DECISION

N. 16/07.06.2010

on change of the implementation date of the Guideline on conduct of consultation with target patient groups in view of the Summary of Product Characteristics, approved through SCD no. 6/23.03.2010

The Scientific Council of the National Medicines Agency, established based on the Order of the Minister of Health No. 1027/22.05.2008, summoned by the NMA President in the ordinary meeting of 07.06.2010, in accordance with Art. 10 of Government Ordinance No. 125/1998 on the set up, organisation and operation of the National Medicines Agency, approved through Law No. 594/2002 as amended, adopts the following

DECISION

Art. 1. – Change of the implementation date of the Guideline on conduct of consultation with target patient groups in view of the Summary of Product Characteristics, approved through SCD no. 6/23.03.2010 is hereby approved, according to the Annex which is integral part of this decision.

Art. 2. - On the date of this decision coming into force, decision of the National Medicines Agency no. 6/23.03.2010 on the approval of the Guideline on conduct of consultation with target patient groups in view of the Summary of Product Characteristics is duly changed.

PRESIDENT
of the Scientific Council
of the National Medicines Agency,

Acad. Prof. Dr. Victor Voicu

ANNEX

Change of the implementation date of the Guideline on conduct of consultation with target patient groups in view of the Summary of Product Characteristics

Considering the number of applications for marketing authorisation (MA)/ marketing authorisation renewal, as well as for MA variation, art. 4 of the Guideline on conduct of consultation with target patient groups in view of the Summary of Product Characteristics, approved through SCD No. 6/23.03.2010 is hereby amended as follows:

1) For MA/MA renewal through national procedure submitted prior to November 2008, outcomes of consultation with target patient groups are to be submitted within 1 year as of MA entry into force.

2) For MA/MA renewal through national procedure submitted after November 2008, outcomes of consultation with target patient groups, submission of outcomes of consultation with target patient groups is mandatory on either application for MA/MA renewal or during MA/MA renewal procedure.

3) For authorised medicinal products for which applications for safety variation have been submitted, outcomes of consultation with target patient groups are to be submitted within 1 year as of the date of their approval, when an application for type II variation is to be submitted including the respective outcomes of consultation with target patient groups.

4) For all other authorised medicinal products, irrespective of the date of their marketing authorisation/marketing authorisation renewal, an application for type II variation is to be submitted within 1 year as of 1 June 2010, including respective outcomes of consultation with target patient groups.

5) Marketing authorisation holders as well as companies conducting consultation with target patient groups on their behalf are to be accredited and regularly subject to inspection by the National Medicines Agency (NMA), based on documentation approved by the NMA President.