AESGP
Association Européenne des Spécialités Pharmaceutiques Grand Public
Association of the European Self-Medication Industry
Europäischer Verband der Arzneimittel-Hersteller

AESGP Comments on Guidance on Harmonisation Requirements for Non-Investigational Medicinal Products in CTA Submissions

General Comments		
AESGP would like to thank for the opportunity to comment on this document.		
Simplified NIMPDs should be allowed in case the sponsor has previously submitted CMC information to an EU member state either in a marketing authorisation application or in an IMPD/NIMPD which have been granted in that member state. Referencing to the CMC information already approved should be allowed where the draft guidance requires a "full dossier".		
The document would gain in user-friendliness by the addition of illustration or examples		
Detailed comments		
Section 3.2.2	**Comment:** the 2nd bullet "information on any repackaging and/or relabeling and a list of sites involved" should be reworded to be completely clear	**Proposed change:** information on any repackaging and/or relabelling and a list of packaging and relabelling sites involved
Section 3.2.3 bullet points #6 and #7	**Comment:** "*Justification for the use of the product if there is a comparable product authorized in the concerned Member State or another EU Member State but one with a MA in an ICH/MRA country is used in the trial"* These two bullets are not clear and seem to contradict one another. The language used is also confusing.	**Proposed change**:
Section 3.2.5	**Comments:** A full dossier is required when the NIMP has no marketing authorisation but the drug substance is known.	**Proposed change:** In case the sponsor of the clinical trial is using a drug substance which is used in medicinal products authorized in an EU member state, a simplified dossier may be applied when the sponsor is also the marketing authorisation holder. The drug substance information may be referenced.
Section 3.2.6 + section 2	**Comments:** Certain products referred to in Section 3.2.6 (e.g. anti-emetics) are prescribed to patients in the course of clinical trials, whereby it is possible to track prescriptions but not the compliance of the patients with the treatment. Hence compliance cannot be evaluated in these cases.	**Proposed change:** In Section 2, we suggest changing the last sentence of the 2nd paragraph, as follows: "It has at least to include a procedure, established with the investigator and if applicable, with the hospital pharmacy, to record which patients received which NIMPs during the trial ~~with an evaluation of the compliance~~."

August 31, 2010

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