EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SmPC guideline and paediatric aspects

SmPC training presentation

Note: for full information refer to the European Commission's Guideline on summary of product characteristics (SmPC)

SmPC Advisory Group

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This presentation does not include SmPC examples, please refer to the individual section training presentations for SmPC paediatric examples

Introduction

- A key objective of the Paediatric Regulation is:

  "to improve the information available on the use of medicinal products in the various paediatric populations."

- The SmPC is the basis of information on how to use the medicinal product safely and effectively

- Revision 2 of the SmPC guideline (September 2009) implements requirements of the Paediatric Regulation

Overview of Paediatric information in the SmPC

4.1 Therapeutic indications	Target disease (+ target population)+ **age groups**
4.2 Posology & method of administration	Paediatric population: **Information** should be given for **all subsets of the paediatric population** + *cross-reference*
4.3 Contraindications	Lack of data alone should not lead to a contraindication.
4.4 Special warnings & precautions for use	*<Paediatric population>*_Warnings and precautions that are specific to the paediatric population, should be identified in this subheading.
4.5 Interaction with other medicinal products & other forms of interaction	*<Paediatric population>:*_Any **identified difference in the paediatric population should be presented**
4.8 Undesirable effects	*<Paediatric population>:*_Any CLINICALLY RELEVANT DIFFERENCES (i.e. in nature, frequency, seriousness or reversibility of adverse reactions) should be described and presented by age group
4.9 Overdose	*<Paediatric population>:*_Specific paediatric consideration (e.g. mention of risk of fatal poisoning with the ingestion of only one single dose unit of a product by children)
5.1 Pharmacodynamic properties	*<Paediatric population>* **- Study results** **- Waiver and deferrals**
5.2 Pharmacokinetic properties	*<Paediatric population>:*_Results of studies in the different paediatric age groups should be summarised, with a comparison to adults if available.
5.3 Preclinical safety data	**Juvenile animals:** if necessary present findings with discussion on clinical relevance
Pharmaceutical aspects	-Composition: "knowledge of which is essential for proper administration" -Form: tablets of 5 mm (…). The tablet can be divided into equal halves -6.6: Information on extemporaneous formulation (exceptionally)

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4.1: Therapeutic Indications

Target disease or condition

Target population

It should be stated in which age groups the product is indicated, specifying the age limits

e.g. 'X is indicated in <adults><neonates><infants><children> <adolescents> <aged x to y <years, months>>'

4.2 Posology and method of administration (1/2)

A sub-section "Paediatric population" should always be included and cover all subsets of the population

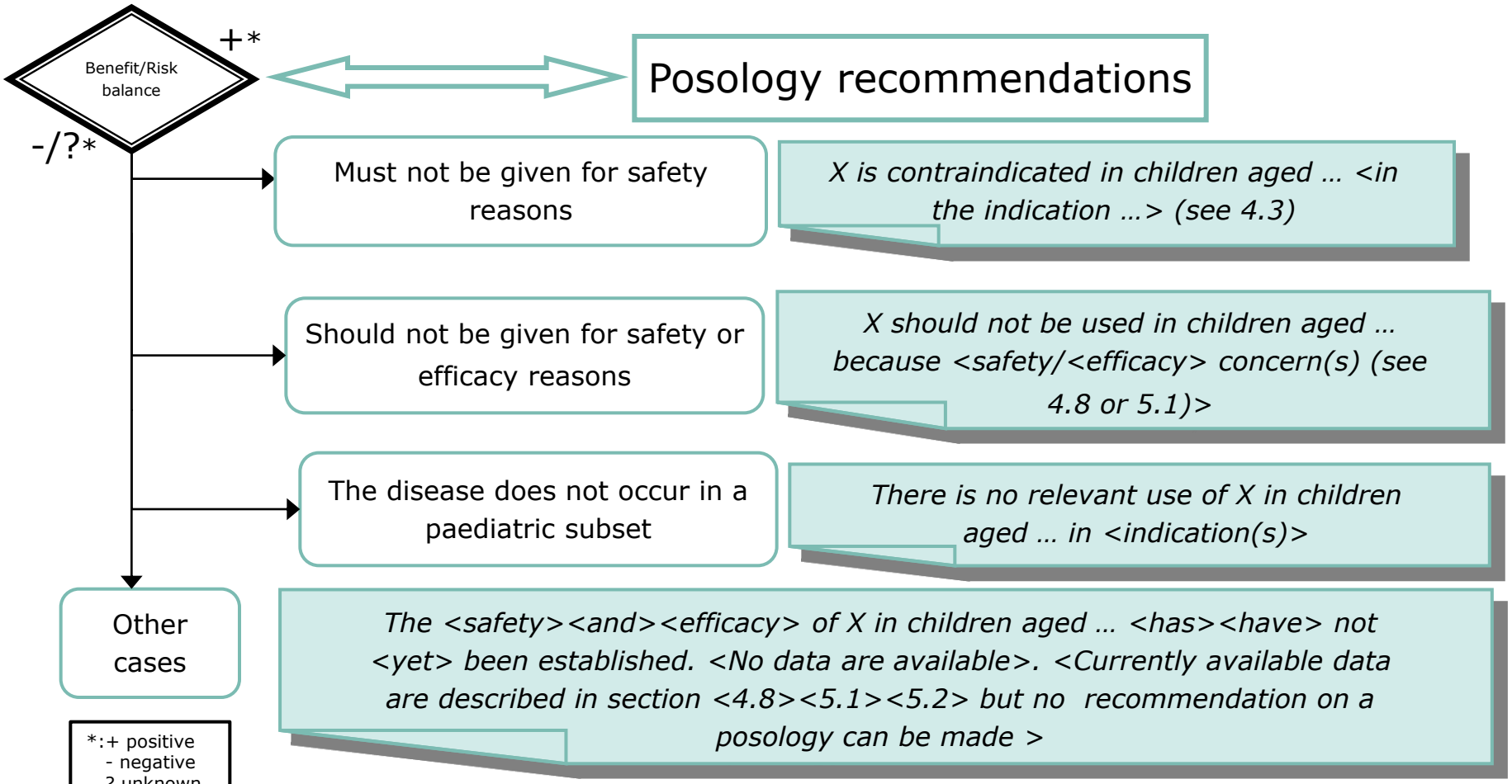
If the product is indicated in the paediatric population, posology recommendations should be given for each of the relevant subsets.

- Dose expressed according to weight or body surface area
- Dose specified per dose interval

(Dose recommendations [e.g.mg, mg/kg, mg/m2], dose interval, timing of intake, …)

If the posology is the same in adults and children, then a statement to this effect is sufficient

4.2 Posology and method of administration (2/2)



4.4: Special warnings and precautions for use

- When product indicated in one or more subsets of the paediatric population and there are warnings and precautions for use that are specific to the **paediatric population**, they should be identified under this subheading
- Warning and precautions in relation to **long-term safety** or **specific monitoring**. When long-term safety data are necessary but not yet available, it should be stated in this section
- If **measures** requested that are **specific to the paediatric population** for which the product is indicated (e.g. part of a RMP), these measures should be described in this section

4.5: Interaction with other medicinal products and other forms of interaction

The resulting exposure and clinical consequences of a pharmacokinetic interaction can differ between adults and children, or between older and younger children

Information specific to a subset of the paediatric population, if there is an indication for the particular age group, should be given such as:

- Any identified treatment recommendations in relation to concomitant use in the paediatric subset(s)
- If interaction studies have been performed in adults, the statement 'Interaction studies have only been performed in adults' should be included
- If extent of interaction know to be similar in a paediatric age group to that in adults, this should be stated. If this is not know, this should be stated

4.8: Undesirable effects

Paediatric sub-heading should always be included (unless irrelevant)

The following is information which should be given:

- Extent and age characteristics of safety database. Uncertainties due to limited experience
- If observed safety profile is similar in children and adults state "Frequency, type and severity of adverse reactions in children are <expected > to be the same as in adults". Also state whether safety profile in different subsets are similar or not
- Any clinical relevant differences between safety profiles in adults and paediatric population or in any subset(s). If need for monitoring, highlight, and cross reference to section 4.4. If major differences, a summary of safety profile in children could be presented

5.1 Pharmacodynamic properties (1/2)

Paediatric population

The results of all pharmacodynamic (clinically relevant) or efficacy studies conducted in children should be presented

- Results should be presented by age or relevant subsets
- Both efficacy and safety data main endpoints
- Main endpoints (whether positive or negative) – Dose/formulation used
- If data are considered inconclusive, this should be stated

When there are data available, but there is no authorised paediatric indication, data should be presented and a cross-reference should always be made to section 4.2 and, as appropriate to 4.3

Information should be updated when new relevant information becomes available

When they are available, information and results of confirmatory studies should usually supersede and replace those of exploratory studies

5.1 Pharmacodynamic properties (2/2)

- ***For waivers applying to all subsets:***

"The European Medicines Agency has waived the obligation to submit the results of studies with *<name of the product>* in all subsets of the paediatric population in *<condition as per PIP decision, in the granted indication>*. See 4.2 for information on paediatric use."

- ***For deferrals applying to at least one subset:***

"The European Medicines Agency has deferred the obligation to submit the results of studies with *<name of the product>* in one or more subsets of the paediatric population in *<condition, as per PIP decision in the granted indication>*. See 4.2 for information on paediatric use."

More information on paediatrics

Further paediatric information can be accessed here

In particular information on:

- Paediatric Investigation Plans (PIPs)
- Scientific guidance

Further guidance illustrated with examples of wording related to the paediatric population can be found within the presentations dedicated to each section of the SmPC

Thank you for consulting this training presentation

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Please note the presentation includes examples that may have been modified to best illustrate the related principle