MARTK EXCLUSIVITY EXPIRY HAS LIMITED EFFECT ON PRICES OF BRAND-NAME ORPHAN DRUGS

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Background and importance

- R&D and market entry for orphan medicinal products (OMPs) are incentivized with a ten-years market exclusivity period as stated in Orphan Regulation (EC) No 141/2000
- OMP prices often remain high after market exclusivity expiry (MEE), leading to societal debates on the affordability of medicines
- Transparency on purchase prices of OMPs is lacking due to confidentiality issues
- Research on actual OMP prices and trends is needed to support policy making

Aim and objectives

- Explore trends and price developments in list prices (LP) and purchase prices (PP) of brand-name OMPs before and after market exclusivity expiry in Western-European countries

Materials and methods

- Collection of unweighted annual average LPs and PPs of brand-name OMPs from several university hospitals in Western-European countries
- Only OMPs for which market exclusivity ended no later than 2019 were included
- The annual average LP in the year of market exclusivity expiry (MEE=0) in the Netherlands was set as index price (p=100%)
- Proportions were created to illustrate price trends and to overcome any confidentiality restraints

Results

- Participation of 5 university hospitals in 4 countries
  - Netherlands (NL)
  - Denmark (DK)
  - France (FR)
  - Germany (DE)
- Inclusion of 13 OMPs

<table>
<thead>
<tr>
<th>Country</th>
<th>MEE+2</th>
<th>MEE+3</th>
<th>MEE+4</th>
<th>Overall LP-PP*100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>NL</td>
<td>-3.82% (sd=5.61)</td>
<td>-4.42% (sd=6.17)</td>
<td>-4.70% (sd=6.35)</td>
<td>-1.99%</td>
</tr>
<tr>
<td>DK</td>
<td>-10.75% (sd=12.17)</td>
<td>-8.80% (sd=12.20)</td>
<td>-8.58% (sd=12.84)</td>
<td>-2.44%</td>
</tr>
<tr>
<td>FR</td>
<td>-14.18% (sd=10.55)</td>
<td>-15.30% (sd=10.17)</td>
<td>-15.83% (sd=10.03)</td>
<td>-0.004%</td>
</tr>
<tr>
<td>DE</td>
<td>-11.16% (sd=26.08)</td>
<td>-10.89% (sd=26.57)</td>
<td>-10.61% (sd=26.84)</td>
<td>-31.75%</td>
</tr>
</tbody>
</table>

Table 1. Average price drops of OMPs per country 2, 3 and 4 years before and after MEE=0 incl. overall average price reduction

Conclusion and relevance

- Overall average PPs drop gradually but limited until MEE+4, but the extent to which prices drop differs per country
- In the four countries, LPs seem to differ more than the PPs mainly due to a difference in discount
- Between MEE=0 and MEE+4 the differences between LPs and PPs remain relatively small (after MEE+4 more outliers occur due to lack of data points)
- Average annual LPs and PPs are the highest in Germany and the lowest in France. Denmark has negotiated the biggest discount

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References