EXPLORING BIOSIMILAR MARKET ACCESS CONSIDERATIONS ACROSS EUROPE

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Introduction/objective

- Biosimilars are becoming more widely available across Europe, with many payers at each level involved in decision-making regarding their market access.
- Despite recognition of the benefits of biosimilars (reducing cost of treatment thus freeing up resources to treat more patients, maximising health care outcomes and enabling cost savings to support new innovation) decision-making and access processes are still finding their place within each country’s healthcare system.
- This study investigates the local market access needs of European countries in relation to biosimilars, in order to identify and understand the key criteria which currently drive payer decision making.

Methods

- The research incorporated insights gathered through a targeted secondary literature review across 15 European markets, which identified relevant recent biosimilar publications and country-specific biosimilar policy documentation.
- Supplementary payer research across was also conducted to address any evidence gaps in payer decision-making.
- Key factors were assessed including, stakeholder roles, decision-drivers and pricing and market access requirements, which allowed us to identify clear payer archetypes across countries and critical success factors for biosimilar launch.

Results

- Through comparing and contrasting stakeholder roles (Table 1), decision-drivers (Table 2) and access requirements (Figure 1), 4 distinct payer archetypes were identified: single-country tender, regional contracting/tendering, local (hospital contracting/tendering) and retail. The assessment allowed for critical success factors to be defined in terms of strategies/tactics that pharmaceutical companies ‘should and shouldn’t do’.

Table 1: Stakeholder influence on access by payer archetype

<table>
<thead>
<tr>
<th>Payer Archetypes</th>
<th>Stakeholder influence on access</th>
</tr>
</thead>
<tbody>
<tr>
<td>National body (PMA)</td>
<td>Single-country tender, Regional contracting/tendering</td>
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<tr>
<td>Regional body</td>
<td>Regional contracting/tendering</td>
</tr>
<tr>
<td>Hospital procurement</td>
<td>Local (hospital) contracting/tendering</td>
</tr>
<tr>
<td>Hospital pharmacist</td>
<td>Retail</td>
</tr>
<tr>
<td>P&amp;T committee</td>
<td>Retail pharmacist</td>
</tr>
<tr>
<td>Hospital specialist</td>
<td>Retail prescriber</td>
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</tbody>
</table>

Figure 1: Differences in key access requirements across payer archetypes

- National payers are the primary decision-maker; price is the main decision driver particularly in winner-takes-all tenders.
- Price is a key driver but as many tenders are not ‘winner takes all’, other product value attributes, such as device design are also taken into account.
- In addition to price as a priority driver, specialists are a key stakeholder, with clinical data an important driver.
- Multiple stakeholders play a role in retail pharmacy markets where treatment is initiated by a hospital specialist but continued in primary care.

Discussion and conclusions

- Although European payers welcome biosimilars, differences in their assessments and access requirements mean that pharmaceutical companies need to adapt their access approaches in order to support positive access decisions.
- The use of payer archetypes can help in the development of effective, tailored local market access strategies.
- Recognising the combination of relevant payer archetypes within each country and the strategies and tactics which may be used to leverage key decision-makers can further add further granularity to local access plans.
- Highly tailored local access strategies could support many components of the access process such as, successful interactions with key stakeholders, identification of ideal value proposition for negotiations (i.e. product value levers vs use of price as a lever), reducing focus on price to ensure ‘sustainability’, optimal contracting arrangements with regional/local payers and optimal tender wins or tender shares.

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