





Working Party 2 Life Sciences & Biotechnology Healthcare & Well-being

Working Party Leaders:

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Recommendations 2016 from WPB [Our position]

The BRT members have seen that the EU and the Japanese governments made some efforts on regulatory harmonization in these fields.

In anticipation of post-EPA between both regions, we hope the governments will continue further actions for regulatory harmonization and collaborations.







Recommendations 2016 from WPB [Summary]

Total: 19 recommendations

- General: 1 recommendation
 - Implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing under coordination with industries
- Healthcare: 10 recommendations
 - Regulatory harmonisation and MRA for pharmaceuticals and medical devices
 - Evaluation of innovation value for pharmaceuticals and medical devices
- Plant Protection & Biotechnology: 3 recommendations
 - Faster process for approval / registration
 - Acceleration and dissemination of scientific knowledge on GMOs by both the authorities and the private sector
- Animal Health : 5 recommendations
 - Regulatory harmonisation and MRA for Animal Health products
 - Faster and Efficient process for approval/registration of Animal Health products







Appropriate evaluation of innovative pharmaceuticals and medical devices

In Europe

- Relatively long time from approval of new product to eligible patient
- Introduction of HTA possibly to hinder patient's access to new products
- Authorities refer "External Price Referencing" to lower drug prices
- In Japan
- Reduction of prices of patent protected innovative drugs by "re-pricing rules"
 - Products with sales (>10 billion yen, >15 billion yen): ~25% price cut
 - Products with sales (>100 billion yen, >150 billion yen): ~50% price cut (since 2016)

Discouraging challenge to innovative R&D

For sustainable medical system, we should consider both control of the cost and encourage of investments in R&D

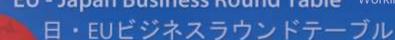






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Recommendations 2016 from WPB [Summary]

Plant Protection & Biotechnology:

Accelerate the approval & registration process for Plant Protection products by working more closely with foreign countries to reach a harmonized safety dossier. Thus, ensuring sustained food supply and competitiveness of the agricultural industry.

Animal Health:

- Mutually accept "Good Manufacturing Practice" certifications for veterinary medicines.
- Provide animal owners with faster access to Animal Health products by simultaneous reviews of the related authorities instead of sequential reviews.





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Recommendations 2016 from WPB [Healthcare (1)]

Regulatory harmonization & MRA in the Healthcare sector

- WP-B / # 02* / EJ to EJ
- MRA of GMP for pharmaceuticals
- WP-B / # 03* / EJ to EJ
- Mutual recognition of quality management audit results for medical devices between EU and Japan
- WP-B / # 04* / EJ to EJ
- Mutual recognition of medical devices product licenses
- WP-B / # 05* / EJ to EJ
- Mutual recognition of clinical trial results for medical devices
- WP-B / # 17* / E to J
- Application of GMP on medicinal gases (manufacture of medicinal gases) in Japan
- WP-B / # 18* / E to J
- Requirement of Japanese version of the clinical trial protocol and investigators brochure
- WP-B / # 19* / E to J
- Shorten or eliminate national tests for vaccines

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Recommendations 2016 from WPB [Healthcare (2)]

Evaluation of innovations pharmaceuticals & medical devices

- WP-B / # 09** / EJ to E
- Evaluation of innovation values for pharmaceuticals in prices
- WP-B / # 12** / EJ to J
- The revision of the rules for the pricing and prescription of innovative new drugs
 - Full-fledged implementation of the new drug pricing system
 - Abolition of the market expansion re-pricing
 - Abolition of the 14-day prescription rule
 - Sufficient discussion with stakeholders on introduction of HTA for the drug pricing
 - Maintain biennial drug price revision
- WP-B / # 13** / EJ to J
- Appropriate assessment of innovative values of medical devices in prices
 - Sub-dividing the current functional classification
 - Careful introduction of HTA based on characteristics of medical devices
 - Abolition of the foreign price reference system
 - Maintain biennial drug price revision







Recommendations 2016 from WPB [Plant protection & Biotechnology]

Improve the business environment for acceleration of utilizing biotechnologies to increase productivity

- WP-B / # 06* / EJ to EJ
- Shortening review times of Plant Protection & biotechnology products
- WP-B / # 07* / EJ to EJ
- Acceleration and dissemination of scientific knowledge on GMOs by both the authorities and the private sector
- WP-B / # 11* / EJ to E
- Maintenance of Import MRLs into the EU to allow free trade of food commodities





Recommendations 2016 from WPB [Animal Health]

Regulatory harmonization & MRA for Animal Health products

- WP-B / # 08* / EJ to EJ
- Mutual recognition of GMP and marketing authorization for Animal Health products
- WP-B / # 10* / EJ to E
- Introduction of "1-1-1 concept" for all Animal Health products
- WP-B / # 14* / E to EJ
- Prudent use of antibiotics in Animal Health
- WP-B / # 15* / E to J
- Regulatory harmonization for Animal Health products
- WP-B / # 16* / E to J
- Shortening review times for Animal Health products