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Japan Pharmaceutical Manufacturers' Association
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Pharmaceutical Research and Manufacturers of America
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European Business Community
Pharmaceutical Committee(EBC-PC)

Tripartite Meeting (JPMA/PhRMA/EBC-PC) hosted by EMEA
"Approving Innovative Medicines in 21st Century"

The above joint meeting was held on 11th and 12th May in London, hosted by EMEA (The European Agency for the Evaluation of Medicinal Products) and under the co-sponsorship of JPMA (Japan Pharmaceutical Manufacturers Association), PhRMA (Pharmaceutical Research and Manufacturers of America) and EBC-PC (European Business Community Pharmaceuticals Committee), in association with EFPIA (European Federation of Pharmaceutical Industries and Associations). About 90 persons participated from the governmental and industrial bodies in Japan, the USA and Europe, including:

Mr. Fernand Sauer (Executive Director of EMEA)
Mr. Yasunori Usui (Director, Economic Affairs Division, Health Policy Bureau of MHW)
Mr. Toshiki Hirai (Director of Evaluation & Licensing Div., Pharmaceutical & Medical Safety Bureau of MHW)
Dr. R. Yetter (Acting Associate Director for Policy, Center for Biologics Evaluation & Research of FDA)
Mr. Osamu Nagayama(President of JPMA)
Sir Richard Sykes (Chairman of Glaxo Wellcome plc)
Mr. Brian Ager (Director General of EFPIA)
Dr. Stuart Dombey (Vice President, Research and Development, Japan, Parke-Davis, Pharmaceutical Research Division, Warner Lambert, representing PhRMA)
Mr. Jacques Selmes Van Den Bril (Vice-Chairman of Alzheimer Europe)

and other speakers and discussants detailed below.

The Meeting was held on the principal theme of "Approving Innovative Medicines in 21st Century" and comprised of three sessions, namely (1) Value of Innovation, (2) Acceleration and Streamlining of the Regulatory Reviews, and (3) Present and Future of Policy on Biotechnology. Respective sessions were started with presentations by specialists, mainly from the administrative side, to give the status quo and the expectations of the session themes. The presentations were followed by discussions and Q&A sessions by panelists and audience on the future direction of the topics.

The Meeting's opening address was given by Mr. Christopher Adam (EBC-PC

Chairman, Japan), to commence the three sessions.

At the Session (1), Dr. Heinz Redwood (independent pharmaceutical industry consultant) gave a report on his study "Value of Innovation – will health care pay for innovative drugs?" compiled through interviews in seven countries. The report underlined the points such as:-

1) "Innovation" of medicine differs from one region to another or from one association concerned to another
2) "Ménage à trois" among payers, providers and patients of prescribing medicines
3) Efforts exerted by the manufacturers to demonstrate value of "innovation"
4) Individual budget system for drug management is suspected to improperly evaluate the value of "innovation".
5) Necessity to judge the value of "innovation" not only from the aspects of quality and cost of healthcare but also from industrial and technical points of view

In response patients' representative, government representative, industry representatives and discussants expressed the following views, which was followed by an active discussion:

1) Medicine should not be the sole target for the healthcare reform. The reform should be well-balanced, in that issues pertaining to the elderly and improvement of quality of healthcare must be tackled on and at the same time development of innovative medicines, provision of quality generic products, assurance of transparency must be ensured.
2) Because healthcare and health security systems are products of history and culture, systems may differ from one country to another. Stability of a healthcare system and the development of superior medicines should not be in conflict. Rather it is a question of balance.
3) Innovation is to enhance the "value" and it necessitates the "informed decision" and educated patients. For the purpose, it is essential that the "value" is properly recognized.
4) Industry side should claim the "value" based on sound science and objectivity.

In this session, the recognition of the following points was deepened:

a) Importance of evaluation standard for the value, provision of accurate and sufficient information, and understanding of economic usefulness, concerning medicines.
b) Necessity of involvement of patients' representatives to political decision-making.

At the Session (2), Mr. Hirai (Director of Evaluation & Licensing Div., Pharmaceutical & Medical Safety Bureau of MHW) reported the status quo of acceleration and streamlining of review process in Japan. He reported that in order to shorten the NDA review period without sacrificing the review quality, the MHW has enforced the NDA review capability through establishment of new organization and the reform of existing mechanism. As a result, the review process has been substantially improved. Mr. Hirai also reported that the MHW revised the policy for acceptance of foreign clinical data in accordance with the development of ICH, and that at the same time, they saw the improvement in the quality of NDA data. He reported that one of the current challenges for the MHW is drug misadministration incidents and that their causes must be clarified and the preventive measures must be established. He stressed the necessity of internationally harmonized approach toward the review of new technology and post-marketing safety measure as common future denominators of EU, Japan and US.

Next, Dr. R. Yetter, FDA, explained the pros and cons of the existing system. Furthermore, in order to expedite the review timing, industry side needs to clearly demonstrate the characteristics of the product, to understand the systems thoroughly and to utilize the pre-consultation. Especially it was emphasized that close communication between the regulators and the industry is necessary via regulations, guidelines, internet, advisory committees' hearings and direct meetings.

Prof. A. Broekmans, (Chairman of Board of EMEA) explained the following:

· Systems and role of EMEA, functions of CPMP (Committee for Proprietary Medicinal Products), system and process of centralized procedure and mutual

recognition, and the details of recently enforced Orphan Drug Law.

Furthermore, he stressed that the review timing, that used to be 4 to 6 years, has been shortened to one year after the establishment of EMEA, via utilization of IT, improvement of the review quality by peer review, and assurance of transparency, etc. streamlined the review process, and that regulation of medical expenditure is just a part of the total healthcare system in each country. On the other hand, in the environment of cost pressure on medical expenditures, professionals' expertise and perceptions dictate the prerequisites for approval of innovative drugs.

In this session, it was recognized on one hand that simultaneous development and applications of medicines are expected among the tripolar regions with the advancement of ICH. On the other hand, governmental level coordination is important to resolve the issue of gaps between the scientific decision and people's culture and characteristics that differ by country, and to further improve the quality and efficacy of the review process.

At the Session (3), Mr. Hirai reported that in view of growing role of medicinal products in medical care of the 21st century, the MHW is positively approaching toward pharmaceutical innovation and is also supporting proper development, to smoothly supply the innovative drugs without compromising public safety. He commented that the MHW fully recognizes recent remarkable progress in biotechnology area and subsequent development of new technologies, which have potential to expand the range of pharmaceutical product development and therapeutic alternatives. Mr. Hirai introduced from this point of view the MHW's involvement into the Millennium Project, an intergovernmental project to support the biotech R&D activities. He mentioned that the MHW is planning to prepare framework for drug regulations in response to rapid progress of biotechnology. At last he gave his view that new technical development of biotechnology is not an issue of single country but worldwide, which will need harmonized regulatory approach on an international basis. To fulfil this purpose, the regulatory authorities in the world should continue to collaborate, keeping good partnership with the pharmaceutical industries.

Dr. R. Yetter, representing FDA, pointed out the factors to promote the biotechnology

should be:

- Expectations to innovative products
- Keeping abreast of globalization and international harmonization
- Development of information technology

He expressed his view that in the early 21st century, vaccines, gene therapy, clone products and anagenesis technique, etc. of new types will become reality, and biotechnology will generate innovative methods in the area of diagnosis and drug research and development. It was reported that as a result of FDA's streamlining of the review process of biotechnological products the number of bio-related INDs increased from 41 in 1997 to 63 in 1999. The FDA expects the highest number of IND-submissions concerning such products in 2000. Dr. Yetter emphasized that a prompt and appropriate approach must be taken to ensure the safety of bio-generated products and to establish ethics concerning biotechnology. He expressed that FDA would aim at the prompt examination of new technology without sacrificing the safety and the establishment of a system to constantly prove the safety of biotech products.

Drs. John Purves and Marisa Papaluca Amati, representing biotechnology and biologics sector of EMEA, introduced the background of biotechnology in EU, referring to the establishment of legal and regulatory framework, the progress of analytical and bio-related technologies and the development of harmonization among the EU countries. They reported that EMEA makes efforts to clarify the scope of treatment and scientific validity of new technology, through retrieval of scientific archives, cooperation with research scientists and EMEA's studies. The importance of gathering and diffusion of further information was pointed out, to keep pace with the progress in genome research.

It was followed by presentation concerning gene therapy in the EU; it is regarded as:

- Integration of various technologies
- Integration of diagnosis and therapy
- Integration of product and service
- The state-of-art technology which connotes risks

Drs. Purves and Papaluca explained the gist of the guideline issued by CPMP in 1997 regarding the genetically transferred products. They also underlined that EMEA

continue to give priorities to openness, mutual conversation and communications, networking and transparency in its approach to biotechnology.

In this session, the current circumstances and the future issues of biotechnology and genome-related matters were reported and discussed. It was recognized that it is important to maintain and extend the tripolar cooperation, utilizing ICH discussions.

After these three Sessions, Mr. O. Nagayama (President of JPMA) presented a wrap-up of the whole Meeting and Mr. S. Heppell (former Chairman Management Board of EMEA) delivered a closing address. The Meeting highlighted the common issues and directions shared by Japan, EU and US concerning the value of innovation, shortening of regulatory review process, and genome technologies, etc. Through the Meeting, the three parties recognized the importance of provision of innovative drugs without delay, and the necessity of the tripolar collaboration and good partnership at the government level as well as those between the administrations and pharmaceutical industry, taking the needs of patients fully into account.