European Medicines Agency
Celebrating ten years – 1995 – 2005

"A Scientific Perspective on the Future of Medicines"

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Contribution of Jean MARIMBERT, Director General of AFSSAPS
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Ladies and Gentleman,

I feel very honoured to be allowed to speak before such a distinguished audience, for the 10th anniversary of EMEA.

I shall express myself as head of a national agency that have always been deeply involved in the work of EMEA and sincerely committed to its success, and that firmly intends to remain so. But I shall also, and above all, try to give you an insight in the point of view of my numerous colleagues, whose agencies together form the European network, in close connection with EMEA which is actually part of that network.

From the start, EMEA was meant not as an alien body, overlooking and dominating the network of national agencies, but as a common building, designed to mutualize the best skills of the members of the European club and put them at the service of European patients and citizens.

That proved to be a good recipe for achievement and success during the last ten years. It helped a lot to secure a high level of expertise and bring about excellence in the field of evaluation of medicinal products, whether human or veterinary. EMEA succeeded in building a strong scientific credibility and a true institutional legitimacy. It achieved this commendable performance by relying on the involvement of the best experts, originating from national agencies or from the scientific community inside Europe. But its european and worldwide reputation also derives from the added-value brought by a robust

regulatory capability and by the quality of EMEA's management, from Fernand Sauer to Thomas Lonngren, both of them being assisted by talented individuals and skilful teams.

As the first European agency operating in the field of health, EMEA, with the support of its scientific committees, paved the way for a more global evolution of the European health policy.

Il demonstrated the accuracy and relevance of a model that combines an adequate degree of centralized power and a substantial amount of decentralization and national autonomy. This model is in accordance with the special status of public health, which poses major and mounting challenges at European level while being deeply rooted in national tradition that account for the diversity of the design of health care systems and the variety of medicinal habits. This balanced and sensible approach remains valid in the enlarged Union of 2005.

But this anniversary can't be solely the moment when on praises past achievements, however outstanding they may be..

As a matter of fact, on the very moment when we rightly celebrate the 10th anniversary of a successful institution, we are confronted with new and demanding challenges, and we have to cope with a climate of mounting uneasiness, if not distrust, that is bound to undermine the credibility of the whole network of health products agencies. In that uncertain and troubled context, our common task must be to strengthen and enlarge our coordinated approach, with a view to safeguard the high level of safety, quality and efficacy of medicines that the European citizens are legitimately expecting. Some of the key words for the near future are bound to be :

- transparency of evaluation procedures, decision making processes, clinical trials, conflicts of interests…., : transparency is a source of confidence ;

- reliable and clear information on the good use of products : sound prescription and adequate consumption are key factors to preserve the health of the patients and avoid destabilizing crises ;
- close monitoring of the effects of medicines : we must combine a coordinated effort to strengthen and connect pharmacovigilance systems with a renewed emphasis on the development of post-marketing studies, whether epidemiological or not ;
- innovation : the regulatory network must promote genuine innovation in uncovered or insufficiently covered areas of public-health needs, such as paediatrics, rare diseases or neuro-degenerative illnesses related with aging ; it must foster new therapeutic approaches such as cell-and gene-therapy or pharmacogenomics, while constantly keeping in mind the need to protect the safety of patients as well as the physical integrity of people that accept to take part in clinical trials.

By emphasizing such values and developing corresponding actions, the European network will be in a position to contribute to vindicate and, if necessary, restore confidence in the reliability of the evaluation and monitoring framework. Il will thus be able to promote a sound vision of the risk/benefit balance that is at the heart of the missions of public agencies and underlies their daily work.

All members of the network must share a clear vision of the challenges and of the tasks that are ahead of us. EMEA's road map, adopted last December by the management board after intense consultation of all the stakeholders, sets a clear vision of the course that has to be taken with a view to fulfil the obligations stemming from the new pharmaceutical legislation and to take due account of the high expectations of our environment.

To complement this valuable vision, the heads of agencies have recently decided to embark on the drafting of a strategic document. Il will sketch the major orientations that are necessary to meet the need of enhanced coordination in all the matters that are

outside the scope of community competences. Il will be drafted by next fall, on the basis of the analyses and suggestions of several working groups that will soon be set up and chaired by heads of agencies. That work will be completed in a spirit of consistency with the content of EMEA's road map and of coordination with the reflexions that will take place in the months to come in order to secure a good implementation of the new pharmaceutical legislation, under the auspices of EMEA and of the Commission.

As you can see, this 10th anniversary of EMEA is not the end of a story, but rather the beginning of a new stage, both challenging and promising. The national agencies are determined to be active partners in designing the frame of this new stage, as contributors to EMEA's work as well as members of an ever closer and performing network.

Thank you for your attention.