Basic information

2023/0131(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Awaiting Council's 1st reading position
Authorisation and supervision of medicinal products for human use and governing rules for the European Medicines Agency Repealing Regulation 2000/141 1998/0240(COD) Repealing Regulation 2004/726 2001/0252(COD) Repealing Regulation 2006/1901 2004/0217(COD) Amending Regulation 2007/1394 2005/0227(COD) Amending Regulation 2014/536 2012/0192(COD) **Subject** 4.20.01 Medicine, diseases 4.20.04 Pharmaceutical products and industry 4.60.08 Safety of products and services, product liability 8.40.08 Agencies and bodies of the EU **Legislative priorities** Joint Declaration 2023-24	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
SANT Public Health		

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Climate and Food Safety	WÖLKEN Tiemo (S&D)	11/05/2023

Former committee for opinion	Former rapporteur for opinion	Appointed
BUDG Budgets	VAN OVERTVELDT Johan (ECR)	23/05/2023
CONT Budgetary Control	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy (Associated committee)	VIRKKUNEN Henna (EPP)	05/10/2023
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
AGRI Agriculture and Rural Development	LINS Norbert (EPP)	23/05/2023

	LIBE Civil Liberties, Justice and Home Affairs	The committee decided not to give an opinion.	

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)0193	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	A9-0141/2024	
10/04/2024	Decision by Parliament, 1st reading	T9-0221/2024	Summary
10/04/2024	Results of vote in Parliament		
10/04/2024	Debate in Parliament	CRE link	
13/11/2024	Committee referral announced in Parliament, 1st reading		

Technical information

Procedure reference	2023/0131(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Regulation 2000/141 1998/0240(COD) Repealing Regulation 2004/726 2001/0252(COD) Repealing Regulation 2006/1901 2004/0217(COD) Amending Regulation 2007/1394 2005/0227(COD) Amending Regulation 2014/536 2012/0192(COD)
Legal basis	Rules of Procedure EP 57_o Treaty on the Functioning of the EU TFEU 114 Treaty on the Functioning of the EU 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 Council's 1st reading position
Committee dossier	ENVI/9/11874

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE753.550	20/10/2023	
Amendments tabled in committee		PE756.138	21/11/2023	
Amendments tabled in committee		PE756.137	21/11/2023	
Amendments tabled in committee		PE756.136	21/11/2023	
Amendments tabled in committee		PE756.134	21/11/2023	
Amendments tabled in committee		PE756.133	21/11/2023	
Amendments tabled in committee		PE756.132	21/11/2023	
Amendments tabled in committee		PE756.131	21/11/2023	
Amendments tabled in committee		PE756.135	21/11/2023	
Amendments tabled in committee		PE757.081	30/11/2023	
Amendments tabled in committee		PE757.080	30/11/2023	
Specific opinion	AGRI	PE757.314	17/01/2024	
Committee opinion	ITRE	PE754.772	22/02/2024	
Specific opinion	BUDG	PE759.054	23/02/2024	
Committee report tabled for plenary, 1st reading/single reading		A9-0141/2024	21/03/2024	
Text adopted by Parliament, 1st reading/single reading		T9-0221/2024	10/04/2024	Summary

European Commission

Document type	Reference	Date	Summary
Document attached to the procedure	SWD(2023)0193	26/04/2023	
Document attached to the procedure	SWD(2023)0192	26/04/2023	
Legislative proposal	COM(2023)0193	26/04/2023	Summary
Document attached to the procedure	SWD(2023)0194	26/04/2023	
Commission response to text adopted in plenary	SP(2024)377	29/07/2024	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	CZ_CHAMBER	COM(2023)0193	06/09/2023	
Contribution	CZ_SENATE	COM(2023)0193	10/11/2023	
Contribution	RO_SENATE	COM(2023)0193	20/11/2023	
Contribution	DE_BUNDESRAT	COM(2023)0193	04/12/2023	
Contribution	IT_SENATE	COM(2023)0193	07/12/2023	
Contribution	FR_SENATE	COM(2023)0193	28/10/2024	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EDPS	Document attached to the procedure	N9-0082/2023 OJ C 000 14.11.2023, p. 0000	19/06/2023	

Additional information

Source	Document	Date
EP Research Service	Briefing	03/04/2024

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

Rapporteurs, Shadow Rapporteurs and Committee Chairs

Name	Role	Committee	Date	Interest representatives
WÖLKEN Tiemo	Rapporteur	ENVI	18/02/2025	Permanent Representation of Spain to the European Union
WÖLKEN Tiemo	Rapporteur	ENVI	18/02/2025	Permanent Representation of Italy to the European Union
WÖLKEN Tiemo	Rapporteur	ENVI	06/02/2025	The Mission of Japan to the EU
WÖLKEN Tiemo	Rapporteur	ENVI	28/01/2025	Deutsches Netzwerk gegen Antimikrobielle Resistenzen (DNAMR)
WÖLKEN Tiemo	Rapporteur	ENVI	28/01/2025	Permanent Representation of Denmark to the European Union
WÖLKEN Tiemo	Rapporteur	ENVI	27/01/2025	Vertretung des Bundestages in Brüssel
WÖLKEN Tiemo	Rapporteur	ENVI	14/01/2025	European Commission - DG SANTE
WÖLKEN Tiemo	Rapporteur	ENVI	14/01/2025	Permanent Representation of Slovakia to the EU
BOSSE Stine	Shadow rapporteur	ENVI	05/11/2024	European Federation of Pharmaceutical Industries and Associations
METZ Tilly	Shadow rapporteur	ENVI	10/04/2024	Asociación de Sarcomas Grupo Asistencial
WÖLKEN Tiemo	Rapporteur	ENVI	08/04/2024	MEDEV
METZ Tilly	Shadow rapporteur	ENVI	08/04/2024	Standing Committee of European Doctors
METZ Tilly	Shadow rapporteur	ENVI	11/03/2024	BEAM Alliance
RIES Frédérique	Shadow rapporteur	ENVI	07/03/2024	EUROPEAN ORGANISATION FOR RARE DISEASES
RIES Frédérique	Shadow rapporteur	ENVI	07/03/2024	Acumen Public Affairs
WÖLKEN Tiemo	Rapporteur	ENVI	06/03/2024	Beglian PermRep
WÖLKEN Tiemo	Rapporteur	ENVI	05/03/2024	European Confederation of Pharmaceutical Entrepreneurs
WÖLKEN Tiemo	Rapporteur	ENVI	05/03/2024	European Patients' Forum (EPF)
WÖLKEN Tiemo	Rapporteur	ENVI	05/03/2024	Eurordis - Rare Disease Europe
WÖLKEN Tiemo	Rapporteur	ENVI	05/03/2024	GARDP Foundation

METZ Tilly	Shadow rapporteur	ENVI	23/02/2024	European Society of Cardiology
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	22/02/2024	F. Hoffmann-La Roche Ltd
WÖLKEN Tiemo	Rapporteur	ENVI	22/02/2024	EMA
METZ Tilly	Shadow rapporteur	ENVI	21/02/2024	Association of European Cancer Leagues
WÖLKEN Tiemo	Rapporteur	ENVI	20/02/2024	Euorpean Commission
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	20/02/2024	Lääketeollisuus ry
RIES Frédérique	Shadow rapporteur	ENVI	19/02/2024	Bureau Européen des Unions de Consommateurs
METZ Tilly	Shadow rapporteur	ENVI	19/02/2024	Innovative Medicines for Luxembourg
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	16/02/2024	Laboratorio Reig Jofre, S.A.
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	16/02/2024	Bayer AG
RIES Frédérique	Shadow rapporteur	ENVI	14/02/2024	Algemene vereniging van de Geneesmiddelenindustrie
METZ Tilly	Shadow rapporteur	ENVI	13/02/2024	European Society for Paediatric Oncology
RIES Frédérique	Shadow rapporteur	ENVI	08/02/2024	European Federation of Pharmaceutical Industries and Associations
METZ Tilly	Shadow rapporteur	ENVI	08/02/2024	EUROPEAN ORGANISATION FOR RARE DISEASES
RIES Frédérique	Shadow rapporteur	ENVI	07/02/2024	EUROPEAN ORGANISATION FOR RARE DISEASES
SOKOL Tomislav	Shadow rapporteur	ENVI	07/02/2024	GSK
RIES Frédérique	Shadow rapporteur	ENVI	06/02/2024	BioMarin UK Limited
SOKOL Tomislav	Shadow rapporteur	ENVI	06/02/2024	European Federation of Pharmaceutical Industries and Associations
METZ Tilly	Shadow rapporteur	ENVI	02/02/2024	AIM
RIES Frédérique	Shadow rapporteur	ENVI	01/02/2024	Teva Pharmaceuticals Europe BV
SOKOL Tomislav	Rapporteur	ENVI	30/01/2024	Unicancer
WÖLKEN Tiemo	Rapporteur	ENVI	29/01/2024	Permanent Representation of Malta
SOKOL Tomislav	Shadow rapporteur	ENVI	26/01/2024	Association of the European Self-Care Industry
RIES Frédérique	Shadow rapporteur	ENVI	25/01/2024	Merck
SOKOL Tomislav	Rapporteur	ENVI	24/01/2024	Belgium Ministry of social affairs and public health
SOKOL Tomislav	Shadow rapporteur	ENVI	24/01/2024	American Chamber of Commerce to the European Union
METZ Tilly	Shadow rapporteur	ENVI	24/01/2024	EURORDIS
SLABAKOV Andrey	Shadow rapporteur	ENVI	24/01/2024	EFPIA
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	23/01/2024	AbbVie American Chamber of Commerce to the European Union Amgen Inc Astellas Pharma Europe Limited Eli Lilly and Company Merck Sharp & Dohme Europe Belgium SRL
SOKOL Tomislav	Shadow rapporteur	ENVI	23/01/2024	A. Menarini Industrie Farmaceutiche Riunite s.r.l.
WÖLKEN Tiemo	Rapporteur	ENVI	19/01/2024	Party of European Socialist

BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	19/01/2024	Grifols, S.A.
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	17/01/2024	Bayer AG
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	17/01/2024	European Federation of Pharmaceutical Industries and Associations
RIES Frédérique	Shadow rapporteur	ENVI	17/01/2024	European Confederation of Pharmaceutical Entrepreneurs
METZ Tilly	Shadow rapporteur	ENVI	17/01/2024	GIRP
SOKOL Tomislav	Shadow rapporteur	ENVI	16/01/2024	BioNTech SE Moderna Inc.
WÖLKEN Tiemo	Rapporteur	ENVI	12/01/2024	DG SANTE
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	12/01/2024	Acumen Public Affairs
WÖLKEN Tiemo	Rapporteur	ENVI	10/01/2024	IGCBE
WÖLKEN Tiemo	Rapporteur	ENVI	20/12/2023	Bundesverband der Pharmazeutischen Industrie e.V.
WÖLKEN Tiemo	Rapporteur	ENVI	18/12/2023	A. Menarini Industrie Farmaceutiche Riunite s.r.l.
WÖLKEN Tiemo	Rapporteur	ENVI	18/12/2023	AbbVie
WÖLKEN Tiemo	Rapporteur	ENVI	13/12/2023	Novo Nordisk A/S
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	12/12/2023	European Federation of Pharmaceutical Industries and Associations
RIES Frédérique	Shadow rapporteur	ENVI	12/12/2023	AbbVie
WÖLKEN Tiemo	Rapporteur	ENVI	07/12/2023	ReAct - Action on Antibiotic Resistance
NIINISTÖ Ville	Shadow rapporteur	ITRE	07/12/2023	Bayer Oy
RIES Frédérique	Shadow rapporteur	ENVI	06/12/2023	GSK
SOKOL Tomislav	Shadow rapporteur	ENVI	05/12/2023	European Federation of Pharmaceutical Industries and Associations
RIES Frédérique	Shadow rapporteur	ENVI	05/12/2023	Acumen Public Affairs
RIES Frédérique	Shadow rapporteur	ENVI	05/12/2023	European Confederation of Pharmaceutical Entrepreneurs FIPRA International SRL Thalassaemia International Federation European Alliance for Transformative Therapies (TRANSFORM)
RIES Frédérique	Shadow rapporteur	ENVI	30/11/2023	Teva Pharmaceuticals Europe BV
RIES Frédérique	Shadow rapporteur	ENVI	29/11/2023	DG SANTE
RIES Frédérique	Shadow rapporteur	ENVI	28/11/2023	EUROPEAN ORGANISATION FOR RARE DISEASES
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	27/11/2023	Johnson & Johnson
RIES Frédérique	Shadow rapporteur	ENVI	22/11/2023	Johnson & Johnson
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	22/11/2023	EUROPEAN ORGANISATION FOR RARE DISEASES
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	22/11/2023	AEMPS
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	21/11/2023	MEDICINES FOR EUROPE
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	21/11/2023	Salud por Derecho
	Shadow rapporteur for			

NIINISTÖ Ville	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
RIES Frédérique	Shadow rapporteur	ENVI	16/11/2023	Permanent Representation of the Kingdom of the Netherlands to the European Union
SOKOL Tomislav	Shadow rapporteur	ENVI	15/11/2023	Bristol-Myers Squibb Company
SOKOL Tomislav	Shadow rapporteur	ENVI	15/11/2023	MSD
SOKOL Tomislav	Shadow rapporteur	ENVI	15/11/2023	Novo Nordisk A/S
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	15/11/2023	Oriola Corporation GIRP, European Healthcare Distribution Association
RIES Frédérique	Shadow rapporteur	ENVI	15/11/2023	European Confederation of Pharmaceutical Entrepreneurs
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	15/11/2023	Cofares
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	15/11/2023	Novo Nordisk A/S
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	14/11/2023	Bayer AG
SOKOL Tomislav	Shadow rapporteur	ENVI	13/11/2023	Biogen Idec
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	13/11/2023	MEDICINES FOR EUROPE
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	13/11/2023	Salud por Derecho
SOKOL Tomislav	Shadow rapporteur	ENVI	10/11/2023	European Confederation of Pharmaceutical Entrepreneurs
SOKOL Tomislav	Shadow rapporteur	ENVI	10/11/2023	Pharma Net d.o.o.
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	10/11/2023	Plataforma de Pacientes
RIES Frédérique	Shadow rapporteur	ENVI	09/11/2023	GSK
WÖLKEN Tiemo	Rapporteur	ENVI	08/11/2023	BEUC
WÖLKEN Tiemo	Rapporteur	ENVI	08/11/2023	European Commission - DG SANTE
SOKOL Tomislav	Shadow rapporteur	ENVI	08/11/2023	EPODIN
SOKOL Tomislav	Shadow rapporteur	ENVI	08/11/2023	DSW (Deutsche Stiftung Weltbevoelkerung)
SOKOL Tomislav	Shadow rapporteur	ENVI	08/11/2023	Teva Pharmaceuticals Europe BV
WÖLKEN Tiemo	Rapporteur	ENVI	08/11/2023	Alliance for Regenerative Medicine
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	08/11/2023	European Medicines Agency
SOKOL Tomislav	Shadow rapporteur	ENVI	07/11/2023	Viatris
SOKOL Tomislav	Shadow rapporteur	ENVI	07/11/2023	Eurordis
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	07/11/2023	Farmaindustria
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	06/11/2023	DSW (Deutsche Stiftung Weltbevoelkerung)
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	06/11/2023	AEMPS
BALLARÍN	Shadow rapporteur for			

CEREZA Laura	opinion	ITRE	03/11/2023	Bureau Européen des Unions de Consommateurs
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	31/10/2023	Bayer AG
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	31/10/2023	Acumen Public Affairs
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	30/10/2023	Johnson & Johnson
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	30/10/2023	BioNTech SE Moderna Inc.
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	30/10/2023	Vaccines Europe
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	27/10/2023	Servier
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	26/10/2023	Affordable Medicines Europe
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	26/10/2023	CardioSignal
SOKOL Tomislav	Shadow rapporteur	ENVI	25/10/2023	AbbVie
SOKOL Tomislav	Shadow rapporteur	ENVI	25/10/2023	Seagen
SOKOL Tomislav	Shadow rapporteur	ENVI	25/10/2023	BEAM Alliance
SOKOL Tomislav	Shadow rapporteur	ENVI	25/10/2023	Alexion Pharmaceuticals
SOKOL Tomislav	Shadow rapporteur	ENVI	25/10/2023	European Society of Cardiology
SLABAKOV Andrey	Shadow rapporteur	ENVI	25/10/2023	AbbVie
KONENÁ Kateina	Shadow rapporteur	ENVI	25/10/2023	European Federation of Pharmaceutical Industries and Associations
KONENÁ Kateina	Shadow rapporteur	ENVI	25/10/2023	EURORDIS
WÖLKEN Tiemo	Rapporteur	ENVI	25/10/2023	European Medicines Agency
WÖLKEN Tiemo	Rapporteur	ENVI	25/10/2023	Bundesgesundheitsministerium
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	25/10/2023	Grifols, S.A.
SOKOL Tomislav	Shadow rapporteur	ENVI	24/10/2023	Vaccines Europe
SOKOL Tomislav	Shadow rapporteur	ENVI	24/10/2023	EMA
WÖLKEN Tiemo	Rapporteur	ENVI	24/10/2023	Psychedelics EUROPE
METZ Tilly	Shadow rapporteur	ENVI	24/10/2023	European Medicines Agency
WÖLKEN Tiemo	Rapporteur	ENVI	23/10/2023	Affordable Medicines Europe
WÖLKEN Tiemo	Rapporteur	ENVI	23/10/2023	Novo Nordisk Foundation
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	23/10/2023	Orion Corporation
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	23/10/2023	Avicenna Alliance
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	23/10/2023	Affordable Medicines Europe
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	23/10/2023	European Patients' Forum (EPF)
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	23/10/2023	European Federation of Pharmaceutical Industries and Associations

TARDINO Annalisa	Shadow rapporteur for opinion	ENVI	18/10/2023	Associazione Distributori Farmaceutici
KONENÁ Kateina	Shadow rapporteur	ENVI	18/10/2023	Vaccines Europe
METZ Tilly	Shadow rapporteur	ENVI	18/10/2023	Eurordis
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	13/10/2023	EUROPEAN ORGANISATION FOR RARE DISEASES
WÖLKEN Tiemo	Rapporteur	ENVI	11/10/2023	Bayer AG
METZ Tilly	Shadow rapporteur	ENVI	10/10/2023	BEUC
METZ Tilly	Shadow rapporteur	ENVI	09/10/2023	BEUC
METZ Tilly	Shadow rapporteur	ENVI	04/10/2023	BEUC
SOKOL Tomislav	Shadow rapporteur	ENVI	03/10/2023	Pfizer Inc.
METZ Tilly	Shadow rapporteur	ENVI	03/10/2023	BEUC
SOKOL Tomislav	Shadow rapporteur	ENVI	28/09/2023	European Confederation of Pharmaceutical Entrepreneurs
KONENÁ Kateina	Shadow rapporteur	ENVI	28/09/2023	Teva Pharmaceuticals Europe BV
KONENÁ Kateina	Shadow rapporteur	ENVI	22/09/2023	European Patients' Forum (EPF)
SOKOL Tomislav	Shadow rapporteur	ENVI	21/09/2023	European Self-Care Industry Association
SOKOL Tomislav	Shadow rapporteur	ENVI	20/09/2023	EuropaBio
SOKOL Tomislav	Shadow rapporteur	ENVI	20/09/2023	European Patients' Forum (EPF)
SOKOL Tomislav	Shadow rapporteur	ENVI	19/09/2023	Pfizer Inc.
WÖLKEN Tiemo	Rapporteur	ENVI	15/09/2023	Bundesverband des pharmazeutischen Großhandels e.V.
SOKOL Tomislav	Shadow rapporteur	ENVI	13/09/2023	Novartis International AG
WÖLKEN Tiemo	Rapporteur	ENVI	07/09/2023	AbbVie Alexion Pharmaceuticals Bundesverband der Pharmazeutischen Industrie e.V. Eli Lilly and Company European Federation of Pharmaceutical Industries and Associations Fresenius SE & Co.KGaA Merck PHARMIG - Verband der pharmazeutischen Industrie Österreichs SANOFI Verband der Chemischen Industrie e.V. Bundesverband der Arzneimittel-Hersteller e. V.
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	06/09/2023	Jaakkoo-Taara Oy
WÖLKEN Tiemo	Rapporteur	ENVI	06/09/2023	European Commission . DG SANTE
SOKOL Tomislav	Shadow rapporteur	ENVI	04/09/2023	Hrvatska ljekarnika komora
WÖLKEN Tiemo	Rapporteur	ENVI	31/08/2023	Burgwedel Biotech GmbH
WÖLKEN Tiemo	Rapporteur	ENVI	30/08/2023	Bundesministerium für Gesundheit
WÖLKEN Tiemo	Rapporteur	ENVI	29/08/2023	Johnson & Johnson
WÖLKEN Tiemo	Rapporteur	ENVI	29/08/2023	Deutsche Krankenhausgesellschaft e.V.
WÖLKEN Tiemo	Rapporteur	ENVI	23/08/2023	Bristol Myers Squibb
WÖLKEN Tiemo	Rapporteur	ENVI	03/08/2023	Umweltbundesamt - German Environment Agency

WÖLKEN Tiemo	Rapporteur	ENVI	03/08/2023	BEAM Alliance
WÖLKEN Tiemo	Rapporteur	ENVI	31/07/2023	MEDICINES FOR EUROPE
WÖLKEN Tiemo	Rapporteur	ENVI	19/07/2023	European Patients' Forum (EPF)
WÖLKEN Tiemo	Rapporteur	ENVI	19/07/2023	EMA
SOKOL Tomislav	Shadow rapporteur	ENVI	18/07/2023	MEDICINES FOR EUROPE
WÖLKEN Tiemo	Rapporteur	ENVI	18/07/2023	Edwards Lifesciences RPP Group
WÖLKEN Tiemo	Rapporteur	ENVI	18/07/2023	European Social Insurance Platform AISBL
WÖLKEN Tiemo	Rapporteur	ENVI	18/07/2023	EurEau
WÖLKEN Tiemo	Rapporteur	ENVI	18/07/2023	European Brain Council
WÖLKEN Tiemo	Rapporteur	ENVI	18/07/2023	The European Society for Paediatric Oncology - SIOP Europe
WÖLKEN Tiemo	Rapporteur	ENVI	17/07/2023	Plasma Protein Therapeutics Association Europe, international Association without lucrative purpose
WÖLKEN Tiemo	Rapporteur	ENVI	06/07/2023	AstraZeneca PLC
WÖLKEN Tiemo	Rapporteur	ENVI	06/07/2023	Affordable Medicines Europe
WÖLKEN Tiemo	Rapporteur	ENVI	06/07/2023	Bundesverband der Arzneimittel-Hersteller e.V.
SOKOL Tomislav	Shadow rapporteur	ENVI	05/07/2023	Teva Pharmaceuticals Europe BV
WÖLKEN Tiemo	Rapporteur	ENVI	05/07/2023	Deutsche Sozialversicherung
WÖLKEN Tiemo	Rapporteur	ENVI	05/07/2023	BEUC
WÖLKEN Tiemo	Rapporteur	ENVI	03/07/2023	EURODIS
WÖLKEN Tiemo	Rapporteur	ENVI	28/06/2023	AbbVie
WÖLKEN Tiemo	Rapporteur	ENVI	28/06/2023	Bundesverband der Pharmazeutischen Industrie e.V.
WÖLKEN Tiemo	Rapporteur	ENVI	28/06/2023	Deutsche Krankenhausgesellschaft e.V.
SOKOL Tomislav	Shadow rapporteur	ENVI	27/06/2023	DSW (Deutsche Stiftung Weltbevoelkerung)
WÖLKEN Tiemo	Rapporteur	ENVI	26/06/2023	International Association of Mutual Benefit Societies
WÖLKEN Tiemo	Rapporteur	ENVI	07/06/2023	SANOFI
WÖLKEN Tiemo	Rapporteur	ENVI	07/06/2023	BioMarin UK Limited
WÖLKEN Tiemo	Rapporteur	ENVI	07/06/2023	European Federation of Pharmaceutical Industries and Associations
WÖLKEN Tiemo	Rapporteur	ENVI	06/06/2023	MEDICINES FOR EUROPE
WÖLKEN Tiemo	Rapporteur	ENVI	05/06/2023	Novartis International AG
WÖLKEN Tiemo	Rapporteur	ENVI	05/06/2023	European Social Insurance Platform AISBL Dachverband der österreichischen Sozialversicherungen
WÖLKEN Tiemo	Rapporteur	ENVI	02/06/2023	UK Mission to the EU
WÖLKEN Tiemo	Rapporteur	ENVI	02/06/2023	European Chemical Industry Council
WÖLKEN Tiemo	Rapporteur	ENVI	26/05/2023	AMR Action Fund GP, LLC
SOKOL Tomislav	Shadow rapporteur	ENVI	23/05/2023	European Federation of Pharmaceutical Industries and Associations

Other Members

Name	Date	Interest representatives
JARUBAS Adam	09/07/2024	Chambre de Commerce et d'Industrie France Pologne
ECKE Matthias	28/03/2024	European Federation of Pharmaceutical Industries and Associations GSK
KNOTEK Ondej	20/03/2024	BioMarin UK Limited
GUALMINI Elisabetta	19/03/2024	European Confederation of Pharmaceutical Entrepreneurs
ZAMBELLI Stefania	13/03/2024	Assosalute
GLAVAK Sunana	29/02/2024	Bayer AG
DANZÌ Maria Angela	27/02/2024	European Society of Cardiology
LIESE Peter	23/02/2024	European Federation of Pharmaceutical Industries and Associations
DANZÌ Maria Angela	21/02/2024	La Roche - Hoffmann
SIDL Günther	21/02/2024	AOP Orphan Pharmaceuticals GmbH
CLUNE Deirdre	21/02/2024	Bristol-Myers Squibb Company
LUENA César	21/02/2024	Roche Farma
LIESE Peter	19/02/2024	Nuclear Medicine Europe
COLIN-OESTERLÉ Nathalie	19/02/2024	Roche France
COLIN-OESTERLÉ Nathalie	19/02/2024	Haleon
COLIN-OESTERLÉ Nathalie	19/02/2024	GSK
GLÜCK Andreas	19/02/2024	AbbVie
DANTI Nicola	15/02/2024	European Confederation of Pharmaceutical Entrepreneurs
LIESE Peter	15/02/2024	STADA Arzneimittel
KYMPOUROPOULOS Stelios	15/02/2024	European Confederation of Pharmaceutical Entrepreneurs
LIESE Peter	14/02/2024	Merck Healthcare
CLUNE Deirdre	14/02/2024	BioMarin UK Limited
TOIA Patrizia	07/02/2024	European Confederation of Pharmaceutical Entrepreneurs
LIESE Peter	07/02/2024	Weleda BPI German Pharmaceutical Industry Association
MONTSERRAT Dolors	05/02/2024	GSK
KNOTEK Ondej	01/02/2024	Ipsen Pharma
CLUNE Deirdre	24/01/2024	Merck Sharp & Dohme Europe Belgium SRL
GLAVAK Sunana	18/01/2024	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
KYMPOUROPOULOS Stelios	12/01/2024	
KNOTEK Ondej	11/01/2024	GSK
DANTI Nicola	19/12/2023	Angelini Pharma
CLUNE Deirdre	13/12/2023	European Paper Packaging Alliance
MONTSERRAT Dolors	11/12/2023	Boiron
ANGEL Marc	08/12/2023	ALAN asbl-Maladies Rares Luxembourg
WINZIG Angelika	07/12/2023	PHARMIG - Verband der pharmazeutischen Industrie Österreichs
DANZÌ Maria Angela	05/12/2023	Insightec Ltd.
NOVAK Ljudmila	30/11/2023	Sandoz International GmbH
PATRICIELLO Aldo	29/11/2023	Confindustria

PATRICIELLO Aldo	29/11/2023	MEDICINES FOR EUROPE
LIESE Peter	27/11/2023	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
TOVAGLIERI Isabella	23/11/2023	Angelini Pharma
KYMPOUROPOULOS Stelios	16/11/2023	Novo Nordisk A/S
GLAVAK Sunana	15/11/2023	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
TOIA Patrizia	15/11/2023	EURORDIS
NOVAK Ljudmila	09/11/2023	Forum of International Research and Development Pharmaceutical Companies, EIG 786313251884-04
PAPANDREOU Nikos	09/11/2023	The European Society for Pediatric Oncology
KYMPOUROPOULOS Stelios	08/11/2023	Eli Lilly and Company
DANTI Nicola	07/11/2023	Associazione delle Imprese del farmaco
DANTI Nicola	07/11/2023	A. Menarini Industrie Farmaceutiche Riunite s.r.l.
NOVAK Ljudmila	07/11/2023	Novartis International AG 91269481588-28
MONTSERRAT Dolors	07/11/2023	Gilead Sciences
VANDENKENDELAERE Tom	06/11/2023	Kom op tegen Kanker
KYMPOUROPOULOS Stelios	27/10/2023	MEDICINES FOR EUROPE
KYMPOUROPOULOS Stelios	24/10/2023	Boehringer Ingelheim
KYMPOUROPOULOS Stelios	18/10/2023	Avicenna Alliance
KYMPOUROPOULOS Stelios	09/10/2023	Affordable Medicines Europe
VANDENKENDELAERE Tom	05/10/2023	Bristol-Myers Squibb Company
CARVALHO Maria da Graça	19/09/2023	Janssen Portugal
WINZIG Angelika	07/09/2023	PHARMIG - Verband der pharmazeutischen Industrie Österreichs
VANDENKENDELAERE Tom	04/09/2023	Novartis International AG

Authorisation and supervision of medicinal products for human use and governing rules for the European Medicines Agency

2023/0131(COD) - 26/04/2023 - Legislative proposal

PURPOSE: to ensure the authorisation of high-quality medicinal products, including for paediatric patients and patients suffering from rare diseases throughout the Union.

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: the Union pharmaceutical framework has enabled the authorisation of safe, efficacious and high-quality medicines in the Union, contributing to a high level of public health and a smooth functioning of the internal market of these products.

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.

Addressing unequal patient access of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe as has been highlighted by the Council and the European Parliament. Member States have called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring patient access and availability of medicinal products in all Member States.

Previous amendments to the Union pharmaceutical legislation have addressed access to medicinal products by providing for accelerated assessment for marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies, these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicines.

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

CONTENT: this proposal lays down Union procedures for the **authorisation, supervision and pharmacovigilance of medicinal products for human use** at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency (EMA).

This Regulation will not affect the powers of Member States' authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions. Member States may choose from the particulars shown in the marketing authorisation those therapeutic indications and pack sizes which will be covered by their social security bodies.

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 regulation includes the following **main areas of revision**:

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

- modulation of the **length of the market exclusivity** for orphan medicinal products. For rare disease medicines, the standard duration of market exclusivity would be 9 years with the possibility of granting a one-year extension of market exclusivity, based on patient access in all Member States concerned;

- **paediatric investigation plans** for medicinal products for children, based on a medicinal product’s mechanism of action;

- measures related to **antimicrobials** and provisions on transferable data exclusivity **vouchers.** A voucher system will provide ‘transferable data exclusivity vouchers’ under strict conditions to developers of new antimicrobials. Such a voucher will grant an additional year of regulatory data protection to the developer of the priority antimicrobial, which the developer can either use for any product in their own product portfolio or sell it to another marketing authorisation holder;

- strengthening the **scientific and regulatory support** of the European Medicines Agency, in particular for developers of medicines that address unmet medical needs;

- enhanced pre-authorisation scientific and regulatory support;

- temporary **emergency marketing** authorisation;

- improving security of supply of medicines;

- a framework for activities to be undertaken by Member States and the Agency to improve the EU's ability to respond in an effective and coordinated manner to support the management of medicines **shortages** at all times;

- EMA capacity to inspect sites located in non-EU countries;

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

- improved structure and governance of EMA and the regulatory network.

Authorisation and supervision of medicinal products for human use and governing rules for the European Medicines Agency

2023/0131(COD) - 10/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 488 votes to 67, with 34 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.

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

Subject matter and scope

The proposed regulation: (i) lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, (ii) establishes rules and procedures at Union and at Member State level relating to the monitoring and management of shortages and critical shortages and the security of supply of medicinal products and (iii) lays down the governance provisions of the European Medicines Agency.

Environmental risk assessment

The environmental risk assessment of medicinal products consisting of or containing genetically modified organisms should include the identification and characterisation of risks to the environment, animals and human health **throughout the life-cycle** of the medicinal product, including its production, and the risk reduction and mitigation strategies proposed to address the identified risks.

Combating antimicrobial resistance (AMR)

In order to support the development of antimicrobials and address existing market failures, Members wish to introduce market entry rewards and intermediate reward payment systems. Accordingly, they suggested developing a **milestone payment reward scheme**, complemented by a subscription model voluntary joint procurement scheme, should be developed to ensure that a market exists for developers that delink volumes sold from payment received.

Milestone payments are an early-stage financial reward granted upon achieving certain R&D objectives prior to market approval. While such mechanisms would serve primarily to provide access to existing antimicrobials, they could also support new antimicrobials in the development phase.

Granting the right to a transferable data exclusivity voucher

Following a request by the applicant for a marketing authorisation, made before the marketing authorisation is granted, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial', under certain conditions based on a scientific assessment by the Agency. The voucher should give the right to its holder to a maximum of **additional 12 months** of data protection for one authorised medicinal product.

The Commission should adopt delegated acts by setting up the eligibility of pathogens for the protection periods referred to in the regulation in accordance with the WHO priority pathogens list or an equivalent established at Union level, with **12 months** of data protection for an authorised product ranked 'critical'**, 9 months** of data protection for those ranked 'high' and **6 months** of data protection for those ranked 'medium'.

A voucher should only be **used once** and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection. The voucher should not be used for a product which already benefited from the maximum regulatory data protection period.

By five years from the date of entry into force of this regulation, the Commission should submit an evaluation report to the European Parliament and to the Council containing a scientific assessment measuring the progress with regard to antimicrobial research and development and the effectiveness of the incentives and rewards in this regulation.

Agency's scientific advice

The Agency should, to the greatest extent possible, ensure that there is a separation between those responsible for providing scientific advice to a given medicinal product developer and those subsequently responsible for the evaluation of the marketing authorisation application for the same medicinal product. The Agency should ensure that at least one of the two rapporteurs for a marketing authorisation application has not taken part in any pre-submission activities concerning the medicinal product.

Orphan drugs

Orphan drugs (medicines developed to treat rare diseases) would benefit from up to **11 years of market exclusivity** if they address a high unmet medical need. By 24 months from the date of entry into force of this regulation, the Commission should, following a consultation with the Member States, patient organisations and other relevant stakeholders, propose a needs-driven and goals-based **Union Framework for Rare Diseases** with a view to better framing and coordinating Union policies and programmes.

Transparency

To increase transparency of scientific assessments and all other activities, a user-friendly **European medicines web-portal** should be created and maintained by the Agency. The portal should provide information for all centrally authorised medicinal products, *inter alia* on safety, efficacy, environmental risk, patient populations, and where relevant information on antimicrobial resistance, shortages, and pending obligations for marketing authorisation holders. Sufficient budgetary resources should be allocated to the Agency to ensure its transparency obligations and commitments are appropriately implemented.

Medicine shortages

The marketing authorisation holder should notify and explain its decision to temporarily suspend the marketing of a medicinal product in that Member State as soon as possible and no less than **six months** before the start of the temporary suspension of supply of that medicinal product into the market of a given Member State by the marketing authorisation holder.

The Agency should be empowered to monitor shortages of medicinal products that are authorised through the centralised procedure, also based on notifications of marketing authorisation holders. Information on such shortages should be made available on the **European medicines web-portal** provided for in this regulation.

When critical shortages are identified, both national competent authorities and the Agency should work in a coordinated manner to communicate the necessary information to patients, consumers and healthcare professionals, including on the estimated duration of the shortage and available alternatives, and manage those critical shortages.