European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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Recommendation of the Paediatric Committee to the European Commission regarding the symbol

1. Legal basis

Regulation (EC) N° 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use of 12 December 2006 (the Paediatric Regulation), as amended, states in Recital 18, "in order to identify medicinal products authorised for use in the paediatric population and enable their prescription, provision should be made for the labels of medicinal products granted an indication for use in the paediatric population to display a symbol which will be selected by the Commission on a recommendation by the Paediatric Committee".
Article 32 states: "Where a medicinal product is granted a marketing authorisation for a paediatric indication, the label shall display the symbol agreed in accordance with paragraph 2. The package leaflet shall contain an explanation of the meaning of the symbol.

1. By 26 January 2008 (one year from entry into force) the Commission shall select a symbol following recommendation of the Paediatric Committee. The Commission shall make the symbol public.
2. The provisions of this Article shall also apply to medicinal products authorised before the entry into force of this Regulation, and to medicinal products authorised after entry into force of the Regulation but before the symbol has been made public, if they are authorised for paediatric indications. In this case, the symbol and the explanation referred to in paragraph 1 shall be included in the labelling and package leaflet respectively of the medicinal products concerned not later than two years after the symbol has been made public."

2. Basis for the recommendation of the Paediatric Committee

The Paediatric Committee considered the following definition:
A symbol is as an arbitrary sign (written or printed) that has acquired a conventional significance. A symbol should be understood without text and without translation. The legislation was understood as meaning a single symbol.

The Paediatric Committee held extensive discussions on the potential benefits and risks of a symbol.

A. Benefits of the symbol

It is noteworthy that Article 32 was discussed extensively in the Council when the Regulation was under review. Two conflicting aims were recognised, the first was to reward medicinal products authorised through the PUMA only; the second one was to identify any medicinal products authorised for use in the paediatric population. The latter was eventually retained. It was felt the symbol would promote the awareness and long-term recognition of the Paediatric Regulation.

The Committee agreed that the symbol would mostly be a marketing advantage for the products displaying the symbol. Another benefit would be to fulfil the obligations of article 32. The Committee was not convinced that the symbol would encourage carers and patients to read the package leaflet where they would find the explanation for the symbol.
The explanation was considered a mitigating factor, but it is recognised that there is no assurance that the parents would read the explanation and experience shows that a lot remains to be done to ensure systematic reading of the package leaflet, although the recommendation is already made on each packaging.

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B. Risks of the symbol.

The risks have been presented in the previous Position Paper from the Paediatric Committee. In summary, in view of the Committee, the main risk is misunderstanding of the symbol, as this has been the case with previous medicinal products. The symbol would be present on any product having an indication in children regardless of its the strength, dose or formulation, and its presence on any presentation including those never to be administered to children would be extremely difficult to understand by parents or carers. Misinterpretation by the public (families, older children themselves, carers) has led, can and will lead to medication errors. Young children have the highest risk of medication errors (and accidental intoxications). Parents or carers may link the symbol on a particular medicine to a particular context, and misread it in another context, for a different medicinal product, or a different child. Products may have additional indications that are not suitable for children and those with multiple indications have different dosing information. The risk is considered major and certainly unacceptable where a single unit dose (of a medicinal product which has a paediatric indication) can kill a child (paracetamol, colchicine, digoxine, chloroquine, etc.).

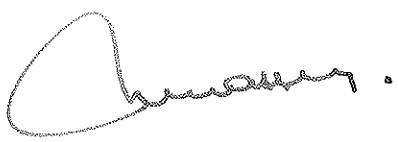
A figurative symbol could only convey a single message. The complexity of the message on safe use of a medicinal product in the various subsets, and weight ranges of the paediatric population could not be covered by a single symbol.
An abstract symbol would lead to misunderstanding.

C. Conclusions

Taking these risks seems conflicting with other measures taken simultaneously to reduce medication errors; it is not in keeping with the objectives of the Paediatric Regulation. Additionally, once taken such a measure would not be reversible.
Some members of the Paediatric Committee were of a different view and their position is appended to this document.

2. RECOMMENDATION

As a consequence of its analysis balance of benefits and risks of the symbol, the Paediatric Committee was unable to recommend to the European Commission any symbol for which the benefits would outweigh the risks identified and dominated by potentially fatal medication errors.



On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

Declaration of divergent recommendation

Implementation of Regulation EU 1901/2006 with regard to the recommendation of a paediatric symbol

At the December PDCO meeting the Committee has decided, based on a vote, that the Paediatric committee may not recommend any symbol posed on the outer package, which outweighs the benefit over the risk of such a paediatric symbol for the concerned population. A minority of the PDCO members voted for a recommendation of a symbol.
The mentioned PDCO members would like to state the arguments of this divergent recommendation.

In Recital 18 and Article 32 the reference is mentioned regarding 'a symbol', which shall identify a medicinal products authorised for use in the paediatric population and enable their prescription to the paediatric population. Further explanation of the meaning of the symbol shall be included in the package leaflet.

In general, a symbol is per se not self-explanatory. A symbol serves as a sign and is always a result of an agreement of conventions followed by a professional explanation. In this regard, an appropriate explanation of a symbol could even serve as an additional guide leading to specific, age relevant information in the package leaflet regarding formulation, dosage, indication, warnings etc.

The argument in this respect, that physicians/ parents will not read the package leaflet ant its information should not be taken into account, as this would include both situations whether the package will have a symbol or not. Additionally, all discussions and obligations resulting from the amendment of Directive 2001/83/EC like user testing of the package leaflet could be regarded as questionable following this recommendation of the PDCO.

Instead, it should be considered, that all parents and health care professionals responsible for the health and treatment of diseases in children will be careful considering the treatment of the/their child by selecting and treating the child with medicinal products.

The majority of the medicinal products, which will be eligible for a (paediatric) symbol, will be most likely prescription only medicinal products and consequently, it should be within the responsibility of the physician to inform the patients/parents appropriately. A symbol, in this respect, could be a very useful reminder to the physician.
For those medicinal products available without prescription it is arbitrary to assume, that the dosing and indication will only be guided by just "a symbol" on an outer package. In the unlikely event that this is true, the case of having "no symbol" would at least serve the same risk of medication error.

Taking these arguments into consideration, an appropriate (abstract) symbol on the outer package could serve as an important mediator and indicator, that this medicinal product has been approved for a special condition/patient group. Furthermore, this symbol has the potential to guide the prescriber/ consumer into the package leaflet to receive further important information on approved benefits and also possible harms of the concerned medicinal product.
In this respect, having no symbol on the outer package an important opportunity will be neglected to highlight the essential information on paediatric use of the concerned medicinal product to the prescriber/ consumer and this surely may outweighs the benefit by the risks.

In summary, having a clearly defined (paediatric) symbol on the outer package will outweigh the risks by the clear benefit of a (paediatric) symbol connected with the appropriate information concerning the labelled use of the medicinal product.

Furthermore, this symbol will give the competent authorities the advantage of using a specific tool for the communication of important information to the consumer concerning the medicinal product specially approved for the paediatric population.

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