Chapter 1 Marketing Authorisation European Commission

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Marketing Authorisation in EU| European Medicines Agency (EMA)| MRP, DCP, CP \u0026 National Procedure

An overview of requirements for the marketing-authorisation holder

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1 EUROPEAN COMMISSION HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL Health systems and products Medicinal products Revision 5 NOTICE TO APPLICANTS VOLUME 2A Procedures for marketing authorisation CHAPTER 1 MARKETING AUTHORISATION July 2015 This Chapter 1 Marketing Authorisation will be included in The Rules governing

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CHAPTER 1 SUBJECT MATTER AND DEFINITIONS. Article 1. Subject matter. Article 2. Definitions. CHAPTER 2 MARKETING AUTHORISATION REQUIREMENTS. Article 3. Donation, procurement and testing. Article 4. Clinical trials. Article 5. Good manufacturing practice. Article 6. Issues specific to medical devices. Article 7.

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NOTICE TO APPLICANTS - European Commission

This page lists questions that marketing-authorisation holders (MAHs) may have on type-II-variation and extension applications.It provides an overview of the European Medicines Agency's position on issues that are typically addressed in discussions or meetings with MAHs in the post-authorisation phase.Revised topics are marked 'New' or 'Rev.' upon publication.

Extensions of marketing authorisations: questions and ...

A reference medicinal product is a medicinal product that has been granted a marketing authorisation by a Member State or by the European Commission on the basis of a complete dossier, i.e. with the submission of quality, preclinical and clinical data in accordance with Articles 8(3), 10a, 10b or 10c of Directive 2001/83/EC, as amended, and to which the marketing-authorisation application for a generic, hybrid or similar biological medicinal product (i.e. application under Articles 10(1), 10 ...

Pre-authorisation guidance | European Medicines Agency

Chapter 5 - Guidelines of 16 May 2013 on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, 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 and on ...

EudraLex - Volume 2 - European Commission

Chapter 1: Introduction of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the EMA (PDF/154.74 KB)

Guidance documents | European Medicines Agency

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Volume 2A Procedures for marketing authorisation

CHAPTER 1 Marketing Authorisation Rev 2005 11 11 05 clean...
CHAPTER 1 Marketing authorisation procedures for applications falling within the scope of Articles 7 and 8. Article 28. (1.) Applications may be submitted in accordance with the procedure.....

Regulation (EC) No 1901/2006 of the European Parliament ...
CHAPTER 1 Marketing authorization. Article 6. (1.) No medicinal product may be placed on the market... Article 7. A marketing authorization shall not be required for a radiopharmaceutical.....

Directive 2001/83/EC of the European Parliament and of the ...
CHAPTER 1 Marketing authorization Article 6 (1.) No medicinal product may be placed on the market... Article 7 A marketing authorization shall not be required for a radiopharmaceutical... Article 8...

Directive 2001/83/EC of the European Parliament and of the ...
If the referrer is an applicant/marketing authorisation holder, in advance of initiating a referral under Article 30(1) of Directive 2001/83/EC, he is recommended to have a pre-referral discussion and meeting, as necessary, with EMAFollowing notification of the referral, the applicant/marketing authorisation holder and the Member States concerned forward to EMA any information relevant to the referral.

NOTICE TO APPLICANTS - European Commission
Marketing authorisation holders need to ensure that information on all medicinal products, which is submitted electronically to the Agency, is accurate and up to date. The Agency – with the support of a contractor – will perform an overall review of the quality and integrity of the medicinal product information submitted.

Article 57 Detailed Guidance_Chapter 1
The marketing authorisation number is: EU/1/13/999/001. The marketing authorisation holder is company MAH-ABC. Section 1. Name of the medicinal product states of the SmPC states: COMET 10 mg tablets COMET 40 mg tablets. The marketing authorisation holder should submit one medicinal product entity with the two pharmaceutical products (i.e. 10 mg tablets and 40 mg tablets) to the XEVMPD:

Chapter 3.II: Extended EudraVigilance product report ...
The European Medicines Agency (EMA) assesses applications from companies to market generic medicines in the European Union (EU). To help applicants, EMA has published questions and answers (Q&As) on its position on issues applicants preparing to request marketing authorisation for generic or hybrid medicines typically raise.. Theses Q&As complement the Agency's pre-authorisation guidance.

Generic and hybrid applications | European Medicines Agency
Marketing Authorisation: A medicinal product may onlySix scientific committees, composed of members

of all EU be placed on the market in the European Economic Areaand EEA-EFTA states, conduct the main scientific work of (EEA) when a marketing authorisation has been issued bythe Agency: the competent authority of a Member State (or EEACHMP: Committee for Medicinal Products for Human Use country) for its own territory (national authorisation) or(CHMP), when an authorisation has been granted in …