



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

Report on the survey of all paediatric uses of medicinal products in Europe

Questions and answers

Why was this survey done?

The survey of the use of medicinal products in children was mainly done for two reasons: to get an overarching view on the existing use and help identify the unmet needs for the children in Europe and to fulfil a legal requirement, as mentioned by article 42 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council.

Which data were collected?

The survey aimed to collect data on all existing uses: authorised use (use of the medicinal product within the terms of the marketing authorisation), off-label use (use of the medicinal product outside the terms of the marketing authorisation) and unauthorised use (use of an unauthorised medicinal product).

What has this survey taught us?

The survey has shown that prescription of off-label and unauthorised medicines for children is widespread in Europe and that further steps need to be taken, both by scientists and regulators, to make the current situation better in the near future. It is a starting point for identifying the unmet therapeutic needs of children in Europe.

Are there some European countries "better" than others with regard to the paediatric use of medicines?

It was not possible to compare the data submitted by the participating countries, despite an initial effort to standardise the answers, mainly because every country has different information sources and different levels of details for the requested information. It is therefore not possible to say which countries "performed better".

What are the paediatric needs?

This survey has highlighted the main therapeutic areas in which more needs to be done in the future: gastroenterology, cardiovascular and respiratory medicine, contraceptives (for use in adolescents). It



will be for sure an important aid to the Paediatric Committee to establish an inventory of therapeutic needs for the paediatric population in the future.

What are the next steps?

Starting from the results of this survey, we will identify the practical means to make medicines which are available for children in some EU Member States to all European children. This can be done by a relatively simple regulatory procedure.

What is the Paediatric Committee (PDCO) going to do with the data?

The PDCO will use the survey results to work towards revising its established inventory of therapeutic needs for the European children.

Which diseases are the most neglected?

Cardiac arrhythmias, arterial hypertension, asthma, gastritis, ulcer and depression have been identified as having the highest unmet needs in children.

Which age group is the most neglected?

The group of neonates, in particular those born preterm is the group of children which should be focused with priority in the future.

Are studies needed for all the identified products?

No, studies will not be necessary for every single product identified. A lot of data have been already generated for many products and these could be used to grant a paediatric indication for these medicines. There are also regulatory ways to make medicines for children available in all EU countries and these should be used more in the future.