DECISION
No. 7 /24.10.2017
on approval of the change of classification for release of Eptavit 2500 mg/880 IU,
effervescent tablets (combinations)

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 classification for release of Eptavit 2500 mg/880 IU, effervescent tablets (combinations) - Marketing Authorisation Holder: BIOCODEX - FRANCE, from release based on medical prescription to release without medical prescription, is approved, under the following conditions:

1. Packaging size: Box x 1 tub of PP x 15 effervescent tablets
2. Restriction of indications to:
- vitamin-calcium intake in patients at high risk of vitamin-calcium deficit
3. Change of trade name.

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

Prof. Dr. Anca-Dana Buzoianu