

Basic information	
<p><b>2023/0131(COD)</b></p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p>	Awaiting Council's 1st reading position
<p>Authorisation and supervision of medicinal products for human use and governing rules for the European Medicines Agency</p> <p>Repealing Regulation 2000/141 <a href="#">1998/0240(COD)</a> Repealing Regulation 2004/726 <a href="#">2001/0252(COD)</a> Repealing Regulation 2006/1901 <a href="#">2004/0217(COD)</a> Amending Regulation 2007/1394 <a href="#">2005/0227(COD)</a> Amending Regulation 2014/536 <a href="#">2012/0192(COD)</a></p> <p><b>Subject</b></p> <p>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</p> <p><b>Legislative priorities</b></p> <p><a href="#">Joint Declaration 2023-24</a></p>	

Key players			
European Parliament	<b>Committee responsible</b>	<b>Rapporteur</b>	<b>Appointed</b>
	<a href="#">SANT</a> Public Health	WÖLKEN Tiedo (S&D)	19/02/2025
		<p>Shadow rapporteur</p> <p><a href="#">DE LA PISA CARRIÓN</a> Margarita (P/E)</p> <p><a href="#">PICARO</a> Michele (ECR)</p> <p><a href="#">BOSSE</a> Stine (Renew)</p> <p><a href="#">METZ</a> Tilly (Greens/EFA)</p> <p><a href="#">GEORGIOU</a> Giorgos (The Left)</p> <p><a href="#">ANDERSON</a> Christine (ESN)</p>	
	<b>Former committee responsible</b>	<b>Former rapporteur</b>	<b>Appointed</b>
	<a href="#">ENVI</a> Environment, Public Health and Food Safety	WÖLKEN Tiedo (S&D)	11/05/2023
	<b>Former committee for opinion</b>	<b>Former rapporteur for opinion</b>	<b>Appointed</b>

	<b>BUDG</b> Budgets	VAN OVERTVELDT Johan (ECR)	23/05/2023
	<b>CONT</b> Budgetary Control	The committee decided not to give an opinion.	
	<b>ITRE</b> Industry, Research and Energy (Associated committee)	VIRKKUNEN Henna (EPP)	05/10/2023
	<b>IMCO</b> Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	<b>AGRI</b> Agriculture and Rural Development	LINS Norbert (EPP)	23/05/2023
	<b>LIBE</b> Civil Liberties, Justice and Home Affairs	The committee decided not to give an opinion.	
Council of the European Union			
European Commission	<b>Commission DG</b>	<b>Commissioner</b>	
	Health and Food Safety	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		
13/11/2024	Committee referral announced in Parliament, 1st reading		
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 72)		
18/03/2026	Approval in committee of the text agreed at early 2nd reading interinstitutional negotiations		

<b>Forecasts</b>	
11/11/2026	Indicative plenary sitting date, 1st reading

<b>Technical information</b>	
<b>Procedure reference</b>	2023/0131(COD)
<b>Procedure type</b>	COD - Ordinary legislative procedure (ex-codecision procedure)
<b>Procedure subtype</b>	Legislation
<b>Legislative instrument</b>	Regulation
<b>Amendments and repeals</b>	Repealing Regulation 2000/141 <a href="#">1998/0240(COD)</a> Repealing Regulation 2004/726 <a href="#">2001/0252(COD)</a> Repealing Regulation 2006/1901 <a href="#">2004/0217(COD)</a> Amending Regulation 2007/1394 <a href="#">2005/0227(COD)</a> Amending Regulation 2014/536 <a href="#">2012/0192(COD)</a>
<b>Legal basis</b>	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
<b>Other legal basis</b>	Rules of Procedure EP 165
<b>Mandatory consultation of other institutions</b>	<a href="#">European Economic and Social Committee</a> <a href="#">European Committee of the Regions</a>
<b>Stage reached in procedure</b>	Awaiting Council's 1st reading position
<b>Committee dossier</b>	ENVI/9/11874

<b>Documentation gateway</b>				
<b>European Parliament</b>				
<b>Document type</b>	<b>Committee</b>	<b>Reference</b>	<b>Date</b>	<b>Summary</b>
Committee draft report		<a href="#">PE753.550</a>	20/10/2023	
Amendments tabled in committee		<a href="#">PE756.131</a>	21/11/2023	
Amendments tabled in committee		<a href="#">PE756.132</a>	21/11/2023	
Amendments tabled in committee		<a href="#">PE756.133</a>	21/11/2023	
Amendments tabled in committee		<a href="#">PE756.134</a>	21/11/2023	
Amendments tabled in committee		<a href="#">PE756.135</a>	21/11/2023	
Amendments tabled in committee		<a href="#">PE756.136</a>	21/11/2023	
Amendments tabled in committee		<a href="#">PE756.137</a>	21/11/2023	
Amendments tabled in committee		<a href="#">PE756.138</a>	21/11/2023	
Specific opinion	<a href="#">AGRI</a>	<a href="#">PE757.314</a>	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
Legislative proposal	COM(2023)0193 	26/04/2023	Summary
Document attached to the procedure	SWD(2023)0192	26/04/2023	
Document attached to the procedure	SWD(2023)0193	26/04/2023	
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	
EESC	Economic and Social Committee: opinion, report	CES1968/2023	25/10/2023	

#### Additional information

Source	Document	Date
EP Research Service	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
SOKOL Tomislav	Shadow rapporteur	SANT	03/12/2025	President of the Association of Pharmacy Employers (PharmaNET)
PICARO Michele	Shadow rapporteur	SANT	03/12/2025	EFPIA
SOKOL Tomislav	Shadow rapporteur	SANT	02/12/2025	Executive Vice President of Novo Nordisk and board member of Efpia
PICARO Michele	Shadow rapporteur	SANT	02/12/2025	Redcare Pharmacy N.V.
WÖLKEN Tiemo	Rapporteur	SANT	02/12/2025	Permanent Representation of Denmark to the European Union
WÖLKEN Tiemo	Rapporteur	SANT	25/11/2025	Permanent Representation of the Slovak Republic to the EU Permanent Representation of the Czech Republic to the EU
SOKOL Tomislav	Shadow rapporteur	SANT	18/11/2025	Novo Nordisk A/S
WÖLKEN Tiemo	Rapporteur	SANT	17/11/2025	The Permanent Representation of the Kingdom of the Netherlands to the European Union
SOKOL Tomislav	Shadow rapporteur	SANT	12/11/2025	European Society for Phenylketonuria and Allied Disorders Treated as Phenylketonuria
WÖLKEN Tiemo	Rapporteur	SANT	10/11/2025	kohlpharma
WINZIG Angelika	Rapporteur for opinion	ITRE	05/11/2025	Boehringer Ingelheim PHARMIG - Verband der pharmazeutischen Industrie Österreichs
SOKOL Tomislav	Shadow rapporteur	SANT	16/10/2025	European Society of Cardiology
WÖLKEN Tiemo	Rapporteur	SANT	15/10/2025	European Patients' Forum (EPF)
WÖLKEN Tiemo	Rapporteur	SANT	15/10/2025	Permanent Representation of Malta to the European Union
SOKOL Tomislav	Shadow rapporteur	SANT	14/10/2025	Merck Sharp & Dohme Europe Belgium SRL
WÖLKEN Tiemo	Rapporteur	SANT	13/10/2025	GSK
WINZIG Angelika	Rapporteur for opinion	ITRE	11/09/2025	PHARMIG - Verband der pharmazeutischen Industrie Österreichs
WÖLKEN Tiemo	Rapporteur	SANT	01/09/2025	European Patients' Forum (EPF)
WÖLKEN Tiemo	Rapporteur	SANT	22/07/2025	Permamnent Representation of Austria to the EU
WÖLKEN Tiemo	Rapporteur	SANT	17/07/2025	GSK
WÖLKEN Tiemo	Rapporteur	SANT	16/07/2025	Danish Health Minister
WÖLKEN Tiemo	Rapporteur	SANT	15/07/2025	Affordable Medicines Europe
SOKOL Tomislav	Shadow rapporteur	SANT	15/07/2025	Eli Lilly and Company
WÖLKEN Tiemo	Rapporteur	SANT	14/07/2025	Eli Lilly and Company
WÖLKEN Tiemo	Rapporteur	SANT	10/07/2025	Permanent Representation of the Netherlands to the EU

SOKOL Tomislav	Shadow rapporteur	SANT	09/07/2025	Permanent Representation of the Kingdom of the Netherlands to the European Union
WÖLKEN Tiemo	Rapporteur	SANT	04/07/2025	MEDICINES FOR EUROPE
WÖLKEN Tiemo	Rapporteur	SANT	03/07/2025	Centre for reproductive Rights
WÖLKEN Tiemo	Rapporteur	SANT	02/07/2025	Permanent Representation of Denmark to the EU
SOKOL Tomislav	Shadow rapporteur	SANT	02/07/2025	Miltenyi Biomedicine GmbH
WÖLKEN Tiemo	Rapporteur	SANT	24/06/2025	European Healthcare Distribution Association
WÖLKEN Tiemo	Rapporteur	SANT	24/06/2025	Global Life Sciences Solutions Operations UK Ltd (doing business as Cytiva)
WÖLKEN Tiemo	Rapporteur	SANT	23/06/2025	IGBCE
METZ Tilly	Shadow rapporteur	SANT	17/06/2025	European Commission
SOKOL Tomislav	Shadow rapporteur	SANT	03/06/2025	Affordable Medicines Europe
SOKOL Tomislav	Shadow rapporteur	SANT	21/05/2025	MSD
WÖLKEN Tiemo	Rapporteur	SANT	02/04/2025	Permanent Representation of the Republic of Cyprus to the EU
WÖLKEN Tiemo	Rapporteur	SANT	19/03/2025	Permanent Representation of Germany to the EU
WÖLKEN Tiemo	Rapporteur	SANT	17/03/2025	Permanent Representation of Malta to the EU
WÖLKEN Tiemo	Rapporteur	SANT	17/03/2025	Phage EU
BOSSE Stine	Shadow rapporteur	SANT	20/02/2025	H. Lundbeck A/S
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	GARDP Foundation
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	European Confederation of Pharmaceutical Entrepreneurs
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
VIRKKUNEN Henna	Rapporteur for opinion	ITRE	20/02/2024	Lääketeollisuus ry
WÖLKEN Tiemo	Rapporteur	ENVI	20/02/2024	European Commission
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	Bayer AG
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	16/02/2024	Laboratorio Reig Jofre, S.A.
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
METZ Tilly	Shadow rapporteur	ENVI	08/02/2024	EUROPEAN ORGANISATION FOR RARE DISEASES
RIES Frédérique	Shadow rapporteur	ENVI	08/02/2024	European Federation of Pharmaceutical Industries and Associations
SOKOL Tomislav	Shadow rapporteur	ENVI	07/02/2024	GSK
RIES Frédérique	Shadow rapporteur	ENVI	07/02/2024	EUROPEAN ORGANISATION FOR RARE DISEASES
SOKOL Tomislav	Shadow rapporteur	ENVI	06/02/2024	European Federation of Pharmaceutical Industries and Associations
RIES Frédérique	Shadow rapporteur	ENVI	06/02/2024	BioMarin UK Limited
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
SLABAKOV Andrey	Shadow rapporteur	ENVI	24/01/2024	EFPIA

SOKOL Tomislav	Shadow rapporteur	ENVI	24/01/2024	American Chamber of Commerce to the European Union
SOKOL Tomislav	Rapporteur	ENVI	24/01/2024	Belgium Ministry of social affairs and public health
METZ Tilly	Shadow rapporteur	ENVI	24/01/2024	EURORDIS
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	European Confederation of Pharmaceutical Entrepreneurs FIPRA International SRL Thalassaemia International Federation European Alliance for Transformative Therapies (TRANSFORM)
RIES Frédérique	Shadow rapporteur	ENVI	05/12/2023	Acumen Public Affairs

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
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	22/11/2023	EUROPEAN ORGANISATION FOR RARE DISEASES
RIES Frédérique	Shadow rapporteur	ENVI	22/11/2023	Johnson & Johnson
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
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
RIES Frédérique	Shadow rapporteur	ENVI	16/11/2023	Permanent Representation of the Kingdom of the Netherlands to the European Union
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	15/11/2023	Oriola Corporation GIRP, European Healthcare Distribution Association
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
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	Salud por Derecho
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	13/11/2023	MEDICINES FOR EUROPE
SOKOL Tomislav	Shadow rapporteur	ENVI	10/11/2023	Pharma Net d.o.o.
SOKOL Tomislav	Shadow rapporteur	ENVI	10/11/2023	European Confederation of Pharmaceutical Entrepreneurs
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
WÖLKEN Tiemo	Rapporteur	ENVI	08/11/2023	Alliance for Regenerative Medicine
SOKOL Tomislav	Shadow rapporteur	ENVI	08/11/2023	Teva Pharmaceuticals Europe BV
SOKOL Tomislav	Shadow rapporteur	ENVI	08/11/2023	DSW (Deutsche Stiftung Weltbevölkerung)
SOKOL Tomislav	Shadow rapporteur	ENVI	08/11/2023	EPODIN
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	08/11/2023	European Medicines Agency
SOKOL Tomislav	Shadow rapporteur	ENVI	07/11/2023	Viatrix
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 Weltbevölkerung)
BALLARÍN CEREZA Laura	Shadow rapporteur for opinion	ITRE	06/11/2023	AEMPS
BALLARÍN CEREZA Laura	Shadow rapporteur for 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	Vaccines Europe
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	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	Alexion Pharmaceuticals
SOKOL Tomislav	Shadow rapporteur	ENVI	25/10/2023	European Society of Cardiology
SOKOL Tomislav	Shadow rapporteur	ENVI	25/10/2023	BEAM Alliance
WÖLKEN Tiemo	Rapporteur	ENVI	25/10/2023	Bundesgesundheitsministerium
WÖLKEN Tiemo	Rapporteur	ENVI	25/10/2023	European Medicines Agency
SLABAKOV Andrey	Shadow rapporteur	ENVI	25/10/2023	AbbVie

KONEČNÁ Kateřina	Shadow rapporteur	ENVI	25/10/2023	European Federation of Pharmaceutical Industries and Associations
KONEČNÁ Kateřina	Shadow rapporteur	ENVI	25/10/2023	EURORDIS
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 Tiedo	Rapporteur	ENVI	24/10/2023	Psychedelics EUROPE
METZ Tilly	Shadow rapporteur	ENVI	24/10/2023	European Medicines Agency
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	23/10/2023	Orion Corporation
WÖLKEN Tiedo	Rapporteur	ENVI	23/10/2023	Novo Nordisk Foundation
WÖLKEN Tiedo	Rapporteur	ENVI	23/10/2023	Affordable Medicines Europe
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
KONEČNÁ Kateřina	Shadow rapporteur	ENVI	18/10/2023	Vaccines Europe
TARDINO Annalisa	Shadow rapporteur for opinion	ENVI	18/10/2023	Associazione Distributori Farmaceutici
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 Tiedo	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
KONEČNÁ Kateřina	Shadow rapporteur	ENVI	28/09/2023	Teva Pharmaceuticals Europe BV
KONEČNÁ Kateřina	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	European Patients' Forum (EPF)

SOKOL Tomislav	Shadow rapporteur	ENVI	20/09/2023	EuropaBio
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.
WÖLKEN Tiemo	Rapporteur	ENVI	06/09/2023	European Commission . DG SANTE
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	06/09/2023	Jaakkoo-Taara Oy
SOKOL Tomislav	Shadow rapporteur	ENVI	04/09/2023	Hrvatska ljekarnička 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 Weltbevölkerung)
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

Transparency		
Name	Date	Interest representatives
NEVADO DEL CAMPO Elena	16/10/2025	AbbVie
NEVADO DEL CAMPO Elena	02/10/2025	Merck Sharp & Dohme Europe Belgium SRL
JERKOVIĆ Romana	23/04/2025	Angelini Pharma
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 Ondřej	20/03/2024	BioMarin UK Limited
GUALMINI Elisabetta	19/03/2024	European Confederation of Pharmaceutical Entrepreneurs

ZAMBELLI Stefania	13/03/2024	Assosalute
GLAVAK Sunčana	29/02/2024	Bayer AG
DANZI Maria Angela	27/02/2024	European Society of Cardiology
LIESE Peter	23/02/2024	European Federation of Pharmaceutical Industries and Associations
DANZI Maria Angela	21/02/2024	La Roche - Hoffmann
SIDL Günther	21/02/2024	AOP Orphan Pharmaceuticals GmbH
LUENA César	21/02/2024	Roche Farma
CLUNE Deirdre	21/02/2024	Bristol-Myers Squibb Company
LIESE Peter	19/02/2024	Nuclear Medicine Europe
COLIN-OESTERLÉ Nathalie	19/02/2024	Haleon
COLIN-OESTERLÉ Nathalie	19/02/2024	GSK
COLIN-OESTERLÉ Nathalie	19/02/2024	Roche France
GLÜCK Andreas	19/02/2024	AbbVie
DANTI Nicola	15/02/2024	European Confederation of Pharmaceutical Entrepreneurs
LIESE Peter	15/02/2024	STADA Arzneimittel
KYMPOROPOULOS Stelios	15/02/2024	European Confederation of Pharmaceutical Entrepreneurs
LIESE Peter	14/02/2024	Merck Healthcare
CLUNE Deirdre	14/02/2024	BioMarin UK Limited
LIESE Peter	07/02/2024	Weleda BPI German Pharmaceutical Industry Association
TOIA Patrizia	07/02/2024	European Confederation of Pharmaceutical Entrepreneurs
MONTERRAT Dolores	05/02/2024	GSK
KNOTEK Ondřej	01/02/2024	Ipsen Pharma
CLUNE Deirdre	24/01/2024	Merck Sharp & Dohme Europe Belgium SRL
GLAVAK Sunčana	18/01/2024	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
KYMPOROPOULOS Stelios	12/01/2024	ΦΑΡΜΑΚΕΥΤΙΚΟΣ ΣΥΛΛΟΓΟΣ ΑΤΤΙΚΗΣ
KNOTEK Ondřej	11/01/2024	GSK
DANTI Nicola	19/12/2023	Angelini Pharma
CLUNE Deirdre	13/12/2023	European Paper Packaging Alliance
MONTERRAT Dolores	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
DANZI Maria Angela	05/12/2023	Insightec Ltd.
NOVAK Ljudmila	30/11/2023	Sandoz International GmbH
PATRICIELLO Aldo	29/11/2023	MEDICINES FOR EUROPE
PATRICIELLO Aldo	29/11/2023	Confindustria
LIESE Peter	27/11/2023	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
TOVAGLIERI Isabella	23/11/2023	Angelini Pharma
KYMPOROPOULOS Stelios	16/11/2023	Novo Nordisk A/S
TOIA Patrizia	15/11/2023	EURORDIS

GLAVAK Sunčana	15/11/2023	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
PAPANDREOU Nikos	09/11/2023	The European Society for Pediatric Oncology
NOVAK Ljudmila	09/11/2023	Forum of International Research and Development Pharmaceutical Companies, EIG 786313251884-04
KYMPOUROPOULOS Stelios	08/11/2023	Eli Lilly and Company
MONTERRAT Dolors	07/11/2023	Gilead Sciences
NOVAK Ljudmila	07/11/2023	Novartis International AG 91269481588-28
DANTI Nicola	07/11/2023	A. Menarini Industrie Farmaceutiche Riunite s.r.l.
DANTI Nicola	07/11/2023	Associazione delle Imprese del farmaco
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) - 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.

## **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.