












Procedure file

Basic information		
RSP - Resolutions on topical subjects	2016/2902(RSP)	Procedure completed
Resolution on the regulation on paediatric medicines		
Subject 4.20.01 Medicine, diseases		

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 Environment, Public Health and Food Safety		30/06/2016
		 GROSSETÊTE Françoise	30/06/2016
		 LA VIA Giovanni	30/06/2016
		 GENTILE Elena	30/06/2016
		 PIECHA Bolesław G.	30/06/2016
		 RIES Frédérique	30/06/2016
		 MÉLIN Joëlle	30/06/2016
		Shadow rapporteur	
		 RIVASI Michèle	
	 PEDICINI Piernicola		
European Commission	Commission DG Health and Food Safety	Commissioner ANDRIUKAITIS Vytenis Povilas	

Key events			
14/12/2016	Debate in Parliament		
15/12/2016	Results of vote in Parliament		
15/12/2016	Decision by Parliament	T8-0511/2016	Summary

Technical information	
Procedure reference	2016/2902(RSP)
Procedure type	RSP - Resolutions on topical subjects
Procedure subtype	Debate or resolution on oral question/interpellation
Legal basis	Rules of Procedure EP 136-p5
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/06980

Documentation gateway					
Amendments tabled in committee		PE593.984	11/11/2016	EP	
Oral question/interpellation by Parliament		B8-1818/2016	24/11/2016	EP	
Motion for a resolution		B8-1340/2016	14/12/2016	EP	
Text adopted by Parliament, single reading		T8-0511/2016	15/12/2016	EP	Summary
Commission response to text adopted in plenary		SP(2017)243	04/07/2017	EC	

Resolution on the regulation on paediatric medicines

The European Parliament adopted by 441 votes to 97, with 8 abstentions, a resolution on the regulation on paediatric medicines tabled by the Committee on the Environment, Public Health and Food Safety.

Although the [Paediatric Medicines Regulation](#) has had a substantial impact on paediatric medicine development, Members considered that not enough progress has been made in a number of fields, in particular paediatric oncology and neonatology.

Childhood cancer remains the first cause of death by disease in children aged one year and over. 6 000 young people die of cancer each year in Europe. Fewer than 10 % of children with a non-curable life-threatening relapse have access to new, experimental drugs in clinical trials from which they could benefit.

Parliament called on the Commission to present a report which identifies an in-depth analysis of the obstacles currently hampering innovation in medicinal products targeting the paediatric population.

On the basis of those findings, the Commission should consider making changes, including through a legislative revision of the Paediatric Medicines Regulation, that give due consideration to:

- mechanism-of-action-based, rather than only disease-type-based, paediatric development plans,
- disease and drug prioritisation models that take account of unmet paediatric medical needs and feasibility,
- earlier and more feasible paediatric investigation plans (PIPs),
- incentives that better stimulate research and more effectively serve the needs of the paediatric population, while ensuring there is an evaluation of the research and development costs and full transparency of the clinical results, and
- strategies to avoid paediatric off-label use where authorised paediatric medicines exist.

Parliament stressed that paediatric needs and drugs from different companies should be prioritised, on the basis of scientific data, in order to match the best available therapies to the therapeutic needs of children, especially those affected by cancers, and would allow the resources used for research to be optimised.

Members stressed the urgent need to assess how different types of funding and rewards including the numerous tools based on delinkage mechanisms can be best utilised to drive and accelerate paediatric drug development in areas of need, in particular drugs for neonatology and childhood cancers.

The Commission is urged to:

- work as a matter of urgency on any possible regulatory changes that could help improve the situation in the meantime;
- renew in Horizon 2020 the funding provisions developed to support high-quality paediatric clinical research, following a critical review of the projects currently funded;
- strengthen the role of European networking for paediatric clinical research, and to ensure that Member States enact measures to support research into and the development and availability of medicinal products for paediatric use.