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Committee for Medicinal Products for Human Use (CHMP)

Concept paper on the need for revision of the note for guidance on manufacture of the finished dosage form

Agreed by Quality Working Party	May 2013
Adopted by CHMP for release for consultation	17 June 2013
Start of public consultation	4 July 2013
End of consultation (deadline for comments)	31 December 2013

The proposed guideline will replace "Note for Guidance on Manufacture of the Finished Dosage Form" (CPMP/QWP/486/95)

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

Keywords	Guideline, manufacture, finished dosage form, dosage form

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

1. Introduction

This concept paper addresses the need to update and revise the CPMP/QWP/486/95 note for guidance on manufacture of the finished dosage form (1). This guideline was originally adopted in September 1995 and came into operation in 1st April 1996. Since then, the references to directives and format of dossier has been changed, new guidance (i.e. ICH Q8(2), Q9(3), Q10(4)) has been developed. Also the manufacture of finished dosage form has spread worldwide and terms like holding time and bulk product are now important part of the description of manufacturing process. The guideline therefore needs to be revised to be in line with all these changes.

2. Problem statement

The current guideline does not fully reflect recent development and changes both in legislation and available guidance documents. The text of guideline should be brought up to recent manufacturing practices and should allow different approaches to manufacture of finished dosage form.

3. Discussion (on the problem statement)

The objective of the guideline on manufacture of finished dosage form is to underline all aspects of manufacture that are important both for applicant and regulator. The guideline also indicates that information which fall under Good Manufacturing Practice should not be part of the MA file and that only product specific issues need to be described. The intention of revision is not to repeat the information already stated in other guidance documents or create new guidance, but to update the information to be in line with recent development. The following issues will be taken into account during revision:

The current guideline was developed before the introduction of common technical document format (CTD)(5) of dossier, and before introduction of new current directive (2001/83/EC). The guideline should thus be restructured to follow the CTD structure and out of date references to directives should be revised.

The ICH guideline Q8 pharmaceutical development, Q9 risk management and Q10 quality systems have been introduced, but are not reflected in this guideline. The information in the guideline will be updated accordingly.

The on-going revision of guidelines on process validation(6) and real time release testing(7) also has impact on current guideline on manufacture of finished dosage form especially on chapter 6- validation data of the manufacturing process and chapter 7- special items therefore the relevant information will be used for revision.

With new manufacturing practices and more complex manufacturing chains a need to incorporate holding times and conditions as well as shipping transportation conditions has been identified and will be discussed.

4. Recommendation

The Quality Working Party recommends revision of the note for guidance on manufacture of the finished dosage form in order to refer to concepts defined in other relevant guidance documents (ICH Q8, Q9, Q10, guideline on process validation, guideline on real time release testing) and to update information about manufacture of finished dosage form in line with recent development and the current EU legislation.

The revised guideline will not introduce new requirements on medicinal products already authorised and on the market.

5. Proposed timetable

May 2013 - discussion on concept paper in QWP

It is anticipated that the draft guideline could be available 6 months after adoption of the concept paper and that this would then be released for external consultation for 6 months before its finalisation within another 6 months.

It is expected that the guideline will come into operation six months after adoption.

6. Resource requirements for preparation

The revision will involve the EMA-QWP secretariat, the Joint CHMP/CVMP Quality Working Party, the CHMP, and GMP/GDP Inspectors Working Group, who would be consulted, as necessary. The QWP should appoint rapporteur and drafting group from the members of QWP.

7. Impact assessment (anticipated)

No adverse impact on industry with respect to either resources or costs is foreseen.

The guidance will clarify requirements for regulators and industry with respect to manufacture of finished dosage form taking into account the concepts of recent development. Elaboration of the guideline will facilitate different approaches to manufacturing process than currently detailed in the guideline and thus increase flexibility for industry.

8. Interested parties

Pharmaceutical Industry, EU Competent Authorities, GMP/GDP Inspectors Working Group

9. References to literature, guidelines, etc.

1: CPMP/QWP/486/95 Note for Guidance on Manufacture of the Finished Dosage Form

2: ICH Q8 (R2) Pharmaceutical Development

3: ICH Q9 Quality Risk Management

4: ICH Q10 Pharmaceutical Quality System

5: ICH M4 Common Technical Document

6: EMA/CHMP/CVMP/QWP/99/738/2012 Process Validation

7: EMA/CHMP/QWP/811210/2009-Rev1 Real Time Release Testing