MARKET UPTAKE OF DIRECT ORAL ANTICOAGULANTS (DOACS) IN GERMANY.

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Objectives

We investigate the market uptake of direct oral anticoagulants (DOACs) and differences in early and late market entrance. Since 2008, the DOACs dabigatran etexilate (Pradaxa®), rivaroxaban (Xarelto®), apixaban (Eliquis®), and edoxaban (Lixiana®) were commercialized in Germany for the indications

- VTEp – (primary) prophylaxis of venous thromboembolic events (VTE) after total knee or hip replacement surgery,
- VTEt – treatment of VTE including secondary prophylaxis,
- SPAF – stroke prevention in atrial fibrillation in high-risk cases.

*VTE describes deep venous thrombosis (DVT) and pulmonary embolism (PE).

Methods

The IMS Pharmascope® data base contains information about prescription and other pharmacy sales in Germany (Fig. 1).

- Pharmacy computing centers record invoiced prescriptions with >99% coverage and deliver anonymized data to IMS.
- Private prescriptions and sales without prescriptions are projected from a pharmacy panel onto all pharmacies.

We focus on data for statutory health insurance (SHI) patients due to their full coverage. These data were analyzed for the years 2008 to 2016 and compared to dates of EMA approvals.

Results

The total number of DOAC units sold to SHI patients increased from 2,060 to 143,900 units from 2008 to 2011. From 2011 to 2015, a sharp and constant increase occurred up to 4,128,356 units (Fig. 3). Since 2008, several substances were approved for the indications VTEp/VTEt and SPAF as follows (Fig. 2):

<table>
<thead>
<tr>
<th>Substance</th>
<th>VTEp</th>
<th>SPAF</th>
<th>VTEt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dabigatran</td>
<td>03/2008</td>
<td>06/2011</td>
<td>06/2014</td>
</tr>
<tr>
<td>Rivaroxaban</td>
<td>09/2008</td>
<td>12/2011</td>
<td>11/2012†</td>
</tr>
<tr>
<td>Apixaban</td>
<td>05/2011</td>
<td>11/2012</td>
<td>07/2014</td>
</tr>
<tr>
<td>Edoxaban</td>
<td>-</td>
<td>06/2015</td>
<td></td>
</tr>
</tbody>
</table>

†Partially approved (DVT treatment, VTE secondary prophylaxis) in 12/2011.

Conclusions

The market uptake of DOACs is driven by indication extensions granted in 2011/12, which started the strong growth, and in 2014/15, which drive a continued growth (Fig. 3 – 4).

- Dabigatran sales remain on an almost constant level.
- Rivaroxaban has been the best selling substance and dominated the market for many years. Sales seem to stagnate.
- Apixaban shows a steady increase in sales and shares since 2014, which seems to result from approval extensions.
- Edoxaban has started new as well on a second option on the market. It remains to be seen how the introduction of DOAC antidotes will affect the market. For vitamin K antagonists, the number of units sold decreased by 11.9% from 2012 to 2015, while the sales of low-molecular weight heparins remained almost constant (-1.2%).

2. Gemeinsamer Bundesausschuss (G-BA), http://www.g-boa.de/ (accessed 21 October 2016)

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