
American Chamber of Commerce in North Macedonia
AmCham Healthcare Committee



HEALTHCARE CONFERENCE REPORT

Conclusions and policy recommendations

**2nd HEALTHCARE
CONFERENCE**

NOVEMBER 8, 2023

Skopje, North Macedonia

A Glimpse into the
FUTURE
of our
HEALTHCARE
System

A vertical white EKG (heart rate) line graphic on the right side of the page, set against a dark purple background.

Overview of the Conference

The second AmCham Healthcare Conference, titled "A Glimpse into the Future of Our Healthcare System," was held on November 8, 2023, in Skopje, North Macedonia. It was organized by the American Chamber of Commerce in North Macedonia with invaluable support from its Healthcare Committee member companies and partners.

The conference focused on two key areas pivotal to the design of the healthcare system in the country: access to medicines as a fundamental element of the right to health and the secondary use of health data.

The conference included engaging discussions with prominent government representatives and subject-matter experts, focusing on the current state of play and discussing innovative approaches, technologies, and collaborations aimed at achieving sustainable access to medicines.

It also explored the vast potential of secondary use of health data, emphasizing its positive impact on research, personalized medicine, and public health initiatives.

Ultimately, the conference featured a dedicated session on North Macedonia's healthcare system, highlighting its recent developments, challenges, and future directions with potential policymakers – political party representatives. Analyzing and presenting different points of view on the country's healthcare journey regarding some of the pressing issues provided valuable lessons and perspectives for policymakers in designing the country's future healthcare system.

Key Policy Recommendations for Future Actions

Key Principle:

To build a sustainable health system and lower the prevalence of chronic diseases, healthcare must be seen as an investment and not as a cost. This principle needs to drive decision - making.

Recommendations:

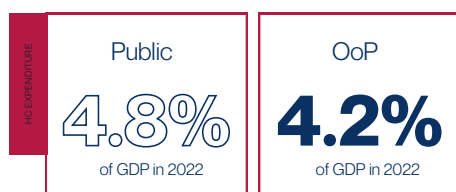
- 1. Access to medicines must be improved** as a priority in healthcare policy. This can be achieved through the following actions:
 - The HIF, with the support of the MoH and MF, must **urgently update the reimbursement list** with new medicines by April 2024 as stated publicly;
 - The reimbursement Commission needs to **prioritize medicines already available through conditional budgets** to be included in the reimbursement list;
 - MoH needs to **urgently use the managed entry agreements** in the Law on Medicines and Medical Devices **to create savings in the planned 2024 state budget**, for medicines on the reimbursement list (HIF budget), for medicines covered by the MoH programs (for rare diseases and others), and for medicines covered by conditional budgets (HIF budget);
 - MoH and MALMED need to **increase the registration rate** through legal and contractual requirements for unregistered medicines funded by the public budget.
- 2. Healthcare digitalization must be a priority** for the government. In 2024 the MoH needs to develop a **national digital health strategy**. The ODI report policy framework could be employed to tailor a clear roadmap of actions and timelines.
3. Political parties and decision makers need to make **clear commitments on healthcare and act on them, which can be achieved by** establishing a cross-political party platform that facilitates discussions on critical issues within the health sector.
4. The Government needs to establish a **national healthcare council composed of all relevant stakeholders** as soon as possible as the forum for collaboration on specific actions.

Summary of Key Takeaways: Recommendations and Call for Action

Topic 1: Access to medicines – a fundamental element of the right to health

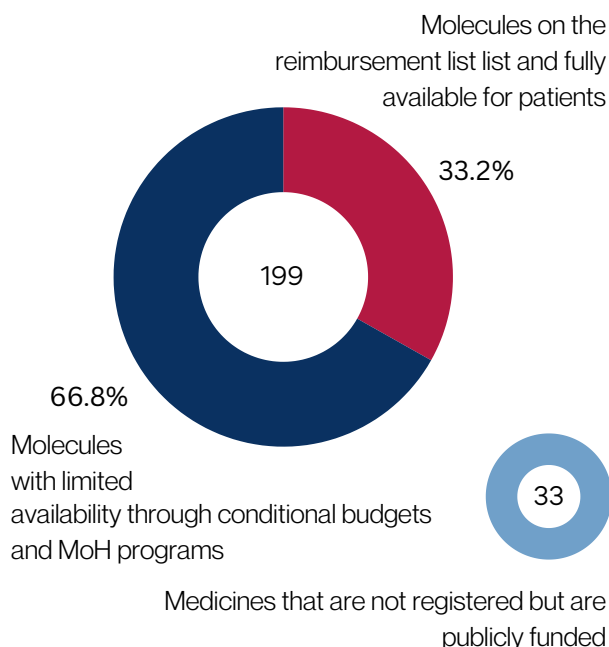
Takeaways

Prof. Marcin Czech delivered a presentation on “Access to medicines – registration and reimbursement”. North Macedonia is among the countries with the lowest investments in the healthcare of citizens, compared to the countries of the region and especially to those in the European Union, with total HC expenditure amounting to around 9% (4.8% public and 4.2% OoP) of GDP in 2022[1].



The data from the Patient WAIT Indicator 2023 Survey[1] and from IQVIA analysis shows that North Macedonia is lagging behind on access to medicines:

- Registration rate - of total 1.028 EMA authorized molecules (1996-2023) only 278 are registered in North Macedonia (27%), and not even all of them are available on the market.
- In total 199 molecules are publicly funded through 3 main pathways - reimbursement, conditional budgets and MoH programs.
 - Only 66, or 33% of the total number, are on the reimbursement list and fully available for patients, many of which are older generic drugs
 - The other 133 molecules are with limited availability through conditional budgets (93) or through MoH programs (43).
 - There are 33 medicines that are not registered but are publicly funded, leaving them outside of the system on quality control, safety and monitoring, continuity of supply obligations, and all other rules applicable to registered medicines.



- When comparing with the official reference countries (Serbia, Croatia, Slovenia, Bulgaria), the rate of reimbursed molecules in North Macedonia represents only 17-24% of the reimbursed molecules in these countries. Even if the total number of 199 publicly funded molecules is compared with the number of reimbursed molecules in the reference countries it is still around a 52-73% rate. This comparison is relevant because in the reference countries reimbursement is the only public funding pathway, they do not have conditional budgets or MoH programs.

The conclusion from the discussions was that there is a pressing need to speed up the reimbursement update and create health policies with focus on registering a greater number of molecules. The issue of access to medicines is primarily a financing issue, and financial projections and budgetary implications of placing new medications on the reimbursement list are needed.

[1] <https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?end=2022&locations=MK&start=2017>

[2] https://www.efpia.eu/media/s4qf1eqo/efpia_patient_wait_indicator_final_report.pdf

Recommendations and call for action:

1. The HIF needs to **urgently update the reimbursement list**, which requires funds allocated from the 2024 public budget. The publicly stated commitment by the government to have an updated list by April 2024 must be fulfilled.

2. **Medicines funded from conditional budgets** are already available and covered by the public budget, so they **need to be prioritized for inclusion on the reimbursement list**. The budgetary impact can be minimized through the conclusion of **managed entry agreements**.

3. **Managed entry agreements** need to be used by the MoH also to optimize the health budgets for those medicines that will remain to be covered by conditional budgets, as well as for those medicines funded through the MoH programs.

4. The MoH, the national medicines agency and all other stakeholders need to **encourage registration of medicines** through clear legal and contractual requirements.

5. The government together with the MAHs and other relevant stakeholders, taking the Polish example, should create a visual **map of the system of public financing of medicines**, outlining clearly the SHs, the process and the steps, who is responsible for each step, the lines of communications, and the deadlines for each step. The aim is to identify gaps and missing elements that need to be addressed by policy measures (changes in legislation or bylaws, financing mechanisms etc.). This can be done by the National healthcare council as its first activity.

6. Due to the budgetary constraints that limit the extent to which publicly funded medicines can have full availability, the pharma companies are open to start immediately working together with the HIF and the other state institutions (MoH, MF) and healthcare institutions in providing **financial projections on the impact of including new medicines on the reimbursement list**.

7. The Government needs to establish a National Healthcare Council as soon as possible to bring all relevant stakeholders together. The aim of the council would be to provide a formal structure for regular dialogue and implementation of specific policy actions that require cross - sectoral expertise, and to ensure consensus on long-term policies in the health sector.

Topic 2: Secondary Use of Health Data - State of secondary use of health data and policy recommendations

Takeaways

Mark Boyd from the ODI presented the report on the policy landscape on the secondary use of health data in the Western Balkan countries, focusing on North Macedonia[3]. The secondary use of health data has its role in health system optimization, treatment monitoring, cost reduction, and medical innovation.

There are solid foundations in place for health data infrastructure and secondary uses in North Macedonia. Healthcare data in North Macedonia is collected in MojTermin, MoeZdravje and by different institutions including healthcare providers, IPH, SSO, HIF, MoH, and MALMED. In particular, MojTermin is a good system with big potential.

One of the challenges is the interoperability between the institutions that hold various health data and the formats of data collection and processing that sometimes prevent further use and analysis. Following the example of modern European healthcare practices, there is a need for aggregated and integrated data that will be transparently available to the public, to decision makers, or to professionals for additional analyses and research. In light of the increased activity at the EU level in healthcare digitalization, in particular the creation of the EHDS, this area should be prioritized in the next period. A national digital health strategy is needed, based on the principles that the public sharing and use of health data for well-defined purposes, and with respect of data privacy and all other legal and ethical requirements, can bring great benefits for the health system.

Recommendations and call for action:

1. The government should consider digital health policy goals. A **national digital health strategy** should be developed by the MoH, involving government bodies, the private sector and other stakeholders, with clear actions and timelines. For this, the ODI report policy framework and the scorecard for North Macedonia might be used.

2. Increase **regional cooperation and knowledge sharing** with different stakeholders, especially in the adoption of open standards and open data models: there are areas where North Macedonia can offer leadership examples and areas where we can learn from others.

3. Seek to **partner with European countries participating in the emergent European Health Data Space**: Slovenia, Estonia, Germany, Lithuania, and Netherlands to take best practices applicable to our own digital health context

4. Ensure that the digitization and secondary use of health data initiatives **do not further widen health inequalities**.

[3] <https://secondary-use-health-data.theodi.org/assets/pdf/Roche-Secondary-Use-of-Health-Data-Report-Western-Balkans.pdf>

Topic 3: At a turning point: North Macedonia healthcare system

Takeaways

Representatives of the four largest political parties in the country AA, DUI, SDSM and VMRO-DPMNE shared their thoughts and political visions of how the country's health care system should look in the future, explaining the key steps for which they, as political stakeholders, will advocate. The need for having common priorities was mentioned, and the specific areas of focus included reviewing the healthcare financing, prevention, decentralization, and digitalization.

Recommendations and call for action:

1. Political party programs need to make clear, actionable, time-bound commitments on healthcare.
2. To establish a cross-political party platform that facilitates discussions on critical issues within the health sector, fosters consensus on long-term objectives, and secures enduring commitment from all stakeholders.

Table of Abbreviations

Abbreviation	Full Form
AmCham	American Chamber of Commerce in North Macedonia
HC	Healthcare
OoP	Out-of-Pocket
GDP	Gross Domestic Product
EMA	European Medicines Agency
HIF	Health Insurance Fund
MoH	Ministry of Health
MF	Ministry of Finance
MALMED	Macedonian Agency for Medicines
SHs	Stakeholders
MAHs	Marketing Authorization Holders
ODI	Open Data Institute
EHDS	European Health Data Space
IPH	Institute of Public Health
SSO	State Statistical Office

Supporting Conference Partners



About AmCham

The American Chamber of Commerce in North Macedonia is a business community comprising 140+ members, with a diverse spectrum of businesses, from small enterprises and local companies to large foreign investors, collectively employing over 42.000 individuals and generating an annual revenue of over 9 billion \$.

AmCham North Macedonia serves as a platform for advocacy, networking, exchange of knowledge and sharing of best practices, where business professionals dedicate their time and expertise to co-create a better business environment in the country.

AmCham North Macedonia is accredited by the U.S. Chamber of Commerce and the AmChams in Europe Network, the umbrella organization representing 49 American Chambers of Commerce in 47 countries throughout Europe and Eurasia.