

JBCE POSITION PAPER ON THE EUROPEAN BIOTECH ACT

INTRODUCTION

The Japan Business Council in Europe (JBCE) welcomes the opportunity to present its views on the European Commission's proposal for a European Biotech Act.¹ JBCE supports the proposal's ambitious and innovation-oriented framework for the competitiveness of the European Union (EU)'s biomanufacturing sector. In particular, JBCE welcomes the proposal's commitment to rewarding innovation, as well as its measures to accelerate and simplify clinical trials, foster a more innovation-friendly regulatory environment, strengthen access to scale-up capital, and promote biomanufacturing in the EU.

We believe that the proposal's policy objectives will be achieved more effectively by attracting investment from outside Europe and by ensuring smooth market access for innovative products developed and manufactured abroad. JBCE therefore calls on the co-legislators to give due consideration to the concerns and proposals set out in this paper.

KEY MESSAGES

- ❖ **Strengthening investment incentives and cooperation with trusted partners:** JBCE calls for the conditions for extending the supplementary protection certificate laid down in **Article 27** to be made more flexible, so that it functions as an effective, non-discriminatory incentive for investment from outside the EU. JBCE also calls for the proposal to better reflect the strategic value of trusted partners, by amending the recognition criteria for Strategic Projects under **Article 3** to reward supply-chain resilience and diversification rather than strict localisation, and by broadening international cooperation under **Article 30**.
- ❖ **Broadening the definition of biomanufacturing:** JBCE calls for the definition in **Article 2(1)(5)** to cover not only commercial-scale manufacturing but also clinical-stage production and technology transfer, which are essential to bridging research and commercial production.
- ❖ **Simplifying, clarifying and ensuring the feasibility of regulatory requirements:** JBCE calls for the amendment to the Clinical Trials Regulation to deliver genuine harmonisation among Member States. JBCE also calls for the scope of the biosecurity provisions in **Chapter VIII** to be clarified and kept proportionate, in line with international frameworks. JBCE further suggests that the growing number of frameworks that may overlap be made coherent and clearly prioritised, in particular for the use of AI.

¹ [Proposal for a European Biotech Act](#)

1. Refining the SPC extension conditions to ensure an effective and non-discriminatory investment incentive

JBCE acknowledges the objective of **Article 27**, namely, to strengthen investment incentives for innovative biological medicinal products and advanced therapy medicinal products (ATMPs) through a 12-month extension of the supplementary protection certificate (SPC). However, the current provision risks having the opposite effect. It could deter non-EU innovators from investing in Europe and accelerate the very outflow of investment in the biotechnology sector that the proposal is intended to prevent. JBCE therefore calls on the co-legislators to address the following two points.

a. **Introducing non-discriminatory and flexible eligibility criteria**

Article 27(1) imposes four cumulative conditions. In particular, **point (d)** requires at least one manufacturing step to occur in the EU, thereby turning what should be a non-discriminatory, innovation-oriented incentive into a structure defined by manufacturing location. Companies making substantial research and development investments, conducting clinical development and creating employment in Europe may nevertheless be excluded from the SPC extension solely because their manufacturing network lacks an EU-based step. These networks, which have been optimised over decades in line with regulatory changes, supply continuity and technological capabilities, cannot be reconfigured in the short term. This is particularly evident when manufacturing takes place in trusted partner countries such as Japan, whose biotechnology supply chains are closely interconnected with those of Europe.

JBCE calls on the co-legislators to introduce more flexibility into **Article 27(1)**: (i) by making the criteria non-cumulative, or at least (ii) by reducing the number of criteria that must be met cumulatively (for instance, by requiring that two of the four criteria be met rather than all of them), thereby enabling companies with diverse forms of engagement in Europe to qualify for the incentive according to their respective contributions, and (iii) by ensuring that manufacturing in trusted partner countries, including Japan, is deemed equivalent to manufacturing within the EU.

Separately, JBCE calls for **point (d)**, which requires that at least one manufacturing step take place in the EU, to be modified, so that the condition, which was originally intended to be required from the marketing authorisation stage, is deferred to a later stage, for example, several years before the expiry of the patent or SPC. For companies based outside the EU, manufacturing within the Union is generally the medium-to-long-term result of commercial success rather than a precondition for it, and the decision to establish such manufacturing is usually made at a later stage of the product's lifecycle. Deferring the timing of this requirement would effectively encourage companies to invest in EU manufacturing at the appropriate stage of the product lifecycle.

In this way, the EU can ensure that innovative products are manufactured on its territory in the medium or long term, without abruptly disrupting established global supply chains.

b. Clarifying the terms "distinctly different"

JBCE calls for the term "distinctly different" in **Article 27(1)(a)** and **(b)** to be defined in alignment with the existing European Medicines Agency (EMA) concepts, and for clear guidance to be issued promptly after adoption. Indeed, the term is not currently defined in the proposal, and its relationship with existing EMA concepts is not articulated. This uncertainty, when making investment decisions, will deter investment in higher-risk innovative biological medicinal products and ATMPs in the EU.

2. Reflecting the strategic value of trusted partners in securing strategic autonomy and resilience

We support the proposal's positioning of the EU's strategic autonomy and supply chain resilience among its principal objectives. However, the current provisions do not fully translate this ambition into practice.

In particular, existing regulatory cooperation frameworks with trusted partners such as Japan (including the EU-Japan Economic Partnership Agreement, the Mutual Recognition Agreement on Good Manufacturing Practices for medicinal products, and the EMA-PMDA regulatory data-sharing framework) risk being underutilised rather than leveraged for Europe's competitiveness and strategic autonomy. JBCE strongly believes that the EU and Japan can achieve resilience together, rather than separately.

In addition, a competitive and resilient EU biotechnology sector depends not only on biological medicines themselves but also on the surrounding technologies that support their development and manufacturing, including the specialised equipment and research-use tools, which should not be disadvantaged on the basis of origin.

a. Better reflecting the resilience logic and the value of cooperating with trusted partners

While we acknowledge the importance of localisation for biotechnology manufacturing, the proposal is heavily weighted towards intra-EU concentration and does not sufficiently reflect the resilience logic, which calls for diversification away from single-source dependency and cooperation with trusted partners. Such concentration does not, by itself, guarantee resilience: events such as pandemics and geopolitical disruptions can themselves expose EU-concentrated supply chains to significant vulnerabilities.

More specifically, the recognition criteria for Strategic Projects and High-Impact Strategic Projects place excessive weight on uniform third-country dependency reduction, leaving no room to reflect the strategic value of cooperation with trusted partners. **Article 30** on international cooperation, in turn, is limited to biosimilars, missing wider opportunities across biotechnology medicinal products.

b. Amending strategic projects recognition criteria and broadening the scope of international partnerships

JBCE calls on the co-legislators to: amend the wording of **Article 3(1)(a)(iv)** from “reducing dependencies on third-country suppliers for key biotechnology inputs and intermediates” to “contributing to diversification of supply chains” and recognise Strategic Projects and High-Impact Strategic Projects on the basis of supply chain resilience, including via partnerships with trusted partners, rather than strict geographic requirements.

JBCE further calls on the co-legislators to broaden the scope of **Article 30** from biosimilars to the entire field of biotechnology medicinal products, aligning international cooperation with the Proposal’s wider objectives.

3. Expanding the definition of “biomanufacturing” to include the manufacturing capacity supporting the health biotechnology ecosystem

JBCE calls on the co-legislators to expand the definition of “biomanufacturing” in **Article 2(1)(5)**, currently limited to “the production of biotechnology products at a commercial scale”, so that it also covers manufacturing that supports the health biotechnology ecosystem, including production at the clinical development stage, investigational batches, technology transfer and bio-industrial applications. Such pre-commercial manufacturing underpins the development and scale-up of biological medicinal products, vaccines, diagnostics and ATMPs, enabling a seamless transition from research to commercial production, consistent with the proposal’s own objectives of strengthening the Union’s competitiveness and supply chain resilience.

4. Coupling clinical trials acceleration with genuine harmonisation among Member States

JBCE calls for genuine harmonisation among Member States to be made a priority objective of the amendment to the Clinical Trials Regulation (CTR), alongside the shortening of approval timelines. We welcome both the acceleration measures introduced through the amendment and the steps already being taken to ensure consistency in its application. If

inconsistencies among Member States nonetheless arise in the interpretation and operation of CTR provisions, in ethical review, or in mutual recognition between Member States, they could risk turning those measures into “accelerated fragmentation” and undermining the predictability that companies require within the Single Market.

5. Clarifying the scope of the biosecurity provisions and aligning them with existing international standards

JBCE calls for the scope of “biotechnology products of concern” in **Annex I** and the reach of the reporting obligations under **Articles 46, 47** and **50** to be clarified and aligned with existing international standards. We support the policy objective of the biosecurity provisions in **Chapter VIII**. However, the current provisions could impose a disproportionate burden on legitimate research and development activities, particularly those of smaller research institutions and companies, and undermine predictability for companies’ compliance with existing international frameworks.

6. Ensuring coherence and clear prioritisation across regulatory frameworks that may overlap, in particular for AI

JBCE welcomes the proposal’s ambition to enable the responsible use of AI and data across the biotechnology lifecycle. At the same time, the growing number of frameworks that may overlap, such as the Cyber Resilience Act, the Data Act and the AI Act, calls for clear prioritisation and coherence. JBCE therefore invites the co-legislators and the Commission to keep these requirements consistent and predictable, in particular for AI.

CONCLUSION

JBCE reaffirms its support for the objectives of the proposal: to foster innovation, strengthen competitiveness and secure supply chain resilience. JBCE calls on the co-legislators to carefully consider the concerns and proposals set out above, and to make the necessary adjustments to ensure that the proposal effectively achieves these objectives.

JBCE stands ready to continue its constructive dialogue with the European Commission, the European Parliament and the Council of the European Union throughout the legislative process.

ABOUT JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organisation representing the interests of over 110 multinational companies of Japanese parentage active in Europe. Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceuticals, textiles, and glass products.

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