Basic information

2023/0131(COD)

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

Awaiting Parliament 2nd reading

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

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE753.550	20/10/2023	
Amendments tabled in committee		PE756.131	21/11/2023	
Amendments tabled in committee		PE756.132	21/11/2023	
Amendments tabled in committee		PE756.133	21/11/2023	
Amendments tabled in committee		PE756.134	21/11/2023	
Amendments tabled in committee		PE756.135	21/11/2023	
Amendments tabled in committee		PE756.136	21/11/2023	
Amendments tabled in committee		PE756.137	21/11/2023	
Amendments tabled in committee		PE756.138	21/11/2023	
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
Text agreed during interinstitutional negotiations		PE792.227	17/09/2026	
Committee draft report		PE796.377	12/10/2026	

Council of the EU

Document type	Reference	Date	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2026)201324	19/03/2026	
Council position	07105/2/2026	01/10/2026	

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	
Commission communication on Council's position	COM(2026)0527	29/09/2026	

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	