European Medicines Agency
Celebrating ten years – 1995 – 2005

"A Scientific Perspective on the Future of Medicines"

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Dr Osamu Doi,
Senior Executive Director, PMDA, Japan

EMEA 10th Anniversary presentaion addressed by Dr. Osamu Doi, Senior Executive Director, PMDA, Japan

Thank you for your kind introduction.

1. On behalf of the Pharmaceuticals and Medical Devices Agency, Japan, I would like to offer my congratulations to all EMEA staff on the 10th anniversary of the establishment of the Agency. I would also like to express my deep respect for the ten years' efforts of all EMEA staff in creating the European centralized review system and to provide safe innovative medicines in a timely manner to patients of EU member states. It is the very objective of ICH to make innovative medicines available to patients with a minimum of delay.

2. It was 16 years ago in 1990 that I began to take part in ICH activities as one of the founders of ICH. Together with my partners in the EU ···known as EC at that time··· and the US, we exerted ourselves to lay the groundwork in establishing ICH.

3. And in 1995, the EMEA was established, with the global expectation that it would serve as the model of the harmonization. When the 5th anniversary celebration took place 5 years ago, at which I was honored to attend, the EMEA at that time was on its way to develop into a stronger organization. Expansion of office space was under work, and I remember I felt the vitality emerge out of the organization.

4. And today, EMEA has marked its 10th anniversary of the inauguration, and have achieved a high international reputation as a centre for evaluation of medical products in Europe, under the leadership of Dr. Loenngren. I remain excited about EMEA's potential to further extend the scope of the product evaluation to

biological products in the future.

5. Since the first ICH conference in Brussels in 1991, the world of medicinal products has become increasingly globalized, and is fast entering into the era of borderlessness.

6. With a substantial increase in the number of member countries in the EU, the role of EMEA to provide effective and safe medicines in a timely manner to patients of the member countries has become ever more important. Furthermore, the expectation is also high for EMEA to play its role in evaluating the efficacy and safety of products utilizing new technologies, or those of biological products.

7. As for our country, the Pharmaceuticals and Medical Devices Agency (PMDA) was established on April 1st last year in order to further strengthen the approval reviews for pharmaceuticals and medical devices, and to strengthen post-marketing safety activities. PMDA, in coordination with the Ministry of Health, Labour and Welfare, will continue to endeavour to promote international harmonization through ICH.

8. Finally, I hope that EMEA and EU, both as the partners of ICH, will continue to promote and pursue international harmonization to ensure faster accessibility to better and safer medicinal products for the patients of the world. I also trust that EMEA and the member countries of EU will take the leadership role in promoting information exchanges among medicines regulatory authorities.

I would like to close my address by once again extending my congratulations to all EMEA staff, and hope that EMEA and PMDA will continue to build a strong mutual partnership.
Thank you very much for your kind attention.