DECISION

No. 24/03.09.2010

regarding approval of the manner of resolution of applications for marketing authorisation/marketing authorisation renewal for medicinal products for human use submitted to the National Medicines Agency (NMA) prior to 2007

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), set up based on Order of the Minister of Public Health no. 1123/18.08.2010, as amended, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.09.2010, in accordance with Article 12(5) of Government Ordinance no. 734/2010 related to the set up, organisation and operation of the National Medicines Agency, agrees on the following

DECISION

Sole article - The approval of the manner of resolution of applications for marketing authorisation/marketing authorisation renewal for medicinal products for human use submitted to the National Medicines Agency (NMA) prior to 2007 is approved, in accordance with the Annex which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX

Approval of the manner of resolution of applications for marketing authorisation/marketing authorisation renewal for medicinal products for human use submitted to the National Medicines Agency (NMA) prior to 2007

Taking into account that several applications for marketing authorisation/marketing authorisation renewal for medicinal products for human use submitted to the NMA prior to 2007 fail to meet requirements mentioned by the regulations into force in their entirety, notwithstanding repeated requests by the Agency to the marketing authorisation holders (MAHs) to supplement their application support documentation and taking into account that these applications have been assessed at least 2 – 3 times up to this date, as well as because of the lack of adequate human resources/qualified staff the Agency has recently had to confront, the following manner will be put in place for resolution of such applications:

- As applicants respond to Agency requests for supplementation and update of the documentation in support of the application for marketing authorisation/marketing authorisation renewal for medicinal products for human use submitted to the NMA prior to 2007, these shall be assessed definitively, leading to either medicinal product authorisation or recall of the application for authorisation, if the submitted documentation is incomplete/inadequate.
- If, within 1 year as of receipt of the request letter, the applicants do not comply with requests for supplementation and update of the documentation in support of applications for marketing authorisation/marketing authorisation renewal for medicinal products for human use submitted to the NMA prior to 2007, these applications are to be cancelled, in accordance with the provisions of Order of the Minister of Health No. 1203/2006.