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{ENVI}Committee on the Environment, Public Health and Food Safety

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<TitreType>DRAFT MOTION FOR A RESOLUTION</TitreType>

<TitreSuite>further to Question for Oral Answer B8‑000000</TitreSuite>

<TitreRecueil>pursuant to Rule 128(5) of the Rules of Procedure</TitreRecueil>

<Titre>on the Regulation on Paediatric Medicines</Titre>

<DocRef>(2016/2902(RSP))</DocRef>

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B8‑0000/2016

European Parliament resolution on the Regulation on Paediatric Medicines

(2016/2902(RSP))

*The European Parliament*,

– having regard to Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 amending Regulation 1901/2006 on medicinal products for paediatric use[[1]](#footnote-1) (“the Paediatric Medicines Regulation”),

– having regard to the report from the Commission to the European Parliament and the Council Better Medicines for Children - From Concept to Reality - General Report on experience acquired as a result of the application of Regulation (EC) No 1901/2006 on medicinal products for paediatric use (COM/2013/0443),

– having regard to the Council conclusions of 17 June 2016 on “Strengthening the balance in the pharmaceutical systems in the EU and its Member States”,

– having regard to the question to the Commission on the Regulation on Paediatric Medicines (O-000000 – B8‑000000),

– having regard to Rules 128(5) and 123(2) of its Rules of Procedure,

A. whereas the Paediatric Medicines Regulation had a substantial impact on paediatric medicines development as most pharmaceutical companies consider paediatric development to be an integral part of the overall development of a product; whereas the number of paediatric research projects has increased considerably and there is more high quality information available on approved medicines; whereas the relative number of paediatric clinical trials has also increased;

B. whereas the Paediatric Medicines Regulation contributed to improve the overall situation and led to tangible benefits for a series of childhood diseases but not enough progresses were made in a number of fields, in particular in paediatric oncology and neonatology;

C. whereas childhood cancer remains the first cause of death by disease in children aged one year and over and 6,000 young people die of cancer each year in Europe; whereas two thirds of those who survive suffer from treatment-related side effects (severe for up to 50% of survivors) due to the effects of existing chemotherapy drugs prescribed in highly toxic doses;

D. whereas the Paediatric Medicines Regulation fostered increased multi-stakeholder dialogue and cooperation on paediatric medicines development;

E. whereas less 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;

F. whereas significantly increased access to innovative therapies can save the lives of children and adolescents with life-threatening diseases;

G. whereas the Paediatric Medicines Regulation lays down rules concerning the development of medicinal products for human use in order to meet the specific therapeutic needs of the paediatric population;

H. whereas only two innovative targeted anti-cancer drugs were authorised for a paediatric malignancy since the Paediatric Medicines Regulation came into force;

I. whereas under the current regulatory framework, the legal requirement to pursue paediatric drug development is often waived because drugs are developed in typical pathologic conditions for adults that do not occur in children;

J. whereas many childhood cancer types do not occur in adults, but the mechanism of action of drugs works in an adult type of cancer may be relevant to a cancer type that occurs in children;

K. whereas for those cancers (or rare diseases) that only occur in children, the industry has no financial incentive for the development of specific paediatric drugs;

L. whereas there are major delays in starting clinical trials of oncology drugs for children as it is expected that the drug shows promise in adult cancer patients;

M. whereas financial rewards for developing drugs in the paediatric population come late; whereas the existing system of rewards must be assessed to determine how it could be improved to better stimulate research and development of paediatric medicines, especially in paediatric oncology, by pharmaceutical companies;

N. whereas Paediatric Investigation Plans (PIPs) are approved following lengthy negotiations with regulatory authorities and too often prove unfeasible or are conducted too late because of their focus on the rare occurrence of an adult cancer in a child, rather than the potentially wider use of the new drug in other relevant children’s cancers;

O. whereas under Article 50 of the Paediatric Medicines Regulation the Commission is required to present, by 26 January 2017, a report to the European Parliament and the Council on the experience acquired as a result of the application of Articles 36, 37 and 38, including an analysis of the economic impact of the rewards and incentives, together with an analysis of the estimated consequences for public health of this Regulation, with a view to proposing any necessary amendments;

1. Calls on the Commission to deliver the report foreseen in Article 50 of the Paediatric Regulation in a timely fashion;

2. Urges the Commission, on the basis of those findings, to consider changes, including through a legislative revision of the Paediatric Medicines Regulation that give due consideration to (a) mechanism-of-action-based, and not only cancer-type-based, paediatric development plans, (b) drug prioritisation models, (c) earlier and more feasible PIPs and (d) incentives that better stimulate research and more effectively serve the need of the paediatric population, while ensuring transparency of the research and development process;

3. Stresses the life-saving benefits, in paediatric oncology, of mandatory paediatric development based on a drug’s mechanism of action matched to a tumour’s biology rather than on indication limiting the drug’s use to a specific type of cancer;

4. Stresses that prioritisation of drugs from different companies, based on scientific data, should be done to match the best available therapies to the therapeutic needs of children affected by cancers and would enable to optimise the resources used for research;

5. Stresses that conducting timely PIPs enables early regulatory dialogue and joint development with the European Medicines Agency, allowing companies to develop more feasible PIPs;

6. Stresses the urgent need to assess how different types of rewards can be best utilised to drive and accelerate clinical development of drugs for childhood cancers and specifically for those cancers which only occur in children. The rewards should drive paediatric development of any oncology-targeted drug to start as soon as sufficient scientific rationale for use in a paediatric population and adult safety data are available, and should not be dependent on proven therapeutic value in an adult cancer indication;

7. Calls on the Commission to urgently work on any possible regulatory changes that could help improve the situation in the meantime;

8. Instructs its President to forward this resolution to the Commission.

1. OJ L378, 27.12.2006, p.20. [↑](#footnote-ref-1)