**DECISION**

**No. 3/23.03.2010**

**on approval of implementation rules for enforcement of SCD No. 17/27.11.2009 on supply of free medicine samples for human use authorised for marketing in Romania**

The Scientific Council of the National Medicines Agency, set up based on Minister of Public Health Order No. 1027/22.05.2008, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 23.03.2010, in accord with Article 10 of Government Ordinance no. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002, as further amended, agrees on the following

**DECISION**

**Single article.** – The Implementation rules on supply of free medicine samples for human use authorised for marketing in Romania are approved, according to the Annex, which is integral part of this Decision.

**PRESIDENT**
**of the Scientific Council**
**of the National Medicines Agency**

**Acad. Prof. Dr. Victor Voicu**

*ANNEX*

# Implementation rules for enforcement of SCD No. 17/27.11.2009 on supply of free medicine samples for human use authorised for marketing in Romania

Art. 1. – These Rules establish the manner of handling free medicine samples for human use provided by Marketing Authorisation Holders (MAHs) to those persons only who are qualified for such products prescription or release.

Art. 2. – These Rules apply to all Marketing Authorisation Holders and/or their representatives (representatives, specialist service providers, wholesale distributors who are also MAHs).

Art. 3. – In order to provide free medicine samples, MAHs or their representatives in Romania shall meet the following requirements:

a) Assign a person responsible for the handling of this activity (Product Manager, Marketing Manager, Logistics Manager – in accordance with each company's organisational chart)

b) Set up a procedure concerning management of free medicine samples supply

c) To draw a contract for custodial and pharmaceutical logistic service with a wholesale distributor authorised by the National Medicines Agency (NMA)

d) To hold records concerning the quantity of samples received from the MAH/manufacturer and quality documents accompanying these products

e) To hold records concerning requests for samples from persons qualified prescribers/dispensers

f) To hold centralised records of free medicine samples provided in compliance with the requests confirmed by the assigned person.

Art. 4. – All documents have to be filled in, dated and signed by the persons involved in the development of the procedure which are to be approved by the assigned person.

Art. 5. – Wholesale distributors storing free medicine samples have the same responsibilities as in the case of storing medicinal products from their own portfolio for distribution purposes (maintaining records about the monitoring of storage conditions during storage and records of the quantitative management of samples).

Art. 6. – Records pertaining of the sample handling procedure must include sufficient information to allow traceability of each batch sample provided.

Art. 7. – Free medicine samples provided to the assigned persons shall be fully compliant with provisions of Art. 807, Chapter IX of Law 95/2006, Title XVII – The medicinal product, as amended.

Art. 8. – Whenever the samples are not imprinted by the manufacturer, in accordance with Art. 807 d) and e), as „free medicine sample – not for sale" or do not carry a mention to the same effect, the labelling/re-labelling operation is to be performed on a manufacturing flow authorised in accordance with provisions of Art. 748 of Law 95/2006.

Art. 9. – Mandatory reporting of the status of handling of free medicine samples (every 6 months) goes to the person assigned under Art. 3 a) of these rules.