DECISION

No. 7/23.03.2010

on approval of switch of classification for supply of certain medicinal products

The Scientific Council of the National Medicines Agency, set up based on Minister of Public Health Order no. 1027/09.05.2005, 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 - Switch of classification for supply of certain medicinal products is approved, according to the Annex, which is an integral part of this decision.

PRESIDENT of the Scientific Council of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

Medicinal products for which the Scientific Council of the National Medicines Agency has approved switch of their classification for supply

- 1. PACID 20 mg gastroresistant tablets, (INN Pantoprazole), box with one blister containing 7 gastroresistant tablets and box containing 2 blisters of 7 gastroresistant tablets each, Marketing Authorisation Holder Ranbaxy, Romania, is approved for switch from the onprescription medicinal product (P-6L) to over-the-counter status (OTC).
- 2. QUARELIN tablets (INN combinations: Metamizole sodium 400 mg, caffeine 60 mg and drotaverine chloride 40 mg), box with one blister containing 10 tablets, Marketing Authorisation Holder Chinoin Pharmaceuticals & Chemical Works Co. Ltd, Hungary, is approved for switch from over-the-counter status (OTC) to on–prescription status (P-RF).
- **3. ALGOCALMIN 500 mg tablets** (INN Metamizolum natricum), box containing 2 blisters of 10 tablets each, Marketing Authorisation Holder Zentiva S.A., Romania, is approved for switch from over-the-counter status (OTC) to on–prescription status prescription (P-RF).