

Chapter 7 – General information

- CMDh accepted to take over the responsibility for handling/publishing some of the information contained in NtA, Chapter 7 (General information)
- Identify sections that will be taken over by CMDh
- Identify redundant information
- Decide where to publish the information on the website

Chapter 7 – What to take over?

Table of Content	CMDh	Comments
1. Format for applications in the E.U.	No	Information on the presentation and format of a dossier is given in ' <i>The Rules Governing Medicinal Products in the European Union, Vol. 2B and Vol. 2C</i> '.
2. Languages to be used for dossier, responses, variations and renewals	X	For MRP/DCP and NP only
3. Number of copies of the dossier, responses, variations and renewals	No	Obsolete, covered by published guidelines

Chapter 7 – What to take over?

Table of Content	CMDh	Comments
4. Dossier Check-in Procedure	?	To be further discussed
5. Specimens and samples	X	For MRP/DCP and NP only
6. National procedure after a commission decision on a referral	X	

Chapter 7 – What to take over?

Table of Content	CMDh	Comments
7. List of official journals	No	Keep it on EC website
8. Addresses for receipt of the dossier and subsequent correspondence	X	For MRP/DCP and NP only
9. Addresses for receipt of fees and terms for payment	X	For MRP/DCP and NP only
10. "Blue box" requirements	X	For MRP/DCP and NP only

Chapter 7 – Where to publish?

Heads of Medicines Agencies: General Info - Windows Internet Explorer

http://www.hma.eu/90.html

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Heads of Medicines Agencies: General Info

You are here: [Human Medicines](#) > [CMDh](#) > [Procedural Guidance](#) > General Info

General Information

In order to view some of the documents on this website you need **Acrobat Reader** ([click here to download](#))

- [Best Practice Guide for the Reference Member State in the MRP/DCP \(June 2011\)](#) [[Track changes](#)]
- [CMDh procedural advice on changing the RMS \(March 2009\)](#) [[Track version](#)]
- [Best Practice Guide for the exchange of regulatory and administrative information regarding orphan medicinal products between EMEA and National Competent Authorities \(February 2007\)](#)
- [CMDh agreement on sunset clause and its application to marketing authorisations granted in more than one MS \(March 2011\)](#) [[Track version](#)]
- [Phasing in EU procedures: MRP and referrals \(September 2003\)](#)
- [Notifications to the EMEA/CHMP in MRP/DCP \(March 2006\)](#)
- [CMDh Recommendation for Marketing Authorisation Holders on the Pharmacovigilance System and Risk Management Plan in the Mutual Recognition and Decentralised Procedures \(July 2011\)](#) [[Track version](#)]
- [CMDh Best Practice Guide for the Public Assessment Report in MRP/DCP \(January 2006\)](#)

For the template of the Public Assessment Report and Updates, please refer to [Assessment Report](#)

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Chapter 7 – Next steps

- Get the files from the EC
- Find rapporteurs responsible for each section
- Inform the EC that CMDh is ready to publish the updated sections
- Publish the updated sections as separate documents
- Target date: June 2012
- Get feedback from the users