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HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT

Directorate general for Medicinal Products

eSubmission Guidelines

New ways of working at DGMP

Version 2.51

28/8/06

DOCUMENT HISTORY

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15/6/2005	Rudi Princen	0.2	Adding chapters on e-mail and eCTD tools
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28/8/06	Michel Genot	2.51	Spelling correction

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Table of Content

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1. Introduction

One of the conclusions of the Business Process Reengineering project that was conducted by the DGMP in 2003-2004, was to implement a new back-office and case management system with document and workflow management capabilities in order to:

- Automate administrative processes and improve the operational efficiency of the NCA
- Ameliorate case management and decision-making processes
- Eliminate paper handling (storage, copying, transportation, confidential shredding, etc.)
- Increase communication and knowledge transfer
- Enabling access to a centralized data model in line with European legislation
- Further improve the quality carried out by the NCA
- Build an electronic interface to industry stakeholders for electronic applications and communications

This document completes and clarifies the previous Guidelines Ver. 1.0 and all FAQs already published.

This document supersedes previous versions.

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2. Important reminder

The applicant is fully responsible for the correctness and completeness of the submitted file within any type of e-dossier submitted to the DGMP.

To this end the applicant must include four declarations in the cover letter:

1. The submitted dossier is compliant with the DGMP eSubmission Guidelines,
2. A statement of good quality of the data in the file,
3. A declaration that the content of the proposed leaflets (SmPC, PIL & Labelling) is identical to the approved version and that the proposed changes only reflect the content of the submitted file,
4. The conformity statement of translation.

(1) The roadmap presented by the DGMP at the January session 2006 as well as the guidelines for electronic submissions have to be followed meticulously for the preparation of an electronic file to be submitted at the DGMP (Both can be found on the website health.fgov.be).

The applicant has to add a formal conformity declaration of the files towards the e-submission guidelines.

Only conform files can be handled. To avoid delay during registration procedures, it is of great importance and in the best interest of both the industry and the DGMP to submit all files conform to the current guidelines. A file which is not conform to the e-submission guidelines will be refused by the DGMP.

(2) The applicant is responsible for the quality of the scientific data in the submitted file. Therefore, the applicant adds a statement of good quality of the data in the file.

(3) The applicant is responsible for the conformity of the leaflets (SmPC and PIL) and the labeling according to the file (registration or variation). As for the variations or files which cause change in the leaflets or labelling, the applicant has to declare that the content of the proposed leaflets is identical to the approved version and that the proposed changes only reflect the content of the submitted file.

(4) The applicant should use of the conformity statement on translation of SmPC into two national languages (Dutch and French), and PIL and labeling into the three national languages (Dutch, French, German). A template of this conformity statement is available on the website. The conformity statement itself has to be sumitted together with the translations at the end of the procedure.

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3. Glossary

Please find below a list of abbreviations and key words used in this Guidelines document:

Key word or abbreviation	Explanation or definition
AMM	Autorisation de Mise sur le Marché (Marketing Authorisation)
CHMP	Committee on Human Medicinal Products of the EMEA
CP	Centralised Procedure
CTD	Common Technical Document (Document standard developed by ICH and supported by EMEA)
DCP	Decentralised Procedure
DGMP	Directorate General for Medicinal Products (www.health.fgov.be)
EAF	electronic Application Form
ECTD	The electronic CTD
EMEA	European Medicines Agency (www.emea.eu.int)
eSubmission system	The new document and workflow management system which is implemented at DGMP that manages the electronically submitted applications for new drug registrations, variations, renewals, etc.
EUDRALINK	System developed by EMEA for secure electronic transfer of files
FDA	Food and Drug Administration
ICH	International Conference on Harmonisation (www.ich.org). The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
NP	National Procedure
Paper dossier	The hard copy (paper copy) of a drug application
PIL	Patient Information Leaflet
SPC	Summary of Products Caracteristics
XML	Extensible Markup Language (XML) is a simple, very flexible text format derived from SGML (ISO 8879). Originally designed to meet the challenges of large-scale electronic publishing, XML is also playing an increasingly important role in the exchange of a wide variety of data on the Web and elsewhere.

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4. Different types of e-Submission dossiers identified by the DGMP

The DGMP has defined three types of dossiers for electronic submission.

A. Type 1: eCTD or electronic Common Technical Document

This is a standard agreed by the ICH and endorsed by the CHMP. Regarding Module I EU specifications are requested. It consists of 3 main elements:

- The electronic Application Form (eAF) in XML specification ('generated from electronic source').
- The directory structure, a tree structure with all the required documents for registration based on the eCTD structure standard.
- an XML file ('XML backbone') containing valuable and structured information on all documents in the dossier (e.g. meta data such as versioning information, check sum, table of contents, etc.).

The eCTD is the recommended format by the DGMP in Belgium.

This format allows the DGMP to import and classify the registration dossier. As it contains versioning data on the documents, it enables the DGMP to manage different document versions (modified documents, unmodified documents, deleted documents, etc.). Without the XML backbone the DGMP needs to manually verify the versions of the submitted documents.

The eCTD specification is available on www.ich.org (CTD modules 2 to 5) and http://esubmission.eudra.org for the European specifications (CTD Module 1) and more specifically for the application forms at http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm.

There are eCTD software tools on the market that can help the pharmaceutical industry to view and/or create eCTD dossiers.

Both FDA and EMEA have contracted firms to develop such tools. Please take contact directly EMEA or FDA representatives to obtain a full list of these software suppliers.

As of 1st of December 2006 it is likely this will be the preferred format by EMEA and as of 1st of January 2007 this will be the recommended format for new registration by the DGMP in Belgium.

Please pay attention to the following remark:

As the eCTD format evolves it is important that the pharmaceutical industry respects the last eCTD specification version as approved by the EMEA.

The applicable eCTD specifications version is always the current versionThe XML versions applicable are:

- For Modules 2 to 5: ich-eCTD- DTD (current version)
- For EU Module 1: EU-index. DTD (current version)
- For the new application form: EU-application. DTD (current version) and XLS version
- For the variation form: DTD current version

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As of 1st of January 2007, the DGMP highly recommand to use eCTD format to submit all new registration in order to get the benefit of this technology when submitting next variation for this product.

B. Type 2: CTD structured dossier with an XML application form

This is a hybrid format. It contains the eCTD structured dossier as well as the electronic Application Form (eAF) based on eCTD specifications (XML format) but without the XML backbone.

The electronic documents or content in a standardized directory (tree) structure (based on the eCTD directory structure).

C. Type 3: CTD or Common Technical Document

This standard for structuring the registration application and documentation lies at the basis of the eCTD, but contains no XML files (application form or backbone).
The CTD specifications are available on www.ich.org and http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm.

Obviously, this format does not allow automatic import or classification of the incoming dossier, but needs manual intervention.

The minimal electronic CTD structured dossier (Type 3). This dossier consists of:

1. The application form in MS Word or PDF.
2. The electronic documents or content in a standardized directory (tree) structure (based on the eCTD directory structure).

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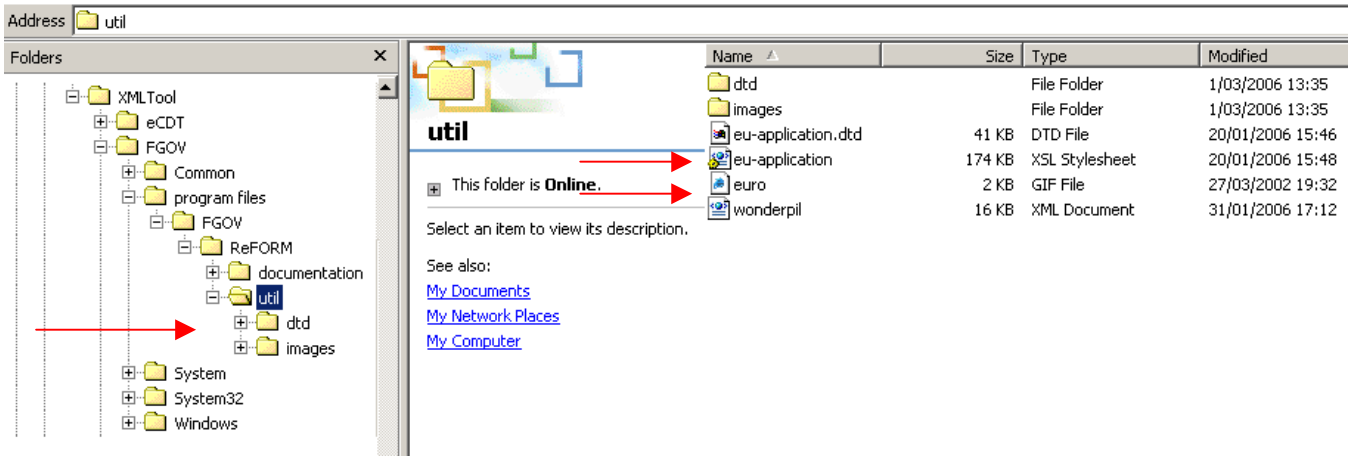
Attention points when submitting an XML file

When submitting an XML file (Application form) please be sure to add the DTD and the XSL properly linked to the XML file. The AF XML should be correctly located in the 1.2 Folder.

Both DTD and XSL file are to be present in the UTIL directory. To be sure to have the correct information which help us when downloading the XML Form, please copy either the complete "Util" directory or the both mentioned files within an "Util" directory.



Please be sure that your XML file is valid before sending to the DGMP.

D. Type 4: Volume based PDF

No longer acceptable.

Nice to know

1. Which type of dossier (1, 2 or 3) do I need to use for my e-submission?

For a new application (MRP, DCP and NP) and variations (MRP, DCP and NP the type I dossier is preferred. However type 2 and type 3 dossiers will be allowed. Note that from January 1, 2007 all new CP European applications will be accepted to be submitted in eCTD format).

It is highly recommended to submit a type 1 full eCTD dossier for new drug applications (type 1), because this allows a partially automatic import of the data in the eSubmission system. Also, it will allow the Applicant to re-use the eCTD structure when sending in Variations and keep track of the changes and product lifecycle attributes as this is managed by the eCTD logic.

For Renewals (MRP, DCP and NP), parallel import and declarations a type 3 dossier should be submitted.

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2. Which tool do I need to use for creation of the XML application form?

It is recommended to use the AFSSAPS tool (freeware) for the creation of the application form, available on:

https://portal.health.fgov.be/portal/page?_pageid=56,1364388&_dad=portal&_schema=PORTAL

3. Where to download the form and get information on how to fill it?

For **new registrations:** http://esubmission.eudra.org/documents.html.

For **variations** and **European Renewals**: http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm.

https://portal.health.fgov.be/portal/page?_pageid=56,1364388&_dad=portal&_schema=PORTAL

For **National Renewals** and **parallel import dossiers** the application forms as published on the DGMP website (medicines – formulieren/formularies, dutch and French version of website only) are to be used.

For **declarations** no specific application form is needed.

4. Are all non- volume based PDF formats accepted?

NO, only those which contain TEXT Select functionality for module 1.

In exceptional cases, for module 2 - 5 all non-volume based PDF-formats can be accepted

The DGMP advise the applicant to submit files in MS Word format to facilitate the DGMP reviewers work.

5. What about complex dossiers (parent and child)?

Type 1 electronic dossiers.

Complex dossiers are not allowed since for a eCTD parent as well as child should contain full date, therefore they are not considered being complex dossiers as outlined hereafter.

Type 2 and 3 electronic dossiers

When submitting the same variation for different medicinal product strengths, you can make a parent dossier accompanied by the relevant child dossiers:

- Build a “Parent dossier” for the first strength/ form respecting CDT structure
- Create for each new strength/ form a new “Child dossier
- Letter of Intent and Cover Letter should clearly specify the different products and strengths.
- Parent dossier contains overall retribution form (no need to split up in child dossiers).
- Parent dossier contains all inforamtion which is valid for parent and all childs included.
- Child dossiers contains all information only applicable to that child, empty folders can be deleted.

Exception: retribution form need to be present in the parent dossier.

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6. What about the Letter of Intent?

The letter of intent can be used for all dossier types except for Type Ia/b variations. If you use the Letter of Intent, please submit the Letter at least 15 days in advance of your file submission.

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5. Submission dossier: eCTD Directory structure and naming conventions

The specifications for the directory structure and for naming and numbering conventions for folders and documents in the CTD directory structure have all been defined in detail in the v3.2 Specifications Document (Appendix 3: General Considerations for the CTD Modules, p16-30) published by the ICH (www.ich.org). These naming conventions need to be adopted by the applicants for all e-Submissions.

We have developed a helpfull tool which offers the empty directory structure with all the folders and subfolders of the eCTD dossier. This is made publicly available on the DGMP website (https://portal.health.fgov.be/portal/page?_pageid=56,1364388&_dad=portal&_schema=PORTAL).

It enables the pharmaceutical companies to directly classify the registration dossier documents in the right folders compliant to the CTD standard.

The content of module I such as it should be submitted with integrated the DGMP good practice remarks (in italics) is given below:

Module 1

Please delete empty folders.

1.0 Cover Letter

- Should be listed in the folder "be".
- *The cover letter should be the original signed Cover Letter.*
- *The subject of the cover letter should contain the following: Name of the medicinal product in Belgium Type of procedure (MRP, CP, DCP, …), Type of dossier: type IA, IB, IInc, IIc, renewal, new, E, PI, DECL).*
    - *Also mention the dossier ID if known.*
    - *If you are using different dossiers (for the same product or the same group of products) but based on the same common variation, please noyify all the related dossiers (and variation) on the cover letter of each submitted dossier.*

1.1 Comprehensive Table of Contents

- *Include a Table of Contents with hyperlinks, if possible, to the related document in the respective CTD modules.* ***When submitting a type 2 or 3 dossier,ensure that all the paths in the links are relative when building the hyperlink, ie: use './m1' instead of '/0001/m1'***
- *Make sure all file names are clear and logic and respect the eCTD nomenclatur0*

1.2 Application Form

- *Application form should be stored in the "be" folder.*
- *Annexe should be stored in the "Common" folder.*

- *For new registrations, one application form per medicinal product strength is expected.*

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- *For variations (concerning same variation type and variation content), you can use one form for different strengths or pharmaceutical forms as long as they belong to the same umbrella (= same active substance, same company.*
- *Never submit a scanned document, the option text select should always be available if submitting a PDF file (the DGMP prefers MS Word document if possible).*
- *Signature on the application form is not mandatory.*
- *The Application form refers to any form (new applications, applications for variations or renewals). Always use the country directory at this level for all procedures even when only one file is submitted to only one country during the life cycle of the submission.*
- *The filename for the Application Form should be composed of a fixed component "CC", a fixed component "form" and an optional variable component to be used if required (e.g. fr-form-annex01.pdf). When only the application form is submitted in this directory the file name should be CC -form.pdf. Annexes that apply to more than one country in MRP should be placed in the 'common' sub-directory (e.g. common-form-annex12.pdf, common-form-pheurcertificate.pdf). The variable component, if used, should be a logical name preferably without hyphens or spaces.*
- *Delete empty folders.*

Annexes

- *Documents concerned by the folder annexes are: e.g .retribution form, ticked guideline, GMP-certificate, proof of establishment,dossier description, justification of type IA, other… .*
- *Seperate documents per annex..*

1.3 Product Information

1.3.1 SPC, Labelling and Package Leaflet

- *The proposed European SPC and PIL are to be included in the 'common' subfolder for European dossiers.Please note that in case of European dossiers, the national proposals may be submitted at the end of the procedure.*
- *The proposed national SPC and leaflet are to be included in the 'be' subfolder for national dossiers.*
- *The proposed labeling text should include braille in normal text format (this is in compliance with NtA requirements).*

1.3.2 Mock-up

The proposed mock-up should visualise braille using dots (this is in compliance with NtA requirements).

1.3.3 Specimen

1.3.4 Consultation with Target Patient Groups

- Subfolder: "be" for national procedures, include here readability testing results.
- Subfolder "common": for European procedures include here readability testing results

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1.3.5 Product Information already approved in the Member States

- *The approved European SPC and PIL have to be included here. Moreover, the last approved national SPC and PIL have to be included here as well. Pay attention that the version submitted is to be the last one approved by the DGMP, and not the version already containing adaptation concerning dossiers that are still ongoing!!!*

1.3.6 Braille

- "be": for national procedures, the applicant should address the proposed implementationof the braille requirements.
- "common": for European procedures, the applicant should address the proposed implementationof the braille requirements.

1.4 Information about the Experts

1.4.1 Quality

1.4.2 Non-Clinical

1.4.3 Clinical

1.5 Specific Requirements for Different Types of Applications

1.5.1 Information for Bibliographical Applications

1.5.2 Information for Generic, 'Hybrid' or Bio-similar Applications

1.5.3 (Extended) Data/Market Exclusivity

1.5.4 Exceptional Circumstances

1.5.5 Conditional Marketing Authorisation

1.6 Environmental Risk Assessment

1.6.1 Non-GMO

1.6.2 GMO

1.7 Information relating to Orphan Market Exclusivity

1.7.1 Similarity

1.7.2 Market Exclusivity

1.8 Information relating to Pharmacovigilance

1.8.1 Pharmacovigilance System

1.8.2 Risk-management System

1.9 Information relating to Clinical Trials

Responses to Questions

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Additional Data

- *Include both the approved AMM and the proposal AMM (4 pages). Note that submission of an AMM proposal is mandatory, if changes to the AMM are a consequence of the submitted dossier.*
- *- Include here all TSE relative information (see circular letter 383) , the Delegation Of Power (if applicable) and all documents related to other national requirements.*

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6. Which communication channel is most appropriate for my eSubmission?

The following communication channels will be allowed for submitting electronic registration dossiers to the NCA:

A. E-mail

For NP, CP, DCP, MRP registration dossiers as well as any type of correspondence related to the dossiers, emails up to a size of 20,00 Mb will be allowed. Please compress or 'zip' the file.

The generic e-mail address for electronic dossier submission is dgg_dispatching_dgm@health.fgov.be except for

- National renewals for which the generic e-mail address for electronic dossier submission is dgg_vigilanceh_dgm@health.fgov.be.
- PSUR for which the generic e-mail address for electronic dossier submission is dgg_psurh_dgm@health.fgov.be.

The generic e-mail address for correspondence/additional data/post-approval commitments concerning an (ongoing) dossier is DGG_FTGX_DGM@health.fgov.be in which the 'X' has to be replaced by the respective number of the concerned PharmacoTherapeuticGroup.

!!! Pay attention to the following:

1. The **mail subject** always need to mention: (all field should separated by "-")
   1. Type of procedure (MRP, DCP, CP, NP)
   2. Type of dossier (type IA, IB, IInc, IIc, renewal, new, E, PI, DECL, PSUR)
   3. The name of the medicinal product in Belgium
   4. Dossier ID (if known)

2. The **content** of the cover letter should be in the body of the mail.

3. **Dossiers** in a CTD directory structure that are sent via e-mail need to be **compressed** ("zipped" with WinZip) so that the relative CTD folder structure is respected.
   - If you are using a different compression software than WinZip, please mention it in the Cover Letter.
   - If you locked the ZIP files or any files with a password, please mention it in the Cover Letter and how we can get the password.

Please use the eCTD directory structure as it is defined in our empty folder structure tool (published on the DGMP website).

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A compressed or zipped folder can keep its directory structure thanks to a function of WinZip (see below):

a. First compress ('zip') the dossier folder by using the WinZip program (see below)

b. Then check the Option "Save full path info". This will store the whole folder structure information.

c. Verify the result in the compressed ('zipped') document

d. Send the compressed document via email to DGMP (unless its size is larger than 20,00Mb)

4. **Eudralink (EMEA):** This option could be used to submit electronic dossiers to the DGMP (Dispatching EudraLink E-mail: dgg_dispatching_dgm@health.fgov.be). This solution is a secure solution and allows to submit lager files. This option may also be used to submit additional info to the FTG concerned.

B. CD-ROM/DVD:

When the size of the registration dossier exceeds the size of 20,00 Mb, the pharmaceutical company needs to submit the dossier on a CD-ROM or DVD which needs to be shipped to the NCA (for DVD's all standards are accepted).

!!! Pay attention to the following:

1. Please don't forget to print the cover letter and put it in the envelop when mailing the CD/DVD.

2. Do not password protect your files! Or communicatehow to get this password clearly to the NCA.

3. Do not send parts of dossiers by email and parts on CD/DVD.

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7. How to know the status of your dossiers in process?

A. Automatic e-mails sent by the system during the workflow:

Remark: automatic mail is not applicable for CP.

During the workflow e-mails are sent at the following workflow steps:

- Acknowledgement of receipt of the Letter of Intent (not yet in production)
- Acknowledgement of receipt of the dossier
- End of validation process / start of the evaluation of the file
- End of the evaluation of the file/start of the administrative phase (not yet in production)
- After final decision of the Medicines commission on the dossier / before sending the approval documents
- End of payment tracking (not yet in production)

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