DECISION

No. 16/23.05.2008

on approval of changing the classification for the 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 Health No. 1027/22.05.2008, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 23.05.2008 in accordance 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, with further changes and completions, agrees on the following

DECISION

Single article. - The change of the classification for the supply of certain medicinal products 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

List of medicinal products
for which the Scientific Council of the National Medicines Agency
has accepted the change of classification for supply

1) **CAL-D-VITA 600 mg/400 I.U. effervescent tablets** (calcium/vitamin D3), box containing an aluminium/polypropylene tube of 10 effervescent tablets each, Marketing Authorisation Holder: Bayer S.R.L., ROMANIA, changes the status of medicinal product released by medical prescription (P-6L) with the OTC status.

2) **CAL-D-VITA 600 mg/400 I.U. chewable tablets** (calcium/vitamin D3), box containing 6 PVDC/PE/PVC blisters of 10 chewable tablets each or box containing a PEID vial of 60 chewable tablets, Marketing Authorisation Holder: Bayer S.R.L., ROMANIA, changes the status of medicinal product released by medical prescription (P-6L) with the OTC status.

3) **MYCOSPOR 10 mg/g cream** (bifonazole), box containing an aluminium tube of 15 g cream, Marketing Authorisation Holder: Bayer Healthcare AG, GERMANY, changes the status of medicinal product released by medical prescription (P-6L) with the OTC status.

4) **MYCOSPOR 10 mg/g cutaneous solution** (bifonazole), box containing a vial of 15 ml cutaneous solution, having a dripping device, Marketing Authorisation Holder: Bayer Healthcare AG, GERMANY, changes the status of medicinal product released by medical prescription (P-RF) with the OTC status.

5) **MYCOSPOR ONICHOSET 10 mg/40 mg/g ointment** (bifonazole/urea), box containing an aluminium tube of 10 g ointment, a device for the extraction of the ointment, 15 waterproof patches and a nail polisher, Marketing Authorisation Holder: Bayer Healthcare AG, GERMANY, changes the status of medicinal product released by medical prescription (P-6L) with the OTC status.