

Press release

Meeting of Heads of Agencies

12 and 13 October 2000

The first meeting of the Heads of Agencies under the French Presidency was held on 12 and 13 October 2000 in Paris (Afssaps – Saint-Denis). All European agencies including the EMEA attended the meeting as well as representatives from the European Commission (DG Entreprises). Observers from Iceland, Norway and Cadreac (Bulgaria and the Slovak Republic) also participated.

In the follow-up of the June Sintra meeting held under Portuguese Presidency, discussions focussed on the review of the European system for evaluation and control of medicinal products. The Heads of Agencies endorsed a common statement of main principles with the view to strengthening the European procedures. This statement based on the HoA experience should enlighten the European Commission while elaborating an architecture paper on the revision of the current system.

The MRFG was mandated to work on very specific issues, which will be discussed at further HoA meetings in order to concretely define the changes needed for the implementation of an effective European networking system.

The Information Technology project was also addressed. It was decided that both the European Commission and the French Presidency specify their own priorities to allow the HoA to go further in the debate at their next meeting. The HoA asked the Telematic Steering Committee to come with concrete proposals on the priorities, the way it should be executed and financed.

A concept paper on the necessity of a European co-operation and harmonisation in GMP inspection standards for competent authorities was presented. This would be an example of training and experience showed by all the agencies.

In addition, the HoA group was given information on paediatric medicinal products. The French Presidency informed HoA of its intention of convening a meeting between the various agencies with the aim of both exchanging their experience of providing suitable medicinal products for children and creating a paediatric network gathering all national agencies and the EMEA.

Finally the HoA meeting decided to recommend that national and mutual recognition public assessment reports should be mandatory and that their format and content should be defined by the legislator.

The next meeting of the Heads of Agencies will be held in Paris (Afssaps – Saint-Denis) on 6 p.m. and 7 December 2000.

Heads of Agencies Common Statement on Reviewing the European System for Evaluation and Control of Medicinal Products

During the meeting of the Heads of Agencies held in Saint-Denis on 12th and 13th October, 2000, discussions focussed on the review of the European system for evaluation and control of medicinal products.

The Heads of Agencies considered the preliminary results of the audit presented by the European Commission and discussed contributions based on their experience. As a result, they agreed on the following main principles to strengthen the European procedures.

The Heads of Agencies agreed that these principles should be maintained and serve as a basis for the review of the European system for evaluation and control of medicinal products, while taking into account the enlargement of the European Union:

- Public health should be safeguarded and should remain a key-priority.
- The need for the regulatory system to recognize global regulatory developments and to effectively support European innovation, research and development as well as providing patients with better access to medicinal products.
- The scientific quality and the transparency of the assessment process should be fully guaranteed.
- The single market of medicinal products should be taken into due consideration.

The Heads of Agencies actually stressed that the European expertise provided by national competent authorities met its main expectations ; therefore the Heads of Agencies recommended that the future system should be maintained and reinforced as a network basis.

The Heads of Agencies stressed that this network requires common data bases, electronic communication tools, information systems and training of assessors to support effective functioning. Whatever the procedures agreed upon, the future system should favour the quality of information to patients and health professionals.

Details concerning the reviewing of the system will be discussed on the occasion of coming Heads of Agencies meetings.

Friday, 13 October 2000