

**Basic information**

**2025/0406(COD)**

Awaiting committee decision

COD - Ordinary legislative procedure (ex-codecision procedure)  
Regulation

European Biotech Act

- Amending Regulation 2002/178 [2000/0286\(COD\)](#)
- Amending Regulation 2007/1394 [2005/0227\(COD\)](#)
- Amending Regulation 2014/536 [2012/0192\(COD\)](#)
- Amending Regulation 2019/6 [2014/0257\(COD\)](#)
- Amending Regulation 2024/1938 [2022/0216\(COD\)](#)
- Amending Regulation 2024/795 [2023/0199\(COD\)](#)

**Subject**

- 3.50.08 New technologies; biotechnology
- 4.20 Public health

**Key players**

European Parliament


Joint committee responsible	Rapporteur	Appointed
<span style="border: 1px solid red; padding: 2px;">SANT</span> Public Health	ANDRIUKAITIS Vytenis Povilas (S&D)	12/02/2026
<span style="border: 1px solid red; padding: 2px;">ITRE</span> Industry, Research and Energy	BEKE Wouter (EPP)	12/02/2026
	<b>Shadow rapporteur</b> TER LAAK Ingeborg (EPP) NARDELLA Dario (S&D) DE LA PISA CARRIÓN Margarita (PFE) STORM Kristoffer (ECR) CICCIONI Carlo (ECR) BOSSE Stine (Renew) KULMUNI Katri (Renew) TOUSSAINT Marie (Greens /EFA) NIINISTÖ Ville (Greens/EFA) HAZEKAMP Anja (The Left) SMITH Anthony (The Left) ANDERSON Christine (ESN)	
Committee for opinion	Rapporteur for opinion	Appointed

	<b>ECON</b> Economic and Monetary Affairs	The committee decided not to give an opinion.	
	<b>ENVI</b> Environment, Climate and Food Safety	GONZÁLEZ CASARES Nicolás (S&D)	09/03/2026
	<b>IMCO</b> Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	<b>JURI</b> Legal Affairs	WÖLKEN Tiemo (S&D)	05/03/2026
	<b>LIBE</b> Civil Liberties, Justice and Home Affairs	The committee decided not to give an opinion.	
	<b>Committee for budgetary assessment</b>	<b>Rapporteur for budgetary assessment</b>	<b>Appointed</b>
	<b>BUDG</b> Budgets	The committee decided not to give an opinion.	
Council of the European Union			
European Commission	<b>Commission DG</b>	<b>Commissioner</b>	
	Health and Food Safety	VÁRHELYI Olivér	
European Economic and Social Committee			
European Committee of the Regions			

Key events			
Date	Event	Reference	Summary
16/12/2025	Legislative proposal published	COM(2025)1022	Summary
18/05/2026	Committee referral announced in Parliament, 1st reading		

Technical information	
Procedure reference	2025/0406(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amending Regulation 2002/178 2000/0286(COD)

	<a href="#">Amending Regulation 2007/1394 2005/0227(COD)</a> <a href="#">Amending Regulation 2014/536 2012/0192(COD)</a> <a href="#">Amending Regulation 2019/6 2014/0257(COD)</a> <a href="#">Amending Regulation 2024/1938 2022/0216(COD)</a> <a href="#">Amending Regulation 2024/795 2023/0199(COD)</a>
<b>Legal basis</b>	Rules of Procedure EP 58 Treaty on the Functioning of the European Union TFEU 114 Treaty on the Functioning of the European Union TFEU 168-p4 Treaty on the Functioning of the European Union TFEU 173-p3
<b>Mandatory consultation of other institutions</b>	<a href="#">European Economic and Social Committee</a> <a href="#">European Committee of the Regions</a>
<b>Stage reached in procedure</b>	Awaiting committee decision
<b>Committee dossier</b>	CJ53/10/04842

Documentation gateway				
European Commission				
Document type	Reference	Date	Summary	
Legislative proposal	<a href="#">COM(2025)1022</a>	16/12/2025	<a href="#">Summary</a>	
Document attached to the procedure	<a href="#">SWD(2025)1055</a> 	17/12/2025		
Document attached to the procedure	<a href="#">SWD(2026)0450</a>	28/05/2026		
Other institutions and bodies				
Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	<a href="#">CES0031/2026</a>	18/03/2026	

Additional information		
Source	Document	Date
EP Research Service	<a href="#">Briefing</a>	
European Commission	<a href="#">EUR-Lex</a>	

## Meetings with interest representatives published in line with the Rules of Procedure

### Rapporteurs, Shadow Rapporteurs and Committee Chairs

Transparency				
Name	Role	Committee	Date	Interest representatives
<a href="#">WÖLKEN Tiemo</a>	Rapporteur for opinion	<a href="#">JURI</a>	08/06/2026	Eli Lilly and Company
	Rapporteur for			

WÖLKEN Tiemo	opinion	JURI	28/05/2026	A. Menarini Industrie Farmaceutiche Riunite s.r.l.
WÖLKEN Tiemo	Rapporteur for opinion	JURI	27/05/2026	Food Forward Europe
WÖLKEN Tiemo	Rapporteur for opinion	JURI	27/05/2026	GSK
TER LAAK Ingeborg	Shadow rapporteur	SANT	26/05/2026	Vereniging Innovatieve Geneesmiddelen
TER LAAK Ingeborg	Shadow rapporteur	SANT	26/05/2026	Amgen Inc
TER LAAK Ingeborg	Shadow rapporteur	SANT	26/05/2026	Vaccines Europe
WÖLKEN Tiemo	Rapporteur for opinion	JURI	26/05/2026	Humane Society International/Europe
WÖLKEN Tiemo	Rapporteur for opinion	JURI	26/05/2026	Pandemic Action Network
WÖLKEN Tiemo	Rapporteur for opinion	JURI	26/05/2026	Standing Committee of European Doctors
WÖLKEN Tiemo	Rapporteur for opinion	JURI	26/05/2026	Johnson & Johnson
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	21/05/2026	A. Menarini Industrie Farmaceutiche Riunite s.r.l.
WÖLKEN Tiemo	Rapporteur for opinion	JURI	18/05/2026	European CRO Federation
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	18/05/2026	EUROPEAN ORGANISATION FOR RARE DISEASES
BOSSE Stine	Shadow rapporteur	SANT	13/05/2026	European Patient Organisation for Dysimmune and Inflammatory Neuropathies
BOSSE Stine	Shadow rapporteur	SANT	13/05/2026	OM Pharma SA
TOUSSAINT Marie	Shadow rapporteur	SANT	13/05/2026	Eurogroup for Animals human world for animals
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	13/05/2026	Bayer AG
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	13/05/2026	BIOTON S.A.
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	13/05/2026	Deutsche Sozialversicherung Arbeitsgemeinschaft Europa European Federation of Pharmaceutical Industries and Associations MEDICINES FOR EUROPE Rijksinstituut voor ziekte- en invaliditeitsverzekering
TER LAAK Ingeborg	Shadow rapporteur	SANT	12/05/2026	Genmab A/S
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	12/05/2026	European Centre for Disease Prevention and Control (ECDC)
WÖLKEN Tiemo	Rapporteur for opinion	JURI	12/05/2026	BIO Deutschland
BOSSE Stine	Shadow rapporteur	SANT	11/05/2026	HIPRA, S.A.
TER LAAK Ingeborg	Shadow rapporteur	SANT	11/05/2026	Humane Society International/Europe
	Shadow			

BOSSE Stine	rapporteur	SANT	08/05/2026	European University Hospital Alliance
BOSSE Stine	Shadow rapporteur	SANT	08/05/2026	Gilead Sciences
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	07/05/2026	European CRO Federation European Federation of Pharmaceutical Industries and Associations
WÖLKEN Tiemo	Rapporteur for opinion	JURI	06/05/2026	Bristol-Myers Squibb Company
TER LAAK Ingeborg	Shadow rapporteur	SANT	05/05/2026	MEDICINES FOR EUROPE
BOSSE Stine	Shadow rapporteur	SANT	05/05/2026	Bioarctic Neuroscience AB
WÖLKEN Tiemo	Rapporteur for opinion	JURI	04/05/2026	EORTIC
BOSSE Stine	Shadow rapporteur	SANT	04/05/2026	European Federation of Pharmaceutical Industries and Associations
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	04/05/2026	GSK
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	04/05/2026	EFPIA
WÖLKEN Tiemo	Rapporteur for opinion	JURI	29/04/2026	AstraZeneca PLC
GONZÁLEZ CASARES Nicolás	Rapporteur for opinion	ENVI	29/04/2026	American Chamber of Commerce to the European Union Amgen Inc Johnson & Johnson
TER LAAK Ingeborg	Shadow rapporteur	SANT	28/04/2026	European Patients' Forum (EPF)
TER LAAK Ingeborg	Shadow rapporteur	SANT	28/04/2026	AbbVie Abbott American Chamber of Commerce to the European Union Amgen Inc Bristol-Myers Squibb Company Eli Lilly and Company Fleishman-Hillard Illumina, Inc. Johnson & Johnson Pfizer Inc. UPS Healthcare Viatri
BOSSE Stine	Shadow rapporteur	SANT	28/04/2026	Plasma Protein Therapeutics Association Europe, international Association without lucrative purpose
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	28/04/2026	Brunswick Group Limited srl
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	28/04/2026	American Chamber of Commerce to the European Union
				AstraZeneca PLC Bavarian Nordic A/S BioInnovation Institute Fonden Confederation of Danish Industry Genmab A/S H. Lundbeck A/S Novo Nordisk A/S Novo Nordisk Foundation Novozymes A/S The Danish Chamber of Commerce

BOSSE Stine	Shadow rapporteur	SANT	24/04/2026	Xellia Pharmaceuticals Novo Nordisk Foundation Cellerator Medtech Denmark Danish Association of the Pharmaceutical Industry (Lif) FUJIFILM Biotechnologies The Export and Investment Fund of Denmark (EIFO) University of Copenhagen Amplify Therapeutics Technical University of Denmark 21st BIO Spora ApS Bactolife A/S NOON Ventures
TER LAAK Ingeborg	Shadow rapporteur	SANT	23/04/2026	Juvenile Diabetes Research Foundation
TER LAAK Ingeborg	Shadow rapporteur	SANT	23/04/2026	Novartis International AG
WÖLKEN Tiemo	Rapporteur for opinion	JURI	23/04/2026	Breakthrough T1D
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	22/04/2026	Bristol-Myers Squibb Company
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	22/04/2026	Food Supplements Europe
BEKE Wouter	Rapporteur	ITRE	22/04/2026	VIB VOKA UGent Centre for synthetic Biology Essencia Pharma.be VVEU Vlaamse Overheid - Departement Zorg
BEKE Wouter	Rapporteur	ITRE	22/04/2026	EUCOPE
BEKE Wouter	Rapporteur	ITRE	22/04/2026	EFSA
TER LAAK Ingeborg	Shadow rapporteur	SANT	22/04/2026	Kaneka Belgium N.V.
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	22/04/2026	Kaneka Belgium N.V.
GONZÁLEZ CASARES Nicolás	Rapporteur for opinion	ENVI	22/04/2026	Amgen Inc
CICCIOLI Carlo	Shadow rapporteur	ITRE	22/04/2026	AstraZeneca PLC
BOSSE Stine	Shadow rapporteur	SANT	22/04/2026	LEO Pharma A/S
BOSSE Stine	Shadow rapporteur	SANT	21/04/2026	Juvenile Diabetes Research Foundation
BOSSE Stine	Shadow rapporteur	SANT	21/04/2026	WinQure Medicine
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	21/04/2026	Juvenile Diabetes Research Foundation
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	21/04/2026	SANOFI
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	21/04/2026	Juvenile Diabetes Research Foundation
BEKE Wouter	Rapporteur	ITRE	20/04/2026	EuropaBio

BEKE Wouter	Rapporteur	ITRE	20/04/2026	UHasselt VOKA Health Community Mindwalk Anima Research Health Campus Limburg DC Simabs Limburg Clinical Research Center Innoser Archer Research C4growth Heran & Partners Argenx SwiftPharma
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	20/04/2026	Digestive Cancers Europe
KULMUNI Katri	Shadow rapporteur	ITRE	20/04/2026	Novo Nordisk A/S
BOSSE Stine	Shadow rapporteur	SANT	17/04/2026	Confederation of Danish Industry
WÖLKEN Tiemo	Shadow rapporteur	SANT	16/04/2026	Médecins Sans Frontières International
TER LAAK Ingeborg	Shadow rapporteur	SANT	16/04/2026	European Federation of Pharmaceutical Industries and Associations
TER LAAK Ingeborg	Shadow rapporteur	SANT	16/04/2026	EuropaBio
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	16/04/2026	Ultragenyx Pharmaceutical Inc.
BEKE Wouter	Rapporteur	ITRE	16/04/2026	Ultragenyx Europe GmbH MetabERN
BEKE Wouter	Rapporteur	ITRE	16/04/2026	Bristol-Myers Squibb Company
TER LAAK Ingeborg	Shadow rapporteur	SANT	16/04/2026	European Patients' Forum (EPF)
TER LAAK Ingeborg	Shadow rapporteur	SANT	16/04/2026	Patiëntenfederatie Nederland
TER LAAK Ingeborg	Shadow rapporteur	SANT	16/04/2026	Burson Cohn & Wolfe SRL Ultragenyx Europe GmbH
WÖLKEN Tiemo	Rapporteur for opinion	JURI	16/04/2026	European Federation of Pharmaceutical Industries and Associations
BOSSE Stine	Shadow rapporteur	SANT	16/04/2026	BioMarin UK Limited
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	15/04/2026	Deutsche Sozialversicherung Arbeitsgemeinschaft Europa
BEKE Wouter	Rapporteur	ITRE	15/04/2026	Pfizer Inc.
BEKE Wouter	Rapporteur	ITRE	15/04/2026	Medaxes
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	15/04/2026	Health Emergency Preparedness and Response (HERA)
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	15/04/2026	The European Food Safety Authority
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	14/04/2026	Merck
BEKE Wouter	Rapporteur	ITRE	14/04/2026	SANOFI

CICCIOLI Carlo	Shadow rapporteur	ITRE	14/04/2026	Amgen Inc
WÖLKEN Tiemo	Rapporteur for opinion	JURI	14/04/2026	Merck Sharp & Dohme Europe Belgium SRL
BEKE Wouter	Rapporteur	ITRE	13/04/2026	KU Leuven Research and Development (LRD)
BOSSE Stine	Shadow rapporteur	SANT	10/04/2026	MEDICINES FOR EUROPE
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	09/04/2026	MEDICINES FOR EUROPE
WÖLKEN Tiemo	Rapporteur for opinion	JURI	09/04/2026	rani (Resilience Action Network International)
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	08/04/2026	European Patients' Forum (EPF)
BEKE Wouter	Rapporteur	ITRE	08/04/2026	Biotallys NV Legend Biotech Biolynx Zymofix Anacura Biolizard Bio Base Europe Pilot Plant
TER LAAK Ingeborg	Shadow rapporteur	SANT	08/04/2026	European Patient Organisation for Dysimmune and Inflammatory Neuropathies
BOSSE Stine	Shadow rapporteur	SANT	08/04/2026	FIPRA International SRL
TER LAAK Ingeborg	Shadow rapporteur	SANT	07/04/2026	SANOFI
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	02/04/2026	Eurogroup for Animals
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	02/04/2026	CropLife Europe
TER LAAK Ingeborg	Shadow rapporteur	SANT	01/04/2026	Johnson & Johnson
TER LAAK Ingeborg	Shadow rapporteur	SANT	31/03/2026	AstraZeneca PLC
TER LAAK Ingeborg	Shadow rapporteur	SANT	31/03/2026	European Federation of Pharmaceutical Industries and Associations GlaxoSmithKline
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	31/03/2026	BeOne Medicines I GmbH
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	26/03/2026	Merck Sharp & Dohme Europe Belgium SRL
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	26/03/2026	Johnson & Johnson
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	26/03/2026	Pfizer Inc.
BEKE Wouter	Rapporteur	ITRE	26/03/2026	Novartis International AG
CICCIOLI Carlo	Shadow rapporteur	ITRE	26/03/2026	European Federation of Pharmaceutical Industries and Associations
BOSSE Stine	Shadow rapporteur	SANT	26/03/2026	Brussels Institute for Geopolitics
	Shadow			

BOSSE Stine	rapporteur	SANT	26/03/2026	Bristol-Myers Squibb Company
BOSSE Stine	Shadow rapporteur	SANT	26/03/2026	Biomedical Alliance in Europe
BEKE Wouter	Rapporteur	ITRE	24/03/2026	European Federation of Pharmaceutical Industries and Associations
TER LAAK Ingeborg	Shadow rapporteur	SANT	24/03/2026	Vereniging Innovatieve Geneesmiddelen
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	24/03/2026	European Federation of Pharmaceutical Industries and Associations
BEKE Wouter	Rapporteur	ITRE	23/03/2026	Johnson & Johnson
BOSSE Stine	Shadow rapporteur	SANT	20/03/2026	SANOFI
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	19/03/2026	Bayer AG
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	18/03/2026	Corteva Agriscience International SARL
TER LAAK Ingeborg	Shadow rapporteur	SANT	18/03/2026	Vereniging VNO-NCW
BEKE Wouter	Rapporteur	ITRE	17/03/2026	EuropaBio EU Health Coalition
BEKE Wouter	Rapporteur	ITRE	17/03/2026	Pharma.be
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	17/03/2026	Pandemic Action Network
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	17/03/2026	Novartis International AG
BOSSE Stine	Shadow rapporteur	SANT	17/03/2026	EuropaBio
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	16/03/2026	Burson Cohn & Wolfe Sprl
GONZÁLEZ CASARES Nicolás	Rapporteur for opinion	ENVI	13/03/2026	AbbVie
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	13/03/2026	Psychedelic Participant Advocacy Network
BOSSE Stine	Shadow rapporteur	SANT	12/03/2026	GSK
BEKE Wouter	Rapporteur	ITRE	10/03/2026	AstraZeneca PLC Boehringer Ingelheim European Venture Philanthropy Association Novartis International AG Lif BioArtic
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	10/03/2026	AstraZeneca PLC Läkemedelsindustriföreningen Novartis International AG
ANDRIUKAITIS Vytenis Povilas	Rapporteur	SANT	10/03/2026	EuropaBio
BOSSE Stine	Shadow rapporteur	SANT	06/03/2026	PHARMABIOTIC RESEARCH INSTITUTE
BOSSE Stine	Shadow rapporteur	SANT	06/03/2026	Aarhus University

GONZÁLEZ CASARES Nicolás	Rapporteur for opinion	ENVI	04/03/2026	ASOCIACIÓN ESPAÑOLA DE MEDICAMENTOS BIOSIMILARES
BOSSE Stine	Shadow rapporteur	SANT	26/02/2026	Novozymes A/S
TER LAAK Ingeborg	Shadow rapporteur	SANT	25/02/2026	Raad voor Dierenaangelegenheden
CICCIOLI Carlo	Shadow rapporteur	ITRE	24/02/2026	Bristol-Myers Squibb Company Cattaneo Zanetto Pomposo & Co.
GONZÁLEZ CASARES Nicolás	Rapporteur for opinion	ENVI	18/02/2026	HIPRA, S.A.
BOSSE Stine	Shadow rapporteur	SANT	26/01/2026	European Food Safety Authority (EFSA)

## Other Members

Transparency		
Name	Date	Interest representatives
METZ Tilly	19/05/2026	Humane World for Animals Europe
KÖHLER Stefan	13/05/2026	BIO Deutschland
SOKOL Tomislav	07/05/2026	Bristol-Myers Squibb Company
HADJIPANTELA Michalis	28/04/2026	MEDICINES FOR EUROPE
HADJIPANTELA Michalis	28/04/2026	European Confederation of Pharmaceutical Entrepreneurs
SOKOL Tomislav	28/04/2026	American Chamber of Commerce to the European Union
CHASTEL Olivier	24/04/2026	Nuclear Medicine Europe
SOKOL Tomislav	15/04/2026	European Patients' Forum (EPF)
VIGENIN Kristian	08/04/2026	EPODIN
PAPANDREOU Nikos	08/04/2026	MSD
LØKKEGAARD Morten	24/03/2026	Genmab A/S
GYŪRK András	12/03/2026	MEDICINES FOR EUROPE
VIGENIN Kristian	05/03/2026	Fresenius SE & Co.KGaA
SOKOL Tomislav	04/03/2026	Bayer AG
LØKKEGAARD Morten	27/02/2026	AstraZeneca PLC
LØKKEGAARD Morten	16/02/2026	Novo Nordisk Foundation
GONZÁLEZ CASARES Nicolás	10/02/2026	Gilead Sciences
GONZÁLEZ CASARES Nicolás	04/02/2026	Juvenile Diabetes Research Foundation
GONZÁLEZ CASARES Nicolás	04/02/2026	ASOCIACION ESPAÑOLA DE BIOEMPRESAS
ANDREWS Barry	27/01/2026	Ibec Biopharmachem Ireland
PAPANDREOU Nikos	11/03/2025	EuropaBio

## European Biotech Act

**PURPOSE:** to establish an EU Biotech Act to strengthen the competitiveness, resilience and strategic autonomy of the Union's biotechnology and biomanufacturing sectors,

**PROPOSED ACT:** Regulation of the European Parliament and of the Council.

**ROLE OF THE EUROPEAN PARLIAMENT:** the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

**BACKGROUND:** Biotechnology is one of the fastest growing sectors in the EU. It currently accounts for more than 900 000 jobs – 75% of which are in the health sector - and contributes close to EUR 40 billion to the European economy. Biotech can revolutionise healthcare, as a source of ground-breaking new treatments and therapies, more precise diagnoses and personalised medicines. However, the EU lags behind other global regions when it comes to translating its worldclass science and innovation into commercially viable products, and even more so in manufacturing such products at scale.

The proposed Biotech Act will increase Europe's biotechnology potential by supporting the transition of innovative ideas from laboratory to market. It will explore new means of funding and investment for biotech companies, through a new health biotech investment pilot to be developed in cooperation with the EIB Group. It will aim to boost bio-manufacturing via targeted support.

**CONTENT:** the Commission proposal on a European Biotech Act establishes a **comprehensive EU framework** to strengthen the competitiveness, resilience and strategic autonomy of the Union's biotechnology and biomanufacturing sectors, with a particular focus on health-related applications. It introduces measures to facilitate investment, innovation and scale-up of biotechnological and biomanufacturing activities, including improved access to funding, infrastructure and skills.

The general objective of this Regulation is threefold:

- (i) to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector, from research to production;
- (ii) to create the conditions for the development and timely placing on the EU market, of biotechnology innovations, products and services;
- (iii) to safeguard high standards for the protection of human health, animal health, patients and consumers, the environment, ethics, quality, food and feed safety, and biosecurity.

This general objective translates into the following specific objectives:

- strengthen the biotechnology sector and reinforce the EU's research, development and production capabilities, by establishing a framework for the recognition of, and support measures for, strategic health biotechnology projects and high impact strategic health biotechnology projects;
- **support funding of, investments** in, and access to capital for, biotechnology companies and projects, including through the setting up of an EU health biotechnology investment pilot to fill the gap in spending on biotechnology innovation;
- improve the **EU manufacturing capacity** of, and expertise in **biosimilars**, including through international cooperation;
- facilitate the application of **AI into the EU's biotechnology and health technology** manufacturing ecosystems and frameworks, in line with the Regulation (EU) 2024/1689;
- ensure a legislative framework that encourages innovation and takes account of technological and scientific developments and progress, by establishing provisions for health biotechnology products;
- prevent the **misuse of biotechnologies** and strengthen **biodefence** capabilities;
- enable the effectiveness of the above-mentioned measures through a legislative framework conducive to the use of biotechnology innovations, by amending Union legislation in particular on clinical trials, veterinary medicinal products, food and feed safety and related legislation.

### ***Budgetary implications***

Without prejudice to the outcome of the negotiations on the next Multiannual financial framework (MFF) proposal, strategic health biotechnology projects and high-impact strategic biotechnology projects may be supported by Union programmes, funds and instruments, in accordance with the objectives set out in the regulations establishing those funds and programmes. A contribution is expected to come from the 'health, biotechnology, agriculture and bioeconomy' window under the European Competitiveness Fund which, according to the proposal of the Commission, would receive a total allocation of EUR 20.4 billion over the MFF 2028-2034.

Two agencies, EMA and EFSA are proposed to be reinforced in staff and financially to conduct tasks related to these projects. The necessary financial resources will be compensated from applicable programmes under the agencies' headings in the 2028-2034 MFF and where possible by additional income to be generated from third parties.