Introduction

The suitability is the organization and the methodologies that are employed in health technology assessment (HTA) and decision-making processes between different countries results in considerable challenges in the meaningful comparison of the activities and resources of such agencies.

In addition, such variability represents a barrier to the understanding of which agencies include in the current initiatives for HTA-Regulatory authority interaction and perhaps some long-standing practice initiatives, such as those presented by the triumvirate level Acta.

Thus, there is a need for consistent characterization of the organizations and their activities within each country, so as to be able to understand, in a comparison, to screen and identify which is effective and efficient in a national regulatory framework.

The aim of this study was to develop a systematic process-mapping methodology to both clarify how these systems are organized and to enable comparison between the different systems.

National Process Maps

Australia

- Sponsor: A company that submits the dossier of evidence in applications for market authorisation.
- Agency: A specific organisation or committee tasked with performing key and sometimes related to the regulatory, evaluation, reimbursement, or assistance processes.
- Government: A government organisation and controlled by the state and other directly, indirectly accountable by the government.
- Government: An organisation that and controlled by the state and other directly, indirectly accountable by the state.

France

- Sponsor: The company that submits the dossier of evidence in applications for market authorisation.
- Agency: An organisation or committee tasked with performing key activities related to the regulatory, evaluation, reimbursement, or assistance processes.
- Government: An organisation or committee accountable by the state.

Germany

- Sponsor: A company that submits the dossier of evidence in applications for market authorisation.
- Agency: An organisation or committee tasked with performing key activities related to the regulatory, evaluation, reimbursement, or assistance processes.
- Government: An organisation or committee accountable by the state.

Sweden

- Sponsor: A company that submits the dossier of evidence in applications for market authorisation.
- Agency: An organisation or committee tasked with performing key activities related to the regulatory, evaluation, reimbursement, or assistance processes.
- Government: An organisation or committee accountable by the state.

Processes Maps and Key

Step 1

For each country, the primary agencies that were identified in market authorisation & reimbursement, HTA, reimbursement, approval, pricing and reimbursement process mapping were used and/or were validated by each country. The pathways had a series of evidence tables form the sponsor to the various agencies involved in the mapping process. Each table included a series of key processes that were involved in the decisions to ensure that the processes were captured.

Step 2

Seven sections that represented meaningful key components of the system were defined and then mapped onto the agencies. These components included, in order to draw a pathway in the system: key functions performed and how they related to one another. The functions were as follows:

- HTA: Assessment of the health technology that is required to ensure the drug is the best choice and is safe for patients.

Step 3

The processes were mapped onto the pathways to ensure that each process was captured. The processes were then compared between the different countries. The processes were then compared between the different countries. The processes were then compared between the different countries.

Development of Process Maps and Key

Application of Process Maps

How therapeutic value and economic value attributes are linked to appraisal and decision making functions

Outcome

Systematic mapping is a useful tool for the comparison visualization of the process between different countries. By creating the mapping using systematic methodologies, it is possible to capture and contest the organizations of different authorities. Additional features of information added to the maps, such as the agencies, and activities further enhance the understanding of these systems.

Next steps

Validation of evidence

These maps have been created from data in the public domain and in several instances, such data was either conflicting or there was a lack of transparency in how particular agencies were represented. Therefore, to ensure the accuracy of the appraisal, the pathways and activities need to be validated by each country to ensure that each agency is adequately represented within the national maps.

Establishing evidence framework

This methodology enables the establishment of indicators that can be used to establish a benchmarking program for the purpose of comparative performance evaluation between different countries. When benchmarking is done on an ongoing basis, it can help to ensure that each agency is adequately represented within the national maps.

Data Sources

The process maps were originally developed using data gathered from the public domain, primarily from the agencies' websites and secondarily from the authors' knowledge of other sources, such as the HTA Europe Network and HTA Europe Network.

Selected References


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