EUnetHTA Joint Action 3 WP4

Relative Effectiveness Assessment of Other Technologies

SUBMISSION REQUIREMENTS

Version 1.1, December 2019

DOCUMENT HISTORY AND CONTRIBUTORS

Version	Date	Description
V1.1	**December 2019**	First version of Submission Requirements

- **Disclaimer**

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- **Contributors**

This document was prepared by EUnetHTA WP4 LP and CoLPs.

Scope

This submission requirements document describes which other technologies are eligible for the EUnetHTA REA process. The requirements specify the principal content of the submission dossier, when the submission dossier is required and EUnetHTA's policy on publishing the submission dossier information.

Eligible other technology products

Other Technologies include non-pharmaceutical technologies i.e. medical, surgical, dental, or other interventions, as well as diagnostic or screening technologies.

EUnetHTA will require a submission dossier for

- medical devices (MDs, class IIb and III) and in vitro diagnostic medical devices (IVDs, class C and D)

For dossier submission, manufacturers are only eligible, if their medical device has been (or shortly will be) placed on the European market in accordance with EU regulation (i.e. CE marking of conformity).

Submission dossier requirements by EUnetHTA

The submission dossier provides the technical and manufacturing characteristics of the technology assessed in the REA of technologies other than pharmaceutical products. To ensure complete submission of the required information, EUnetHTA will provide the manufacturer with a submission dossier template specifying the requirements. This template must be completed appropriately by the manufacturer as requested.

Submission dossier
• Includes all information required for the Technology (TEC) and Current use of the technology (CUR) domains of the assessment • Marked questions relevant to the technology as requested by the authoring team

The submission dossier should include all non-confidential information required to answer the research question(s) of the assessment relevant to the CUR and TEC domains. Details of the content of the submission dossier will be defined in the submission dossier template and the completed dossier will be made available to all members of the assessment team upon receipt. If required by the assessment team, the Submission Dossier will also be made available to the EUnetHTA Senior Scientific Officer.

The manufacturers have 30 working days to complete the submission dossier. The authoring team will check the dossier and may ask for supplementary information, if required. The manufacturers will have 5-10 working days to clarify any open issues or supply the requested information.

Publication policy of the REA assessment report and submission dossier

The final REA assessment report and the submission dossier will be published without redaction on the EUnetHTA website. Any extra or redundant information supplied will not be published unless the information is used in the assessment.

The authoring teams are free to cite and transcribe relevant information and data from the submission dossier describing the technology.

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 and Collaborative 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.