



Recommendations to the Leaders of the EU and Japan

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

Working Party Leaders:

Mr. Hans-Dieter Hausner
President, Representative Director &
Senior Bayer Representative for
Japan, Bayer Holding Ltd.

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

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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.



Appendix



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



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