eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA Joint Action 3 WP4

Pharmaceutical Joint Assessments

SUBMISSION REQUIREMENTS

Version 2, August 2019

DOCUMENT HISTORY AND CONTRIBUTORS

Version	Date	Description
V1.0	**December 2018**	First version of Submission Requirements
V2.0	**August 2019**	Adaptation to clarify the process

Contributors

This document was prepared by EUnetHTA WP4, in collaboration with WP6.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

AT	Assessment Team *Consists of: Author, Co-author, Dedicated Reviewers and Observers*
CHMP	Committee for Medicinal Products for Human Use
COI	Conflict of Interest
DR	Dedicated Reviewer
DOICU	Declaration of Interest and Confidentiality Undertaking *Please find more information here.*
EMA	European Medicines Agency
EUnetHTA	European Network for Health Technology Assessment
MA	Market Authorisation
pMAH	Prospective Marketing Authorisation Holder
PM	Project Managers
REA	Relative Effectiveness Assessment
SSO	Senior Scientific Officer

1 SCOPE OF THE DOCUMENT

This document describes the structure and principle content of the Submission Dossier, when the Submission Dossier is required and EUnetHTA's policy on publishing the Submission Dossier. The requirements also specify which pharmaceutical products are eligible for the EUnetHTA Relative Effectiveness Assessment (REA) process.

1.1 Eligible pharmaceutical products

Medicinal products falling within the mandatory scope of marketing authorisations granted under the centralised procedure by the EMA.

2 SUBMISSION DOSSIER REQUIREMENTS BY EUNETHTA

The Submission Dossier, which comprises the Core Submission Dossier and attachments, serves as the basis of the REA of the pharmaceutical product. The structure of the Submission Dossier is depicted in Figure 1: Structure of the Submission Dossier

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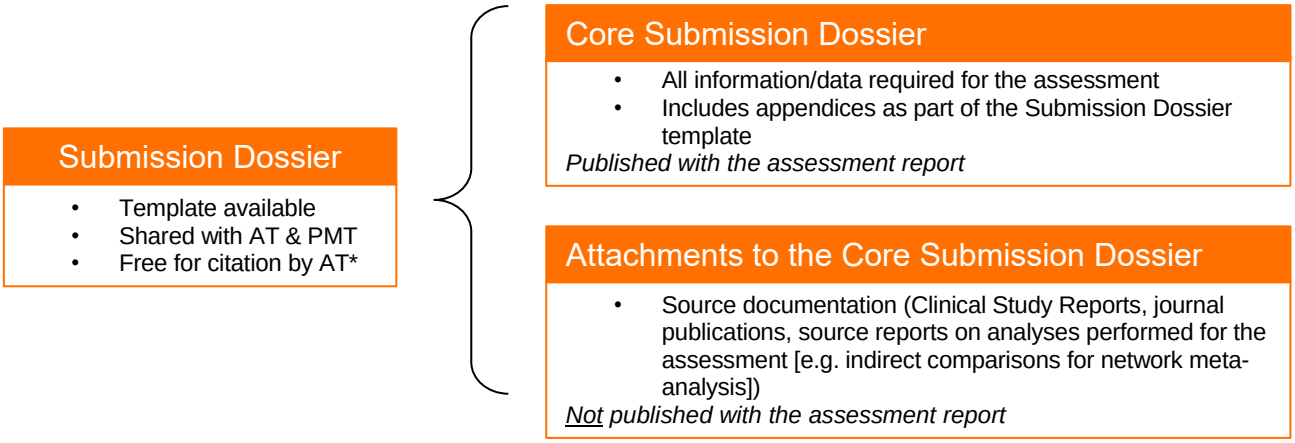
The Core Submission Dossier includes all information and data required to answer the research question(s) of the assessment defined in the Project Plan. The attachments to the Core Submission Dossier include source documentation to support the submission. Details of the content of both parts of the Submission Dossier will be defined in the following section 2.1: Submission Dossier template.

2.1 Submission Dossier template

An assessment of the medicinal product requires all data regarding the medicinal product. To ensure complete submission of the required information and data, EUnetHTA will provide the manufacturer with a Submission Dossier template specifying the mandatory requirements. It is important that the manufacturer populates the template appropriately, because EUnetHTA will not accept additional data from the manufacturer without a request from the assessment team.

The Submission Dossier includes a statement by which the manufacturer confirms that their submission is complete, so that it is ensured that the assessment team is always resorting to a full data set. Guidance on this completeness statement is provided in the Submission Dossier template. By means of this statement, the authoring teams are reassured to have all necessary information available during the assessment period.



Abbreviations: AT=Assessment Team; PMT=EUnetHTA Project Management Team.

*The AT are free to cite and transcribe information from the Core Submission Dossier, and information on methods and results of clinical studies and their analyses from the Core Submission Dossier Attachments, supporting the production and transparency of the assessment of the pharmaceutical compound.

Figure 1: Structure of the Submission Dossier

The Submission Dossier is made available to the assessment team (consisting of the author, co-author(s), dedicated reviewers and observers) and the Project Manager (PM) of the assessment. If required by the assessment team, the Submission Dossier will also be made available to the EUnetHTA Senior Scientific Officer (SSO).

Once the Submission Dossier is received it will be checked for formal completeness, i.e. it will be verified if the Submission Dossier template has been filled in completely and if the required source documentation is included in the attachments. If items are missing from the Submission Dossier, the manufacturer will have 5 calendar days to provide the missing items upon request of the authoring team. After that date, EUnetHTA will not accept additional data from the manufacturer. Any incompleteness in the Submission Dossier will be considered in the assessment and will be described as such in the Assessment Report.

The Submission Dossier may be updated after CHMP decision if there have been changes to the expected CHMP opinion, e.g. if there is a need to make restrictions to the indication. If such amendments are needed, the manufacturer will be given time to prepare an addendum to the Submission Dossier. This could be a separate document, that follows the same structure and headings as the Submission Dossier. The addendum document should include clear references to the specific page of the Submission Dossier that are impacted by the described changes. In addition, the manufacturer has to provide an executive summary in which all changes and the implications of the changes are highlighted.

The date for receipt of the addendum to the Submission Dossier due to changes in CHMP opinion will be specified by the WP4 pharma Co-Lead Partner. After this time point and after receipt of the addendum to the Submission Dossier, EUnetHTA will not accept additional data from the manufacturer, unless requested by the assessment team.

2.2 Publication policy of the rapid REA assessment report and Core Submission Dossier

To support the production and transparency of the assessment of the pharmaceutical product, the assessment teams are free to cite and transcribe information from the entire Submission Dossier, including information on methods and results of Clinical Study Reports from the attachments to the Core Submission Dossier. However, only the final rapid REA assessment report and the Core Submission Dossier will be published (without redaction) on the EUnetHTA website. The attachments to the Core Submission Dossier will not be published as a stand-alone document. Please see Table 1 for an overview of the publication and citation policy per submitted document.

2.3 GDPR compliance

EUnetHTA's data policy will follow the rules the EMA outlined in their 0070 policy, regarding individual patient data. No patient level data will be provided by EUnetHTA in the Joint Assessment reports, nor any information which may possibly result in the identification of individual patients. Only aggregated data will be presented in the reports.

In conclusion, manufacturers are not required to submit personal data (i.e. patient ID number, patient name, address), however the assessment teams require access to individual patient characteristics and individual patient results for the purpose of their scientific evaluations. EUnetHTA citations will be GDPR compliant.

3 APPENDIX – OVERVIEW PUBLICATION DIFFERENT PRODUCTS

Table 1: Publication of the different products

Process step	Product		Shared with*	Free to cite?	Redaction possible?	Published by EUnetHTA?
Topic selection & establish team	Letter of Intent (pMAH)		All EUnetHTA partners that assess pharmaceuticals, EMA, PM & SSO	Yes	For the call for collaboration the MA status and contact details are redacted (sections 5 and 14)	No
Scoping phase	Project Plan (EUnetHTA)		Draft version is shared with AT, pMAH, PM & SSO	NA	No	Yes, final version is published after CHMP opinion
	Scoping document (pMAH)		AT, PM & SSO	Yes	No	No
(pre-) assessment phase	Submission Dossier (pMAH)	Core Submission Dossier	AT, PM & SSO	Yes	No	Yes, at time of publication of the final Joint Assessment Report
		Attachments to Core Submission Dossier	AT, PM & SSO	Yes	No	No, unless explicitly requested by (p)MAH
	Joint Assessment Report (EUnetHTA)		Draft versions are shared with AT, external clinical experts (if without a COI), medical editor and (p)MAH for a factual accuracy check, PM & SSO	NA	No	Yes, publication after EPAR publication.

Abbreviations: AT=Assessment Team; CHMP=Committee for Medicinal Products for Human Use; COI= Conflict of Interest; EMA=European Medicines Agency; MA=Marketing Authorisation; NA=Not applicable; PM=Project Managers; pMAH=prospective Marketing Authorisation Holder; SSO=Senior Scientific Officer.

* AT consists of: Author, Co-author, Dedicated Reviewers and Observers
All involved individuals have completed and signed our Declaration of Entity and Confidentiality Undertaking (DOICU). All DOICU's have been assessed by the EUnetHTA Conflict of Interest Committee.