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MOTION FOR A RESOLUTION

further to Question for Oral Answer B8-1818/2016

pursuant to Rule 128(5) of the Rules of Procedure

on the regulation on paediatric medicines
(2016/2902(RSP))

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on behalf of the Committee on the Environment, Public Health and Food Safety

B8-1340/2016

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 (EC) No 1901/2006 on medicinal products for paediatric use (hereinafter the 'Paediatric Medicines Regulation')[1],

– having regard to the Commission report to the European Parliament and the Council entitled '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 United Nations Secretary-General's High-Level Panel on Access to Medicines report entitled 'Promoting innovation and access to health technologies', published in September 2016,

– having regard to the question to the Commission on the review of the regulation on paediatric medicines (O-000135/2016 – B8-1818/2016),

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

A. whereas the Paediatric Medicines Regulation has had a substantial impact on paediatric medicine 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 whereas there is now more high-quality information available regarding paediatric use of approved medicines; whereas the relative number of paediatric clinical trials has also increased;

B. whereas the Paediatric Medicines Regulation has helped to improve the overall situation and has led to tangible benefits in respect of a series of childhood diseases; whereas, however, not enough progress has been made in a number of fields, in particular paediatric oncology and neonatology;

C. whereas childhood cancer remains the first cause of death by disease in children aged one year and over, and whereas 6 000 young people die of cancer each year in Europe; whereas two thirds of those who survive suffer from treatment-related side effects due to existing treatments (reported to be severe for up to 50 % of survivors), and whereas there is a need to continuously improve the quality of life of childhood cancer survivors;

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

[1] OJ L 378, 27.12.2006, p. 20.

E. whereas 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;

F. whereas significantly increased access to innovative therapies can save the lives of children and adolescents with life-threatening diseases such as cancer, and whereas these therapies therefore need to be investigated without undue delay via appropriate studies in children;

G. whereas off-label use of medicine in children is still widespread in the EU in several therapeutic areas; whereas, although studies on the extent of off-label use in the paediatric population differ in scope and patient population, there has not been a decrease in off-label prescribing since the introduction of the Paediatric Medicines Regulation; whereas the European Medicines Agency (EMA) has already been called on to develop guidelines on the off-label/unlicensed use of medicines based on medical need, and to compile a list of off-label medicines in use despite licensed alternatives;

H. 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;

I. whereas only two innovative targeted anti-cancer drugs have been authorised for a paediatric malignancy based on an agreed paediatric investigation plan (PIP) since the Paediatric Medicines Regulation came into force;

J. whereas under the current regulatory framework the legal requirement to pursue paediatric drug development is waived when drugs are developed for adult conditions that do not occur in children; whereas this regulatory approach is unsatisfactory in the case of specific diseases that are found only in children; whereas, furthermore, the number of annual reports on deferred measures submitted to the EMA under Article 34(4) of the Paediatric Medicines Regulation is increasing every year;

K. whereas many childhood cancer types do not occur in adults; whereas, however, the mechanism of action of a drug that is effective in treating an adult type of cancer may be relevant to a cancer type that occurs in children;

L. whereas for those diseases that occur only in children, such as paediatric cancers, the market provides limited incentives for the development of specific paediatric drugs;

M. whereas the third EU Health Programme (2014-2020) includes a commitment to improving resources and expertise for patients affected by rare diseases;

N. whereas there are major delays in starting paediatric clinical trials for oncology drugs, as developers wait for the drug to show promise in adult cancer patients first;

O. whereas there is nothing to stop an investigator from terminating a promising paediatric trial early if a drug fails to deliver positive results in the target adult population;

P. whereas financial rewards and incentives for developing drugs in the paediatric population, such as paediatric-use marketing authorisation (PUMA), arrive late and have a limited effect; whereas, while it is necessary to ensure that the rewards and

incentives are not misused or abused by pharmaceutical companies, the existing rewards system must be assessed in order to determine how it could be improved to better stimulate research and development in the area of paediatric medicines, especially in paediatric oncology;

Q. whereas marketing authorisation holders are required to update product information to take account of the latest scientific knowledge;

R. whereas PIPs are approved following complex negotiations between regulatory authorities and pharmaceutical companies and too often prove unfeasible and/or are started too late because of their misuse through a focus on the rare occurrence of an adult cancer in a child, rather than on the potentially wider use of the new drug in other relevant children's cancers; whereas not all approved PIPs are completed, given that research into an active substance is often abandoned at a later stage if initial hopes regarding the safety and efficacy of the medicinal product are not confirmed; whereas to date only 12 % of approved PIPs have been completed;

S. whereas Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use provides for the establishment of a single application portal allowing sponsors to submit a single application for trials conducted in more than one Member State; whereas such cross-border trials are particularly important for rare diseases such as paediatric cancers, as there may not be enough patients in one country to make a trial viable;

T. whereas a large number of modifications are made to PIPs; whereas, however, if extensive modifications to a PIP are discussed with the Paediatric Committee, where the modifications have a lesser impact, the issue is less clearly defined;

U. whereas, in accordance with Article 39(2) of the Paediatric Medicines Regulation, the Member States must provide the Commission with detailed proof of a concrete commitment to supporting research into and the development and availability of medicinal products for paediatric use;

V. whereas, pursuant to Article 40(1) of the Paediatric Medicines Regulation, funds for research into medicinal products for the paediatric population are to be provided for in the Community budget in order to support studies relating to medicinal products or active substances not covered by a patent or a supplementary protection certificate;

W. whereas, under Article 50 of the Paediatric Medicines Regulation, the Commission is required to present, by 26 January 2017, a report to 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 public health impact of this regulation, with a view to proposing any necessary amendments;

1. Calls on the Commission to deliver the report provided for in Article 50 of the Paediatric Medicines Regulation in a timely fashion; stresses the need for this report to provide comprehensive identification and an in-depth analysis of the obstacles currently hampering innovation in medicinal products targeting the paediatric population; highlights the importance of a solid evidence-base of this kind for effective policy-

making;

2. Urges the Commission, on the basis of those findings, to consider making changes, including through a legislative revision of the Paediatric Medicines Regulation, that give due consideration to (a) mechanism-of-action-based, rather than only disease-type-based, paediatric development plans, (b) disease and drug prioritisation models that take account of unmet paediatric medical needs and feasibility, (c) earlier and more feasible PIPs, (d) 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 (e) strategies to avoid paediatric off-label use where authorised paediatric medicines exist;

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 an indication limiting the drug's use to a specific type of cancer;

4. Stresses 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;

5. Stresses the importance of cross-border trials for research into many paediatric and rare illnesses; therefore welcomes Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, which will make it easier to carry out these sorts of trials, and calls on the EMA to ensure that the infrastructure necessary for its implementation is in place as soon as possible;

6. Stresses that conducting early PIPs, and early scientific and regulatory dialogue and interaction with the EMA, allows companies to optimise global paediatric development, and in particular to develop more feasible PIPs;

7. Calls on the Commission to consider amending the Paediatric Medicines Regulation so that promising trials in the paediatric population cannot be terminated early because of disappointing results in the target adult population;

8. Stresses 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, especially those cancers which occur only in children; believes that the rewards should drive paediatric development of these drugs 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 indication;

9. Calls on the Commission to work as a matter of urgency on any possible regulatory changes that could help improve the situation in the meantime;

10. Calls on the Commission to renew in Horizon 2020 the funding provisions developed to support high-quality paediatric clinical research, following a critical review of the projects currently funded;

11. Calls on the Commission to 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;

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