



Health Care Committee Position Document

The American Chamber of Commerce in Montenegro is focused on improving the business climate in order to attract U.S. and other foreign investments to Montenegro. The Health Care Committee deals with issues relevant for Health Care and contributes to the improvement of the system. AmCham's Health Care Committee strives to be a partner to the Montenegrin authorities in providing sustainable, patient oriented health care solutions.

This position document is produced by the members of the Health Care Committee and represents the their experience with regards to doing business in Montenegro.

LIST OF DRUGS PRESCRIBED AND ISSUED BY THE HEALTH INSURANCE FUND – REIMBURSEMENT LIST

The AmCham Montenegro Health Care Committee believes the process for placing patient medication on the List of Drugs Prescribed and Issued by the Health Insurance Fund (Reimbursement List) is a key priority to improving the Health Care system in Montenegro.

Currently, the lack of a transparent process in Montenegro affects patients in such manner that new, more modern therapeutic drugs are not covered by the state Health Care Fund and made available at no cost to a wider population or even specific group of patients. The pharmaceutical companies are hesitant to develop their businesses in Montenegro having in mind that the process of planning is uncertain, with rules not being clearly defined and the RL lacking transparency. The result is a relatively low amount of investment in the pharmaceutical industry and a small number of employees working for pharmaceutical companies in Montenegro.

Greater transparency with the inclusion and exclusion of drugs on the Reimbursement List would help maximize potential savings for both individual patients and the healthcare sector by increasing affordability, patient access, and health budget control. In this manner, patients would spend less money for buying drugs in private pharmacies as these drugs would be reimbursed by the Health Insurance Fund. On the other hand, the Health Insurance Fund would certainly have savings in the Health Care Budget, as the pharmaco-economic criteria for new drug entry to the Reimbursement List would be defined. Likewise, the cost–benefit or cost-effectiveness parameters would be applied to

current and future drugs on the Reimbursement List. As the end result, this would render the market more predictable and more attractive for further investments of pharmaceutical companies.

An exemplary practice can be found under the framework of the European Union (EU). The Member States of the EU have defined a common procedural framework under the Transparency Directive (Council Directive 89/105/EEC). The aim of this framework is to ensure that national pricing and reimbursement decisions are made in a transparent manner and do not distort the functioning of the Internal Market and to ensure that national systems achieve an adequate balance between cost-containment, pharmaceutical innovation and patients' access to medicines.

Definition of the Reimbursement List:

The Reimbursement List (the Positive List of Drugs) is defined in Montenegro as the list of drugs which is paid by the Health Insurance Fund. This means that the patient who possesses health insurance is not required to pay for medicine that are on the official Reimbursement List.

The Government of Montenegro determines which drugs are placed and removed from the official Reimbursement List, based on the proposal of the Ministry of Health. The Government is also entitled to determine the criteria for placing medication on the State Reimbursement List, in accordance with the Article 9 of the Law on Amendments to the Law on Health Insurance (Official Gazette of Montenegro No. 14/2012). The latest Reimbursement List was adopted in Montenegro on December 23, 2011.

The AmCham Health Care Committee recommends the following as it pertains to placing medication on the State Reimbursement List:

- I. A single Rulebook should be created in order to specifically stipulate the criteria and timeline for placing and removing medication from the State Reimbursement List.**

The National Plan for Rational Use of Drugs in Montenegro for 2012-2016, published in 2012 stipulates the following: "In order to strengthen the trust in the state system, the Fund must introduce a Rulebook on criteria for placing drugs on the List of drugs. This Rulebook should be a public document."

The AmCham Montenegro Health Care Committee recommends that a rulebook be introduced as soon as possible so that it can clearly define criteria for placing medication on the Reimbursement List. Furthermore, the Rulebook should be made public for patients and health care professionals to review. The Rulebook should reflect the realities of the Montenegrin market and should be drafted in accordance with the Law on Prescription Medication, i.e. according to the status of registered drugs and drugs that are being administered and are awaiting formal approval for registration¹. Furthermore, the

¹ Prior to March 31, 2010 certain drugs were able to be granted semi-approved status and were able to be administered upon preliminary approval. These drugs, however, did not receive full registration status and some drugs are still waiting for official registration.

manner of forming prices for medication on the Reimbursement List should be defined in order to make that process predictable and transparent.

II. The method by which a decision is reached to include prescription medication on the State Reimbursement List should be made more transparent.

The current overall process, from applying to reaching a decision, for including medication on the State Reimbursement List is obscure and the procedure is unknown to most relevant stakeholders. The lack of transparency with respect to the Reimbursement List inclusion has been previously acknowledged by the Ministry of Health of Montenegro, which confirmed that “the procedure of producers delivering their offer for placing their drugs on the positive list is not transparent at this moment”, as stated in the National Plan for Rationale for Use of Drugs in Montenegro 2012-2016.

AmCham’s Health Care Committee considers that the following criteria should be defined in the proposed Rulebook in order to help make the inclusion process less ambiguous and consistent:

- Clearly stated required documentation for applying in order to include and exclude medication from the Reimbursement List.
- Implement the ability to track the status of an application at any point in time.
- Define a timeline or deadline at which point a decision must be made about placing a drug on the List or removing a drug from the Reimbursement List. If the medication is not placed on the List, the decision rationale must be provided for the applicant.
- Introduce an appeals procedure that would allow producers to use when medication has not been approved for inclusion on the Reimbursement List. The procedure should be defined in accordance with the Law on Administrative Procedure.

The Directive of the European Council (89/105/EEC) from December 21, 1988 specifies the transparency of measures regulating the price of medicinal products for human use and their inclusion within the scope of national health insurance systems. The European Commission also proposed, in March 2012, the adoption of a new Directive, which would stipulate shorter deadlines and enhance the transparency of decisions made on pricing and reimbursement of medicines for all EU member states.

Accordingly, the AmCham Montenegro Health Care Committee proposes the introduction of the above-mentioned Directive into the Montenegrin legal system. Thus, the Rulebook on the criteria for placing drugs on the Reimbursement List should be introduced as soon as possible. The entire process should be clearly defined and transparent in order to ensure that the most modern treatment for illnesses are made available for patients and health care professionals. A Rulebook will also establish a more predictable and dependable business environment.