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
ENVI Environment, Public Health and Food Safety		17/02/2021
	MONTSERRAT Dolors	
	Shadow rapporteur	
	MORETTI Alessandra	
	SØGAARD-LIDELL Linea	
	METZ Tilly	
	BALDASSARRE Simona	
	SLABAKOV Andrey	
	KONEČNÁ Kateřina	

Committee for opinion	Rapporteur for opinion	Appointed
ITRE Industry, Research and Energy (Associated committee)		08/02/2021
	BOTENGA Marc	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
TRAN Transport and Tourism	The committee decided not to give an opinion.	
JURI Legal Affairs		18/03/2021
	REGIMENTI Luisa	

European Commission

Commission DG	Commissioner

	Health and Food Safety	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		
23/11/2021	Results of vote in Parliament		
24/11/2021	Decision by Parliament	T9-0470/2021	Summary

Technical information

Procedure reference	2021/2013(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 54; Rules of Procedure EP 57
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	Summary
Commission response to text adopted in plenary		SP(2022)49	18/03/2022	EC	

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.

A Pharmaceutical Strategy for Europe

The European Parliament adopted by 527 votes to 92, with 70 abstentions, a resolution 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 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

Recognising the existence of inequalities in access to quality health services between and within Member States, Members called for national and European measures, including legislation, to address these disparities and ensure patients' right to universal, affordable, effective, safe and timely access to essential and innovative medicines.

Particular attention should be paid to people in vulnerable situations, including pregnant women, children, the elderly, people with disabilities, patients with chronic diseases and comorbidities, patients in intensive care units and people on long-term treatment.

Antimicrobial resistance (AMR)

Considering that AMR constitutes a serious threat to public health, Members recommend that the Commission 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

Parliament 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, rare diseases and neurodegenerative diseases. Members 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;

- explore the possibility of establishing, subject to conditionalities, an EU fund, co-financed by the Member States, for negotiating and purchasing orphan medicines and other new medicines;

- 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.

Role of generic and biosimilar medicines

Parliament stressed the importance of generic, biosimilar and value-added medicines for consistently increasing equitable access for patients and making healthcare systems sustainable in a European Union where access is still uneven. It called on the Commission to ensure healthy competition after the expiry of intellectual property exclusivities by ensuring access to biosimilar medicines from day one and removing all barriers to access to competition.

Parliament also recommended, inter alia, to:

- address the differences in the average number of days between the approval of a medicine and the moment it becomes available to patients in the EU, and implement solutions to reduce delays to the market entry of medicines;

- facilitate the launch of large clinical trials conducted in a harmonised and coordinated manner at EU level;

- reassess the system that leads from conditional marketing authorisation to standard marketing authorisation or exceptional renewal of authorisation, based on robust clinical data;

- develop an early warning system for drug shortages based on a European digital platform;

- ensure full and harmonised application of the General Data Protection Regulation (GDPR) with regard to the conduct of clinical research across the EU;

- establish a structured dialogue on manufacturing and the supply chain and a broader, high-level political pharmaceutical forum to share the lessons learned from the COVID-19 emergency and to define an effective policy framework to prevent long-term shortages;

- ensure quality and environmental sustainability standards for active pharmaceutical ingredients imported from non-EU countries and address the problem of pharmaceutical household waste, through measures to reduce packaging.

Transparency

MONTSERRAT Dolors	Rapporteur	ENVI	19/11/2021	ASOCIACIÓN ESPAÑOLA DE MEDICAMENTOS BIOSIMILARES
MONTSERRAT Dolors	Rapporteur	ENVI	03/11/2020	ASOCIACIÓN NACIONAL EMPRESARIAL DE LA INDUSTRIA FARMACÉUTICA