Basic information

2020/2071(INI) INI - Own-initiative procedure	Procedure completed
Shortage of medicines - how to address an emerging problem **Subject** 4.20.01 Medicine, diseases 4.20.06 Health services, medical institutions	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	COLIN-OESTERLÉ Nathalie (EPP)	25/03/2020
	Shadow rapporteur MORETTI Alessandra (S&D) TRILLET-LENOIR Véronique (Renew) RIVASI Michèle (Greens/EFA) KOPCIŃSKA Joanna (ECR) REGIMENTI Luisa (ID) KONEČNÁ Kateřina (GUE/NGL)	

Committee for opinion	Rapporteur for opinion	Appointed
DEVE Development	KEMPA Beata (ECR)	13/05/2020
INTA International Trade	KOVATCHEV Andrey (EPP)	15/04/2020
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy (Associated committee)	MÉLIN Joëlle (ID)	23/04/2020
TRAN Transport and Tourism		
JURI Legal Affairs	LEBRETON Gilles (ID)	04/05/2020

Key events

Date	Event	Reference	Summary
27/05/2020	Committee referral announced in Parliament		
27/05/2020	Referral to associated committees announced in Parliament		
14/07/2020	Vote in committee		
22/07/2020	Committee report tabled for plenary	A9-0142/2020	Summary
17/09/2020	Decision by Parliament	T9-0228/2020	Summary
17/09/2020	Results of vote in Parliament		
17/09/2020	End of procedure in Parliament		

Technical information

Procedure reference	2020/2071(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 55
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/02769

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE650.394	30/04/2020	
Committee opinion	INTA	PE650.551	28/05/2020	
Amendments tabled in committee		PE652.627	08/06/2020	
Amendments tabled in committee		PE652.628	08/06/2020	
Amendments tabled in committee		PE652.629	08/06/2020	
Committee opinion	TRAN	PE650.657	11/06/2020	
Specific opinion	JURI	PE652.652	15/06/2020	
Committee opinion	ITRE	PE650.634	16/06/2020	
Committee opinion	DEVE	PE653.840	17/06/2020	
Committee report tabled for plenary, single reading		A9-0142/2020	22/07/2020	Summary

Text adopted by Parliament, single reading		T9-0228/2020	17/09/2020	Summary

European Commission

Document type	Reference	Date	Summary
Commission response to text adopted in plenary	SP(2020)597	11/02/2021	

Shortage of medicines - how to address an emerging problem

2020/2071(INI) - 17/09/2020 - Text adopted by Parliament, single reading

The European Parliament adopted by 663 votes to 23, with 10 abstentions, a resolution on shortage of medicines - how to address an emerging problem.

The long-standing problem of shortages of medicines within the EU has worsened during the COVID-19 pandemic, with direct negative consequences for the health and safety of patients and the continuation of their treatment.

Parliament called for the establishment of a genuine pharmaceutical industrial strategy to enable the EU to regain its health sovereignty and called for better coordination between EU countries to address the drug shortage.

The European response to the shortage of medicines shall be based on four pillars:

(1) Restoring the EU's independence in health matters by securing supply

With 40% of medicines marketed in the EU today coming from third countries and between 60-80% of chemical active substances being produced in China and India, Parliament considered it geostrategically imperative for the EU to regain its independence in the field of healthcare, to ensure a rapid and efficient supply of medicines, medical equipment, diagnostic tools and vaccines at affordable prices and to prevent shortages in these areas, giving priority to the interests and safety of patients.

Members called on the Commission and Member States to:

- take the necessary measures to guarantee the security of supply of medical products, reduce the EU's dependence on third countries and support the local manufacture of medicines of major therapeutic interest, giving priority to medicines of health and strategic interest;

- establish a precise mapping of potential production sites within the European Union in order to be able to preserve, modernise and strengthen their capacity where necessary;

- make the shortage of medicines one of the pillars of the Commission's forthcoming pharmaceutical strategy and create a Pharmaceutical Forum, overseen by the European Medicines Agency, bringing together relevant stakeholders in the healthcare supply chain to prevent shortages;

- introduce financial measures and incentives in line with state aid rules in order to encourage the industry to locate its activities in Europe, from the production of active ingredients to the manufacturing, packaging and distribution of medicines;

- consider setting up harmonised shortage prevention and management plans that require manufacturers to identify drugs of major therapeutic interest that require the introduction of measures to avoid supply disruptions;

- make security of supply a priority criterion in drug-related tendering procedures;

- create one or more non-profit European pharmaceutical undertakings capable of producing certain medicines of strategic importance for health care in emergencies, in the absence of existing industrial production, in order to prevent possible shortages of medicines in case of emergency;

- assess foreign direct investment in pharmaceutical production sites, which are part of Europe's essential health infrastructure;

- creating an environment to ensure that Europe continues to be an attractive location for R&D investment to encourage research, development and manufacturing in Europe and to ensure that Europe remains the leading region in the world for the manufacture of active ingredients for patent medicines.

Members called for joint action on the prevention of shortage of medicines, to be funded by the future health programme.

(2) Strengthen European action to better coordinate and complement Member States' health policies

Parliament recommended:

- greater transparency in the production and distribution chain of medicines and the creation of a European unit for the prevention and management of shortages;

- the development of health strategies at European level with a common basket of drugs against cancer, infectious diseases, rare diseases and in other areas particularly affected by shortages, as well as examining the possibility of setting harmonised criteria for pricing to make these medicines affordable;

- the creation of a European contingency reserve for medicinal products of health and strategic importance (MISSs) that are at high risk of shortage, along the lines of the 'RescEU' mechanism, in order to alleviate recurrent shortages and create an emergency European pharmacy;

- the development of innovative and coordinated strategies and the strengthening of the exchange of best practices in stock management;

- the introduction of new European joint procurement procedures to combat shortages, particularly in times of health crises, with simplified and transparent procedures for greater responsiveness.

(3) Strengthening cooperation among Member States

Members considered it essential to improve early communication to both health professionals and patients on the availability of medicines through innovative digital tools. Member States shall share information such as epidemiological forecasts with all relevant stakeholders to help them plan their activities better in the face of rising demand and respond better to needs at times of shortages.

Members pointed out that misinformation can lead to the inappropriate use of medicines and the creation of unnecessary stockpiling.

(4) Preventing and responding to shortages in the event of health crises

Parliament called on the Commission, in close collaboration with the Member States, to adopt a European pandemic preparedness plan in order to ensure a coordinated and effective response. It also called for simplified legislation and more flexible regulatory measures in times of crisis to alleviate shortages and facilitate the movement of medicines between Member States, such as the acceptance of different packaging formats, extended expiry dates or the use of veterinary medicines.

Shortage of medicines - how to address an emerging problem

2020/2071(INI) - 22/07/2020 - Committee report tabled for plenary, single reading

The Committee on the Environment, Public Health and Food Safety adopted an own-initiative report by Nathalie COLIN-OESTERLÉ (EPP, FR) on the shortage of medicines - how to address an emerging problem.

The long-standing problem of shortages of medicine in the EU has worsened during the COVID-19 health crisis, with direct negative consequences on the health and safety of patients and their continued treatment.

The report called for the establishment of a genuine pharmaceutical industrial strategy to enable the European Union to regain its health sovereignty and called for better coordination among EU countries to address the shortage of medicines.

Members believe that the European response to the shortage of medicines should be based on four pillars:

1) Restoring the EU's independence in health matters by securing supply

Recalling that 40% of medicinal end products marketed in the EU originate in third countries and 80% of active pharmaceutical ingredients are produced in China and India, Members called on the Commission and Member States to:

- take the necessary measures to guarantee the security of supply of medical products, reduce the EU's dependence on third countries and support the local manufacture of medicines of major therapeutic interest, giving priority to medicines of health and strategic interest;

- establish a precise mapping of potential production sites within the European Union in order to be able to preserve, modernise and strengthen their capacity where necessary;

- make the shortage of medicines one of the pillars of the Commission's forthcoming pharmaceutical strategy and create a Pharmaceutical Forum, overseen by the European Medicines Agency, bringing together relevant stakeholders in the healthcare supply chain to prevent shortages;

- introduce financial measures and incentives in line with state aid rules to protect the EU pharmaceutical industrial base and encourage the industry to locate its activities in Europe, from the production of active ingredients to the manufacturing, packaging and distribution of medicines;

- consider setting up harmonised shortage prevention and management plans that require manufacturers to identify drugs of major therapeutic interest that require the introduction of measures to avoid supply disruptions;

- make security of supply a priority criterion in drug-related tendering procedures;

- create one or more non-profit European pharmaceutical undertakings capable of producing certain medicines of strategic importance for health care in emergencies, in the absence of existing industrial production, in order to prevent possible shortages of medicines in case of emergency;

- create an environment to ensure that Europe remains an attractive location for R&D investment and maintain a strong European intellectual property system in the context of the forthcoming pharmaceutical strategy, in order to encourage research, development and manufacturing in Europe, to ensure that Europe remains a world-class innovator and ultimately to protect and strengthen Europe's strategic autonomy in the field of public health.

Members called for joint action to prevent drug shortages, to be funded by the future health programme.

2) Strengthen European action to better coordinate and complement Member States' health policies

The committee recommended:

- greater transparency in the production and distribution chain of medicines and the creation of a European unit for the prevention and management of shortages;

- the development of health strategies at European level with a common basket of drugs against cancer, infectious diseases, rare diseases and in other areas particularly affected by shortages, as well as examining the possibility of setting harmonised criteria for pricing to make these medicines affordable;

- the creation of a European contingency reserve for medicinal products of health and strategic importance (MISSs) that are at high risk of shortage, along the lines of the 'RescEU' mechanism, in order to alleviate recurrent shortages and create an emergency European pharmacy;

- the development of innovative and coordinated strategies and the strengthening of the exchange of best practices in stock management;

- the introduction of new European joint procurement procedures to combat shortages, particularly in times of health crises, with simplified and transparent procedures for greater responsiveness.

3) Strengthening cooperation among Member States

- set up an innovative, transparent and centralised digital platform to report harmonised information provided by national agencies and all stakeholders on available stocks and shortages of medicines and medical equipment;

- improve early communication with healthcare professionals and patients on the availability of medicines through the use of innovative digital tools;

- share with all the actors involved information such as epidemiological forecasts to help them plan their activities better in the face of rising demand and respond better to needs at times of shortage.

4) Preventing and responding to shortages in the event of health crises

Members called on the Commission, in close collaboration with the Member States, to adopt a European pandemic preparedness plan in order to ensure a coordinated and effective response. They also called for simplified legislation and more flexible regulatory measures in times of crisis to alleviate shortages and facilitate the movement of medicines between Member States, such as the acceptance of different packaging formats, extended expiry dates or the use of veterinary medicines.