European Medicines Agency
Human Post-Authorisation Unit

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REPORT ON THE WORKSHOP "EXPRESSION OF STRENGTH IN THE NAME OF MEDICINES"

London, 31 October 2008

EMEA organised on the 31st of October 2008 a workshop with healthcare professionals (HCP) to discuss the draft 'QRD Recommendations on the Expression of Strength in the Name of Centrally Authorised Human Medicinal Products'. Attendees included hospital pharmacists (from Norway, Ireland, Spain) and representatives from the National Patient Safety Agency (NPSA, UK), the Institute for Safe Medication Practices (ISMP), and the European Specialists Nurses Organisations (ESNO).

Background of the initiative

The need for general rules or recommendations in this area arises from the legal requirement in Directive 2001/83/EC a. o. to label a medicinal product with its full name which consists of "*(invented) name + strength + pharmaceutical form*". However, there is no European guidance at present on how to define the concept of strength, or how to best express it in the name of the product in order to ensure its safe and correct use.

The QRD group engaged in active discussions regarding the expression of strength for different types of medicines, in particular medicines for parenteral use. This brainstorming led to the creation of some general principles for the expression of strength. However, as these draft recommendations were principally developed within a regulatory environment, EMEA considered essential to share the QRD views with the participants of the workshop, in order to have a better understanding of the concept of strength and its use in practice by physicians, hospital pharmacists, nurses etc.

During the workshop the QRD views were illustrated with examples of outer and inner packaging materials of Centrally Authorised products.

Main topics discussed

Among others, the following points were discussed during the meeting:

- Strength of parenterals as content per volume unit versus total content per total volume
- Powders for reconstitution for parenteral use
- Use of percentage (%)
- 'Total' versus 'partial' use single dose preparations
- Multidose presentations

All participants agreed that the main purpose of the strength in the name of a medicinal product is to provide the most relevant quantitative information for the user regarding the content of the product, taking every step of the complex medication management process into account (e.g. prescribing, documenting, dispensing, administration and monitoring). The 'strength', together with other content information in the labelling, should ensure the unambiguous identification of the product (content) concerned, a clear distinction between different presentations of the same product, and the appropriate and safe use of the medicine by healthcare professionals, caregivers and patients, therefore, minimising potential confusion and medication errors.

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National medication error reporting programs have found that inappropriate expression of the content and/or concentration of active substance in a medicinal product frequently cause or contribute to medication errors. In the case of liquid preparations, in particular for parenteral use, the use of amount per volume unit (e.g. ‘mg/ml’) without clear total content information has been reported to lead to inappropriate dosing errors, since it may be mistaken for the total amount in the container.

The participants also noted that most of the errors were reported at the point of administration, and hence both the interpretation of the information on the labelling and the practicalities of avoiding risks and errors during this particular step of the process should be the focus of the discussion.

The particulars displayed on the labelling should avoid misinterpretations and/or miscalculations by the users, including especially the total content to avoid the risk of overdose.

Conclusions - Recommendations

- “Total content per total volume” and “concentration per unit volume” were considered as two critical and important elements which should be clearly stated on the product’s labelling, in order to ensure the safe and correct use of the product.

- In the case of medicines for parenteral use, the expression of strength as “total content per total volume (z mg/y ml)” was supported by most of the participants, as it was found to be more informative and would minimise the risk of medication errors due to possible misinterpretations of the total amount in the container. However, some participants favoured the use of ‘x mg/ml’ in line with current national practices, with the total content to be displayed with sufficient prominence on the labelling.

- In case of the total volume being less than 1 ml, the expression of the total quantity per total volume would particularly minimise the risk of infra-dosing.

- Most participants were of the view that there should be no distinction between parenteral products for ‘total’ or ‘partial’ use, and also ‘multidose’ products should ideally be labelled in the same way (total content per total volume). However, the impact of potential administration devices on the expression of strength of such ‘multidose’ products was acknowledged (e.g. in case of spoons, pre-filled pens).

- The expression of strength as a percentage should in principle not be used.

- In those cases where two different units can be used for the quantitative declaration (e.g. IU or mg), the correspondence should be clearly stated on the labelling, given that depending on the purpose, they could be reflected differently on the prescription (e.g. heparins).