



Recommendations to the Leaders of the EU and Japan

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

Working Party Leaders:

Dr. Thomas-Peter Hausner
President, Representative
Director & Senior Bayer
Representative for Japan,
Bayer Holding Ltd.

Mr. Osamu Nagayama
Senior Advisor,
Honorary Chairman
Chugai Pharmaceutical Co., Ltd.



Overview of WP-2 Recommendations

- WP-2 recommends to take actions, in order to improve the innovation capabilities in the sectors below;
 - Healthcare (9) * () number of recommendations
 - Industrial Biotechnology (4)
 - Plant Biotechnology (2)
 - Animal Health (1)

- WP-2 strongly calls EU and Japan to foster sustainable business eco-system and accelerate the following actions;
 - Support R&D for COVID-19 by companies / academia
 - Properly evaluate innovations
 - Expedite regulatory harmonization



Prioritized WP-2 Recommendations

- Support R&D for COVID-19 (Joint Recommendation only)
 - Coordinately promote company-academia collaboration
 - Provide compensation / protection scheme for providers / recipients

- Properly evaluate innovations
 - Properly reward innovations to fulfill patients' unmet needs
 - Exclude innovative drugs from off-year drug price cut in Japan
 - Continuously refine the system of HTA^{*1} and CEA^{*2}

- Expedite regulatory harmonization
 - Further harmonize and mutually recognize the regulations
 - Further shorten approval process of new products

*1 Health Technology Assessment

*2 Cost Effectiveness Analysis



Possible Topics for Future EU-Japan BRT

■ Bioeconomy

- The European Commission announced a new bioeconomy strategy for a sustainable Europe in October 2018, revised from 2012 version. Also, the Japanese government introduced the Bio Strategy 2019 in June 2019, aiming to develop sustainable economy by actively utilizing / focusing on biotechnology.
- Planning / implementation of actions for these bio-strategies allows us to collaborate between stakeholders in both regions.

■ Global regulatory convergence

- Accelerating regulatory harmonization with an eye on future regulatory convergence must be beneficial for both regions.