European Industrial Pharmacists Group
Groupement des Pharmaciens de l'Industrie en Europe

Comments on:

European Commission
"Targeted Public Consultation – Excipients Guidelines"

"*Targeted stakeholder consultation on the revised guidelines on excipients in the labelling and package leaflet of medicinal products for human use*"

From: **E.I.P.G.** (***European Industrial Pharmacists Group***)

General comment

1.1. If there is insufficient information on an excipient, what should be declared by the MAH?

Observations

Nomenclature:

1.2. At Point 5
It should be stated that as pH adjusters are very often used, in most cases in limited amounts, in the pharmaceutical manufacturing process (e.g. neutralization) they should not be considered as excipients. Furthermore, we consider the appearance of the name of a pH adjuster, such as hydrochloric acid, may alarm a patient.

1.3. At Point 7
It is suggested a definition of an "abbreviation rule" be applied to avoid confusion and to obtain uniformity in written declarations by MAHs

Excipients in the package leaflet

1.4. Please add clarification that a type-IA/IAin variation can be submitted in both cases (for new MAA and existing MAA), as is currently accepted for the wording of pharmacovigilance

1.5. Please add clarification as to when a notification according to article 61(3) can be applied and explain why this notification cannot be generally applied

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Annex: Excipients and Information for the Package Leaflet

1.6. Threshold
We suggest better clarification of any possible difference in the application of the guideline, when the threshold is identified as:
- "per dose"
- "/dose"
- "/delivered dose"

Should it be always referred to the maximum daily dose? And what is the difference when the threshold is expressed in grams?

1.7. Information for the package leaflet
We suggest the explanation about the term "per dose" is maintained as it was in the previous version of the guideline.

1.8. To assist MAHs implement the guideline, it might be useful to include an example of information for the package leaflet

18th May 2017

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