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**Guidance on the content and the format of data
to be collected by the Member States
on all existing uses of medicinal products in the paediatric population**

INTRODUCTION

Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, as amended, (referred to here as The Paediatric Regulation) aims to facilitate the development and accessibility of medicinal products for use in the paediatric population, to ensure that medicinal products used to treat the paediatric population are subject to research of high quality and are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric populations.

One of the legal requirements to achieve the objectives of the Paediatric Regulation is the establishment of an Inventory of Therapeutic needs, in particular with a view to identifying research priorities. The Paediatric Committee is in charge of providing guidance on the content and format of the data to be collected by the Member States. The responsibility to establish the Inventory of Therapeutic needs lies with the Paediatric Committee, following the collection of data on all existing uses of medicinal products in the paediatric population by the Member States. The guidance of the Paediatric Committee takes into account discussions held by the members of the Paediatric Working Party (PEG), the EMEA/CHMP's former temporary expert working party on paediatric medicines.

LEGAL BASIS

Article 42 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, as amended, states that "Member States shall collect all available data on all existing uses of medicinal products in the paediatric population and shall communicate these data to the Agency by 26 January 2009. The Paediatric Committee shall provide guidance on the content and the format of the data to be collected by 26 October 2007.

TIMELINES

26 October 2007: Paediatric Committee to provide guidance on the content and format of the data.

26 January 2009: Member States to communicate data collected according to the guidance to the Agency.

GUIDANCE ON DATA TO BE COLLECTED BY MEMBER STATES

Principle

The Paediatric Regulation states that the data needs to be collected on **all** existing uses of medicinal products in the paediatric population, which is referred to as the survey in the following. The paediatric population means from birth to adolescent (up to and including 17 years old), and information needs to be collected on all subsets of the paediatric population. All existing uses include

use of authorised medicinal products within as well as outside the terms of the marketing authorisation and use of unauthorised medicinal products.

The data to be collected need to be such that they are of added value with a view to establishing - at the level of the Community - unmet needs and an inventory for research priorities. Use outside the Terms of the marketing authorisation and of unauthorised medicinal products is of higher interest for identifying the needs.

It is recognised that different Member States might have different sources of information and tools to collect part or all of this information, which will vary in its level of detail and completeness. For efficiency reasons, existing sources of information at the Member State level should be considered when collecting the data. Results should be consolidated by the Member State. The survey is expected to provide general statistics on the frequency and extent of use, and the survey should also take into account public health priorities. Information should be collected where such uses bear the highest risk to public health and with a view to informing the inventory of therapeutic paediatric needs.

Once consolidated and sent to the agency, this means that data provided by the Member States will be merged into an inventory of existing uses of medicinal products in the paediatric population at the level of the European Community.

Content and format of data to be collected

The information to be collected needs to be useful, bearing in mind the objective of the survey in identifying unmet paediatric needs, determining research priorities.

This is the list of items on the paediatric use of a medicinal product to be collected in a Member State:

- Member State and source(s) of information
- Name of medicinal product (MP) (international non-proprietary name [INN], if not available, active substance including salt, ester etc.)
- Is this an unauthorised MP in this Member State?
- Specification of use in the paediatric population (to be repeated for each product as necessary):
 - Condition/disease
 - Formulation (including extemporaneous preparations)
 - Setting where product is used (hospital dispensing / in-patient, out-patient, subspeciality / paediatrician / general practitioner etc.)
 - Age group where product used
 - Route of administration
 - Dose and / or dose range
 - Treatment duration
 - Estimate of extent of use (e. g., according to number of treatment episodes, of paediatric patients treated per year; or DDD [Defined Daily Doses] in total for the paediatric population using the Anatomical Therapeutic Chemical (ATC) classification of the WHO Collaborating Centre for Drug Statistics Methodology)
 - Is the specified use according to an explicitly authorised paediatric indication (SmPC section 4.1) or an explicitly authorised paediatric dosing (SmPC section 4.2) in this Member State?
 - Is the specified use outside the explicitly authorised paediatric indication (SmPC section 4.1) and outside the explicitly authorised paediatric dosing (SmPC section 4.2) in this Member State? (off-label)
- Information on safety as available
- Authorised indication(s) in children and adults, including age group(s) (if not available in Eudrapharm)

For communicating the data to the Agency, a structured electronic format (using an Excel spreadsheet) with a single table according to the preceding list of items should be used.

Sources of data to be collected, as examples

The tools used to collect information on use of medicinal products by the paediatric population can be linked to the Healthcare System of each Member State. Each Member State will need to specify the sources of information available within its territory as these will vary between different MS. It is recognised that it may be easier to collect information for hospital medicines and prescriptions rather than ambulatory care or “over-the-counter” products^[RHE1]. Other examples (not exhaustive) of sources could hold information on off-label/unauthorised use of medicines in children:

1. Databases in hospitals or held by hospital pharmacists (bulk prescriptions / dispensing for use in paediatric and neonatal care units or patient-related dispensing data)
2. National compendiums, especially if paediatric (e.g., BNF for children in UK)
3. Periodic safety update reports (PSURs)
4. Compassionate use databases (e.g., ATU in France)
5. Controlled sales systems
6. Pharmaceutical industry sales databases
7. Healthcare insurance companies
8. Social security registers
9. Prescription databases (drug utilisation databases, e.g., General Practice Research Database)
10. Existing (national) surveys (e.g., one-day prescription survey)
11. National paediatric associations’ databases

If data on authorised medicinal products are in EudraPharm, the Member State does not need to replicate this information and just needs to indicate it.

In view of the requirement on marketing authorisation holders to submit paediatric studies in respect of products authorised in the community to competent authorities (Article 45 of the Paediatric Regulation), Members States could take this opportunity to collect information on the paediatric use of medicinal products from marketing authorisation holders.

The following examples were provided by members of the Paediatric Committee as sources of information to collect such information. This only serves to exemplify potential approaches.

<i>Austria</i>	Project on combining information from tertiary paediatric care hospital pharmacy, social security institutions and other sources
<i>France</i>	“1-day survey” in hospital pharmacies for paediatric or neonatal / intensive care wards; information on “Autorisations Temporaires d’Utilisations” (ATU; documentation of early access to new medicinal products for serious or rare diseases)
<i>Germany</i>	National committee and export groups on “off-label use” National committee “Complementary and Alternative Medicines”
<i>Sweden</i>	Computerised population-based prescription database produced by the National Corporation of Swedish Pharmacies

Adopted by the Paediatric Committee on 26 October 2007.