DECISION

no. 2/26.06.2017
on adoption of the Guideline on Good Manufacturing Practice for Medicinal Products 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, convened on summons by the NAMMD President in the ordinary session of 26.06.2017, 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

Article 1. - The Guideline on Good Manufacturing Practice for Medicinal Products for human use is adopted, in accordance with the Annex which is integral part of this Decision.

Article 2. – On this Decision coming into force, Scientific Council Decision no. 23/03.07.2015 on adoption of the Guideline on Good Manufacturing Practice for Medicinal Products for human use is repealed.

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

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the document "The rules governing medicinal products in the European Union", Volume 4, Good manufacturing practice (GMP) Guidelines, published by the European Commission.
Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.
Therefore, for the Annex to this Decision, please see the "The rules governing medicinal products in the European Union", Volume 4, Good manufacturing practice (GMP) Guidelines, available at
https://ec.europa.eu/health/documents/eudralex/vol-4_en