The process of evidence-based decision-making for the reimbursement and pricing of pharmaceuticals in Europe: mapping approaches in 36 countries

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The OPEN (**O**vercome Failure to **P**ublish N**e**gative Fi**n**dings) Project

- 7th Framework Programme of the European Union
- Current practice by various key groups involved in knowledge generation and translation regarding dissemination bias
- Recommendations for change
- Work Package 10: regulatory institutions responsible for determining value of pharmaceuticals for statutory coverage

Research aims of Work Package 10

- Map pricing and reimbursement processes in all countries included in the project (EU/EFTA), focusing on participating institutions and their standards

- Identify existing approaches towards dissemination bias and determine level of awareness/ operationalization, exemplary practices and possible steps for the future

Background

- Efficient allocation of finite ressources is one of the primary goals of HTA
- Increasing financial constraints call for a closer commitment to rational policies
- General shift towards decision-making rooted in scientific findings

Background (cont‘d.)

- Most formal systems established for pharmaceuticals despite the broader scope of HTA activities
- Outpatient pharmaceutical expenditure 17% of THE in OECD countries in 2011
- Wide range of cost-containment policies (reference pricing, public tendering, price cuts, discounts, prescription guidelines etc.)
- HTA most common along with reference pricing

Methods

Identification of relevant regulatory institutions in EU/EFTA countries:

- Websites of EUnetHTA, European Observatory on Health Systems and Policies, INAHTA, ISPOR, WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement
- Websites of all related ministries
- Systematic search for publications in Pubmed

Focus on institutional practices

- Online sources to create country profile (table and process map)
- Direct contact with institutions to verify profiles

Information availability and transparency

- Separate institutions in charge of decision-making on reimbursement and pricing of pharmaceuticals identified in 34/36 countries (except MK, LI)

- Type and extent of information available on the evaluation of relative effectiveness and decision-making varied considerably

- General lack of transparency: only 12 countries provide sufficient information

Assessment

- Structurally separate from appraisal
- Special groups within regulatory institution or commissioned independent public bodies
- Manufacturer submissions build the initial evidence base, sometimes supplemented by own searches
- 3-20 members, multidisciplinary scientific
- Produces evidence report with conclusions/ recommendations on (relative) effectiveness
- Public availability of reports variable

Appraisal

- Separate Pricing/Reimbursement Committees
- Discuss results of reports provided by assessment groups and formulate conclusions / give advice to final decision-makers or act as final decision-makers themselves
- Representatives of ministries, health care provider organisations (e.g. physicians and pharmacists), health insurers, representatives of patient groups, pharmaceutical industry
- Ad hoc consultations of external experts
- Closed doors policy, public availability of minutes variable

Conclusions

- Several similarities despite fundamentally different systems but no two systems with identical processes
- Coverage decisions likely to remain at national or regional level
- International collaboration beneficial for scientific assessment (EUnetHTA, INAHTA, HTAi)
- Increase in transparency is required

Thank you

for your time and attention!

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