DECISION

No. 17/15.06.2007

on approval of change of classification for release of certain medicinal products

The Scientific Council of the National Medicines Agency,
set up based on Minister of Public Health Order no. 485/09.05.2005, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 15.06.2007, 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 change 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

ANNEX

List of medicinal products for which the National medicines Agency's Scientific Council has approved the change of classification concerning their release

1. **IBALGIN FORTE 400 mg film-coated tablets** (ibuprofen), box containing one blister of PVC/Al of 12 film-coated tablets, the marketing authorisation holder Zentiva S.A., Czech Republic, is approved for transfer from the status of medicinal product released via medical prescription (P-6L) to the OTC status.

2. **EXODERIL** 1 g/100 g cream (naphthyfin hydrochloride), box with aluminum tube and filleted polyethylene cap, 15 g cream, the marketing autorisation holder Sandoz GmbH, Austria, is approved for transfer from the status of medicinal product released via medical prescription (P-RF) to the OTC status.

3. **EXODERIL** 1 g/100 ml cutaneous solution (naphthyfin hydrochloride), box containing one brown glass vial, with a filleted polyethylene capcontaining , containing 10 ml solution, the marketing authorisation holder Sandoz GmbH, Austria, is approved for transfer from the status of medicinal product released via medical prescription (P-RF) to the OTC status.