

American Chamber of Commerce
North Macedonia

Healthcare Position Paper: Policy Actions

Recommendation

Improving access to
healthcare services
and medicines

Access to healthcare services in the country faces significant challenges even compared to its official reference countries such as Serbia, Croatia, Slovenia, and Bulgaria. For instance, the rate of reimbursed medicines by unique INN in the country represents only 17-24% of the reimbursed molecules in these countries. Moreover, from 168 new molecules approved by EMA in 2018-2021, only 10 are fully available in the country while the EU average is 76, which places North Macedonia at the bottom of the rankings in Europe (IQVIA, EFPIA Patients W.A.I.T. Indicator 2022 Survey, 2023). Additionally, the “Moj Termin” system aimed to streamline clinic operations and reduce wait times, but many patients still face long delays for critical diagnostics and treatments. Furthermore, healthcare services are heavily centralized in Skopje, leaving other cities with insufficient resources and forcing patients to travel for adequate care. Addressing these issues is essential for improving healthcare access and outcomes in North Macedonia.

Actions:

- Urgent update of the medicine reimbursement list (List A and List B) and ensuring regular updates (at least four times per year) to include new and effective medicines, prioritizing treatments for diseases with the highest unmet needs, such as NCDs.
- Implement the Managed Entry Agreements in practice, in accordance with the Law on Medicines and Medical Devices, to ensure wider and timely access to innovative medicines and optimize healthcare spending.
- Establish a Health Technology Assessment (HTA) body for North Macedonia, which should be part of the EU HTA network as in the example of other EU accession countries.

Ensuring a
sustainable financing
of healthcare sector

Ensuring sustainable financing of the healthcare sector is essential for improving healthcare outcomes in the country. The healthcare sector faces numerous challenges, including lack of proper planning and resource allocation, delays in public procurement - especially for life-saving medicines where continuity of treatment is crucial - and a lack of clear financial reporting and accountability. Furthermore, North Macedonia is significantly lagging behind EU countries in health expenditure per capita (\$560 in North Macedonia versus \$4,215 in the EU average

(World Bank, “Current health expenditure per capita Indicator”, 2021)) and in health expenditure as a share of GDP (8.52% in North Macedonia versus 10.95% in the EU average (World Bank, “Current health expenditure (% of GDP)”, 2021). On the other hand, not investing in healthcare has a massive economic cost. Non-communicable diseases (NCDs) account for around 95% of all deaths, and the country could lose approximately 19,900 productive years annually due to premature deaths caused by NCDs (World Bank, “Former Yugoslav Republic of Macedonia Systematic Country Diagnostic”, 2018).

Actions:

- Explore additional financing models in the healthcare sector to ensure sustainability, efficiency, and access to services, including public-private partnerships, private insurance, fintech solutions, and other financial instruments.
- Increase healthcare investments in non-communicable diseases through broader universal health coverage, including an update of the reimbursement list and access to diagnostics and treatment closer to the patient at local and regional levels.
- Ensure transparency and accountability through regular public reporting and independent audits from the State Audit Office to guarantee that all revenues collected for the healthcare sector are allocated and utilized exclusively for healthcare purposes.
- Promote greater transparency in the financial management of the Health Insurance Fund by enabling real-time tracking of fund allocations and expenditures/ publishing detailed financial reports on a quarterly basis.

Digitalization of the healthcare sector and enhancing access to data

By embracing digitalization and improving data accessibility, North Macedonia can significantly enhance its healthcare system and provide better outcomes for its citizens. Healthcare generates a significant portion of the world’s total volume of data - currently estimated at around 30% - which has the potential to generate crucial insights necessary for improving nearly all aspects of healthcare. However, we are still failing to fully capture its value. As the EU moves forward with initiatives such as the European Health Data Space (EHDS) and the AI Act, it is essential for national policies, frameworks, and infrastructure to be developed in line with EU and global trends. These efforts must ensure data quality, access, sharing, privacy, security, ethics, interoperability, and the infrastructure necessary for new health data-enabled technologies.

Actions:

- Enhance the reimbursement process transparency through the establishment of an e-platform for tracking and publishing submissions, as required by the Reimbursement Rulebook.
- Enhance transparency and data availability regarding the consumption of medicines and medical devices by establishing an Open Data platform for health data.
- The e-health Directorate, together with the Institute of Public Health and the healthcare organizations, should establish comprehensive disease registries, integrated with the Moj Termin system, to systematically collect, analyze, and disseminate data on specific diseases, with priority being placed on cancer and rare diseases registries, in line with European Commission recommendations.
- Integration of hospital information systems: Transparent waiting lists for in-patient interventions: surgery, coronarography, endoscopy, general surgery, ophthalmology, etc. Integrated therapy issuance and drug dispense for in-patient treatments.
- National ERP system: Tracking the drug and medical device inventory for each hospital. Tracking of framework contract execution for drugs on the national level.
- The e-health Directorate should promote and improve patient access to their own health data by developing secure and user-friendly platforms that empower individuals with the information necessary to actively participate in their healthcare decisions and management.
- Improve the electronic system “Moj Termin” between primary healthcare providers and specialists in order to have all referrals in electronic form, signed with electronic signature, accepted at the point of care, as opposed to requesting from the patient a paper copy with a wet-ink signature and stamp from the healthcare provider who issued the referral.
- Establish the infrastructure, policies and legal framework to share, integrate and access relevant data for regulatory, access and clinical purposes.
- Develop a concept to ensure and motivate healthcare professionals for appropriate data collection in the Moj Termin system.

Enhancement of the
Legal and Policy
Framework

Strengthening the legal framework can improve the overall quality of healthcare, provide timely and effective treatments, and support the well-being of its citizens. The transposition of EU legislation into national law is progressing very slowly, hindering advancements in the healthcare sector. Additionally, the adoption of the new Law on Medicines has been postponed numerous times without clear explanations to stakeholders, and there is no information about the timeframe for the new Law on Medical Devices.

Actions:

- Adoption of the Law on medicines and the Law on Medical Devices as critical steps toward aligning national legislation with European Union standards and directives.
- Harmonize and simplify the medicines pricing policies between the Ministry of Health and the Health Insurance Fund by unifying the various pricing approaches and by considering the Managed Entry Agreements as a new pricing modality to ensure the policy remains responsive to market conditions.
- Adoption of a national cancer strategy in line with Europe's Beating Cancer Plan, in a process that closely involves the business community alongside other stakeholders,
- Review and amend the Rulebook on the Manner of Use of Healthcare Services for Insured Persons Abroad ("Rulebook") to address the challenges patients face when injured or diseased abroad and to facilitate their treatment.
- Partnering with the private sector, international organizations & NGOs to create ongoing and open dialogue about current and future policy needs.

Enhance healthcare
infrastructure and
support medical
personnel

Improving healthcare infrastructure and supporting personnel is crucial for advancing healthcare in North Macedonia. Inefficient resource management has led to an overburdened tertiary healthcare level and underutilized primary and secondary levels. Many patients are routinely sent to the Skopje University Clinic Center, even when regional hospitals have the necessary conditions for diagnostics and treatment. The shortage of physicians and nurses, exacerbated by their transfer to the private sector and emigration abroad for better opportunities, further strains the system. Addressing these issues requires reforms to enhance primary and secondary healthcare, provide adequate conditions and infrastructure, promote regionalization and

decentralization, and modernize education and incentives for public health sector staff.

Actions:

- Prioritization of the speedy construction of a new, modern university hospital center in Skopje.
- Implement measures to provide the application of hospital-administered medicines as close to the patient as possible, using the network of regional hospitals, primary healthcare, and local pharmacies.
- Improve the working conditions for healthcare providers by providing competitive salaries, benefits and opportunities for career advancement and continued education.
- Provide subsidies for specializations in deficient medical fields.

Improve screening and early diagnosis

Early detection of diseases, particularly non-communicable diseases (NCDs) like cancer, significantly enhances treatment success rates and patient outcomes. For instance, early-stage breast cancer has a 5-year survival rate of over 90%, compared to less than 30% for late-stage detection. In North Macedonia, NCDs account for approximately 95% of all deaths, with many cases diagnosed at advanced stages due to insufficient screening programs (Ministry of Health, “Healthcare Strategy of Republic of North Macedonia 2021-2030”, 2021). Implementing comprehensive screening and early diagnosis initiatives can reduce mortality rates, lower healthcare costs by avoiding expensive late stage treatments, and improve the quality of life for patients. Prioritizing these measures aligns with global best practices and can lead to a healthier, more resilient population in North Macedonia.

Actions:

- Guidelines should be established, and capacity built for risk-based screening and early diagnosis using the latest technologies, with a focus on prioritizing cardiovascular diseases, cancers, diabetes and chronic respiratory diseases.
- Improve involvement of the general practitioners and launch public health campaigns to educate the population about the importance of regular screenings and early diagnosis.