DECISION

No. 15/26.06.2009

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. 1027/09.05.2005, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 26.06.2007, 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

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

TYROSUR 1 mg/g gel (Tyrothricin), box with a tube containing 5 g gel or box with a tube containing 25 g gel, Marketing Authorisation Holder Engelhard Arzneimittel GmbH & Co. KG, Germany, is approved for transfer from the status of medicinal product released via medical prescription (P-RF) to over-the-counter status (OTC).

NUROFEN for children Orange 100 mg/5 ml (Ibuprofen), box with a vial containing 100 ml oral suspension and syringe for oral administration, Marketing Authorisation Holder Reckitt Benckiser, Great Britain, is approved for transfer from the status of medicinal product released via medical prescription (P-RF) to over-the-counter status (OTC).

NUROFEN for children Strawberry 100 mg/5 ml (Ibuprofen), box with a vial with a secured closure system for children, containing 100 ml oral suspension and syringe for oral administration, Marketing Authorisation Holder Reckitt Benckiser, Great Britain, is approved for transfer from the status of medicinal product released via medical prescription (P-RF) to overthe-counter status (OTC).