DECISION
No. 9 /24.10.2017
on approval of change of classification for release of Lagosa 150 mg, drops (silibinum)

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 Lagosa 150 mg, drops (silibinum), Marketing Authorisation Holder: WORWAG PHARMA GMBH & CO. KG – GERMANY, from release based on medical prescription to release without medical prescription, is approved, under the following conditions:

1. packaging size: Box with one Al/PVC blister x 25 drops
2. restriction of indications to: cases of exposure to potentially hepatotoxic substances
3. change of trade name.

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

Prof. Dr. Anca-Dana Buzoianu