ACHIEVING FASTER PRODUCT LAUNCH: HOW DO YOU OBTAIN NON-REIMBURSED PHARMACEUTICAL PRICES ACROSS EUROPE?

Craddy P1, Bailey S2, Wolfram V2, Foxon G2
1Remap Consulting, Bern, Switzerland, 2Remap Consulting, Cheshire, United Kingdom

Introduction

- Approximately one in four prescription-only medicinal products are paid out of pocket by EU patients, whereas the rest is funded by the health care system or compulsory health insurances via reimbursement procedures.1
- For reimbursed products, the price setting process for new pharmaceutical products are clearly defined across EU markets with information being readily accessible.
- There is a lack of published information concerning the pricing processes for non-reimbursed prescription-only medicinal products.
- The objective of this research was to determine national price submission procedures across Europe required for launch and patient access for non-reimbursed prescription-only medicinal products.

Methods

- To determine markets for inclusion within this study, Organisation for Economic Co-operation and Development (OECD) pharmaceutical spend data across Europe (based on 2012 [or latest available year]) was utilized to identify the countries that account for 90% of European pharmaceutical spend.
- Only countries covered by the centralized marketing authorisation procedure of the European Medicines Agency (EMA) were included in the analysis.
- 11 countries, covered by the EMA, were found to represent 90% of European pharmaceutical spend.
- National price submission procedures for non-reimbursed prescription-only medicinal products across these 11 countries were analysed.
- Pricing authorities were contacted to obtain additional information related to price setting if ambiguities existed.

Results

National price submission procedures for non-reimbursed prescription-only medicinal products across 11 European countries

- Price submission procedures were classified as: full price submission process; abridged price submission process, or no price submission (Figure 2).
- Nine of the 11 countries mandate submission of pricing documents (Table 1).
  - Six countries require a full price submission to the national pricing authority.
  - Three countries ask for an abridged pricing submission (i.e. price notification).
  - Two countries have no price submission or notification requirements.
- Negotiations with pricing bodies for non-reimbursed prescription-only products are limited, enabling manufacturers to have control over the price setting.

Table 1. Price submission procedures across 11 European countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Price level to be submitted</th>
<th>Pricing body</th>
<th>Prices publicly available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Ex-factory</td>
<td>The Federal Ministry of Health, Family and Youth (BMG)</td>
<td>No</td>
</tr>
<tr>
<td>Belgium</td>
<td>Ex-factory</td>
<td>Federal Public service of Economic affairs</td>
<td>Yes</td>
</tr>
<tr>
<td>Germany</td>
<td>Ex-factory</td>
<td>Lauar Taxe, Rote Liste</td>
<td>Yes</td>
</tr>
<tr>
<td>Greece</td>
<td>Ex-factory</td>
<td>National Organization for Medicines (EOF)</td>
<td>Yes</td>
</tr>
<tr>
<td>Italy</td>
<td>Ex-factory</td>
<td>Italian Medicines Agency (AIIFA)</td>
<td>Yes</td>
</tr>
<tr>
<td>UK</td>
<td>Pharmacy selling price</td>
<td>UK Department of Health</td>
<td>Yes</td>
</tr>
<tr>
<td>France</td>
<td>Ex-factory</td>
<td>L’Agence nationale de sécurité du medicament et des produits de santé (ANSM)</td>
<td>No</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Wholesale selling price</td>
<td>Z index</td>
<td>Yes</td>
</tr>
<tr>
<td>Spain</td>
<td>Ex-factory</td>
<td>Ministerio de Sanidad Asuntos Sociales e Igualdad Subdirección de Calidad de Medicamentos</td>
<td>No</td>
</tr>
<tr>
<td>Poland</td>
<td>N/A</td>
<td>Ministry of Health</td>
<td>No</td>
</tr>
<tr>
<td>Sweden</td>
<td>N/A</td>
<td>Dental and Pharmaceutical Benefits Agency (TLV)</td>
<td>No</td>
</tr>
</tbody>
</table>

Discussion and Conclusion

- The majority of countries require submission of pricing documents for non-reimbursed prescription-only medicinal products prior to product launch. As a result, the prices of these products are placed on official drug lists, which raises physician awareness of product availability.
- Typically, price submission processes are less burdensome for non-reimbursed products when compared to reimbursed products. Nevertheless, they are still time and resource intensive to achieve a successful outcome.
- It is important for manufacturers to actively manage international prices, as several non-reimbursed markets require prices from other EU countries to be declared during the pricing process.
- With more freedom over prices manufacturers need to consider patient willingness to pay when determining the optimal non-reimbursed price levels.

Health technology assessments for non-reimbursed prescription-only medicinal products are undertaken in some markets. This has not been included within this scope and could be a further area for research.

Typically, time to patient access is faster for non-reimbursed prescription-only products compared to reimbursed products, but it is likely that the revenues will be lower, as patients may have lower willingness to pay.

Whilst seeking a non-reimbursed launch price in Europe can be an optimal strategy for certain therapy areas, manufacturers should ensure such an approach optimizes revenues when compared to a reimbursed approach.

References