European Medicines Agency
Celebrating ten years – 1995 – 2005

"A Scientific Perspective on the Future of Medicines"

11 March 2005

Mr Mars Di Bartolomeo
Minister of Health, Luxembourg

Déclaration de Monsieur le Ministre de la Santé Mars Di Bartolomeo
lors de la célébration du 10ième anniversaire
de l'Agence Européenne du Médicament,
Londres, le 11 mars 2005.

Mrs. Dagmar Roth-Berendt, Vice President of the European Parliament,
Mr Günther Verheugen, Commissioner DG Enterprise,
Mr. Thomas Lönngren, Executive Director.

Distinguished Guests,
Ladies and Gentlemen,

It is for me a great pleasure to be among you today to celebrate the tenth anniversary of the start of the European Medicines Agency formerly known as the European Medicines Evaluation Agency.

The creation of the Agency in nineteen ninety three (1993) was the achievement of a long journey in the pharmaceutical sector which started in nineteen sixty three (1963) with the first discussion in Brussels on pharmaceutical matters, the creation of the European Pharmacopoeia in nineteen sixty four (1964), the first european legislation in nineteen sixty five (1965), followed by the nineteen seventy five (1975) directives and the creation of the CPMP, the concertation procedure for biotechnological products in the eighties (80ies), the first attempt at a single european evaluation of high technology medicinal products.

Today the Agency has a key role in the pharmaceutical area and symbolizes harmonization and integration in Europe. It has also become a central reference point in the pharmaceutical world.

It was a remarkable performance, starting from scratch to build up to a high-performance, world-wide recognized agency in medicines regulation. One remarkable feature was that CPMP and CVMP were very rapidly able to give scientific opinion: the reason for this was that all the people involved EMEA staff, CPMP/CVMP members, national experts, EU commission were very much dedicated to ensuring the success of this enterprise.

One of the strengths of the system can also be found in the multidisciplinary approach. The fact that the various scientific experience from experts of the member states with different backgrounds cultures, habits can come together in one central institution or committee, to achieve a single scientific objective. This allows for a very high quality discussion, often debating controversial issues. This is a great opportunity which should not be neglected.

10 years is a long period when looking back but a short period when looking ahead to what still needs to be achieved and every day brings new challenges. Among them it will be the integration of our new member states, the implementation of new therapies like gene therapy or cell therapy into the regulatory framework or even the new paradigm called Process Analytical Technology which might change the way how to ensure quality of medicinal products in the future.

Pharmaceuticals of course play an important role in public health issues, but are also an important economic factor and being, not only Minister of Health but also Minister of Social Security, I know what I am talking about. This is sometimes a critical issue as a good balance has to be found between economic need and patient safety. Over the past years there have been some events with safety concerns for medicines and these have resulted in a large echo in the press. The danger and this has to be absolutely avoided, is that people lose confidence in the system. It is absolutely necessary that we learn from such events, both the Licensing Authorities and Industry, in order to try to avoid such situations in the future.

If, in this context Pharmacovigilance plays here of course a key role, Scientific Advice as foreseen by the new legislation will be more and more important, as it will involve both Industry and the Agency at an early stage of medicine development to promote together studies using their best knowledge and, this as a final goal, for the benefit of the patient.

During the Luxembourg Presidency, there are several topics in relation to Public Health which are prioritized, like the concept of prevention especially with regard to AIDS, response to communicable diseases, the promotion of healthy lifestyles (including the fight against tobacco, obesity and mental disease), the collaboration with WHO, but I would like to mention specifically two topics which are currently under discussion at the Council of Ministries under our Presidency and which are directly related to the activities current or further of the European Medicines Agency.

The first topic regards communicable diseases, and in a more particular way pandemic influenza. WHO puts during these months a lot of effort in the revision of the International Health Regulations, the most important global alert mechanism, which I hope will be concluded in time for the World Health Assembly in May. As all of us know, communicable diseases do not respect national frontiers and can spread rapidly if actions are not taken to combat them. Global alert mechanisms have therefore to be completed by regional and national anti-pandemic preparedness plans.

I am personally strongly in favor of a coordinated and common european approach in this matter. A common approach could be adapted in creating common stocks and in common negotiation with the pharmaceutical industry. Speaking of the pharma industry one should not forget that the challenge of a world pandemie demands solidarity from all of the partners.

I was very glad to hear that the Agency through its scientific committee the CHMP has issued recommendation to the Commission on the use of anti-viral medicines in a pandemic situation and that for pandemic influenza vaccines a Note for Guidance will be issued soon. It is important that the EMEA not only gets more involved in this type of recommendation, but, why not, also in advising which types of medicines are lacking- as it was stated for instance in the case of anti-viral medicines by some experts in this field- and therefore to indicate in which area further research is needed.

This recommendation could result in specific research projects. May be here there are new ways to go within the Commission: instead of deciding research programs and financing the traditional collaboration between research groups, why not initiating also specific research projects, if there is a need especially in case of public health. This is an option which could be discussed and a partnership being set up between Public Bodies, Commission and Industry. A similar approach is under discussion for pandemic influenza vaccines.

The second topic is the Regulation on pediatric medicines which is currently under discussion at the Pharmaceuticals Working Party of the Council. I do hope that I do not have to emphasize here the responsibility which we have towards our children and this underlines the importance of this Regulation. The Luxembourg Presidency will concentrate all its efforts to advance this Regulation as much as possible. The EMEA will in the future play an important role here as the foreseen Pediatric Committee will be placed at the Agency. I was pleased to hear that preliminary work has already started in the Pediatric Working Group within the Agency.

Distinguished Guests,
Ladies and Gentlemen,

The Luxembourg Presidency on behalf of the Council would like to congratulate all the staff of the Agency, the experts of the different scientific Committee for all these achievements, to thank them for working so hard for the benefit of the patient and to wish them to be in future as successful as in the past.

Thank you for your attention.