



FORMULARY DECISION MAKING PROCESS IN FIVE COUNTRIES: IMPLICATIONS FOR SINGAPORE

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PURPOSE

As healthcare costs increase globally, striking a balance between societal affordability of healthcare with individual access to state-of-the-art life saving technology, including pharmaceuticals, becomes increasingly significant. Important policy issues are raised when national authorities establish procedures to determine which medicines to reimburse, at what price and for which patients. **The objective of this comparative analysis is to describe the process of drug formulary and reimbursement decisions in five countries and to discuss the implications for Singapore**

RESULTS

1. Initiation of the process

Manufacturer is main initiator

Clinician is main initiator

Allows for members of public / patient groups to initiate

2. Inputs into decisions

Assessment of information
Manufacturer main input

Review of published evidence

Expert opinion

No information available

3. Opportunities for public involvement

Public/ industry involvement is part of process

Public members/ consumer rep in appraisal committee

Industry given right of reply

No avenue to provide feedback

4. Transparency

Intermediate reports are publicly available

Formulary decisions are publicly available

No information wrt formulary decisions publicly available

METHODS

We reviewed the formulary decision process in five countries, United Kingdom [UK], Australia, Canada, Germany and Hong Kong and compared it to the process in Singapore. We focused on the following **aspects**:

1. Initiation of the process
2. Inputs into decisions
3. Opportunities for public and industry involvement
4. Transparency



Data collection involved:

- Reviewing the literature (searching with 'national formulary process', 'national drug reimbursement decision-making process', 'regulation drug reimbursement' in PubMed and Google Scholar resulted in 12 relevant articles)
- Accessing official websites of various healthcare authorities and various international institutes (such as OECD, WHO, European Commission etc.)
- Interviewing local and foreign experts

	United Kingdom ¹	Australia ²	Canada ²	Germany ³	Hong Kong ⁴	Singapore ⁵
Back-ground	<ul style="list-style-type: none"> National Institute for Health and Clinical Excellence (NICE) plays the biggest part in the drug review process NHS is legally obliged to fund medicines and treatments recommended by NICE 	<ul style="list-style-type: none"> Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to Minister for Health No product may be listed in Pharmaceutical Benefits Scheme in absence of recommendation by PBAC 	<ul style="list-style-type: none"> Common Drug Review (CDR) provides formulary listing recommendations to all Canadian publicly funded federal/provincial/territorial Drug Plans with exception of Quebec 	<ul style="list-style-type: none"> Federal Joint Committee (G-BA) decides if new pharmaceutical is categorized as innovative German Institute for quality and efficiency in healthcare (IQWiG) subsequently conducts assessment 	<ul style="list-style-type: none"> Hospital Authority (HA) Drug Advisory Committee (DAC) decides whether new drug can be listed in central formulary 	<ul style="list-style-type: none"> Pharmacoeconomics & Drug Utilization Unit in Health Sciences Authority (HSA) assists Drug Advisory Committee (DAC) DAC recommends Minister of Health which drugs to be listed
Initiation of the process	<ul style="list-style-type: none"> Potential topics come from: healthcare professionals, general public, DH, National Horizon Scanning Centre (NHSC) Manufacturers should contact the NHSC 	<ul style="list-style-type: none"> Industry sponsors, medical bodies, health professionals and private individuals can apply at PBAC For new products/indications, normally manufacturer will hold information required 	<ul style="list-style-type: none"> CDR is initiated by Manufacturer, Advisory Committee on Pharmaceuticals (ACP) or one or more Drug Plans, filing a submission with the CDR Directorate 	<ul style="list-style-type: none"> Physicians, organisations or sickness funds apply at the Federal Joint Committee (G-BA) G-BA or Federal Ministry of Health commissions a new assessment to IQWiG 	<ul style="list-style-type: none"> Clinicians, patient groups and industry can apply for listing at the HA Standard Drug Formulary Committee 	No information available
Inputs into decisions	<ul style="list-style-type: none"> Academic centre, commissioned by NICE, reviews published evidence Appraisal Committee considers report and comments on it and makes recommendations to NICE after hearing clinical experts, patients and carers 	<ul style="list-style-type: none"> PBAC assesses sponsors' information, incl review of literature PBAC may seek expert opinion from relevant professional bodies, including its Economics Sub-Committee and its Drug Utilisation Sub-Committee 	<ul style="list-style-type: none"> Review team formed by CDR conducts systematic literature search to supplement data provided by sponsor Based on review report Canadian Expert Drug Advisory Committee (CEDAC) makes common formulary listing recommendations 	<ul style="list-style-type: none"> Project group prepares literature review and scientific evaluation IQWiG prepares non-binding recommendations based on preliminary report and comments on it 	No information available	No information available
Opportunities for public and industry involvement	<ul style="list-style-type: none"> Consultees and commentators - groups representing patients, health professionals, manufacturers and research groups - can comment on report and preliminary recommendations, also available for health professionals and public to comment Consultees can appeal against final recommendations 	<ul style="list-style-type: none"> No explicit involvement of public, other than involvement of experts/specialists if requested by PBAC and composition of PBAC One member of PBAC is a consumer representative Where PBAC seeks opinions of external parties, sponsor is informed and given an opportunity to reply 	<ul style="list-style-type: none"> No explicit involvement of public But CEDAC has at least 2 public members out of 13 members Review reports are forwarded to Manufacturer for comments Manufacturers have right to file request for reconsideration of recommendation 	<ul style="list-style-type: none"> Formal procedure for submission of comments by all interested persons, institutions, or commercial enterprises exists Oral hearing can optionally be held. Only persons who have submitted written comments, can attend hearing 	No opportunities for public or industry involvement, during specific drug assessment process	No opportunities for public or industry involvement
Transparency	<ul style="list-style-type: none"> All intermediate consultation and evaluation documents and final decisions are made publicly available 	<ul style="list-style-type: none"> Positive/ negative recommendations as well as summary documents by product or PBAC meeting are published online 	<ul style="list-style-type: none"> Review reports and final recommendation with discussion are publicly available 	<ul style="list-style-type: none"> Reports by IQWiG are public documents, however reports do not include economic evaluations as yet 	Final formulary decisions are publicly available	No information publicly available on formulary decisions

CONCLUSION

Reimbursement decisions in Singapore are not made publicly available, whereas all countries reviewed publish their decisions online. Singapore has no mechanism for members of the public or industry to initiate a drug listing process, or to provide feedback on the outcomes. Singapore may want to further explore international models and analyze the level of adaptation possible in the local context.

1. Guide to the methods of technology appraisal, National Institute for Health and Clinical Excellence, April 2004; *Pharmaceutical Pricing and Reimbursement Information project*, United Kingdom, Commissioned by European Commission and the Austrian Ministry of Health, Family and Youth, June 2007. www.nice.org.uk.
 2. Guidelines for the pharmaceutical industry on preparation of submissions to the pharmaceutical benefits advisory committee, Commonwealth Department of Health and Ageing, September 2002; accessed June 2009
 3. *Pharmaceutical Pricing and Reimbursement Policies in Canada*, Valerie Paris and Elizabeth Docteur, OECD Health Working Papers, 2006; *Procedure for Common Drug Review*, Canadian agency for Drugs and Technologies in Health, April 2009.
 4. *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member states*, OBIG, 2006; website International Society for Pharmacoeconomics and Outcomes Research www.ispor.org/HTARoadmap/Germany.asp; *Assessment of benefit, Implementation of medical innovations in Germany*, Federal Joint Committee (G-BA), Jan 2007; Website Institute for Quality and Efficiency in Healthcare, www.iqwig.de/index-507.en.html, accessed August 2009
 5. *Review of Hospital Authority Drug Formulary Mechanism*, Hospital Authority, June 2006; Appeals and responses Legislative council: www.dh.gov.hk/english/legislative/legislatve_0708.html, accessed July 2009
 6. *Recent changes in the Healthcare Scene in Singapore*, Li Shu Chuen, ISPOR 2nd Asia Pacific Conference, March 2006