European Medicines Agency
Celebrating ten years – 1995 – 2005

"A Scientific Perspective on the Future of Medicines"

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Mr Fernand Sauer
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EMEA: 10 years of public health excellence

Fernand Sauer, Director for Public Health, European Commission

Whilst the European Centre for Disease Prevention and Control (ECDC) is starting this month in Stockholm, the 10th anniversary of European Medicines Agency and the progress made by the EMEA over the years is spectacular and of major importance for public health in Europe and the World.

The EMEA has provided the European Union and its citizens with the best scientific assessments of the quality, safety and efficacy for biotech or other novel products for human or veterinary use. This work has been extended to Norway, Iceland and Lichtenstein and could in future directly benefit the World Health Organization.

The EMEA harmonises at a top level the conditions of use of innovative medicines, and provides packaging leaflets and medical information in all Community languages. The EMEA is increasingly consulted during the research and development stages of new drugs and on the merits of orphan medicinal products destined for rare diseases. When needed, the EMEA also delivers sound pharmacovigilance advice on all products on the market, including those authorised nationally.

Ten years ago, the EMEA initiated a new tradition of full transparency of its operation by publishing all its assessment reports and conducting a permanent dialogue with its stakeholders: national authorities, doctors, pharmacists, consumers and patient groups.

It also contributed to an intense effort of standardisation of data requirements involving the USA, Japan and the World Health Organization in the context of the International Conference of Pharmaceutical Harmonisation (ICH) and later also in the veterinary field (V-ICH). Many aspects of pharmaceutical quality control are co-ordinated with the European Pharmacopoeia based in the Council of Europe, which celebrated its 40th anniversary last year in Strasbourg.

I was privileged to start the operation of the EMEA in 1995, with several colleagues who are still working in the EMEA and with the crucial support of European scientific experts. Let me associate one of them in particular to today's celebration: Pr Jean-Michel Alexandre.

The EMEA recently underwent a major review and extension of its tasks through a complex revision of the European pharmaceutical legislation, learning from its own experience since 1995 and adjusting to the challenges of the enlargement of the European Union from 15 to 25 Member States in 2004. The EMEA road map to 2010 commits this agency to further develop its worldwide role as a public health regulatory authority and to provide for better protected and informed patients and users.

Happy Birthday!