challenges of benefit assessment

how to optimize your market access strategy
Rigorous benefit evaluation procedures for new pharmaceuticals have added significant challenges to the market access process in several countries. We are proud to provide the first issue of “advice”, a collection of tips for healthcare decision makers who will have to tackle these new challenges.

In order to pass the “AMNOG” process in Germany, pharmaceutical companies will have to go far beyond the traditional strategies of KOL engagement and pricing panels.

Market access has been the hot topic during the last two years, and it is not a transient trend anymore. In Germany, more than 70 benefit dossiers were assessed by the authorities. Currently, pharma seems to be struggling with the right strategy for getting global market access requirements, dossier project management, pricing, marketing & sales and post-launch regional market access aligned.

In this issue of “advice”, we would like to present you with the Advisors in Healthcare way of managing the demands of modern pharma marketing. In order to achieve sustainable success in the German healthcare market, let us introduce you to our powerful solutions to one of your most important strategic challenges.

With best regards,

Roman Rittweger, MD & MBA
## Contents

### Section

1. Integrated launch management
   1.1 Benefit assessment - strategy
   1.2 Benefit assessment - dossier project management
   1.3 Pricing strategy
   1.4 Marketing & sales
   1.5 Regional market access

2. Alignment of post-launch marketing & market access activities

3. Results from our market access leader survey
1 Integrated launch management

Before initiating a product launch process, a company’s strategy has to be adapted and pivotal workstreams need to be defined. Global market access requirements and country-specific regulatory and marketing & sales strategies have to be aligned. Under the rigorous German benefit assessment regime, delivering evidence of clinical value is the key success factor for achieving the recognition of additional benefit and eventually reimbursement by statutory health insurance. In the post-launch phase, regional market access resources must be involved to ensure nationwide market penetration.

note
Start out with an aligned strategy and make sure all project workstreams stay synchronized.
1.1 Benefit assessment

Strategy

Apply German benefit assessment criteria to clinical trial results, global value story and global marketing strategy.

Identify critical issues where German market requirements differ from global strategy, such as:
- clinical comparator
- definition of clinical endpoints
- definition of subgroups

Simulate the consequences of sticking to global strategy or adapting to German benefit assessment requirements.

Decide on the strategy for market entry in Germany.

**Note**
Before deciding on a product launch in Germany, always plan the benefit assessment strategy:
- What is a realistic price point?
- Could a launch in Germany jeopardize the international pricing strategy?

**Note**
Align the global value story with German requirements and get headquarter commitment if a launch in Germany is pursued.
1.2 Benefit assessment

Dossier project management

Do not compromise on quality – German authorities do not flinch from rejecting dossiers on grounds of formal errors. According to our survey “1,000 days of AMNOG – factors influencing the early benefit assessment” 8 out of 10 market access and HEOR decision makers are using external consulting services to support dossier preparation. Sometimes, these services are limited to data analysis and medical writing. However, external consultants can be of great value in managing the complete benefit assessment process. The external resources can exert additional quality control and will speed up the process by:

- accepting unpleasant duties in order to preserve in-house peace
- ensuring adherence to timelines and quality control
- speeding up internal decision making
- creating awareness of technical problems
- alerting internal attention to unpleasant issues

Using external support throughout the process from strategy to launch can ensure strategy-conform implementation of project steps and a consistently high level of quality.

Have you calculated the extra revenue you might realize if launching your product two months earlier?
1.3 Pricing strategy

The judgment on a drug’s additional benefit will determine its market price. The “G-BA” bases its assessment on an argumentation supporting three criteria: morbidity, mortality and quality of life for each identified subgroup of patients. The price will be negotiated between the pharmaceutical company and the National Association of Statutory Health Insurance Funds. A potential price premium will be calculated on the basis of the market price of the comparator therapy. Any additional benefit and the price levels in 15 European countries will also be considered in the price negotiation. There is no straightforward formula regarding the dimension of the rebate the pharmaceutical company has to grant on its retail price.

**note**

Use our network of experienced negotiators and invest a significant amount of time in the preparation.
1.4 Marketing & sales

Adjustment of the consistent value story to the needs of the different target groups:
- KOLs
- payors
- prescribing physicians

Test of pre-launch communication strategy with internal resources, KOLs and payors

Sales force visiting prescribing physicians is still an important factor for a successful product launch. Intensive sales force training ensures proper communication of the value story to prescribing physicians

**note**
- set up cross-functional teams and frequent alignment meetings
- perform interviews in order to identify unmet needs and develop story lines
- perform mock sales force visits
1.5 Regional market access

- Preparation of argumentation adapted to the different regional statutory health insurance providers
- Development of ideas for payor contracts based on
  - gaps in patient care
  - product characteristics
  - competition
- Develop and position targeted messages

(Regional) stakeholder management is crucial

<table>
<thead>
<tr>
<th>High impact</th>
<th>Low impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>difficult access</td>
<td>good access</td>
</tr>
</tbody>
</table>

roman rittweger advisors in healthcare
2 Alignment of post-launch marketing & market access activities

<table>
<thead>
<tr>
<th></th>
<th>communication strategy</th>
<th>messages</th>
<th>stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>marketing</td>
<td>~</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>market access</td>
<td>~</td>
<td>~</td>
<td>~</td>
</tr>
</tbody>
</table>

What innovative contracts are you prepared to offer to payors?

product-specific development together with you
3 Results from our market access leader survey

Since the introduction of the AMNOG in 2011, more than 70 dossiers have been reviewed by the “G-BA”. We asked the responsible market access executives about costs, timeframe and expected result.

Our survey shows that there is a significant discrepancy between expected result and “G-BA” assessment:

<table>
<thead>
<tr>
<th>level of additional benefit</th>
<th>pharma expectation</th>
<th>“G-BA” decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>major additional benefit</td>
<td>$$$$$</td>
<td>33 %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 %</td>
</tr>
<tr>
<td>important additional benefit</td>
<td>$$$$$$$</td>
<td>33 %</td>
</tr>
<tr>
<td></td>
<td>$$$$</td>
<td>33 %</td>
</tr>
<tr>
<td>slight additional benefit</td>
<td>$$$$</td>
<td>22 %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11 %</td>
</tr>
<tr>
<td>no quantifiable additional benefit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>no additional benefit</td>
<td>$$$$</td>
<td>11 %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>56 %</td>
</tr>
</tbody>
</table>

*note*

when you are forecasting the level of benefit, use outsiders to overcome your organizational bias
We provide expert support along the entire market access pathway

“Roman Rittweger Advisors in Healthcare” is a specialized healthcare advisory supporting companies in their market driven strategy.

Did we spark your interest? Just contact us!
+49 89 212 69 33 0 - office@advisorsinhealthcare.com - www.advisorsinhealthcare.com

Roman Rittweger Advisors in Healthcare GmbH
Maximilianstrasse 31
D-80539 Munich

Managing Partner: Dr. med. Roman Rittweger
Registered office of the company: Munich