

Why pharmacoeconomics is needed

Steven Kayne reports from a session jointly organised by the Administrative Pharmacy Section and the Pharmacoepidemiology and Pharmacoeconomics Special Interest Group

Jean-Pierre Grégoire, professor and acting dean, faculty of pharmacy, Laval University Quebec City, Canada, outlined the general requirements for inclusion on a drug reimbursement list. These include (i) a clinical dossier giving a review of clinical studies as evidence of therapeutic benefit of the drug together with an estimate of the prevalence and direct costs contributing to the target disease burden, (ii) economic analysis from societal and payer perspectives, and (iii) a budget impact analysis for the payer based on marketing assumptions (eg, market size and expected growth).

Twenty-two authorities issued pharmacoeconomic guidelines to assist in providing the required data. However, it was difficult to provide economic evidence because of the assumptions that needed to be made and the lack of real data at the time of launch. The time from submission of dossier to reimbursement decision varied among national authorities from at product launch in Germany and the UK, at four to six months in France and at three to nine months in Canada. Professor Grégoire reported on work he had carried out with collaborators that showed wide variation in Canadian inter-provincial agreement in formulary listing.

He said there were also sources of variation in the way in which price agreements were negotiated. The UK and Germany enjoyed a free market while in France, Italy and Canada the authorities used a method that fixed prices based on the prices charged in other countries. The reimbursement process varied — in Australia, France and Sweden drug costs were paid nationally while in Germany and the UK they were paid locally.

"Biggest bang for your buck"

The topic of pharmacoeconomics was explored by Brenda Waning, assistant professor of international health, Boston University, in her presentation entitled "Cost-effectiveness analyses in national insurance schemes and national essential medicine lists". Ms Waning defined pharmacoeconomics as being "a set of analytical tools that can help you identify which of several alternatives offers the greatest benefit compared with the cost and thus facilitate drug supply management". She explained that it is necessary to use pharmacoeconomics in the medicine selection process to ensure that "you get the biggest bang for your buck", to provide a tool for policy makers and administrators to balance competing public health priorities, and to introduce transparency and formal process into a system vulnerable to outside influences.

Ms Waning said that pharmacoeconomic analyses (PEAs) should be viewed critically as

they are potentially subject to modeling errors (clinical assumptions, inaccurate cost estimates and calculations). Further, many countries using PEAs in insurance systems still have high prices. Drug utilisation review, prescribing restrictions, prior approvals and generic promotion are still needed for cost containment. PEAs should be considered in context.

Ms Waning then discussed the extent to which cost-effectiveness analysis (CEA) had been incorporated in the developed world and compared this with its use in developing and traditional country settings. She said that limited resources for medicines purchase require cost considerations to be made at national, facility, practitioner and consumer levels of health care. CEA has been widely used by policy makers in many developed countries to guide decisions about medicines coverage. However, in many developing countries where resources are highly constrained, CEA is not being adequately used for decision making associated with national essential medicine lists and national medicines insurance schemes (NMISs). They are being created in a vacuum without any consideration of the budget available to treat populations or of household affordability. Many essential medicines are unavailable or unaffordable. For example, before development of an NMIS reimbursement list in Kyrgyzstan, CEA was carried out to predict

which medicines would be most cost-effective. But, the analysis was not conducted with reference to available funds and the scheme could not afford to supply all medicines to all people enrolled in it. In Kazakhstan, a list of approved medicines was created using projected costs based upon disease prevalence. PEA was not part of the original selection process, or part of decision making for expanding the list. In many developing countries few people have the skills to apply PEA techniques and inadequate efficiency data are available.

Industry's view

David Andersson, director of government affairs, AstraZeneca, presented the industry view on country variability in pharmacoeconomic analyses. According to the European Federation of Pharmaceutical Industries and Associations (EFPIA) transparency is the most important demand from the pharmaceutical industry in relation to reimbursement decisions. The relative value of the criteria used for assessment should be clearly stated. Cost-effectiveness seems to be dominated by clinical effect and budget impact, he said. If quality of life measures are used, it is important to know the limit for an accepted cost. How much is society willing to pay for maintaining quality of life? The industry believes in real competition and PEA is not wholly consistent with this view. "The prices of medicines should reflect the value of products and reward innovation," he said.

Mr Andersson added that temporary uncertainty as to the full therapeutic value of a new product should be allowed while data are being collected; the EFPIA wants no delay in the introduction of innovative medicines. Patients should also have input to reimbursement decisions for new drugs. He cited some examples of how assessment agencies worked (see Panel).



Assessment around the world

- **Sweden** The Pharmaceutical Benefits Board issues general guidelines for economic evaluation and recommends the quality-adjusted life year as a measure of cost-effectiveness. Comparisons with the most appropriate alternative treatment are required.
- **England and Wales** The National Institute for Health and Clinical Excellence identifies best practice using best available evidence, assesses cost-effectiveness and whether products add value to health care.
- **Germany** The Institute for Quality and Efficiency in the Health Care System receives appraisal requests from either the Federal Ministry of Health or the Joint Federal Committee. It formulates research questions, determines targets and produces reports.
- **The Netherlands** Assessments are made by the advisory committee of the Health Care Insurance Board. The QALY is preferred as an outcome measure.
- **France** The Commission of Transparency assesses product value, patient group volume, therapeutic alternatives, budget impact and other costs. There is a lack of transparency and it is difficult to forecast the time taken to reach a decision.