European Medicines Agency
Celebrating ten years – 1995 – 2005

"A Scientific Perspective on the Future of Medicines"

11 March 2005

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SPEECH/05/ANNIVERSARY

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10 Years of EMEA – a success story

10th Anniversary of the European Medicines Agencies

London, 11 March 2005

Ladies and Gentlemen,

It is a great pleasure to be here today to celebrate the 10th anniversary of the European Medicines Agency.

I. 10 years of EMEA – a success

It has been ten years since we created this Agency. We set out to provide European citizens with high quality, safe and effective medicines for humans and animals. At the same time, we wanted to advance towards a single market for medicines.

With the creation of the Agency, we wanted to build on existing national expertise and by bringing that expertise together, we wanted to provide Europeans with an even better system of medicines regulation. Patients in all Member States should benefit from the knowledge and expertise of the best experts, wherever in Europe they may be.

By having a truly European system we can also minimise duplication of work in the Member States so that resources can focus on the highest quality scientific assessments.

Today we are looking back at the first ten years of the European Medicines Agency. I am pleased to say that the European system with the Agency at its core has become a success story.

The Agency has won confidence and the appreciation of healthcare professionals and industry, and most importantly, the European patient. The Agency can be proud that it now serves as a reference for the creation of other new agencies in Europe and, indeed, around the world.

Over the last decade, the Agency has continuously developed to take on new roles and responsibilities and each new challenge has been met. The Agency has also taken an important international role, for example it has established a very close cooperation with FDA in the U.S. and with the W.H.O. to deliver medicines to developing countries.

II. Moving ahead

Let us use this anniversary not only for the rear view, but also to look at current challenges and reflect on the future.

1. Challenges for industry and regulators

Despite the advances made over the last ten years, major challenges lie ahead. I would like to highlight just a few:

It is no secret that the historical dominance of the European pharmaceutical industry has been eroded, particularly by the growth of the industry in the United States. Europe needs a strong and competitive pharmaceutical industry because a strong and competitive industry is necessary to deliver innovative medicines for the benefit of public health. Without a strong industry the incurable diseases of today will remain incurable. Competitiveness drives innovation and innovation saves lives. A strong industry will not only benefit the health of Europeans but will also improve the lives of Europeans through the creation of high quality employment and wealth.

The Commission believes that we need to drive competitiveness and innovation. Thus we need to be active. An important part of this is using legislation to ensure thorough regulation of medicines while, at the same time, increasing competitiveness and innovation. A few examples:

The orphan regulation, through its incentives, has so far led to twenty-one medicines being developed and authorised for rare diseases, i.e. diseases where previously treatments were either inadequate or totally lacking. And there is clear evidence that the orphan regulation has led to the creation of small and medium-sized enterprises. Thus it is fair to state that the orphan regulation has stimulated innovation for the benefit of patients and increased the competitiveness of the European pharmaceutical industry.

Another example is the Commission proposal for a regulation on medicines for children. We need legislation to create opportunities for industry to develop paediatric pharmaceuticals. When the proposal becomes law new markets will be created and medicines will be developed and authorised to meet the specific needs of our children. I therefore call on the Council and the European Parliament to adopt this proposal as quickly as possible, to improve child health and increase at the same time the competitiveness of the European pharmaceutical industry.

One last example: advances in science and technology offer the opportunity for new innovative treatments to address unmet medical needs. I am thinking particularly of gene therapy, cell therapies and tissue engineering. The industry needs a clear regulatory framework for new technologies so that it can design its studies and develop products for the benefits of patients. If the regulatory framework is unclear then this increases the uncertainty and risks for industry and reduces innovation. The Commission is committed to ensuring that a clear regulatory framework for these advanced therapies is put in place as quickly as possible. This is yet another example of legislation that will provide sound regulation and stimulate competitiveness and innovation in the European pharmaceutical industry.

Ladies and Gentlemen,

I believe that the second key challenge is the need to reinforce our community system for ensuring the safety of medicines. As recent product withdrawals have reminded us, we cannot know the full safety profile of all products at the time of authorisation. Therefore, we must have systems in place to learn more about the safety of medicines once they are marketed. Europe has already made major advances in this area and the recent update of the pharmaceutical legislation has given new tools to the regulators and industry, such as risk management plans and conditional marketing authorisations. An ongoing study launched by the Commission into the robustness of the system should tell us whether these measures are sufficient.

The third and last challenge I would like to highlight lies in the fact that patients have a right to more and better information about their medicines. They ask for a transparent system providing them with high quality and understandable information. The Commission is currently preparing a “partnership on information to patients” involving all stakeholders. Another aspect of this initiative to increase the availability of quality information on medicines is the setting up of a European public database on medicines.

2. State of play and next steps

Ladies and Gentlemen,

The last Commission has already done a lot to respond to the various challenges in the pharmaceutical sector: A first, but big step forward was achieved with the adoption of the Pharma Review in 2004. This major reshape of the EU's pharmaceutical legislation strengthens public health, while supporting a competitive European pharmaceutical industry.

The fast-track approval, an increased role for the Agency in scientific advice as well as specific measures for small and medium sized enterprises will increase the chances of new medicines reaching the market, to the benefit of patients while increasing industrial competitiveness.

Important measures relating to data protection and the approval of generic and over-the-counter medicines establish a favourable environment for the different industry sectors. It is essential that those parts of the new legislation needing transposition into national law be transposed faithfully so that patients and industry can reap the maximum benefit. I call on the Member States to do all they can to achieve this. The Agency will also have a crucial role in providing coordination and leadership during the implementation.

Ladies and Gentlemen,

The European system for medicines regulation and, above all the Agency, have achieved great progress. But we should not sit back and twiddle our thumbs. We need to move on in close cooperation and partnership between the EMEA, Member States, industry, health-care professionals and, of course, patients. With the end of the G10 High Level group, the Commission is now reflecting on how to build further on this positive experience. While the G10-group has delivered valuable outcomes, I am fully aware that some of its recommendations still have to be implemented and require further discussions between Member States and industry under active participation of the Commission. However, already now there can be no doubt that the G10-process has demonstrated that dialogue and collaboration are the best way forward.

To finish I would like to say happy birthday to the Agency and thank you to all those who have worked so hard to achieve its success.