EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Concept paper on the need for revision of the guideline on excipients in the label and package leaflet of medicinal products for human use (CPMP/463/00)

Draft

Agreed by SWP	**December 2011**
Adoption by CHMP for release for consultation	6 February 2012
End of consultation (deadline for comments)	31 May 2012

The proposed guideline will replace Guideline on Excipients in the Label and Package Leaflet of Medicinal Products for Human Use (CPMP/463/00).

Comments should be provided using this template. The completed comments form should be sent to SWP-H@ema.europa.eu

Keywords	***excipients, summary of product characteristics, package leaflet, label, medicinal products, human use***

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1. Introduction

The current guideline on Excipients in the Label and Package Leaflet of Medicinal Products for Human Use (CPMP/463/00) contains warning statements relating to the presence of certain excipients in medicinal products. This is a Commission guideline pursuant to Article 65 of Directive 2001/83/EC. Article 54(d) of the above Directive requires that all excipients need to be declared on the labelling if the medicinal product is an injectable, or a topical or an eye preparation. Furthermore, Article 54 (d) provides that excipients known to have a recognised action or effect, and included in the guidelines published by the Commission pursuant to Article 65, need to be declared on the labelling of all other medicinal products.

2. Problem statement

The current guideline on Excipients in the Label and Package Leaflet of Medicinal Products for Human Use (CPMP/463/00) remains valid. However, since the last revision of the guideline in July 2003 several safety concerns regarding excipients have been identified which are not currently addressed in the guideline. Proper labelling is needed to ensure the safe use of medicinal products containing certain excipients of concern.

3. Discussion (on the problem statement)

The main safety concerns identified regarding excipients which are not currently addressed in the guideline include the following:

1. The current guideline does not cover the paediatric population, for which a new specific regulation (No 1901/2006) has been implemented following the last revision of the excipient guideline in July 2003. It is important to note that the safety of excipients can affect children differently than adults due to the ongoing organ development and incomplete maturation depending on the age.

2. Pregnant women are another sensitive population currently not covered in the guideline. Safety labelling is needed for products intended for use in this population to ensure the safety of the unborn child(ren).

3. The labelling of several excipients currently addresses only a limited number of routes of administrations. In addition, some of the used terms need to be updated. Therefore, additional routes of administration need to be considered for some of the excipients.

4. Additional excipients need to be added to the guideline to ensure consistency in the safety labelling of medicinal products.

5. Incomplete information is currently provided on how warnings in the package leaflet should be addressed in the summary of product characteristics (SmPC) in accordance with Article 59 (1) of Directive 2001/83/EC.

4. Recommendation

It is recommended that a revision of the guideline on Excipients in the Label and Package Leaflet of Medicinal Products for Human Use (CPMP/463/00) is undertaken to ensure the safe use of medicinal products containing certain excipients of concern.

5. Proposed timetable

The draft revised guideline is expected to be released for 6 month external consultation in 3Q 2013-1Q 2014. After the external consultation the final guideline is expected to be available within 6-12 months.

6. Resource requirements for preparation

The revision of the guideline will be performed by a multidisciplinary drafting group with expertise covering the safety, quality and pharmacovigilance of medicines (including product-specific expertise on vaccines, biologicals, blood products and paediatrics). Therefore, the revision will result in an increased workload on the Scientific Committees (including the CHMP and PDCO), the CMD(h), QRD group and several of the CHMP working parties (i.e., SWP, PVWP, QWP, BWP, BPWP, and VWP).

7. Impact assessment (anticipated)

A revision of the guideline might impact both new and already authorised medicinal products. If there are identified safety concerns for excipients already present in authorised medicinal products, the product information of these products (i.e. summaries of product characteristics, labelling and patient leaflets) may need to be updated. This will ensure a consistent and safe use of medicinal products.

8. Interested parties

Once completed, the new version of the guideline is anticipated to facilitate the activities of relevant regulatory bodies, industry, healthcare professionals and patients' associations.

9. References

The EC Guideline on Excipients in the label and package leaflet of medicinal products for human use http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003412.pdf