Post-licensing evaluation of new medicines

A valuable tool to foster "true" pharmaceutical innovations?

An international perspective

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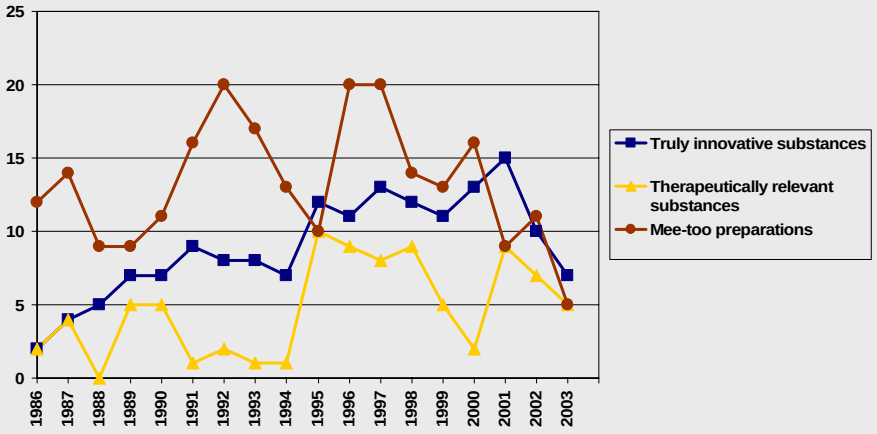
Rationale behind post-licensing evaluation



Source: Schwabe and Paffrath 2004

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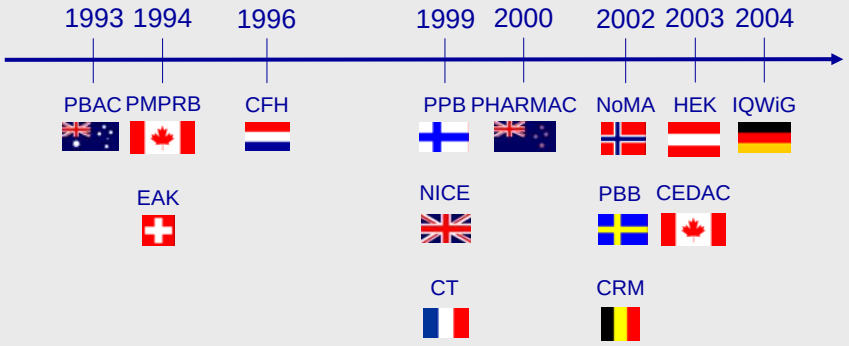
Establishing comparative post-licensing evaluation



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Agenda

- Evaluation criteria / process
- Methodological challenges
- Policy challenges

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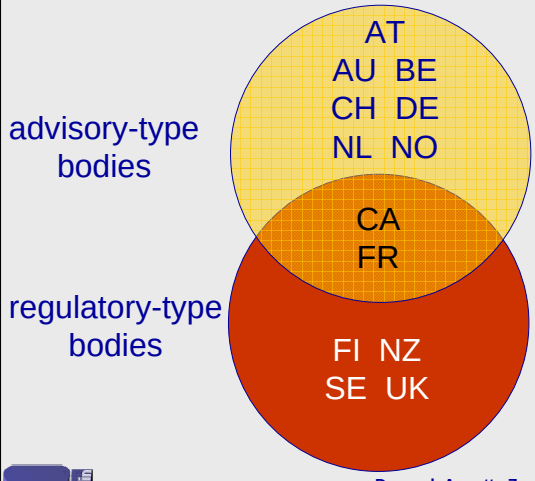
Everything is relative...

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



- Physicians
- Health economists
- Pharmacists, clinical pharmacologists
- Epidemiologists
- Government/insurance fund representatives
- Consumers (AU, SE, UK)
- Industry (UK)

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Criteria for Assessment and Decision-Making

	AT	AU	BE	CA	CH	DE	FI	FR	NL	NO	NZ	SE	UK
Therapeutic benefit	■	■	■	■	■	■	■	■	■	■	■	■	■
Patient benefit	■	■	■	■	■	■	■	■	■	■	■	■	■
Cost-effectiveness	■	■	■	■			■		■	■	■	■	■
Budget impact		■	■	■			■	■	■	■	■		■
Pharmacological/innovative characteristics	■		■	■				■	■				■
Availability of therapeutic alternatives	■	■							■		■	■	■
Equity considerations				■						■	■	■	■
Community need		■									■		
Public health impact				■				■					
R&D		■					■						
Government priorities											■		

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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

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Dealing with the risk of delayed access

Different tracks of urgency (e.g. SE)

- orphan diseases
- incurable diseases
- diseases of great social/political interest

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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)

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...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)

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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.

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Rewarding manufactures

- positive lists/full reimbursement
- exemption from reference pricing
- free/premium pricing

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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.

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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

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National drug evaluating institutions and their advisory bodies

Austria	Federation of Austrian Social Insurance Institutions/Drug Evaluation Commitee (*Hauptverband der Österreichischen Sozialversicherungsträger/Heilmittel-Evaluierungs-Kommission*)
Australia	Pharmaceutical Benefits Advisory Committee/Economic Sub-Committee
Belgium	National Institute for Sickness and Invalidity Insurance/Commission for Reimbursement of Medicines (*Institut national de l'assurance maladie-invalidité/Commission de réimboursement des médicaments*)
Canada	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
Finland	Pharmaceuticals Pricing Board (*Lääkkeiden hintalautakunta*)
France	Economic Committee for Health Products/Transparency Commission (*Comité économique des produits de santé/Commission de Transparence*)
Germany	Federal Joint Committee/Institute for Quality and Efficienty in Health Care (*Gemeinsamer Bundesausschuss/Institut für Wirtschaftlichkeit und Qualität im Gesundheitswesen*)
The Netherlands	Health Care Insurance Board/Committee for Pharmaceutical Aid (*College voor zorgverzekeringen/Commissie Farmaceutische Hulp*)
Norway	Norwegian Medicines Agency (*Statens Legemiddelverk*)
New Zealand	Pharmaceutical Management Agency/Pharmacology and Therapeutic Advisory Committee
Sweden	Pharmaceutical Benefits Board (*Läkemedelsförmånsämnden*)
Switzerland	Swiss Federal Office of Public Health/Confederal Drug Commission (*Bundesamt für Gesundheit/Eidgenössische Arzneimittelkommission*)
United Kingdom	National Institute for Clinical Excellence