CONTINUUM

Interviews with key informants identified cancer prevention and early diagnosis as the target areas for improvement. Investments in prevention, particularly behavior change – reducing risky behavior and increasing awareness and care seeking practices – can lower the burden of cancer on the economy in terms of morbidity and mortality, as well as relieve the pressure on the health system by reducing financial costs of treatment. While acknowledging that palliative care has not yet evolved in Serbia, most key informants stated that investment is more urgently needed for prevention and early diagnosis.

Within the range of possibilities, key informants considered oncology treatment in Serbia to be the strongest component of the continuum of care. The main reasons for this are trustworthy, competent medical specialists, and accessibility of treatment free of charge through the NHIF. Most key informants held that the medical staff work above and beyond their expected capacity considering the tremendous resource constraints that they face. Additional details about the oncology care continuum are provided in Annex 1.

¹ Along with NHIF’s expenditure on health services and pharmaceuticals, oncology expenditure includes infrastructure investments made by the MOH and the Health Secretariate of Vojvodina. Between 2016 and the present date, the MOH invested approximately USD 22.6 million in radiology equipment using a World Bank loan with a goal to achieve international standards for cancer diagnosis capacity and radiotherapy coverage. They procured six linear accelerators (LINACs), 10 MRIs, six CT scanners and 20 ultra-sounds in the value of USD 21 million. In addition, the Government of the Autonomous Region of Vojvodina invested USD 1.6 million in an MRI and a mammography machine in 2020 alone.
ONCOLOGY PROGRAM FINANCING

Total public expenditure on oncology

The NHIF receipts show that expenditure on oncology amounted to USD 222 million in 2017, which represents 11.7% of its total budget (Figure 5). Oncology is the second largest disease expenditure, behind circulatory diseases which consumed USD 301 million in the same year. The share of the budget that the NHIF dedicates to oncology care has been increasing,\(^2\) from 10% in 2011 to 10.6% in 2014 and finally to 11.7% in 2017, along with the increasing burden of disease.

**Figure 5. 2017 Cancer Expenditures (NHIF Reimbursements)**

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Expenditure on Tumors ([C00-D48])</td>
<td>2011</td>
<td>2012</td>
<td>2013</td>
<td>2014</td>
<td>2015</td>
<td>2016</td>
<td>2017</td>
</tr>
<tr>
<td>Health Expenditure on cancer USD (millions)</td>
<td>$165</td>
<td>$164</td>
<td>$208</td>
<td>$208</td>
<td>$173</td>
<td>$201</td>
<td>$222</td>
</tr>
<tr>
<td>Health Expenditure on cancer RSD (billions)</td>
<td>$12</td>
<td>$14</td>
<td>$18</td>
<td>$18</td>
<td>$19</td>
<td>$22</td>
<td>$24</td>
</tr>
<tr>
<td>RSD/USD exchange rate</td>
<td>$73</td>
<td>$88</td>
<td>$85</td>
<td>$89</td>
<td>$109</td>
<td>$111</td>
<td>$107</td>
</tr>
<tr>
<td>Health Expenditure on cancer (USD per capita)</td>
<td>$23</td>
<td>$23</td>
<td>$29</td>
<td>$29</td>
<td>$24</td>
<td>$28</td>
<td>$32</td>
</tr>
<tr>
<td>Oncology expenditure as % of total health expenditure</td>
<td>10%</td>
<td>10%</td>
<td>11%</td>
<td>11%</td>
<td>10%</td>
<td>12%</td>
<td>12%</td>
</tr>
</tbody>
</table>

\(^{2}\) RSD adjusted for inflation, CPI (2017=100)
\(^{3}\) Source: Institute for Public Health Batut report on the costs of healthcare by ICD-10 category

Per NHIF reimbursement claims, the average public expenditure for an oncology patient is USD 860 per year, 58% of which covers health services, and 42% covers drugs and medical supplies. The NHIF reimburses all oncology related services and drugs\(^3\) provided through the public health sector. Due to the inefficiencies in the provision of care such as long waiting times, patients who can afford it often turn to the private health sector mainly for diagnosis and follow up screening. Key informants’ estimates suggest that this oncology related OOP spending averages approximately USD 120 per month per patient. This fragmentation of the system leaves the treatment, which is the costliest segment of the cancer care continuum, as the full responsibility of the government to cover.

Market for oncology pharmaceuticals

The market for oncology drugs represents only 10% of the whole pharmaceutical market in Serbia, by far the lowest share in the region. Bulgaria has a similarly sized population and its pharmaceutical market is almost twice the size with 20% going towards oncology medicines. Pharmaceutical markets in comparable reference countries are also more heavily weighted towards oncology: 18% in Slovenia, 19% in Italy, and 26% in Croatia. Considering that Serbia regionally has the second highest burden of cancer in terms of both standardized incidence and mortality, 10% dedicated to oncology is disproportionately small in comparison to what others in the region spend.

\(^2\) note: the USD/RSD exchange rate has fluctuated a lot over the period 2011-2017 (shown in the table); the RSD was particularly strong relative to USD in 2015, so demonstrating the expenditure trend in RSD gives a more realistic picture. It is unclear whether the USD/RSD exchange rate had an impact on health expenditures in foreign currency, that would require a special additional analysis.

\(^3\) with certain restrictions addressed below
Serbia has the lowest per capita expenditure on oncology drugs (USD 13) among its neighbors (Figure 6). Even though drug expenditure cannot be directly linked to health outcomes without an in-depth health system analysis, it is evident that Serbia underinvests in oncology drugs relative to the neighboring countries. In comparison, Bulgarian expenditure on oncology drugs is 3.5 times higher at USD 48 per capita. Serbia clearly underspends relative to burden, a concerning trend given the projected cancer incidence trajectory.

The market for oncology drugs (Figure 7) has been steadily increasing per year since 2016, driven mainly by the introduction of special regimen therapies which essentially doubled between 2016 and 2019. Drugs for oncology represented 10.6% of the total pharmaceutical market in 2019, amounting to USD 91.7 million. Supportive therapies – such as antiemetics and morphine – represent 4.3% of the total oncology drug market.

**Figure 7. Pharmaceutical Market in Serbia**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharma market size</td>
<td>$615</td>
<td>$693</td>
<td>$836</td>
<td>$862</td>
</tr>
<tr>
<td>Special regimen cancer therapies (C list)</td>
<td>$35</td>
<td>$50</td>
<td>$65</td>
<td>$73</td>
</tr>
<tr>
<td>Anti-cancer drugs (B and D list)</td>
<td>$11</td>
<td>$12</td>
<td>$15</td>
<td>$15</td>
</tr>
<tr>
<td>Supportive therapies (A and B lists)</td>
<td>$3</td>
<td>$4</td>
<td>$4</td>
<td>$4</td>
</tr>
<tr>
<td>Total oncology (USD)</td>
<td>$49</td>
<td>$65</td>
<td>$84</td>
<td>$92</td>
</tr>
<tr>
<td>Oncology-related drugs (% of total market)</td>
<td>8.0%</td>
<td>9.4%</td>
<td>10.1%</td>
<td>10.6%</td>
</tr>
</tbody>
</table>

Source: internal analysis of MSD data, 2020

**Sources and pools**

Sources of finance for oncology – as is the case for the entire public health system – include compulsory social contributions, general taxes and OOP payments. Given the structure of the system, the bulk of public expenditures on oncology are financed through aggregated payroll contributions managed by the NHIF.
Centrally collected payroll contributions for health are channeled into unitary pool: the NHIF. All formal employees pay compulsory health insurance premiums to the NHIF through direct payroll deductions on a monthly basis, representing two-thirds of NHIF’s revenue. The contribution rate for has gradually declined from 20.2% of the gross salary in 1994 to 10.3% currently (Figure 8), while the breadth of the benefits package was only minimally reduced over the last five years (dental, cosmetic surgery and travel costs have been removed list of defined benefits). According to the most recent estimates from the World Bank, the share of uncollected premiums is as high as 40% of total potential payroll funded revenues.

The MOH is the second largest pool for oncology financing. It receives funds from the budget of the Republic of Serbia filled through general taxation, based on historic trends. Besides the MOH, other ministries such as the Ministry of Education and the Ministry of Youth and Sports play a role in financing the oncology program mainly by organizing behavior change campaigns and activities aimed at cancer prevention. Figure 9 provides a visual presentation of the flow of funds for oncology in Serbia.

Figure 8. Trends in Payroll Contributions (1994-2019)

Source: World Bank

![Figure 8. Trends in Payroll Contributions (1994-2019)](image)

Figure 9. Serbia Fund Flow

![Figure 9. Serbia Fund Flow](image)

*Out-patient and in-patient service costs include: salaries, consumables, general capital investments and maintenance*

Source: Authors
The Regional Health Secretariat of Vojvodina and municipal governments also participate in oncology financing to a lesser extent. They receive allocations from the national budget, and their contribution to total health expenditure is approximately 2%. Autonomous Regional Government of Vojvodina accounts for half of that amount, with 1.4% of its total budget allocated to its Regional Health Secretariat in 2018. Regional and municipal pools create programs following the national priorities set by the MOH and make investments in oncology accordingly.

**Purchasers**

*The NHIF is the largest purchaser of oncology services.* The NHIF acts more as a claims-processing agency than a strategic purchaser, given the input-based nature of the financing system. It signs contracts with public service providers and reimburses them for the provision of services, including salaries, and medical consumables. Reimbursements for primary and hospital care are primarily based on inputs, with limited incentives for efficiency and quality improvement. With support from the World Bank, the NHIF is moving towards more active purchasing of health services at both the primary and hospital level of care, aiming to fully institutionalize performance-based payment modalities in a phased manner. At the primary care level, these modalities are aimed at improving quality of care using capitation; payments based on diagnosis-related groups (DRGs) are being piloted in hospitals (Box 2).

**Besides purchasing services,** the NHIF manages centralized procurement and purchasing of pharmaceuticals for the entire public health system, including treatment and supportive drugs for oncology. Procurement was centralized in 2018 and purchasing in 2019. While centralization did improve access to medicines and reduce delays in payments, it substantially reduced the autonomy of health care providers in managing their budgets and expenditures, particularly at the tertiary level of care.

**As the steward of the health system,** the MOH finances all governance functions. It is responsible for setting national health priorities, including the priorities within the oncology program. Through institutions such as the Institute of Public Health, the National Cancer Institute, the Medicines and Medical Devices Agency of Serbia, it finances the development and implementation of cancer care policies.

**The Regional Health Secretariate of Vojvodina provides support to health care providers for various functions.** ARG Vojvodina is the only regional government with autonomy, and it dedicates between 1% and 2% of its regional budget to health. At the moment, Vojvodina’s Health Secretariat runs programs for cancer prevention: “First Mammography” and the pilot program “Early Detection of Lung Cancer in the Territory of Vojvodina.” These oncology expenditures fund public awareness programs and support radiology infrastructure investments such as CT scanners and MRIs for local hospitals.

**OOP expenditure for oncology goes mainly towards private sector outpatient diagnostic and follow-up services, and supplemental drugs.** Internal analyses of various cancer patient associations reveal that an
average cancer patient spends between USD 100-200 a month on immune system boosters, follow up imaging in private clinics and supportive drugs. Few face catastrophic expenditures. This is the case with patients who do not meet the NHIF Medical Expert Committee’s assessment criteria for receiving innovative therapy and instead they opt for paying expensive innovative therapies from private funds. In these cases, patients opt for paying for therapies out-of-pocket, either because their desired therapy is not on the reimbursement list or because they are not eligible for it due to volume caps and indication restrictions imposed by the NHIF. While these cases are infrequent, such expenditures can be catastrophic for the families involved.

**Oncology pharmaceuticals**

As the sole public purchaser, the NHIF holds tremendous power when negotiating contracts with suppliers. The maximum wholesale prices for a particular drug in the country are determined by the MOH and the Ministry of Trade, based on the listed prices in reference countries: Italy, Slovenia and Croatia. There are three types of contracts between the NHIF and suppliers, all of which contain a volume cap determined by the NHIF, which is set based on the available budget. If the need for a particular therapy exceeds the volume cap defined in the contract, the pharmaceutical companies cover 90% of the cost for additional therapies provided, while the NHIF pays 10%. The NHIF holds control over how many therapies will be approved to patients any given year.

The NHIF uses centralized procurement and purchasing for pharmaceuticals that are on its reimbursement list. Up until 2018, NHIF oversaw procurement, while health providers were purchasing drugs from pharmaceutical companies. There were delays in payments given that hospitals had to wait for NHIF reimbursements, and hospitals did not always prioritize paying supplier invoices over resolving other operational deficits. To resolve this inefficiency, the NHIF started purchasing directly from the suppliers. This solution did improve the purchasing efficiency, but it has limited the autonomy of public hospitals to manage their own resources according to need.

Besides NHIF revenues and OOP, there have been ad hoc national budget allocations for innovative therapies. In April 2020, the Ministry of Finance allocated USD 50 million for sixteen innovative therapies, seven of which are for oncology. An additional USD 35 million were earmarked for the same list of innovative therapies for 2021. These funds are one-off national budget allocations channeled through the NHIF, and their institutionalization and reoccurrence in the coming years remain uncertain.

**Access to innovative drugs**

Serbia lags behind other European countries in adoption of innovative therapies, such as bio-, immuno- and hormone-therapies. The latest IQVIA analysis of adoption of the latest 43 innovative drugs in Europe for oncology ranks Serbia as the last with only one innovative therapy on the reimbursement list. Bulgaria, a country with comparable economic and health expenditure indicators has 21. Reference countries for the pharma market – Italy, Slovenia and Croatia – have 33, 25, and 18, respectively, while the EU average is 24. In addition, in April of 2020 the NHIF added seven new innovative drugs for 4

The following innovative therapies were added to the NHIF reimbursement list in April 2020:

- Three drugs for lung cancer: target therapies Alecensa (Alectinib) *Roche* and Tagrisso (Osimertinib) *AstraZeneca*, and one immunotherapy Keytruda (pembrolizumab) *MSD*
- Four drugs for melanoma: Tafinlar (Dabrafenib) *Novartis*, Mekinist (trametinib) *Novartis*, Cotellic (cobimetinib) *Roche*, changed indications for Zelboraf (vemurafenib) *Genentech aka Roche*, and Opdivo (nivolumab) *Bristol Myers Squibb*
- Expanded indications for two drugs for prostate cancer: Xtandi (enzalutamide) *Pfizer/Astellas* and Zytiga (abirateron) *Cougar Biotechnology, Inc.*
oncology onto the reimbursement list. Financed by the NHIF using a one-time direct transfer from the national budget makes the status of these therapies on the reimbursement list uncertain, given the large resource demands of the ongoing COVID-19 crisis.

The process of adding innovative therapies onto the NHIF reimbursement list is not transparent and not aligned with the EU standards (Figure 10). The NHIF and the MOH are the key decision-makers in this regard; they share the responsibility for introducing new drugs to the reimbursement list. The process is slow and cumbersome, taking 200-300 days to add a drug onto the list, and for expensive innovative oncology therapies it can last three times as long. The NHIF only notifies applicant suppliers in the event of a positive adoption decision.

![Figure 10. Drug Decision Making Pathway](image)

**THE PATHWAY OF AN INNOVATIVE ONCOLOGY DRUG: DECISION-MAKING MAP**

Serbia’s capacity to conduct health technology assessment (HTA) is limited. Serbia has two HTA committees, both with limited capacity to assess population needs and conduct tailored cost-effectiveness analyses. One HTA committee is within the MOH and another separate committee is housed by the NHIF, the Central Drug Committee (CDC). The CDC primarily assesses the pharmaceutical companies’ HTA submitted as a part of the application for inclusion of new drugs on the NHIF reimbursement list. CDC does so in collaboration with 40 Republic Expert Committees composed of medical specialists and NHIF’s Pharmacoeconomic Committee. After conducting an NHIF budget impact analysis, the CDC submits recommendations for final approval to the MOH. The ultimate criteria for accepting a drug is the budget availability. Key informants reported, in contrast to most of the EU countries, Serbian GDP per capita and other economic indicators are too low to make innovative therapies appear cost-effective using the standard National Institute for Health and Care Excellence (NICE) style HTA assessment.

Public pressure can have a substantial impact on NHIF’s decision to include innovative therapies and medical technologies to the reimbursement list. Adding innovative therapies to the reimbursement list is not a systematic, transparent process and it is not based on a comprehensive HTA. Instead, key informants report that the decision to include new therapies is primarily political. Patient association
activists report that the NHIF is responsive to their demands particularly if they are accompanied with media coverage.

**Even when they are introduced to the NHIF reimbursement list, innovative cancer therapies are reimbursed with significant restrictions.** The NHIF deploys formal and informal cost containment mechanisms, both of which create equity issues in terms of access. Formal restrictions are in the form of volume caps, e.g., restricting the number of patients that can receive a therapy in any given year, or the NHIF requires a patient to meet certain clinical indications to qualify for a therapy. One informal cost containment mechanism is the NHIF’s practice of refusing to reimburse a therapy even after it has been approved by the Medical Expert Committee based on clinical indications due to budgetary concerns.

**Resource constraints are exacerbated by the lack of clear clinical pathways, which further limit drug accessibility.** Innovative cancer therapies are administered in a centralized manner only through tertiary level providers, while the standard chemotherapy can be also administered at the secondary level of care. Nonetheless, due to unclear clinical pathways, the eight tertiary institutions can become overburdened with referrals for chemotherapy from the entire country, which causes long waiting times and prolongs the gap between diagnosis and treatment initiation. In addition, according to the MOH, the 32 existing clinical pathways for cancer have not been updated since 2017, and there are no clinical pathways for children with cancer.

### ONCOLOGY PROGRAM FINANCING CHALLENGES

**Sufficiency and efficiency of resources for oncology**

The mandatory benefits package is defined based on political imperatives, and not economic possibilities. Serbian benefits package is not prioritized and includes virtually all services provided in the public health system with few exceptions. The resulting impact is an NHIF budget that is insufficient to cover existing benefits, much less new proposed benefits. Most key informants indicated that such broad benefits package coupled with rising costs of care and a reduction in the payroll contribution percentages is an unsustainable path forward.

**The centralized funding arrangements and organization of the health system limits opportunities for raising additional revenue at other levels of the system.** A centralized system has advantages, particularly in the context of governance, oversight, and procurement of pharmaceuticals and medical equipment. Nonetheless, the MOH has been tightening control to the extent which hinders innovation for raising additional revenue at hospital level. The government did implement some experimental policies granting greater autonomy to tertiary hospitals, such as allowing health workers to work overtime for earning additional revenue. These were quickly discontinued because the central level did not have an adequate management and monitoring capacity to reduce the risks of effort and fund misallocation.

**Inefficient administration and allocation of resources.**

There are substantial administrative inefficiencies in collecting compulsory insurance premiums. The World Bank estimated that roughly 40% of the payroll contributions are not collected by the tax
department. This deficit is then compensated for via transfers from the national budget. Even though this is a broader system inefficiency and not a health sector issue per se, it negatively impacts fiscal space for health and leads to unpredictability in terms of available funds year-to-year.

**The benefits package is not adequately costed and priced, leading to hospital deficits.** The NHIF reimburses health providers on a fee-for-service basis, with caps determined by historic service utilization trends. At the moment, prices that public providers receive for basic services – such as a visit to the pediatrician – are even ten times lower than the going market price for the same service in the private sector. One way of addressing this issue at the hospital level is the introduction of the DRG financing mechanism, which now allows hospitals to seek reimbursement based on the average costs for each pre-defined disease group, for up to 5% of their revenue. Currently, oncology services are not planned for inclusion in the DRG pilot program.

**There are no clearly defined priorities and actionable strategies for oncology.** Despite there being a National Program for Improving Cancer Management, checks and balances are not in place to keep track of progress and keep providers responsible for it. While there is a written commitment to strengthening cancer prevention, there is little action taken in the form of introducing new laws that discourage the consumption of tobacco, alcohol, unhealthy diet, or increase preventative screening.

**Pharmaceuticals purchasing is not evidence-based.** Despite the formal existence of two HTA committees, the introduction of new drugs and medical equipment is conducted based on *ad hoc* assessments that for the most part take into account budgetary impact without much regard to the optimal cost-benefit ratio. In addition, key informants reported public pressure, political pressure, and supplier lobby as important factors that lead to the introduction of new items to the reimbursement list. The MOH and NHIF do not yet have the necessary expertise to transition into a meaningful health technology assessment adapted to the Serbian economic conditions.

**In the absence of evidence-based prioritization, the NHIF applies *ad hoc* cost containment mechanisms which limit transparency and predictability of financing and cause great equity concerns.** In the context of drugs, these cost-containment mechanisms include volume caps, limited clinical indications for the reimbursable therapies, and right to refuse to reimburse therapies even after they had been approved by the Medical Expert Committee.
**OPTIONS FOR IMPROVED ONCOLOGY FINANCING**

This Serbian oncology financing review concludes with a series of potential policy options that could be implemented to improve oncology financing and the performance of the health system. These options, and their relative feasibility and acceptability are outlined on the following pages.

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Grant greater financial autonomy to public hospitals</th>
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<tbody>
<tr>
<td>Policy intervention logic</td>
<td><em>Enable hospitals to generate additional revenue.</em> Hospitals in Serbia hold great potential to become financing pools for oncology care. By generating additional revenue through providing medical or non-medical services, public hospitals can reduce the dependence on NHIF reimbursements, cover their deficits, and make additional investments to improve the quality of cancer care.</td>
</tr>
<tr>
<td>Technical and administrative feasibility</td>
<td><em>Greater hospital autonomy coupled with strong oversight can improve administrative efficiencies.</em> If granted greater flexibility to optimize their revenues and expenditures, hospitals can improve the quality of care they provide. Decentralization pilots need to be supported by strong monitoring mechanisms from the central level.</td>
</tr>
<tr>
<td>Political acceptability</td>
<td>There are very strong equity arguments for this. However, there is a high risk of political backlash unless administrative issues are resolved.</td>
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<tr>
<th>Option 2</th>
<th>Introduce earmarked taxes</th>
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<tr>
<td>Policy intervention logic</td>
<td><em>Mobilize additional resources for oncology through earmarked taxes.</em> Imposing sin taxes on tobacco and alcohol could be a way of promoting healthier behavior and reducing cancer incidence, while also raising additional revenue for cancer care. Another option to be explored in the Serbian context is taxing casino earnings for funding a specific segment of oncology care continuum. Such taxation has been successfully implemented in Argentina’s Mendoza Province.(^5)</td>
</tr>
<tr>
<td>Technical and administrative feasibility</td>
<td>Taxing casino revenues, or ‘sin tax’ revenue generating schemes can generate additional financing for oncology and are relatively straightforward to implement.</td>
</tr>
<tr>
<td>Political acceptability</td>
<td>Imposing a tax on any industry is politically challenging; Ministers of Economy tend to view earmarks unfavorably.</td>
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### Option 3  Increase the number of cancer studies

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<tr>
<td><strong>intervention logic</strong></td>
<td>Promote regional collaboration for attracting additional financing in the form of clinical studies. Cancer studies are an underutilized source of financing for oncology in Serbia and in Eastern Europe in general. Individual countries have too few patients to be an attractive market for larger clinical studies of innovative therapies. The number of patients included in cancer studies in Serbia was 37 in 2018, while the National Plan for Improving Cancer Management aims to lift that number to 90 by 2022. Key informants pointed out that the number could be far greater for a broader range of cancers if legal bottlenecks were loosened, and if there were regional collaboration.</td>
</tr>
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| Technical and administrative feasibility | Besides additional financing, cancer studies would bring contextualized cost-effectiveness evidence to the decision-makers’ desks. Such collaboration could contribute to building ownership of evidence at the national level and raising awareness on the importance of strategic planning and purchasing. |

| Political acceptability | There are very strong equity arguments for this. However, there is a high risk of political backlash unless legal and administrative issues are resolved. |

### Option 4  Build the evidence base

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<td><strong>intervention logic</strong></td>
<td>Build an evidence base to strengthen the MOH and NHIF planning units’ capacity to make financing cost-efficient instead of basing it on historical expenditure trends. Improving the cancer registry to allow for measuring treatment outcomes is the crucial first step. Once able to assess survival rates and treatment outcomes, it is key to promote the use of a tailored health technology assessment, adoption, and testing of peer countries’ best practices and benchmarking performance against them. Evidence-based decision-making on where to invest limited health resources will lead to better health outcomes and a stronger business case for raising additional revenue from the national budget and beyond.</td>
</tr>
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| Technical and administrative feasibility | Linking investments with health outcomes will help improve the allocation of resources implementable with support in the form of training, guidance, and capacity building. |

| Political acceptability | There are very strong equity arguments for this. |
ANNEX 1 - CANCER CARE CONTINUUM

1. Prevention
The government’s efforts to reduce the leading risk factors for cancer are insufficient. Even though policies and laws are in place for changing behavior – such as those limiting tobacco and alcohol consumption – they are not strictly implemented. Therefore, Serbia remains a leader in consuming alcohol and cigarettes in Europe.

Previous national comprehensive preventative screening programs are no longer active due to the lack of funding. In the period from 2013-2018, there were three two-year cycles of preventative screening for early detection of breast, colorectal, and cervical cancer, as mandated by the National Program for Early Cancer Detection. The targeted populations for screening were at the time aligned with the European Union standards: for breast cancer women aged 50-69, for cervical cancer women aged 25-64, and for colorectal cancer adults aged 50-74. While the programs lasted, the adherence was 34% for breast cancer, 60% for cervical cancer, and 52% for colorectal cancer. The government recognized that, in order to continue with the secondary prevention, top priorities are acquiring additional mammographs to reach 100 for the whole country, establishing additional centralized cyto-laboratories and purchasing tests for stool testing.

Preventative vaccination coverage is low. Hepatitis B is on the recommended immunization schedule with 90% coverage financed through the NHIF. HPV vaccine is not included in the recommended list and therefore not covered by the NHIF. Nationally, HPV vaccine coverage is very low, with some studies making estimates as low as 2%. The Cancer Program 2020-22 aims to secure public financing for HPV as a recommended vaccine to boost coverage rates.

2. Screening and diagnosis
Late diagnosis is one of the key challenges of the Serbian oncology program. In 52.5% of cases, the disease in Serbia is diagnosed in an advanced stage (III-b or IV) with regional and distant metastases. On the one hand, risky behavior and poor health care seeking practices are the reasons behind late diagnosis. On the other hand, resource constraints lead to delays in diagnosis, ranging from the lack of specialists to the limited availability of cytological, pathological, biochemical and genetic testing, and long waiting lines for screening. Late diagnoses of cancer reduce treatment options for patients, lower their chances of survival, and reduce the quality of life. At the same time, it increases the total costs of oncology care.

Tertiary hospitals are overwhelmed with diagnostic work that should be done at primary health care centers. Clinical pathways do not connect physicians with doctors in specialized hospitals in an effective manner. Primary and tertiary levels of care are particularly disconnected in large urban areas, which causes inefficiencies in utilization of expensive hospital infrastructure, duplication of diagnostic testing, delays in the provision of diagnosis and treatment, and worse treatment outcomes. While Serbia has 1.62 oncology specialists per 100,000 people compared to the EU range of 2 to 7.1, the number of diagnoses per oncologist in Serbia matches the European average.

Serbia has the lowest number of CT scanners and MRIs for cancer screening in Europe. According to EUROSTAT, Serbia had the lowest number of CT scanners per 100,000 inhabitants in 2016 along with Hungary (both 0.9) and the lowest number of MRIs per 100,000 people (0.3), followed by Hungary (0.4). Several neighboring countries had 0.1 PET scanners per 100,000 people, while Serbia had 0 with only 2 PET scanners total for the whole country. Between 2016 and 2019, the MOH procured nine CT scanners and five MRIs but there is still a long way to go to reach international standards.

Due to long waiting times for cancer screening in the public sector, patients frequently seek referrals in the private sector. Interviews with cancer patient associations revealed that the largest OOP expenditure
goes toward screening for diagnosis and follow-up in private clinics where there are no waiting lines. This stark public-private fragmentation of the system is a concern that leads to both inequities and waste; patients who have sought a diagnosis in the private sector are often required to repeat the screening in public health facilities in order to receive a specialist consultation or be referred for treatment.

The MOH purchases medical equipment, but the NHIF has the financial responsibility for its maintenance. The total replacement value of medical equipment installed in the public health care facilities is approximately USD 850 million. The internationally accepted figure for the annual cost of maintenance is 6-8% of the capital value, which in Serbia amounts to USD 56-63 million. Nonetheless, the NHIF annually budgets only USD 300,000 – 500,000 for repairs and maintenance, with absorption capacity of only 50% consistently over the last five years. Such low allocation of funds for repairing devices and the challenges that the hospitals face to procure spare parts for high-tech machinery, to a great extent explain the large number of unrepaired machines sitting idle. This lack of adequate maintenance and delays in repairs limit patients’ access to lifesaving technology and accelerate the depletion of existing investments.

3. Treatment

Resource constraints limit care accessibility and delay treatment initiation. The key resource constraints are reflected in an insufficient number of radiotherapy machines and oncology specialists for the population size. Eurostat reported that the average number of oncology specialists in Europe ranged from two to 7.1 per 100,000 people in 2015, while Serbia had 1.62 oncologists per 100,000 people in 2018 with a total of 114 of them. In 2018, there were significant delays in initiating radiotherapy. Less than half of the patients were able to initiate radiotherapy within a month of being diagnosed: breast cancer 31.6%, cervical cancer 32.9%, prostate cancer 39.3%, and lungs 45.6%.

Serbia is moving towards the EU standard when it comes to radiotherapy. Between 2016 and 2019, the Ministry of Health invested in 15 linear accelerators for radiology treatment, so significant lowering of waiting times and increases in patient survival rate are expected to take place by 2022. Moreover, the MOH has also purchased other innovative radiation surgery equipment, such as the Gamma Knife.

Data on one-year and five-year survival rates are not available due to the limitations of the national cancer registry. It is therefore not possible to make comparisons of treatment effectiveness with countries in the region. The current cancer registry allows only for incidence, morbidity, and mortality analysis. The MOH is taking steps to refine the cancer registry as a part of the National Cancer Management Plan 2020-22. These efforts are necessary although not sufficient for improving the local HTA assessment capacity for adopting new therapies.
4. Palliative care and rehabilitation

Palliative care is still in a nascent phase in Serbia. In 2018, there were only 146 hospital beds reserved for palliative care for oncology patients. By 2022, the goal is to have 350. In 2018, 56 primary health centers provided home treatment services with palliative care, and the goal for 2022 is 88.

Psycho-oncology is underdeveloped. For a population of just under 7 million people, there are only three psycho-oncologists, three psychologists specialized for work with adult oncology patients and six specialized for work with children. In 2018, there were only two specialized psycho-oncology centers in the country, although the MOH’s cancer management program 2020-22 set a goal of creating 10 by 2022.

5. Governance

The Ministry of Health has strong centralized oversight capacity, although its monitoring capacity is not strong enough to decentralize decision-making. Quite the contrary, the trend has been towards centralization in order to tightened control and eliminate leakages and other system inefficiencies.

There is a limited political will and awareness of the need to conduct strategic planning and programming. Serbia does not have a comprehensive oncology program. The three years long National Program for Improving Cancer Management set broad targets for improving prevention, early diagnoses and treatment but does not hold stakeholders accountable for achieving the targets. Oncology financing is based on historical trends just like for the rest of the health system, with occasional one-off transfers of additional funds from the national budget based on priorities that are not transparent nor predictable.

The National Cancer Registry has rudimentary features limited to information on cancer morbidity and mortality. The registry still heavily relies on outdated paper forms and does not provide information on the disease stage, the amount of time between the first symptom and diagnosis, the adopted therapy nor survival rates. The registry has been in place since 1970, but the data were of very poor quality up until recently. Since 2014, the Law on Health Documents and Records in the Area of Health care mandates that the Institute of Public Health be responsible for managing the National Cancer Registry. Despite the relevant legislative amendments passed to modernize data collection, the necessary by-laws and regulations are yet to be enacted.

The Institute of Public Health reorganized the database and published the first report on malignant tumors in 2020, presenting the data up to 2017. Upon adoption of the World Bank recommendations on improving the National Cancer Registry, two new indicators will soon be readily available for international comparison: (1) the amount of time it takes to initiate chemotherapy, and (2) the share of patients who initiated radiotherapy within 28 days of diagnosis.
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