# DECISION

## No. 9/10.07.2012

## on approval of the mandatory monthly reporting of placement on the market in Romania, respectively of sales of medicinal products for human use by authorised wholesale distributors/importers/manufacturers

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Minister of Health Order no. 1123/18.08.2010, in accordance with Art. 8 (1) of the Regulation on organisation and operation of the NAMMD Scientific Council, hereby adopts the following through written procedure

## DECISION

**Art. 1.** - (1) Mandatory monthly reporting by wholesale distribution units of trade operations, including *parallel import* and *parallel trade*, respectively, concerning medicinal products for human in their own portfolio is hereby approved; the report is submitted to the NAMMD, at the end of each month.

(2) In accordance with provisions of the *Guideline on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted*, approved through Scientific Council Decision (SCD) no. 1/09.03.2007:

- ”*Parallel import* of a medicinal product represents a legal form of trade within the Internal Market, based on Art. 28 of the EC Treaty and under the waivers mentioned in Article 30 of the EC Treaty.”

- **“***Parallel trade* is a legal form of trade in goods between Member States of the European Union.”

(3) The final purpose of reporting is to ensure traceability of medicinal products throughout the distribution chain, from manufacturing and/or distribution to the level of community pharmacy, hospital pharmacy, drugstore, to assess the propriety of on-prescription/off-prescription medicinal product release, to detect falsified products and prevent their entry into the authorised distribution network, to combat illegal parallel circuits for medicinal product sale and respectively warrant rapid recall of non-compliant product batches or in case of health emergencies.

**Art. 2**. – As required, the report submitted to the National Agency for Medicines and Medical Devices – the Pharmaceutical Inspection Department contains:

(a) The List of medicinal products for human use entered in /exited from stocks of wholesale importers/distributors authorised in accordance with Order of

the Minister of Health no. 312/2009, as amended, and with Order of the Minister of Public Health no. 1964/2008, respectively, on various types of wholesale import/distribution activities stating the amounts, manufacturing batches, supplier(s), beneficiary(ies) of medicinal products, as well as identification data for the respective fiscal documents (number, batch, date of invoice and/or delivery notification).

b) The List of medicinal products for human use exited from the inventory of Romanian manufacturers authorised in accordance with Order of the Minister of Health No. 312/2009, as amended, stating the amounts, manufacturing batches, recipient(s) of the respective products, as well as identification data of respective fiscal documents (number, batch, date of invoice and/or delivery notification).

**Art. 3.** – (1) The report is forwarded in electronic format, accompanied by the statutory declaration of the reporting company's legal representative on conformity of submitted data.

(2) The first reporting necessarily contains the Romanian distributor/importer/manufacturer's product stock at the time of report drafting.

(3) The tabulated form and the Guideline for its filling in (also specifying the e-mail address for submission of the report) are posted on the NAMMD website (www.anm.ro/anmdm/med.html, under "*Important notifications*").

**Art. 4.** – Non-compliance with provisions of this Decision is a breach of Order of the Minister of Health no. 1963/02.12.2008 on approval of the Guideline on Good Distribution Practice of Wholesale Medicinal Products and is sanctioned in accordance with provisions of Law 95/2006 on healthcare reform, as amended.

**Art. 5.** – This Decision is approved through Order of the Minister of Health.

**Art. 6.** – SCD no. 5/22.02.2011 on mandatory monthly reporting of placement on the market in Romania, and of sales of medicinal products for human use, respectively, by authorised wholesale distributors and SCD no. 17/6.07.2011 on extension of the deadline provided in Article 4 of NAMMD Scientific Council Decision No.5/22.02.2011 on mandatory monthly reporting of placement on the market in Romania, and of sales of medicinal products for human use, respectively, by authorised wholesale distributors is repealed on the coming into force of the Order of the Minister of Health approving this Decision.

**PRESIDENT**
**of the Scientific Council**
**of the National Agency for Medicines and Medical Devices,**

**Acad. Prof. Dr. Leonida Gherasim**