



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

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**Working Party 2
Life Sciences and Bioeconomy,
Healthcare and Well-Being**

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List of Abbreviations

| Abbreviation | Meaning |
|---------------------|---|
| ABS | Access and Benefit-Sharing |
| AMR | Antimicrobial Resistance |
| BBNJ | Biodiversity Beyond National Jurisdiction (Agreement) |
| BPR | Biocidal Products Regulation |
| BRT | EU-Japan Business Round Table |
| CDMO | Contract Development and Manufacturing Organization |
| CGP | Cancer Genome Profiling |
| CMO | Contract Manufacturing Organization |
| COP | Conference of the Parties |
| CRO | Contract Research Organization |
| DSI | Digital Sequence Information on Genetic Resources |
| DX | Digital Transformation |
| ECHA | European Chemicals Agency |
| EFSA | European Food Safety Authority |
| EHDS | European Health Data Space |
| ESG | Environmental, Social and Governance |
| EU | European Union |
| GHG | Greenhouse Gas |
| GMO | Genetically Modified Organism |
| GMP | Good Manufacturing Practice |
| GSP | Good Simulation Practice |
| HTA | Health Technology Assessment |
| ICH | International Council for Harmonisation (of Technical Requirements for Pharmaceuticals for Human Use) |
| IMDRF | International Medical Device Regulators Forum |
| IP | Intellectual Property |
| IPM | Integrated Pest Management |
| ISO | International Organization for Standardization |
| JPMA | Japan Pharmaceutical Manufacturers Association |
| KMGBF | Kunming-Montreal Global Biodiversity Framework |
| LCA | Life Cycle Assessment |
| MDR | Minimum Data Requirements |
| METI | Ministry of Economy, Trade and Industry |
| MHLW | Ministry of Health, Labour and Welfare |
| MFN | Most Favored Nation |
| MLM | Multilateral Mechanism |
| MRA | Mutual Recognition Agreement |
| NAMs | New Approach Methodologies |
| QMS | Quality Management System |
| R&D | Research & Development |
| RNA | Ribonucleic Acid |



| Abbreviation | Meaning |
|---------------------|--------------------------------|
| RWD | Real World Data |
| SME | Small-to-Mid-sized Enterprises |
| SUPD | Single-Use Plastics Directive |
| US | United States |
| WP | Working Party |

Executive Summary

Advancing a Sustainable Future Through the Bioeconomy

Europe and Japan share common challenges — including declining competitiveness, mounting healthcare pressures, climate change, and food security. Advances in life sciences and biotechnology offer a powerful pathway to address these challenges and promote sustainable economic growth towards a bioeconomy society. In 2026, the urgency of this transition has intensified, driven by new geopolitical dynamics in pharmaceutical pricing, imminent international decision points on biodiversity, and growing strategic competition with the US and China across the biosciences.

What is the Bioeconomy?

The bioeconomy encompasses a broad range of activities — from utilizing biological resources (biomass), bioprocesses, and biotechnology — to producing goods, services, and energy in a sustainable, renewable, and recyclable manner. It represents a fundamental shift away from fossil fuel dependency towards an economy grounded in biological innovation.

Working Party 2's Commitment

Working Party 2 (WP-2) has been actively promoting the transition from a fossil fuel-based economy to a more sustainable, bio-based economic model. This shift aims to address critical issues including climate change, resource scarcity, and environmental degradation, while enhancing EU-Japan economic security and industrial competitiveness.

WP-2 is focused on enhancing innovation across three interconnected pillars:

- **Healthcare & Life Sciences:** Establishing predictable pricing systems, accelerating patient access to innovative medicines and medical technologies, and strengthening EU-Japan drug discovery collaboration.
- **Bioeconomy & Biodiversity:** Developing internationally harmonized rules for Digital Sequence Information (DSI) that balance innovation incentives with biodiversity conservation obligations.
- **Food Systems & Biomanufacturing:** Building robust agricultural innovation frameworks and comprehensive industrial support measures for the biomanufacturing sector.

Updates from 2025-2026

The EU and Japanese governments have implemented numerous initiatives in the past year relevant to the life sciences, biotechnology, healthcare, and bioeconomy landscape. All recommendations have been reviewed and updated in light of this progress.

Key developments reflected in this year's recommendations include:

- **US MFN Pricing Policy:** The announcement of US Most Favored Nation drug pricing policy creates new cross-border implications for EU and Japanese pharmaceutical pricing systems, adding urgency to pricing reform recommendations (*Rec #1*).
- **Japan's Health and Medical Strategy (2025):** Japan's updated Health and Medical Strategy and Comprehensive Economic Measures (*December 2024*) include measures for drug discovery ecosystem development, drug loss countermeasures, and regenerative medicine manufacturing (*Rec #2, #3*).
- **COP16 Cali Fund Launch (February 2025):** The Multilateral Mechanism (MLM) and Cali Fund for DSI benefit-sharing were officially launched, and discussions on contribution rates and thresholds are now entering a critical phase ahead of COP17 in Armenia (October 2026) (*Rec #4*).
- **EU Food and Feed Safety Omnibus (December 2025):** The EU's publication of the Food and Feed Safety Omnibus introduces new procedures for biological and RNA pesticides and biocontrol agents, directly informing WP-2's food systems recommendations (*Rec #5*).

New and significantly updated recommendations in 2026:

- Pharmaceutical pricing reform addressing US MFN policy spillover effects and Japan's annual price reduction mechanism (*Rec #1*)
- DSI rule-making and Cali Fund contribution framework ahead of COP17 (*Rec #4*)
- Comprehensive biomanufacturing industry support including LCA standardization, GX product certification, and CMO/CDMO infrastructure development (*Rec #6*)

Introduction

In light of the key importance but also fast evolving landscape of life sciences and bioeconomy, the following recommendations aim to foster collaboration and innovation between the EU and Japan. By addressing key challenges and leveraging mutual strengths, both regions can enhance their competitiveness and ensure sustaining R&D activities as well as access to innovative production, services and technologies. Both the EU and Japan face a growing innovation gap with the US and China, compounded by increasingly interconnected global pricing policies and supply chain vulnerabilities. In this context, strengthening our partnership is not only strategically important but urgent.

The BRT puts a priority on three interconnected pillars:

- ① **Healthcare & Life Sciences Innovation** (#1, #2, #3)
Predictable pricing, accelerated patient access, drug discovery collaboration
- ② **Bioeconomy Sustainability** (#4)
International DSI rules for biodiversity and industrial competitiveness
- ③ **Food Systems & Biomanufacturing** (#5, #6)
Comprehensive support for strategically critical industries

WP-2 | Recommendation #1

Establishing a predictable and sustainable drug pricing and evaluation system to promote innovation

The BRT calls on EU and Japanese Authorities to:

- Duly consider international geopolitical situations, particularly the US MFN pricing policy, recognizing that low drug prices in either EU or Japanese markets create cross-border policy spillover effects and risks of drug lag and drug loss in both regions.
- Establish a predictable pharmaceutical pricing system that appropriately rewards innovation, supporting the industry to accelerate new drug development and bring new drugs rapidly to patients in Japan and EU, thereby eliminating "drug lag" and "drug loss".
- Optimize reimbursement and payment systems for emerging technologies, including cell and gene therapies, and determine drug prices through a transparent and highly predictable process that properly reflects comprehensive evaluation including clinical efficacy and patient-reported outcomes.
- Secure supply chain of critical raw materials, and ensure pricing matches the growing cost of innovation so that premium pricing for critical raw materials is sustainable when innovations made with those materials are better valued.
- Take disease severity, unmet needs, and ethical and social considerations as additional elements in pharmaceutical value evaluation, and halt any expansion of Health Technology Assessment (HTA) until a thorough third-party review ensures it does not hinder patient access.
- Refrain from using HTA to determine reimbursement eligibility, and establish HTA systems tailored to the characteristics of medical devices.
- In Japan, contribute further to the economic growth of the pharmaceutical industry as a growth and core industry by improving the current pricing system to strengthen rewards for innovation and maintain incentives, in line with the Health and Medical Strategy (2025).
- Limit the scope of off-cycle price revisions to exceptional cases with huge discounts, protect drug prices of innovative patented products from off-cycle price cuts, and abolish the market expansion repricing system to ensure innovation is rewarded.
- Avoid frequent revisions of the pharmaceutical pricing system and secure sufficient lead time before enforcement of any pricing rule changes to ensure long-term business predictability and facilitate investment decisions.

- In Europe, Member States should not set their annual healthcare budgets below the calculated forecast of their population's needs. Clawback taxes should be an exception and not a recurring component of the budget.

The BRT believes that:

- In the current international landscape, pharmaceutical pricing policies in major markets are increasingly interconnected, and the US MFN policy presents an opportunity for the EU and Japan to strengthen their innovation ecosystems through rigorous pricing and regulatory reforms.
- Unless technological innovation is properly evaluated, it becomes increasingly challenging for the industry to continuously create innovative drugs to fulfill unmet medical needs.
- A paradigm shift in the reimbursement and payment systems is needed for transformative cell and gene therapies with the potential to cure diseases.
- Expanding HTA scope without revising the evaluation method, or using HTA to determine reimbursement, could become a barrier to patient access and exacerbate drug lag/drug loss.
- Outline of 2026 drug pricing system reform in Japan, including the verification of HTA and the abolition of the application of market expansion recalculation to similar drugs, has received a positive response from the pharmaceutical industry to a certain extent, but is not sufficient as a system reform.
- It fails to address the critical need for a macroeconomic price adjustment mechanism to counter inflation, and does not fully restore the Price Maintenance Premium to cover all patented drugs, leaving a significant gap in ensuring the sustainability of pharmaceutical innovation.
- The repeated revisions to the pharmaceutical pricing system with as short as three-month notice created significant issues with business predictability, as the development of innovative drugs requires long-term, substantial investment.
- Japan is the only country among key developed markets with pricing rules that provide mandatory annual price reductions for new drugs during the patent period, and the market expansion repricing system disincentivizes companies from investing in treatments for serious diseases with large patient populations.

WP-2 | Recommendation #2

Enabling rapid patient access to innovative medicines and medical technologies

The BRT calls on EU and Japanese Authorities to:

- Enable patients to access innovative diagnostic technologies such as cancer genome profiling (CGP) testing at optimal timings and types of samples using the public insurance system.
- Abolish the 14-day prescription limit for new pharmaceuticals in Japan to accelerate patient access to innovative treatments and simplify packaging needs.
- Increase opportunities and time for constructive and meaningful dialogues between authorities and industry to allow the industry to provide input and ensure transparency of policy decisions.
- In Japan, promote measures including drug discovery infrastructure development, drug loss countermeasures, and establishment of domestic manufacturing systems for regenerative and cell medicine outlined in the "Comprehensive Economic Measures for Strengthening Drug Discovery Capabilities" announced in December 2024.

The BRT believes that:

- Enhanced accessibility to CGP testing at early and optimal timings is expected to improve access to safer and more effective treatments tailored to individual patient needs.
The 14-day prescription limit for newly approved drugs creates unnecessary barriers that delay patient access to innovative treatments.

WP-2 | Recommendation #3

Fundamental strengthening of an internationally competitive drug discovery ecosystem through Japan-Europe collaboration

The BRT calls on the EU and Japanese Authorities to:

- Guarantee strong IP protection as a mandatory enabler for innovation, and facilitate access to investment (national and Foreign Direct Investment) for pharmaceutical and life science projects across both territories with clear numerical targets for R&D funding, startup formation, and clinical trials.

- Accelerate and expand drug discovery venture ecosystem promotion projects while promoting measures to attract outstanding talent and investment, and facilitate introduction of AI, quantum computing, and smart manufacturing to accelerate R&D and manufacturing.
- Promote biosciences sectors more effectively, facilitate exchange for university students and highly skilled workers, and consider establishing pilot shared facilities for biomanufacturing that startups can utilize.
- Incentivize the use of CRO and CDMO facilities located within allied nations, and establish an EU-Japan working group on biosciences and biotechnology to explore joint R&D, regulatory harmonization, and trade facilitation.
- In Japan, ensure efficient collaboration between METI and MHLW, and maintain strong bridges between EU and Japan while implementing respective economic security plans to prevent market isolation.

The BRT believes that:

- The capabilities to create innovative drugs are critically important for both regions' health and economic security, and both are leading scientific powers with top research universities.
- EU and Japan share the problem of lagging behind a growing gap with US and China regarding the speed and level of pharmaceutical innovation, caused by low R&D investment, delays in transitioning to biopharmaceuticals, and shortage of skilled personnel.
- Strong IP protections are essential to foster an environment where drug discovery and biomanufacturing can thrive, yet current policies only attempt to maintain or reduce IP protections, never to improve them.
- The global share of clinical trials conducted in the EU and Japan has decreased, hampering innovation and relocating critical clinical activities overseas.
- 86% of biopharmaceuticals approved in Japan are manufactured at overseas plants or CMOs, and while METI is investing in manufacturing capabilities further measures are required to utilize this effectively.

WP-2 | Recommendation #4

Rule-making for the Use of Digital Sequence Information on Genetic Resources (DSI)

The BRT calls on EU and Japanese Authorities to:

- Maintain contributions to the Cali Fund as "voluntary" based on the voluntary will of companies, as per the COP16 decision. Do not introduce mechanisms such as mandatory contributions or taxation on companies in domestic legislation in both EU and Japan. Prioritize incentive design that allows companies to receive business benefits (such as improved ESG ratings) by making contributions, and promote voluntary contributions from companies.
- Recognize that the guideline of "0.1% of revenue or 1% of profit" indicated at COP16 could lead to withdrawal from related industries, create barriers to new entry, hinder innovation, and seriously affect international competitiveness with companies from non-party countries. Determine contribution rates within a range that does not impede corporate activities, fully considering the actual use of DSI and its contribution to products. Establish exemption measures particularly for companies in the pre-profit stage and fields directly related to public health.
- Agree internationally on the principle of "safe harbor" whereby contributions to the Cali Fund (MLM) fulfill or substitute existing bilateral ABS obligations under the Nagoya Protocol, pandemic agreements, and the Agreement on Biodiversity Beyond National Jurisdiction (BBNJ Agreement). Ensure legal certainty so that companies are not forced to make "double payments" or bear duplicate administrative burdens between domestic laws and multilateral mechanisms.
- Do not expand the definition of "DSI" indefinitely to include amino acid sequences, metabolites, AI-generated data, etc. Clarify the definition of "direct and indirect use" to eliminate the ambiguity where downstream companies and service providers in the supply chain are unexpectedly included. Implement simple and transparent operations based on self-reporting by companies.
- Include industry representatives in the Steering Committee of the Cali Fund to establish a mechanism to monitor whether the use of funds efficiently contributes to biodiversity conservation. Establish regular and official consultation venues to adequately reflect private sector opinions when developing domestic legislation in each country.
- Work closely together toward COP17 in October 2026 to lead the development of rational international rules that do not undermine industrial

vitality. Respond with a common position to access restrictions and mandatory benefit-sharing demands by developing countries.

The BRT believes that:

- Following the decision at the 16th Conference of the Parties (COP16) to the Convention on Biological Diversity in November 2024, the Multilateral Mechanism (MLM) and the "Cali Fund" for benefit-sharing of DSI were officially launched in February 2025. Toward COP17 in Armenia (Yerevan) in October 2026, discussions on the operational details of the fund, contribution rates, and corporate thresholds are now entering their final phase.
- The BRT supports the conservation and sustainable use of biodiversity. However, DSI is a source of innovation in drug discovery, agriculture, biomanufacturing, and other fields, and maintaining an open access environment is essential for achieving the bioeconomy strategies advocated by EU and Japan. Establishing an effective mechanism that does not hinder innovation and respects corporate autonomy is the top priority for 2026. DSI is a "global public good" for solving common challenges (health, food, environment) between the EU and Japan, and it is desirable that it be accessible without restrictions for the advancement of science.
- As initial contribution cases to the Cali Fund are being observed, mechanisms are needed (such as logo usage, tax incentives, positive listing, etc.) that evaluate contributions as "investments" rather than costs to encourage participation by large enterprises.
- Both Japan's "Bioeconomy Strategy" and the EU's "Life Sciences Strategy" position data utilization as a source of competitiveness. Regulatory inconsistencies or excessive burdens regarding DSI pose a risk of threatening the achievement of strategic objectives in both regions.
- COP17 is an important milestone toward achieving the 2030 biodiversity goals (KMGBF), and by demonstrating leadership, EU and Japan can present a global standard for a sustainable and equitable innovation ecosystem.

WP-2 | Recommendation #5

Promoting Innovation to Ensure the Sustainability of Food Systems

The BRT calls on EU and Japanese Authorities to:

Establishment of evaluation and approval systems for new technology pesticides

- Clearly position evaluation items and test requirements as guidelines for biological pesticides and RNA pesticides, taking into account the specificity of the mode of action, degradation behavior in the environment, and potential exposure to non-target organisms.
- Apply simplified data requirements for biological pesticides and RNA pesticides when low risk is reasonably assumed based on scientific risk assessment, thereby ensuring expedited review and predictability.
- Regarding the Food and Feed Safety Omnibus (2025) published by the EU in December 2025, BRT requests the following three points:
 - Establish Minimum Data Requirements (MDR) for biocontrol agents distinct from those for synthetic chemical pesticides.
 - Introduce a Data Call-in procedure modeled after the U.S. EPA's Registration Review.
 - Respect international standards and do not uniformly reject the setting of EU Import Tolerances (EU-I/T) based solely on EU approval criteria.

System development for decarbonization of food production systems

- Improve the efficiency of the evaluation and registration process and enhance the predictability of the review period for feed additives and nutritional optimization technologies.
- Clarify standards and operations regarding the utilization of livestock manure, composting, and biogas production to support circular agriculture initiatives.
- Proceed with the development of MRV (Measurement, Reporting, Verification) methods and data platforms that can be commonly used throughout the food supply chain, premised on public-private utilization.
- Establish a system where environmentally conscious initiatives lead to improved income for producers by developing mechanisms to appropriately certify emission reduction results and pay compensation based on them.

Industrial infrastructure development for new proteins (plant-based, precision fermentation, cellular, insects, etc.)

- Establish a transparent, science-based approval pathway for novel foods related to new proteins, including pre-application consultation, clear

evaluation criteria and submission requirements, and improved transparency of review processes.

- Build a EU-Japan joint platform for mutual referencing of safety and quality assessment data on new proteins, reducing review duplication and exploring joint reviews.
- Expand EU-Japan joint investment in open-access pilot facilities to reduce technical and financial barriers in the pre-commercialization stage of new proteins.

The BRT believes that:

- Agriculture and livestock farming underpin global food supply, yet face mounting pressures from GHG emissions, resource constraints, and climate change. Addressing these challenges requires risk-proportionate regulation, international harmonization, and cross-sector data and facility sharing to unlock investment in new technologies and achieve both environmental sustainability and stable food and protein supplies. While protecting the "quality" and "food culture" of traditional agriculture, by incorporating diverse protein sources (soybeans, legumes, nuts, mushrooms, insects, cellular foods, etc.) and combining efficiency and stable supply through new technologies, it is possible to achieve improved farmer income, market creation, and stable supply.
- EU and Japan should emphasize the general principles of IPM (Integrated Pest Management) and promote prioritization of non-chemical means and risk reduction. With the revision of EFSA's guidance on novel foods, pre-advice and checklists are being developed, improving application quality and enhancing review transparency.
- Through measures against greenwashing and standardization of environmental labeling, carbon footprints, and LCA with third-party verification, corporate environmental considerations will be properly evaluated and business opportunities will expand.
- While agriculture and forestry account for approximately 22% of global GHG emissions, climate finance allocation to these sectors remains at only 4.3%. Strengthening fund mobilization through public-private partnerships and expanding allocation to agriculture, forestry, and fisheries sectors is necessary.
- Public investment in the alternative protein sector globally remains at approximately \$560 million as of 2024, only about 6% of the \$10.1 billion annually needed for the industry to become self-sustaining. In both EU and Japan, high-cost stages such as large-scale demonstration immediately before commercialization and factory construction and equipment installation

are not sufficiently supported, and insufficient public investment is constraining industrial development.

- Advancing biotechnology commercialization requires specialists across manufacturing, safety evaluation, quality control, and regulatory affairs. Yet both Japan and Europe face structural shortages of advanced science and regulatory personnel, leading to deficiencies in review documents, declining data quality, and consequent delays in approvals and commercialization.
- New technology pesticides require preferential regulatory frameworks distinct from conventional synthetic chemicals. While the EU's Food and Feed Safety Omnibus (2025) is a step toward procedural simplification, gaps remain: biocontrol agents beyond microbial pesticides still face data requirements equivalent to synthetic chemicals; the non-binding pre-submission process risks post-submission data gaps and review stagnation; and the EU's refusal to set import tolerances based solely on its own approval criteria creates barriers to food distribution.

WP-2 | Recommendation #6

Promotion of comprehensive support measures for establishing the biomanufacturing industry

The BRT calls on EU and Japanese Authorities to:

Market environment development

- Lead the international standardization of LCA methods to prove the environmental value of bio-based products, establish a mechanism to certify products with recognized environmental value as "GX products," and build incentives for consumers (companies, etc.) that actively use "GX products."
- Mandate priority procurement by national and local governments to narrow the price gap between bio-based and petroleum-based products, and establish common EU-Japan procurement standards.
- Promote product standardization and the creation of mechanisms for international demand creation aimed at price reduction, toward the formation of an international market for bio-based products.
- In the EU's Single-Use Plastics Directive (SUPD) and Packaging and Packaging Waste Regulation (PPWR), environmentally friendly bio-mass material which is bio-degradable in soil and sea water must be appropriately evaluated and excluded from usage restrictions.

Production infrastructure development and human resource development

- In Japan, support the further development and expansion of commercial-scale CMOs/CDMOs compliant with genetic modification regulations.
- Strongly promote a comprehensive financial support package consisting of "equipment investment subsidies," "investment tax reductions," and "running cost subsidies" for biomanufacturing companies making new facility investments.
- In Japan, strengthen the training system for biomanufacturing personnel. In particular, urgent expansion of existing educational bases for human resource development courses using small-scale and pilot-scale culture tanks is needed.

Securing raw materials

- Urgently advance systems for circular utilization of forest resources and resource recovery through separate collection of organic waste under inter-ministerial cooperation toward commercial use of currently available and promising biomass resources (wood, organic waste).
- In Japan, consider establishing a domestic production system utilizing fallow land, etc., for non-edible starch resource crops such as sorghum and cassava to avoid competition with food supply.

- Exempt tariffs and adjustment fees imposed on sugar and starch imported to Japan from overseas when used as raw materials for biomanufacturing.

The BRT believes that:

- The problem is that standardized LCA methods to appropriately evaluate the environmental value of bio-based products do not currently exist domestically or internationally. Once scientific lifecycle assessment becomes possible, the environmental value of bio-based products will become objectively demonstrable.
- The price gap between bio-based products and petroleum-based products is difficult to resolve through private sector efforts alone, and government-led procurement is essential to create stable initial demand.
- Diverging product specifications across countries undermine the competitiveness of bio-based products, making international standardization essential.
- Currently, innovative technological development is progressing in multiple manufacturing-related national projects, but domestic CMOs/CDMOs necessary to deploy these technologies to commercial scale are severely lacking.
- The biomanufacturing industry is in its development stage, and new facility investment involves significant risks for new entrants. In addition to corporate self-help efforts, government support is essential.
- There is a shortage of personnel who can operate pilot and commercial-level manufacturing facilities, and expansion of educational systems in academia is necessary beyond current company-led training.
- Circular utilization of forest resources (covering two-thirds of Japan's land) and organic waste recovery — as already implemented in France — provide practical reference models for securing biomass at internationally competitive prices
- Non-edible crops such as sorghum and cassava, which avoid food competition and are well-suited to Japan's climate, are viable candidates for domestic biomass production on fallow land.

Currently in Japan, tariffs and adjustment fees on sugar and starch are designed to protect domestic food producers; exemptions should apply specifically to imports used as fermentation raw materials for biomanufacturing.

Annex

WP-2 / # A-1 / EJ to EJ

Mutual recognition of Medical Devices should be improved.

The BRT calls on the EU and Japanese Authorities to:

- Streamline approval processes: promote mutual recognition of medical devices between the EU and Japan and reduce duplicative reviews,
- Harmonize requirements for data and documentation: harmonize requirements for clinical trial data, technical documents, and application forms as much as possible between the EU and Japan,
- Harmonize quality management systems: advance adoption of international standards such as ISO 13485 and harmonize requirements for quality management system, and optimize QMS audit, and
- Coordinate post-market surveillance: harmonize safety information sharing and post-market surveillance requirements between the EU and Japan to facilitate product management in both regions.

The BRT believes that:

- If mutual recognition of medical devices progresses between the EU and Japan, the two regions could be regarded as a single market. This would not only enable the medical device industry to develop products more rapidly through streamlined development, approval processes and optimization of QMS audit, but also facilitate cost reductions in development and further global expansion beyond the two regions. This would promote the development of medical devices in both the EU and Japan, enabling the provision of better services, enhancing the global competitiveness of the medical device industries in the EU and Japan, and leading to their further growth.

WP-2 / # A-2 / EJ to E

Measures should be established to secure a stable supply of agricultural chemicals to importing countries.

The BRT calls on the EU Authorities to:

- Not to immediately stop production and exportation of the pesticidal active substances banned in the EU as they are critically important for stable food production in the countries that import them from the EU.

The BRT believes that:

- Pesticides are essential materials for the stable and sustainable production of affordable foods,
- The EU policy not to produce and export the pesticidal active substances banned in the EU under the Chemicals Strategy for Sustainability in the EU New Green Deal will affect the stable and sustainable production of affordable foods globally, while the BRT respects the EU decision,

- Because of their intrinsic hazardous properties of pesticidal active substances, the quality and use of pesticides are highly regulated, and they are only used after intensive risk assessments in respective countries. Any addition or change in the sourcing of pesticidal active substances is strictly controlled and requires demonstration of the equivalence, and thereby stable production and supply of high-quality active substances is critically important, and
- Pesticides are highly regulated in the destination countries and the use of such pesticides in the destination countries is different from that in the EU and thereby the outcomes of the pesticide use are different.

WP-2 / # A-3 / EJ to E

Streamlining household insecticide regulations and promoting bio-based household insecticides derived from natural products.

The BRT calls on the EU and Japanese Authorities to:

- Introduce an expedited review system for natural product-derived insecticides and novel ingredients, drawing on advanced international models such as the U.S. EPA's Biopesticides registration system.
- Implement simplified and expedited application and evaluation procedures specifically for household insecticides, including standardized application documents, clear data requirements, and a system for multiple consultations with regulatory authorities such as ECHA.
- Establish rational data requirements that are aligned with actual usage environments and exposure levels, and introduce exemptions or significant simplifications for additional data requirements for ingredients with a long history of confirmed safety.

The BRT believes that:

- The current application and evaluation procedures for household insecticides under the EU-BPR (Biocidal Products Regulation) are excessively complex, imposing significant burdens on both applicants and regulatory authorities, and often resulting in prolonged review periods. Furthermore, interpretations and enforcement of the regulation can vary among EU Member States, leading to a lack of consistency and transparency in the review process.
- Although household insecticides are required to provide detailed toxicity and environmental impact data at a level equivalent to agricultural or professional-use pesticides, many of these data requirements do not sufficiently account for actual use patterns or consumer exposure levels, creating a disconnect from realistic risk assessment. In particular, even for ingredients with a long history of confirmed safety, the requirement to submit new data results in excessive financial burdens due to high testing costs.
- Under the current system, natural product-derived insecticides and novel ingredients are subject to the same review criteria as conventional chemical

products. This results in significant time and cost before reaching the market, acting as a barrier to market entry. By referencing expedited and rational review systems based on scientific evidence, such as the U.S. EPA's Biopesticides registration system, it is possible to expand consumer choices and foster corporate innovation.

- As excessive regulation and review delays risk reducing the availability of safe and effective household insecticides in the EU market, streamlining the system and promoting innovation are essential for consumer protection, the promotion of EU-Japan trade, and sustainable market development.

WP-2 / # A-4 / EJ to EJ

Legal clarity for and appropriate regulation for agricultural innovation, including genetically modified crops and genome-edited crops, should be established.

The BRT calls on the EU and Japanese Authorities to:

- Regulate agricultural technologies, including crop protection, genetically modified (GM) and genome-edited (GE) crops in a science-based and proportionate manner,
- Advance and adhere to global harmonization of genetically modified organisms' risk assessments, and support the Global Low Level Presence Initiative,
- Provide legal clarity on the status of techniques such as genome editing and corresponding labelling requirements (e.g., for genome edited derived food), and
- Work with industry and other stakeholders to increase trust in the regulatory science and gain greater societal acceptance.

The BRT believes that:

- A fact-based platform for dialogue and sharing of information as well as a risk-proportionate, predictable, science-based treatment of new technologies is required.
- Taking a science-based and proportionate regulatory approach to agricultural technologies will aid in gaining societal acceptance and help weed out misinformation, and
- Ongoing regulations regarding data requirements for emerging technologies are not fully updated resulting in duplication of studies.

WP-2 / # A-5 / EJ to EJ

Environments to enhance development of treatments and vaccines for infectious diseases should be improved, and incentives for AMR research should be reinforced.

The BRT calls on EU and Japanese Authorities to:

- Protect and respect intellectual property rights of vaccines, diagnostics, and therapeutics to maintain strong incentives for innovation and ensure a sustainable and secure supply of these critical medical products.
- Continuously promote research and development for infectious diseases — with particular emphasis on antimicrobial resistance (AMR) — by reinforcing financial and regulatory incentives for industry, including SMEs, to invest in this strategically important area.

The BRT believes that:

- Respect for intellectual property rights is fundamental to stimulating R&D and ensuring supply security; waiving IP rights would undermine the capacity to innovate and deter long-term investment in infectious disease preparedness.
- The number of drug-resistant bacteria is increasing globally, with deaths potentially rising to 10 million annually by 2050, making AMR an urgent and shared public health priority for both the EU and Japan.
- The European Commission's initiative to step up EU actions to combat AMR, and Japan's 2024 Basic Policy promoting incentives for antimicrobial development, are positive and necessary steps that should be further strengthened through concrete and sustained measures.
- Further public support — including targeted measures for SMEs — is necessary to hedge R&D risks, attract private investment, and secure adequate resources dedicated to solving the AMR challenge before it becomes a global health crisis.

WP-2 / # A-6 / EJ to J

Health Technology Assessment (HTA) for medical devices should be carefully applied with evaluation frameworks tailored to the unique characteristics of medical devices.

The BRT calls on Japanese Authorities to:

- Consider evaluation methods specifically tailored to the characteristics of medical devices, which differ fundamentally from pharmaceuticals in terms of innovation cycle, mode of action, and evidence generation.
- Accumulate sufficient real-world information on evaluated devices before expanding the scope of HTA application, ensuring that decisions are grounded in robust and representative evidence.
- Ensure flexible and transparent communication between analysis teams and industry throughout the HTA process, and guarantee meaningful industry involvement at appropriate stages of evaluation.
- Be mindful of the significantly shorter improvement and iteration cycles of medical devices compared to pharmaceuticals, and reflect this in the design of evaluation timelines and data requirements.

The BRT believes that:

- HTA for medical devices should remain supplementary and complementary to the existing pricing and reimbursement system; using HTA as a primary determinant of reimbursement eligibility would create serious barriers to patient access and risk exacerbating medical device lag in Japan.
- Expanding the price adjustment range through HTA without adequately revising the evaluation methodology would negate the recognized value of medical innovations and undermine incentives for companies to introduce devices to the Japanese market.
- HTA frameworks designed primarily for pharmaceuticals are not directly applicable to medical devices and should not impose excessive or disproportionate burdens — including in terms of human resources, data generation, and timelines — on the medical device industry.

WP-2 / # A-7 / EJ to J

A foundation for utilizing medical information and Real-World Data (RWD) should be established, and the legal framework should be improved with reference to EU initiatives such as the European Health Data Space (EHDS).

The BRT calls on Japanese Authorities to:

- Promote the standardization and alignment of relevant laws and regulations, such as the Personal Information Protection Act and the Clinical Trials Act, while referencing initiatives such as the European Health Data Space (EHDS). This should foster a regulatory environment premised on more open data utilization for both primary and secondary purposes to facilitate data-driven innovation and robust evidence generation across the healthcare ecosystem.
- Develop infrastructure for systematically collecting, integrating, and analyzing RWD — including genomic data and medical imaging data — based on the diverse needs of researchers, regulators, healthcare providers, and industry.

The BRT believes that:

- Integration of accurate and comprehensive RWD enables robust scientific evidence for drug discovery, the development of innovative care models, and high-quality individualized medical decision-making.
- The US, Europe, and China are advancing RWD utilization rapidly and systematically; the EU's EHDS represents a model framework enabling cross-border health data access and use that Japan should learn from and adapt to its own context.
- While Japan is advancing medical digital transformation (DX), significant improvements are needed to enable life-course data integration and to facilitate access to genomic and medical imaging data for research and regulatory purposes.
- Urgent priorities include data standardization, interoperability across institutions and systems, data quality assurance mechanisms, the standardization and alignment of relevant laws and regulations, such as the Personal Information Protection Act and the Clinical Trials Act, while referencing, and the

establishment of secure data storage and governance environments that preserve and reinforce patient trust.

WP-2 / # A-8 / EJ to J

New technologies including biopesticides and biostimulants should be further promoted in Japan, and the use of antimicrobials and chemical soil fumigants in agriculture should be reduced.

The BRT calls on Japanese Authorities to:

- Actively promote the adoption of biopesticides, biostimulants, and other biological alternatives in Japanese agriculture, by establishing clear regulatory pathways, streamlined approval procedures, and appropriate incentives for their use.
- Encourage a sustained and measurable reduction in antibiotic use in agriculture through regulatory guidance, best practice frameworks, and support for farmers in transitioning to alternative crop protection approaches.
- Promote the development and adoption of technologies that reduce reliance on soil fumigants — which currently account for approximately 50% of total chemical pesticide inputs in Japan — through support for innovative alternatives including safer chemicals with higher selectivity, crop rotation systems, and improved soil health diagnostic tools.
- Clearly position biostimulants not merely as inputs aimed at reducing environmental burden, but as foundational technologies that enhance agricultural resilience and productivity, and establish an enabling environment for the sound, medium- to long-term development of the biostimulant market, including support for research and development, demonstration and pilot testing sites, and technical dissemination and guidance for farmers.

The BRT believes that:

- The reduction of antimicrobial use in agriculture is not only an environmental and sustainability imperative, but also a critical measure in the global fight against antimicrobial resistance (AMR), and Japan has both an opportunity and a responsibility to lead in this area.
- Biopesticides, biostimulants, and biological crop protection technologies represent proven, science-based alternatives that can maintain agricultural productivity while significantly reducing the environmental and health burden of conventional chemical inputs.
- Supporting the transition to these technologies requires not only regulatory reform but also investment in farmer education, agronomic advisory services, and collaborative research between public institutions and industry.
- Biostimulants constitute key productivity-enhancing technologies that help stabilize crop yield and quality under challenges such as climate change, water constraints, and soil degradation, and by strengthening the foundation of agricultural production, they contribute to enhancing sustainability while

underpinning Japan's long-term agricultural productivity and international competitiveness.

WP-2 / # A-9 / EJ to J

Reviewing periods for biotechnology products (GMOs) in Japan should be shortened to accelerate farmers' access to agricultural innovation

The BRT calls on Japanese Authorities to:

- Shorten review periods for GMO approval through data harmonization and the acceptance of English-language summaries and submissions, reducing administrative burden on applicants without compromising the scientific rigor of safety evaluations.
- Leverage existing safety evaluation results and data packages from trusted foreign regulatory authorities to eliminate unnecessary duplication of review efforts and accelerate Japan's approval timelines for products already approved in major markets.
- Exclude requirements for local confined field testing for additional crops and traits where sufficient and scientifically robust safety data from the cultivation country or other recognized regulatory bodies is already available.

The BRT believes that:

- Novel seed and crop technologies are vital for food security, agricultural sustainability, and reducing the environmental impact of farming; regulatory delays in Japan create technology gaps that directly disadvantage Japanese farmers relative to their international counterparts.
- Japan and China are currently the only major agricultural markets that require local confined field testing for imported GMO products; the EU, Korea, and other key markets accept data generated in the cultivation country, placing Japan at a competitive and practical disadvantage.
- Streamlining Japan's GMO review process does not compromise safety standards, but rather modernizes the regulatory framework in line with international best practice and reduces unnecessary barriers to the timely adoption of beneficial agricultural technologies.

WP-2 / # A-10 / EJ to EJ

Harmonized regulation for Good Computational Modelling & Simulation Practice (GSP) for medical products should be established.

The BRT calls on EU and Japanese Authorities to:

- Actively engage with the International Medical Device Regulators Forum (IMDRF) to advance the international standardization of Good Simulation Practice (GSP) for medical devices and other medical products, referencing the

concept of "Model Credibility" (e.g., as discussed in ICH), and ensuring that in silico methodologies are recognized as scientifically valid within regulatory frameworks.

- Involve Japanese stakeholders and policymakers in the harmonization of GSP standards and their integration with HTA and regulatory submission frameworks, building on and continuing the valuable contributions of Japan Pharmaceutical Manufacturers Association (JPMA) and relevant Japanese institutions in this field.

The BRT believes that:

- In silico methodologies including computational modelling and simulation are scientifically validated alternatives and complements to in vitro, ex vivo, and in vivo experiments, offering transformative advantages in efficiency, cost reduction, speed, and ethical responsibility in the development of medical products.
- The adoption of harmonized GSP standards delivers benefits across three interconnected dimensions: *Reducing* the number of physical experiments required through faster and more targeted computational testing; *Refining* the quality and predictive accuracy of experiments where they remain necessary; and *Replacing* physical experiments within a scientifically valid scope, upon ensuring the robustness of in silico methods through integration with New Approach Methodologies (NAMs) and novel in vitro systems.
- Harmonized international GSP standards are essential to enable consistent regulatory acceptance of in silico data across the EU and Japan, preventing fragmentation that would otherwise impose duplicative costs on innovators and slow the development and approval of safer, more effective medical products.

WP-2 / # A-11 / J to EJ

Mutual recognition of GMP for Animal Health products should be ensured.

The BRT calls on EU and Japanese Authorities to:

- Agree on mutual recognition of marketing authorizations for veterinary medicinal products between the EU and Japan, reducing duplicative regulatory requirements and accelerating the availability of innovative and effective animal health treatments in both markets.
- Include veterinary medicinal products within the scope of the existing Mutual Recognition Agreement (MRA) framework, establishing a clear, efficient, and legally robust pathway for the mutual recognition of GMP certification for animal health products.

The BRT believes that:

- Mutual recognition of GMP certification for veterinary medicinal products will enable significantly faster market access to new and beneficial treatments in both the EU and Japan, directly improving animal health outcomes and welfare standards in both regions.



- Aligning veterinary product regulatory frameworks between the EU and Japan supports the broader strategic goals of regulatory harmonization and partnership, strengthens the international competitiveness of the animal health industry in both regions, and sets a positive precedent for further regulatory convergence in adjacent areas.