Post-licensing evaluation of new medicines

A valuable tool to foster “true” pharmaceutical innovations?

An international perspective

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Rationale behind post-licensing evaluation

Source: Schwabe and Paffrath 2004

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Establishing comparative post-licensing evaluation

PBAC PMPRB CFH PPB PHARMAC NoMA HEK IQWIG
EAK NICE PBB CEDAC
CT CRM

Agenda

• Evaluation criteria / process
• Methodological challenges
• Policy challenges
Everything is relative...

**Comparator**

- *common practice* in most countries (i.e. most frequently prescribed medicine or most prevalent non-pharmaceutical treatment)
- **best** available treatment (e.g. FI, NO, NZ, UK)
- **least expensive** therapeutic alternative (e.g. CA, FR, NZ)
Drug Review Bodies: Role and Structure

- advisory-type bodies
  - AT
  - AU
  - BE
  - CH
  - DE
  - NL
  - NO

- regulatory-type bodies
  - CA
  - FR
  - FI
  - NZ
  - SE
  - UK

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Criteria for Assessment and Decision-Making

<table>
<thead>
<tr>
<th>Therapeutic benefit</th>
<th>AU</th>
<th>BE</th>
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<td>Patient benefit</td>
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<td>Cost-effectiveness</td>
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<td>Budget impact</td>
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<td>Pharmacological/innovative characteristics</td>
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<td>Availability of therapeutic alternatives</td>
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<td>Equity considerations</td>
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<td>Community need</td>
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<td>Public health impact</td>
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<td>R&amp;D</td>
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<td>Government priorities</td>
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Conclusion I: Criteria and Process

Post-licensing evaluation of drugs is a valuable policy tool

IF...

- ...it follows a systematic, evidence-based, comparative approach,
- ...it is independently performed and supplemented by other criteria in the decision-making process

Dealing with the risk of delayed access

Different tracks of urgency (e.g. SE)
- orphan diseases
- incurable diseases
- diseases of great social/political interest
Dealing with missing or unreliable data...

- **Statistical methods**
  - meta-analyses
  - indirect comparisons
  - economic modelling
- **Re-evaluation**
  - pre-defined period (e.g. FI, FR, UK)
  - new characteristics of drug (e.g. extended indication)
  - additional clinical/economic evidence (e.g. AT, CH)

...and targeting resources

**Restrictions**: drug’s use limited to
- specific indications
- type and severity of diseases or conditions, populations (e.g. age, sex)
- therapeutic strategies (e.g. first line, second line treatment)
- treatment settings (e.g. inpatient/ outpatient care, general/specialist care, within trials)
- prescribers (e.g. only specialists; FI, NZ)
- pre-authorisation through sickness fund (AT, BE)
Conclusion II: Methodological Challenges

Post-licensing evaluation of drugs is a valuable policy tool

IF…

...decision-makers are aware of its methological strenghts and limitations,

...it is repeated according to gain in new evidence.

Rewarding manufactures

• positive lists/full reimbursement
• exemption from reference pricing
• free/premium pricing
Conclusion III: Policy Challenges

Post-licensing evaluation of drugs is a valuable policy tool

IF...

...it has reliable impact on rewarding manufacturers in terms of full reimbursement and/or free or premium pricing,

...if potential for international collaboration to increase transparency and acceptability is increasingly used.

Thank you for your attention!

This presentation and the study’s executive summary (in English) will soon be available at

http://mig.tu-berlin.de
### National drug evaluating institutions and their advisory bodies

<table>
<thead>
<tr>
<th>Country</th>
<th>Institution/Advisory Committee</th>
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<tbody>
<tr>
<td>Austria</td>
<td>Federation of Austrian Social Insurance Institutions/Drug Evaluation Committee (Hauptverband der Österreichischen Sozialversicherungsträger/Heilmittel-Evaluierungs-Kommission)</td>
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<tr>
<td>Australia</td>
<td>Pharmaceutical Benefits Advisory Committee/Economic Sub-Committee</td>
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<tr>
<td>Belgium</td>
<td>National Institute for Sickness and Invalidity Insurance/Commission for Reimbursement of Medicines (Institut national de l’assurance maladie-invalidité/Commission de réimbursement des médicaments)</td>
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<tr>
<td>Canada</td>
<td>PMPRB - Patented Medicine Prices Review Board/Human and Veterinary Drug Advisory Panels CDR - Canadian Expert Drug Advisory Committee/Common Drug Review-Directorate at Canadian Coordinating Office for Health Technology Assessment</td>
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<tr>
<td>Finland</td>
<td>Pharmaceuticals Pricing Board (Lääkkeiden hintalautakunta)</td>
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<tr>
<td>France</td>
<td>Economic Committee for Health Products/Transparency Commission (Comité économique des produits de santé/Commission de Transparence)</td>
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<td>Germany</td>
<td>Federal Joint Committee/Institute for Quality and Efficiency in Health Care (Gemeinsamer Bundesausschuss/Institut für Wirtschaftlichkeit und Qualität im Gesundheitswesen)</td>
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<tr>
<td>The Netherlands</td>
<td>Health Care Insurance Board/Committee for Pharmaceutical Aid (College voor zorgverzekeringen/Commissie Pharmaceutische Hulp)</td>
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<td>Norway</td>
<td>Norwegian Medicines Agency (Statens Legemiddelverk)</td>
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<td>New Zealand</td>
<td>Pharmaceutical Management Agency/Pharmacology and Therapeutic Advisory Committee</td>
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<td>Sweden</td>
<td>Pharmaceutical Benefits Board (Läkemedelsförvaltningsnämnden)</td>
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<td>Switzerland</td>
<td>Swiss Federal Office of Public Health/Confederal Drug Commission (Bundesamt für Gesundheit/Eidgenössische Arzneimittelkommission)</td>
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<td>United Kingdom</td>
<td>National Institute for Clinical Excellence</td>
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