European Commission - Press release

State of children's medicines in the EU

Brussels, 26 October 2017

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Today, the Commission presents a report to the European Parliament and the Council, on progress made in children's medicines since the Paediatric Regulation[1] came into force 10 years ago. It concludes that positive advances in the development of medicines for children could not have been achieved without specific EU legislation – e.g. the authorisation of 260 new medicines. The Paediatric Regulation also gives a good return on investment. However, the report acknowledges that more effort is needed to combine the effects of the Paediatric with those of the Orphan medicines Regulation to address shortcomings in treating rare diseases in children.

Commenting on the report, Vytenis **Andriukaitis**, Commissioner for Health and Food Safety, said: *"Whereas I am pleased with the overall progress made in improving children's access to safe, tailored medicines, I am committed to extending these positive gains to children with rare diseases. When we consider the advances in adult oncology, it upsets me deeply that we have not made the same progress in treating the cancers that affect children. In the next 10 years we must focus on making similar breakthroughs for children, by combining the incentives under the Orphans and the Paediatric Regulations, and by ensuring that the European Reference Networks[2] - in particular 'ERN PaedCan'[3] on paediatric cancer, reach full capacity".*

Key findings:

- The number of agreed paediatric investigation plans (PIPs)[4] – the first step in developing medicines for children, surpassed 1 000 in 2017. Of these, 131 were completed by the end of 2016.
- There is a clear upward trend in the number of completed PIPs, with over 60 % finalised in the last three years.
- The conditions with the highest number of completed PIPs are immunology/rheumatology (14 %), infectious diseases (14 %), cardiovascular diseases and vaccines (each 10 %).
- Due to the Regulation there has been a significant surge in new treatments for children with rheumatologic diseases, and area where there were very limited therapeutic options before 2007.
- Oncology (childhood cancer) is at the lower end of the agreed paediatric investigation plans, representing only 7% of completed PIPs.
- The report shows that the Regulation works best in areas where the needs of adult and paediatric patients overlap.
- There is also more research into paediatric medicines. The proportion of clinical trials that include children increased by 50 % between 2007 and 2016 from 8.25 % to 12.4 %, leading to more evidence-based information when medicines are used in children.

Next steps

As an integral part of its assessment of the impact of the Paediatric Regulation, the Commission held a targeted stakeholder consultation which ran from November 2016 to February 2017. Following its adoption, Commissioner **Andriukaitis** will present the report's findings to people working in regulatory affairs, patients' groups and other stakeholders at a conference in Brussels on 21 November 2017.

This report is an essential intermediate step in the debate on a joint vision about the future parameters for paediatric and orphan medicines. Before proposing any amendments, the Commission will evaluate – in consultation with stakeholders and experts, how the combined effects of the Orphan and Paediatric Regulation can support medicine development in subpopulations of particular need, e.g. children with cancer. Results of this reflection will be presented by 2019 to allow the next Commission to take informed decision about possible policy options.

Further information

Children's medicines report

Questions and Answers on 10 years of the EU Paediatric Regulation

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[1] Regulation (EC) 1901/2006

[2] European Reference Networks for rare or low prevalence complex diseases

[3] ERN PaedCan Factsheet

[4] A Paediatric Investigation Plan (PIP) is a research and development programme that aims to ensure that a new product is tested for its potential use in children and that such tests become an integral part of the overall product development.

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