The New Reimbursement Route for Digital Health Applications (DlGA) in Germany: Critical Appraisal and First Evaluation of the Possible Effect on the German Healthcare System

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BACKGROUND

In Germany, 73 million citizens are insured under the statutory health insurance scheme.

Digital health applications (“Digitale Gesundheitsanwendungen”, DlGA) are medical devices of low-risk classes (I to IIa) for detecting, monitoring, treating or alleviating diseases.

The Digital Supply Act (“Digitale Versorgungsgesetz”, DVG) can be seen as an adaptation of the German early benefit assessment for pharmaceuticals (“Kostenträgerarzneimittelneuordnungsgesetz”, AMNOG) which was introduced in 2011.

In November 2020, 5 DlGA were listed in the DlGA directory at BfArM (Table 1).

First DlGA listed in the DlGA directory

On November 4th 2020, 5 DlGA were listed in the DlGA directory at BfArM (Table 1).

Evidence: When the DVG was introduced, the evidence requirements of the BfArM were far from being clear. Judging from the preliminary experiences, it seems now that an RCT is necessary to achieve a permanent listing.

Platforms: All DlGA are available for Android and iOS, somnio and velibra additionally offer web applications.

Listing: The listing in the DlGA directory can be temporary or permanent. To achieve a permanent listing, the manufacturer has to prove a “positive care effect” based on clinical studies. So far, only somnio and velibra have received a permanent listing as they are the only DlGA with RCT data to prove their “positive care effect”.

Prices: The prices of the already listed DlGA ranged from 117€ to 467€.

METHODS

We critically assessed the DlGA procedure using our extensive experience from consulting pharmaceutical companies regarding market access in the related AMNOG procedure for pharmaceuticals:

- Analysis of the first listed DlGA according to the indication, the evidence which was provided by the app manufacturer, platforms, and the prescription prices.
- Assessment of the possible impact of the DVG on the German healthcare system by conducting qualitative structured interviews with relevant stakeholders (physicians, patients, app manufacturers, health insurance funds).

RESULTS I

First DlGA listed in the DlGA directory

On November 4th 2020, 5 DlGA were listed in the DlGA directory at BfArM (Table 1).

<table>
<thead>
<tr>
<th>DlGA</th>
<th>Manufacturer</th>
<th>Indication</th>
<th>Evidence</th>
<th>Platform</th>
<th>Listing</th>
<th>Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kalma</td>
<td>eyenova, Berlin, Germany</td>
<td>Refractive treatment of vision</td>
<td>Prospective RCT</td>
<td>Android, iOS</td>
<td>Temporary</td>
<td>117€/90 days</td>
</tr>
<tr>
<td>sonnio</td>
<td>eyenova, Berlin, Germany</td>
<td>Refractive treatment of astigmatism</td>
<td>RCT</td>
<td>Android, iOS, web application</td>
<td>Permanent</td>
<td>467€</td>
</tr>
<tr>
<td>velibra</td>
<td>Dr. Ahlers &amp; Sohn, Germany</td>
<td>Refractive treatment of pseudo-strabismus, cataracts, glaucoma</td>
<td>RCT</td>
<td>Android, iOS, web application</td>
<td>Permanent</td>
<td>467€/90 days</td>
</tr>
<tr>
<td>WIFA</td>
<td>Viva Health Technologies, Germany</td>
<td>Sensor therapy and monitoring of chronic diseases</td>
<td>Prospective RCT</td>
<td>Android, iOS</td>
<td>Temporary</td>
<td>230€</td>
</tr>
<tr>
<td>Lasso</td>
<td>aidhere GmbH, Germany</td>
<td>Mobile treatment of anxiety</td>
<td>RCT planned</td>
<td>Android, iOS</td>
<td>Temporary</td>
<td>99€</td>
</tr>
</tbody>
</table>

Table 1: DlGA listed in the DlGA directory at the BfArM and November 4th 2020

CONCLUSIONS

- With the introduction of the DVG, DlGA can get access to the German healthcare system more easily.
- A crucial point in the process is that a DlGA can be listed temporarily for 12 months and prescribed to the patient at a price which is freely set by the manufacturer without any evidence for a positive outcome.
- On the other hand, it should be taken into account that the fast innovation cycles in digital healthcare call for a faster reimbursement than for medicines.
- As expected, different stakeholders have quite different opinions on the effect of the DVG.
- As soon as more data are available, further analyses should be performed to better understand the impact of the DVG on the German healthcare system.

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