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Public Questionnaire informing the European Biotech Act

Fields marked with * are mandatory.

Introduction

The European Biotech Act

Biotechnology and biomanufacturing hold great promise for advancing competitiveness and innovation within the European Union (EU). As previously acknowledged in the Communication on Biotechnology and Biomanufacturing (March 2024) and the reports by Enrico Letta (April 2024) and Mario Draghi (September 2024), it is necessary to address the challenges faced by European companies, users and consumers, and all stakeholders involved to boost the technological advancement, competitiveness and economic growth of the EU.

To this end, the Commission has announced in the 2024-2029 political guidelines a new European Biotech Act, aimed at creating an enabling environment to make it easier to bring biotech products from the laboratory to the factory and then onto the market, while maintaining the highest safety standards for the protection of the population and the environment.

EU policy initiatives relevant for this sector are for example the Strategy for European Life Sciences, the Competitiveness Compass, new EU Bioeconomy Strategy, the AI in science Strategy, the Vision for Agriculture and Food, the European Innovation Act, the EU Start-Up and Scale-up Strategy, the Union of Skills and the Savings and Investment Union. Some of these are currently still under development and the European Biotech Act will be defined in synergies with them.

The public consultation

The European Commission is launching a **public consultation** on the European Biotech Act in the form of an online questionnaire. The aim is to gather evidence and views from stakeholders across all relevant sectors of biotechnology and biomanufacturing, including the medical and pharmaceutical, agricultural, food and feed, industrial, environmental and marine sectors. Your feedback is crucial for identifying the most important challenges and barriers that could be addressed by the Act and for shaping targeted policy actions.

Instructions

The first section of the questionnaire contains questions about you or the organisation you represent, which is then followed by questions on the regulatory and non-regulatory environment in the EU to inform the policy-

making process of the European Biotech Act.

Whenever possible, please substantiate your replies with data and sources of information or practical examples.

This questionnaire is available in all EU official languages and you can reply in any EU official language. You can pause at any time and continue later. You can download your contribution once you have submitted your answers.

About you

* Language of my contribution

- ○ Bulgarian
- ○ Croatian
- ○ Czech
- ○ Danish
- ○ Dutch
- ◉ English
- ○ Estonian
- ○ Finnish
- ○ French
- ○ German
- ○ Greek
- ○ Hungarian
- ○ Irish
- ○ Italian
- ○ Latvian
- ○ Lithuanian
- ○ Maltese
- ○ Polish
- ○ Portuguese
- ○ Romanian
- ○ Slovak
- ○ Slovenian

- ○ Spanish
- ○ Swedish

* I am giving my contribution as

- ○ Academic/research institution
- ◉ Business association
- ○ Company/business
- ○ Consumer organisation
- ○ EU citizen
- ○ Environmental organisation
- ○ Non-EU citizen
- ○ Non-governmental organisation (NGO)
- ○ Public authority
- ○ Trade union
- ○ Other

You have identified yourself as a business association or a company/business.
Please indicate whether you belong to one of the following areas:

- ☑ Company conducting research and/or development in biotechnology and/or biomanufacturing
- ☐ Company supplying materials or equipment to the biotechnology manufacturing sector (e.g. strains, bioreactors)
- ☐ Biotechnology manufacturer
- ☐ Biotechnology distributor or retailer
- ☐ Other

Do you identify yourself as a private investor (e.g. venture capitalist, business angel)?

- ○ Yes
- ◉ No
- ○ I don't know/I'd rather not say

Are you or the organisation you represent part of a **cluster** or of a **cluster organisation**?

'**Clusters** are groups of firms, related economic actors, and institutions located near each other and with sufficient scale to develop specialised expertise, services, resources, suppliers and skills.' [**link to definition of clusters**]

'**Cluster organisations** are the legal entities that support the strengthening of collaboration, networking and learning in innovation clusters and act as innovation support providers by providing or channelling specialised and customised business support services to stimulate innovation activities, especially in SMEs. They are usually the actors that facilitate strategic partnering across clusters.' [**link to definition of cluster organisations**]

- ○ Yes
- ○ No
- ◉ I don't know/Not applicable

* This questionnaire covers **all areas of biotechnologies.** Please indicate the **sector s** that are relevant to you or the organisation you represent, or which you have most knowledge on.

You can select multiple sectors.

Please note that your answers to the questionnaire will be analysed in relation to the sector(s) you have selected.

- ☑ Medical/pharmaceutical
- ☐ Agricultural
- ☐ Food/feed
- ☐ Industrial
- ☐ Environmental
- ☐ Marine
- ☐ Bioinformatics
- ☐ Biotechnology for defence and security

- [ ] Other areas of biotechnology
- [ ] Not applicable

If a different sector of biotechnology is relevant to you or the organisation you represent, please specify.

*First name

Kateryna

*Surname

Khmilevska

*Email (this won't be published)

kateryna.khmilevska@efpia.eu

*Organisation name

255 character(s) maximum

Vaccines Europe (VE)

*Organisation size

- (•) Micro (1 to 9 employees)
- ( ) Small (10 to 49 employees)
- ( ) Medium (50 to 249 employees)
- ( ) Large (250 or more)

Transparency register number

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

53073567234-18

*Country of origin

Please add your country of origin, or that of your organisation.

This list does not represent the official position of the European institutions with regard to the legal status or policy of the entities mentioned. It is a harmonisation of often divergent lists and practices.

- Afghanistan
- Åland Islands
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Saint Martin
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka

- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Türkiye
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu

- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

* Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- **Anonymous**

  Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

- **Public**

  Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

☑ I agree with the personal data protection provisions

Questions regarding a future European Biotech Act

*Mandatory questions are indicated with an *.*

Please note that the answers to the questionnaire will be analysed in relation to the area(s) you have selected in the 'About you' section.

Section 1 - General views on biotechnology

Biotechnology can be defined as the application of science and technology to living organisms, as well as parts, products and models of them, to alter living or non-living materials for the production of knowledge, goods and services.

Biomanufacturing is the use and conversion of biotechnology and biological resources into chemicals, products and energy.

Q1. Considering **biotechnology and biomanufacturing products overall,** to what extent do you agree with the following:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
* Biotechnology and biomanufacturing products can **positively impact the EU economy**	○	○	○	○	◉	○
* Biotechnology and biomanufacturing can **positively impact the EU society**	○	○	○	○	◉	○
* Biotechnology and biomanufacturing can **positively impact the environment**	○	○	○	◉	○	○
* Biotechnology and biomanufacturing products that reach the EU market are **safe and secure**	○	○	○	◉	○	○
* **Information to users and consumers** on biotechnology and biomanufacturing is available and accessible	○	○	◉	○	○	○
* Consumes are **willing to pay a price premium** for biotechnology and biomanufacturing products	○	○	◉	○	○	○

Section 2 - The regulatory environment in the EU

The following questions seek to collect views on the regulatory environment in the EU, in particular the perceived regulatory barriers.

Q1. Taking into account recent initiatives and legislation adopted or under discussion at EU level, to what extent do you agree with the following statement: **EU rules lead to regulatory barriers for biotechnology and biomanufacturing products to reach the market in the following phases:**

Not all phases may be applicable to all biotechnology and biomanufacturing products.

This specific question covers EU rules, i.e. legislation stemming from the European Union.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
* In early-stage or pre-clinical development	○	○	○	○	◉	○
* In product development	○	○	○	○	◉	○
* In pre-commercial testing or clinical trials	○	○	○	○	◉	○
* In the assessment and in obtaining authorisation to market products	○	○	○	○	◉	○
* In techno-economics (outside of health) or health technology assessment	○	○	○	○	◉	○
* In commercialising products	○	○	○	○	◉	○
* In scaling-up production or manufacturing	○	○	○	○	◉	○
* In post-market activities, including monitoring and surveillance	○	○	○	○	◉	○

Q2. Please indicate **other phases of the innovation and manufacturing cycle** where there are **regulatory barriers** caused by EU rules.

600 character(s) maximum

A coherent, end-to-end EU framework is needed for all medicinal products, including those spanning multiple legislative areas such as combination products, ATMPs and radioligand therapies. Fragmented pathways create duplication, inefficiency, and weaken knowledge continuity. Environmental and GMO rules targeting GMO crops hinder recombinant vaccine and therapy development. The manufacture is also inhibited by overlapping chemicals, food and environmental legislation. Frameworks must adapt to scientific progress and enable agile manufacturing to sustain EU competitiveness and patient access.

Q3. Please substantiate your statements with **additional evidence** on the **challenge s** resulting from the **EU regulatory environment**.

600 character(s) maximum

● Regulatory assessment procedures for clinical research are slow, lack harmonisation allow for duplication of assessment, fragmented timelines, and complex due to multiple national-level actors, overlapping requirements, and lack of alignment across frameworks. ● Fragmented and non-interoperable IT systems hinder data reliability, efficiency, and coordination. ● Limited linkage between national and EU advice, fragmented oversight, and slow uptake of new manufacturing technologies hinder innovation and scale-up. ● Environmental and chemical legislation adds further complexity and burden.

The following questions seek to collect views on possible ways forward to simplify and streamline the EU regulatory environment applicable to biotechnology and biomanufacturing products.

* **Q4.** In your view, what **actions at EU level** are necessary to **improve the regulatory environment for biotechnology and biomanufacturing** in the EU? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

We need a connected EU regulatory system that keeps pace with innovation and works seamlessly from start to finish. One governance: EMA in a strengthened, orchestrating role across the product lifecycle, ensuring coordination, reliance, and risk-based oversight, driving uptake of advanced manufacturing technologies. One process: E2E, connected, and adaptive processes spanning all stages of research and development. One evidence lifecycle: dynamic, integrating complementary data sources. One system: interoperability and “enter data once, use many times".

The following questions refer to views or experience with regulatory environments in countries outside of the EU and of the EEA (Norway, Iceland and Liechtenstein).

Q5. To what extent do you agree that the EU regulatory environment in comparison with some of the countries outside of the EU...:

For each statement, you will have the possibility to indicate the third country(ies) your answer refers to.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
... is more **predictable**	○	◉	○	○	○	○
... is **less complex and clearer**	◉	○	○	○	○	○
... leads to lower **costs** for **complying** with the regulation	◉	○	○	○	○	○
... **enables** biotechnology and biomanufacturing products to **reach the market faster**	◉	○	○	○	○	○
... ensures a **higher level of safety and security**	○	○	◉	○	○	○

Q5a. Regarding predictability: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

Overall predictability in the EU declines when new or revised regulations are implemented nationally, leading to “gold-plating” and divergent timelines, as seen with GDPR. Despite harmonised frameworks, differences across 27 Member States persist — for example under the CTR, where MS decide on the timelines differently, averaging around 112 days, which is far too long. While the EMA’s centralised procedure provides predictability and transparency, broader EU processes remain less timely and flexible, with limited expedited options compared to global peers.

Q5b. Regarding complexity and clarity: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

Multiple regulators, bodies and IT systems operate without integrated governance, leading to duplication and unclear accountability. Rigid, milestone-based processes limit adaptability, while evolving science and technology expose overlaps between frameworks (CTR/IVDR/MDR, SoHO/ATMP), persistent national rules (e. g. GMO), and unclear applicability (e.g. AI Act). Environmental and chemical legislation further adds complexity and reduces coherence.

Q5c. Regarding compliance costs: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

Compared to the some other countries / regions (e.g. US, Japan), compliance costs in the EU are higher due to: ex-ante assessment design for low-risk post-marketing activities, while other regions apply risk-based approaches; unique EU-specific requirements such as translations, environmental risk assessments, multiple system data entries (xEVMPD, PML, CTIS) and CCI redactions; and a lack of reliance and coordinated approaches, as seen in multi-country clinical trials.

Q5d. Regarding speed of reaching the market: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

In addition to the CTA that exceeds 110 days (and longer for ATMPs),and low adoption of accelerated pathwayspost-approval,pricing,reimbursement and access disparities further delay patient availability averaging 578 days,with only 29% fully reimbursed.Creating market pull for innovation,ensure proper implementation of the Transparency Directive across all MS can create more predictable,and transparent pricing and reimbursement processes that are conducive to innovation.The EU HTA must prove its value by streamlining 27 national evidence frameworks into one;otherwise, it risks becoming barrier

Q5e. Regarding the level of safety and security: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

Europe's safety and quality standards remain strong, but limited use of risk-based oversight and fragmented procedures add complexity without enhancing protection. Applying proportionate, risk-based assessments—particularly for clinical trials—would maintain safety while reducing duplication and administrative burden. Better coordination across EU authorities would ensure consistency and trust in decisions.

Q6. Please indicate any **other relevant factors that characterise the regulations in non-EU countries** and that are applicable to biotechnology and biomanufacturing products.

600 character(s) maximum

Non-EU countries increasingly use reliance, work-sharing and collaborative pathways with accelerated reviews (e.g. Project Orbis, Access Consortium, Uk ILAP and innovation passport). Many have strategic biotech and life science plans creating coherent regulatory frameworks, supportive infrastructures and incentives for advanced manufacturing and R&D (e.g. China, Canada, UK, India, Saudi Arabia). Regulatory sandboxes in Canada, Singapore, UK and Japan generate practical insights to future-proof innovation.

Section 3 - Access to capital

The following questions seek to collect views on access to public and private capital and related barriers.

Q1. To what extent do you agree it is **easy to access the following types of public investments in the EU:**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Grants and subsidies (e.g. at EU level: HORIZON, EU4Health)	○	◉	○	○	○	○
* Debt and equity instruments (e.g. European Innovation Council, European Investment Bank, Strategic Technologies for Europe Platform)	◉	○	○	○	○	○
* Commercialisation support	○	◉	○	○	○	○
* Support to capacity expansion	○	◉	○	○	○	○

Q2. To what extent do you agree it is **easy to access the following types of private investments in the EU:**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
* Angel investors	○	○	○	◉	○	○
* Venture capital: Start-up/early stage (Series A)	○	◉	○	○	○	○
* Venture capital: Expansion stage (Series B)	○	◉	○	○	○	○
* Venture capital: Growth stage (Series C, etc)	○	○	◉	○	○	○
* Debt financing	○	◉	○	○	○	○
* Private equity	○	○	◉	○	○	○
* Strategic research or sales partnerships and collaborations	○	○	○	◉	○	○
* Publicly listing (Initial Public Offering (IPO))	◉	○	○	○	○	○
* Capital markets/shareholders	○	◉	○	○	○	○
* Corporate funding (from other companies in the market)	○	○	◉	○	○	○

* **Q3.** In your views, are there **other financial instruments** relevant for the biotechnology sector in the EU?

- (●) Yes
- ( ) No
- ( ) I don't know

Q3a. Please indicate **other relevant private and public financial instruments**.

600 character(s) maximum

EU public funding instruments should better cover the whole spectrum of research, including late-stage developement, which currently does not get enough support to secure impact, and acceleration and translation of top-tier results. Limited funding mechanisms hinder vaccine R&D and production, affecting Europe's ability to respond to emergencies and maintain routine immunisation. Dedicated funding for vaccine research and innovative approaches will enhance immunisation's role as a vital healthcare investment.

Q4. Based on your experience, to what extent do you agree that the following factors **drive investment in a biotechnology company**?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Innovative science	( )	( )	( )	( )	(●)	( )
* Groundbreaking technology (e.g. health biotech: a breakthrough that significantly improves upon existing therapies or addresses unmet medical needs; food biotech: solution that can boost food security)	( )	( )	( )	( )	(●)	( )
* Scientific evidence, including data, concerning innovation	( )	( )	( )	( )	(●)	( )
* Access to data held by public sector bodies	( )	( )	( )	(●)	( )	( )
* Experienced management team	( )	( )	( )	( )	(●)	( )
* Robust supply chain	( )	( )	( )	(●)	( )	( )
* Regulatory certainty (e.g. length and predictability of authorisation process)	( )	( )	( )	(●)	( )	( )

* Sufficient protection of intellectual property	○	○	○	○	◉	○
* Financial health and projections	○	○	○	◉	○	○

Q5. Please indicate **other factors that drive investment** in a biotechnology and/or biomanufacturing company here.

1000 character(s) maximum

Industrial policy can stimulate investment by combining public funding, tax incentives, and support to innovation clusters. Governments can co-invest through grants and public–private partnerships, lowering risk and attracting private capital into long-term R&D. Targeted tax incentives help reduce effective costs. Cluster development policies can help creating biotech hubs linking universities, startups, and manufacturers. Prioritising immunisation and prevention policies drives investment in vaccines sector. When MS ensure sustainable immunisation programmes, infrastructure support, and long-term planning, they create stable, predictable demand for innovation. Yet 77% of MS allocate under 0.5% of health budgets to immunisation, weakening Europe's appeal to vaccine biotechs. Prioritising immunisation ensures equity in access, investor confidence, and sustainable manufacturing within Europe, by de-risking private investment and aligning industrial policy with public health objectives.

Q6. When seeking investments, is the EU **a priority region** under the growth strategy of the organisation you represent?

- ○ Yes
- ◉ No
- ○ I don't know

Q8. Please substantiate your statements with **additional evidence** on the **challenges** related to **access to finance in the EU**.

600 character(s) maximum

SMEs face significant challenges to access finance. Availability of capital is an issue, from limited private funding from VCs in earlier stages development to accessing public funding through stock market listing in later stages. Risk aversity from large institutional investors, such as pension funds, contributes to lack of cash. Also, Euronext does not offer same benefits and incentives as Nasdaq. In addition, EIB does not support enough small companies with its limited size of investment and a lack of specific instrument for biotech.

The following questions seek to collect views on possible ways forward to support access to finance in the EU.

* **Q9.** In your view, what **actions at EU level** are necessary for the public sector **to attract/derisk private investments in biotechnology and/or biomanufacturing**? Please substantiate your statements with views and evidence on the ways forward.

You can provide references of successful schemes existing at EU level, national level or in other jurisdictions to attract private capital in biotechnology.

600 character(s) maximum

Europe should introduce non-discriminatory framework conditions that improve its competitiveness and resilience, attract investment and support innovation in biotech for both European-headquartered and international companies heavily invested in Europe. Europe should recognize that its resilience depends on diversified, globally integrated supply chains. The Dutch National Growth Fund for projects with high potential is an example of a successful scheme.

* **Q10.** In your view, what **actions at EU level** are necessary to prioritise **funding for high-risk and high-reward biotechnology research and innovation?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

● Need to reform pension funds to increase flexibility in favor of VCs and SME investment, to boost sector growth, and offer higher returns for pension funds Improve cost of raising capital via Euronext to attract more domestic and international investors. ● Establish a guarantee fund for biopharma SMEs (of EUR 1 billion) for limited partners to minimise losses through lower hurdle rates and risk sharing. ● Reward in a fair and appropriate manner high-risk, complex endeavor such as pediatric product.

* **Q11.** In your view, what **other actions** are necessary at EU level? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

Fill gaps in the funding tools for late-stage research and upscaling of results. Design appropriate, swifter and more agile tools in EU programmes (and in future MFF and Competitiveness Fund), to support SMEs and midcaps via grants or financial instruments. In addition, encourage MS to make sustainable investments in lifecourse immunisation programmes that ensure vaccine equity and health security. The EC should collect data on and monitor national immunisation budgets via the European Semester process for economic and social policy coordination and/or the State of Health in the EU cycle.

Section 4 - Biotechnology clusters and/or cluster organisations

The following questions seek to collect views on biotechnology clusters and/or cluster organisations in the EU.

'**Clusters** are groups of firms, related economic actors, and institutions located near each other and with sufficient scale to develop specialised expertise, services, resources, suppliers and skills.' [**link to definition of clusters**]

'**Cluster organisations** are the legal entities that support the strengthening of collaboration, networking and learning in innovation clusters and act as innovation support providers by providing or channelling specialised and customised business support services to stimulate innovation activities, especially in SMEs. They are usually the actors that facilitate strategic partnering across clusters.' [**link to definition of cluster organisations**]

Q1. To what extent do you agree that biotechnology clusters and/or cluster organisations in the EU face the **following barriers** in order to reach their full potential?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Insufficient number of academic institutions with long standing expertise in the area of biotechnology	○	○	◉	○	○	○
* Insufficient presence of industrial players	○	◉	○	○	○	○
* Insufficient higher education or vocational training institutions	○	○	◉	○	○	○
* Insufficient startup incubators or business support infrastructure (providing for example regulatory affair support)	○	○	○	○	◉	○
* Lack of technology transfer offices	○	◉	○	○	○	○
* Incapacity to reach a critical mass of stakeholders	○	○	○	◉	○	○
* Insufficient public support	○	○	○	◉	○	○
* Insufficient collaboration among existing clusters	○	○	○	◉	○	○
* Insufficient financial support	○	○	○	◉	○	○

Q2. Please indicate **other factors impacting biotechnology clusters and/or cluster organisations** in the EU.

1000 character(s) maximum

Pharmaceutical clusters are concentrated in Europe's most developed regions, which restricts their eligibility for cohesion funds and state aid under current EU rules. Yet these clusters are strategic in today's geopolitical context marked by supply chain fragility and global competition. EU biotech clusters are influenced not only by science and capital, but also by numerous frameworks: CTR, HTA, EHDS ; and MDR/IVDR that add to compliance pressures. As well as access to skilled talent, GMP infrastructure, and public trust remain decisive for cluster growth.

Q3. Please substantiate your statements with **additional evidence** on the **challenges** faced by **biotechnology clusters and/or cluster organisations** in the EU.

600 character(s) maximum

Research infrastructures remain too fragmented, lack sustained investment, and are not always designed to fit the needs of the private sector. Lack of overarching EU centres of excellence, leading to fragmentation of research, talent, funding and outputs. Difficulty to raise capital and scale up in case of discovery.

The following questions seek to collect views on possible ways forward to support biotechnology clusters and/or cluster organisations in the EU.

* **Q4.** In your view, what **actions at EU level** are necessary to **enhance the impact of biotechnology clusters and/or cluster organisations in the EU**? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

Facilitate access of private sector, in particular for start-up and scale-ups, to research infrastructures, and bring existing infrastructures to the industrial and regulatory grade quality. More efforts needed to facilitate synergies in public private partnerships, e.g. on ATMPs.

* **Q5.** In your view, what **actions at EU level** are necessary to create more **synergies** between existing clusters and/or cluster organisations and facilitate **pooling of expertise and resources** in the EU? Please substantiate your statements with views and evidence on the ways forward here.

600 character(s) maximum

To maximise Europe's biotech potential, the EU should foster stronger synergies between existing clusters through targeted measures. This includes designing Horizon Europe and cohesion funding calls that require cross-cluster consortia, expanding EU-wide platforms like EIT Health to pool expertise, and supporting shared pilot plants and biobanks across regions. Finally, activities aiming at boosting global visibility and positioning clusters as core infrastructure in Europe's industrial strategy.

Section 5 - Biotechnology manufacturing

The following questions seek to collect views on biotechnology manufacturing in the EU.

Q1. To what extent do you agree that biotechnology manufacturing in the EU faces the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Length and/or complexity of permitting processes for new facilities	○	○	○	◉	○	○
* High cost of raw material and/or of the operations	○	◉	○	○	○	○
* High energy costs	○	○	◉	○	○	○
* Other operational costs	○	◉	○	○	○	○
* Limitations in logistics and physical infrastructure	◉	○	○	○	○	○
* Vulnerabilities in supply chains and strategic dependencies	○	◉	○	○	○	○
* Labour costs	○	◉	○	○	○	○
* Inconsistent environmental and sustainability policies or lack of a policy	○	○	○	○	◉	○
* Taxation and customs barriers (e.g. tax credits, import duties)	○	○	○	○	◉	○
* Global competition	○	○	○	○	◉	○
* Difficulty scaling up from pilot to industrial production	◉	○	○	○	○	○
* Maintaining product quality and consistency at scale	◉	○	○	○	○	○

Q2. Please indicate **other challenges impacting biotechnology manufacturing in the EU**.

600 character(s) maximum

Challenges for EU biotech manufacturing include increasingly complex and fragmented regulatory requirements, difficulties in scaling innovations compared to global competitors after early-stage research,and

the needs to increase cooperation on R&D and funding and reform public procurement to better reflect the complex realities of the supply of medicines and to promote long-term resilience.Talent shortages and barriers to mobility reduce competitiveness, while slower adoption of new technologies and lengthy approval pathways delay innovation. Uneven incentives across MS add further pressure.

Q3. Please substantiate your statements with **additional evidence** on the **challenges impacting biotechnology manufacturing in the EU**.

600 character(s) maximum

Please see in the Annex the Vaccines Europe position on manufacturing in EU.

The following question seeks to collect views on possible ways forward to support biotechnology manufacturing in the EU.

* **Q4.** In your view, what **actions at EU level** are necessary to **enhance the impact of biotechnology manufacturing in the EU?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

To boost EU biotech manufacturing,actions should cut barriers to talent and trade,secure supply, and harmonise regulation while fostering R&D,skills, and regional collaboration.Focusing on EU innovation and competitive advantage, policies must ensure strong IP, tax and research incentives, infrastructure investment, open trade,strengthened collaboration with international partners(not self-sufficiency)and faster market access. A predictable framework, simplified regulatory pathways, compliance with WTO and the EU's international obligations, non-discriminatory incentives attract investments.

Section 6 - Availability, upskilling and reskilling the biotechnology workforce

The following questions seek to collect views on the needs of the workforce in biotechnology in the EU.

Q1. To what extent do you agree that **the EU workforce for biotechnology** faces the following **challenges?**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Shortage of vocational skills especially for biotechnology and biomanufacturing (e.g. lab technicians, operators, etc.)	○	○	○	◉	○	○
* Insufficient STEM education graduates (STEM: Science, Technology, Engineering, Mathematics)	○	○	○	○	◉	○
* Insufficient research and technical skills	○	○	○	◉	○	○
* Insufficient regulatory and quality assurance expertise	○	○	○	○	◉	○
* Insufficient digital and data science skills	○	○	○	○	◉	○
* Insufficient intellectual property skills	○	○	◉	○	○	○
* Limited financial, entrepreneurial skills and mindsets	○	○	○	○	◉	○
* Other	○	○	○	○	◉	○

Q2. Please indicate **other challenges faced by the workforce for biotechnology in the EU**.

600 character(s) maximum

Misalignment between education and fast-paced innovation, especially for skills in demand across industries (data, predictive sciences). Regulatory expertise, especially in emerging areas such as gene and cell therapies, personalised medicine, digital health, and new technologies like mRNA vaccines, is critical to support biotechnology innovation. In addition to technical training, entrepreneurship, alongside communication, leadership, and teamwork skills, should be embedded in biotech education to foster innovation and collaboration.

Q3. To what extent do you agree that **the following factors** lead to the EU workforce facing the above-mentioned challenges?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Difficulty in attracting, developing and retaining global talent	○	○	○	○	◉	○
* Misalignment between education and industry needs	○	○	○	◉	○	○
* Regional disparities in the availability of skilled workers in the EU (for example as a result of brain drain or lack of availability of training courses)	○	○	○	○	◉	○
* Insufficient public and private investment in skilled workforce	○	○	○	◉	○	○

Q4. Please indicate **other factors** leading to the **EU workforce facing the above-mentioned challenges**.

1000 character(s) maximum

Lack of coordination between academia and industry, lack of incentives for mobility, insufficient recognition of research collaboration and IP in academic. EU fragmentation, with differing languages, regulations, funding mechanisms, pension schemes, training certifications and standards limits collaboration and mobility as do barriers to obtaining work and residence permits. Works Councils can be a hurdle in upskilling initiatives. More EU funding, centres of excellence, and better funded, more flexible university programmes are needed. Insufficient programmes to increase the number of skilled workers across the development cycle (ideation to market access) in smaller countries limits their ability to grow strong biotech ecosystems. Regulatory

frameworks often overlook the skills, workforce planning, and resources needed to sustain innovation, especially in emerging fields (gene editing, personalized medicine) creating a gap between ambitions and operational capabilities.

Q5. Please substantiate your statements with **additional evidence on the challenges faced by the workforce for biotechnology in the EU**.

600 character(s) maximum

** **Q6.** In your view, what **actions at EU level** are necessary to **enhance specialised training programmes/curricula?** Please substantiate your statements with views and evidence on the ways forward.*

600 character(s) maximum

Regulatory science underpins EU medicines regulation: strengthening capabilities, digital tools, and infrastructure is vital. Sustainability of the EU Regulatory Network requires skilled experts especially in new areas (gene and cell therapies, personalised medicine, digital health). Expert careers need to be made more attractive. Without investment, Europe risks delays in patient access, fragmentation across Member States, and loss of competitiveness. Strong regulatory science keeps the EU agile, trusted and globally influential regulator, enabling innovation while safeguarding public health

** **Q7.** In your view, what **actions at EU level** are necessary to **enhance support for scientists to launch a business** (e.g. through incubators, pilot facilities for knowledge transfer and idea testing, etc.)? Please substantiate your statements with views and evidence on the ways forward.*

600 character(s) maximum

Expand EU incubators, pilot-scale biomanufacturing facilities, knowledge-transfer hubs for market analysis, IP, investment, regulation support. Facilitate access to research infrastructures. Provide targeted training in IP, regulatory, business, management, entrepreneurship skills. Jointly funded partnerships between the biotech industry and educators are critical for workforce upskilling. Facilitate public-private mobility: better recognition of experience in private sector, of IP (patents) and of collaborations in academic career (Horizon Europe MSCA and ERA can play a role).

** **Q8.** In your view, what **actions at EU level** are necessary to support **programmes to attract talent from other geographical areas**? Please substantiate your answers with views and evidence on the ways forward.*

600 character(s) maximum

Simplify researcher mobility, visas, and recognition of qualifications. Continue supporting EU programmes such as MSCA. Harmonise work and residence permits and experience recognition to ease movement. Strengthen excellence clusters to retain talent. Increase funding for AI- and digital-focused training, and mobility programmes financing and flexibility. Use Member States diplomatic networks and Science and Technology offices to promote EU opportunities serve as talent matchmaking platforms and attract global researchers.

* **Q9.** In your view, what **other actions at EU level** are necessary for the availability, upskilling and reskilling of the biotechnology workforce? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

Introduce biotechnology modules at school level to spark interest and create foundation in life sciences. Promote STEM careers. Fund continuous upskilling/reskilling. Foster cross-country talent hubs and publicprivate partnerships to address regional disparities to build a robust, future-ready biotech and biomanufacturing workforce. Embed biotech skills in EU Skills Agenda and Pact for Skills. Embed soft-skills training to foster innovation and collaboration. Ensure sustainable funding of EU-level initiatives for higher education, vocational training, and lifelong learning.

Section 7 - Data and Artificial Intelligence

The following questions seek to collect views on the challenges related to access to data and on the development, deployment and use of Artificial Intelligence (AI) in biotechnology.

* **Q1.** Are you or the organisation you represent having difficulties in **accessing or using relevant data** for the development of biotechnology or biomanufacturing products?

- (●) Yes
- ( ) No
- ( ) Partially
- ( ) Not applicable/I don't know

Q1a. What barriers are you currently facing?

600 character(s) maximum

Access to high-quality data remains a challenge in Europe i.e for clinical endpoints like biomarkers, disease severity, long-term outcomes. It can be difficult to follow a patient’s care pathway due to challenges associated with linking datasets. The datasets may not exist in MS. Sample sizes are limited i.e, in rare diseases, where data is often sparse. Application of GDPR also varies amongst MS. Regional variation in medical coding systems creates consistent cross-walked medical definitions across terminology sets. In the US datasets are larger and access to claims, EHR, data is streamlined.

* **Q2.** Are you or the organisation you represent relying on **data sourced from outside of the EU/EEA** for the development of biotechnology and biomanufacturing products and services?

- (●) Yes
- ( ) No
- ( ) Not applicable/I don't know

Q2a. What are the main reasons for relying on data sourced from outside of the EU /EEA?

- [ ] Clear legal framework for access to data
- [ ] Less strict requirements for compliance with privacy and data protection
- [ ] More favourable IP rules
- [x] Available datasets are more reliable and of a higher quality
- [ ] Access to data is less costly
- [x] Other

Q2b. Please specify what the other reasons are.

600 character(s) maximum

US-based RWD sources,such as EHRs,and disease registries,are pivotal in informing the clinical studies.This reliance underscores the need for the EU to strengthen its data ecosystem to reduce dependency on external sources and foster data sovereignty.US data is not necessarily more reliable or of higher quality however it is much easier to find data at scale needed for advanced AI/Data Science approaches.Using one large dataset is simpler than using data from multiple smaller data sets.Nevertheless, use of data from outside the EU depends on it being generalisable to the EU patient population

Q3. To what extent do you agree that **data synthetisation** is a viable means to overcome data scarcity in the EU?

- ( ) Strongly disagree
- ( ) Disagree
- ( ) Neutral
- (●) Agree
- ( ) Strongly agree
- ( ) Not applicable/I don't know

The next set of questions specifically cover the implementation of the European Health Data Space (EHDS) and consequently focus on health data.

In the health domain, the EHDS aims to alleviate challenges in accessing data for secondary use by establishing a legal framework facilitating the reuse of health data for research and innovation, including in the biotechnology sector. The EHDS Regulation entered into force on 26 March 2025 and its key provisions will enter into application and be operational by March 2029.

Q4. Regarding the health biotechnology sector, are you or the organisation you represent **actively preparing for the entry into application of the EHDS?**

- (●) Yes
- ( ) No
- ( ) Not applicable/I don't know

* **Q4a.** In what capacity does your organisation expect to be involved in the European Health Data Space? Please select the capacity(ies) that is/are most relevant for you.

- [x] Data user
- [x] Data holder
- [ ] Health Data Access Body
- [ ] Authorised participant to HealthData@EU infrastructure (e.g. as a health-related research infrastructure or other data-sharing infrastructure)
- [ ] Health Data Intermediation Entity
- [ ] Single Trusted Data Holder
- [ ] Cross-border registry
- [ ] Other

Q4b. What are the specific challenges related to the implementation of the EHDS that you or the organisation you represent encounter?

600 character(s) maximum

To foster balanced data sharing environment,contractual arrangements with the Data User should be always available to the Data Holder in order to maintain appropriate control and protect its IP rights,including trade secrets.As a data holder,the need to map all relevant, in scope data sets a challenge given the size of some organisations and the many data sets in different formats with patients from many different countries.This will present a challenge in parsing out EU data from multinational data sets.The obligation to share retrospective data with no time limit creates an extreme burden.

Q5. Which types of services of research and health data infrastructures (e.g. biobank research infrastructures) are currently used in the biotechnology sector?

600 character(s) maximum

Varying types of health data are currently accessed to support medicines R&D, including, health registries, biobanks, data from medical device technologies, genetic/genomic data. Some of this data is used as RWD to generate RWE to support regulatory decision making for medicinal products and has the potential to be leveraged for development of AI models for example.

The following questions specifically concern the transformative potential of AI for biotechnology.

In the following questions, a distinction is made between two categories of AI use in biotechnology, representing different phases of the innovation cycle:

1. Use of AI in Research and Development (R&D): Biotech companies using AI toolsto support or accelerate their R&D processes (e.g. using AI to identify drug targets or design new molecules, applying machine learning to analyse omics data, etc).

2. Deployment and scale-up of AI-based Biotechnology Products: Biotech companies developing AI-powered products or services and deploying these products into real-world settings (e.g.AI-powered biomanufacturing platforms aimed to be integrated in production facilities, AI powered diagnostic tool that analyses blood based biomarkers to detect early stage cancer using a biological model of tumour progression, etc).

Q6. To what extent do you agree that **the use of AI in R&D** is facing the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* **Technological challenges, access and use of data** (e.g. outdated infrastructure to support the integration of AI tools, lack of interoperability, lack of local validation (performance testing), lack of post-deployment monitoring mechanisms, lack of AI transparency and explainability etc)	○	○	○	◉	○	○
* **Challenges in the implementation of regulatory frameworks** (e.g. complex regulatory landscapes for AI users and/or deployers, concerns over liability, concerns surrounding data security and privacy etc)	○	○	○	○	◉	○
* **Organisational and business challenges** (e.g. lack of end-user involvement in the development and deployment of AI tools, lack of added value assessment in deploying AI, lack of AI strategy for use/deployment in the entity)	○	◉	○	○	○	○
* **Social and cultural challenges** (e.g. lack of trust in AI tools, lack of digital literacy among users/deployers/the public, concerns on job security, concerns surrounding overreliance on AI tools, etc	○	○	○	◉	○	○

Q7. To what extent do you agree that **the deployment of AI-based biotech products** is facing the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* **Technological challenges, access and use of data** (e.g. outdated infrastructure to support the integration of AI tools, lack of interoperability, lack of local validation (performance testing), lack of post-deployment monitoring mechanisms, lack of AI transparency and explainability etc)	○	○	○	◉	○	○
* **Challenges in the implementation of regulatory frameworks** (e.g. complex regulatory landscapes for AI users and/or deployers, concerns over liability, concerns surrounding data security and privacy etc)	○	○	○	○	◉	○
* **Organisational and business challenges** (e.g. lack of end-user involvement in the development and deployment of AI tools, lack of added value assessment in deploying AI, lack of AI strategy for use/deployment in the entity)	○	○	◉	○	○	○
* **Social and cultural challenges** (e.g. lack of trust in AI tools, lack of digital literacy among users/deployers/the public, concerns on job security, concerns surrounding overreliance on AI tools, etc	○	○	○	○	◉	○

Q8. Please substantiate your statements with **additional evidence** on **access to data, the use of AI in R&D,** and **deployment of AI-based biotech products in the EU biotechnology sector** here.

600 character(s) maximum

For the use of AI in medicines R&D: ● The pharmaceutical sector mainly use data from outside the EU, primarily from the US for example RWD, registry data etc. is used in medicines R&D to support research and decision making ● For the EU AI Act, we need clarity in understanding how the R&D exemption will apply to the use of AI in medicines lifecycle, and secondly we strongly advocate not overregulating this area given the EMA (and the broader EMRN) is has oversight over how AI is used in medicines R&D in the context of medicines legislation.

The following questions seek to collect views on possible ways forward to support the deployment and use of AI and data in biotech.

* **Q9.** In your view, what **actions at EU level** are necessary to enhance **the use of AI in R&D in biotechnology** in the EU?

600 character(s) maximum

Regarding the use of AI in medicines R&D: ● a) to develop a FAQ for the application of the AI Act based on example use cases with industry input, and b) ensure no unnecessary duplication of efforts to provide guidance to industry on the use of AI in medicines development (something which is already being addressed by the European Medicines Agency and broader Medicines regulatory network via their AI workplan) ● For data – access to broad range of sources of data to train AI algorithms – EHDS

* **Q10.** In your view, what **actions at EU level** are necessary to enhance the **deployment of AI-based biotechnology products** in the EU?

600 character(s) maximum

Clearer, less duplicative regulatory frameworks and requirements, legal clarity on applicable rules at the sectoral level. Creation of the sandboxes to help balancing innovation with patient safety, accelerate trustworthy adoption, and ensure ethical, transparent integration of AI throughout the medical lifecycle. In a highly regulated sectors such as ours, testing of compliance mechanisms in realistic but risk-free settings encourages innovation and fosters join trust in the AI enabled solutions.

Q11. In your view, what **other actions** should be prioritised **at EU level** related to **data and AI in the field of biotechnology and biomanufacturing** (e.g. on data, on use of high-performance computers (HPC), etc.)?

600 character(s) maximum

For the EHDS to be a success, EU needs to empower platforms that foster harmonised implementation i.e. EHDS Board to mandate standardised approaches across the EU.To establish shared confidence in the system the data holder must be given a right to refuse access to data if it can cause economic damage. For HPC,given that many models are trained on US based cloud infrastructure,we recommend the Commission to prioritize

sufficient funding to actions listed in the AI Factories that are meant to build infrastructure,offering access not just to HPC compute power but also data and training facilitie

Q12. The European Commission is supporting the creation of **AI Factories** to accelerate trustworthy AI development. AI Factories are dynamic ecosystems bringing together computing power, data, and talent to create cutting-edge AI models and applications across various sectors (e.g. health, manufacturing, climate etc.).

In your views, how can the AI factories be leveraged to advance biotechnology innovation in Europe?

	Yes	No	Not applicable /I don't know
* Host public-private AI model development for biotech use cases	◉	○	○
* Support validation and certification of AI tools in the biotech field	◉	○	○
* Secure and high-performance processing of health data made available through the EHDS for development of innovative products and tools for the biotech sector	◉	○	○
* Provide access and/or facilitate the use of high-quality datasets through 'data labs'	◉	○	○
* Other	◉	○	○

Q12a. If you would like to indicate other factors, you can do so here.

600 character(s) maximum

To enable access to private and public sector AI developers and researchers to AI factories, which would support the development of new AI models, testing, training, validation and fine tuning of algorithms

Q13. To what extent do you agree that the following types of support would help biotech companies, particularly SMEs, **develop and deploy AI solutions more effectively** in the EU?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know

* Dedicated funding instruments for biotech-related AI research and development	○	○	○	◉	○	○
* Access to annotated datasets (e. g. biological, clinical, genomic data)	○	○	○	○	◉	○
* Access to synthetic datasets	○	○	○	◉	○	○
* Regulatory sandboxes for testing biotech-related AI models	○	○	○	○	◉	○
* Partnerships with public research institutions or AI hubs /factories	○	○	○	○	◉	○
* Simplified IP and data-sharing frameworks	◉	○	○	○	○	○
* Skills development and AI training for biotech personnel	○	○	○	○	◉	○
* Roadmaps for implementation and scalability of AI tools in the EU ecosystem	○	○	○	◉	○	○
* Other	○	○	○	○	○	◉

Q14. If you would like to substantiate any of your statements with additional evidence on **the ways forward** to **support the deployment and use of data and AI in biotechnology,** you can do so here.

600 character(s) maximum

• Access to datasets is critical, and efforts should be made at the MS level to ensure the EHDS can deliver the promise of enabling secondary access to data without weakening the IP and commerciality sensitive information protection • Regulatory sandboxes are paramount to allow testing different types of AI solutions and to permit the innovators maximising its benefits while minimizing risks

Section 8 - Defence and security

Advanced biotechnological possibilities including development of synthetic pathogens, aided by AI-driven software systems, are creating new risks related to future health preparedness and potential of weaponisation by State or non-State actors (Sauli Niinistö report, October 2024).

The following questions seek to collect views on biotechnology for defence and security in the EU.

Q1. To what extent do you agree that application of **biotechnology in defence and security related areas** faces the following **challenges in the EU**?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Threats related to biosecurity and biosafety, including misuse of biotechnology	○	○	◉	○	○	○
* Risks to strategic autonomy in biomanufacturing, and availability of medical and non-medical countermeasures	○	○	○	◉	○	○
* Vulnerabilities in the resilience of biotech supply chains	○	○	◉	○	○	○
* Insufficient civil military cooperation in biotechnology sector	○	○	○	○	○	◉
* Cybersecurity risks to biotech infrastructure and AI tools used in biotechnology	○	○	◉	○	○	○
* Other	○	○	○	○	○	◉

* **Q2.** Please indicate **other challenges** impacting biotechnology for defence and security in the EU.

600 character(s) maximum

For the sector, economic security means stable access to inputs, innovation incentives, and competitive conditions (including solid IP protection). The needs and complexities of the sector and its supply chains should be recognised and supported by trade policies which complement Europe's efforts to attract R&D and manufacturing and partnerships with aligned countries. In the pharma sector, complete autonomy is unrealistic. In case of dependencies, policies should aim to manage rather than eliminate them.

Q3. To what extent do you agree that **biotechnology for defence and security** is creating the following **opportunities in the EU**?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Facilitate detecting biological and chemical threats, including via availability of biosensors	○	○	○	○	○	◉
* Opportunity to revolutionise defence logistics with biotechnology products (including food) manufacturing close to its point of use	○	○	○	○	○	◉
* Development of new innovative medical countermeasures including vaccines and antidotes	○	○	○	○	○	◉
* Developments of materials with new functions and/or improved characteristic	○	○	○	○	○	◉
* Increased food security	○	○	○	○	○	◉
* Other	○	○	○	○	○	◉

The following questions seek to collect views on possible ways forward to support biotechnology for defence and security in the EU.

* **Q4.** In your view, what **other actions at EU level** are necessary to **enhance the impact of biotechnology for defence and security in the EU**? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

During crises,the pharmaceutical sector provides surge capacity for vaccines, therapeutics,and diagnostics. Sustaining “ever-warm” capability requires predictable frameworks and industrial incentives. Data-intensive technologies underpin both public-health security and biodefence,but EU digital legislation is not yet tailored to biomedical use-cases.Effective response to bio-threats depends on early coordination, rapid contracting,and clear liability-sharing mechanisms.For biotechnology to reach its full potential the policy coherence, industrial investment, trust frameworks are essential.

Section 9 - Additional information

Is there anything else you would like to add that has not been covered by this consultation?

While robust R&D processes and a predictable regulatory framework are essential to enable the discovery, research, and development of innovative medicines, improving market conditions is equally important to ensure their effective uptake. Without an environment that supports timely access, adequate funding, and recognition of the value of innovation, many breakthroughs risk not reaching patients who could benefit from them. Addressing national and regional fragmentation requires strong will, country-specific solutions and real alliance between EU policy makers, Member States and the pharmaceutical industry to cut red tape, reduce duplicative processes, and ensure swift and pragmatic pricing and reimbursement decisions that truly value and reward innovation. A holistic approach — combining scientific excellence, regulatory predictability, and supportive market dynamics — is therefore key to realising the full potential. Innovation doesn’t happen in a vacuum — it depends on an ecosystem of supportive market, regulatory, and investment conditions. In terms of aspects that have not been covered in the consultation and are critical in creating a fertile environment for sustained innovation in medicines, we would like to flag those related to strengthening of the Intellectual Property (IP) framework. The current IP framework, while functional, still has a number of gaps that prevent the EU from being considered as having a best-in-class system when compared to its peers. Furthermore, progress on recent policy proposals, both in the General Pharmaceutical Legislation and the Patent Package, do not meaningfully move the needle to a more competitive IP system, and in some cases, actually do the opposite. The Biotech Act, however, provides an excellent chance to ensure the European IP system is fit-for-purpose and can support a more competitive future for Europe, driving innovation in biotechnology to bring the benefits of rapid scientific advancement to European patients. The innovative pharmaceutical industry is faced with a number of challenges in its current operating climate. First and foremost, developing innovative medicines fundamentally entails challenging science, very lengthy and risky clinical development, multiple failures of assets that do not reach the market and overall, extensive development and regulatory approval timelines. The sum of these realities is that remaining patent protection is often very short and insufficient to offset these inherent burdens; this was, in effect, the rationale for the introduction of the Supplementary Protection Certificate (SPC) to create an avenue for at least partial compensation. The challenges of the current situation, however, have recently only grown, as the industry is also facing lengthy pricing & reimbursement procedures,

as well as sector-unique and steadily increasing transparency / sharing obligations, which require ever-earlier patenting and undermine incentives for the industry to invest into research and development (R&D). Existing incentives are also broadly undermined by the difficulties in practically, timely and efficiently enforcing IP rights in Europe, such as the SPC manufacturing waiver and the expansion of the exemption to the protection of IP rights in the proposed revision to the general pharmaceutical legislation (GPL). The Draghi Report underscores the urgency of addressing these gaps, calling for bold reforms to unlock innovation, reduce regulatory fragmentation, and increase investment in digital infrastructure and data ecosystems. Importantly, it recognized IP as a cornerstone of economic growth and competitiveness. Concretely, VE proposes strengthening the baseline of RDP compared to the existing legislation or ongoing legislative proposals. In addition, and in light of the challenges described above, while all therapeutics, regardless of whether they are small molecule or biologics, ought to benefit from an increased period of RDP, facilitating biopharmaceutical R&D in cutting-edge technologies could be achieved with an attractive RDP regime for biologics and certain complex therapies that require additional measures to encourage investments. The rest of this submission added to the Annex outlines in more detail challenges and proposes principles for solutions that can drive a stronger biotech system for the benefits of patients.

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