Basic information

2023/0132(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Awaiting Parliament 2nd reading
Medicinal products for human use Repealing Directive 2001/83 1999/0134(COD) Repealing Directive 2009/35 2008/0001(COD) **Subject** 4.20.01 Medicine, diseases 4.20.04 Pharmaceutical products and industry **Legislative priorities** Joint Declaration 2023-24	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
SANT Public Health	MONTSERRAT Dolors (EPP)	19/02/2025
	Shadow rapporteur GONZÁLEZ CASARES Nicolás (S&D) DE LA PISA CARRIÓN Margarita (PfE) STORM Kristoffer (ECR) VASILE-VOICULESCU Vlad (Renew) METZ Tilly (Greens/EFA) GEORGIOU Giorgos (The Left) ANDERSON Christine (ESN)	

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	WEISS-EHLER Pernille (EPP)	15/05/2023

Former committee for opinion	Former rapporteur for opinion	Appointed
BUDG Budgets	The committee decided not to give an opinion.	

	ITRE Industry, Research and Energy	VIRKKUNEN Henna (EPP)	05/10/2023
	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	JURI Legal Affairs (Associated committee)	Chair on behalf of committee VÁZQUEZ LÁZARA Adrián (Renew)	14/12/2023

Council of the European Union

European Commission

Commission DG	Commissioner
Health and Food Safety	KYRIAKIDES Stella

European Economic and Social Committee

European Committee of the Regions

Key events

Date	Event	Reference	Summary
26/04/2023	Legislative proposal published	COM(2023)0192	Summary
14/09/2023	Committee referral announced in Parliament, 1st reading		
14/09/2023	Referral to associated committees announced in Parliament		
19/03/2024	Vote in committee, 1st reading		
21/03/2024	Committee report tabled for plenary, 1st reading	A9-0140/2024	
10/04/2024	Decision by Parliament, 1st reading	T9-0220/2024	Summary
10/04/2024	Results of vote in Parliament		
10/04/2024	Debate in Parliament		
13/11/2024	Resumption of business from the previous parliamentary term		
03/06/2025	Committee decision to open interinstitutional negotiations after 1st reading in Parliament		
16/06/2025	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 73)		
18/03/2026	Approval in committee of the text agreed at early 2nd reading interinstitutional negotiations	GEDA/A/(2026)201324 PE792.228	
01/10/2026	Council position published	07106/2/2026	
08/10/2026	Committee referral announced in Parliament, 2nd reading		
10/11/2026	Vote in committee, 2nd reading		

13/11/2026	Committee recommendation tabled for plenary, 2nd reading	A10-0297/2026	

Forecasts

23/11/2026	Indicative plenary sitting date, 2nd reading

Technical information

Procedure reference	2023/0132(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Repealing Directive 2001/83 1999/0134(COD) Repealing Directive 2009/35 2008/0001(COD)
Legal basis	Rules of Procedure EP 57_o Treaty on the Functioning of the European Union TFEU 114 Treaty on the Functioning of the European Union TFEU 168-p4
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Awaiting Parliament 2nd reading
Committee dossier	SANT/10/02415

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE753.470	03/10/2023	
Amendments tabled in committee		PE754.916	21/11/2023	
Amendments tabled in committee		PE754.917	21/11/2023	
Amendments tabled in committee		PE756.260	21/11/2023	
Amendments tabled in committee		PE756.261	21/11/2023	
Specific opinion	JURI	PE758.884	13/02/2024	
Committee opinion	ITRE	PE754.773	22/02/2024	
Committee report tabled for plenary, 1st reading/single reading		A9-0140/2024	21/03/2024	
Text adopted by Parliament, 1st reading/single reading		T9-0220/2024	10/04/2024	Summary
Text agreed during interinstitutional negotiations		PE792.228	17/09/2026	
Committee draft report		PE796.189	12/10/2026	
Committee recommendation tabled for plenary, 2nd reading		A10-0297/2026	13/11/2026	

Council of the EU

Document type	Reference	Date	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2026)201324	19/03/2026	
Council position	07106/2/2026	01/10/2026	
Draft final act	00066/2026/LEX	06/11/2026	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2023)0192	26/04/2023	Summary
Document attached to the procedure	SEC(2023)0390	26/04/2023	
Document attached to the procedure	SWD(2023)0191	26/04/2023	
Document attached to the procedure	SWD(2023)0192	26/04/2023	
Document attached to the procedure	SWD(2023)0193	26/04/2023	
Commission response to text adopted in plenary	SP(2024)377	29/07/2024	
Commission communication on Council's position	COM(2026)0526	29/09/2026	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	CZ_CHAMBER	COM(2023)0192	06/09/2023	
Contribution	CZ_SENATE	COM(2023)0192	10/11/2023	
Contribution	RO_SENATE	COM(2023)0192	20/11/2023	
Contribution	DE_BUNDESRAT	COM(2023)0192	04/12/2023	
Contribution	IT_SENATE	COM(2023)0192	07/12/2023	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1968/2023	25/10/2023	

Additional information

Source	Document	Date
European Parliament	Briefing	03/04/2024
European Commission	EUR-Lex	

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
METZ Tilly	Shadow rapporteur	SANT	09/12/2025	Pharmaceutical Group of the European Union
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	02/12/2025	European Federation of Pharmaceutical Industries and Associations
MONTSERRAT Dolors	Rapporteur	SANT	26/11/2025	European Federation of Pharmaceutical Industries and Associations
MONTSERRAT Dolors	Rapporteur	SANT	26/11/2025	MEDICINES FOR EUROPE
MONTSERRAT Dolors	Rapporteur	SANT	26/11/2025	Almirall
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	26/11/2025	Affordable Medicines Europe
MONTSERRAT Dolors	Rapporteur	SANT	25/11/2025	Pharmaceutical Group of the European Union
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	25/11/2025	Pharmaceutical Group of the European Union
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	19/11/2025	AstraZeneca PLC
JARUBAS Adam	Committee chair	SANT	14/11/2025	European Association of E-Pharmacies
MONTSERRAT Dolors	Rapporteur	SANT	06/11/2025	Pharmaceutical Group of the European Union
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	30/10/2025	Novartis International AG
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	27/10/2025	Permanent Representation of the Netherlands to the EU
JARUBAS Adam	Committee chair	SANT	24/10/2025	European Federation of Pharmaceutical Industries and Associations
MONTSERRAT Dolors	Rapporteur	SANT	17/10/2025	Teva Pharmaceuticals Europe BV
SOKOL Tomislav	Shadow rapporteur	SANT	15/10/2025	European Carton Makers Association
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	14/10/2025	MEDICINES FOR EUROPE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	14/10/2025	AEMPS (Agencia Española de Medicamentos y Productos Sanitarios)
MONTSERRAT Dolors	Rapporteur	SANT	14/10/2025	Aboca S.P.A. Società Agricola
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	08/10/2025	Bayer AG
JARUBAS Adam	Committee chair	SANT	01/10/2025	Związek Pracodawców Innowacyjnych Firm Farmaceutycznych INFARMA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	30/09/2025	Miltenyi Biomedicine GmbH
JARUBAS Adam	Committee chair	SANT	29/09/2025	Affordable Medicines Europe

GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	16/09/2025	European Society of Cardiology
MONTSERRAT Dolors	Rapporteur	SANT	10/09/2025	MEDICINES FOR EUROPE
MONTSERRAT Dolors	Rapporteur	SANT	04/09/2025	Association of the European Self-Care Industry
MONTSERRAT Dolors	Rapporteur	SANT	08/07/2025	Gilead Sciences
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	08/07/2025	Permanent Representation of Spain to the EU
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	08/07/2025	Permanent Representation of France to the EU
JARUBAS Adam	Committee chair	SANT	04/07/2025	Affordable Medicines Europe
MONTSERRAT Dolors	Rapporteur	SANT	01/07/2025	Teva Pharmaceuticals Europe BV
MONTSERRAT Dolors	Rapporteur	SANT	25/06/2025	European Federation of Pharmaceutical Industries and Associations
MONTSERRAT Dolors	Rapporteur	SANT	20/06/2025	MEDICINES FOR EUROPE
METZ Tilly	Shadow rapporteur	SANT	19/06/2025	MEDICINES FOR EUROPE
MONTSERRAT Dolors	Rapporteur	SANT	11/06/2025	GSK
MONTSERRAT Dolors	Rapporteur	SANT	26/05/2025	Merck
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	14/05/2025	EFPIA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	SANT	25/04/2025	Affordable Medicines Europe
MONTSERRAT Dolors	Rapporteur	SANT	01/04/2025	Affordable Medicines Europe
MONTSERRAT Dolors	Rapporteur	SANT	19/03/2025	Novo Nordisk A/S
MONTSERRAT Dolors	Rapporteur	SANT	19/03/2025	European Federation of Pharmaceutical Industries and Associations
VASILE-VOICULESCU Vlad	Shadow rapporteur	SANT	11/02/2025	The Mission of Japan to the EU
STORM Kristoffer	Shadow rapporteur	ENVI	04/12/2024	Confederation of Danish Industry
MONTSERRAT Dolors	Rapporteur	ENVI	03/12/2024	Bayer AG
METZ Tilly	Shadow rapporteur	ENVI	26/11/2024	MEDICINES FOR EUROPE
METZ Tilly	Shadow rapporteur	ENVI	19/11/2024	Innovative Medicines for Luxembourg
MONTSERRAT Dolors	Rapporteur	ENVI	18/11/2024	Medical Leaflets Patient Safety
MONTSERRAT Dolors	Rapporteur	ENVI	24/10/2024	MEDICINES FOR EUROPE
MONTSERRAT Dolors	Rapporteur	ENVI	08/10/2024	BioMarin UK Limited
MONTSERRAT Dolors	Rapporteur	ENVI	26/09/2024	Teva Pharmaceuticals Europe BV
MONTSERRAT Dolors	Rapporteur	ENVI	12/09/2024	GSK
STORM Kristoffer	Shadow rapporteur	ENVI	23/07/2024	Novo Nordisk A/S
WEISS-EHLER Pernille	Rapporteur	ENVI	18/06/2024	Novo Nordisk A/S

WEISS-EHLER Pernille	Rapporteur	ENVI	08/05/2024	Johnson & Johnson
AMALRIC Catherine	Shadow rapporteur	ENVI	02/05/2024	Laboratoires Delbert
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	23/04/2024	AFEPADI
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	18/04/2024	Farmaindustria
WEISS-EHLER Pernille	Rapporteur	ENVI	05/04/2024	Novo Nordisk A/S
WEISS-EHLER Pernille	Rapporteur	ENVI	03/04/2024	Alliance Promotion Microbiote
WEISS-EHLER Pernille	Rapporteur	ENVI	27/03/2024	Confindustria
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	21/03/2024	Spanish Ministry for Health
WEISS-EHLER Pernille	Rapporteur	ENVI	21/03/2024	Confederation of Danish Industry
WEISS-EHLER Pernille	Rapporteur	ENVI	21/03/2024	Novo Nordisk Foundation
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	15/03/2024	Hospital Clinic
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	15/03/2024	Hospital Vall de Hebron
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	13/03/2024	Novo Nordisk A/S
WEISS-EHLER Pernille	Rapporteur	ENVI	11/03/2024	European Federation of Pharmaceutical Industries and Associations
WEISS-EHLER Pernille	Rapporteur	ENVI	08/03/2024	Novo Nordisk A/S
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	07/03/2024	COFARES SOCIEDAD COOPERATIVA FARMACEUTICA ESPAÑOLA
WEISS-EHLER Pernille	Rapporteur	ENVI	07/03/2024	Bayer AG
WEISS-EHLER Pernille	Rapporteur	ENVI	07/03/2024	European Confederation of Pharmaceutical Entrepreneurs
WEISS-EHLER Pernille	Rapporteur	ENVI	06/03/2024	F. Hoffmann-La Roche Ltd
WEISS-EHLER Pernille	Rapporteur	ENVI	06/03/2024	Lægemiddelindustriforeningen
WEISS-EHLER Pernille	Rapporteur	ENVI	05/03/2024	The Danish Permanent Representation to the EU
WEISS-EHLER Pernille	Rapporteur	ENVI	05/03/2024	GSK
AMALRIC Catherine	Shadow rapporteur	ENVI	25/02/2024	Association nationale des étudiants en pharmacie
WEISS-EHLER Pernille	Rapporteur	ENVI	23/02/2024	European Patients' Forum (EPF)
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	22/02/2024	European Medicines Agency
WEISS-EHLER Pernille	Rapporteur	ENVI	22/02/2024	Alexion Pharmaceuticals
WEISS-EHLER Pernille	Rapporteur	ENVI	22/02/2024	Fresenius SE & Co.KGaA
WEISS-EHLER Pernille	Rapporteur	ENVI	21/02/2024	Permanent Representation of Malta to the European Union
WEISS-EHLER Pernille	Rapporteur	ENVI	21/02/2024	Permanent Representation of the Kingdom of the Netherlands to the European Union

AMALRIC Catherine	Shadow rapporteur	ENVI	21/02/2024	NéreS
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	20/02/2024	BEUC
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	20/02/2024	European Resucitation Council
AMALRIC Catherine	Shadow rapporteur	ENVI	20/02/2024	European Organisation for Research and Treatment of Cancer
WEISS-EHLER Pernille	Rapporteur	ENVI	16/02/2024	France Assos Santé
WEISS-EHLER Pernille	Rapporteur	ENVI	16/02/2024	Biogen
WEISS-EHLER Pernille	Rapporteur	ENVI	15/02/2024	BioMarin UK Limited
WEISS-EHLER Pernille	Rapporteur	ENVI	14/02/2024	AbbVie
WEISS-EHLER Pernille	Rapporteur	ENVI	14/02/2024	Haleon
WEISS-EHLER Pernille	Rapporteur	ENVI	14/02/2024	Pharma Deutschland e.V
WEISS-EHLER Pernille	Rapporteur	ENVI	12/02/2024	Novo Nordisk A/S
WEISS-EHLER Pernille	Rapporteur	ENVI	01/02/2024	Alexion Pharmaceuticals
WEISS-EHLER Pernille	Rapporteur	ENVI	31/01/2024	Bureau Européen des Unions de Consommateurs
WEISS-EHLER Pernille	Rapporteur	ENVI	31/01/2024	BIDAFARMA
WEISS-EHLER Pernille	Rapporteur	ENVI	31/01/2024	argenx
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	31/01/2024	Afaquim
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	31/01/2024	Asociación Española de Cancer de Mama Metastásico
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	31/01/2024	argenx
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	30/01/2024	BioMarin UK Limited
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	30/01/2024	Edwards Lifesciences
WEISS-EHLER Pernille	Rapporteur	ENVI	29/01/2024	European Patients' Forum (EPF)
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	26/01/2024	Spanish medicines agency (AEMPS)
AMALRIC Catherine	Shadow rapporteur	ENVI	26/01/2024	Europa Nova
WEISS-EHLER Pernille	Rapporteur	ENVI	25/01/2024	AbbVie
WEISS-EHLER Pernille	Rapporteur	ENVI	24/01/2024	Takeda Pharmaceuticals International AG
WEISS-EHLER Pernille	Rapporteur	ENVI	23/01/2024	Novo Nordisk Foundation
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	23/01/2024	American Chamber of Commerce to the European Union
WEISS-EHLER Pernille	Rapporteur	ENVI	22/01/2024	EuropaBio
WEISS-EHLER Pernille	Rapporteur	ENVI	22/01/2024	Novo Nordisk A/S

WEISS-EHLER Pernille	Rapporteur	ENVI	22/01/2024	MEDICINES FOR EUROPE
WEISS-EHLER Pernille	Rapporteur	ENVI	19/01/2024	Vaccines Europe
WEISS-EHLER Pernille	Rapporteur	ENVI	17/01/2024	Novo Nordisk A/S
WEISS-EHLER Pernille	Rapporteur	ENVI	17/01/2024	Novartis
WEISS-EHLER Pernille	Rapporteur	ENVI	15/01/2024	GSK
WEISS-EHLER Pernille	Rapporteur	ENVI	11/01/2024	EUROPEAN ORGANISATION FOR RARE DISEASES
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	11/01/2024	Merck
AMALRIC Catherine	Shadow rapporteur	ENVI	10/01/2024	UniHA
WEISS-EHLER Pernille	Rapporteur	ENVI	08/01/2024	European Patients' Forum (EPF)
WEISS-EHLER Pernille	Rapporteur	ENVI	05/01/2024	Bristol-Myers Squibb Company
WEISS-EHLER Pernille	Rapporteur	ENVI	05/01/2024	Affordable Medicines Europe
WEISS-EHLER Pernille	Rapporteur	ENVI	04/01/2024	Johnson & Johnson
WEISS-EHLER Pernille	Rapporteur	ENVI	20/12/2023	Bundesverband der Pharmazeutischen Industrie e.V.
WEISS-EHLER Pernille	Rapporteur	ENVI	18/12/2023	AMR Action Fund GP, LLC
WEISS-EHLER Pernille	Rapporteur	ENVI	15/12/2023	Gilead Sciences
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	14/12/2023	Vaccines Europe
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	13/12/2023	Novo Nordisk A/S
WEISS-EHLER Pernille	Rapporteur	ENVI	13/12/2023	Novo Nordisk A/S
WEISS-EHLER Pernille	Rapporteur	ENVI	12/12/2023	Amgen Inc Astellas Pharma Europe Limited Bayer AG CSL Eli Lilly and Company European Federation of Pharmaceutical Industries and Associations SANOFI Servier Takeda Pharmaceuticals International AG CSL Vifor Bial MSD Pharma Industry Finland VFA Farmaindustria
WEISS-EHLER Pernille	Rapporteur	ENVI	08/12/2023	ReAct - Action on Antibiotic Resistance
WEISS-EHLER Pernille	Rapporteur	ENVI	08/12/2023	Pharma Deutschland e.V
WEISS-EHLER Pernille	Rapporteur	ENVI	07/12/2023	AbbVie
WEISS-EHLER Pernille	Rapporteur	ENVI	07/12/2023	Platform for Better Oral Health in Europe
NIINISTÖ Ville	Shadow rapporteur	ITRE	07/12/2023	Bayer Oy

WEISS-EHLER Pernille	Rapporteur	ENVI	05/12/2023	Permanent Representation of Denmark to The European Union
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	04/12/2023	Harmon Corporate Affairs
WEISS-EHLER Pernille	Rapporteur	ENVI	01/12/2023	Boiron
WEISS-EHLER Pernille	Rapporteur	ENVI	30/11/2023	Novo Nordisk A/S
WEISS-EHLER Pernille	Rapporteur	ENVI	30/11/2023	EUROPEAN ORGANISATION FOR RARE DISEASES
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	28/11/2023	Gilead Sciences
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	22/11/2023	EUROPEAN ORGANISATION FOR RARE DISEASES
WEISS-EHLER Pernille	Rapporteur	ENVI	22/11/2023	European Confederation of Pharmaceutical Entrepreneurs
WEISS-EHLER Pernille	Rapporteur	ENVI	22/11/2023	Acumen Public Affairs British American Tobacco British Chamber of Commerce | EU & Belgium City of London Corporation Instinctif Partners/Policy Action Liberty Global Corporate B.V. Make UK (formerly EEF) RELX International Rud Pedersen Brussels SEC NEWGATE EU BMW group MSD National Grid
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	21/11/2023	MEDICINES FOR EUROPE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	21/11/2023	Pancreatic Cancer Europe
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	21/11/2023	Bayer AG
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	16/11/2023	Pharmaceutical Group of the European Union
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	16/11/2023	European Public Health Alliance
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	15/11/2023	Oriola Corporation GIRP, European Healthcare Distribution Association
TOVAGLIERI Isabella	Committee chair	ITRE	13/11/2023	Vaccines Europe
WEISS-EHLER Pernille	Rapporteur	ENVI	10/11/2023	Bayer AG European Federation of Pharmaceutical Industries and Associations
AMALRIC Catherine	Shadow rapporteur	ENVI	10/11/2023	SANOFI
WEISS-EHLER Pernille	Rapporteur	ENVI	09/11/2023	European Patients Organization for Dysimmune & Inflammatory Neuropathies
WEISS-EHLER Pernille	Rapporteur	ENVI	09/11/2023	ALK
WEISS-EHLER Pernille	Rapporteur	ENVI	09/11/2023	Novo Nordisk A/S
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	09/11/2023	Affordable Medicines Europe
WEISS-EHLER Pernille	Rapporteur	ENVI	08/11/2023	Permanent Representation of Denmark to The European Union

WEISS-EHLER Pernille	Rapporteur	ENVI	08/11/2023	PHARMIG - Verband der pharmazeutischen Industrie Österreichs
WEISS-EHLER Pernille	Rapporteur	ENVI	08/11/2023	Permanent Representation of Hungary to the EU
AMALRIC Catherine	Shadow rapporteur	ENVI	08/11/2023	Bristol-Myers Squibb Company
AMALRIC Catherine	Shadow rapporteur	ENVI	08/11/2023	Société française de pharmacie oncologique
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	08/11/2023	APETP
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	08/11/2023	Fedifar
WEISS-EHLER Pernille	Rapporteur	ENVI	07/11/2023	Novartis International AG
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	07/11/2023	Boehringer Ingelheim
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	07/11/2023	BEUC
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	07/11/2023	Gilead Sciences
WEISS-EHLER Pernille	Rapporteur	ENVI	03/11/2023	BEAM Alliance
WEISS-EHLER Pernille	Rapporteur	ENVI	31/10/2023	AbbVie
WEISS-EHLER Pernille	Rapporteur	ENVI	31/10/2023	Permanent Representation of Hungary to the EU
WEISS-EHLER Pernille	Rapporteur	ENVI	27/10/2023	EUCOPE
WEISS-EHLER Pernille	Rapporteur	ENVI	27/10/2023	GSK
WEISS-EHLER Pernille	Rapporteur	ENVI	27/10/2023	MEDICINES FOR EUROPE
WEISS-EHLER Pernille	Rapporteur	ENVI	26/10/2023	ARCHIMED
AMALRIC Catherine	Shadow rapporteur	ENVI	26/10/2023	EUROPEAN ORGANISATION FOR RARE DISEASES
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	26/10/2023	Affordable Medicines Europe
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	26/10/2023	CardioSignal
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	26/10/2023	EFPIA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	26/10/2023	AEMPS
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	26/10/2023	Valneva
WEISS-EHLER Pernille	Rapporteur	ENVI	25/10/2023	European Society of Cardiology
WEISS-EHLER Pernille	Rapporteur	ENVI	25/10/2023	Bayer Consumer Health
WEISS-EHLER Pernille	Rapporteur	ENVI	25/10/2023	Permanent Representation of the Federal Republic of Germany to the European Union
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	25/10/2023	MEDICINES FOR EUROPE
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	24/10/2023	Helsingin yliopisto

GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	24/10/2023	European medicines agency
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	24/10/2023	European Blood Alliance
AMALRIC Catherine	Shadow rapporteur	ENVI	23/10/2023	The European Association of Hospital Pharmacists
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	23/10/2023	Orion Corporation
WEISS-EHLER Pernille	Rapporteur	ENVI	20/10/2023	European Federation of Pharmaceutical Industries and Associations
WEISS-EHLER Pernille	Rapporteur	ENVI	20/10/2023	Vaccines Europe
WEISS-EHLER Pernille	Rapporteur	ENVI	20/10/2023	German Pharmaceutical Industry Association
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	20/10/2023	Novartis International AG
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	20/10/2023	Orion Pharma
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	20/10/2023	European Federation of Pharmaceutical Industries and Associations
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	20/10/2023	European Confederation of Pharmaceutical Entrepreneurs
WEISS-EHLER Pernille	Rapporteur	ENVI	19/10/2023	Plasma Protein Therapeutics Association Europe, international Association without lucrative purpose
WEISS-EHLER Pernille	Rapporteur	ENVI	18/10/2023	Eli Lilly and Company
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	18/10/2023	Eli Lilly and Company Kangaroo Group
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	17/10/2023	Johnson & Johnson
WEISS-EHLER Pernille	Rapporteur	ENVI	16/10/2023	Servier
AMALRIC Catherine	Shadow rapporteur	ENVI	16/10/2023	Pfizer Inc.
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	13/10/2023	Fimea
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	13/10/2023	Permanent Representation of Finland to the EU
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	13/10/2023	Lääketeollisuus ry
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	13/10/2023	Bayer AG
WEISS-EHLER Pernille	Rapporteur	ENVI	13/10/2023	Confederation of Danish Industry Novartis International AG Novo Nordisk A/S Pfizer Inc. LEO Pharma A/S Roche Pharmaceuticals A/S
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	13/10/2023	Eucope
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	13/10/2023	Acumen Public Affairs
WEISS-EHLER Pernille	Rapporteur	ENVI	13/10/2023	BioNTech SE Moderna, Inc.
AMALRIC Catherine	Shadow rapporteur	ENVI	12/10/2023	Sundicat national des pharmaciens des établissements publics de santé
AMALRIC Catherine	Shadow rapporteur	ENVI	12/10/2023	Syndicat national des pharmaciens hospitaliers

WEISS-EHLER Pernille	Rapporteur	ENVI	11/10/2023	EuropaBio Merck SwiftPharma Olon Group
AMALRIC Catherine	Shadow rapporteur	ENVI	11/10/2023	European Cancer Organisation
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	11/10/2023	ECO
WEISS-EHLER Pernille	Rapporteur	ENVI	10/10/2023	Bristol-Myers Squibb Company
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	10/10/2023	Bayer AG
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	10/10/2023	Sanofi
AUKEN Margrete	Shadow rapporteur	ENVI	09/10/2023	Bristol Myers Squibb
AMALRIC Catherine	Shadow rapporteur	ENVI	09/10/2023	Médecins Sans Frontières International
AMALRIC Catherine	Shadow rapporteur	ENVI	09/10/2023	European Social Insurance Platform AISBL représentation européenne des institutions françaises de sécurité sociale
AMALRIC Catherine	Shadow rapporteur	ENVI	09/10/2023	Académie nationale de Pharmacie
WEISS-EHLER Pernille	Rapporteur	ENVI	06/10/2023	Pfizer Inc.
WEISS-EHLER Pernille	Rapporteur	ENVI	05/10/2023	EUROPEAN ORGANISATION FOR RARE DISEASES
WEISS-EHLER Pernille	Rapporteur	ENVI	05/10/2023	West
WEISS-EHLER Pernille	Rapporteur	ENVI	05/10/2023	Gilead Sciences
AUKEN Margrete	Shadow rapporteur	ENVI	03/10/2023	BEUC
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	03/10/2023	Philips
AMALRIC Catherine	Shadow rapporteur	ENVI	02/10/2023	SANOFI
AMALRIC Catherine	Shadow rapporteur	ENVI	27/09/2023	MEDICINES FOR EUROPE
AMALRIC Catherine	Shadow rapporteur	ENVI	26/09/2023	Revue Prescrire
AMALRIC Catherine	Shadow rapporteur	ENVI	26/09/2023	Johnson & Johnson
WEISS-EHLER Pernille	Rapporteur	ENVI	26/09/2023	Affordable Medicines Europe European Healthcare Distribution Association European Community Pharmacists
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	26/09/2023	H Advisors AP
AMALRIC Catherine	Shadow rapporteur	ENVI	25/09/2023	DG HERA
AMALRIC Catherine	Shadow rapporteur	ENVI	25/09/2023	DG SANT
AMALRIC Catherine	Shadow rapporteur	ENVI	25/09/2023	Ordre national des pharmaciens
AMALRIC Catherine	Shadow rapporteur	ENVI	25/09/2023	European Patients' Forum (EPF)
AUKEN Margrete	Shadow rapporteur	ENVI	22/09/2023	European Federation of Pharmaceutical Industries and Associations

WEISS-EHLER Pernille	Rapporteur	ENVI	22/09/2023	European Federation of Pharmaceutical Industries and Associations
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	22/09/2023	EFPIA
AUKEN Margrete	Shadow rapporteur	ENVI	21/09/2023	KMC Danish Agriculture and Food Council (Landbrug og Fødevarer)
AMALRIC Catherine	Shadow rapporteur	ENVI	21/09/2023	Novartis International AG
AMALRIC Catherine	Shadow rapporteur	ENVI	21/09/2023	Bureau Européen des Unions de Consommateurs
WEISS-EHLER Pernille	Rapporteur	ENVI	20/09/2023	Alliance for Regenerative Medicine
WEISS-EHLER Pernille	Rapporteur	ENVI	20/09/2023	Novo Nordisk A/S
AUKEN Margrete	Shadow rapporteur	ENVI	19/09/2023	Testbiotech
AUKEN Margrete	Shadow rapporteur	ENVI	18/09/2023	European Patients' Forum (EPF)
AMALRIC Catherine	Shadow rapporteur	ENVI	18/09/2023	European Federation of Pharmaceutical Industries and Associations
AMALRIC Catherine	Shadow rapporteur	ENVI	18/09/2023	Les entreprises du médicament
AMALRIC Catherine	Shadow rapporteur	ENVI	18/09/2023	European Public Health Alliance France Assos Santé
WEISS-EHLER Pernille	Rapporteur	ENVI	18/09/2023	Confederation of Danish Industry
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	18/09/2023	AstraZeneca PLC
WEISS-EHLER Pernille	Rapporteur	ENVI	15/09/2023	International Diabetes Federation European Region
WEISS-EHLER Pernille	Rapporteur	ENVI	13/09/2023	2K/DENMARK
WEISS-EHLER Pernille	Rapporteur	ENVI	13/09/2023	Affordable Medicines Europe
WEISS-EHLER Pernille	Rapporteur	ENVI	12/09/2023	Regulatory Institute
WEISS-EHLER Pernille	Rapporteur	ENVI	11/09/2023	GSK
WEISS-EHLER Pernille	Rapporteur	ENVI	08/09/2023	MSD
WEISS-EHLER Pernille	Rapporteur	ENVI	07/09/2023	Pfizer Inc.
WEISS-EHLER Pernille	Rapporteur	ENVI	07/09/2023	EUCOPE
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	06/09/2023	Jaakkoo-Taara Oy
WEISS-EHLER Pernille	Rapporteur	ENVI	06/09/2023	Bundesverband der Pharmazeutischen Industrie e.V.
WEISS-EHLER Pernille	Rapporteur	ENVI	06/09/2023	MEDICINES FOR EUROPE
WEISS-EHLER Pernille	Rapporteur	ENVI	06/09/2023	EurEau
WEISS-EHLER Pernille	Rapporteur	ENVI	04/09/2023	European Federation of Pharmaceutical Industries and Associations
WEISS-EHLER Pernille	Rapporteur	ENVI	01/09/2023	Alexion Pharmaceuticals
WEISS-EHLER Pernille	Rapporteur	ENVI	01/09/2023	MEDICINES FOR EUROPE
AUKEN Margrete	Shadow rapporteur	ENVI	31/08/2023	Affordable Medicines Europe

WEISS-EHLER Pernille	Rapporteur	ENVI	31/08/2023	European Patients' Forum (EPF)
WEISS-EHLER Pernille	Rapporteur	ENVI	29/08/2023	Johnson & Johnson
WEISS-EHLER Pernille	Rapporteur	ENVI	25/08/2023	Grakom Stibo Complete Medical Leaflets = Patient Safety (MLPS) Intergraf
WEISS-EHLER Pernille	Rapporteur	ENVI	24/08/2023	Novo Nordisk A/S
WEISS-EHLER Pernille	Rapporteur	ENVI	18/08/2023	European Society for Paediatric Oncology Childhood Cancer International - Europe
WEISS-EHLER Pernille	Rapporteur	ENVI	19/07/2023	Advanced Accelerator Applications SA
WEISS-EHLER Pernille	Rapporteur	ENVI	18/07/2023	AbbVie Alexion Pharmaceuticals Amgen Inc Astellas Pharma Europe Limited AstraZeneca PLC BioMarin UK Limited Boehringer Ingelheim Novartis International AG Novo Nordisk A/S PTC Therapeutics SANOFI Servier BMS Roche Vertex pharmaceuticals
AUKEN Margrete	Shadow rapporteur	ENVI	14/07/2023	GIRP — European Healthcare Distribution Association
AUKEN Margrete	Shadow rapporteur	ENVI	14/07/2023	MEDICINES FOR EUROPE
WEISS-EHLER Pernille	Rapporteur	ENVI	14/07/2023	European Association of E-Pharmacies
AUKEN Margrete	Shadow rapporteur	ENVI	13/07/2023	Janssen, Pharmaceutical Company of Johnson & Johnson
WEISS-EHLER Pernille	Rapporteur	ENVI	13/07/2023	Association of the European Self-Care Industry
AUKEN Margrete	Shadow rapporteur	ENVI	12/07/2023	European Fine Chemicals Group (EFCG)
WEISS-EHLER Pernille	Rapporteur	ENVI	12/07/2023	Affordable Medicines Europe
WEISS-EHLER Pernille	Rapporteur	ENVI	12/07/2023	Gilead Sciences
AUKEN Margrete	Shadow rapporteur	ENVI	11/07/2023	MLPS, Medical Leaflets = Patient Safety, a subgroup of ECMA
WEISS-EHLER Pernille	Rapporteur	ENVI	11/07/2023	American Chamber of Commerce to the European Union Bristol-Myers Squibb Company Edwards Lifesciences Johnson & Johnson Pfizer Inc. MSD Viatris
AUKEN Margrete	Shadow rapporteur	ENVI	10/07/2023	Umweltbundesamt Deutschland - UBA
WEISS-EHLER Pernille	Rapporteur	ENVI	07/07/2023	European Healthcare Distribution Association
AUKEN Margrete	Shadow rapporteur	ENVI	05/07/2023	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) EFPIA
WEISS-EHLER Pernille	Rapporteur	ENVI	04/07/2023	EuropaBio

WEISS-EHLER Pernille	Rapporteur	ENVI	03/07/2023	Alexion Pharmaceuticals
WEISS-EHLER Pernille	Rapporteur	ENVI	03/07/2023	Novo Nordisk Foundation
WEISS-EHLER Pernille	Rapporteur	ENVI	29/06/2023	UK Mission to the EU
WEISS-EHLER Pernille	Rapporteur	ENVI	28/06/2023	Novo Nordisk A/S
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	28/06/2023	Hologic BV
BEŇOVÁ Monika	Shadow rapporteur	ENVI	27/06/2023	Merck Sharp & Dohme Europe Belgium SRL
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	27/06/2023	Valneva
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	26/06/2023	VIPOC
WEISS-EHLER Pernille	Rapporteur	ENVI	21/06/2023	Edwards Lifesciences
WEISS-EHLER Pernille	Rapporteur	ENVI	16/06/2023	Standing Committee of European Doctors
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	14/06/2023	Abbvie
WEISS-EHLER Pernille	Rapporteur	ENVI	13/06/2023	AbbVie
WEISS-EHLER Pernille	Rapporteur	ENVI	13/06/2023	European Federation of Pharmaceutical Industries and Associations
WEISS-EHLER Pernille	Rapporteur	ENVI	09/06/2023	European Society for Paediatric Oncology
AUKEN Margrete	Shadow rapporteur	ENVI	08/06/2023	MSD Norway - Transparency register n°: 09824113589-92
AUKEN Margrete	Shadow rapporteur	ENVI	07/06/2023	Takeda Pharmaceuticals International AG
WEISS-EHLER Pernille	Rapporteur	ENVI	07/06/2023	Takeda Pharmaceuticals International AG
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	07/06/2023	Eli Lilly and Company
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	07/06/2023	MEDICINES FOR EUROPE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	07/06/2023	Teva Pharmaceuticals Europe BV
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	07/06/2023	Insightec Europe
AUKEN Margrete	Shadow rapporteur	ENVI	06/06/2023	Médecins Sans Frontières International Health Action international
WEISS-EHLER Pernille	Rapporteur	ENVI	02/06/2023	International Association of Mutual Benefit Societies
WEISS-EHLER Pernille	Rapporteur	ENVI	02/06/2023	DSW (Deutsche Stiftung Weltbevoelkerung)
AUKEN Margrete	Shadow rapporteur	ENVI	01/06/2023	ESIP
WEISS-EHLER Pernille	Rapporteur	ENVI	31/05/2023	SANOFI
WEISS-EHLER Pernille	Rapporteur	ENVI	26/05/2023	Alliance for Regenerative Medicines
WEISS-EHLER Pernille	Rapporteur	ENVI	25/05/2023	EUCOPE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	25/05/2023	Eucope

WEISS-EHLER Pernille	Rapporteur	ENVI	24/05/2023	Vaccines Europe
WEISS-EHLER Pernille	Rapporteur	ENVI	23/05/2023	AbbVie
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	23/05/2023	Eurocare
WEISS-EHLER Pernille	Rapporteur	ENVI	22/05/2023	GSK
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	17/05/2023	DSW (Deutsche Stiftung Weltbevoelkerung)
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	16/05/2023	GSK
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	15/05/2023	MEDICINES FOR EUROPE
AUKEN Margrete	Shadow rapporteur	ENVI	02/05/2023	MEDICINES FOR EUROPE
AUKEN Margrete	Shadow rapporteur	ENVI	27/04/2023	International Association of Mutual Benefit Societies
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	27/04/2023	Johnson & Johnson
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	27/04/2023	SEME
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	26/04/2023	ROVI
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	26/04/2023	AstraZeneca PLC
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	18/04/2023	Merck
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	13/04/2023	ECO
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	12/04/2023	Vaccines Europe
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	29/03/2023	ViiV Healthcare Limited
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	29/03/2023	Gilead Sciences
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	27/03/2023	Novavax
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	23/03/2023	Stryker
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	23/03/2023	Merck
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	08/03/2023	Colegios Oficiales de Farmacéuticos
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	08/03/2023	Vaccines Europe
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	01/03/2023	Jordi Miró
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	01/03/2023	EFPIA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	01/03/2023	Novartis International AG

GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	28/02/2023	Servier
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	28/02/2023	AstraZeneca PLC
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	28/02/2023	RPP Group
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	16/02/2023	Eurocare
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	30/01/2023	Novavax
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	30/01/2023	Fundamed
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	27/01/2023	AstraZeneca PLC
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	30/11/2022	PharmaMar SA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	30/11/2022	Novartis International AG
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	25/11/2022	Harmon Corporate Affairs
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	17/11/2022	ECO
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	17/11/2022	ViiV Healthcare Limited
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	14/11/2022	ISGlobal
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	09/11/2022	Aladina
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	03/11/2022	EFPIA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	26/10/2022	Gilead Sciences
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	25/10/2022	Vaccines Europe
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	25/10/2022	Pfizer Inc.
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	13/10/2022	EFPIA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	13/10/2022	Acumen Public Affairs
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	11/10/2022	Eurocare
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	04/10/2022	ECO
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	29/09/2022	Johnson & Johnson
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	28/09/2022	Insurance Ireland
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	28/09/2022	RPP Group

GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	28/09/2022	Novavax
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	27/09/2022	Fedifar
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	13/09/2022	Vaccines Europe
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	07/09/2022	Harmon Corporate Affairs
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	18/07/2022	Vinces Consulting
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	14/07/2022	Ipsen Pharma
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	14/07/2022	Teva Pharmaceuticals Europe BV
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	13/07/2022	EAASM
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	12/07/2022	Acumen Public Affairs
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	30/06/2022	INSUDPHARMA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	30/06/2022	MEDICINES FOR EUROPE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	30/06/2022	Biogen
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	28/06/2022	Bayer AG
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	27/06/2022	AECC
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	21/06/2022	AbbVie
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	21/06/2022	Johnson & Johnson
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	16/06/2022	Eurocare
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	15/06/2022	AESGP
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	08/06/2022	DSW (Deutsche Stiftung Weltbevoelkerung)
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	31/05/2022	Transform
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	30/05/2022	AbbVie
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	17/05/2022	Acumen Public Affairs
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	12/05/2022	MEDICINES FOR EUROPE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	03/05/2022	WHO

Other Members

Transparency		
Name	**Date**	**Interest representatives**
NEVADO DEL CAMPO Elena	03/07/2025	Merck Sharp & Dohme Europe Belgium SRL
NEVADO DEL CAMPO Elena	02/07/2025	Affordable Medicines Europe
CARBERRY Nina	28/01/2025	MSD Ireland
CARBERRY Nina	13/01/2025	Novo Nordisk A/S
BOSSE Stine	16/07/2024	Novo Nordisk A/S
COLIN-OESTERLÉ Nathalie	30/05/2024	Les entreprises du médicament
ŠTEFANEC Ivan	04/04/2024	Národný inštitút pre hodnotu a technológie v zdravotníctve
JARUBAS Adam	15/03/2024	Medicines for Poland The Employers' Union of Innovative Pharmaceutical Companies polityka insight
BERNHUBER Alexander	15/03/2024	Wirtschaftskammer Österreich
KNOTEK Ondřej	08/03/2024	GSK
BERNHUBER Alexander	07/03/2024	Takeda Pharmaceuticals International AG
RASMUSSEN Bergur Løkke	06/03/2024	The Danish Association of the Pharmaceutical Industry
MONTSERRAT Dolors	06/03/2024	Bayer AG
POULSEN Erik	05/03/2024	The Danish Association of the Pharmaceutical Industry
JARUBAS Adam	05/03/2024	The Employers' Union of Innovative Pharmaceutical Companies
MONTSERRAT Dolors	04/03/2024	Teva Pharmaceuticals Europe BV
WINZIG Angelika	04/03/2024	SANOFI
FRITZON Heléne	01/03/2024	Sveriges Kommuner och Regioner (SKR)
COLIN-OESTERLÉ Nathalie	01/03/2024	Leem
KYMPOUROPOULOS Stelios	22/02/2024	Alexion Pharmaceuticals
COLIN-OESTERLÉ Nathalie	21/02/2024	Bristol-Myers Squibb Company
KNOTEK Ondřej	20/02/2024	Bristol-Myers Squibb Company
GAMON Claudia	20/02/2024	PHARMIG - Verband der pharmazeutischen Industrie Österreichs
CUTAJAR Josianne	19/02/2024	European Federation of Pharmaceutical Industries and Associations
BERNHUBER Alexander	19/02/2024	AOP Health EUCOPE
MONTSERRAT Dolors	16/02/2024	MEDICINES FOR EUROPE
COLIN-OESTERLÉ Nathalie	16/02/2024	Collectif de NGO
COLIN-OESTERLÉ Nathalie	13/02/2024	AbbVie
KNOTEK Ondřej	07/02/2024	AbbVie
JARUBAS Adam	31/01/2024	European Federation of Pharmaceutical Industries and Associations European Patients' Forum (EPF) European Social Insurance Platform AISBL MEDICINES FOR EUROPE Polish Confederation Lewiatan
RIES Frédérique	30/01/2024	European Carton Makers Association
FRANSSEN Cindy	29/01/2024	The International Federation of Anthroposophic Medical Associations
DANTI Nicola	25/01/2024	MEDICINES FOR EUROPE

LIESE Peter	23/01/2024	Bayer AG
LIESE Peter	22/01/2024	AbbVie
LIESE Peter	16/01/2024	European Federation of Pharmaceutical Industries and Associations
GRUDLER Christophe	10/01/2024	Groupe Tonnellier
KNOTEK Ondřej	09/01/2024	PTC Therapeutics
KNOTEK Ondřej	13/12/2023	European Federation of Pharmaceutical Industries and Associations
KNOTEK Ondřej	13/12/2023	Novartis International AG
MONTSERRAT Dolors	13/12/2023	Servier
ARIMONT Pascal	13/12/2023	AbbVie RPP Group
POULSEN Erik	12/12/2023	Novo Nordisk A/S
MONTSERRAT Dolors	11/12/2023	Boiron
MONTSERRAT Dolors	04/12/2023	Instituto de Salud Carlos III (ISCIII) - RICORS/TERAV
JARUBAS Adam	04/12/2023	Medicines for Poland
MONTSERRAT Dolors	30/11/2023	AstraZeneca PLC
PATRICIELLO Aldo	28/11/2023	Associazione delle Imprese del farmaco
MONTSERRAT Dolors	28/11/2023	European Confederation of Pharmaceutical Entrepreneurs
MONTSERRAT Dolors	28/11/2023	Haleon
KNOTEK Ondřej	22/11/2023	European Confederation of Pharmaceutical Entrepreneurs
MONTSERRAT Dolors	21/11/2023	Bayer AG
LIESE Peter	15/11/2023	European Patients' Forum (EPF)
GYÜRK András	08/11/2023	Novartis International AG
ANGEL Marc	07/11/2023	Innovative Medicines for Luxembourg
CLUNE Deirdre	07/11/2023	MEDICINES FOR EUROPE
CLUNE Deirdre	07/11/2023	Novartis International AG
ENGERER Cyrus	07/11/2023	PsychedelicsEUROPE
FRANSSEN Cindy	06/11/2023	Kom op tegen Kanker
MONTSERRAT Dolors	06/11/2023	MEDICINES FOR EUROPE
MONTSERRAT Dolors	06/11/2023	Novartis International AG
POULSEN Erik	30/10/2023	European Federation of Pharmaceutical Industries and Associations EFPIA
POULSEN Erik	30/10/2023	AbbVie
POULSEN Erik	30/10/2023	GSK
WINZIG Angelika	25/10/2023	PHARMIG - Verband der pharmazeutischen Industrie Österreichs
WÖLKEN Tiemo	25/10/2023	MEDICINES FOR EUROPE
CHAHIM Mohammed	24/10/2023	Vaccines Europe
WÖLKEN Tiemo	23/10/2023	European Society of Cardiology
MONTSERRAT Dolors	23/10/2023	Teva Pharmaceuticals Europe BV
BALLARÍN CEREZA Laura	20/10/2023	Medical Leaflets = Patient Safety
MONTSERRAT Dolors	19/10/2023	GSK

WÖLKEN Tiemo	18/10/2023	MEDICINES FOR EUROPE
WÖLKEN Tiemo	18/10/2023	BioNTech SE Moderna, Inc.
CHAHIM Mohammed	16/10/2023	MEDICINES FOR EUROPE
CLUNE Deirdre	10/10/2023	European Society for Paediatric Oncology
WÖLKEN Tiemo	07/09/2023	Graphic packaging International
WINZIG Angelika	20/07/2023	PHARMIG - Verband der pharmazeutischen Industrie Österreichs
CLUNE Deirdre	19/07/2023	Amgen Inc
CLUNE Deirdre	11/07/2023	American Chamber of Commerce to the European Union
PEKKARINEN Mauri	14/06/2023	RPP Group
LUENA César	07/06/2023	Merck
ZORRINHO Carlos	01/06/2023	WLPARTERS.pt
PEKKARINEN Mauri	24/05/2023	Bayer Nordic
PEKKARINEN Mauri	23/05/2023	Novartis Finland Oy

Medicinal products for human use

2023/0132(COD) - 10/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 495 votes to 57, with 45 abstentions, a legislative resolution on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.

The position adopted by the European Parliament at first reading under the ordinary legislative procedure is as follows:

Subject matter and scope

The proposed Directive should apply to medicinal products for human use intended to be placed on the market in Member States. Where questions arise as to the regulatory status of a substance or a product, the competent authority or, in the case of a centralised marketing authorisation, the Agency should consult other relevant advisory and regulatory bodies with a view to reaching a decision on the regulatory status of the substance or a product concerned.

Advanced therapy medicinal products prepared under hospital exemption

Member States should ensure that advanced therapy medicinal products prepared under hospital exemption comply with the **good pharmacy preparation practices** that are adapted to hospital processes while still equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products. This should include site inspections as well as traceability and pharmacovigilance plans and the evaluation of the preclinical and clinical data generated by the applicant.

Any relevant data from patient follow-up for a sufficient period of time after the administration of the advanced therapy medicinal product should be collected and reported by the hospital exemption approval holder to the competent authority of the Member State at least annually.

The Agency should, in collaboration with the competent authorities of Member States and the Commission, set up and maintain via regular updates a repository of that data as well as of information on the authorisation, suspension or withdrawal of hospital exemption approvals, which should be updated regularly. The repository should be publicly available except for personal data and commercially confidential information.

Animal testing

The marketing authorisation applicant should not carry out animal testing in case scientifically satisfactory non-animal testing methods are available. Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing should ensure that the **principle of replacement, reduction and refinement** of animal testing for scientific purposes has been applied with regard to any animal study conducted for the purpose of supporting the application.

Antimicrobials

The marketing authorisation holder should ensure, wherever possible, that the antimicrobial may be **dispensed per unit** in a number corresponding to the quantities corresponding to the duration of treatment. If an antimicrobial cannot be dispensed per unit, the marketing authorisation holder should ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment. Member States should promote the use of **unit dose pre-cut blisters** in hospital environment and, progressively, in dispensing pharmacies, when necessary.

The Commission should therefore issue, after consulting the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the European Environment Agency (EEA), guidelines on how to conduct ERAs for AMR selection for microbials other than bacteria.

Environmental risk assessment and other environmental information

Members insisted that risk mitigation measures (relating to the prevention and limitation of emissions into the air, water and soil) should cover the entire lifecycle of medicinal products.

Medicinal products subject to medical prescription

A medicinal product should be subject to medical prescription where it: (i) is an antibiotic or any other antimicrobial for which there is an identified risk of antimicrobial resistance; or (ii) contains an active substance, adjuvants or any other ingredients or constituent parts which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment.

A prescription for antibiotic products should: (a) be **limited to the amount required for the treatment** or therapy concerned; (b) only be prescribed for a limited duration to cover the period of risk when used as prophylaxis; (c) in the event that a diagnostic test has not been performed, a justification should be required.

Pharmacists and other health care professionals should play a role in antimicrobial stewardship, including advising on the prudent use of antibiotics and other antimicrobials, as well as their correct disposal.

Application for pricing and reimbursement

In order to increase the availability of medicines and contribute to reducing access inequalities within the Union, the marketing authorisation holders of medicinal products should submit an application for pricing and reimbursement in Member States upon request. The application for pricing and reimbursement for the medicinal product should be submitted no later than 12 months from the date when the Member State made its request, or within 24 months from that date in the case of SMEs.

Product information and labelling

Member States should make the package leaflet available **electronically and in paper format**, except where the Member State decides to make only the electronic product information available. The package leaflet should be easily legible, clearly comprehensible by users, including especially the target patient groups, and indelible.

With a view to combating misinformation, in particular during health pact of online pharmaceutical advertising and promotions and adopt specific rules to regulate such advertising and promotional practices. emergencies such as the COVID-19 pandemic, Member States should ensure that healthcare professionals are not hampered in their ability to communicate **clear, impartial and independent information**, whether in their dialogue with a patient or in broader communications.

Members States should introduce **appropriate disposal systems for antimicrobials** in the community setting and inform the general public on the correct disposal methods for antimicrobial. The Commission should assess the exposure and impact of pharmaceutical advertising and promotions online and adopt specific rules to regulate such advertising and promotional practices.

Pharmacovigilance

Member States should record all suspected adverse reactions occurring on their territory and brought to their attention by healthcare professionals or patients. They should endeavour to inform directly interested parties who have reported a suspected adverse reaction about decisions taken concerning the safety of the medicinal product. Reports of **adverse reactions** arising from incorrect administration or dispensation of a medicinal product should be available in the Eudravigilance database and shall be included in periodic safety update reports.

Medicinal products for human use

2023/0132(COD) - 26/04/2023 - Legislative proposal

PURPOSE: to review pharmaceutical legislation with a view to establishing rules on medicinal products ensuring the protection of public health and the environment as well as the functioning of the internal market.

PROPOSED ACT: Directive 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: EU pharmaceutical legislation has enabled the authorisation of safe, efficacious and high-quality medicinal products. However, patient access to medicinal products across the EU and security of supply are growing concerns. There is also a growing problem of shortages of medicinal products for many EU/EEA countries. Consequences of such shortages include decreased quality of treatment received by patients and increased burden on health systems and on healthcare professionals, who need to identify and provide alternative treatments. While the pharmaceutical legislation creates regulatory incentives for innovation and regulatory tools to support timely authorisation of innovative and promising therapies, these medicinal products do not always reach the patient, and patients in the EU have differing levels of access.

Moreover, innovation is not always focused on unmet medical needs, and there are market failures, especially in the development of priority antimicrobials that can help address antimicrobial resistance. Scientific and technological developments and digitalisation are not fully exploited, while the environmental impact of medicinal products needs attention.

The **Pharmaceutical Strategy for Europe** marks a turning point with the addition of further key objectives and by creating a **modern framework** that makes innovative and established medicinal products available to patients and healthcare systems at affordable prices, while ensuring security of supply and addressing environmental concerns.

The proposed revision of the pharmaceuticals legislation consists of this proposal for a new directive and a proposal for a new regulation, which will also cover orphan and paediatric medicinal products.

CONTENT: the overall pharmaceutical framework needs to be simplified, adapted to scientific and technological changes, and contribute to reducing the environmental impact of medicinal products. This proposed reform is comprehensive but targeted and focuses on provisions relevant to achieving its specific objectives; therefore it covers all provisions apart from those concerning advertising, falsified medicinal products, and homeopathic and traditional herbal medicinal products.

The proposed Directive lays down rules for the **placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use**. It will apply to medicinal products for human use intended to be placed on the market. It will also apply to starting materials, active substances, excipients and intermediate products.

Objectives

The objectives of the proposal are the following:

- guarantee a high level of public health by ensuring the quality, safety and efficacy of medicinal products for EU patients;

- harmonise the internal market for the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States;

- make sure all patients across the EU have timely and **equitable access** to safe, effective, and affordable medicines;

- enhance **security of supply** and ensure medicines are always available to patients, regardless of where they live in the EU;

- offer an attractive **innovation-and competitiveness** friendly environment for research, development, and production of medicines in Europe;

- make medicines more **environmentally sustainable**.

The proposed Directive includes the following main areas of revision:

- promoting **innovation and access** to affordable medicinal products - creating a balanced pharmaceutical ecosystem;

- introduction of variable incentives related to regulatory data protection and **rewarding of innovation** in areas of unmet medical needs: companies marketing innovative medicines will benefit from a minimum regulatory protection period of 8 years, including 6 years of data protection and 2 years of market protection. They will be eligible for additional periods of data protection if they launch the medicinal products in all Member States covered by the marketing authorisation (+2 years), if the medicinal product meets an unmet medical need (+6 months) or if comparative clinical trials are conducted (+6 months);

- measures that will facilitate faster market entry of **generics and biosimilars**, thereby increasing competition;

- increased **transparency** on the contribution of public funding to research & development costs;

- strengthening the requirements for environmental risk assessment (ERA) in the marketing authorisation of medicines;

- reducing the **regulatory burden** and providing a flexible regulatory framework to support innovation and competitiveness;

- specific provisions for **new platform technologies**;

- specific measures related to **quality and manufacturing**: a flexible, risk-based approach will enable the manufacture or testing of a wide range of medicinal products in close proximity to the patient.