

**Basic information****2001/0252(COD)**

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

Authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

Amended by [2004/0217\(COD\)](#)  
Amended by [2005/0227\(COD\)](#)  
Amended by [2007/0064\(COD\)](#)  
Amended by [2008/0257\(COD\)](#)  
Amended by [2012/0023\(COD\)](#)  
Amended by [2014/0256\(COD\)](#)  
Amended by [2017/0328\(COD\)](#)

**Subject**

3.10.08 Animal health requirements, veterinary legislation and pharmacy  
4.20.04 Pharmaceutical products and industry  
8.40.08 Agencies and bodies of the EU

Procedure completed

**Documentation gateway****European Parliament**

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		<a href="#">A5-0330/2002</a>	02/10/2002	
Text adopted by Parliament, 1st reading/single reading		<a href="#">T5-0504/2002</a> OJ C 300 11.12.2003, p. 0166-0308 E	23/10/2002	<a href="#">Summary</a>
Committee recommendation tabled for plenary, 2nd reading		<a href="#">A5-0425/2003</a>	27/11/2003	
Text adopted by Parliament, 2nd reading		<a href="#">T5-0576/2003</a> OJ C 091 15.04.2004, p. 0133-0253 E	17/12/2003	<a href="#">Summary</a>

**Council of the EU**

Document type	Reference	Date	Summary
Council statement on its position	<a href="#">12155/1/2003</a>	24/09/2003	
Council position	<a href="#">10949/2/2003</a> OJ C 297 09.12.2003, p. 0001-0040 E	29/09/2003	<a href="#">Summary</a>

**European Commission**

Document type	Reference	Date	Summary
Legislative proposal	<a href="#">COM(2001)0404</a> 	26/11/2001	<a href="#">Summary</a>
	<a href="#">COM(2002)0735</a>		

Modified legislative proposal		10/12/2002	<a href="#">Summary</a>
Commission communication on Council's position	SEC(2003)1082 	07/10/2003	<a href="#">Summary</a>
Commission opinion on Parliament's position at 2nd reading	COM(2004)0124 	17/02/2004	<a href="#">Summary</a>
Follow-up document	C(2012)5562	08/08/2012	
Follow-up document	C(2012)9279	14/12/2012	
Follow-up document	COM(2015)0138 	30/03/2015	<a href="#">Summary</a>
Follow-up document	COM(2016)0498 	08/08/2016	<a href="#">Summary</a>
Follow-up document	SWD(2016)0284 	08/08/2016	
Follow-up document	COM(2019)0591 	15/11/2019	<a href="#">Summary</a>
Follow-up document	COM(2021)0497 	31/08/2021	

#### Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1007/2002	18/09/2002	
EU	Implementing legislative act	32005R2049 OJ L 329 16.12.2005, p. 0004-0007	15/12/2005	<a href="#">Summary</a>
EU	Implementing legislative act	32006R0507 OJ L 092 30.03.2006, p. 0006-0009	29/03/2006	<a href="#">Summary</a>