LÄÄKELAITOS
LÄKEMEDELSVERKET
NATIONAL AGENCY
FOR MEDICINES

21 December 2007 Dnr 1/0.5.1./2008

Mr. Nicolas Rossignol
European Commission, DG Enterprise & Industry, Unit F2 'Pharmaceuticals'
45 Avenue d'Auderghem, Office 10/128
B-1049 Brussels - Belgium
Telephone: direct line (32-2) 2987354. Fax: (32-2) 2998046.
E-mail: nicolas.rossignol@ec.europa.eu

COMMISSION REGULATION concerning the examination of amendments to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products

Comments from the National Agency for Medicines (NAM)

The NAM welcomes the initiative to make the procedures for handling the variations simpler, clearer and more flexible. In general the NAM is in agreement with most of the proposed elements of the proposal. We would like to take the opportunity to stress a few key points in the current proposal:

The NAM endorses the concept of the key item 1 (to extend the scope to purely national authorisations).

Concerning the key item 4 (work sharing), a strong role for EMEA in both classifying the variations and in providing the source of regulatory memory is endorsed. The selection of the co-ordinating body for the organisation of work sharing (EMEA or CMD/HMA) should be considered carefully. The handling of a huge number of variations is very challenging. A fully centralised system may become too rigid for the handling of the variations, especially of the large mass of variations to non-harmonised marketing authorisations. The concept of mutual recognition might provide a better way of handling this complex situation. However, the current mutual recognition procedure, with comments from the concerned Member States (CMS), may be too heavy for the large number of relatively simple variations. We urge the Commission to consider a simplified system in which the reference Member State (RMS) will provide its assessment report for the consideration of the CMSs. The CMSs may accept the recommendation of the RMS or, in exceptional cases, revert to a national procedure. This simplified system could encourage many MSs to participate in work sharing.

In addition, the NAM presents the following specific points for consideration:

The key item 2 (ICH Q8-Q9-Q10), the use of "Design space concept", should be carefully considered in case of biological products.

In principle, the NAM supports the concept of "do and tell" (Key item 3) as an approach to certain IA variations. The classification of these variations into those that can be annually reported and into those to be immediately notified is also endorsed. However, the NAM cannot endorse the proposal that, in the same annual report, changes relating to different products (from the same MAH) are included in the same report. In addition, the NAM proposes that the time to review the annual reports is extended to 60 days.

The proposal to revise the classification of some variations concerning biological products should be considered carefully taking into account the complex nature of biologicals. Currently, many of these Type I variations are Type II variations by default and this approach should be retained also in future.

Concerning key item 5 (type IB by default) the NAM can in principle agree to this. However, the problem foreseen here is that there will be several cases where the classification has to be changed to type II and there is indeed a very short time to review the variation. Therefore, it is important that the system is predictable and that the classification of variations is regularly updated.

Finally, as there are many new elements in the proposal, the NAM would like to propose to add a transitional period of two years to the implementation of the new system. This would make it possible to pilot the new system in order to find the optimal working methods.

Head of Department, Professor
on behalf of Director General, Professor Hannes Wahlroos

Erkki Palva

Head of Section
on behalf of Head of Department, Professor Pekka Kurki

Marjo-Riitta Helle