Procedure file

Basic information

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

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	S&D CABEZÓN RUIZ Soledad Shadow rapporteur epp FARIA José Inácio epp FLORENZ Karl-Heinz ECR BAREKOV Nikolay MEISSNER Gesine AUKEN Margrete EFD PEDICINI Piernicola ENF D'ORNANO Mireille	09/03/2016

Committee for opinion	Rapporteur for opinion	Appointed
DEVE Development	EFD CORRAO Ignazio	16/03/2016
INTA International Trade	The committee decided not to give an opinion.	
EMPL Employment and Social Affairs	ENF MÉLIN Joëlle	02/05/2016
JURI Legal Affairs	DURAND Pascal	11/07/2016
PETI Petitions		18/04/2016

		EVI Eleonora
European Commission	Commission DG Health and Food Safety	Commissioner ANDRIUKAITIS Vytenis Povilas

Key events

28/04/2016	Committee referral announced in Parliament		
31/01/2017	Vote in committee		
14/02/2017	Committee report tabled for plenary	A8-0040/2017	Summary
01/03/2017	Debate in Parliament		
02/03/2017	Results of vote in Parliament		
02/03/2017	Decision by Parliament	T8-0061/2017	Summary
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 54
Other legal basis	Rules of Procedure EP 159
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/05895

Documentation gateway

Committee draft report		PE587.690	19/09/2016	EP	
Amendments tabled in committee		PE592.300	21/10/2016	EP	
Amendments tabled in committee		PE592.302	21/10/2016	EP	
Committee opinion	DEVE	PE585.778	09/11/2016	EP	
Committee opinion	PETI	PE582.217	15/11/2016	EP	
Committee opinion	JURI	PE589.174	18/11/2016	EP	
Committee report tabled for plenary, single reading		A8-0040/2017	14/02/2017	EP	Summary
Text adopted by Parliament, single reading		T8-0061/2017	02/03/2017	EP	Summary
Commission response to text adopted in plenary		SP(2017)348	29/06/2017	EC	

EU options for improving access to medicines

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

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.