DECISION

No. 5/27.03.2009

on approval of change of classification for supply of certain medicinal products for human use

The Scientific Council of the National Medicines Agency, set up based on Order of the Minister of Public Health No. 1027/22.05.2008, reunited on summons of the National Medicines Agency President in the ordinary meeting of 27.03.2009, in line with Article 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 amended, hereby adopts the following

DECISION

Single article. – The change of classification for supply of certain medicinal products for human use is 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

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

1. **HYDRASEC 100 mg capsules** (racecadotril), box containing 10 capsules, Marketing Authorisation Holder Laboratoires Fournier SA, France, hereby changes status from on prescription medicinal product (P-RF) to OTC status.

2. **BANEOCIN cutaneous powder** (Bacitracin Zinc and Neomycin as Neomycin Sulphate), box containing one polyethylene powder vial of 10 g cutaneous powder, Marketing Authorisation Holder Sandoz GmbH, Austria, hereby changes status from on prescription medicinal product (P-RF) to OTC status.

3. **BANEOCIN ointment** (Bacitracin Zinc and Neomycin as Neomycin Sulphate), box containing one aluminium tube of 20 g ointment, Marketing Authorisation Holder Sandoz GmbH, Austria, hereby changes status from on prescription medicinal product (P-RF) to OTC status.