DECISION

No. 30/01.11.2010

on approval of the handling of implementation of Type IA and IB variations not affecting marketing authorisation terms for medicinal products authorised through national procedure

The Scientific Council of the National Agency for Medicines and Medical Devices, established based on Minister of Health Order No. 1123/18.08.2010, reunited on summons of the NAMMD President in the ordinary meeting on 01.11.2010, in accordance with Art. 12(5) of Government Ordinance No. 734/2010 regarding the organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Sole article. – The handling of implementation of Type IA and IB variations not affecting marketing authorisation terms for medicinal products authorised through national procedure is approved.

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

ANNEX

Manner of handling of implementation of Type IA and IB variations not affecting marketing authorisation terms for medicinal products authorised through national procedure

1. This is meant for applications concerning type IA and IB applications not affecting marketing authorisation terms following expiry of the deadline for resolution of Type IA and IB notifications, as mentioned in Order of the Minister of Public Health No. 874/17.07.2006, Art. 9-10, namely Art. 17-18.

2. The Marketing Authorisation Holder submits to the NAMMD a notification on implementation of the change proposed in the initial application, in accordance with Annex 1.

3. The NAMMD shall no longer issue letters of approval, after MAH submission of the notification on implementation of type IA and IB variations to marketing authorisation.

4. If, on further evaluation of such applications, the NAMMD considers additional documents are necessary, the supplementation of the support documentation or submission of a separate variation(s) is required, when the proposed changes are found to not be covered by the initially submitted variation.

5. If the Marketing Authorisation Holder does not respond to the respective requests, the NAMMD shall take the necessary measures in line with regulations in force.

ANNEX 1

Notification on implementation of type IA and IB variations to marketing authorisation

Registration name Marketing Authorisation Holder Marketing Authorisation Number(s) Name and address of the representative/contact persons Registry address of the application for variation/variation type

SCOPE
(Please briefly specify the scope of the change(s), when the heading has not appropriately been filled in in the initial application)

CURRENT*)	**PROPOSAL*)**

*) Please clearly specify the current and proposed situation, when the heading has not appropriately been filled in in the initial application

DECLARATION OF THE APPLICANT ON IMPLEMENTATION OF TYPE IA OR IB VARIATIONS

I hereby declare that (*Please check the appropriate declarations*):

 There are no further changes apart from those listed in the application for variation/the notification on implementation of the variation.

 The change(s) will not have a negative impact on the quality, efficacy or safety of the medicinal product.

 All conditions provided for this type of variation are met.

 The required documentation has been submitted in accordance with the Guideline on the content of the dossier for Type IA and IB notifications

Please attach (*If applicable*)

 A letter of approval of the variation issued by the competent authority of the Reference Member State, in case of MRP/DCP procedures within the European Union

 A letter of approval of the variation issued by the national competent authorities in other EU Member States (Great Britain, Denmark, Sweden, Holland, France, Germany, Austria)

Date of variation implementation _____

MARKETING AUTHORISATION HOLDER/REPRESENTATIVE IN ROMANIA

NAME **SIGNATURE** **DATE**