**DECISION**

**No. 17/27.11.2009**

**on the approval of the Rules concerning the supply of free samples of medicinal products 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 27.11.2009, 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 Rules concerning the supply of free samples of medicinal products for human use authorised for marketing in Romania, in accordance with 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*

**Rules concerning the supply of free samples of medicinal products for human use authorised for marketing in Romania**

Art. 1. – In order to supply free samples of medicinal products for human use authorised for marketing in Romania, in accordance with the provisions of Art. 807 of Law No. 95/2006 on healthcare reform, as amended, it is necessary that Marketing Authorisation Holders (MAHs) submit to the National Medicines Agency (ANM) – Pharmaceutical Inspection Department (PID) the following:

- list of wholesale distributors which store free medicinal samples, accompanied by the service delivery contracts signed with respective societies;
- the updated list of the medicinal products provided as free medicinal samples;
- procedure concerning the manner in which the MAH handles the supply of free medicinal samples.

Art. 2. – Every 6 months, MAHs have the duty to submit reports to the NMA - PID concerning the distribution of free samples of medicinal products, in accordance with the form below:

„Situation concerning the handling of free medicinal product samples by the MAH/Romanian representative of the MAH ……., during

| No. crt. | Trade name | INN | Packaging size of the samples | Manufacturing batch and expiry date of the samples | Number of samples received by the MAH | Wholesale distributor who has received samples | Number of samples provided by the distributor | Number of requests for samples received by the MAH | Applicant physician samples |
|---|---|---|---|---|---|---|---|---|---|
| 1. | …….. | | | | | | | | |
| | | | | | | | | | |

Date,

Clear name and signature of the responsible person of the MAH/the Romanian representative of the MAH”

Art. 3. – Within 60 days as of adopting this Decision, all MAHs for medicinal products for human use authorised in Romania should be in line with the above provisions of Art. 1 and 2.