The European Agency for the Evaluation of Medicinal Products

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COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS (CVMP)

NOTE FOR GUIDANCE ON START OF SHELF-LIFE OF THE FINISHED DOSAGE FORM

(ANNEX TO NOTE FOR GUIDANCE ON THE MANUFACTURE OF THE FINISHED DOSAGE FORM)

DISCUSSION IN THE QUALITY WORKING PARTY	Oct. 1995 February 1996
TRANSMISSION TO THE CPMP	June 1996
RELEASE FOR CONSULTATION	June 1996
DEADLINE FOR COMMENTS	December 1996
Development of guideline postponed pending decision on inclusion in GMP guidance or publication as Quality guideline	
ADOPTION BY CPMP/CVMP	May 2001
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NOTE FOR GUIDANCE ON START OF SHELF LIFE OF THE FINISHED DOSAGE FORM: ANNEX TO NOTE FOR GUIDANCE ON MANUFACTURE OF THE FINISHED DOSAGE FORM

The expiration period of a production batch should be calculated from the date of release of that batch.

The date of such a release should, under normal circumstances, not exceed 30 days from the date of production of that batch.

If batches are released exceeding 30 days from the production date, the date of production, as defined below, should be taken as the start of the shelf-life.

The date of production of a batch is defined as the date that the first step is performed involving combining the active ingredient with other ingredients. For medicinal products consisting of a single active ingredient filled into a container, the initial date of the filling operation is taken as the date of production.

Note: This annex does not pertain to biological medicinal products such as vaccines, sera, toxins and allergens, products derived from human blood and plasma as well as medicinal products prepared biotechnologically.