
















Procedure file

Basic information		
INI - Own-initiative procedure	2021/2013(INI)	Procedure completed
A Pharmaceutical Strategy for Europe		
Subject 4.20.04 Pharmaceutical products and industry		

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 Environment, Public Health and Food Safety (Associated committee)	 MONTSERRAT Dolors	17/02/2021
		Shadow rapporteur	
		 MORETTI Alessandra	
		 SØGAARD-LIDELL	
		 METZ Tilly	
		 BALDASSARRE Simona	
		 SLABAKOV Andrey	
		 KONEČNÁ Kateřina	
		Committee for opinion	Rapporteur for opinion
	 Industry, Research and Energy (Associated committee)	 BOTENGA Marc	08/02/2021
	 Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	 Transport and Tourism	The committee decided not to give an opinion.	
	 Legal Affairs		18/03/2021
		 REGIMENTI Luisa	
European Commission	Commission DG Health and Food Safety	Commissioner KYRIAKIDES Stella	

Key events			
11/03/2021	Committee referral announced in Parliament		

11/03/2021	Referral to associated committees announced in Parliament		
12/10/2021	Vote in committee		
08/11/2021	Committee report tabled for plenary	A9-0317/2021	Summary
22/11/2021	Debate in Parliament		
24/11/2021	Decision by Parliament	T9-0470/2021	

Technical information

Procedure reference	2021/2013(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 57; Rules of Procedure EP 54
Other legal basis	Rules of Procedure EP 159
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/05419

Documentation gateway

Committee draft report		PE681.109	03/05/2021	EP	
Amendments tabled in committee		PE693.845	10/06/2021	EP	
Committee opinion	JURI	PE692.709	14/07/2021	EP	
Committee opinion	ITRE	PE689.816	07/10/2021	EP	
Committee report tabled for plenary, single reading		A9-0317/2021	08/11/2021	EP	Summary
Text adopted by Parliament, single reading		T9-0470/2021	24/11/2021	EP	

A Pharmaceutical Strategy for Europe

The Committee on the Environment, Public Health and Food Safety adopted an own-initiative report by Dolors MONTSERRAT (EPP, ES) on a pharmaceutical strategy for Europe.

Health is fundamental to the well-being of Europeans and equitable access to healthcare is a cornerstone of the EU and Member States national health policies. 40 % of medicinal end products marketed in the EU originate in non-EU countries, while 60 % to 80 % of active pharmaceutical ingredients are produced in China and India. The report noted that the disruption of the global supply chain ensuing from the COVID-19 pandemic has highlighted the EUs dependency on third countries in the health sector.

Putting patients at the centre of all health policies

Members regretted the disparities in access to high-quality healthcare services, including access to medicinal products, among Member States and also among different regions within Member States. They called for national and EU measures, including legislative measures where appropriate, to address these disparities and guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative medicines.

Antimicrobial resistance (AMR)

Considering that AMR constitutes a serious threat to public health, Members recommend to the Commission to introduce an EU therapeutic guide for antimicrobials, setting up traceable antimicrobial use reduction targets at EU level, and that communication campaigns on AMR be coordinated through a single calendar at EU level.

Research in pharmaceuticals

The report called on the Commission to assess, and revise where appropriate, the system of incentives to promote research into and the development of new medicines for unmet diagnostic and therapeutic needs, prioritising public interests and patient safety when assessing projects promoted by the pharmaceutical industry to combat cancers, including paediatric cancers. They suggested that an EU framework should be created to guide and regularly evaluate the implementation of national plans to fight these diseases.

Pricing and costs of pharmaceuticals

Members called on the Commission to:

- promote dialogue with the Member States and all relevant stakeholders to promote Made in Europe pharmaceuticals by strengthening manufacturing and supply resilience;
- promote information sharing among Member States on net medicine prices through the European Integrated Price Information Database (EURIPID) collaboration;
- introduce measures to increase transparency in the area of research into and the development and production of medicinal products;
- address the root causes of shortages of pharmaceuticals and propose sustainable solutions and mitigations plans;
- be alert to anti-competitive conduct and investigate anti-competitive practices in the pharmaceutical industry.

Access to medicines in the EU

Members are concerned that the accessibility and affordability of medicines remain a challenge for national health systems, and that innovative medicines are expensive or in certain Member States not even brought to the market for commercial reasons. In this regard, the Commission is called on to assess policy options that help guarantee that centrally authorised medicines are marketed in all Member States and not just in those that are commercially interesting.

Structured dialogue with stakeholders

Members considered that a wider political High Level Pharmaceutical Forum is needed, bringing together policymakers and other relevant stakeholders in the healthcare supply chain, in order to share the lessons learnt from the COVID-19 emergency situation and to establish an effective policy framework to prevent shortages in the long term, enable access to medicines for patients, reduce delays, and ensure competitiveness and innovation.

Sustainable and environmentally friendly medicines

Lastly, the report stressed the need for the pharmaceutical industry to be environmentally friendly and climate-neutral throughout the lifecycles of medicinal products, while ensuring access to safe and effective pharmaceutical treatments for patients. The Commission is urged to ensure quality environmental sustainability standards for active pharmaceutical ingredients imported from non-EU countries and to address the problem of pharmaceutical household waste, through measures to reduce packaging.