Effective Communication with Federal Authorities for Scientific Advice Early in Product Development

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Scientific Symposium
ISPOR 2012 Berlin, Germany
Agenda

• Introductions
• Early advice process in Federal Agencies
  – Germany
  – Sweden
  – UK
• Open discussion
• Closing remarks
Introduction

- New decision processes for assessment of new technologies for pricing and reimbursement in the EU
- Early scientific advice offered by agencies to facilitate process
- Objectives of symposium
  - Gain understanding of agencies’ advice processes
  - Gain insight into relevant issues and questions to address during early advice meetings
  - Increase effectiveness of early advice meetings in new product development planning
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Communication with the Federal Joint Committee (G-BA) for Early Scientific Advice

Dr. Michael Kulig, PhD MPH
Scientific Advisor, Head of Working Group Pharmaceuticals
Medical Consultancy Department
Obligatory assessment within G-BA

1. Any new pharmaceutical after marketing authorisation

2. Medicine-like “medical products” (*physical* mode of action: e.g. anti-diarrhea agents, osmotic solutions etc)

3. For outpatients care:
   Medical devices, testing examination and treatment methods
   – New law (§ 137e, effective 2012), optional for:
     Testing examination and treatment methods (benefit not yet been sufficiently proved, but potential as a treatment alternative)

→ advisory procedure on request by
   • manufacturer of a medical product whose use significantly depends on the application of a new examination or treatment method
   • Companies that are not providers of a new method, but that have an economic interest in its provision by the statutory health insurance providers
Scope of the AMNOG

1. Assessment of pharmaceuticals on additional benefits compared with appropriate comparators for:
   - Pharmaceuticals with new active ingredients launched after 1 January 2011
   - Pharmaceuticals authorised and marketed before 1 January 2011 upon request by the G-BA according to Rules of Procedure (Chapter 5, §16)

2. Price regulation based on benefit assessment
   → no exclusion from reimbursement (no “fourth hurdle”)
Early Drug Benefit Assessment (AMNOG)

Manufacturer Consultancy 
on request

Manufacturer Market access

Dossier

G-BA Efficiency assessment (published)

Hearing

G-BA Efficiency assessment decision

No benefit

GKV Pricing:
Price negotiation
Or
Arbitral verdict

No ref. price

Rebate

Manufacturer’s price
Free price setting for the 1st year

Reference price
Maximum GKV reimbursement price

during product development

Market access

3 months

3 months

6 months (+ 3 month)
Interaction with the G-BA
Drug benefit evaluation (AMNOG)

1. CONSULTANCY* on
   - Documents needed for dossier submission
   - Procedural steps
   - Appropriate comparator
   - Endpoints
   - Study population, subgroups

2. HEARING during assessment process
   - Company: short statement of benefit claims
   - G-BA: Clarification of controversial or unclear points during benefit assessment

* Any given scientific advice not legally binding for any future appraisal

NO CONSULTANCY ON:
- Closed procedures
- Court proceedings
- Pre-evaluation of studies and data
Consultancy with the G-BA

8 weeks

Submission of Request for advice
- Special form
- general information, questions, position of the company and substantiation by the company
- fees apply

Processing of request by secretariat of the G-BA
- Check for completeness of the request
- search for potential comparators, endpoints
- structured, systematic literature search, extraction of important information

Discussion at the Committee
agreement on appropriate comparator
and on further question of the company

Advice meeting with the company
Advice meeting with company

Face-to-face meeting with the Company
- Meeting led by G-BA
- No formal restrictions for number of company’s representatives
- No presentation by the manufacturer
- Formal advice (no modification of advice during meeting)
- Explanation and discussion the key themes

Written protocol and formal advice report within 14 days, including
- Decision criteria
- Overview of potential comparators (available medicines in GER)
- Scientific evidence of potential comparators

Fees: 3 categories (2000€, 7000€, or 10,000€)
might be modified according to complexity of themes
Benefit Assessment of Pharmaceuticals pursuant to § 35a SGB V

This page is a compilation of information concerning the assessment of the benefits of pharmaceuticals pursuant to the Arzneimittelmarkt-Neuordnungsgesetz (German Law for Reforming the Market for Pharmaceuticals).

This English version is a courtesy translation only. Only the German version is legally binding. You will specifically find the following here:

- Benefit Assessment of Pharmaceuticals pursuant to § 35a SGB V
- The new tasks of the Federal Joint Committee pursuant to Arzneimittelmarkt-Neuordnungsgesetz (German Law for Reforming the Market for Pharmaceuticals)
- Arzneimittel-Nutzanbewertungsverordnung (German Ordinance for Assessing the Benefits of Pharmaceuticals)
- Supplementing the Rules of Procedure of the Federal Joint Committee
- Further Information for Pharmaceutical companies
- Submitting dossiers pursuant to § 35a SGB V
- Email Post-Office Box for Further Questions
- Transitional Arrangement
- The consultation procedure pursuant to § 35a SGB V
- Questions and Answers about the Procedure
Joint Scientific Advice
– TLV and MPA

Fredrik Nilsson, PhD
Health Economist
Background

- Initiated on request from pharma.
- 12 meetings, 10 companies.
- Purpose of JSA:
  - facilitate appropriate and cost-effective use of pharmaceuticals.
  - meet companies’ expectations.
The meetings

• Mostly big pharma.
• Mostly between Phase II and Phase III.
• Fairly sharp questions.
• Focus on performed and planned studies.
  – Lack: medical need, costs, subgroups.
Experiences

• Insight into MPA – company guidance.
• Understanding development.
  – What is problematic?
• Agency resource use?

• Company concerns?

• National vs. International advice?
Current processes

• Apply on standard MPA application form.
• Fee: SEK 45 000, no additional TLV charge.
  – Free for universities and other non-profit org.
• Time from application to meeting, 2-3 months.
  – All materials completed 3 weeks prior to meeting.

• We continue with joint scientific advice.
• Up to 10 – 15 meetings per year.
DISCUSSION