Basic information

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

Key players

European Parliament	**Committee responsible**	**Rapporteur**	**Appointed**
	ENVI Environment, Climate and Food Safety	GROSSETÊTE Françoise (PPE) LA VIA Giovanni (PPE) GENTILE Elena (S&D) PIECHA Bolesław G. (ECR) RIES Frédérique (ALDE) ECK Stefan (GUE/NGL) MÉLIN Joëlle (ENF)	30/06/2016 30/06/2016 30/06/2016 30/06/2016 30/06/2016 30/06/2016 30/06/2016
		Shadow rapporteur RIVASI Michèle (Verts/ALE) PEDICINI Piernicola (EFDD)	

European Commission	**Commission DG**	**Commissioner**
	Health and Food Safety	ANDRIUKAITIS Vytenis Povilas

Key events

Date	Event	Reference	Summary
14/12/2016	Debate in Parliament		
15/12/2016	Decision by Parliament	T8-0511/2016	Summary
15/12/2016	Results of vote in Parliament		
15/12/2016	End of procedure in Parliament		

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 142-p5
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/06980

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Amendments tabled in committee		PE593.984	11/11/2016	
Motion for a resolution		B8-1340/2016	14/12/2016	
Text adopted by Parliament, single reading		T8-0511/2016	15/12/2016	Summary

European Commission

Document type	Reference	Date	Summary
Commission response to text adopted in plenary	SP(2017)243	04/07/2017	

Resolution on the regulation on paediatric medicines

2016/2902(RSP) - 15/12/2016 - Text adopted by Parliament, single reading

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.