

AMENDMENTS TO THE LAW ON MEDICINES OF MONTENEGRO*

1. **Article 60** of the Law on Medicines shall be amended to read as follows:

Article 60

Trade in medicines shall take a form of wholesale and retail.

Wholesale of medicines shall comprise purchase, warehousing and distribution of medicines.

The following entities shall be entitled to the wholesale of medicines:

- 1) Legal persons having their central headquarters in Montenegro, who have wholesale license issued by the Agency (hereinafter referred to as: wholesalers)
- 2) Manufacturers of medicines having their central headquarters in Montenegro, for the medicines they manufacture.

Trade in medicines referred to in paragraph 1 of this Article shall be allowed only with respect to medicines that have a license to be placed on the market, and to those referred to in Article 20 of this Law.

2. **Article 61** shall be amended to read as follows:

Article 61

Import and export of medicines shall be performed by wholesalers referred to in Article 60, paragraph 3, item 1 of this Law, and by any other domestic or foreign person (hereinafter referred to as: importers), registered at the Agency.

Importers of medicines shall be entitled to deliver medicines to wholesalers, however they shall not have the right to distribute and retail such medicines.

Detailed requirements for the registration of importers referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

* The purpose of amendments to the Law Medicines (Official Gazette of the Republic of Montenegro, No. 80/04), was, *inter alia*, to include provisions that would enable person not established in Montenegro to import medicines in or export them from Montenegro. This translation comprises only the relevant provisions that provide for the rights of persons not established in Montenegro (foreign persons) to import or export medicines. The rights of such persons do not include right to distribute or retail. By making a clear distinction between importation and distribution, Montenegro believes that these provisions resolve the issue of “trading rights” raised by a Member.

3. After Article 61, new **Article 61a** is being inserted, which reads as follows:

Article 61a

Wholesalers shall purchase medicines directly from manufacturers, importers and other wholesalers.

Manufacturers of medicines referred to Article 60, paragraph 3, item 2 of this Law shall be entitled to export medicines they manufacture.