EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP) & Committee for Medicinal Products for Veterinary Use (CVMP)

Concept Paper on the Need for Revision of the Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation

Agreed by Quality Working Party	February 2010
Adoption by CVMP for release for consultation	11 February 2010
Adoption by CHMP for release for consultation	18 February 2010
End of consultation (deadline for comments)	30 April 2010

The proposed guideline will replace guideline "Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation" (CPMP/QWP/576/96 Rev 1 / EMEA/CVMP/373/04)

Comments should be provided using this template. The completed comments should be sent to *QWP@ema.europa.eu*

Keywords	Guideline, Stability Testing, Variations, Marketing Authorisation

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1. Introduction

The Joint Human/Veterinary "Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation" (CPMP/QWP/576/96 Rev 1; EMEA/CVMP/373/04) came into effect on 1 December 2005. Since then, changes have been made to the underlying variations legislation. The guideline therefore needs to be revised to be in line with these changes.

2. Discussion

In January 2010, Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products ('the Variations Regulation') came into force. This replaces 2 previous Regulations and changes the nomenclature of, and procedures for, some types of variations to medicinal products.

In addition, two Commission Guidelines came into effect in January 2010, the "Guideline on the details of the various categories of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products" ('the Classification Guideline') and the "Guideline on the operation of the procedures laid down in Chapters II, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products" ('the Procedural Guideline').

As a consequence of all the above changes, the relevant sections of the Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation now need to be revised.

3. Recommendation

The CHMP and CVMP both recommend revising the current guideline in line with current legislation. The Joint CHMP/CVMP Quality Working Party would be the main party involved in the revising the guideline. CMD-h and CMD-v would also be informed of the revision.

4. Proposed timetable

31 May 2010	Deadline for comments on Concept Paper
Q2 2010	Discussion of draft (revised) guideline in the Joint CHMP/CVMP Quality Working Party
Q3 2010	Discussion of draft (revised) guideline in CHMP and CVMP
Q3 2010	Release of draft (revised) guideline for public consultation

5. Resource requirements for preparation

The revision will involve the EMEA Secretariat, the Joint CHMP/CVMP Quality Working Party, the CHMP and CVMP, as well as CMD-h and CMD-v, who would be consulted, as necessary.

6. Impact assessment (anticipated)

The proposed revision will provide updated, current, clear and practical guidance for the competent authorities throughout the EU Member States to ensure a uniform assessment of variations and thus will facilitate applications for variations, regardless of which type of procedure is used (Mutual Recognition, Decentralised, Centralised or National).

For industry and other interested parties the revision of this guideline will contribute to the clarity and harmonisation of data requirements for variations involving stability issues and so provide benefits for the pharmaceutical industry.

7. Interested parties

Experts involved in the assessment of applications for variations for (human or veterinary) medicinal products in the EU Member States, and the pharmaceutical industry.

8. References to literature, guidelines etc

Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products ('the Variations Regulation')

Commission "Guideline on the details of the various categories of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products" ('the Classification Guideline')

Commission "Guideline on the operation of the procedures laid down in Chapters II, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products" ('the Procedural Guideline')

ICH Guideline Q1A (R2): Note for Guidance on Stability Testing: Stability Testing of New Drug Substances and Products (CPMP/ICH/2736/99)

VICH Guideline GL3: Guideline on Stability: Stability Testing of New Veterinary Drug Substances and Medicinal Products (EMEA/CVMP/VICH/899/99-Rev.1)

CPMP Guideline on Stability Testing: Stability Testing of Existing Active Substances and Related Finished Products (CPMP/QWP/122/02 Rev.1 Corr)

CVMP Note for Guidance on Stability Testing of Existing Active Substances and Related Medicinal Products (EMEA/CVMP/846/99)
and
CVMP Guideline on Stability Testing: Stability Testing of Existing Active Substances and Related Finished Products (EMEA/CVMP/QWP/846/99-Rev.1) *(implementation date = September 2011)*