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COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS (CVMP)

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(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
Date for Coming into Operation	December 2001

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.
생산 배치의 유효 기간은 배치 출하 승인 일자부터 계산한다.

The date of such a release should, under normal circumstances, not exceed 30 days from the date of production of that batch.
정상적인 상황에서 이 출하 승인 일자는 배치의 생산 일자로부터 30일을 넘지 않아야 한다.

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.
생산 일자로부터 30일을 넘어 출하 승인되는 배치가 있다면, 아래에 규정된 바와 같은 생산 일자를 유효 기간의 시작 시점으로 한다.

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.
배치의 생산 일자는 활성 성분과 다른 성분을 섞는 첫 단계를 실시하는 일자로 정의한다. 단일 활성 성분을 용기에 충전하는 의약품인 경우, 충전 작업의 개시 일자를 생산 일자로 한다.

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.
주: 백신, 혈청, 독소와 알레르겐, 사람 혈액 및 혈장 유래 제품, 생명 공학 의약품 등 생물학적 의약품에는 이 부록이 적용되지 않는다.