What is the level of transparency in Health Technology Assessment process in Hungary, Romania and Turkey?

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I - Introduction

- According to the European Commission Transparency Directive the reimbursement decision should be taken in a transparent, objective and verifiable manner within strict timelines. [1]
- Introducing health technology assessment (HTA) processes in a country can lead to fulfill this objective [2], however, the HTA system itself should satisfy these conditions as well.
- Arguably, transparency throughout the reimbursement or HTA processes may lead to several benefits; provides justification for decision-makers, increase the possibility of reflecting appropriately on patients’ needs and gives clear market access criteria for manufacturers.
- On the other hand lack of transparency might be also linked to:
  - Protecting and withholding manufacturers’ sensitive information (e.g. price) from competitors;
  - Leaving more room for corruption and vested interest in case of decision-makers who are involved into the reimbursement process;
  - Weak or complete absence of patient advocates and/or patients organizations who could raise their voices for better reflection on patients’ need
- Our objective was to highlight the level of transparency in 3 European countries: Hungary, Romania, Turkey.

II. METHOD & HTA Background

We evaluated HTA process, against a pre-defined set of criteria to determine HTA transparency level in Hungary, Romania and Turkey.

All 3 countries have different HTA systems with different history and background:

- In Hungary, the HTA Office was established in 2004 in order to support reimbursement decisions by the National Health Insurance Fund. The HTA Office is a governmental organization, with its own budget from manufacturers’ submission fees.
- In Romania, the HTA process, as it is today, was put in place in 2014, replacing a non-functional system based clinical incremental system and functions as a separate Unit under National Drug Agency. The current regulation is based on a scorecard evaluation that consists of different numbers of points for HTA reports from UK, France and Germany, No. of EU countries with reimbursement and Cost of therapy vs SoC.
- In Turkey, there have been three HTA structures: two in Ministry of Health and one in Ministry of Labour and Social Security since 2012.

Information was obtained from public sources including websites of governmental institutions, official legislations and scientific articles.

Evaluation was made on the following six elements;

1) published requirements for reimbursement
2) availability of submitted documents or parts of documents by manufacturers
3) process evaluation or appraisal of the submissions
4) recommendations by those who conducted evaluation
5) final reimbursement decision
6) follow-up on decisions.

III. RESULTS

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<th>Hungary</th>
<th>Romania</th>
<th>Turkey</th>
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<tr>
<td>Published requirements</td>
<td>Available from guideline</td>
<td>Available</td>
<td>Available from legislation</td>
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<tr>
<td>Submission / parts of submission</td>
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<td>Not available</td>
<td>Available from legislation</td>
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<tr>
<td>Process of appraisal</td>
<td>Only internal checklist</td>
<td>HTA public reports</td>
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<td>Recommendation</td>
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<td>Published final decision</td>
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<td>Transmitted to MAH</td>
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<td>Follow-up of decisions</td>
<td>Not available</td>
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Table I: Criteria for HTA transparency evaluation in Hungary, Romania and Turkey

In Hungary

- The Hungarian HTA best-practice guideline for preparing submissions is publicly available. However, it currently under review and expected to be published in the end of 2016. The National HTA Office is responsible with coordinating the review process.
- HTA submissions are not publicly available, neither in full nor partially. They are evaluated by the HTA Office and discussed on a committee made up of representatives of manufacturers, the national payer, medical experts and members of the HTA Office.
- An internal checklist has been published, with the purpose of standardizing the evaluation process of HTA submissions. [3]
- The HTA Office does not issue a public Recommendation or opinion on a given submission. Only the owner of the submission and the national payer are informed.
- The final decision with the date of the decision is published on the website of the National Health Insurance Fund.
- Currently the HTA Office does not have any publicly known activity that focuses on follow-up evaluation of HTA submissions.

In Romania

- HTA legislation provides clear timelines and evaluation criteria but in reality, the deadlines are not met.
- Evaluation criteria are mentioned in the legislation but CoT comparison with SoC still needs a clear guidance. HTA legislation provides a decreasing reimbursement level.
- Final evaluations reports are not published in 3 months as stated in the legislation and do not guarantee immediate reimbursement.
- Although the scorecard HTA system makes no direct evaluation of the value of drugs, authorities consider it to be effective, being designed only to favor cost-saving drugs and to promote high discounts. [4]

In Turkey

- In Turkey, the legislation provides information about requirements and submission period, but the evaluation period is not known.
- The Evaluation process is based on product and public health needs.
- Recommendations are not publicly available, and no report has been published yet.
- Alternative reimbursement methods are an option for innovative products.
- Submission holder is informed about the decision with a letter.
- Cost-effectiveness analysis is mandatory for innovative products. However, it is significant that it is not only criterion taking into account and budget-impact analysis, or burden of illness, which have considerably more impact on decisions than cost-effectiveness analysis.

IV - Conclusion

- For all 3 countries, we can see a clear development of HTA framework towards a evidence-based decisions, regarding the reimbursement of new drugs.
- Even if important steps in providing a clear and transparent HTA process had been established in the legislative framework of the 3 countries, many areas require improvement.
- This could be done through clear published submission timeline, closing the gap between evaluation process and actual reimbursement, functional appealing committee. Objective evaluation criteria are still missing in key points of the evaluation process.

References: