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**CVMP CONCEPT PAPER ON THE REVISION OF THE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS (CVMP) AND
COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)**

NOTE FOR GUIDANCE ON PLASTIC PRIMARY PACKING MATERIALS

1 Scope and Introduction

This concept paper is applicable to the joint (human and veterinary) Note for Guidance on Plastic Primary Packaging Materials (3AQ10A) which entered into force in August 1994.

2 Problem statement

The present guideline was adopted in February 1994 and it now needs to be revised in order to bring it in line with current regulatory guidance and requirements.

3 Discussion

The requirements outlined in the present guideline need to be re-assessed after having been in force since 1994. In particular, requirements common to all types of primary packaging materials (that is, non-plastics) should be omitted from the guideline, whereas reference to pharmacopoeial and foodstuffs requirements need to be updated. Also, with respect to human medicines only, this guideline needs to be revised inline with the new CTD format of the dossier. Whilst the CTD format does not apply to veterinary medicinal products, the QWP decided it would be wise to maintain the joint nature of this guideline and hence to include a format conversion table in an annex to achieve this.

4 Recommendations

- To maintain the joint human/veterinary nature of this guideline and to achieve this by the inclusion of a CTD/veterinary dossier format conversion table in an annex.
- To widen the scope to plastic primary packaging materials for active substances.
- To omit requirements not specific to plastics but common to all types.
- To update references to pharmacopoeial monographs and requirements for foodstuffs.
- *For human marketing authorisations only - to revise the present Note for Guidance on Plastic Primary Packaging Materials in order to bring it into line with the CTD structure.*

5 Timetable

The draft revised Note for Guidance is planned to be released for a 6-month consultation period in December 2003.