



Pricing and reimbursement of pharmaceuticals in Germany

What lessons can be learned from abroad?

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Prepared for:

Prepared by: Pharmerit International
Dr. Harald Heemstra

Objective

To discuss the German pricing and reimbursement reform in the context of reimbursement systems in other EU countries

- In particular the Netherlands

Introduction



HTA in the Netherlands

- 1999: Plan to introduce HE as requirement for reimbursement applications
- 2000: Postponement of HE requirements to 2005
- 2002: Trial period with voluntary submission of HE dossier
- 2005: Mandatory HE reimbursement applications

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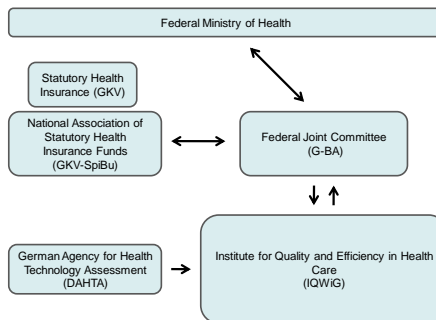
- Founded in 2000 in the Netherlands
- Offices in Rotterdam (NL), York (UK) and Bethesda (US)

Outline of the presentation

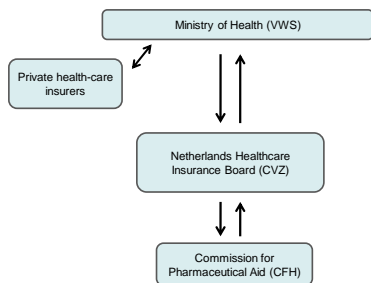
- Introduction and background
- Timelines
- Data requirements
- Assessment of incremental clinical benefit
- Health economics
- Exceptions and advice
- Summary and implications

INTRODUCTION AND BACKGROUND

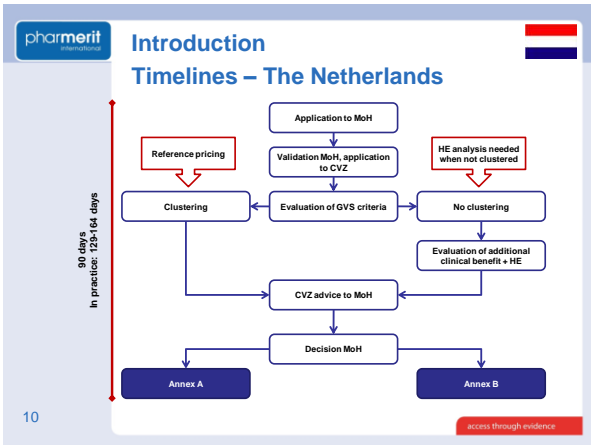
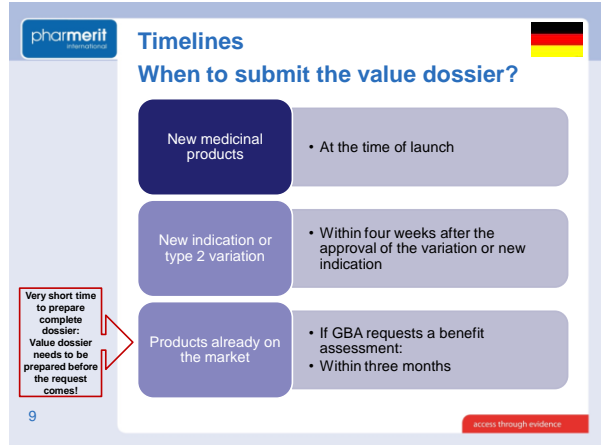
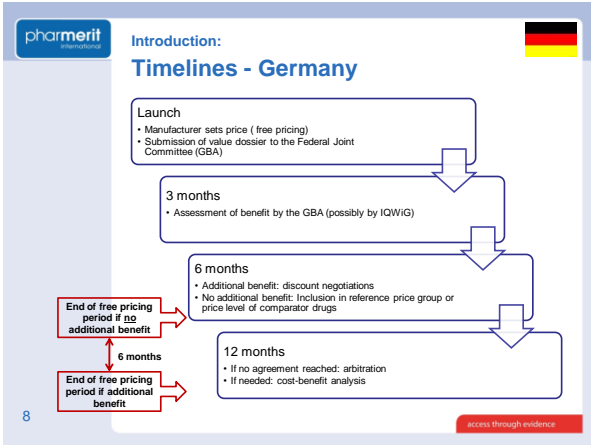
Background Primary actors - Germany



Background Primary actors – the Netherlands



TIMELINES



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DATA REQUIREMENTS

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Value dossier - Germany



- The approved therapeutic indication(s)
- The medical benefit
- The additional clinical benefit compared to appropriate comparative therapy
- The number of patients and patient groups for whom there is a therapeutically meaningful additional benefit
- The cost of the therapy for GKV
- The requirements for a quality assured application

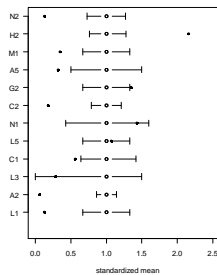
Crucial for successful reimbursement

Reimbursement dossier - Netherlands



- Pharmacotherapeutic dossier
 - Therapeutical (added) value
- Pharmacoeconomical dossier
 - Only for unclustered products (Annex 1B)
 - Guidelines for pharmacoeconomical research apply
 - Societal perspective
 - Incremental costs per QALY
- Cost-consequence estimation

Budget impact: rough estimations



Often too high or too low estimation of cost consequences

The forecasted gross budget impact (•) with corresponding uncertainty and the actual budget (-).
Thursson PO, Heeg B, Botteman M, ISPOR 2010

ASSESSMENT OF INCREMENTAL CLINICAL BENEFIT

Assessment of incremental clinical benefit
Germany- improvement for the patient



Category	Level of additional benefit
1	Major additional benefit
2	Important additional benefit
3	Slight additional benefit
4	Not quantifiable
5	No additional benefit
6	Smaller

- Incremental clinical benefit seen as crucial factor for successful reimbursement outcomes
- System seems inspired by the French ASMR rating system
- Main clinical trial study design is important!
- Design RCTs to provide hard evidence on the value of the product

Assessment of incremental clinical benefit
Netherlands: two annexes



Annex 1A

- Products with Interchangeable substitutes
 Defined as:
 - Same indication
 - Same route of administration
 - Same age group of patients
 - No clinically relevant differences
- Reimbursement limits based on price of product at reference date (lowest priced product)

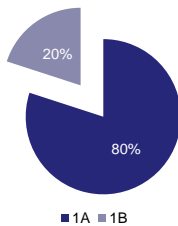
Annex 1B

- Products without interchangeable substitutes
- No reimbursement limits

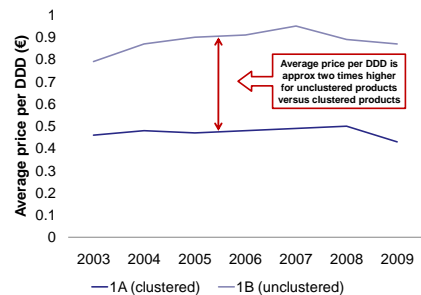
Reference pricing
Share of not substitutable products



Netherlands: substitutable with other products



Reference pricing
Price level of clustered vs unclustered





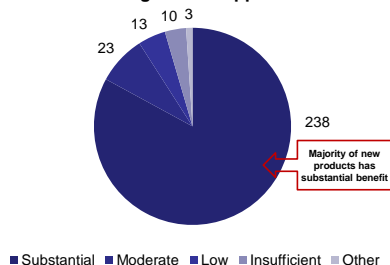
France: the ASMR system

ASMR rating	Explanation
I	Major therapeutic advance
II	Important improvement (effectiveness or side effects)
III	Significant improvement (clear added value)
IV	Minor improvement (slight benefit only)
V	No improvement (similar products and generics)



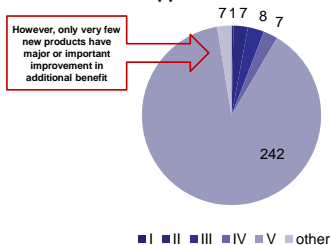
New products: substantial clinical benefit

SMR rating for new applications



New products: limited additional benefit

France: ASMR rating for new applications in 2007



HEALTH ECONOMICS

Germany and the Netherlands




HTA consideration gained importance for market access since mid 1990s

2000: SHI Health Care Reform Act
 - Diagnosis-related Groups
 - The German Agency for Health Technology Assessment

2003: Health Care Modernization Act
 - 2004: Foundation of IQWiG; solely benefit assessments
 - 2010: First economic evaluations to determine maximum reimbursement rate

2011: Pharmaceutical Market Restructuring Act (AMNOG)



HTA evaluations have been performed since the early 1980s

1982: Health Insurance Council published the 'Limits to the Expansion of the Benefit Package' report
 - Evaluation of efficacy and cost-effectiveness

2002: Voluntary submission of HE applications

2005: Mandatory submission of HE applications

2006: Health Insurance Act
 - HTA evaluation by the Health Care Insurance Board (CVZ)

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Germany



- Cost analysis important aspect of the value dossier
- Parties can ask for a cost-benefit analysis after the arbitration committee has reached a decision
- Perspective of the Statutory Health Insurance (GKV)
- General methods for the assessment of the relation of benefits to costs



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The Netherlands



- Pharmacoeconomic analysis is obligatory:
 - For annex B products
 - For extensions of the conditions of Annex A or B products
- Outcomes in incremental costs/QALY
- No formal ICER threshold
- Additional factors that play a role:
 - Disease severity
 - Risk for misuse
 - Budget impact



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Differences



Health economic guidelines in Germany deviate on certain aspects from Netherlands:

	Netherlands	Germany
Perspective	Societal	Statutory Health Insurance (GKV)
Technique	Cost utility	Cost per clinical benefit (presented as efficiency frontier)

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EXCEPTIONS AND ADVICE

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Exceptions

General

- Exceptions apply in both Germany and the Netherlands:

Netherlands: exceptions for pharmacoeconomic research	Germany: exceptions for benefit assessment
Orphan drugs with costs < 1M€	Orphan drugs with costs < 50M€
Products with costs < 0.5M€	Products with costs < 1 M€
Products on annex A (clustered)	

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Exceptions

Outpatient drugs

Policy rule on orphan drugs	Policy rule on expensive hospital drugs
Designated orphan drugs only	All expensive drugs
Academic hospitals only	All hospitals
Estimated costs should be 5% or higher of average drug costs in academic hospitals (600,000 €)	Estimated costs should be 0.5% or higher of total hospital drug costs (2.5 M€)
100% refund of costs	80% refund of costs
Inclusion on the list for 3 years	Inclusion on the list for 3 years
Obligatory effectiveness research	Obligatory effectiveness research

<http://www.nza.nl/regelgeving/beleidsregels/108192/CI-1061>
<http://www.nza.nl/regelgeving/beleidsregels/108192/CI-1114>

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Advice

Scientific advice

Netherlands	Germany
CVZ provides advice concerning disadvantages and deficits	GBA provides advice concerning the benefit assessment
Before submitting a formal application to MoH	May take place before start of P3 studies
	Fees apply
Topics to be discussed include: •Choice of comparative treatment •Relevant endpoints •Design and methodology of HE analysis	Topics to be discussed include: •Choice of the appropriate comparative treatment •Studies to be submitted

Scientific advice can be very helpful in designing trials, choosing comparators etc. Especially in complicated cases

Eligibility for advice expires with the expiration date for submission of the value dossier

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SUMMARY AND IMPLICATIONS

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Summary

Timelines

- Start on time!
 - Also if your product is already reimbursed

Data requirements

- Focus on quality of the data, from main clinical trial design

Assessment of incremental clinical benefit

- Incremental clinical benefit crucial for successful reimbursement outcome

Health economics

- Gaining importance with the introduction of AMNOG?

Exceptions and advice

- Exceptions apply for orphan drugs
- Be encouraged to make use of facilities for advice

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Implications

Effects for international reference pricing:

- Possible choice to maintain a high price if product placed on reference group
- Possible choice to withdraw from the German market if price provided is too low
 - Lower sales in Germany
 - International prices will remain high
 - Effects for German patients

Germany as portal for market access of pharmaceuticals in Europe?

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Thank you

Harald Heemstra, PharmD, PhD
Pharmerit International

hheemstra@pharmerit.com
+31 10 4519924

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