



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

## Concept paper on the need to revise the Guideline on the clinical development of fixed dose combinations of medicinal products regarding dossier content requirements

Agreed by CHMP ad-hoc drafting group	31 January 2013
Adopted by CHMP for release for consultation	11 February 2013
Start of public consultation	1 March 2013
End of consultation (deadline for comments)	31 May 2013

The proposed guideline will replace 'GUIDELINE ON CLINICAL DEVELOPMENT OF FIXED COMBINATION MEDICINAL PRODUCTS' (CHMP/EWP/240/95 Rev. 1).

Comments should be provided using this [template](#). The completed comments form should be sent to [FDCguideline@ema.europa.eu](mailto:FDCguideline@ema.europa.eu)

Keywords	<i>Fixed dose combination products, legal basis, well-established use</i>
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## 1. Introduction

The current guideline *CHMP/EWP/240/95 Rev. 1* contains a section describing the legal basis applicable to fixed dose combination (FDC) product marketing authorisation application (MAA). Here, a strong link between the legal basis of Article 10b of Directive 2001/83/EC and the development of a FDC product is made, which could suggest that Article 10b is the sole legal basis applicable for such MAA submissions, especially in cases where all active mono-components of the FDC are already authorised in the EU.

## 2. Problem statement

There is a need to revise the current version of the above guideline in order to suppress regulatory aspects from the guideline and restrict it to the scientific requirements for clinical development of fixed combinations, regardless of the chosen legal basis.

In addition, the guideline also addresses combination packs, which should not be discussed within the scope of the FDC guideline, as from a regulatory point of view these are not to be considered as fixed-dose combinations.

## 3. Discussion (on the problem statement)

The connection between the regulatory explanations given in the guideline and the principles of clinical development is not comprehensive. Hence, amendment and minimisation of the regulatory part seems appropriate in order to focus primarily on the scientific requirements for FDC developments. In this respect, the current wording of the wide spread use in the section on substitution indication will also be addressed.

Since combination packs are different from fixed dose combination medicinal products, it is no longer considered appropriate to address combination packs within the scope of this guideline.

## 4. Recommendation

The ad-hoc drafting group recommends the revision of the guideline on "*Clinical development of fixed combination medicinal products*" in order to:

- Update the section reflecting the 'Legal Basis' of the guideline;
- Update other relevant sections of the guideline to minimise reference to regulatory aspects (e.g. dossier requirements);
- Update the scientific aspects of the guideline;
- Remove reference to combination packs.

## 5. Proposed timetable

It is anticipated that draft guidance would be available 6 months after the adoption of the Concept Paper for public consultation over 3 months and subsequent finalisation within 3 months.

## **6. Resource requirements for preparation**

The revision of this guideline will involve a CHMP ad-hoc drafting group. Additional consultation at SAWP and CMD(h) is foreseen, as applicable.

## **7. Impact assessment (anticipated)**

The revision of this guideline will clarify the dossier requirements for FDC products regardless of the chosen legal basis and thus, will facilitate the regulatory review process. In addition, the revised guideline will support the applicants in the identification of any gaps of their datasets.

## **8. References to literature, guidelines, etc.**

GUIDELINE ON CLINICAL DEVELOPMENT OF FIXED COMBINATION MEDICINAL PRODUCTS:

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003686.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003686.pdf)