



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2015
EMA/481636/2015
Press Office

Press release

Stimulating the development of medicines for children

EMA's revision of class waiver list expected to push the exploration of many more medicines for use in children

The European Medicines Agency's Paediatric Committee (PDCO) has revised the current list of class waivers for medicines that are not required to submit a paediatric investigation plan (PIP).

These are the most extensive revisions to date, and aim to better balance the need to support development of medicines in children with the goal of avoiding exposing children to unnecessary studies. The revisions will, hopefully, encourage companies to develop more new medicines for use in children.

The revisions follow the PDCO's review of the experience with class waivers since the Paediatric Regulation came into force in 2007. In its review, it noted that most of the class waivers refer only to medicines targeting specific diseases. This could mean that the potential for the use of the medicines in children more generally is not explored. The PDCO concluded that the current class waiver list resulted in insufficient opportunities for the Committee to consider the potential benefits of some new medicines for children.

As a result, the PDCO has assessed, for all class waivers, the available information on the disease area, the characteristics of the medicines and any available evidence on their possible use in children. It has revoked eight class waivers, updated 15 class waivers and confirmed nine class waivers in the current class waiver list.

Companies developing medicines, which are not covered by the revised list of class waivers, will need to submit a request for a PIP or a product-specific waiver, for scientific review and agreement by the PDCO. This means that, in future, more medicines will be reviewed by the PDCO for potential development for use in children.

The PDCO will continue to revise the class waiver list as more information on medicines and diseases becomes available.

More about class waivers



The European Medicines Agency (EMA) through the PDCO plays an important role in stimulating research into the use of medicines in children and increasing medicines authorised for use in children.

Since the Paediatric Regulation came into force, companies applying for marketing authorisation for new medicines need to submit early in the development of the medicine a plan (known as a PIP) that describes how the medicines should be studied in children. The PDCO assesses and agrees the content of the PIP to ensure that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of medicines for children. Companies can only apply for a marketing authorisation for their medicine if they can demonstrate that they have conducted studies in accordance with the plan, unless they have agreed with PDCO to defer these studies or the obligations have been waived.

As it is not always appropriate to develop certain medicines in children, the PDCO can waive the requirement to develop a specific medicine (product-specific waiver) or classes of medicines (class waiver) in children. Waivers aim to avoid unnecessary studies in children where the medicine is likely to be ineffective or unsafe, where the medicine does not represent a significant therapeutic benefit over existing treatments in children or when the medicine is intended to treat a condition that only occurs in adults. When the intended use is covered by a class waiver, the developer is not required to submit an application for a medicine to the PDCO and so the PDCO cannot evaluate the potential of the medicine for children.

For further information, see the Questions and answers on the EMA/PDCO review of the list of granted Class Waivers.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The PDCO adopted its opinion on the review of the class waiver list at its July 2015 meeting. The PDCO opinion is expected to be transformed into a further decision by the Agency and the revised and revoked class waivers will come into effect in 2018.
3. EMA/PDCO Summary Report for the review of the list of granted Class Waivers, Opinion of the Paediatric Committee on the review of the list of class waivers; Questions and answers on the EMA/PDCO review of the list of granted Class Waivers.
4. The review and update of waivers (of medicine development for children) is a task of the PDCO, as per Article 14 of Regulation (EC) No 1901/2006 (the "Paediatric Regulation").
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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