

Press release

Meeting of Heads of Agencies

6 and 7 December 2000

The last meeting of the Heads of Agencies under the French Presidency was held on 6 and 7 December 2000 in Paris (Afssaps – Saint-Denis). All European agencies including the EMEA attended the meeting as well as a representative from the European Commission (DG Enterprises). Observers from Iceland and Norway also participated.

In the follow-up of the first meeting held under the French Presidency, discussions focussed on the review of the European system for evaluation and control of medicinal products and more specifically on the decentralised procedure. The Heads of Agencies endorsed a position paper on the possible improvements of this procedure. The need for scientific discussions and concertation at the earliest was recognised. The HoA also agreed that within the present duration (60 days) the time devoted to evaluation and discussion on answers should be increased.

Moreover, it was decided that harmonisation should be a priority, especially concerning SmPCs and that Member States should commit themselves to nationally follow the harmonised European documents. Further discussion is needed to define the scope for harmonisation.

The work done by the MRFG for the past years was highlighted and the HoA reaffirmed the importance of the group and wish it to facilitate the achievement of a scientific consensus which will be respected by all Member States.

A concept paper on the training of assessors (from the EU legislation to GCP inspections) was presented with a view to improving common understanding with regard to harmonisation. A couple of topics will be chosen among a pre-defined list in order to implement a common programme starting in 2001.

As discussed at the past HoA meeting, the French Presidency proposed to carry out a joint audit programme in the field of GMP inspections (on a voluntary basis). The aim is to evaluate all inspection systems in order to preserve the confidence achieved and to guarantee that the quality is equivalent within all systems. This proposal was fully supported by participants.

The Information Technology was further addressed. It was decided that additional proposals from the troika should be examined at the next meeting in order to complete the European Commission strategy paper.

The next meeting of the Heads of Agencies will be held under the Swedish Presidency on 27 and 28 February 2001.

22 December 2000

Position paper from the Heads of Agencies on the Decentralised Procedure

During the meeting of the Heads of Agencies held in Saint-Denis on the 6th and 7th of December 2000, discussions particularly focussed on the possible improvements of the decentralised procedure. The Heads of Agencies recommended that the current process could be improved with a view to delivering the best and consistent information to patients.

Consequently, the Heads of Agencies endorsed the following proposals:

- 1 · In order to improve the decentralised procedure, the Member States :
 - recognised the need for scientific discussions and concertation in order to improve the mutual recognition procedure and therefore favour well-organised break-out sessions with representatives

empowered to and capable of taking binding decisions. In this context, the Heads of Agencies encourage the efficient and innovative use of ICT.

- agreed that within the present duration a different time-table should be defined in order to increase the period devoted to discussions. It was agreed that for a 6-month trial period for mutual recognition procedures starting in January 2001, concerned Member States send their comments within 50 days in order to have more time for evaluation and discussions on answers.

2 · Harmonisation should be a priority :

SmPCs :

- Via referrals according to article 11 (Dir. 75/319/EEC) which should be preferably raised in a prospective way, priority will be given to widely used active substances which will lose their patent protection within the next two years. It was decided that a list of the substances concerned should be provided by the MRFG to the Heads of Agencies.

When there is a controversy, referrals could be raised on a case by case basis but this should not be the preferred way of handling harmonisation of SmPCs. Moreover, achievement of MR-SmPCs discussed in break-out sessions may facilitate this harmonisation.

- Member States commit themselves to nationally follow the harmonised European documents.
- A common data base gathering harmonised documents and shared by all Member States is the mean to come to harmonisation.

Technical aspects :

- When there still exist different national positions or attitudes relating to the assessment of dossiers, harmonisation should be sought via guidelines or positions papers.

3 · In the future system, the Heads of Agencies confirmed the importance of the MRFG and wish it to facilitate the achievement of a scientific consensus which will be respected by all Member States.