



POSITION PAPER

VALUE AND ACCESS TO INNOVATIVE MEDICINES IN MONTENEGRO

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Introduction

Medicines and vaccines are some of the most powerful tools in helping people all over Europe to live longer, healthier and more productive lives. Also, access to safe, effective and quality medicines and vaccines for all is one of the targets of the Sustainable Development Goals.

Even though pharmaceutical innovation is an obvious and important contributor to the health of a society, in times of economic constraint, new innovations are often considered to be costly and often are shared concerns with regard to the budget impact of new medicines and the sustainability of health systems in Europe.

In the last decades, the life expectancy and quality of life of European citizens have improved dramatically. Many diseases ranging from HIV/AIDS to cancer, once seriously debilitating and often a death sentence, are now manageable. Key to this success are investments made by the pharmaceutical industry, which allow for new innovative treatments to become available to patients.

It was shown across 30 OECD countries, that life expectancy at birth was increased by 1.74 years between 2000 and 2009, and innovative medicines accounted for 73% of this improvement.

Pharmaceutical industry is investing the most among all industries in research and development, and with those investments treatments are not only more effective but also more targeted, reducing side effects and the longer-term consequences of treatment, thereby improving life expectancy, economic productivity, quality of life and quality of overall care.

This document is the result of the work of Montenegrin Health Care Committee of the American Chamber of Commerce and it contains recommendations that address specific issues that are a consequence of the current legal framework and practice in the area of access to innovative medicines. We hope this Position Paper will provide a good basis for further discussion and improvement of the health care system in Montenegro.

Value of Innovative Medicines

Acknowledging the affordability challenges, but also the opportunities for more individualized treatment and more options leading to improved outcomes, it is important that all relevant stakeholders, from policy makers to industry, work together to find jointly agreed and commonly beneficial solutions to ensure that the policy environment is adapting to maximize the benefits and minimize the concerns associated with new treatments.

We would like to highlight few illustrative examples of this among many available. It is estimated that for over 650,000 HIV and breast cancer patients treated between 2007 and 2017 in EU, the subset of innovative medicines analyzed resulted in gains of nearly 2 million healthy life years and 27 billion EUR in terms of productivity. It is worth noting this only quantifies a fraction of the overall health and societal contribution of the pharmaceutical innovation. Aside from addressing only two therapeutic areas, also we have not touched on the ways in which new, more effective drug therapies improve the psychosocial health of patients, family members and the community, and this productivity calculations do not account for increases in informal employment, such as domestic work, childcare, and family caretaking. The imputed value of such unpaid work has been estimated at 20 to 40% of the EU GDP³². Even the impact of the medicines analyzed here are likely to be greater than stated, given that all of them have helped pave the way for further innovations across different medical disciplines.

Another important example is cancer. Improvements in both cutting-edge science and treatment outcomes are changing the profile of all cancers from an acute to a chronic disease, transforming cancer care and most importantly increasing the proportion of cancer survivors. For European patients diagnosed in 2012, over 66,000 more will live for at least five years after diagnosis compared with if they had been diagnosed a decade earlier.

Related to access to innovative medicines, 5-year relative survival for all cancers was improved in the last decade, but still varies across Europe from 40% in Bulgaria to 64% in Sweden. If every country were to achieve the survival rates of Sweden, then an additional 270,700 people would survive for at least five years in EU countries.

Current Situation in Montenegro

The mission of the AmCham Montenegro Health Committee is to be a reliable partner for health authorities in discussion, expertize and experience exchange in order to improve the health care system, baring in mind sustainability and ultimately benefits for Montenegrin citizens.

The AmCham Montenegro Health Care Committee acknowledges huge and many improvements in the area of reimbursement policies and procedures and access to innovative medicines in the last three years. This position statement has a goal to highlight further areas for improvement that we would like to focus with other partners in healthcare sector to ensure sustainable access to innovative medicines, further improvement of related policies and continuous collaboration among all relevant parties.

Activity Areas

We have agreed on 5 key activity areas:

1. Approval of innovative medicines;
2. Pricing;
3. Reimbursement;
4. Funding; and
5. Digitalization of healthcare system.

Activity Area 1:

Approval of innovative medicines

- **Current situation:**
 - CInMED (The Institute for Medicines and Medical Devices) approves innovative medicines usually within one year following EMA approval and/or submission of the approval file to the regulatory agency.
 - Additional indication to the already approved medicine is approved within three months following EMA approval and/or submission of the approval file to the regulatory agency.
- **Our suggestion:**
 - Acknowledging the probable resource challenges CInMED is facing we are highly welcoming agility and pragmatic approach to the approvals of additional indications. Looking at this positive practice we would suggest considering a framework for more predictable approval timelines, e.g. implementation of fast track procedure for all new submissions (therapeutic inovations and CP approved product files)

in line with art. 41 of the Law on medicines. MA issue 150 days as of formal complete application.

- Considering the size of the Montenegrin market, we are also welcoming all pragmatic approaches and flexibility in terms of existing procedures for import of non-registered products when there is need.

Activity Area 2:

Pricing

- **Current situation:**
 - Montenegro adopted international reference pricing model, taking into account 3 countries from the region (Croatia, Serbia and Slovenia) with 95% parity applied to the average price of those three countries, for the maximum price of innovative medicine.
- **Our suggestion:**
 - Even though the 95% parity for first in class and innovative medicines from value perspective can be challenged, we support this regulation as one way to ensure sustainability and continuous access to innovation for Montenegrin patients.

Activity Area 3:

Reimbursement

- **Current situation:**
 - We acknowledge and welcome improved reimbursement policies and procedures during the last three years with updates of Reimbursement List at the end of 2017, the beginning and the end of 2018 as well as in December 2019.
 - During this period we witnessed successful implementation of the first Pricing Agreements between MoH and MAHs that enabled access to many new and effective medicines for Montenegrin patients, but also substantial savings for the system, considering implementation of access schemes with discounted and hidden prices.
 - We also acknowledge and welcome multi-stakeholders involvement in reimbursement decision-making process.
 - We would like to point out that the restrictions, which were made by changes in Article 4 in January 2019 and completely abolishing Article 4 in December 2019 after amendments to the Health Insurance Law, made it impossible for patients in Montenegro to receive medicine if it is not on the Reimbursement List, even in situations when there is no therapeutic alternatives or when all other alternatives have been used.

- **Our suggestion:**
 - To simplify the procedure, the MoH should pass and update the Reimbursement List, in consultation with the Ministry of Finance due to possible budget impact. The way in which the Reimbursement List is adopted and updated requires complex Government procedure, that disables simpler updates for minor changes that affects sometimes only regimen of administration. The practice in which the Government passes the Reimbursement List does not exist in the reference countries, Slovenia and Croatia, and this procedure is under responsibility of the state authorities (MoH, HIF) with competence in the field of health.
 - Improve timelines for reviewing process of new molecules and/or additional indications. In the reference countries: Croatia, Slovenia and Serbia, Reimbursement List is updated several times during the year.
 - It is a good practice and recommendation to include patients representatives in the decision-making process, and this is not the case in Montenegro.
 - To establish as soon as possible a model for approval (legal, administrative and financial) of medicines for the patients with rare diseases. Those medicines in some or even many cases might not be or might not be timely on the Reimbursement List, and these are unique medicines and/or medicines of vital importance for patients' lives.
 - In the surrounding countries, there is always an additional way of approval of the medicines which are not on the Reimbursement List, such as the hospital financing model in Croatia or Article 15 in Serbia. We do not think that any model should be just rewritten, but we need to discuss and establish an acceptable solution to avoid inequity, because a subgroup of patients is left without a solution.
 - Establish a working group that would include health authorities, experts and industry partners to proactively build consensus among all stakeholders, to determine and build needed system capacities for the introduction of innovative MEA models in the future.
 - This approach, introduced in some of the European countries, requires more sophisticated and integrated informational system for reliable data sources, data generation and data analytics as mandatory prerequisite for innovative MEA models.

Activity Area 4:

Funding

- **Current situation:**

- We acknowledge Government and Ministry of Health for funding and drug policy, because many innovative treatments are available for Montenegrin patients, unlike other countries in Western Balkan.
- We acknowledge referencing to Croatia and Slovenia like good examples, for the ultimate benefit of the patients.
- In 2019 overall spending for medicines was 101.072.508,09€, with 78,15% covered by HIF (78.988.728,57€). Considering that in the period before January 2018 there was no Reimbursement List update, growth in spending was naturally expected, especially in 2018 and 2019, following full implementation of new List. Still, per capita spending is below European average in Croatia or Slovenia as reference countries (an example: spending for ATC code L – antineoplastic and immunomodulatory medicines, 2019 per capita spending in Croatia was approx. 71 EUR, whereas in Montenegro 46 EUR).

- **Our suggestion:**
 - Investing in new innovative treatments is cost-effective, and brings real value to the economy and society at large. Innovative medicines help generate savings in other areas of health spending. Appropriate treatment at the right time can also help sustain work productivity and reduce potential sick leaves, or treatment abroad, all representing a burden for public budget. National pricing and reimbursement (P&R) decisions focused only on short-term cost containment negatively impacts access to medicines in the EU and increase health inequalities. Early investment in healthcare may result in increased future health benefits and decreased costs downstream.
 - Allocate sufficient new drug/new indication budget to meet the need to fund and reimburse life-saving, life changing medicines.
 - Continuous Reimbursement List updates enables more efficient budgeting and provide continuous and adequate treatment availability for Montenegrin patients in a sustainable manner.
 - Ensuring the sustainability of healthcare systems requires a strategic and comprehensive policy response. So for the key disease areas that are becoming a public health threat (considering epidemiology data), but also plays an important budget burden, e.g. cancer or rare diseases, we are proposing adoption of national policies (e.g. National Cancer Plan and National Plan for Treatment of Rare Diseases).

Activity Area 5:

Digitalization

- ***Our suggestion:***

- Digitalization and consequently generating, aggregating, and analyzing reliable data is the foundation of the future healthcare and enabler for introduction of the more sophisticated instruments when it comes to access to innovative medicines, as well. Considering that administration of the innovative medicines is mostly centralized in two key institutions, procured by Montefarm and fully covered by HIF, we think this is a good opportunity to work with those stakeholders and MoH on digitalization of the institutions that would allow patient centric and value based healthcare of the future.