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

Tokyo, 3 & 4 April 2012

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

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List of Abbreviations

Abbreviation	Meaning
ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
EFPIA	European Federation of Pharmaceutical Industries and Associations
EU	European Union
FSC	Food Safety Commission
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HTA	Health Technology Assessment
IFAH	International Federation of Animal Health
J-PAL	Japanese Pharmaceutical Affairs Law
LS & BT	Life sciences and Biotechnologies
MAFF	Ministry of Agriculture, Forestry and Fisheries
MDD	Medical Device Directive
MHLW	Ministry of Health Labour and Welfare
METI	Ministry of Economy, Trade and Industry
MIC	Ministry of Internal Affairs and Communications
MOF	Ministry of Finance
MRA	Mutual Recognition Agreement
NHI	National Health Insurance
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Co-operation Scheme
PMDA	Pharmaceutical and Medical Device Agency
QMS	Quality Management System
VPD	Vaccine Preventable Diseases
WP	Working Party

Recommendations from both European and Japanese industries

General Issues

WP-B / # 01 / EJ to EJ Enhancement of bio-venture 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. It is also necessary to support bio ventures financially under the current economic recession. Strong governmental (METI and MHLW) financial support is essential.

No progress has been seen for this recommendation.

<Background>
In the biotechnology-based industries, bio ventures have played an important role to create innovative technologies and products. Bio ventures in the EU and Japan are behind those in the US and need more collaborations or integrations between venture companies. To realize this, expansion and activation of venture networks will be very valuable. Under the current economic situation, it is difficult for ventures to obtain capital from the markets. Some financial support should be considered to vitalize them.

Healthcare

WP-B / # 02 / EJ to EJ Regulatory harmonization and MRA for pharmaceuticals

The regulatory harmonization and further extension of "Mutual Recognition Agreement" should be proceeded in order to avoid redundant inspections of manufacturing facilities.

In addition to oral dosage forms, API, Sterile and Bio products are being requested to apply to the MRA. The new initiative of PIC/S> PIC/S stands for "Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme, jointly refers to PIC/S". Compared to last year a strong MHLW's initiative on PIC/S has been seen. This is an agenda point for the European industry (15 countries), EFPIA and PMDA.

Some progress has been seen for this recommendation.

<Background>
As currently only oral solid dosage 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. Below-mentioned are highly prioritized items for harmonization and expansion of MRA.

<Prioritized items for harmonization and 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*

- *Sharing knowledge and information of inspections by each regulatory authority through PIC/S*

Mutual Recognition Agreement:

- *MRA of GMP should expand to liquids, and sterile forms, API and bio products to avoid redundant inspections and testing*

WP-B / # 03 / EJ to EJ Balance between prevention and treatment in healthcare

Seek balance between prevention and treatment. Thus, confirm inclusion of vaccination programs and include contraception in the scope of public funding.

Some progress has been seen for this recommendation.

<Background>

Disease prevention and diagnostic/ screening procedures are getting a more important position in the healthcare area as they allow to improve the treatment of numerous diseases but also to effectively lower healthcare costs, mid- and long-term. Therefore, vaccines and contraception should be in the scope of public funding. The Japanese government allocated special funds to vaccine-preventable diseases, especially cervical cancer and bacterial meningitis. MHLW provided financial support in the amount of 100 Bio Yen for these kinds of vaccines R&D of

4 drug firms in supplementary budget for FY2010. Further progress should be made.

WP-B / # 04 / EJ to EJ Mutual recognition of quality management audit results for medical devices between EU and Japan

Improve mutual recognition of quality management audit results for lower risk medical devices, e.g. those classified as Class II, ARCB under the Japanese Pharmaceutical Affairs Law, as a first step.

PMDA and MHLW should initiate to introduce a mutual recognition of quality management audit results.

Some progress has been seen for this recommendation.

<Background>
Based on Medical Devices Directive (MDD) of the EU and the Japanese Pharmaceutical Affairs Law (J-PAL), Quality Management System (QMS) audit results are required for each application for a license to introduce new medical devices in the market. In Europe the regular annual ISO audit results can be used for all applications during the period in which the ISO audit is valid. Recently, Japan has started to accept QMS audits at a specific manufacturing site for products with the same generic name within a one year validity of the ISO 13485 certificate. However, a number of RCBs still require submitting QMS audit results for each application. Further alignment is still necessary to reduce the burden on manufacturers.

WP-B / # 05 / EJ to EJ Infrastructure improvement and international harmonization of regulation standards for approval of non-invasive diagnostic medicines and devices

Both governments should promote infrastructure improvement such as regulatory review process and structures to accelerate simultaneous research and development of therapeutic medicines and accompanying diagnostic medicines and devices (companion diagnostics).

Furthermore, both governments should harmonize each regulation on simultaneous development of therapeutic medicines and companion diagnostics, to support advancing science on personalized healthcare (PHC) based on global genome-cohort research.

This is a new recommendation.

<Background>
U.S. Food and Drug Administration (FDA) officially announced in June 2011 a draft guidance for simultaneous development of therapeutic medicines and companion diagnostics. It requires companies to develop simultaneously new therapeutic medicines and companion diagnostics which are able to stratify efficacy and safety of the new medicine.

In EU, the European Medicine Agency (EMA) has already announced a draft for adoption of genome bio-markers in clinical trials. Also in Japan, MHLW officially announced they will draft standards for regulatory approval process of companion diagnostics by FY2014.

PHC is greatly expected to be of benefit not only for government's healthcare finance but also for society and patients. To support advancing PHC, it is required to harmonize regulatory standards and to promote infrastructure improvement such as regulatory review process and structures to accelerate simultaneous research and development of therapeutic medicines and companion diagnostics.

WP-B / # 06 / EJ to EJ Mutual recognition of medical devices product licenses

Introduce a mutual recognition of medical device product licenses between the EU and Japan. PMDA and MHLW should introduce a mutual recognition of medical device product licenses with low risk of class II devices.

No progress has been seen for this recommendation.

<Background>
Mutual recognition of licenses for medical devices in Japan and the EU would make it possible to introduce new products in both the Japanese and European markets within the same time frame and with one process.

As mentioned before, it could be possible to start with lower risk, class II devices.

The evaluation scheme between the Medical Devices Directive of the EU and the Japanese Pharmaceutical Affairs Law are quite similar, with

- Evaluation schemes based on registered 3rd party bodies (Notified Bodies)
- Essentially quite similar requirements
- Based on ISO/IEC or JIS standard compliance

With these similarities, a mutual recognition should be easy to implement.

WP-B / # 07 / EJ to EJ Mutual recognition of clinical trial results for medical devices

Introduce a mutual recognition of clinical trial results for medical device development. Foreign clinical trial data has been accepted as a part of application dossier when; i) standards for conducting medical device clinical trials are set by the regulations of the country or region where the trial was performed, ii) the standards are equivalent or surpass the Japanese medical device GCP, and iii) the clinical trial was conducted in accordance with the standards or considered to have equivalent level of quality. The GOJ encourages active use of consultation service on individual medical device applications in advance provided by the Pharmaceuticals and Medical Devices Agency (PMDA) to address use of foreign clinical trial data for application of the device.

Minor progress has been seen for this recommendation.

<Background>
Differences in the definition of Good Clinical Practice between Japan and the EU currently prevents the use of non-Japanese clinical trial results in the application for new medical devices in Japan. Mutual recognition of clinical trial results would make it possible to make new products available to patients in Japan and the EU within the same time frame and through one process, ensuring high level of quality while reducing the burden on manufacturers.

Plant Protection and Biotechnology

WP-B / # 08 / EJ to EJ Enhancement of cooperation with industry and academia

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

No progress has been seen for this recommendation.

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

Healthcare

WP-B / # 09 / EJ to E Evaluation of innovation values for pharmaceuticals in prices

The EU government should reinforce its innovation policy to member states and clarify its healthcare policy, resulting in the appropriate evaluation of the value of pharmaceuticals.

No progress has been seen for this recommendation.

<Background>
In the EU, innovation policy is stated by the Lisbon declaration and the G10 group report indicating the importance of innovation in pharmaceuticals. However, each state operates its own healthcare system in different ways, resulting in gaps in survival rates and the QOL of citizens. Under the current economic recession, prices of pharmaceutical products are targeted as a major tool for medical cost containment. BRT members call on the EU to clarify its healthcare policy and to discuss and totally improve healthcare situations in member states by securing appropriate healthcare budgets, preventing interference with patient access to new medicines and considering the proper utilization of healthcare technology assessment.

Plant Protection & Biotechnology

WP-B / # 10 / EJ to E Shortening review times of plant protection & biotechnology products

Shorten review times for new applications/ registrations.

No progress has been seen for this recommendation.

<Background>
Research and development of innovative and beneficial Plant Protection & Biotechnology products require high input costs. Therefore, timely access to the markets is crucial for 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

WP-B / # 11 / EJ to E Introduction of "1-1-1 concept" for all animal health products

Introduce 1-1-1 concept for all products (one dossier – one assessment – one decision on marketing authorization applicable to all EU countries). A concept should be worked out between the respective governments / authorities.

No progress has been seen for this recommendation.

<Background>
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.

Healthcare

WP-B / # 12 / EJ to J 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.

MHLW and MIC started this initiative. One of the hurdles is that there are no single social security numbers and centralized data handling in Japan. A strong project promotion is necessary to safeguard people from potential disasters.

No progress has been seen for this recommendation.

<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.

WP-B / # 13 / EJ to J Citizens ID numbering system for taxation and social security in Japan

In line with tax and pension reforms, the Japanese government has started this project and it should commence as from 2015 onwards. Steadily promote the introduction of citizens' ID numbering system in accordance with the roadmap to provide better and impartial public services, especially in taxation and social security fields.
Some progress has been seen for this recommendation.

<Background>
The ruling Democratic Party of Japan (DPJ) clearly mentioned a citizens ID numbering system in its "Manifesto" in the Lower House election in 2009. The roadmap for introduction of citizens ID numbering system mentions that the system will be introduced in the area of social security, taxation and disaster preventions in January 2015. The Japanese government intends to submit relevant bills to the diet sessions in this year.

Industrial organizations such as the Federation of Economic Organizations (Keidanren) consider it essential to develop a firm infrastructure, which can provide public services impartially, certainly, transparently and effectively for the realization of a secure and affluent society. The Japanese government proposed a policy that this ID number will be applied to taxation and social security and allocated to citizens by 2013. For privacy protection, discussions are continuing on the establishment of a "Committee for ID Data Protection", the third-party organization for monitoring illegal usage of ID data, which is separated from other administrative organizations.

WP-B / # 14 / EJ to J Full-fledged implementation of the new drug pricing system and abolishment of market expansion re-pricing

The premium for new drug creation and elimination of unapproved / off-label use drug (the premium for new drug creation) will be continued for another two years, i.e., till March 2014. It is welcomed as it supports incentives for innovative drug development, however, it is only continuation of a trial scheme. The Japanese government should finalize the implementation of the new, internationally competitive

drug pricing system in Japan, , based on the industry proposal.

The abolishment of the market expansion re-pricing was not accepted by the Central Social Insurance Medical Council (Chuikyo) even though industries insisted to eliminate the system. We also urge to abolish the re-pricing rule by market expansion, which is opposite to the policy of evaluating pharmaceutical innovation.

No progress has been seen for this recommendation.

<Background>
The NHI price reform proposed by the industry has been positively reviewed by the Chuikyo in December 2009 and the government decided to start a pilot implementation in April 2010. This represents a significant improvement, as it provides price stability for innovative drugs. As a compensation for this new scheme, the government will attach a system that fosters the registration of "unapproved / off-label use drugs". Companies have received requests on developments of 181 unapproved / off-label use drugs and started forwarding those constructively.

Furthermore, companies will receive additional requests on developments of another hundreds of unapproved / off label use drugs in this year. However, in the draft for FY2012 drug pricing system reform which has been compiled in December 2011, the premium for new drug creation was determined to continue operation as a trial basis. Therefore, the conclusion brings the industry deep concerns about sustainability for evaluation of innovations. The Japanese government should implement the new premium system for innovative new drugs at the FY2014 drug pricing system revision to evaluate the companies' efforts for elimination of the so-called drug lag in Japan and research and development of innovative new drugs.

WP-B / # 15 / EJ to J Regulatory transparency and review time by PMDA

Increase the transparency of evaluation standards, / registration process and consistent consultations & and shorten review time for pharmaceuticals and medical devices by PMDA. There has been some progress and the PMDA should be encouraged to continue on this path.

Some progress has been seen for this recommendation.

<Background>
Innovation can contribute to improved patient quality of life, reduction of social cost and robust industry growth. In order to precede with the proper evaluation and promote innovation, transparency of evaluation standards and evaluation processes should be guaranteed and improved by both governments. Adoption of health

economics / HTA and establishment of a National Data Base for medication / cost are essential for the improvement of transparency.

The increase of staff / personnel at PMDA in 2007, together with an increase of registration fee, is a welcomed 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.

WP-B / # 16 / EJ to J Reinforcement of measures to ensure proper distribution of privately-imported medicines

Take necessary measures to private imports of a certain or more amount of medicines including unapproved products in Japan.

Japan is not as exposed as less developed countries. There is little parallel trade but private imports of medicines which provide a channel for counterfeits, mostly in OTC non-reimbursed drugs are seen. A similar situation is observed for crop-protection products.

This is a new recommendation.

<Background>
In case of private imports of a certain or more amount of medicines including unapproved products in Japan, certificate of medicine imports is required for custom purposes. Under the current regulations, however, there is a concern it will unintentionally provide distribution channels of counterfeit medicines mainly in OTC and non-prescription medicine fields. Furthermore, there are also problems such as the uncertainty where the responsibility lies or who responsibility has, in case health hazards are unfortunately brought to consumers.

WP-B / # 17 / EJ to J Appropriate assessment of innovative values of medical devices in prices

Promote sub-dividing the current functional classification, enhance the premiums for C1 or C2 products and introduce a product-based listing system for new products in order to move toward a product-based, market-oriented reimbursement pricing system in the future.

This is a new recommendation.

<Background>
Different from pharmaceutical brand-oriented pricing systems, about 300,000 medical devices are classified into about 700 functional classes in Japan and one reimbursement price is set for one functional class, based on structure, intended use, effectiveness and so on.

Currently, various old and new products, having various realized prices, have the same reimbursement price within one functional class, which means that the price drop of old products influences the reimbursement price of new ones on the revision of the reimbursement price. This is the reason why the introduction of a product-based reimbursement pricing system is desired.

Plant Protection and Biotechnology

WP-B / # 18 / EJ to J Support research for plant protection & biotechnology

Support research in Plant Protection & Biotechnology

No progress has been seen for this recommendation.

<Background>
Research and development of innovative and beneficial Plant Protection & Biotechnology products is 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.

Recommendations from European industry

Animal Health

WP-B / # 19 / E to EJ Regulatory harmonization for animal health products

Further harmonization and streamlining of regulatory requirements for product registration of animal health products. MAFF should start harmonization with related countries as this is the path to the 1-1-1 concept recommended previously.

No progress has been seen for this recommendation.

<Background>
While such global new veterinary medicinal products go already through rigorous review processes in Europe and the USA prior to registration, it requires substantial additional testing in Japan under the Pharmaceutical Affairs Law before an approval is granted. Restrictions on withdrawal period for innovative oil-adjuvant vaccines 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.

WP-B / # 20 / E to EJ 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. MAFF should work out harmonized regulations leading to the 1-1-1 concept.

No progress has been seen for this recommendation.

<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 work.
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.

WP-B / # 21 / E to EJ Responsible use of antibiotics in animal health

MAFF should promote responsible use of antibiotics in animal health.

No progress has been seen for this recommendation.

<Background>
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 of 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.

Healthcare

WP-B / # 22 / E to J Application of GMP on medicinal gases (manufacture of medicinal gases) in Japan

Reinforce the regulation for GMP on medicinal gases in Japan. MHLW has started these initiatives along with industries. But industries are protective to non-GMP facilities because of financial implications.

Some progress has been seen for this recommendation.

<Background>

Medicinal gases are drugs or medicinal devices and have to be compliant with governmental regulations. Main regulations are national Pharmacopeia, GMP (Good Manufacturing Practices), and GDP (Good Delivery Practices). Annex 6 describes GMP and GDP for medical gases: production and distribution. The currently loose interpretation of GMP in Japan along with relatively low standards of Japanese Pharmacopeia is of lower standards as compared to those applicable in Europe or the US. We would like to suggest a reinforcement of regulations on GMP for medical gases in Japan.

WP-B / # 23 / E to J Requirement of Japanese version of the clinical trial protocol and investigators brochure

The Japanese health authority requires a clinical trial protocol and investigator's brochure in Japanese. Translation from English is required for clinical trial notification in Japan.

MAFF, MHLW and FSC should start harmonized ways to shorten review times.

This is a new recommendation.

<Background>
The Japanese health authority requires a clinical trial protocol and investigator's brochure in Japanese. Translation from the original English version is required for clinical trial notification of global trials in Japan. Therefore, the requirement is considered to be a cause for delay of the start for patients' enrolment in Japan.

WP-B / # 24 / E to J Shorten or eliminate national tests for hemophilia-derived products and vaccines

For imported hemophilia-derived products and vaccines, national tests in both Japan and manufacturing sites have been conducted (for more than 20 years in some cases). National tests for hemophilia-derived products and vaccines should be eliminated or reduced to an absolute minimum.

This is a new recommendation.

<Background>
For a long time, there have been no critical quality issues in Albumins or Immunoglobulins. In addition, production is done according to GMP and PMDA periodical audits of production sites. Concerning the national test results which are published by MOU (memorandum of understanding), manufacturing countries should be accepted by the Japanese authority and the national tests for imported

hemophilia-derived products and vaccines in Japan should be eliminated or reduced to an absolute minimum.

Animal Health

WP-B / # 25 / E to J Shortening review times for animal health products

Shorten review times for new product applications. MAFF, MHLW and FSC should start harmonization to shortening review times.

No progress has been seen for this recommendation.

<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, Labour 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 an extremely long time to be completed. Hence, delaying the access of animal owners and animals to innovative animal health products.

WP-B / # 26 / E to J Japanese customs clearance's (cc) rule for investigational drugs and related materials does not allow efficient investigational drug supply

MAFF should harmonize with VICH guidelines.

This is a new recommendation.

<Background>
To import investigational drugs either 1) the Original Clinical Trial Notification sealed by both sponsor and PMDA or 2) YAKKAN is necessary. Recent clinical trials require frequent investigational drug delivery from overseas investigational drug warehouse to study sites. Since both 1) and 2) should be archived by the sponsor and CC agents do not keep those, frequent and timely CC is not possible. If a certified copy of 1) or 2) (certified by sponsor and kept by CC agent) is accepted by the custom, investigational drug delivery will become efficient.

Recommendations from Japanese industry

Plant Protection

WP-B / # 27 / J to EJ Promote people's understanding of GMOs based on scientific knowledge by both the governments and the private sectors

To gain people's acceptance of GMOs, governments and private sectors should cooperate in educating people about the efficiency and safety of GMO's, based on scientific knowledge, considering world food supply and demand prospects.

No progress has been seen for this recommendation.

<Background>
Stable supply of food is an urgent requirement. In the mid and long term, while world population keeps growing, there is a limit to cover the supply only by enhancing conventional breeding on existing farmland. Considering this situation, the introduction and utilization of GMO should be regarded as an urgent matter. People's understanding is indispensable for market acceptance. Both governments and private sectors need to educate their people based on the scientific knowledge to eliminate these concerns.

Healthcare

WP-B / # 28 / J to E Shorten the approval time to register new micro-organism and introduce new technology for producing seasonings and amino acids

Shortening the approval time needed for registration of new materials and introduction of new technologies which aim for product expansion, cost reduction, environmental concerns or diversification of the fermentation material. Clarification of the approval process is also requested.

No progress has been seen for this recommendation.

<Background>
The long term process for approving a set of safety evaluation such as the bacteria manufacturing process, test products and co-products, delays the enhancement of production and consequently, competitiveness in the EU market. The slow approval process makes companies hesitate to invest in the EU market. On the other hand, it also weakens the export competitiveness of EU companies. For information: US companies are introducing new technologies aggressively.

General Issues

WP-B / # 29 / J to J Formulation and steady implementation of action plans for "The Strategy for Rebirth of Japan"

The Japanese government should finalize concrete action plans for promotion of R&D and faster applications in LS & BT fields.

This is a new recommendation.

<Background>
In "The Basic Policy for Rebirth of Japan", which the council on National Strategy and policy is compiling, the Japanese government shows the flag for creation of new industries and markets which adapt to the environmental changes to reinforce Japan's growth potentials. The Japanese government especially refers to draw up a mid-term strategy to realize "Japan as a forefront runner in the world" in the fields of development of new drugs, medical devices, regenerative medicines and personalized healthcare. Therefore, focused measures on life innovation fields should be included in "The Strategy for Rebirth of Japan", which will be finalized by June 2012.