DECISION

No. 1/24.10.2017

on approval of amendment of SCD no. 4 of 27.03.2009 on approval of the Guideline on change of classification for supply of a medicinal product for human use

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, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Article I: The title of the NAMMD Scientific Council Decision (SCD) no. 4 of 27.03.2009 is amended and reads as follows:

- SCD no. 4 of 27.03.2009 on adoption of the Guideline on approval and change of status on classification for supply of a medicinal product for human use

Article II: The Annex to NAMMD SCD no. 4 of 27.03.20**09** is amended as follows:

1. Article 36 is amended and reads as follows:

"Article 36 – (1) The package size, approved through Marketing Authorisation for each medicinal product, should be decided in relation to the intended length of the treatment approved in the SmPC and leaflet, correlated with the maximum daily dose and/or maximum quantity of active substance on the package, as recommended by the "*Council of Europe Committee of*

ministers Resolution ResAP (2007)1 on the Classification of Medicines as Regards their Supply".

2. Article 60 is amended and reads as follows:

„Article 60.
(2) The trade name cannot be the same for medicinal products with different status as regards classification for supply of medicinal products for human use."

Article III: Following entry into force of this Decision, the NAMMD shall reassess all package sizes approved through the Marketing Authorisations of medicinal products with an „over-the-counter" release status, and modify, as required, packaging sizes in accordance with the provisions of this Decision.

Article IV: Following entry into force of this Decision, packaging sizes approved through Marketing Authorisations shall correspond to the status of the respective medicinal product, as regards the classification for release.

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

Prof. Dr. Anca-Dana Buzoianu