


Basic information	
<b>2016/2057(INI)</b> INI - Own-initiative procedure	Procedure completed
EU options for improving access to medicines  <b>Subject</b> 4.20.01 Medicine, diseases	

Key players					
European Parliament	<b>Committee responsible</b>		<b>Rapporteur</b>	<b>Appointed</b>	
	<b>ENVI</b> Environment, Climate and Food Safety		CABEZÓN RUIZ Soledad (S&D)	09/03/2016	
			Shadow rapporteur FLORENZ Karl-Heinz (PPE) FARIA José Inácio (PPE) BAREKOV Nikolay (ECR) MEISSNER Gesine (ALDE) AUKEN Margrete (Verts/ALE) PEDICINI Piernicola (EFDD) D'ORNANO Mireille (ENF)		
	<b>Committee for opinion</b>		<b>Rapporteur for opinion</b>	<b>Appointed</b>	
	<b>DEVE</b> Development		CORRAO Ignazio (EFDD)	16/03/2016	
	<b>INTA</b> International Trade		The committee decided not to give an opinion.		
	<b>EMPL</b> Employment and Social Affairs		MÉLIN Joëlle (ENF)	02/05/2016	
	<b>JURI</b> Legal Affairs		DURAND Pascal (Verts/ALE)	11/07/2016	
	<b>PETI</b> Petitions		EVI Eleonora (EFDD)	18/04/2016	
	European Commission	<b>Commission DG</b>		<b>Commissioner</b>	
		Health and Food Safety		ANDRIUKAITIS Vytenis Povilas	

Key events			
Date	Event	Reference	Summary
28/04/2016	Committee referral announced in Parliament		
31/01/2017	Vote in committee		
14/02/2017	Committee report tabled for plenary	<a href="#">A8-0040/2017</a>	<a href="#">Summary</a>
01/03/2017	Debate in Parliament	<a href="#">CRE link</a>	
02/03/2017	Decision by Parliament	<a href="#">T8-0061/2017</a>	<a href="#">Summary</a>
02/03/2017	Results of vote in Parliament		
02/03/2017	End of procedure in Parliament		

Technical information	
Procedure reference	2016/2057(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/8/05895

Documentation gateway				
<b>European Parliament</b>				
Document type	Committee	Reference	Date	Summary
Amendments tabled in committee		<a href="#">PE582.218</a>	25/07/2016	
Amendments tabled in committee		<a href="#">PE587.640</a>	07/09/2016	
Amendments tabled in committee		<a href="#">PE589.201</a>	13/09/2016	
Committee draft report		<a href="#">PE587.690</a>	19/09/2016	
Amendments tabled in committee		<a href="#">PE592.063</a>	04/10/2016	
Amendments tabled in committee		<a href="#">PE592.300</a>	21/10/2016	
Amendments tabled in committee		<a href="#">PE592.302</a>	21/10/2016	
Committee opinion	<a href="#">DEVE</a>	<a href="#">PE585.778</a>	09/11/2016	
Committee opinion	<a href="#">PETI</a>	<a href="#">PE582.217</a>	15/11/2016	
Committee opinion	<a href="#">JURI</a>	<a href="#">PE589.174</a>	18/11/2016	
Committee report tabled for plenary, single reading		<a href="#">A8-0040/2017</a>	14/02/2017	<a href="#">Summary</a>
Text adopted by Parliament, single reading		<a href="#">T8-0061/2017</a>	02/03/2017	<a href="#">Summary</a>
<b>European Commission</b>				
Document type	Reference	Date	Summary	

## EU options for improving access to medicines

2016/2057(INI) - 14/02/2017 - Committee report tabled for plenary, single reading

The Committee on the Environment, Public Health and Food Safety adopted an own-initiative report by Soledad CABEZÓN RUIZ (S&D, ES) on the EU options for improving access to medicines.

Members recalled that public health systems are crucial to guaranteeing universal access to health care, a fundamental right of European citizens. Health systems in the EU face challenges such as an ageing population, the increasing burden of chronic illnesses, the high cost of development of new technologies, high and rising pharmaceutical expenses, and the effects of the economic crisis on healthcare spending. These challenges prompt the need for **European cooperation and new policy measures** at both EU and national level.

The report called for national and EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, to guarantee the sustainability of EU public healthcare systems, and to ensure future investment in pharmaceutical innovation.

Among other recommendations, Members called on the Commission and the Member States to:

- reinforce the negotiation capacities of Member States in order to ensure **affordable access** to medicines across the EU;
- develop closer **collaboration** in order to fight such market fragmentation and to work on shared criteria to instruct price and reimbursement decisions at national level;
- propose a **new directive on transparency** of price-setting procedures and reimbursement systems;
- implement [Directive 2011/24/EU](#) on the application of patients' rights in cross-border healthcare in a fair way, avoiding limitations to the application of the rules on reimbursement of cross-border healthcare, including the reimbursement of medicine;
- **foster R&D driven by patients' unmet needs**, such as by researching new antimicrobials, coordinating public resources for healthcare research in an effective and efficient manner, and promoting the social responsibility of the pharmaceutical sector;
- promote initiatives for guiding public and private-sector research towards bringing out innovative medicines for **curing childhood illnesses**;
- promote public and private-sector research into medicines for **female patients**;
- adopt strategic plans to ensure access to life-saving medicines; Members called in this regard, for the coordination of a plan to eradicate **hepatitis C in the EU**;
- establish framework conditions in the areas of research and medicine policy to be established in a way that promotes innovation, particularly against diseases, such as **cancer**, that cannot yet be treated to a satisfactory degree;
- set up a framework to promote, guarantee and reinforce the competitiveness and use of **generic and biosimilar medicines**, guaranteeing their faster entry onto the market and monitoring unfair practices;
- evaluate the implementation of the regulatory framework for **orphan medicines** (especially as regards the concept of unmet medical need, how this concept is interpreted and what criteria need to be fulfilled in order to identify unmet medical need), to provide guidance on priority unmet medical need;
- promote **ethical behaviour and transparency** in the pharmaceutical sector, especially regarding clinical trials and the real cost of R&D, in the authorisation and assessment of innovation procedure;
- observe and reinforce the EU **competition** legislation and its competencies on the pharmaceutical market in order to counter abuse and promote fair prices for patients;
- propose legislation on a European system for health technology assessment as soon as possible;
- increase cooperation between the Member States as regards price-setting procedures.

The Commission is called upon to analyse the **overall impact of intellectual property** on innovation on, and on patient access to, medicines, by means of a thorough and objective study, as requested by the Council in conclusions of 17 June 2016, and, in particular, to analyse in this study the impact of supplementary protection certificates (SPCs), data exclusivity and market exclusivity on the quality of innovation and competition.

Lastly, Members urged the Commission and the Member States to **launch a high-level strategic dialogue** with all the relevant stakeholders, together with representatives of the Parliament on current and future developments in the pharmaceutical system in the EU, with the aim of establishing short-, medium- and long-term holistic strategies for ensuring access to medicines and for the sustainability of healthcare systems and a competitive pharmaceutical industry, leading to affordable prices and faster access to medicines for patients.

## EU options for improving access to medicines

2016/2057(INI) - 02/03/2017 - Text adopted by Parliament, single reading

The European Parliament adopted by 568 votes to 30, with 52 abstentions, a resolution on the EU options for improving access to medicines.

Parliament recalled that public health systems are crucial to guaranteeing universal access to health care, a fundamental right of European citizens. Health systems in the EU face challenges such as an ageing population, the increasing burden of chronic illnesses, the high cost of development of new technologies, high and rising pharmaceutical expenses, and the effects of the economic crisis on healthcare spending. These challenges prompt the need for European cooperation and **new policy measures** at both EU and national level.

**Pharmaceutical market, competition and pricing:** Parliament highlighted the importance of both public and private R&D efforts in discovering new treatments. However, it stressed that the high level of public funds used for **R&D is not reflected in the pricing** which impedes a fair public return on public investment.

Members called for national and EU-wide measures to **guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies**, to guarantee the sustainability of EU public healthcare systems, and to ensure future investment in pharmaceutical innovation.

Deploring the litigation cases aiming to delay generic entry, Members pointed out that **biosimilar medicines** enable increased competition and that their market entry should not be delayed.

Members stressed the importance of **assessing the real therapeutic, evidence-based added value** of new medicines. The price of a medicine should cover the cost of the development and production of that medicine and should be in line with the therapeutic added value it brings to patients.

**Main recommendations:** Parliament called on the Commission and the Member States to:

- reinforce the negotiation capacities of Member States in order to ensure **affordable access** to medicines across the EU;
- develop **closer collaboration** in order to fight such market fragmentation and to work on shared criteria to instruct price and reimbursement decisions at national level;
- propose a **new directive on transparency** of price-setting procedures and reimbursement systems;
- set up a framework to reinforce the competitiveness and use of **generic** and biosimilar medicines, guaranteeing their faster entry onto the market and monitoring unfair practices;
- observe and reinforce the **EU competition legislation** and its competencies on the pharmaceutical market in order to counter abuse and promote fair prices for patients;
- propose legislation on a **European system** for health technology assessment as soon as possible.

The resolution also called for the:

- fostering of R&D driven by patients' unmet needs, such as by researching new **antimicrobials**, given that drug-resistant diseases could cause 10 million deaths annually worldwide up to 2050;
- promotion of research in areas such as rare diseases and **paediatric diseases**;
- adoption of strategic plans to ensure access to life-saving medicines (for instance the coordination of a plan to eradicate **hepatitis C** in the EU);
- establishment of framework conditions in the areas of research and medicine policy to be established in a way that promotes innovation, particularly against diseases, such as **cancer**, that cannot yet be treated to a satisfactory degree;
- evaluation of the implementation of the regulatory framework for **orphan medicines**;
- promotion of ethical **behaviour and transparency** in the pharmaceutical sector, especially regarding clinical trials and the real cost of R&D, in the authorisation and assessment of innovation procedure.

**Intellectual property:** the Commission is called upon to **analyse the overall impact of intellectual property** on innovation on, and on patient access to, medicines, by means of a thorough and objective study, as requested by the Council in conclusions of 17 June 2016, and, in particular, to analyse in this study the impact of supplementary protection certificates (SPCs), data exclusivity and market exclusivity on the quality of innovation and competition.

Lastly, Members urged the Commission and the Member States to launch a **high-level strategic dialogue** with all the relevant stakeholders, together with representatives of the Parliament on current and future developments in the pharmaceutical system in the EU.