DECISION
No. 12/24.10.2017
on approval of the change of status as regards classification for supply of Vigantoletten 500 IU, tablets and Vigantoletten 1000 IU (colecalciferolum)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, convened on summons by the NAMMD President in the ordinary session of 24.10.2017, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government no. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Sole Article - The change of status as regards classification for supply of Vigantoletten 500 IU, tablets and Vigantoletten 1000 IU is approved (Marketing Authorisation Holder: MERCK KGAA – GERMANY) is approved, under the following conditions:

1. packaging size: Box with 1 Al/PVC blister x 15 tablets
2. restriction of indications to:
- prophylaxis of rickets in children
- prophylaxis of vitamin D deficit in children and adults in case of unidentified risks
3. change of trade name.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Prof. Dr. Anca-Dana Buzoianu