

W13: HTA IN GERMANY: EVIDENCE REQUIREMENTS, THE ROLE OF BENEFIT/COST ASSESSMENT, FIRST EXPERIENCES AND CHALLENGES WITH THE GERMAN HEALTH BILL AMNOG

ISPOR - 14th European Congress, 5 – 8 November 2011 in Madrid

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Dr. Jens Grüger, Vice President, Head Global Market Access, Pfizer Ltd.
Anne Heyes, Head Market Access & Outcomes Strategy, RTI Health Solutions – Europe

Agenda

Agenda Item	Presenter	Time
Introduction	Anne Kilburg	5'
Changes, Experiences and Challenges from the perspective of the health technology assessor	PD Dr. Peter Kolominsky-Rabas;	10'
Changes, Experiences and Challenges from an industry perspective	Dr. Jens Grüger	10'
Differences in national HTA requirements and impact on the development of Global Value Dossiers	Anne Heyes	10'

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Introduction

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Anne Kilburg, Senior Director, Market Access & Outcomes Strategy, RTI Health Solutions – Europe

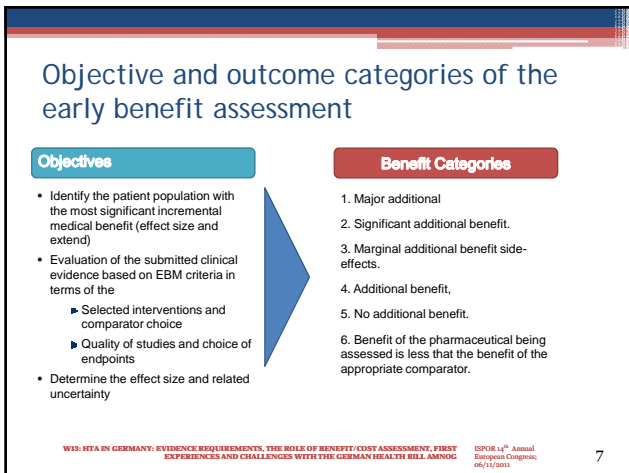
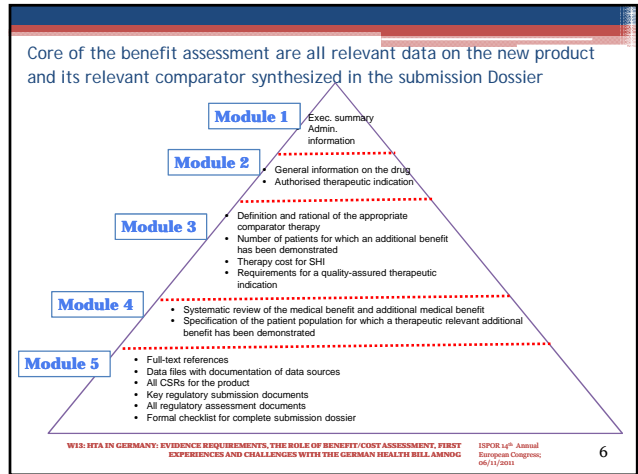
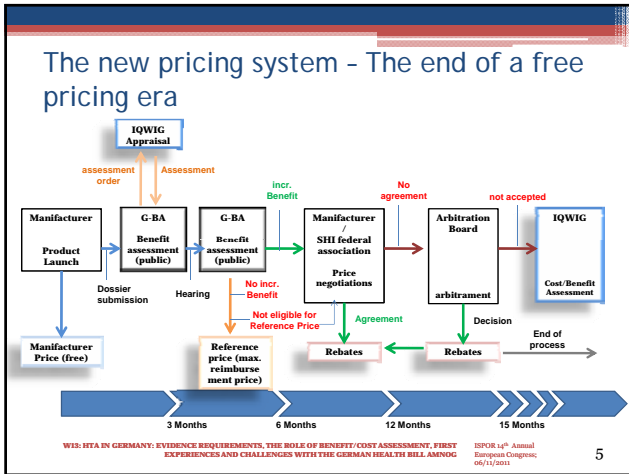
Overview of AMNOG - Key features

- The German Law for Reforming the Market for Pharmaceuticals (AMNOG, §35 a, SGB V) is effective since 1st January 2011
- 3 key elements are
 - Early benefit assessment
 - Central price negotiations between manufacturer and federal association of SHI or reference price determination
 - Decentralized integrated health care contracts between health care provider, health insurer and manufacturer

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- ### Which new treatments will be included in the early benefit assessment?
- All new agents or combination of agents that are launched since 1st January 2011
 - Any new indication for these agents
 - No exemptions are made for new agents for hospital use only
 - Pharmaceuticals registered before Jan 1st 2011 which receive a new indication will not undergo an early benefit assessment (only if already requested by G-BA)
 - Manufacturer can request to be dispensed from the early benefit assessment if the sales of their new drug will be constantly < €1 Mio (burden to the SHI) within 12 month
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First experiences

- What is the experience of HTA assessors? What their recommendations for submissions?
- What is the experience of the industry? What are the implications from a global player's perspective?
- What are international requirements and how can industry plan to meet those?