

Compliance Cases in Market Access

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Bernhard Fischer

Tomasz Kruk

Stephen Nguyen Duc

Ulrich Reese

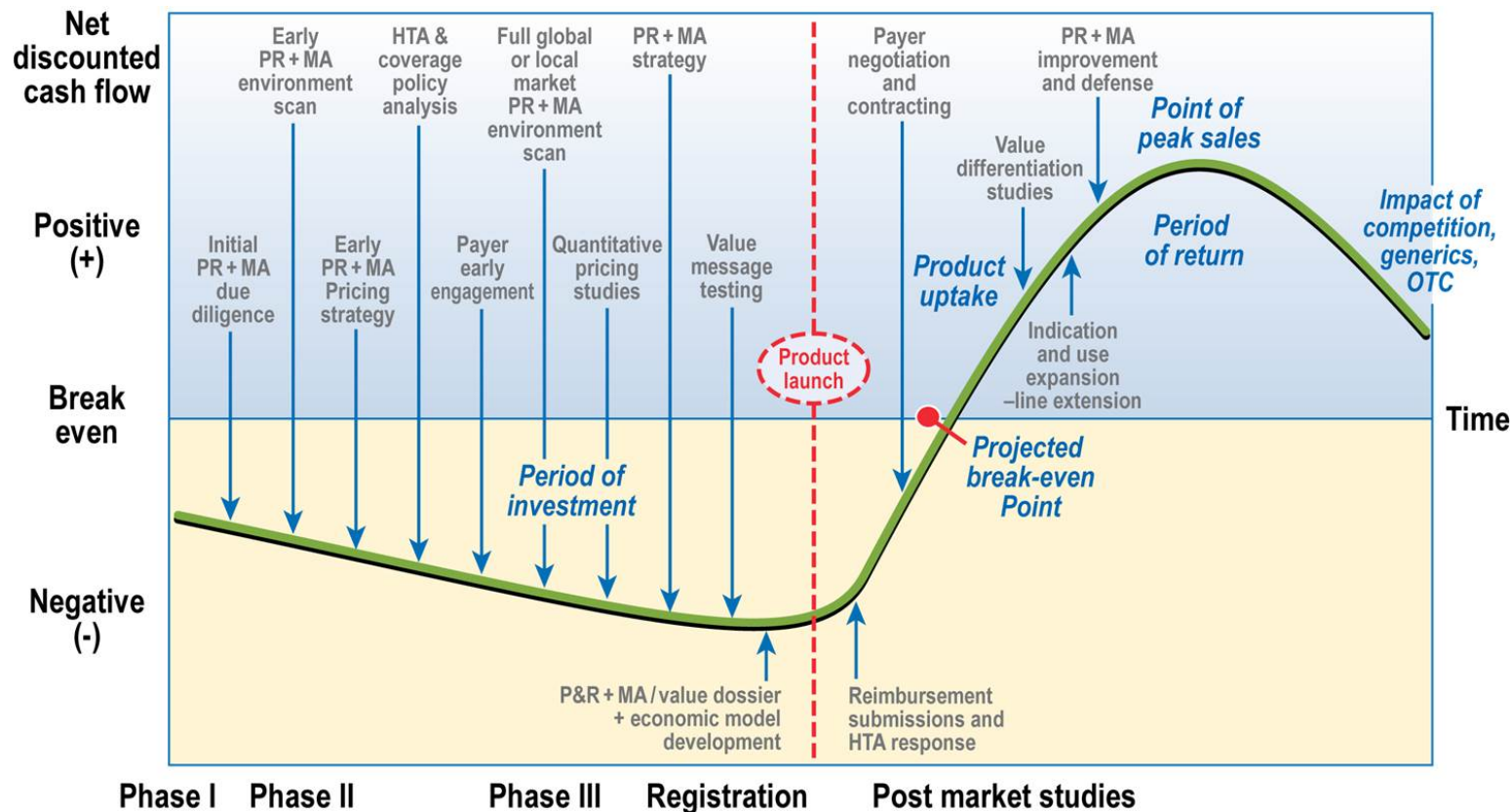
Michael Bartke (Moderator)



Compliance Principles



Market Access Planning Across the Product Lifecycle



PR = Pricing Research; MA = Market Access; HTA = Health Technology Assessment

<https://www.rtihs.org/services/market-access-and-outcomes-strategy/market-access-and-evidence-generation-strategies>



Market Access Challenges

Tasks:

- Business Intelligence
- Advisory Boards
- Clinical Data management
- Market Research
- Strategy & Positioning
- Economic evaluation
- Pricing
- Tender Process(es)
- Publications
- Contracting
- Competitive Intelligence
- etc.
- Medical-, Marketing-, Key Account- & Sales Activities

Market Access Process

early



late

Launch

Stakeholder:

- Agencies
- Experts/Consultants
- Key Opinion Leaders
- Trade Associations
- State Officials/Office bearer
- National/local Committees
- Hospital chains/ Pharmacists & HCPs
- Patient Organisations



Advisory Board

Last year you were told to organize 3 payer advisory boards .

The very well-known *Onco2020* Congress will take place in April in Paris and you would like to leverage this event and organize one Ad board at this occasion.

The timing is ideal to prepare the launch of your product by year-end.

The high level agenda would be some scientific sharing from the congress in the morning and then some discussions on the economical value proposition of your drug in the afternoon.

- **What are the potential risks here?**
- **What would you recommend to do?**



Internship

The Vice-Chair of the French National Economical Review Committee in charge of the price negotiation for one of your drug is informing you that his son is looking for internship opportunities in the context of his upcoming graduation from the London School of Economics.

You have not solicited this and as a matter of fact do have some extra workload that would fit well with this type of internship.

- **What are the potential risks here?**
- **What do you recommend as way forward ?**



Consultants

During a government tender, our consultant indicates that they routinely outsource some of their work to a specific sub-consultant. We are informed cost of the sub-consultant is around \$10K.

When we ask why we need another consultant, including what specific activities the sub-consultant will provide, we are told that in order to be successful, we need to include the sub-consultant, that the sub-consultant has a good relationship with the Minister of Health. He is a university professor and a real influencer.

- **What are the potential risks here?**
- **What would be the correct course of action?**



Trade Association

You have been appointed recently as Rheumatology Market Access Lead in your company and attend the Market Access Committee of the European Pharma Trade Association.

You are very excited about that because you anticipate a good number of topics that can help your understanding and strategy going forward

The draft agenda is signalling the following topics:

1/ Presentation by an external Market Research Agency of the Rheumatology market in Europe including a review of the access and price landscape

2/ Discussion, proposals and next steps from all attendees

- **What are the potential risks here?**
- **What would you recommend to do?**



Awareness Campaign

You are working on an awareness campaign for disease X where your product Y is one of a variety of treatment options. The aim of the campaign is to create a deeper understanding of the disease state and treatment options in general as well as to highlight difficulties for patients to effectively get treated due to the current reimbursement set-up. Amongst other things, you plan to do the following:

1. Do advisory boards with members from sick funds and other public institutions to get a better understanding of the available data to support your campaign. The participants could also be used at a later stage to act as campaign ambassadors in their respective organisations.
 2. Ask a well-respected patient organisation for help to reach out to key political stakeholders. You have supported the organisation in the past and can rely on their good will.
- **What are the potential risks here?**
 - **What would you recommend to do?**



Tender

You are preparing to submit a hospital bid. After careful review of the tender specifications you have the sense that one of your competitor is potentially better placed than you . You decide to go to the hospital to discuss with the Hospital Director .

From that discussion it became obvious to you that the hospital is potentially open to revisit slightly the wording of the tender specification which would place your drug in a much more favourable position.

The Hospital Director has noticed in preparation of this meetings an increase of the Research Grants provided by your company last year and also his long and good standing relationship with your company . .

- **What are the potential risks here?**
- **What would you recommend to do?**

