Assessing Performance and Decision Making by Comparing Key Milestones From Approval to Reimbursement in Eleven Countries

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ABSTRACT

The HTA systems and reimbursement processes were characterised and evaluated in eleven countries. Information for each of these countries was sourced from published national guidelines, government and private agency websites (Table 1), the HITER Health Care Systems Road Map Project (funded EDF) and direct contact with agency officials.

The process maps were constructed as three stages (Figures 3a and 3b).

Stage 1: Overview - Key Activities
- Identify agencies
- Characterise agencies between systems
- Highlight level of sponsor involvement
- Identify where each activity is performed

Stage 2: Detail - Key Activities
- Identify key milestones
- Define time when each milestone is reached
- Identify where each activity is performed

Stage 3: Symbol - Key Activity
- Design an icon to represent each agency
- Identify key milestones
- Determine the connections between agencies
- Identify agencies

The form ation of new HTA agencies in Europe.

Table 1. Overview of the HTA agencies in Europe

<table>
<thead>
<tr>
<th>Country</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom</td>
<td>The National Institute for Health and Care Excellence (NICE) is an independent statutory body that meets three times annually</td>
</tr>
<tr>
<td>France</td>
<td>The French government has a public healthcare system that is mainly (70%) covered by social security</td>
</tr>
<tr>
<td>Spain</td>
<td>An independent public body responsible for providing guidance on the appraisal of new technologies</td>
</tr>
<tr>
<td>Germany</td>
<td>The Federal Joint Committee (G-BA) is responsible for developing recommendations for the reimbursement of health technologies</td>
</tr>
</tbody>
</table>

Table 2. Comparison of key activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>United Kingdom</th>
<th>France</th>
<th>Spain</th>
<th>Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overview</td>
<td>NICE</td>
<td>ANSM</td>
<td>AITC</td>
<td>G-BA</td>
</tr>
<tr>
<td>Decision</td>
<td>NICE</td>
<td>ANSM</td>
<td>AITC</td>
<td>G-BA</td>
</tr>
<tr>
<td>Recommendation</td>
<td>NICE</td>
<td>ANSM</td>
<td>AITC</td>
<td>G-BA</td>
</tr>
<tr>
<td>Reimbursement</td>
<td>NICE</td>
<td>ANSM</td>
<td>AITC</td>
<td>G-BA</td>
</tr>
</tbody>
</table>

Table 3. Reimbursement agencies

<table>
<thead>
<tr>
<th>Country</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>The Canadian system is more similar to European models than the United States system</td>
</tr>
<tr>
<td>England</td>
<td>The English system is more similar to the Canadian system</td>
</tr>
</tbody>
</table>

Figure 4. Overview

Figure 5. England

Figure 6. Spain

Figure 7. France

DISCUSSION

Syntactical maps were created that identify the processes that a new medicinal product must undergo in order to reach the market. Considerable variability between the eleven countries was identified.

The issue is which key milestones are common across the different countries that can result in a harmonised decision-making process. Further research would be needed to identify this.

The position of HTA within the overall reimbursement process varies between countries, as does the role of the HTA agency. A potential application of the syntactical mapping is to allow the user to determine the stages that are common across countries or to identify the difference between different countries. Such information would be useful for projects looking to harmonise or align different aspects of the HTA process.

REFERENCES


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Disclosures

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