EMA

Supporting medicines for children in the EU

The European Union's Paediatric Regulation fosters the authorisation of more medicines for children, better information, better research and development.

Small humans, big needs

Children and newborn babies often react differently to medicines than adults. However, information on the use in children is not always available, and specific, more suitable forms may be required. Therefore, it is important that medicines are appropriately studied and demonstrated to be safe and effective for children.

In 2007, the Paediatric Regulation introduced a system of obligations, rewards and incentives to encourage manufacturers to research and develop medicines for children's specific therapeutic needs.

200 new medicines for children (2007–2017)

25% of all new medicines are for children

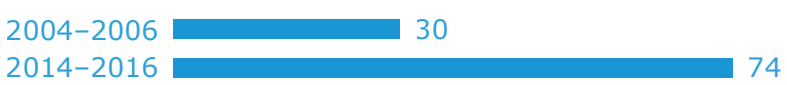
More medicines, better knowledge

In some therapeutic areas, new indications for medicines (e.g. infectious diseases, rheumatology) have led to positive changes in the way children are treated. In other areas, (e.g. oncology, neonatology) the Paediatric Regulation was less effective. EMA is taking steps to improve the situation in these areas.

New medicines for children in selected therapeutic areas (2007–2015)

- **14** Infectious diseases
- **2** Oncology
- **8** Rheumatology
- **1** Neonatology
- **6** Cardiovascular diseases

Positive impact of the Regulation — more medicines available

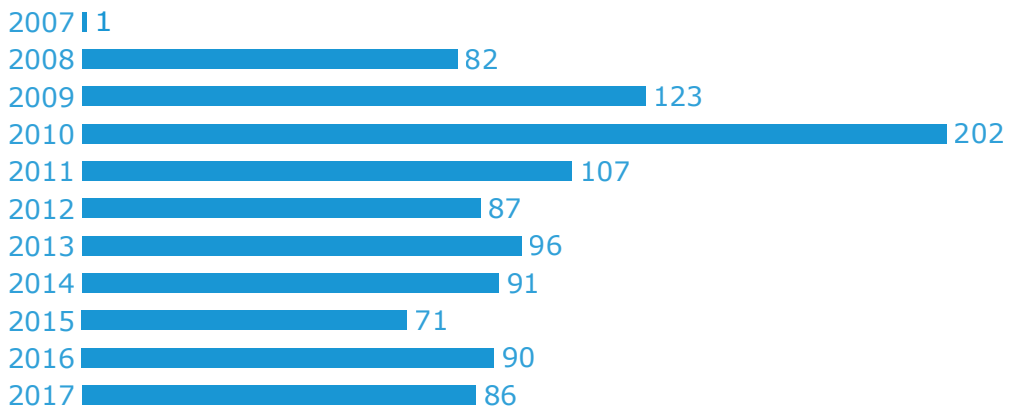


Support for paediatric research

The Paediatric Regulation has created EMA's Paediatric Committee (PDCO) — an expert group that reviews Paediatric Investigation Plans (PIPs).

A **Paediatric Investigation Plan (PIP)** is a plan agreed early in the development of a medicine between the company and the PDCO. It describes what studies in children will be carried out to get relevant data for the evaluation of a medicine for children. The purpose of PIPs is to boost authorisation of more and better medicines for children.

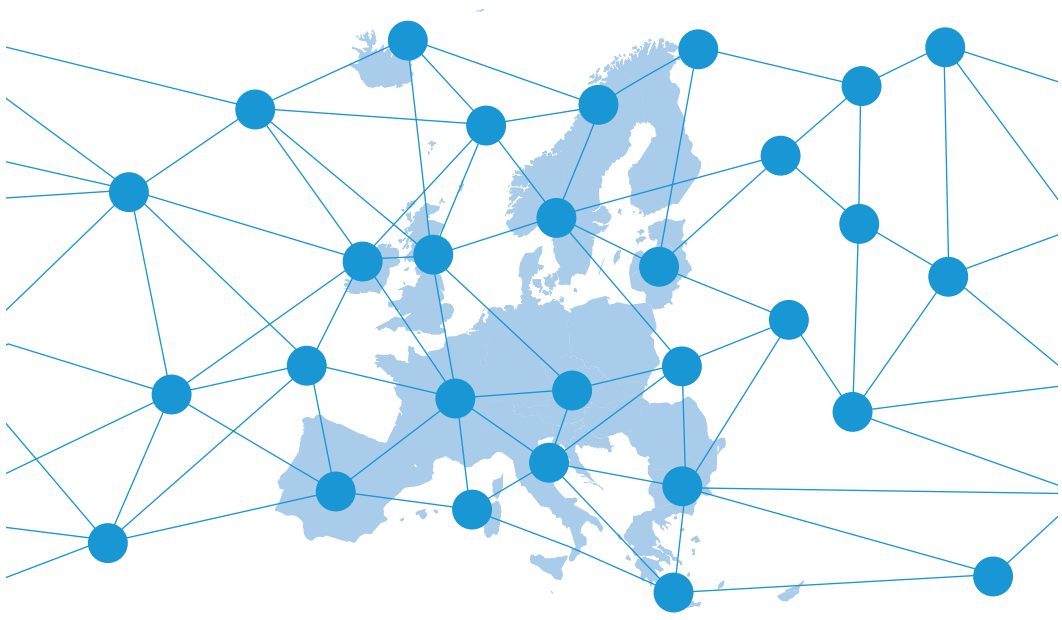
PIPs agreed per year (2007–2017)



European Network of Paediatric Research at EMA (Enpr-EMA)

Enpr-EMA is a network of more than 40 research networks, investigators and centres with recognised expertise in performing clinical studies in children.

Its objectives include collaboration between networks in the EU and beyond and facilitation of high quality studies to increase the availability of medicines for children.



International collaboration

International collaboration between regulators helps to optimise the developments of new medicines by aligning the evidence needs.

EMA, the U.S. Food and Drug Administration (FDA) and other regulators discuss paediatric medicine developments at monthly meetings. In 2017, EMA and the FDA were aligned in their views in 73% of the medicines for children they considered.

A change in thinking

The Paediatric Regulation has led to more awareness on the need to study medicines in children. Research of medicines in children is now standard practice in the development of medicines.