MALTA
MEDICINES
AUTHORITY

Guideline for submission of applications and documents for medicinal product authorisation and post-authorisation activities

Ref: GL-LI04.09
November 2025
Licensing Directorate

Contents

1. Scope

This guideline applies to all the applications including supporting documentation submitted to the Malta Medicines Authority in relation to new product registrations, covering all pre-authorisation and post-authorisation procedures submitted under European and National routes. This document should be read in conjunction with the current revision of the *Harmonised Technical Guidance for eCTD Submissions in the EU* (see References section below)

2. Abbreviations

ADR	Adverse Drug Reactions
ASMFs	Active substance master files
CESP	Common European Submission Portal
CMDh	Co-ordination Group for Mutual Recognition and Decentralised Procedures-Human
CMS	Concerned Member State
CT	Clinical Trial
CTD	Common Technical Document
CTR	Clinical Trial Regulation
CTIS	Clinical Trial Information System
DCP	Decentralised Procedure
EU	European Union
eAF	electronic application forms
eCTD	electronic Common Technical Document
e-forms	Electronic forms
EMA	European Medicines Agency
EOP	End of Procedure
esubmissions	electronic submissions
FUMs/SOs	Post Authorisation Follow-up Measures / Specific Obligations
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
LAB	Labelling
LOQ	List of Questions
MA / MAH	Market Authorisation / Market Authorisation Holder
MRP	Mutual Recognition Procedure
POA	Power of Attorney
PI	Parallel Importation
PL	Patient Leaflet
PMFs	Plasma master files
PSUR(s)	Periodic Safety Update Report(s)
RMS	Reference Member State
SmPC	Summary of Product Characteristics
TIGes	Telematics Implementation Group for Electronic Submission and ICH Implementation

XML	Extensible Markup Language
NCA	National Competent Authority
VAMFs	Vaccine Antigen Master Files

3. Standards to streamline the business process

Standards for electronic submissions have been developed for human medicinal products, by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

The aim of electronic submissions (eSubmissions) is focused on the minimisation of paper use during the exchange of information between applicants and National Competent Authorities and facilitation of business process.
The transition to electronic submissions brings with it several advantages, not only the obvious reduction in printing, archiving and transportation costs, but also facilitates consistency in information viewed across Medicines Agencies, the ability to manage the lifecycle of the product and improved navigation and assessment of documentation.

CONTENT FORMAT	The electronic exchange standard is called electronic Common Technical Document (eCTD). This standard is based on • ICH M2 eCTD Specification • EU Module 1 Specification • Relevant ICH and EU Q&A and guidelines All regulatory submissions related to marketing authorisation applications and lifecycle management of medicinal products to National Competent Authorities must be provided in the electronic Common Technical Document (eCTD) format. For detailed information on the eCTD requirements and version implementation, please refer to Section 4, Annex 1 of the *Harmonised Guidance for eCTD*, Version 6.0.
E-FORMS	For applications where the eCTD format may not applicable, such as parallel import applications and applications for authorisation in accordance with article 126(a) of Directive 2001/83/EC, electronic submissions are still required (see section 3 and Appendix 1) and should also be submitted through CESP. national electronic forms (e-forms) available can be found here: http://www.medicinesauthority.gov.mt/onlineapplications See Section 4.2.2 for details
EXCHANGE/ SUBMISSION	The Malta Medicines Authority requires that any submissions related to marketing authorisation applications and post-authorisation applications be submitted electronically through the Common European Portal (CESP) (https://cespportal.hma.eu). For further information refer to section 5
CLINICAL TRIAL APPLICATIONS	For clinical trial application submission, refer to the Clinical Trials Information System | European Medicines Agency (EMA)
TENT	Relevant CMDh documents referring to submission requirements should be referred to: http://www.hma.eu/277.html.

4. Electronic format for dossier submission

4.*1* *eCTD Submissions*

All submissions (new applications, variations, renewals, PSURs, ASMFs, etc.) are required to be in eCTD format. Please refer to the eSubmissions Roadmap (which can be found on the eSubmissions page) for other important deadlines. This includes submissions for all products with national marketing authorisations.

For other NCA Heads of Medicines Agencies: eSubmissions for requirements of signed paper copies of the cover letter and application form to each NCA.
More information on eCTD submissions can be found on the eSubmissions page of the European Medicines Agency.

The current electronic version was developed by the eCTD Implementation Working Group and released as version 4.0, with implementation date of 2025. For further information refer to https://esubmission.ema.europa.eu/eCTD%20NMV/eCTD.html. The European Union applies the eCTD Specification in the European region and has completed it with the European Module 1. Preparation of the version updates is ongoing within the ICH. For more information, please refer to the eCTD EU M1 specification and eCTD webpages to identify which version is currently valid and acceptable.

For MRP / DCP guidance a cover letter template is provided at the CMDh webpage. https://www.hma.eu/human-medicines/cmdh/procedural-guidance/esubmissions.html

Guidance on placement of documents within the eCTD structure for particular submission types can be found in:
Notice to Applicants EudraLex - Volume 2

The ICH CTD page:
http://www.ich.org/products/ctd.html

TIGes Harmonised eCTD is available on:p
http://esubmission.ema.europa.eu/

ICH Guidance for Industry on Providing Regulatory Information in Electronic Format: eCTD electronic Submissions, available at the following link.

CMDh Guidance for companies on eSubmissions.

4.2 Electronic applications (eAF) & Electronic forms (eForms)

4.2.1 For Mutual Recognition, Decentralised & National Procedures

The word-based application forms (AF) have been replaced by electronic application forms (eAF), with new possibilities like electronic data import/export, data population within the form, online access to standardised catalogue terms, built in business rule validation, and support for validation of form, etc. Implementation of mandatory use of the eAF is part of the HMA eSubmission roadmap http://esubmission.ema.europa.eu/tiges/cmbdocumentation.html.

This applies to all the application forms, i.e.

- New applications and line extensions for national, decentralised, and mutual recognition procedure applications (eAF version implementation plan is important to note).

- Variation applications (eAF version implementation plan is important to note)
- Article 61(3) notification forms
- Applications for the renewal of authorisations/licences- Responses to validation issues
- Responses to list of questions (LOQ) in assessment reports
- Supplementary information
- PSURs
- Follow-up measures (FUMs)/Specific Obligations (SOs)
- Active substance master files (ASMFs)
- Vaccine antigen master files (VAMFs)
- Plasma master files (PMFs)

If you have any questions regarding the electronic application forms, please contact the eAF service desk with your query on eaf@ema.europa.eu.

Technical Validation of all applications and sequences is being performed in line with the eCTD version roadmap.

4.2.2 For other purely national applications

For applications falling under purely national licensing requirements*—where the electronic Application Form (eAF) is not applicable—submissions are to be made using the Online Applications e-Forms available on the Malta Medicines Authority website at: http://www.medicinesauthority.gov.mt/onlineapplications.

For the list of e-forms present therein, wherever a signature is required to be inserted, the separate Declaration form available from http://www.medicinesauthority.gov.mt/onlineapplications. is to be filled in and attached to the e-form and submitted online, through CESP. ***After clicking the print button, save form to PDF and send via CESP. This applies to Licensing forms* ONLY.***

*Licensing e-forms:

- Application for authorisation in accordance with article 126a of Directive 2001/83/EC new application
- Notification of variation to the details and documents of an authorisation in accordance with article 126a of Directive 2001/83/EC
- Parallel import new application/ Parallel import renewal of licence
- Parallel import notification of variation to the details and documents of a parallel import licence
- Request for exemption from the requirements of article 63(3) of Directive 2001/83/EC ('sunset clause' exemption)
- Article 61(3) notification (as applicable to MT only)
- Batch specific request
- Borderline classification request form
- Withdrawal of Marketing Authorisation/licence
- Transfer of MA to a new proposed MAH during procedure
- Transfer of MA to a new MAH after MA is issued
- National Scientific Advice Request (SAR) or Protocol Assistance (PA)

^ *refer to Appendix 1 for mode of transmission for this e-form.*

5. Exchange / Submissions

All applications submitted to the Malta Medicines Authority in relation to pre- and post-authorisation procedures must be submitted through the Common European Submission Portal (CESP).

The purpose of the portal is to:

- Provide a secure method of communicating with the National Competent Authorities via one common platform
- Allow submission of an application once to reach all required Authorities at the same time electronically without the submission of additional paper/other physical formats.
- an immediate acknowledgement of receipt with the possibility of sending outside of working hours and without any additional fees.

It is a secure way of sending and receiving electronic submissions.Please refer to the CESP website on http://cesp.hma.eu/Home for more information and registration with the system.

This is also mandatory for national* applications utilising e-forms, (see section 3.2.2).

No applications are to be sent to personal mailboxes - these will not be accepted and will delay the process.

Please be aware of the following while submitting through CESP:

- Do not drop over the delivery file until the entire submission has fully uploaded to CESP.
- Please refer to our National Requirements which are indicated on the Contacts tab of the CESP Platform prior to submitting documentation.
- CESP supports the upload of zip files

Delivery file:

- Must not be renamed or re-used.
- Ensure the type of submission is correctly identified.
- Ensure the appropriate category on the dropdown list is selected.
- For variations the full MRP/DCP procedure number must be provided.
- Specify the zip software used for compression.
- Where possible please provide the Maltese product authorisation number (MA).

All documents requiring signatory should present with a signature. A scanned signature is acceptable.

For European Procedures, more information on submission requirements for new applications and variations can be found on the CMDh website https://www.hma.eu/27.html .

Applications for the centralised procedure shall be submitted via the EMA's eGateway and Common Repository.

6. Specific documents and application types – how and where to submit

6.1 General considerations Module 1

For European procedures, the cover letter should include as a minimum, the information specified in the CMDh Guidance document and template for European procedures. Please refer the CMDh website and specific documents related to electronic submissions.

For other procedures please refer to any relevant procedural guidance in the specific section of the Malta Medicines Authority website. Please also refer to Appendix 1.

The eCTD technical validation report showing that the submitted sequence has passed technical validation (with the name and version number of the validation software).
- Tracking table for eCTD sequences, including a description of each submission type.
- Statement that the submission is checked with an up-to-date and state-of-the-art virus checker (name and version of the anti-virus programme must be mentioned).

Note: The MMA does not accept password protected submissions

Module 1.3.1: Product Information

Product information (PI), including the Summary of Product Characteristics (SmPC), Package Leaflet (PL), and Labelling (LAB), should be included in the submission via the portal if these are affected by the changes proposed.

Where changes to the product information are proposed, both a clean version and a track-changed version in Word format must be submitted as part of the application process. All product information texts should be provided as working documents in Word format, with the SmPC, PL, and LAB submitted as three separate files. Malta National texts, aside from common product information is required to be included in the submission, or risk invalidation.

The End of Procedure (EOP) product information for National & European procedures and following variations where there are changes to the Product Information should be sent ONLY to the mrp-dcp.adm@gov.mt mailbox. Sending to personal mailboxes or other mailboxes may cause delays in the finalisation process. It is important to ensure that the Malta specific details (e.g. MA number, authorisation dates, MAH name and address, national ADR reporting details) are included.

6.2 Module 2

Module 2 should be additionally sent in Word format as part of the working documents.

6.3 Responses

The organisation of the submission of electronic information in response to a list of questions should follow the same basic principles as the first submission. The written responses should be submitted following the ICH recommended response folder and file structure. Appropriate navigation in the submission should be allowed.

Draft responses to questions are to be submitted– through the CESP and are to be sent to the Reference Member State only. The final Day 106 responses should be sent as a sequence when requested to do so by the RMS to the Reference Member State and the Concerned Member States.

6.4 Parallel import applications

Submission of parallel import licence applications, renewals and notifications of variations should be submitted through CESP. For queries related to Parallel Importation please send emails to the mailbox: parallel.medicinesauthority@gov.mt.

6.5 Applications for the withdrawal of product authorisations/licences

Withdrawal applications should also be submitted through the CESP, as a sequence, where relevant.

6.6 Other procedures

Periodic Safety Update Reports
Follow-up measures /

7. Samples & Mock-ups

Product samples must be submitted at the start of the marketing authorisation application procedure only for procedures where Malta is Reference Member State in the DCP and MRP and for National applications, or when they are specifically requested by the MMA.

One unit of each presentation being proposed is required to be submitted, accompanied by Certificates of analysis. This unit should not necessarily be in the final livery. In the case of Duplicate procedures, where the lead procedure is assessed by MT, samples are not required, unless requested. Any costs of postage and customs release is to be borne by the applicants.

Samples may be also required for centralised procedures where Malta is rapporteur.

Unless otherwise requested, these samples are normally not required for testing but for assessment purposes.

For all procedures for new marketing authorisations in Malta (all routes), mock-ups are to be submitted before marketing/launch to the e-mail address licensing.medicinesauthority@gov.mt , copying miau.medicinesauthority@gov.mt.

A sample of the re-packaged/re-labelled products as intended to be placed on the market, is to be submitted for each parallel imported products with the application form. One unit of each presentation (pack type) being proposed is required to be submitted. Please refer to the Malta Medicines Authority website https://medicinesauthority.gov.mt/parallelimportation and in particular the Guide to Parallel importation and the Guidelines on re-packaging.

8. Submission of post licensing activities on behalf of the Authorisation holder

The submission of all applications is to be covered with a Power of Attorney on behalf of the Authorisation holder, or a declaration for communication signed by the authorisation holder.
Only individuals holding a valid Power of Attorney or Letter of Authorisation from the MAH are authorised to submit, communicate, or receive information on behalf of the MAH. Submissions from other parties will not be accepted

As part of our updated procedural framework, the following provisions shall apply:

- **Validity Period**: All power of attorney documentation and letters of communication shall be considered valid for a maximum period of **three (3) years** from the date of signing, unless otherwise specified by the MAH.

- **Communications on Behalf of Authorisation Holder**: Any individual submitting documentation or communication on behalf of the authorisation holder must ensure that:

    - The content is **accurate**, **up-to-date**, and **relevant** to the authorisation in question.
    - Communications reflect the current regulatory status and do not misrepresent the scope or conditions of the authorisation.
    - The submitter assumes responsibility for maintaining the integrity and relevance of the information provided.

  Power of Attorney: A formal, legally binding document issued by the MAH, authorising a representative to act on their behalf for all licensing-related matters, including submissions, communications, and responses.
  Letter of Authorisation: A more limited document allowing a representative to submit, receive, or communicate information for specific applications or procedures.

9. Contact point for general queries

Should you require more general information please send email to licensing.medicinesauthority@gov.mt.

10. References

EMA esubmissions general page
EMA esubmissions CMB page
EMA esubmissions CMB documentation
Regulatory information – eSubmission Gateway for centralised procedures
CMDh eSubmissions page
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/esubmissions.html
https://www.hma.eu/human-medicines/cmdh/procedural-guidance/esubmissions.html
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/eSubmissions/CMDh_085_2008_Rev_25_04_2021_clean_eSubmission_for_new_MA.pdf
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/eSubmissions/CMDh_006_2008_Rev_25_2021_04_clean_eSubmission_for_Variations_and_Renewals.pdf
Harmonised Technical Guidance for eCTD Submissions in the EU Version 5.0 eCTD Guidance v4 0-20160318-hv (europa.eu) https://esubmission.ema.europa.eu/tiges/docs /eCTD%20Guidance%20v5.0_adopted%20version.pdf Harmonised guidance eCTD - version 6.0 published Dec 2024
Clinical Trials Information System | European Medicines Agency (EMA)
Information for applicants for submission of MA applications through the DCP to Malta as Reference Member State or National procedure

Signatures on file

Appendices

Appendix 1 – Acceptable submission routes

Appendix 1

ACCEPTABLE SUBMISSION ROUTES

	CESP portal submission	Email submission	**EU eAF**	**National eforms**	**EU Repository**
Module 1.3.1 product information – in editable word version, clean and track-changed if applicable	✓		✓		
End of Procedure product information for European variations where there are changes to the PI / National Phase	✓	✓mrp-dcp.adm@gov.mt			
PSURs					✓
Follow up measures	✓	✓mrp-dcp.adm@gov.mt			
126a new application	✓			✓	
126a notification of variation	✓			✓	
Parallel import new application/ Parallel import renewal	✓			✓	
Parallel import notification of variation	✓			✓	
Request for sunset clause exemption	✓			✓	
Article 61(3) notification (as applicable to MT only)	✓			✓	
Article 61(3) notification			✓[1]		
Batch specific request	✓			✓	
Borderline classification request form	✓	✓ classcom.adm@gov.mt		✓	
Withdrawal of MA/licence	✓			✓	
Transfer of MA after MA is issued	✓			✓	
Transfer of MA during National Phase	✓			✓	
Scientific Advice Request (SAR) or Protocol Assistance (PA)	✓	✓ licensing.medicinesauthority@gov.mt		✓	
Sunset Clause request	✓			✓	
New applications for - National MAs - DCP - MRP	✓		✓		

	CESP portal submission	Email submission	**EU eAF**	**National eforms**	**EU Repository**
Variations applications for - National MAs - DCP - MRP	✓		✓		
- Article 61(3) notification forms	✓		✓		
- Line extension applications	✓		✓		
- Responses to validation queries	✓		✓		
- Responses to assessment questions	✓		✓		
- Supplementary information	✓		✓		
-Renewal applications	✓		✓		

[1] CMDh_222_2007_Rev3_2024_06_clean_-_Art_61.3..docx