EU - Japan Business Round Table
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Recommendations of the EU-Japan Business Round Table to the Leaders of the European Union and Japan

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Working Party B
Life Sciences and Biotechnologies, Healthcare and Well-being
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Working Party Leaders:

Bayer Holding Ltd.
Hans-Dieter Hausner
President
Senior Bayer Representative for Japan

Chugai Pharmaceutical Co., Ltd.
Osamu Nagayama
Chairman of the Board of Directors
President & CEO

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List of Abbreviations

WP	Working Party
EU	European Union
LS & BT	Life sciences and Biotechnologies
MRA	Mutual Recognition Agreement
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
MAFF	Ministry of Agriculture, Forestry and Fisheries
NHI	National Health Insurance
MLHW	Ministry of Labor Health and Welfare
MOF	Ministry of Finance
PMDA	Pharmaceutical and Medical Device Agency
HTA	Health Technology Assessment
FSC	Food Safety Commission
CBD	Convention on Biological Diversity
ABS	Access and Benefit Sharing
IFAH	International Federation of Animal Health

Introduction

Currently and in near future our world is facing numerous issues including human-caused global climate change, resource shortages and uncertainty of food supply, fast-ageing societies in developed countries and explosive population growth in developing countries.

Life sciences and biotechnology may possess the potential to offer solutions for many of critical issues identified above. Innovative, fast and cost-efficient development of drugs or productivity increase in agriculture and livestock are just two of the numerous examples how the life science and biotechnology industry can contribute to find the answers for the current global challenges.

The European Union set a revised “Life Sciences and Biotechnology (LS & BT) strategy (Bio4EU)” and a “Strategic Approach on Healthcare for the EU 2008-2013” in 2007 and has implemented them. Also, in Japan the new coalition government, which was formed in September 2009 under the leadership of the Democratic Party of Japan, established and issued basic policies for “New Growth Strategies” in December 2009. The government intends to focus on two leading industries, “Environment & Energy” and “Healthcare,” to grow Japan’s economy through innovative technologies.

These collaborative approaches between the governments and industry in both the EU and Japan can identify and certainly catalyze the much needed change processes in areas of regulations, market policies and economic cooperation in order to allow the industry to fully unfold its potential and deliver innovative, fast and cost-efficient solutions in the areas of Healthcare, Plant Protection & Biotechnology and Animal Health.

Recommendations to the EU and Japan

General issues

B-EJ-1 Cooperation towards the COP10 for CBD in Oct 2010

Towards the COP10 for "Convention on Biological Diversity (CBD)" to be held in Nagoya in October 2010, EU and Japan should work together so that the international regime on CBD, especially on "Access and Benefit Sharing (ABS), can accelerate R&D and innovation to soundly develop the bioindustries, which will produce a useful products that bring social benefits, as well as secure access to those products.

B-EJ-2 Enhancement of bioventure activities

In both the EU and Japan, bio-venture activities should be enhanced further and dynamically integrated with each other. BRT members call for government support to expand these networks of activities through such measures as bio-conferences or the establishment of cluster centres.

Healthcare

B-EJ-3 Regulatory harmonization and MRA for pharmaceuticals

Proceed regulatory harmonization and further extension of "Mutual Recognition Agreement" in order to avoid redundant inspections of manufacturing facilities (delay of new drug launches)

<Background>

As currently only oral forms are included within the MRA between Japan and the EU, there are still a lot of redundant inspections of manufacturing facilities. This is not only a costly process, but it also slows down the launching of new drugs in Japan creating a significant disadvantage for Japanese patients.
In order to eliminate this problem and to integrate EU-Japan economics more efficiently, harmonization of standards/guidelines and expansion of MRA should be conducted under mutual agreements. Followings are highly prioritized items for harmonization and expansion of MRA.

Harmonization:

- *Safety measures from surveillance to vigilance should be harmonized with international standards*
- *Clinical development guideline and biological preparation standards for Vaccine*
- *Minimum Requirements for Biological Products*

Mutual Recognition Agreement:

- *MRA of GMP should expand to non-solid preparations to avoid redundant inspections and testing*

B-EJ-4 Balance between prevention and treatment in healthcare

Seek balance between prevention and treatment. Thus, include vaccination/ programs in scope for public funding

<Background>

Disease prevention and diagnostic/ screening procedures are getting a more important position in healthcare area as they allow to improve the treatment of numerous diseases but also to effectively lower the healthcare cost in mid- and long-term. Therefore, vaccine should be in scope for public funding.

Plant Protection & Biotechnology

B-EJ-5 Measures against counterfeit products

Formulate concrete actions against counterfeit products

<Background>

Counterfeit products do not only represent significant dangers to the consumers but also harm innovative companies.
With EU and Japan together representing over 600 Mio consumers, both governments have be world leaders in the fight against counterfeits in order to protect their population as well as their industries.

Animal Health

B-EJ-6 Regulatory harmonization for animal health products

Further harmonization and streamlining of regulatory requirements for product registration of animal health products

<Background>

While such global new veterinary medicinal products go through rigorous review process in Europe and the USA prior to registration, it requires additional testing in Japan under the Pharmaceutical Affairs Law before an approval is granted. Regulatory requirements for an innovative veterinary medicinal product based on biotechnology are especially stringent in Japan, and therefore, a product which is readily available to veterinarians and animal owners in Europe cannot be used in Japan. Increased harmonization of regulatory requirements would certainly improve access of animals and animal owners to innovative animal health products.

An additional important aspect is the negative impact on animal welfare: since the regulatory requirements are not harmonized, the companies are required to repeat tests on animals in Japan, even though results of identical tests are already available and are fully compliant with stringent frameworks like GLP or VICH.

B-EJ-7 Mutual recognition of GMP and marketing authorization for animal health products

Mutual recognition of European and Japanese marketing authorizations and recognition of GMP certification for veterinary products

<Background>

While the studies conducted under Good Laboratory Practice or Good Clinical Practice are usually accepted by the Japanese government for inclusion in the dossier, there is still no mutual recognition of Good Manufacturing Practice (GMP) for veterinary medicinal products. Moreover, any overseas production facilities that are involved in manufacture of veterinary medicinal products imported into Japan have to be accredited by MAFF even though their GMP status is authorized by European authorities. This process involves a large amount of administrative works.

In order to improve decreased speed, predictability and quality of the registration process in Japan which were pointed out in the benchmark surveys conducted by the International Federation of Animal Health in 2007, several new steps were taken by MAFF with some progress. However, there are still delays in review process of some product segments. An EU – Japan Economic Integration Agreement should aim for Mutual recognition of European and Japanese marketing authorization for veterinary products by starting off with mutual recognition of GMP certification of veterinary medicines. Harmonized regulations on animal vaccines should also be addressed under such an agreement.

Industrial Biotechnology

B-EJ-8 Strengthening activities for industrial biotechnology

To enhance the global competitiveness of the bio-based economy through increase cooperation between the EU and Japan, we suggest a number of actions that would strengthen activities in the area of industrial biotechnology

- ✓ *Develop and implement EU-Japan common R&D programmes and strategies to encourage use of agro-food by-products and wastes*
- ✓ *Support collaborative development of technologies to produce biomass based products and sustainable biofuels*
- ✓ *Benchmark the EU and Japanese policy strategies and legislation/regulations in order to stimulate the market introduction of bio-based products from innovative*

technologies

- ✓ *Set up a common task force to analyse which global incentives can stimulate or support the re-conversion towards a bio-based economy*

Recommendations only to Japan

General issues

B-J-1 Formulation of action plans for "New Growth Strategies"

Formulate concrete action plans for the "New Growth Strategies" focusing on LS & BT fields as well as a new strategy for promotion of R&D and faster applications in LS & BT.

B-J-2 Nation-wide electronic database for individual health/medical records in Japan

Map out the "grand design" of a nationwide electronically integrated database for individual health/medical records as a basic Japan health policy

<Background>

The Japanese government should intend to electronically integrate individual health/medical care related data and information nationwide in order to supply high-quality and patient-suitable medical care, and map out a "grand design" of the systems. The integrated database will also improve the efficiency of medical care by eliminating duplicated examinations or reducing adverse events and treatment for them. Furthermore, the data will be useful for the discovery of new innovative medical treatments and devices. Several European countries have already taken the lead on this issue, so Japan may be able to learn much from the experiences of the EU.

Healthcare

B-J-3 Full-fledged implementation of the new drug pricing system and abolishment of market expansion re-pricing

Finalize the implementation of the new, internationally competitive pharma pricing system in Japan based on the industry proposal and abolish the rule of re-pricing by market expansion

<Background>

The NHI price reform proposed by the industry has been positively reviewed by the Chuyikyo in December 2009 and the government decided to start a pilot implementation in April 2010. This represents a significant improvement, as it provides for price stability for innovative drugs. However, two significant issues still remain to be clarified:

- Implementation for 2010 will be just a trial. Benchmarks to be reached for continuation of scheme after 2012 are not clearly defined.

- As a compensation for this new scheme, government will attach a system that fosters registration of so called non-approved drugs. However, finalization of list of such products, as well as criteria for exclusion from new Exceptional Treatment for Maintenance of NHI Drug Price for companies that do not fulfill requirements towards development of such drugs are not clear.
Furthermore, we urge to abolish the current rule of the re-pricing by market expansion which is opposite to the policy to evaluate pharmaceutical innovation.

B-J-4 Regulatory transparency and review time by PMDA

Increase the transparency of evaluation standards / registration process & Shorten review time by PMDA (J)

<Background>

Innovation can contribute to improved patient quality of life, reduction of social cost and robust industry growth. In order to precede proper evaluation of innovation, transparency of evaluation standards and evaluation process should be guaranteed and improved by both governments. Adoption of health economics/ HTA and establishment of National Data Base for medication/ cost are essential for the improvement of transparency.
The increase of personal at PMDA in 2007, together with an increase of registration fee, is a welcome move towards a reduction of review time. It is important to continue to monitor if this will be linked with a significant reduction of review time. Also, it is suggested that Japanese authorities make more extensive use of overseas data, as this would significantly reduce cost and time required to register products in Japan.

Plant Protection & Biotechnology

B-J-5 Support to research for Plant Protection & Biotechnology

Support research in Plant Protection & Biotechnology

<Background>

Research and development of innovative and beneficial Plant Protection & Biotechnology products is a key to ensure safe food supply but also to increase the efficiency and therefore, the competitiveness of the agricultural sector.
To support this undertaking the governments should increase its spending for the research in Plant Protection & Biotechnology.

B-J-6 Enhancement of cooperation with industry and academia

Enhance international cooperation in development of plants with new beneficial traits/ Promotion of industry & academia cooperation

<Background>

Currently promotion of industry/ academia cooperation in Plant Protection & Biotechnology R&D in Japan is not as developed as in Europe. Global companies can offer worldwide development tools and networks to Japanese academia. Japan has many top class scientific institutes having potential answers to the global challenges (food, climate change, water shortage).

Potential Research Topics:

Genetic improvement of plant growth and yield to stabilize crop production in variable growth conditions by

- *· enhancing plant gene discovery and regulatory network research*
- *· studying cellular growth and plant development*
- *· elucidating growth-promoting plant hormones*

B-J-7 Efforts on increasing output of agriculture in Japan

Continue efforts towards increasing output production of Japanese agriculture

<Background>

Japanese self-sufficiency on a calorie requirement basis is today below 40% so that it can be reasonably expected that the food & feed commodity prices will increase over the mid-long term. In addition, growing global population will also continue to drive demand against increasingly limited supply.

To counter this negative development the Japanese government should reform and drive Japanese agriculture toward increasing output production.

Animal Health

B-J-8 Shortening review times for animal health products

Shorten review times for new product applications

<Background>

In Japan, marketing authorization of a veterinary medicinal product is granted by the Ministry of Agriculture, Forestry and Fisheries (MAFF). For an animal drug intended for use in food-producing animals, the Food Safety Commission (FSC) and the Ministry of Health, Labor and Welfare (MHLW) are also involved in establishing the acceptable daily intake and maximum residue limit, respectively. The review process, involving three different authorities, is rather complex and certainly has some room for efficiency improvement. Also, the review can take extremely long time to be completed, delaying so the access of animal owners and animals to innovative animal health products.

Recommendations only to the EU

Plant Protection & Biotechnology

B-E-1 Shortening review times for products by Plant Protection & Biotechnology

Shorten review times for new applications/ registrations

Research and development of innovative and beneficial Plant Protection & Biotechnology products requires high input costs. Therefore, timely access to the markets is crucial for the R&D-intensive companies in order to successfully market their products and recover their initial R&D investments, which then again are used to finance further innovations.
Establishment and maintenance of science-based, predictable and timely regulatory systems free from undue political influence and the appropriate protection of proprietary data are therefore key requirements for sustainable and innovative research.

Animal Health

B-E-2 Introduction of "1-1-1 concept" for all animal health products

Introduction of 1-1-1 concept for all products (one dossier – one assessment – one decision on marketing authorization)

One of the key objectives of the European Union is to create a single market for goods. This goal has yet to be achieved for the animal health industry, with the exception of centrally authorized products. In line with the concepts already existing in the EU (i.e. quality, safety and efficacy described in one single EU dossier as the basis for granting marketing authorizations for veterinary medicinal products, one single assessment of the dossier employing the best expertise, resulting in one decision for marketing authorization) the animal health industry in Europe is seeking a systemic change based on the one, one, one concept ("1-1-1 Concept") for all products. This appears to be the most simple and straightforward way to address all of the major shortcomings of the current system and to finally achieve the goal of a single market for safe and efficacious veterinary medicines.

B-E-3 Responsible use of antibiotics in animal health

Promote responsible use of antibiotics in animal health

In common with the rest of the world, Europeans and Japanese are concerned by the development of resistance to antibiotic medicines used in human health and the potential threat that the use antibiotics in animal health will accelerate this process. The use of antibiotics as growth promoters has been prohibited in EU since 2006.
As a responsible industry, the animal health industry seeks to work with veterinarians, farmers and the feed industry to dispel the myths about the use of antibiotics in animals and promote their responsible use.