Decision no. 3/26.06.2017
on amendment of SCD no. 19/12.08.2013 on approval of the Guideline on details concerning the various categories of variations to the terms of marketing authorisations and on their examination by the National Agency for Medicines and Medical Devices by the purely national procedure for authorisation of medicinal products for human use, in accordance with Regulation (EC) no. 1234/2008 of the Commission, as amended through Regulation (EU) no. 712/2012

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, setup on summons of the NAMMD President in the ordinary meeting of 26.06.2017, in accordance with Article 12 (5) of Government Decision no. 734 / 21.07.2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Art. 1. - Annex 2 to NAMMD Scientific Council Decision (SCD) no. 19/12.08.2013 on approval of the Guideline on details concerning the various categories of variations to the terms of marketing authorisations and on their examination by the National Agency for Medicines and Medical Devices by the purely national procedure for authorisation of medicinal products for human use is repealed, in accordance with Regulation (EC) no. 1234/2008 of the Commission, as amended through Regulation (EU) no. 712/2012.

Art. 2. – Under Article 14 of Annex to NAMMD SCD no. 19/12.08.2013, paragraph:

The EU application form for variations to a marketing authorisation for medicinal products (human and veterinary) translated into Romanian (Annex 2) is available on the NAMMD website under heading "Forms and fees".

is replaced with

The EU application form for variations to a marketing authorisation for medicinal products (human and veterinary) is available in the EudraLex Volume 2 B – Presentation and content of the dossier eSubmission: EU Electronic Application Forms (Module 1.2 application, variation and renewal form: https://ec.europa.eu/health/documents/eudralex/vol-2_en .„

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Prof. Dr. Anca-Dana Buzoianu