Subgroup on Pharma Templates (SDAT-PHARMA)

Recommendations for a future Assessment Report template for pharmaceutical technologies

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Version log

Version	Date	Description
V0.1	21/10/2020	First draft
V0.2	02/11/2020	Input from the subgroup has been processed
V1.0	04/11/2020	Final report
V2.0	15/12/2020	Final report (revised based on Executive Board's comments)

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1.Introduction

This document provides recommendations for a future Assessment Report template for pharmaceutical technologies (PT), prepared by the EUnetHTA Subgroup on Pharma Templates (SDAT-PHARMA).

These recommendations are mainly based on feedback about the current Assessment Report template provided through a survey (Appendix 1) by assessment teams and EUnetHTA partners of Joint Action 3 (JA3) with experience in PT assessments. According to the survey conducted in June-July 2020, the current template, even if perceived as a benchmark, is not yet considered optimal. The following recommendations take into account aspects/topics on which an agreement already emerged among responders and that could be easily integrated in the Assessment Report template. In addition, areas that need further discussion and agreement and/or more extensive revisions in the future are highlighted.

In addition, two subgroup members have compared the current EUnetHTA template and the tables of contents in HTA reports published by different European HTA organisations, to obtain a clearer picture of the (mis-)alignment between included headings (Appendix 2). This preliminary exercise is seen as a first step for a more complete template comparison analysis and can be further developed to guide any future revisions of the EUnetHTA template. Moreover, information gathered through the EUnetHTA PT (Co-)Authors Feedback Sessions has informed the creation of the recommendations.

2.Principles for revision of the template

The revision of the Assessment Report template must respond to the following principles:

- Improve usability of the template considering the opportunity to improve wording of sections and, in addition, to revise the template framework to improve the ability of users to find data relevant for them.
- Improve transparency of decision processes underlying the assessment (e.g. definition of PICO - population, intervention, comparator, outcomes).
- Improve reporting of relevant methodological aspects such as: indirect comparisons, identification of uncertainties and bias.
- Improve usability of the template, taking into consideration the different national templates. The subgroup team already conducted a comparison as described in Appendix 2. It represents a useful starting point to guide discussion around how the template could or should be aligned to national requirements to enhance adoption.
- Improve alignment between Core Submission Dossier and Assessment Report.

To guide future revisions of the template, it's crucial to recognize and accept that some differences between the EUnetHTA Assessment Report template and the national ones are expected and acceptable. It will be necessary to clarify to what extent the Assessment Report template meets different national requirements.

3.Limitations of the current template and focus areas of future revisions

The main limitations include:

- Low uniformity among assessments due to a lack of indications on specific methodological aspects (i.e. indirect comparisons, the use and role of PICO, identification and reporting of bias and uncertainties). Those aspects must be better addressed in the form of Guidance for authors.
- Lack of transparency. Transparency is requested for some PICO-related aspects, such as reporting

of deviations from planned PICO and selection of (and agreement on) comparators. The same need emerged for discrepancy among Relative Effectiveness Assessments (REAs) (and authoring team decisions) vs. Submission Dossier.
- Difficulties in finding the information. Therefore, a revision of some headings/subheadings is suggested.
- Ongoing presence of redundancies.
- Requested workload. Workload associated with the current report template is perceived as high and, in some cases, excessive compared to the usability of the final output at the national level.

Future revision of the template should be conducted at different levels:

- **Structure**. The way in which methods and results are reported impacts the template structure. Alternative approaches investigated by the survey were: PICO vs. study level, comparator or data source-specific reporting (pivotal studies, meta-analysis, indirect comparisons). Due to differences in opinions among EUnetHTA authors and users, this should be further investigated. In Appendix 2, preliminary results of the comparison of national assessment report headings, conducted by two EUnetHTA partners, are reported.
- **Specific headings/subheadings**. Clearer headings are requested and more detailed subheadings could help to improve some sections.
- **Proper guidance for authors** is clearly needed to ensure a more uniform interpretation of template requirements, i.e. what information should be included and where.
- **Format** to report data/evidence. Tables and graphs/figures could still be improved. Level of details, where to report them, and how to use graph to improve analysis are issues to address.
- **Appendices.** Increased use of appendices could help improve readability and length of the main part of the final REAs.

4.Sections in major need of improvement

Priority should be given to the revision of:

- Methods Section with a focus on information retrieval and data extraction, certainty of the evidence and criteria adopted to select comparators and reach agreement on them.
- Results Section to reduce duplication and improve uniformity in the level of detail among REAs. Both aspects could influence the perception of lack of some specific evidence in the current template, reduce redundancies, and help readers find easily relevant information. Guidance for authors must better identify what kind of information should be reported in the Methods section and what should be reported in the Results section. In addition, guidance would help to enable more uniformity in how results submitted by the manufacturer, EUnetHTA evidence review, and additional analyses are reported.
- Discussions Section could have comparator-specific sub-sections and improve its ability to report strengths and limitations of assessments, and their implications on the assessment's ability to address the policy and research question.

Other needs for improvement mentioned by the survey respondents included:

Template section	**Recommendations for improvement and for further discussions due to differences in opinions**
Executive Summary	It is necessary to work on its length and clarity of scope.

Background	To better connect this section to the following one (Objective and Scope) in order to make its role in the template more clear.
Objective and Scope	Deviations from the Submission Dossier and the level of agreement on the final PICO should be better reported.
Appendix	Appendix could help to simplify the content and length of REAs.

5.Suggestions for minor changes to the template

Minor changes already reported in the revised Assessment Report template attached to recommendations are for:

- Executive Summary:
  - In Objective and Scope: Referral to the European PICO survey and report the PICO table.
  - In Results: Effectiveness and safety outcomes are more clearly reported.
  - In Discussion: The strengths and limitations of the assessment are explicitly mentioned.
  - It is requested to consider structuring each section using the same headers as the main report.
- Background:
  - Guidance for authors suggests to consider using subheadings per described comparator (group), currently used in clinical practice, to structure the text in the different sections.
- Objective and Scope:
  - Guidance is provided on how to report the final PICO and discuss differences compared to the PICO documented in the Project Plan and the Submission Dossier, and their implications.
- Methods:
  - A specific subheading is dedicated to the additional searches performed, compared to Marketing Authorisation Holder's (MAH) literature search.
- Results:
  - Additional subheadings can be dedicated to report differences between assessor and manufacturer performed searches.
  - Two separate sections are dedicated to Results on clinical effectiveness and Results on safety.
  - In each of them, specific headings are dedicated to subgroup analyses.
- Discussion:
  - Elements to consider include differences between EUnetHTA PICO and material provided in the Submission Dossier.
  - Guidance for authors to always include a specific subheading on strengths and limitations of the evidence.

6.Additional documents needed

Crucial is the role of the **Guidance for authors** which guides authors in their activity and could allow a greater level of uniformity among assessments. Currently, lack of guidance is perceived as a lack of agreement on methodological aspects and determines different decisions by different authoring teams.

The publication of the **Core Submission Dossier** will play a crucial role in reducing the length of REAs. Based on the survey results, no clear solution was found to avoid duplication of information between Submission Dossier and REAs and, at the same time, enable REAs to be as comprehensive as possible. It is still a controversial issue and should be further investigated in the future. No agreement was reached on the option to report only a summary of relevant elements of the Submission Dossier in REAs. During the EUnetHTA (Co-)Author Feedback Workshop in September 2020, it was confirmed that there is a lack of agreement on how to link the two documents.
At the moment, the Assessment Report template, after minor changes, includes instructions for specific sections/headings to report and discuss differences in searches and analyses performed in addition to those provided in the Submission Dossier.

In addition, agreement should still be reached on how to structure the **Executive Summary Section**. In particular, the role of tables/graphs must be further investigated to satisfy different needs. Also, the utility of reporting the Executive Summary as a separate document must be explored in terms of national adoption of REAs. As emerged during the EUnetHTA (Co-)Author Feedback Workshop, the final decision to publish the Executive Summary as a separate document depends on the objective and the target group of this document. It is suggested that, in an upcoming Joint Assessment, the Executive Summary can be test published as a separate document.

7.EUnetHTA template and national adoption

One final but not secondary aspect to consider in the revision of the Assessment Report template is the additional work that is requested at the national level to make it relevant for national/local decision-makers. The kind and level of additional work is a crucial aspect.

As stated in the principles for revision of the Assessment Report template, it is crucial to recognize and accept that some differences between the EUnetHTA Assessment Report template and the national templates are acceptable.

Some solutions to adopt in the short-term to reduce workload at the national level are to adapt the template to the possibility of providing comparator-specific data, and report results specific for each type of data source (pivotal studies, meta-analysis, indirect comparisons). As reported in the PICO concept paper[1], it is a relevant guiding principle that the report should result in as little extra local assessment work as possible.

In addition, according to the survey (Appendix 1) the current REA domains do not capture all clinical information (especially regarding endpoints and analyses) useful to inform national economic evaluations. The absence of clinical information relevant for economic evaluations in REAs affects national adaptation/adoption. During JA3, one assessment team (PTJA03) included that kind of additional clinical data in Appendices as extrapolation tables. National adoption levels were relatively high, which could imply that the addition of these appendices was considered important. In the future, the inclusion of such clinical information could be further explored in the context of voluntary co-operations on health technology assessment.

[1] Available in the EUnetHTA Companion Guide.

8.Alignment of the template to EUnetHTA JA3 outputs

Current minor changes already integrated in the new template are due to:

- Alignment of the template with the last version of "Instructions on authorship and copyright"[2].
- Alignment of the template with the last version of "Document history and contributors" according to recommendations of the ARCI (Authoring Rules and Copyright Issues) working group[3].
- Alignment with the Evidence Gaps Table template[4].
- Alignment with the Submission Dossier template[5].

Other EUnetHTA outputs that are potentially related to Assessment Report template are:

- EUnetHTA assessment Evaluation Questionnaire for Patient Input.
- Guidance for how to use patient input in assessments.
- Recommendations for health care professional involvement in REAs[6].
- Common Phrases and GRADE (Grading of Recommendations, Assessment, Development and Evaluations).
- WP6 Standard Operating Procedures (SOPs) and methodological guidelines[7]. E.g. it should be discussed and decided whether to include the Cochrane Risk of Bias tool 2.0 as an alternative method to assess risk of bias.

It is important that the outputs of these task groups are used to inform any future revisions of the Assessment Report template.

However, as far as PICO is concerned, different inputs must be taken into account. First of all, there are the final outputs of the PICO subgroup. Crucial is the decision (as reported in PICO concept paper[8]) that assessments must respond to a policy question, which could be translated into a research question, while it is excluded that an assessment of an intervention should be data-driven. It will have implications in the reporting of discrepancies between PICO defined for the assessment and for the one that guided the submission file and deviation from the planned PICO (given also available data), as suggested by collected feedbacks. Furthermore, survey feedback shows a lack of agreement between how to report the evidence: whether the report template should be PICO-oriented (providing available data explicitly for each PICO element) and study-oriented (where assessment is organised around available studies). This issue requires further investigation.

9.Additional work: recommendations

In conclusion, additional steps – reported in order of complexity - to be taken to guide future revisions of the Assessment Report template are:

- Align the Assessment Report template with other EUnetHTA final outputs.
- Improve guidance provided to authors.
- Reach an agreement on whether the Executive Summary should be presented as a separate document.
- Reach an agreement among HTA agencies on how to link the Core Submission Dossier and the Assessment Report.

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[2] Available in the EUnetHTA Companion Guide.

[3] Available in the EUnetHTA Companion Guide.

[4] Available in the EUnetHTA Companion Guide.

[5] https://eunethta.eu/services/submission-guidelines/submission-template-pharmaceuticals-submission-template-medical-devices/

[6] https://eunethta.eu/stakeholders/health-care-providers/

[7] Available in the EUnetHTA Companion Guide.

[8] Available in the EUnetHTA Companion Guide.

- Reach an agreement among HTA agencies on an acceptable level of alignment of the Assessment Report template with the national ones. An optimal balance should be found among level of details, relevance of REAs, level of national use, and workload both at European and national levels. The preliminary comparison exercise that was started by two members of the subgroup could possibly be extended (Appendix 2).
- Piloting the above recommendations may be necessary to map the impact on national use and workload on both the European and national levels.

10.Conclusions

Based on the collected feedback, the provision of a guidance for authors regarding what to include in the template, where to include it and how, is the highest priority to support better consistency. Major changes in the report structure are suggested in the medium-term.

At the moment, suggestions for improvement of the Assessment Report template are based on feedback collected among EUnetHTA partners, and aim to identify the aspects more in need of revision to improve the national adoption of REAs. Future revisions of the Assessment Report template must take into consideration activities performed by other task groups with different timelines. Then, the template is influenced by some more general decisions in terms of transparency of deviations and disagreements among authoring teams and manufactures, and among EUnetHTA partners. Finally, robust recommendations for revision require knowledge of the future European HTA Collaboration.