european association of hospital pharmacists

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Consultation on IMP definition and use of auxiliary medicinal products

Response from the European Association of Hospital Pharmacists

In general, EAHP supports the consultations document's clarifications on understanding the definition of Investigational Medicinal Product and the use of Auxiliary Medicinal Products.

Given that 'Auxiliary Medicinal Product' is a new terminology in the clinical trial landscape, EAHP recommends simple explanatory tools be developed (e.g. video, and other engaging medium) to ensure fast uptake of understanding within the broad research community, including hospital pharmacists.

Medicinal products "prepared in accordance with magistral formula"

Paragraph 102-109 of the consultation document, discussing the matter of Medicinal products "prepared in accordance with magistral formula", and therefore of especial interest to hospital pharmacy, does not read very clearly in the present draft. EAHP suggests the author's review the paragraph to ensure their intended meaning is clearly delivered.

Requirements for AMPs

EAHP suggests amendment to line 128 as follows:

"To comply with these principles, a trial has to be conducted according to the protocol and all clinical trial information ~~should~~ **must** be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified."

Adverse reactions related to AMPs

EAHP suggests amendment to line 170 as follows:

"Nevertheless, **in the interests of patient safety and ethical responsibility,** sponsors are highly encouraged to report adverse reactions to the Eudravigilance Database…"