EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Better medicines for children

An agency of the European Union

Rewards, incentives and obligations

For unauthorised medicinal products

Marketing-authorisation applications for new medicinal products not authorised in the EU have to include the results of studies conducted in the paediatric population, in compliance with an agreed paediatric investigation plan (PIP), unless the European Medicines Agency has granted a deferral – i.e. the development is deferred until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Waivers may also be granted when such paediatric development is not needed or not appropriate. Some medicines, such as generics, are exempt from these requirements.

Once authorisation is obtained in all Member States and study results are included in the product information, even when negative, the medicine is eligible for six months' supplementary protection certificate (SPC) extension.

For orphan-designated medicinal products, the 10-year period of market exclusivity will be extended to 12 years.

For authorised medicinal products covered by an SPC or eligible for an SPC

The requirements described above also apply to applications to add a new indication (including paediatric), a new pharmaceutical form, or a new route of administration to an existing marketing authorisation.

Paediatric-use marketing authorisation

Medicines not covered by an SPC or eligible for an SPC, developed specifically for paediatric use

and with an age-appropriate formulation, can benefit from a paediatric-use marketing authorisation (PUMA), with a 10-year period of data/market protection as an incentive.

Paediatric investigation plans (PIPs)

A development plan to support use of the medicine in children - known as a paediatric investigation plan (PIP) - must be agreed in advance by the Agency's Paediatric Committee. The PIP covers the timing and measures proposed to generate the data to support a paediatric indication, with an age-appropriate formulation, in all relevant paediatric subsets. Compliance with a PIP is checked when filing an application for a marketing authorisation, new indication, new pharmaceutical form or new route of administration.

Completion of the PIP is necessary to obtain the rewards provided by the Paediatric Regulation.

Information on Agency decisions on PIPs (and waivers) is made public.

Paediatric Committee (PDCO)

The PDCO, established at the Agency in 2007, is a multidisciplinary scientific committee, primarily responsible for the assessment and agreement of PIPs and waivers.

The PDCO interacts with other Agency committees, particularly the Committee for Medicinal Products for Human Use (CHMP), the Pharmacovigilance Risk Assessment Committee (PRAC) and the Committee for Orphan Medicinal Products (COMP) on any matters related to the development of medicines for paediatric use.

Free scientific advice

The Agency provides free scientific advice on questions relating to paediatric development.

European network of paediatric research

In 2009, the Agency launched Enpr-EMA, a European network of existing national and European paediatric-research networks and centres, to support research in children.

Improved communication and transparency of paediatric information

Paediatric studies on authorised medicines sponsored by marketing-authorisation holders should be submitted on an ongoing basis within six months of their completion.

Results of paediatric clinical trials performed both inside and outside the EU are published in the EU clinical trials database, which is publicly accessible through the EU Clinical Trials Register website:

www.clinicaltrialsregister.eu

Global collaboration

The European Medicines Agency and the U.S. Food and Drug Administration (FDA) have agreed on principles for interaction and exchange of information on paediatric matters, to foster the global development of medicines for children.

Collaboration with other regulators outside the EU and with the World Health Organization are also ongoing.

EU Paediatric Regulation[1]

Entered into force on 26 January 2007

The objective of the Paediatric Regulation is to improve the health of children in the European Union (EU) by:

- facilitating the development and availability of medicines for children from birth to less than 18 years,
- ensuring that medicines for use in children are of high quality, ethically researched, and authorised appropriately,
- improving the availability of information on the use of medicines for children,

without:

- subjecting children to unnecessary trials,
- or delaying the authorisation of medicinal products for use in adults.

[1] Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, amended by Regulation (EC) No 1902/2006.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Further information

European Medicines Agency

30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Telephone +44 (0)20 3660 6000
Facsimile +44 (0)20 3660 5510
Send a question www.ema.europa.eu/contact
Website www.ema.europa.eu

Resources on the Agency's website

Human regulatory > Paediatric medicine

Human regulatory > Paediatric medicine > Background

Committees > PDCO

Partners & networks > Networks > Enpr-EMA