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Ministre  
Ministria e Shëndetësisë dhe Mbrojtjes Sociale

Lënda: Përcjellje e dokumentit "Position Paper" me rekomandime, përgatitur nga Grupi i Task Forcë i Farmaceutikës në Dhomën Amerikane të Tregtisë

**E nderuar znj. Koçiu**

Dhoma Amerikane e ka vlerësuar angazhimin tuaj për të nxitur bashkëpunimin institucional në zhvillimin e reformave që afektojnë biznesin i cili operon në sektorin e shëndetësisë, por në të njëjtën kohë kanë ndikim edhe mbi pacientët.

Në vijim të këtij bashkëpunimi dhe takimit që patëm me ju, mbështetur në sugjerimet e biznesit që ne përfaqësojmë, Grupi i Task Forcë i Farmaceutikës në Dhomën Amerikane ka përgatitur një "Position Paper" me rekomandime thelbësore. Dokumenti përmbledh disa gjetje dhe konstatime të ekspertëve të kësaj fushe dhe rekomandimet e tyre për të ndikuar pozitivisht në draftimin e metodologjisë së rimbursimit si dhe implikimet buxhetore.

Për ne është e rëndësishme që në vijim të dorëzimit të këtij dokumenti, të organizohet një tryezë e rrumbullakët pune, pjesë e të cilit dëshirojmë të jenë edhe përfaqësues të Bashkimit Europian në Tiranë dhe ekspertë të Bankës Botërore, etj. Prezenca e tyre ndihmon për ta bërë edhe më konstruktiv diskutimin dhe përpjekjen e përbashkët për të reformuar një nga proceset më ndikuese në sektorin e shëndetësisë.

Ndërkohë, në vijim të komunikimeve që kemi mbajtur me drejtuesi të lartë të Ministrisë së Shëndetësisë, ky grupim po përgatit një dokument ku evidenton shqetësimet e biznesit për çdo hap të zbatimit të procedurës për hartimin e listës së rimbursueshme duke ofruar edhe rekomandimet për përmirësimin e tyre.

Duke ju falenderuar për bashkëpunimin dhe angazhimin tuaj,

Me respekt,

Neritan Mullaj,

Drejtor Ekzekutiv





AMERICAN CHAMBER OF COMMERCE  
DHOMA AMERIKANE E TREGTISË

## Position Paper - Advancing Albania's Healthcare System Towards EU Integration

### Background

The American Chamber of Commerce in Albania, representing a broad coalition of pharmaceutical companies, including international manufacturers, as well as local distributors and stakeholders, presents this position paper to outline key recommendations for enhancing the process of including medicines in the reimbursement list and increasing investment in healthcare.

The group's experts are applying leading lobbying practices, using diagnostics and recommendations to drive meaningful improvements in building effective systems that ensure fair and transparent decision-making, contributing to this crucial societal process.

### Executive Summary

As Albania progresses towards its goal of European Union (EU) accession by 2030, it is imperative that the country's healthcare system undergoes significant reforms to align with EU standards. These steps are crucial to ensuring that Albania's healthcare system not only meets the EU's stringent requirements but also provides its citizens with access to innovative, high-quality, and life-saving treatments.

The group's Position Paper addresses two primary issues: Improving of the Model for Inclusion of Medicines in the Reimbursement List and increasing Healthcare Public Investment to support an innovative list of reimbursable medicines. It's time for the best practices from the EU to be incorporated into the working methods of the Ministry of Health. The Position Paper not only provides a comprehensive overview of the situation but also offers detailed recommendations for both issues.

### 1. Improving the Model for Inclusion of Medicines in the Reimbursement List

#### 1.1 Current Challenges

The current process for the inclusion of medicines in Albania's reimbursement list faces several challenges, including:

- **Lack of Transparency:** The process is often perceived as opaque, with unclear criteria and decision-making processes, and both processes and the results are not transparently shared with the applicants.



- **Absence of a Robust Health Technology Assessment (HTA) Framework:** There is a critical need for a systematic approach to evaluating the value of new medicines considering their clinical efficacy, cost-effectiveness, and overall benefit to public health.
- **Inconsistent Alignment with EU Standards:** The current model is not fully aligned with EU directives, which could pose challenges in the integration process as Albania moves towards EU accession.

### 1.2 Recommendations

To address these challenges, we propose the following recommendations:

- **Establish a Transparent and Predictable Reimbursement Process:** Implement clear guidelines and criteria for the inclusion of medicines on the reimbursement list. This process should be transparent, with all stakeholders, including the public, having access to the criteria and decision-making procedures. The following criteria need to be assessed: Medical information, clinical trial data, reimbursement status in EU countries (list of countries), societal value, pharmacoeconomic analysis (from benchmark countries due to lack of data, institution, capabilities) and budget impact. The reimbursement list should be updated annually, and sufficient resources must be allocated to ensure timely evaluation of submitted applications. The results of the reimbursement decisions should be published, accompanied by a transparent rationale. Additionally, information on the funds allocated per disease area should be publicly available.
- **Move to payment models that reward outcomes over volumes:** Traditional payment models used in healthcare can sometimes incentivize overconsumption of care or inappropriate interventions, while in other cases they may lead to service rationing, inefficient waiting times and patient risk selection. Shifting to outcome-based payment models would address a key challenge faced by healthcare systems today: the lack of incentives for what truly matters—improving patient health. Rather than paying for hospital beds, doctor visits, tests, or medications, healthcare systems should reward improved health outcomes and longer lives for patients. Linking incentives and payments to outcomes is not suitable for certain medicines and therapy areas, but for healthcare services as a whole. While this approach may require additional monitoring and collection of data, it will lead to a better understanding of how to allocate limited resources more effectively and provide incentives for care coordination and service integration.
- **Develop a Comprehensive Health Technology Assessment (HTA) Framework:** Introduce a formal HTA process that evaluates medicines based on their therapeutic value, cost-effectiveness, and overall impact on the healthcare system. The HTA process should align with best practices from EU member states, ensuring that decisions are evidence-based and in line with EU standards. Additionally, closely follow establishment of the EU-wide



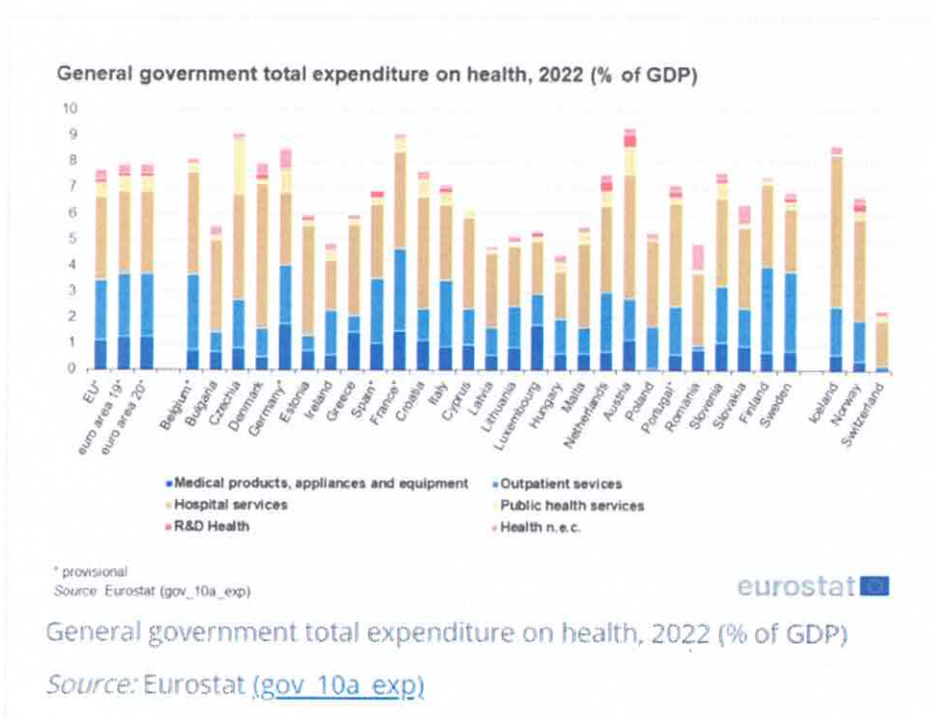
HTA framework, which begins in 2025 for cancer drugs and will expand to other treatments by 2030, to harmonize HTA criteria across EU member states.

- **Align with EU Standards and Practices:** As Albania prepares for EU accession, it is critical to align the reimbursement process with EU standards. This includes adopting EU guidelines for the inclusion of innovative medicines and ensuring that the reimbursement process is consistent with EU regulatory frameworks.

## 2. Increasing Healthcare Public Investment from 3.04% to 6% of GDP

### 2.1 The Case for Increased Investment

Public spending on healthcare remains low: only 3.04%<sup>1</sup> of GDP. This is significantly lower than the EU average which amounted to 7.7% of GDP in 2022. Such underinvestment has several implications.



<sup>1</sup> [https://neighbourhood-enlargement.ec.europa.eu/document/download/ea0a4b05-683f-4b9c-b7ff-4615a5ff3d0b\\_en?filename=SWD\\_2023\\_690%20Albania%20report.pdf](https://neighbourhood-enlargement.ec.europa.eu/document/download/ea0a4b05-683f-4b9c-b7ff-4615a5ff3d0b_en?filename=SWD_2023_690%20Albania%20report.pdf), Albania 2023 Report by EU, page 92



- **Limited Access to Innovative Medicines:** The low level of healthcare funding restricts the availability of new, innovative, and life-saving treatments for patients in Albania. Therefore, as per IQVIA report, there are only 555 molecules in the Albanian reimbursement list, compared to 962 molecules available in the Adriatic region.
- **Increased burden on the households:** According to WHO data, Albanians' out-of-pocket health expenses have significantly increased after the pandemic. In 2015, this indicator was 57.3%, and it has since increased by 2.5 percentage points.
- **Strain on Healthcare Infrastructure:** Insufficient funding hampers the ability to maintain and upgrade healthcare infrastructure, affecting the quality of care provided to patients.
- **Challenges in Meeting EU Healthcare Standards:** As Albania prepares for EU accession, it is essential that the country increases its healthcare investment to align with EU standards, which typically require higher levels of healthcare spending.

## 2.2 Recommendations

To address these challenges and ensure that Albania's healthcare system is prepared for EU integration, we recommend the following:

- **Increase Healthcare Investment to 6% of GDP:** Doubling the current healthcare investment from 3% to 6% of GDP is necessary to support the inclusion of innovative, high-quality, and life-saving products in the reimbursement list. This increase will also help build a more robust healthcare infrastructure, ensuring that Albania can provide its citizens with the level of care expected in EU countries.
- **Prioritize Funding for Innovation and Quality:** Allocate the increased investment towards the inclusion of innovative medicines, technologies, and treatments that improve patient outcomes and enhance the overall quality of care. By focusing on innovation, Albania can improve its healthcare system's effectiveness and efficiency, making it more competitive in the European market.
- **Strengthen Partnerships with innovative pharma industry:** Encourage collaboration between the government and manufacturers of innovative medicines to leverage expertise, resources, and innovation. Such partnerships can play a vital role in enhancing healthcare delivery and ensuring that new treatments are accessible to the population.
- **Creation of separate budgets:** The establishment of separate budgets dedicated to specific healthcare areas such as oncology and rare diseases is a strategic approach that has proven effective across numerous European Union (EU) countries. Adopting the same model in Albania would offer several significant benefits, enhancing the overall efficiency and equity of the healthcare system as the country progresses toward EU integration.

- **Digitalization of the infrastructure in the hospitals:** Collection of data and measuring of the outcomes is critical in order to finance the medicines which are not only beneficial for the patients but also contributing to the economy of the country.

## Conclusion

The path to EU accession presents a unique opportunity for Albania to reform and strengthen its healthcare system. By improving the model for the inclusion of medicines in the reimbursement list and increasing investment in healthcare, Albania can ensure that its healthcare system is prepared to meet the challenges and opportunities of EU integration. The American Chamber of Commerce in Albania stands ready to support the Ministry of Health in these efforts, working together to build a healthcare system that meets the needs of all Albanians and aligns with EU standards.

## Next Steps:

- **Organize a Best Practices Meeting:** We propose organizing a meeting to share best practices aimed at enhancing the efficiency of healthcare systems for patients, payers, hospitals, and providers. This meeting will also help shape better-informed public health policies and contribute to reducing health inequalities. The expected outcome of the meeting is to share best practices from other countries that represent patients' perspectives and unmet needs; find alternative ways to increase access to the medicines.
- **Fund Capability Building:** The industry is committed to funding initiatives that build expertise on key topics critical to establishing a more efficient healthcare system.
- **Consultancy on Reimbursement Model Harmonization:** We are prepared to partially fund third-party experts who will provide consultancy on harmonizing the reimbursement model with EU standards. These experts will share best practices from European countries and assist in selecting the most appropriate criteria for Albania's specific needs.
- **Facilitate International Engagement:** We will facilitate engagement with the World Bank, WHO, and the EU to meet EU requirements and advance Albania's public healthcare plans.
- **Provide Customizable Reimbursement Criteria:** We are ready to provide an example of reimbursement criteria, which can be tailored in collaboration with the Ministry of Health and the Health Insurance Fund (HIF). Additionally, we propose agreeing on a short-term framework for immediate implementation.