eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Appendix 2
A short introductory review of current HTA report structures in European countries conducted by TLV and FIMEA

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1.Background

Within the Subgroup on Pharma Templates, discussions were held on how to improve the EUnetHTA Assessment Report template structure to facilitate the writing and the reading of the reports. Many agencies have, during the last years, indicated that the current template structure is complicated compared to their national report structures, and includes headings that are not needed nationally. In comparison with their national reports, it takes a lot of resources to write a EUnetHTA report.

Lack of provision of relevant evidence for national adoption was identified as one of the main limitations of the current template in the Subgroup document "Recommendations for a future Assessment Report template for pharmaceutical technologies". As reported in the document, "some misalignment of the Assessment Report template with the national ones is expected and acceptable". In addition, the need emerged from the survey to include more clear headings in the EUnetHTA Assessment Report template.

The same survey, conducted by the subgroup, indicates that a large proportion of the authors find the EUnetHTA Assessment Report template too long and detailed. See results below:

Length of the Assessment Report template	N	%
Too long and detailed	6	46.2%
Of appropriate length and with an adequate level of detail	5	38.5%
Too short and lacks relevant evidence and/or references	2	15.4%
Total	13	100.0%

For those reasons, TLV and FIMEA, both members of the Subgroup on Pharma Templates, conducted an introductory overview of how the national reports are structured (Part 1) and proposed a new EUnetHTA report structure based on the overview (Part 2). TLV promoted the initiative and FIMEA has given valuable input and participation in this work.

2.Method

Part 1: A review was conducted, by TLV and FIMEA, to identify and report the tables of contents in HTA reports published by different European HTA organisations. The aim was to identify and include as many national reports as possible and, where available, use the report on Xtandi metastasised prostate cancer in order to have the same type of product. Webpages of the agencies were scanned for examples of reports, and in cases where no national reports were published, the agency was contacted via e-mail and a list of headings and content in English was obtained.

The headings from the EUnetHTA reporting template and the national HTA reports were inserted in an Excel sheet (Appendix 2b) to enable comparison. The Excel sheet was shown to the subgroup on two occasions in spring 2020 to discuss the differences between different national reports and the EUnetHTA template.

Report structures from the following agencies were selected:
HAS (FR)
NICE (UK)
DVSV (=former HVB) (Austria)

SMC (Scotland)
NCPE (Ireland)
ZIN (Netherlands) / BenNeLuxAIr
RIZIV (BE)
FINOSE (FI, NO, SE)
EUnetHTA
AETSA (Andalucia, Spain)
AEMPS (Spain)
AIFA (Italy)
MoH (Croatia)

Part 2: TLV and FIMEA, on the basis of their provisional results, elaborated a proposal for a new shorter template. The proposal was presented at a subgroup meeting in spring 2020.

3.Result

Part 1: The work resulted in an Excel sheet with an overview of all headings (see attachment). In comparison to the EUnetHTA Assessment Report the following observations were made: fewer headings, shorter reports, and a discussion on the content in the reports such as degree of uncertainties rather than risk of bias and GRADE.

Part 2: Based on the overview of report structures, TLV and FIMEA proposed a new shorter structure for the EUnetHTA Assessment Report template (see below-Appendix 2.1). The presentation in the subgroup meeting did not lead to a subgroup consensus on the preferred report structure.

4.Conclusions

This review should not be seen as a final comprehensive review, but as a first step in order to investigate whether the national reports are shorter and whether there are core questions represented in the heading names that all EUnetHTA partners need to answer.

From this pilot study, it could be seen that fewer headings are used in many national reports compared to EUnetHTA reports. This could be seen as a justification for the need to simplify the structure of the current EUnetHTA template to better align with the national reports. A simpler structure could streamline the work of EUnetHTA authors and improve the implementation of EUnetHTA reports. The simplified structure, however, would not meet the current requirements of all EUnetHTA member agencies. More discussion on the matter is needed, and the discussion could also contribute to those agencies who wish to simplify their HTA processes at the national level to benefit patient access.

5.Discussion

Since several agencies have expressed that the current EUnetHTA Assessment Report structure is too complicated and too resource-intensive, TLV and Fimea saw a need to investigate how to diminish the burden on all participants in a Joint Assessment in order to support sustainable processes. This might be achieved by simplification, shortening and adaptation of the current EUnetHTA Assessment Report template to match the local needs. If a core structure could be identified between the reports of the agencies in the Excel document, this could be seen as the main national needs. Anything outside of that would be seen as an individual national need, and could be undertaken at a national level instead of in the EUnetHTA report in order to reduce the burden on all agencies.

There are differences in the level of detail and structure of reporting between the agencies included in this overview. These differences are partly linked to many other issues, such as scoping (PICO reporting) and public availability of the Core Submission Dossier. Therefore, a common solution to satisfy the core

needs of all member organisations and relevant EUnetHTA task groups should be found. A simpler reporting template could motivate authoring agencies and also aid the implementation of EUnetHTA reports in many countries.

A limitation of this work is that the comparison was not made on a large number of reports, and not always on the same compound, even if Xtandi metastasized prostate cancer was used, if possible, in order to have the same type of product. There could be different versions of the reports that were missed in this review, so the page comparison could be misleading.

Another limitation of this review is that it was restricted to headings that were included in the different national reports, not content included under each heading. In addition, the overview did not include information on the public availability of the Core Submission Dossiers, which may have implications on the structure of Assessment Report template and its content.

Finally, the consultation of agencies has been very limited during this overview exercise. Therefore, it is of major importance to continue the work with a wider group of EUnetHTA member agencies.

6.Recommendations

TLV and FIMEA recommend that a larger, more structured review of the different national templates and the content of the national Assessment Reports be performed in order to fine tune the results.

After this larger review, we recommend that the structure of the reporting template is revised and adapted to any new learnings and sent for review to all EUnetHTA members writing pharmaceutical assessments.

Appendix 2.1 Draft structure based on the national headings

EUnetHTA	Proposal by TLV and FIMEA
Document history and contributors **TABLE OF CONTENTS** **List of tables and figures** **List of abbreviations** **Executive summary of the assessment of [COMPOUND]** Introduction Objective and scope Methods Results Discussion Conclusion ***1. BACKGROUND*** Overview of the disease or health condition Current clinical practice Features of the intervention ***2. Objective and Scope*** ***3. METHODS*** Information retrieval Data extraction Risk of bias assessment External validity Results and analyses of included studies Patient involvement ***4. RESULTS*** Information retrieval Studies included in the assessment Excluded studies Characteristics of included studies Outcomes included Risk of bias External validity Results on clinical effectiveness and safety ***5. Patient involvement*** ***6. DISCUSSION*** ***7. Conclusion*** ***8. REFERENCES*** Appendix 1: …	Proposed shorter version of merged headings/topics from published reports **1. Summary of assessment in bullet points** (1-2 sentences per heading) **2. Scope with PICO table** a. Population: Company position and EUnetHTA position b. Intervention: c. Comparison: Company position and EUnetHTA position d. Outcome measures: Company position and EUnetHTA position **3. Regulatory information** (Indication, MoA, posology, ATC code, method of administration) **4. Description of the disease** **5. Treatment guidelines** **6. CLINICAL EFFECTIVENESS** a. Pivotal studies i. Description of pivotal studies ii. Key results iii. Additional analysis (subgroup, sensitivity, etc.) b. Meta-analysis and pooled results i. Methods used in literature review and evidence synthesis ii. Results c. Indirect comparisons i. Methods used in literature review and evidence synthesis, Network structure (if applicable) ii. Description of included studies in tabular form iii. Results of studies included in the indirect comparison in tabular form (short) iv. Description of excluded individual studies and rationale for non-inclusion in tabular form (short) v. Results of MAH's indirect comparison vi. Additional analysis (subgroup, sensitivity, meta-regression, etc.) **7. CLINICAL SAFETY** a. Safety results from pivotal studies b. Safety results from indirect comparisons **8. Patient input** **9. Overall discussion** a. Clinical effectiveness b. Clinical safety **10. Conclusions** a. Clinical effectiveness b. Clinical safety Annex I. Risk of bias of the selected studies