Journal of Health Policy & Outcomes Research
ISSN 2299-1247
jhpor, 2012, 1, 29-38
DOI: 10.7365/JHPOR.2012.1.7

Decision-making processes related to drug pricing and reimbursement. Is Poland far away from global standards?

Robert Kranc
Polish Society of Pharmacoeconomics, ISPOR Polish Chapter, Section of Health Technology Assessment School of Medical Science in Białystok

Marcin Czech
Department of Pharmacoeconomics, Warsaw Medical University Polish Society of Pharmacoeconomics, ISPOR Polish Chapter, Board of Directors

Abstract

A substantial funding from healthcare budgets in the majority of countries is devoted to drugs. In order to make the best use of these scarce public resources, special agencies were established in order to assess efficacy, effectiveness, safety and cost-effectiveness of drugs. Based on their recommendations decisions regarding pricing and reimbursement are made coupled with guidelines for prescribers. Decisions of four agencies: Common Drug Review (CDR) from Canada, the National Institute for Health and Clinical Excellence (NICE) from the UK, Pharmaceutical Benefits Advisory Committee (PBAC) from Australia, Polish Agency of Health Technology Assessment (AOTM) were analysed and compared, main difficulties and controversies of decision making process were discussed. Two case studies were added for more detailed analysis.

Key words: medical decision making, health technology assessment, Polish Agency of Health Technology Assessment, HTA

Introduction

Drug expenditure consumes a substantial proportion of funds allocated to health care in numerous countries in Europe and elsewhere, and this pool seems to grow each year. This trend is observed, among others, in Canada [1, 2], the UK [3], Australia [4] and the US [5, 6], where federal expenditure on the Medicaid and Medicare Part D is expected to total $4,299 billion within the next four years. The situation is similar in Poland, where according to recent reports the pharmaceutical market will be worth almost PLN 31 billion in 2011 in retail prices [30].

In order to control drug spending and assess new medicines, special agencies assisting in reimbursement decisions have been established in a number of countries, particularly National Institute for Health and Clinical Excellence (NICE) in the UK [8-11], Pharmaceutical Benefits Advisory Committee (PBAC) in Australia [12-14] and Common Drug Review (CDR) in Canada [15, 16]. In Poland, this role is performed by the Agency for Health Technology Assessment (Agencja Oceny Technologii Medycznych – AOTM). It is an institution established by the Minister of Health to develop reports related to assessment of health care services. Its duties include formulating recommendations on the inclusion of health care services into the list of guaranteed benefits, delisting of benefits and change of the level or the manner of providing or financing of benefits.

In the first part of this paper the structure and rules of operation of these four agencies will be presented. Then, their recommendations for selected medicines will be analysed retrospectively to identify the values and decision points as well as additional factors accounted for by NICE, PBAC, CDR and AOTM in their decisions. The selection of agencies reflects the fact that the decisions of all of them are based on the evidence of clinical efficacy and cost effectiveness and that they all publish information about their decisions in English.

Commmon Drug Review

The health care system in Canada is a universal system based on financing from public funds, though access to some drugs varies across provinces and territories. Each province has its own drug

financing plan and its own specific guidelines on drug reimbursement. In 2002, the federal government, heads of provinces and the Ministry of Health, concerned with notable differences in reimbursement of drugs and, consequently, access to medicinal products, established the Common Drug Review (CDR) process [15]. Each manufacturer wishing to have a new drug added to reimbursement lists has to submit both clinical efficacy and cost effectiveness data for such a drug in the CDR process. CDR determines whether the given drug should or should not be reimbursed and defines the criteria for and the rate of reimbursement. Each CDR opinion, which contains a recommendation and presents the budget impact of funding, constitutes the basis for a decision whether the drug will be listed and reimbursed. In addition to the CDR process, manufacturers are required to submit their reimbursement dossiers to the Canadian Expert Drug Advisory Committee (CEDAC). It is an independent nationwide body which consists of eleven experts (physicians, pharmacists, health care research specialists and experts in health economics) and, since 2006, two public representatives unrelated to medical science. The Committee formulates its own recommendations on drug reimbursement and its rate. About 90% of reimbursement decisions in Canada are in agreement with these recommendations [2]. There is also the Patented Medicines Prices Review Board (PMPRB), a federal government agency which was established in 1987 by the Parliament to assure general access to medications through price- related regulations. PMPRB sets the maximum price which may be charged for a patented medicine, taking into account the price of the drug in the given market, the prices of other drugs from the same therapeutic class in the given market, the prices of the given drug and other drugs from the same therapeutic class in other countries as well as the Consumer Price Index (CPI) [17].

Once a drug is placed on the market, the manufacturer has to submit initial price data to PMPRB, which carries out a price review in line with the PMPRB Excessive Price Guidelines. The PMPRB's Human Drug Advisory Panel (HDAP) reviews the evidence of the clinical efficacy of the given medication and decides whether it is a breakthrough in medicine or a substantial improvement in treatment of a particular disease (a category 2 drug), a new active substance which brings a moderate or no advance (a category 3 drug) or a new molecule from a group of well-known medicines (a category 1 drug). PMPRB collects data and then determines the actual average sale price of each product. Prices of category 2 drugs are capped by the maximum price which is determined on the basis of the current prices within the same therapeutic class in Canada or on the basis of the mean price of the same drug in seven reference countries, namely UK, US, France, Germany, Switzerland, Sweden and Italy. The prices of category 3 drugs are generally capped at the maximum prices of comparable medicines in the same therapeutic class, if any; otherwise, they may be capped at international mean prices. Prices of any patented drugs cannot exceed the international maximum prices. If a price exceeds the one determined by PMPRB, the manufacturer has the right to submit additional evidence to support the higher price it charges. If the price remains unacceptable to PMPRB, the manufacturer may reduce it voluntarily or the case is referred to court. PMPRB monitors mean sale prices of drugs, updating the data every six months. Drug prices in Canada seem close to European mean prices and are much lower than those charged in the US [17].

The National Institute for Health and Clinical Excellence

In the UK, there is a public health care system as well as a free market in terms of drug prices. There is also a small private health care system parallel to the public one. Formally, the prices are determined by drug suppliers. The government administration, however, has some mechanisms to control its expenditure, e.g. through negotiations with manufacturers and distributors on their profit margin on drug sales. The ministry sets the profit ceiling and if it is exceeded the difference is paid back by pharmaceutical companies. Thus, the British system provides for upper (as well as lower) constraints for company's profits without differentiating prices depending on the therapeutic value of drugs. In theory each registered product is added to the reimbursement list, though in fact a lot of physicians refrain from prescribing it, while awaiting a recommendation by the National Institute for Health and Clinical Excellence (NICE).

NICE was set up in 2005 to formulate nationwide guidelines for health promotion and develop effective methods of prevention and treatment.

The Institute assesses the clinical efficacy and cost effectiveness of various therapies and formulates recommendations based on this appraisal. The recommendations are then used by the National Health Service and communicated to the medical community. NICE also aims to ensure that every citizen has equal access to high quality care and medical procedures. Currently, the organisation is the world's leader in setting norms and standards regarding high quality medical services as well as an important source of guidelines adopted worldwide [18]. NICE's recommendations provide the basis for negotiations under the Pharmaceutical Price Regulation Scheme (PPRS). NICE's decisions concern both the clinical efficacy / cost effectiveness and the budget impact of particular medicines or health technologies [19]. Medicines are available to virtually all people living in the UK who are covered by the National Health System (NHS), except for preparations which have not been appraised by NICE; for them, decisions are made on the local level and may differ from one region to another. NICE evaluates drugs according to specific clinical issues selected by the British government. Typically, the whole class of drugs is assessed during a single review in a multiple technology assessment procedure [10].

Pharmaceutical Benefits Advisory Committee

Australia also has a public health care system with a parallel small private care system. All Australian citizens have access to medicines under the Pharmaceutical Benefits Scheme (PBS). The manufacturer of a medicine submits an application for a recommendation to the Pharmaceutical Benefits Advisory Committee (PBAC). This is an independent body set up in 1953, which makes its recommendations and offers advice to the Ministry of Health on drug reimbursement. PBAC carries out assessment of the clinical efficacy and costs vs. alternative treatments and, since 1993, also the cost effectiveness analysis. PBAC submits its recommendations to the Ministry of Health and Ageing as to medicines, procedures or medical devices which should be subsidised by the Australian government. The Minister of Health refrains from listing particular drugs until positive recommendations are made by PBAC. PBAC receives advisory information from its sub-committees, namely on cost effectiveness from the Economic Sub-Committee and on utilisation and financial forecasts from the Drug Utilization Sub-Committee.

The Australian system is referred to in a number of studies as one of the best health care systems in the world, as it provides for universal and affordable access to high quality medical care, pharmaceuticals and hospital services. Its priority is to assist in maintaining people's healthy lifestyle through active lifestyle promotion and disease prevention. The responsibility for health care is split between the federal and state governments. 70% of health care costs are financed by the government (namely 47% by the federal government and 23% by state authorities), while 30% comes from sources such as insurance systems or private charges. As much as 8.5% of Australia's Gross Domestic Product is spent on health care. Health technology appraisal is carried out, inter alia, by the Adelaide Health Technology Assessment (AHTA), which is part of the University of Adelaide Discipline of Public Health. This team consists of sixteen members, including experts in clinical epidemiology, public health, psychology, pharmacy, medicine, health economics, biostatistics and bioethics. AHTA performs systematic reviews of medical technologies, interventions and procedures, then produces guidelines to provide a rational basis for health care decision-making. AHTA's tasks include medicinal product assessment, vaccine research, health care assessment and research and development of new guidelines related to these issues [20].

Agency for Health Technology Assessment

A medicine seeking reimbursement from public funds in Poland is subject to the appraisal by the Agency for Health Technology Assessment (AOTM). AOTM assesses the applications based on guidelines of January 2010, which are available at the Agency's website [www.aotm.gov.pl]. The Health Technology Assessment (HTA) Guidelines are a set of information guiding the work of AOTM's analysts, which has been developed for conducting transparent analyses summarising health, social, economic and ethical data for particular medical technologies. The Agency's activity is based on scientific evidence, which, for example, demonstrates whether a medicine is effective and safe for patients. This information is necessary in a process of making decisions which shape the health policy of the

state. Complete assessment includes clinical efficacy analysis, economic analysis and analysis of health care system impact. Medical technology assessments constitute the basis for recommendations made by the independent Consultation Council, which has been recently replaced by the Transparency Council, on financing of health services. Taking into account all recommendations by the Consultation Council, 64.5% of them were in agreement with inclusion or non-inclusion to lists of reimbursed drugs, the list of therapeutic health programs or the catalogue of active substances used in chemotherapy. This figure increases to 69.7% for the relation between Council's recommendations on financing of particular medications and the presence of their active substances on reimbursed drug lists [31].

Each opinion of the AOTM Consultation Council regarding financing or non-financing of pharmaceuticals or medical technologies is disclosed to the public. Recommendations are always supported by the rationale and the manner of their development is indicated. The relevant documents describe a health program, the current standard treatment and the analysis of the proposed treatment and its efficacy and safety. In addition, the costs of treatment and its budget impact are presented. Finally, the references used by AOTM's analysts are listed.

Data Sources and uncertain variables in reimbursement decisions

In our analysis we have used data for reimbursement decisions made by CDR, NICE and PBAC, which have been collected by Clement et al. [21]. The time frame was from July 2005 (for PBAC), February 2001 (for NICE) or January 2004 (for CDR) to December 2008. The information regarding ultimate decisions made by the agencies whether to issue a recommendation or not has been gathered. Three categories of outcomes have been considered, namely listing, listing with criteria and non-listing. In order to present the committees' decisions in the clinical context and in line with previous studies [12], it has been indicated whether recommendations concerned life saving/maintaining drugs (less than 50% mean five-year survival rate) or drugs aimed at life extension and/or quality-of-life improvement, or whether other options related to specific conditions were taken into account. In addition, we have collected data on primary end-points in the relevant studies, namely clinical end-points (e.g. death, MI), clinical scales used (e.g. American College of Rheumatology 20% improvement criteria (ACR20) in rheumatoid arthritis) [22] and surrogates (e.g. BP changes, changes in parathyroid hormone levels, etc.) [23, 24]. We have focused on the issues indicated as doubtful in the assessment by the committees; these has been defined as clinically and economically uncertain (no, little or considerable uncertainty). Considerable uncertainty occurred in cases when efficacy data had been based on non- randomised clinical trials, wrong comparators had been used in randomised trials or intermediate end-points (surrogates) had not been validated. Economic uncertainty occurred in cases when structural irregularities in the economic model applied had been found or the cost effectiveness assumptions had been completely different from the assessing body's point of view.

Furthermore, to illustrate similarities and differences between CDR, NICE, PBAC and AOTM in a qualitative manner, two medicines assessed by all four agencies have been chosen for case studies. We have analysed various key problems faced in evidence analysis as well as the influence on reimbursement decisions of the data evaluation process itself. The case studies concerned (i) ranibizumab, an injection solution used in age-related macular degeneration (AMD) to improve affected vision and/or prevent further vision loss, and (ii) teriparatide, a medicine used in osteoporosis treatment in post-menopausal women as well as men at a high risk for fracture. AOTM's decisions have been analysed separately. The analysis has covered recommendations made in 2009 and 2010.

Analysis of results

In the analysed period, CDR reviewed 121 applications (114 new submissions and 7 re-submissions), while PBAC reviewed 282 applications (207 new submissions and 75 re-submissions). NICE conducted assessments of 144 health technologies, out of which 47 have been excluded as not concerning drugs; hence, we have considered 97 applications, which covered 199 medicines (184 new drugs and 15 re-submissions). The characteristics of applications reviewed by the agencies are presented in the Table 1. Note a high number of applications re-submitted upon previous rejection which were received by PBAC: as much as 75 out of 282 applications, or 26.6%, were re-submissions (with narrower medical indications or reduced price).

Table 1. Basic characteristics of all submissions to CDR, NICE and PBAC (RCT – randomised clinical trial, CDR – Common Drug Review (Canada), NICE – National Institute for Heath and Clinical Excellence (UK), PBAC – Pharmaceutical Benefits Advisory Committee (Australia) after Clement FM et al. [21]

Characteristics	CDR n=121	NICEn=199	PBACn=282
Re-submission	7	15	75
Life-threatening disease (≤50% survival rate)	22	38	70
Purpose of Drug Treatment			
1. Quality-of-life improvement	56	90	116
2. Life extension	14	60	63
1. & 2.	51	49	103
Clinical Uncertainty			
No	14	39	38
Little	57	105	121
Considerable	50	54	123
Clinical Evidence Weight			
RCT with a right comparator	95	169	201
RCT with a wrong comparator	23	20	55
No randomised trials	3	10	26
Study End Points			
Clinically significant end points	56	90	116
Clinical scales	14	60	63
Surrogates	51	49	103
Invalid surrogates	51	49	103
Drugs for which it is necessary to determine QALY/Cost per QALY in order to make a decision	73	192	203
Cost-effectiveness Data			
Cost minimisation analysis	43	13	88
Cost-effectiveness analysis	17	15	55
Cost-utility analysis	55	171	138
Cost-consequence analysis	6	0	1
Economic Uncertainty			
No	4	16	20
Little	28	86	65
Considerable	41	90	118

Table 2. AOTM's decisions in 2009–2010. (Yes – financing; No – non-financing)

Year	Number of Decisions Communicated on AOTM's website	Yes	No	Listing with Criteria	Temporary Listing	Rationale for the Decision
2009	66	16	25	21	4	1. Part of health program 2. Provided that a price ceiling is set 3. Provided that it becomes a guaranteed benefit 4. Provided that cost-effective financing with a set price ceiling lower than the cheapest drug from the same group is introduced 5. Provided that a common therapeutic group is established with a price ceiling at the cheapest drug from the group 6. Upon a significant reduction in drug cost within a therapeutic health program 7. Temporarily, e.g. for a period of two years 8. In centres specialising in treatment of the disease and upon price reduction 9. Provided that the treatment cost close to the cost-effectiveness level recommended by WHO is achieved
2010	15	2	11	1	1	1. Temporarily, e.g. for a period of three years 2. Provided that a common price ceiling is set

As the table shows, a key element and a condition for AOTM's positive recommendation is the price, for which a ceiling should be set within the given group of drugs; the condition is a significant reduction in a price within the given therapeutic group (the price ceiling is set at the cheapest drug within the group). A medicine may obtain a temporary listing recommendation e.g. for a two-year period, after which a new opinion by AOTM is required. Medicines used to obtain positive recommendations if they were to be used in centres specialising in treatment of the disease and provided that the treatment cost close to the cost- effectiveness level recommended by the World Health Organization could be achieved.

Problems with clinical efficacy and cost data

Over 40% of all submissions reviewed by CDR and PBAC involved considerable clinical uncertainty, which was much frequent compared to NICE with uncertainty at 27.3% or 54/ 199 (p=0.009).

This is most likely attributed to the fact that NICE evaluates groups of drugs with a longer record in the market, which enables better assessment. Twenty six out of 121 submissions reviewed by CDR (or 21.7%) and 81 out of 282 submissions reviewed by PBAC (or 28.8%) were based on non-randomised clinical trials or randomised trials with a wrong comparator. Very frequently, surrogates were the primary end-points of clinical studies. The estimation of the cost-per-QALY (cost to quality adjusted life years) ratio is required in case of analyses conducted by NICE. The fact that this ratio needs to be determined to make a decision was reflected in economic uncertainty, which stood at 46.1% (90/192), 58.2% (118/ 203) and 55.7% (41/73) for submissions reviewed by NICE, PBAC and CDR, respectively. Note the fact that considerable economic uncertainty was often based on clinical uncertainty (57/245 or 23.4% of cases). This demonstrates the crucial importance of quality clinical evidence in drug-related decisions [21].

NICE made positive recommendations for 87.4% (174/199) of submissions as compared to 49.6% (60/121) listing recommendations issued by CDR and 54.3% (153/282) by PBAC. The listing rates were lower for CDR and PBAC in case of considerable clinical and economic uncertainty, but higher if proper clinical end points had been used. The list of decisions issued by NICE does not seem related to the existence or non-existence of economic uncertainty, which might indicate the identification of subgroups for which this uncertainty may be lower and the cost-utility ratio may be more acceptable. There is some evidence for the threshold range in decisions made by particular agencies, though some medicines obtained positive decisions despite exceeding it. Thirteen submissions (namely 4, 8 and 1 for CDR, NICE and PBAC, respectively) were rejected for the proposed patient populations as a result of economic assessment, yet recommended for more limited subpopulations in which the cost-per-QALY was higher (owing to higher efficacy of drugs and reduced costs in such subpopulations). For 66 submissions which involved considerable economic uncertainty (namely 7, 6 and 53 for CDR, NICE and PBAC, respectively), the listing rates were 28.6% (2/7), 66.6% (4/6) and 3.8% (2/ 53) for CDR, NICE and PBAC, respectively. In 91 cases, the same drug was assessed for the same indications by more than one of these agencies. Note a low consistency rate for recommendations formulated by CDR vs. PBAC (k=0.27) and NICE vs. PBAC (k=0.13) and a moderate consistency rate for recommendation decisions made by CDR vs. NICE (k=0.55), full consistency being at k=1. For 19 medicines assessed by all three agencies, the listing rates stood at 52.6% (10/19), 84.2% (16/19) and 73.6% (14/19) for CDR, NICE and PBAC, respectively. Furthermore, we have conducted qualitative analysis of the most frequent recommendation discrepancies between the agencies. NICE always looked for narrow niches of small patient populations in which drugs could be used and recommended them for such populations, while PBAC used price negotiations in order to ensure cost effectiveness and adopted a different approach to listing drugs in the given therapeutic class. CDR was reluctant to list subsequent, me-too drugs from the given group, whereas PBAC followed a cost minimisation policy by making use of price competitiveness of new drugs.

Ranibizumab

Each agency has recommended reimbursement of this medicine in age-related macular degeneration (AMD). Clinical data from randomised trials with a right comparator had demonstrated that ranibizumab reduced the risk of blindness incidents in AMD patients. Despite high cost, the drug clearly improved the quality of life (considering the effects of blindness). Each agency has set a reimbursement ceiling for the drug, shifting a portion of expenses onto the manufacturer. Initially, in February 2008, ranibizumab did not obtain a positive recommendation of AOTM on its financing in treatment of patients with exudative age-related macular degeneration. However, upon another application, the medicine obtained a listing recommendation in treatment of neovascular (oxidative) AMD, though the active substance was not included in the list of therapeutic health programs.

Teriparatide

Each agency has admitted that there was a significant reduction in the risk of vertebral and non-vertebral fractures vs. placebo. However, they all have agreed that biophosphates would have been a more proper comparator in randomised trials. CDR and PBAC have also pointed out to lack of clinical trials in patients with intolerance to biophosphates or patients continuing biophosphate treatment

despite recurrent fractures, who could get additional benefits from treatment with other medicines. Considering the clinical uncertainty, high costs and non-acceptable results of the cost-effectiveness analysis, CDR and PBAC have not included teriparatide into recommendation lists. NICE has been of opinion that the use of this medicine will be cost-effective in a small subpopulation of patients with severe osteoporosis in whom biophosphates have failed to bring improvement, and recommended teriparatide for this subpopulation.

In 2008, AOTM decided not to recommend financing of teriparatide; the active substance was not included into the list of therapeutic health programs or the catalogue of active substances used in chemotherapy.

Discussion

NICE, CDR and PBAC are institutions which consider both the efficacy/safety and cost-effectiveness of drugs in their listing decisions. While analysing their reimbursement decisions, we have noted some differences concerning various drugs and their subgroups. It is not surprising, considering the differences in the decision-making processes adopted by these agencies. Moreover, differences in decisions resulted less from interpretation of evidence for the clinical or economic effectiveness than from discrepancies in the evaluation process itself, which might reflect differences in the range of risk factors analysed, including search for drugs with quality evidence for clinical efficacy and cost-effectiveness or the importance of competitive drugs in the evaluation process.

The Australian system allows manufacturers to submit applications an unlimited number of times, while changing the price, indication and related evidence. If we consider only the latest attempts for drugs which have been previously rejected in the given indication, the listing rate for PBAC increases to 62%, which seems to suggest that re-submission actually influences the agency's decision-making process. This was also the case with teriparatide, as in the process of final acceptance both the more restrictive indications and lower price were considered. Modified re-submissions are also nothing unusual in Canada, even though more strict re-submission criteria have been adopted and no price negotiations are possible there. There is a growing role of risk-sharing in decision-making processes, especially in Australia, to minimise uncertainty related to both financing base and cost-effectiveness. According to some previous studies, the agencies accounted for varying quality of evidence provided by manufacturers wishing their drugs to be listed [14,25,26], particularly in terms of the quality of experimental studies provided to support the clinically significant effect. While all agencies noted problems with quality and validity of economic data, each of them attempted to solve them in a different manner. NICE used independent economic analyses, while CDR conducted its own sensitivity analysis. PBAC adopted an organised approach to presentation of clinical and economic evidence, focusing on the process of translating clinical data into cost-effectiveness evidence.

This analysis has certain limitations. The NICE and PBAC data are based exclusively on the information in the public domain. Despite the fact that extensive summaries are disclosed to the public, some issues may remain unnoticed, particularly those related to the manner of proceeding, while other aspects, e.g. related to risk-sharing instruments, are confidential. Another limitation is the fact that only a small number of drugs have been assessed by all three agencies, which makes comparisons between them less clear. This is partly reflected in the fact that, unlike other agencies, NICE can chooses which drugs or groups of drugs should be reviewed and in which situations, whereas, notably, CDR has not reviewed drugs used in chemotherapy since 2007. Finally, considering the variety of medicines and the ways of their financing, statistical analysis of the grounds for positive or negative decisions has not been possible. The results seem to indicate that there are some differences in using the information on clinical efficacy and cost-effectiveness in the decision-making process, but further research is required to identify their causes.

Although this study does not provide a direct answer to the question whether the existence of these three agencies improves the health care efficiency, some previous studies have demonstrated that the Australian system, which is based on a policy of price reductions (prices lower than in 38 comparable prices) without compromising on public health, provides for improved quality of activities in this area [27].

What conclusions can be drawn from the analysed material which could be useful for people making

reimbursement decisions in the health care sector, particularly in countries where health technology assessment has not become the golden standard in reimbursement procedures yet? Firstly, the existence of these four agencies confirms that it is possible to set up an institution responsible for comparing the efficacy and cost-effectiveness of pharmaceutical products seeking reimbursement. While cost-effectiveness analysis is not required for all drugs, cost data are critical in the cases where it is necessary to provide information on the quality to price ratio. Secondly, the existing differences between agencies in the decision-making processes demonstrate that these may be adapted to local health care conditions. In fact, the key element of sustained development of these agencies seems to be their ability to adapt to national decision-making processes [28,29]. As demonstrated by the case study of ranibizumab, cost-effectiveness analyses do not have to be a barrier for financing of even expensive drugs, if there is strong evidence for their efficacy at least in some patient subpopulations or there are other factors apart from simple cost-and-benefit statements [11]. Moreover, decision-makers do not necessarily have to make simple dichotomic reimbursement decisions, as a medicine may be reimbursed for a specific subpopulation in which it is considered cost-effective or may be included in a patient co-payment list. The most frequent reason for the Agency for Health Technology Assessment to recommend non-financing of medicines was excessive cost or lack of sufficient hard clinical evidence to support the drug efficacy. Other grounds for non-financing decisions included drug failure to bring new quality to treatment or excessive discrepancies in the reliability of scientific evidence. Another reason for negative decisions was high incidence of adverse reactions reported during clinical trials. The Council often recommended financing of such drugs exclusively within a new health program or in a newly established therapeutic group. According to its members, in case of subsequent me-too drugs, a cost-effective method of financing with a price ceiling lower or equal to the price of the cheapest drug from the same group should be proposed. Decisions were often issued for two or three years and upon expiration of this period another recommendation was made. The materials provided by applicants, including the Summary of Product Characteristics, for medicinal products seeking inclusion into the reimbursement scheme were analysed and experts in the relevant area were consulted. Very frequently, AOTM would modelled its activities on the Canadian or Australian system; in some specific cases, NICE's opinions on drugs were used. AOTM's commitment to follow in the footsteps of the most experienced HTA bodies seems the right option, which will provide for more efficient use of limited health care resources in Poland.

References:

1. Canadian Institute for Health Information. Drug Expenditure in Canada, 1985 to 2006. Ottawa, ON: Canadian Institute for Health Information; 2007.

2. Canadian Agency for Drugs and Technologies in Health. CADTH Presentation on the Common Drug Review to the House of Commons Standing Committee on Health. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health; 2007.

3. Duerden M, Gogna N, Godman B, Eden K, Mallinson M, Sullivan N. Current national initiatives and policies to control drug costs in Europe: UK perspective. J Ambul Care Manage. 2004; 27(2):132-138.

4. Health expenditure Australia 2006-07 [Health and welfare expenditure series No. 35]. Australian Institute of Health and Welfare. http://www.aihw.gov.au/publications/index.cfm/title/10659. Accessed September 10, 2009.

5. Poisal JA. Medicaid drugs. Health Care Financ Rev. 2004; 25(3):1-4.

6. Sales MM, Cunningham FE, Glassman PA, Valentino MA, Good CB. Pharmacy benefits management in the Veterans Health Administration: 1995 to 2003. Am J Manag Care. 2005;11(2):104-112.

7. The budget and economic outlook: fiscal years 2009 to 2019. Congressional Budget Office. http://www.cbo.gov/ftpdocs/99xx/doc9957/toc.htm. Accessed September 3, 2009.

8. Collier J. Parliamentary review asks NICE to do better still. BMJ. 2008;336(7635):56-57.

9. Miners AH, Garau M, Fidan D, Fischer AJ. Comparing estimates of cost effectiveness submitted to the National Institute for Clinical Excellence (NICE) by different organisations: retrospective study. BMJ. 2005;330(7482):65.

10. Morgan SG, McMahon M, Mitton C; et al. Centralized drug review processes in Australia, Canada, New Zealand, and the United Kingdom. Health Aff (Millwood). 2006;25(2):337-347.

10. Steinbrook R. Saying no isn't NICE: the travails of Britain's National Institute for Health and Clinical Excellence. N Engl J Med. 2008; 359(19):1977-1981.

12. Harris AH, Hill SR, Chin G, Li JJ, Walkom E. The role of value for money in public insurance coverage decisions for drugs

in Australia: a retrospective analysis 1994-2004. Med Decis Making. 2008; 28(5):713-722.
13. Henry DA, Hill SR, Harris A. Drug prices and value for money: the Australian Pharmaceutical Benefits Scheme. JAMA. 2005; 294(20):2630-2632.
14. Hill SR, Mitchell AS, Henry DA. Problems with the interpretation of pharmacoeconomic analyses: a review of submissions to the Australian Pharmaceutical Benefits Scheme. JAMA. 2000;283(16):2116-2121.
15. Tierney M, Manns B, Members of the Canadian Expert Drug Advisory Committee. Optimizing the use of prescription drugs in Canada through the Common Drug Review. CMAJ. 2008;178(4):432-435.
16. McMahon M, Morgan S, Mitton C. The Common Drug Review: a NICE start for Canada? Health Policy. 2006;77(3): 339-351.
17. http://www.pmprb-cepmb.gc.ca/english/home.asp?x=1. Accessed July 7, 2011.
18. http://www.nice.org.uk. Accessed August 7, 2011.
19. Czech Marcin. Farmakoekonomika jako narzędzie zarządzania w gospodarowaniu lekami w Polsce. Instytut Przedsiębiorczości i Samorządności. Warsaw 2006.
20. http://www.adelaide.edu.au/ahta/whatwedo. Accessed August 10, 2011.
21. Clement FM, Harris A, Li JJ, Yong K, Lee KM, Manns BJ. Using effectiveness and cost-effectiveness to make drug coverage decisions: a comparison of Britain, Australia, and Canada. JAMA. 2009 Oct 7;302(13):1437-43.
22. American College of Rheumatology Committee to Reevaluate Improvement Criteria. A proposed revision to the ACR20: the hybrid measure of American College of Rheumatology response. Arthritis Rheum. 2007;57(2):193-202.
23. Fleming TR, DeMets DL. Surrogate end points in clinical trials: are we being misled? Ann Intern Med. 1996;125(7): 605-613.
24. Manns BJ, Owen WF Jr, Winkelmayer WC, Devereaux PJ, Tonelli M. Surrogate markers in clinical studies: problems solved or created? Am J Kidney Dis. 2006;48(1):159-166.
25. Hill S, Henry D, Mitchell A. Problems in pharmacoeconomic analyses. JAMA. 2000;284(15):1922-1924.
26. Chalkidou K, Tunis S, Lopert R, Rochaix L, Sawicki PT, Nasser M, Xerri B. Comparative effectiveness research and evidence-based health policy: experience from four countries. Milbank Q. 2009; 87(2):339-367.
27. International pharmaceutical price differences: research report [2001]. Australian Government. http: //www.pc.gov.au/projects/study/pbsprices/docs/finalreport. Accessed September 3, 2009.
29. National Institute for Health and Clinical Excellence. First Report of the Health Committee 2007-2008.London, United Kingdom: Stationary Office; 2008.
30. Williams I, Bryan S, McIver S. How should cost effectiveness analysis be used in health technology coverage decisions? Evidence from the National Institute for Health and Clinical Excellence approach. J Health Serv Res Policy. 2007;12(2): 73-79.
30. Electronic access: http://www.egospodarka.pl/64189,Rynek-farmaceutyczny-w-Polsce-2011-2013,1,39,1.html
31. www.mz.gov.pl. Accessed March 20, 2012.