DECISION

No. 26/03.09.2010

on approval of the set up in Romania of a Medicinal Product National Traceability System

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), set up based on Order of the Minister of Public Health no. 1123/18.08.2010, as amended, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.09.2010, in accordance with Article 12(5) of Government Ordinance no. 734/2010 related to the set up, organisation and operation of the National Medicines Agency, agrees on the following

DECISION

Art. 1. – In order to ensure the traceability of medicinal products throughout the entire manufacturing and distribution chain up to patient level, as well as verification of the accuracy of the prescription and release of prescription or non-prescription medicinal products, identification of counterfeited medicinal products and prevention of their entry into the distribution chain (wholesale distributors, pharmacies), combating parallel medicinal product sale circuits and warranty of rapid recall of noncompliant medicinal product batches or in health emergencies, the NAMMD shall set up an integrated information system, namely the National Medicinal Products Traceability System (NMPTS).

Art. 2. – Within 6 months as of the approval of this decision, the NAMMD shall set up and handle the NMPTS by assigning information labels for all medicinal products authorised for marketing in Romania in accordance with provisions of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended.

Art. 3. – Information labels shall be released for Romanian medicinal product manufacturers/importers, as well as for wholesale distributors authorised in Romania who intend to place medicinal products for human use on the market.

Art. 4. – The implementation of this system shall be performed by all the parties involved within 12 months as of NAMMD posting of the system operating manner.

Art. 5. - This decision does not involve the MAH's obligation to apply for variations from the NAMMD related to the change of the design and imprinting of the secondary package, in line with this decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim