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The politics of health technology assessment in Poland

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ABSTRACT

Objective: First, to identify risks associated with the scientific evaluation of drugs considered for state reimbursement in Poland through exploring strategies of influence employed by multinational drug companies in relation to the Agency for Health Technology Assessment (AHTAPol). Second, to ascertain whether the outcomes of drug evaluation meet the interests of the public payer in reimbursing cost-effective drugs supported by robust pharmacoeconomic evidence.
Methodology: We conducted 109 in-depth semi-structured interviews with a purposive sample of stakeholders involved in the reimbursement process in Poland. We analysed four available documentary sources, including recommendations issued by the AHTAPol.
Results: AHTAPol recommendations were an instrumental part of the blame avoidance strategy by political elites. Drug producers utilised direct and indirect strategies of influence. The direct strategies involved building relationships with a circle of health technology assessment analysts and medical experts working for the Agency. The indirect strategies employed leaders of opinion in the medical milieu, patient organisations, and political elites to endorse policy positions favourable to drug companies. The AHTAPol positively recommended an increasing proportion of the drugs it assessed, many of them reported as not cost-effective or supported by dubious pharmacoeconomic evidence.
Conclusions: The strategies of influence entail a number of risks that may undermine the scientific evaluation of drugs. Some outcomes of drug evaluation may favour the interests of multinational drug companies over those of the public payer. We suggest that the risks involved in drug evaluation might be mitigated through (1) professionalization of health technology assessment; (2) restriction of job seeking and post public-payer employment; (3) disclosure and management of experts' conflicts of interest; (4) institutionalisation of patient and public involvement; and (5) increased institutional separation of the AHTAPol from political elites.

1. Introduction

In the last three decades, health technology assessment (HTA) has been gradually integrated into many European state-funded drug reimbursement systems [1]. However, the political processes inherent in the evaluation of medical products considered for reimbursement have only recently become subject of social science inquiry [2–4], especially in the postcommunist states that acceded to the European Union after 2004. In this article, we focus on Poland, the largest Central and Eastern European country, whose reimbursement system is struggling with profound challenges, some of which could be addressed by effective HTA systems [5].

During the postcommunist transformation, Polish health authorities have faced popular pressure to

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modernise pharmacotherapy, especially in therapeutic areas marked by rapid innovation and sky-rocketing costs of medicines. As the Polish public payer still spends significantly less on original drugs than countries belonging to the pre-2004 EU [6], it must manage intense competition for resources between and within therapeutic areas, while taking account of opportunity costs associated with each treatment.

The Polish Agency for Health Technology Assessment (AHTAPol) has scope to optimise spending on reimbursement by considering "health, social, economic, and ethical" aspects of medical technologies [7,8]. The increasing prominence of the AHTAPol in both domestic reimbursement system and Central Europe [9], has highlighted the need to understand its relationships with stakeholders involved in the drug reimbursement process [3]. The AHTAPol routinely interacts with well-resourced or highly mobilised actors, who are typically strongly interested in the outcomes of drug evaluation. These actors include multinational drug companies, medical experts, patient organisations, and political elites. Among the most powerful actors is the pharmaceutical industry ("pharma") [10–12], which thus forms the focus of our inquiry. In exploring how pharma may influence the evaluation of drugs in Poland for purposes of reimbursement, we build on insights from earlier research conducted in the UK [13,14].

We had two objectives. First, we sought to explore strategies for influence employed by multinational drug companies in relation to the AHTAPol in order to identify risks associated with the scientific evaluation of drugs considered for state reimbursement. Second, we aimed to ascertain whether the outcomes of drug evaluation meet the interest of the public payer in reimbursing cost-effective drugs supported by robust pharmacoeconomic evidence.

This article proceeds as follows. The remainder of this section reviews key insights from the political sociology of pharmaceuticals regarding relationships between the public payer and the pharmaceutical industry. The second section outlines the reimbursement process in Poland. The third details our methodology. The fourth presents our results. The final section sets our findings in the broader context of research on drug regulation and discusses possible improvements to the drug evaluation process.

Seen from the perspective of political sociology of pharmaceuticals, HTA involves conflicting interests of pharma and the public payer with respect to drug expenditure [cf. 15]. Drug companies argue that HTA should prioritise innovation in pharmacology [6,16] and therefore demand that the new medicines are approved for reimbursement. By contrast, the public payer, being interested in reimbursing drugs that offer "value for money", may generally strive to limit the number of medicines approved to those offering a clear therapeutic benefit over existing treatments, are cost-effective, as recommended by the WHO, and supported by robust pharmacoeconomic evidence.[1]

Although earlier literature tended to characterise HTA as a means to advance the interests of the public payer [17], more recent research on drug regulation suggests that evidence-based medicine (EBM) may be outweighed by "anecdotal evidence," provided primarily by patients [19], or transformed into "Marketing-Based Medicine" by the pharmaceutical industry [20,21]. Separately, drawing on research conducted primarily on the pre-2004 EU, Abraham [11,12] specifies a range of strategies, both indirect and direct, that have the potential to influence decisions taken by regulatory agencies. A key *direct* strategy is to involve scientists in activities that create conflicts of interest, thereby seeking to affect their voting decisions in expert advisory bodies [12,22,23]. The "revolving door" between the pharmaceutical sector and regulatory agencies may encourage state officials to support the interests of the pharmaceutical sector [11,12,24,25]. *Indirect* strategies include stimulating pharma's "assimilated allies" – patient associations and key opinion leaders (KOLs) in the medical milieu [26] – to endorse positions favourable to the industry [25]. Overall, the application of the direct and indirect strategies is associated with privileged access to the policy process, with regulatory outcomes prioritising the interests of the pharmaceutical industry [15,27].

Before examining whether pharma employs similar strategies to influence the AHTAPol we must describe the Polish reimbursement system.

2. Background

In this section, we outline the Polish drug reimbursement process [5], indicating, where appropriate, how it has been modified by the ongoing implementation of the new Reimbursement Act (hereafter RA) [28] since the beginning of 2012.

Two main reimbursement schemes exist in Poland: reimbursement lists and therapeutic programmes, the latter scheduled to be transformed into drug programmes in mid-2012. Reimbursement lists concern pharmacy medicines obtained by patients for up to 50% of the reimbursement limit set for particular drugs by the Minister of Health. The therapeutic (or drug) programmes pertain to hospital therapies provided free of charge for narrowly defined groups of patients, such as those suffering from selected types of cancer (e.g. breast cancer, colorectal cancer), inflammatory diseases (e.g. rheumatoid arthritis, ankylosing spondylitis) or rare diseases (e.g. Pompe's disease, Gaucher's disease). Both schemes are published periodically by the Minister of Health and funded by the National Health Fund (NHF).

For new drugs not covered by these schemes a reimbursement application must be submitted by the manufacturer to the Ministry of Health (MoH). The MoH evaluates the application formally and forwards it to the AHTAPol. Next, AHTAPol analytical staff produce an assessment report, based primarily on the HTA report, typically compiled on behalf of the drug manufacturer by a HTA

[1] The WHO utilises three categories of cost-effectiveness: "highly cost-effective (less than GDP *per capita*); cost-effective (between one and three times GDP *per capita*); and not cost-effective (more than three times GDP *per capita*)" [18].

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advisory firm, and present it to the Appraisal Committee [29].

Before the Reimbursement Act, the Appraisal Committee was termed the "Consultative Council" (CC) and comprised 12 (most of the time 10) senior medical experts. The CC selected one of its members to lead on a submission, which involved consulting materials submitted by the manufacturer and other sources of evidence. Appraisal included discussion in a CC session, informed by the assessment report, a summary presented by the member leading on the submission, opinions sent primarily by national and regional consultants (senior ministerial advisors representing 84 areas of medical and pharmacological specialisation) and patient organisations. Both consultants and representatives of patient organisations could be invited to deliver testimonies before the CC. The CC's position (positive or negative) on a submission was by voting based on ordinary majority when at least half of its members were present.

The CC position took into account the nature of the health problem, the existing standard therapy, and the following characteristics of the proposed therapy: clinical effectiveness, safety, cost (typically operationalised as cost-effectiveness) and budgetary impact.

The RA has renamed the CC as the "Transparency Council" (TC) and increased the number of its members to 20 by including representatives of the MoH (four), the NHF (two), The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (two), and the Patients' Rights Advocate (two). To take a position, the TC will normally randomly select 10 members. The RA has specified and extended the content of TC positions. For example, TC positions may now include suggestions concerning newly introduced risk-sharing instruments and details of drug programmes. It has also clarified the measure of cost-effectiveness to be used; prior to the RA, there were no explicit criteria for assessing cost-effectiveness and CC positions had used either 1× GDP *per capita* or 3× GDP *per capita* as thresholds, with no obvious rationale for choosing one or other, [30] but the RA now specifies that the latter should be used.

The outcome of appraisal is a recommendation of the Minister-nominated President of the AHTAPol, which needs to consider but can differ from the CC/TC position.

Before the implementation of the RA, an AHTAPol recommendation was reviewed by the Drug Management Team (DMT) at the MoH. The DMT then issued a recommendation on the suitability of a drug for reimbursement and its price. A negative DMT recommendation that nonetheless stressed clinical benefits of a medicine was typically viewed by the drug company as an invitation to enter price negotiations with the MoH. The negotiation process – not clearly described in legislation – engaged members of the DMT, representatives of the NHF, and sometimes the Minister or Vice-Minister of Health responsible for drug policy. The RA has replaced the DMT with the Economic Commission (EC), formally charged with conducting negotiations with drug firms regarding prices, levels of patient co-payment, indications and risk-sharing instruments. The outcome of negotiations is a recommendation issued to the Minister of Health.

Table 1
Categories of interviewees.

Organisation[a]	Number of interviews[b] (%)
Ministry of Health	21 (19.3%)
National and regional consultants	4 (3.7%)
National Health Fund	3 (2.8%)
Agency for Health Technology Assessment	8 (7.3%
Parliament	8 (7.3%)
Innovative pharmaceutical companies	17 (15.6%)
Associations of innovative drug companies	2 (1.8%)
Associations of generic drug companies	3 (2.8%)
Chamber of commerce associating drug companies	1 (0.9%)
American Embassy	1 (0.9%)
Law firms	4 (3.7%)
Lobbying firms	3 (2.8%)
Freelance lobbyist	1 (0.9%)
Public relations firms	4 (3.7%)
HTA firms	2 (1.8%)
Contract research organisation	2 (1.8%)
Pharmaceutical market consultancies	2 (1.8%)
Patients' organisations	7 (6.4%)
Journalists	6 (5.5%)
Medical doctors dealing with drug reimbursement in their professional activity	10 (9.2)
Total	109 (100%)

[a] We do not provide a more detailed breakdown of organisational categories to minimise the risk of disclosing the interviewees' identity.
[b] We present numbers of interviews as opposed to numbers of interviewees to minimise the risk of disclosing the interviewees' identity.

More broadly, opinions on medicines considered for reimbursement are expressed – both formally and informally – by a range of stakeholders interested in the economic, budgetary and political implications of reimbursement policy, such as the Ministry of Economy, the Ministry of Finance, Members of Parliament and Senators.

It is the Minister of Health who takes the reimbursement decision based on non-binding recommendations issued by the AHTAPol and the DMT/EC.

3. Methods

The fieldwork for this article was conducted between May 2008 and April 2010 by PO in collaboration with LK. We collected the bulk of our data by means of in-depth, semi-structured, anonymised elite and specialised interviews [31] with a purposive sample of representatives of major stakeholders involved in reimbursement policy-making in Poland, as shown in Table 1.

We identified the organisational layer of the sample based on the review of legal documents and press coverage of drug reimbursement, extending it after initial interviews. We focused on Attention Deficit Hyperactivity Disorder (ADHD) and diabetes, two drug-intensive long-term conditions, to maximise the chances of investigating relationships between drug companies, key opinion leaders in the medical milieu, and patient organisations [32]. Next, we used publicly available information to identify individuals responsible for drug reimbursement policy in organisations included in the sample. Overall, of 70 official interview

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requests made by faxes, emails and phone calls, 57 were successful (response rate was 77.2%). To establish contact with under-represented categories of interviewees, especially employees of drug companies and MoH officials, we employed snowball sampling, which also helped us access interviewees who were unlikely to respond to official interview requests. These included occupants of top positions in organisational hierarchies, former state officials, and people who generally prefer to stay out of the spotlight due to the sensitive character of their professional activities. The snowball sampling had the positive response rate of 100% – all 26 interview requests were successful.

In total, we conducted 109 interviews with 83 individuals (20 people were interviewed twice and three were interviewed three times). Furthermore, two interviewees were asked about their two professional roles and we have counted questions concerning the distinct roles as separate interviews. The ultimate size of the sample was determined by reaching "theoretical saturation" [33] – we stopped interviewing, when initial analysis showed that subsequent interviews generated a low amount of new data regarding the study's objectives. The multiple interviewees drawn from various organisations played the role of "key informants" [31] willing to share extensively and openly about their long experience of shaping reimbursement policy. Our interest was in achieving theoretical, not statistical, representatives [34] (p. 118–120). The composition of the sample reflects our emphasis on gaining insight into the operation of public-payer organisations and strategies of influence pursued by multinational drug companies, and the realities of trying to recruit busy people in a sensitive area to a project with finite resources.

Although Polish authorities do not require ethical approval for research solely involving interviews with individuals acting in a professional capacity, all interviewees were briefed about the broad goal of the research and gave their informed verbal consent to participate in it. Interviewees were often reluctant to share details of their involvement in drug reimbursement policy due to a series of scandals regarding pharmaceutical lobbying and marketing; some also feared possible repercussions from employers and others. Assurances about anonymity were crucial to generating high-quality data and thus most interviews were not tape-recorded; instead, extensive notes were taken. When presenting the data, we protect their anonymity by creating broad interviewee categories and sometimes modifying slightly the job titles.

Given the exploratory nature of our research, we carried out semi-structured interviews, with separate sets of questions for each category of interviewees[2] which were used flexibly [35] and evolved over the course of the fieldwork. Initially, we used general questions to gain familiarity with mechanisms of reimbursement policy and avoid excluding potentially significant topics. Following ongoing scrutiny of the interview notes, the questionnaires became more focused on detailed aspects of the reimbursement process.

In line with an "elite and specialised" approach to interviewing [31], we explored participants' definitions of mechanisms of drug reimbursement, encouraged them to structure explanations and allowed them to decide about the weight of particular issues discussed (p. 5). Potentially threatening questions about the details of reimbursement of specific drugs were avoided because of the risks to participants.

The interview data was analysed by PO and discussed with LK. MM contributed to the interpretation. The analysis, utilising Atlas.ti 6.2 software, started with a set of general codes generated from the study's objectives. They were gradually supplemented by more detailed, lower-level codes emerging directly from the data [36]. At a later stage of analysis, some codes were collapsed and code families and networks were established, which covered the main themes emerging from the data. Overall, triangulation of the rich interview data should have identified major misrepresentations and deception by interviewees.

We used "thick description" [37] to explain mechanisms of drug evaluation with the greatest amount of detail possible. We present quotations expressing views shared by interviewees representing various organisational perspectives and offering the greatest insight into the constructed explanation. Where accounts offered by the interviewees differ, we chose quotations that appeared the most adequate in the light of the entire dataset and our background knowledge.

Four sources of documentary data were also used.

- We aggregated information from 55 assessment reports concerning drugs published until the end of 2011 to scrutinise the reporting and managing of conflicts of interest of analysts and external experts working for the AHTAPol [38].
- We aggregated information from the "Register of benefits" [39] published by the MoH in 2011 to analyse relationships between drug companies and medical experts. The "Register" comprised six categories of "benefits" which experts working for the AHTAPol were required to report every year (see Table 2).
- We analysed 26 reports from the sessions of the Consultative Council held in 2007 and 2008[3] to establish how its members' conflicts of interest were managed [40].
- Finally, we examined 276 recommendations issued by the AHTAPol between 2007 and 2011 on the reimbursement of new drugs [38] with respect to: (1) the nature of each decision (positive – with or without conditions, negative, no position); (2) the evaluation of drug cost-effectiveness; (3) the evaluation of the credibility of supporting "economic analyses" submitted by drug companies.

The interview and statistical analysis were closely intertwined. Early statistical analysis of documentary data available at the AHTAPol website during fieldwork informed some interview questions. Interview data from these and other questions were in turn used to interpret findings form statistical analysis.

[2] See Web Supplement 1 for full questionnaires.

[3] The AHTAPol did not publish reports from CC sessions on its website between 2009 and 2011.

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Table 2
Number of CC members[a] reporting particular types of "benefits" (2007–2010).[b]

Category 1: Paid positions and activity (healthcare, academia and research)[c]

Employment and paid work for public healthcare provider organisations[c]	Employment, paid work in private healthcare provider organisations and individual practice	Employment and paid work for higher education institutions	Employment and paid work for research institutes
10	8	7	5

Category 1: Paid positions and activity (state and non-governmental organisations)

Paid work for the Ministry of Health (as a national or regional consultant)	Employment and paid work for state organisations other than the Ministry of Health	Paid work for non-governmental organisations
4	4	1

Category 1: Paid positions and activity (pharmaceutical industry)

Development of reports and analyses	Research on drugs for drug companies	Other types of paid work for drug companies
1	1	2

Category 1: Paid positions and activity (other)

Authorship of books and articles	Lectures, symposiums, conferences (source of financing not disclosed)	Clinical trials (exact source of financing not disclosed)	Provision of continuing medical education[d]
4	1	1	2

Category 1: Paid positions and activity (other)

"Paid research" (exact source of financing not disclosed)
1

Category 2: Sources of material support of public activity

–

Category 3: Received donations whose value exceeds 20% of the average salary in the national economy

Donations made by drug companies
1

Category 4: Sources of sponsorship of trips to national and international conferences, congresses, and symposia

Drug companies	Organisers	Other sources	Not disclosed
6	4	2	5

Category 5: Sources of other benefits whose value exceeds 20% of the average salary in the national economy

	Drug companies	Other organisations	Not disclosed
Clinical trials	–	1	1
Research	3	1	–
Provision of continuing medical education[d]	4	6	1
Authorship of books, articles, analyses	–	4	–
Consultancy	1	1	–
Other paid work	1	7	–
Prizes	-	1	–

Category 6: Membership in governing bodies of foundations, companies and cooperatives

Shareholder at a commercial entity in the healthcare sector	Board member at a commercial entity in the healthcare sector	Work for foundations (not specified if paid)
1	1	2

Source: own calculations based on the "Register of Benefits" completed by CC members, available at: http://www.mz.gov.pl/wwwmz/index?mr=&ms=&ml=pl&mi=&mx=0&mt=&my=&ma=18541.

[a] There are 10 CC members.

[b] The aim of the table is to provide a general overview of CC members' relationships with drug companies against other types of their professional activity. As the unit of analysis are the types of relationships, the table does not show the otherwise substantial differences between the CC members in the extent of their cooperation with drug companies. We do not detail relationships reported by particular CC members because of the varying reporting styles, especially the level of detail provided in the declarations.

[c] While the main categories (in bold) are taken from the "Register of benefits", the detailed ones are inductive. The definitions of the main categories of "benefits" are not elaborated in the Register.

[d] This includes lectures, seminars, workshops.

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4. Results

We start by demonstrating the political significance of recommendations issued by the AHTAPol in the reimbursement process. We then analyse how multinational drug companies attempted to influence the process of drug evaluation. Finally, we examine the outcomes drug evaluation in the context of the interests of the public payer and the pharmaceutical industry.

4.1. "Blame games" around drug evaluation

In order to understand strategies of influence employed by pharma, the political significance of AHTAPol recommendations in the reimbursement process is important. Since its establishment in 2005, the AHTAPol has accumulated substantial scientific authority. According to a high-ranking NHF official, "In line with the AHTAPol's development and its growing experience and effectiveness, we transfer the majority of expert opinions there. The AHTAPol has the most important position [in the reimbursement system] in terms of credibility." Similarly, the president of the local branch of a multinational drug company asserted that "The AHTAPol is a big step forward [. . .] It brings reimbursement out of the 'grey sphere'. [. . .] This Agency really evaluates [reimbursement] applications." Yet the same interviewee also emphasised: "It [the AHTAPol] should not accede to political pressure. [. . .] It can become the field of political games."

The conviction that recommendations were part of a political process was shared by many of our interviewees both inside and outside the AHTAPol [9] (p. 158). Thus, one way to look at the relationship between the AHTAPol and the MoH is as an "agency strategy" of blame avoidance [41,42] pursued by political elites. Despite its "soft" [i.e. non-binding] status (according to a high-ranking MoH official), an AHTAPol recommendation constituted the scientific foundation for the reimbursement decision. As a partner at a law firm recounted, "The Minister can demonstrate with the recommendation that his decision is so fantastic, since it is based on the work of the group of experts. This type of support is vital." In particular, as an MoH official emphasised, "As a rule, if the AHTAPol gives a negative recommendation, the drug is not reimbursed. [. . .] [I]t is the only right and safe solution. It shifts responsibility from the Minister to the AHTAPol." An AHTAPol official criticised this approach thus: "[T]he Ministry should [see] [. . .] the Agency [as] [. . .] not just a fig leaf, which has to cover certain things, or [as] an excuse."

A partner at a law firm maintained that "If a firm gets a positive recommendation [and the Minister declines reimbursement], it can announce that it's the bad Minister who doesn't want to reimburse [the drug], even though the AHTAPol said that he should do so." As a key account manager at a drug company expounded, "Firms don't use a positive recommendation overtly but rely on patients' associations and KOLs. These are hidden actions yet all interested parties know what is going on." Hence, the communications manager at a pharmaceutical company stressed: "We have to do everything to ensure we receive a positive recommendation." What that meant in practice depended, as an AHTAPol official observed, "on the culture of a given firm", particularly the determination of the headquarters to introduce drugs to reimbursement (according to a former MoH official) and "ethical flexibility" of its local staff (according to an NHF official). We now analyse how the otherwise legitimate channels of contact with the AHTAPol became part of direct and indirect strategies that multinational pharma used to maximise the chance of achieving a positive recommendation.

4.2. Direct strategies

In this section, we explore how pharma attempted to access the organisational structure of the AHTAPol.

4.2.1. Establishing access to AHTAPol staff

Drug companies' interactions with the AHTAPol were primarily regulated by the "procedure of receiving external clients." [43] According to an AHTAPol official, "These meetings [. . .] are official and minuted. They typically concern the state of the processing of the application." Drug companies were allowed to also comment on assessment reports [44,45]. Additionally, analysts working on assessment reports had to submit declarations of conflicts of interest. As evidenced in 55 published assessment reports, analysts declared conflicts of interest only once and in another instance the fact of submitting a declaration of conflicts of interests was not mentioned. In the remaining 53 assessment reports, no conflicts of interest were declared (we must note, however, that neither the format nor contents of declarations were disclosed).

Our research indicates that interactions between AHTAPol analysts and the pharmaceutical sector were not entirely captured by these regulations. This is because AHTAPol staff and a group of advisory firms developing HTA reports submitted together with reimbursement applications constituted a small and tightly knit "social circle" (*środowisko*) [46,47]. The public affairs director at a pharmaceutical company asserted: "That the AHTAPol and commercial HTA agencies are one social milieu is an open secret." An AHTAPol official elaborated: "[T]hey have strong relationships. These people graduate from the same medical academies and departments. Quite often, they have common teachers, supervisors, professors." While not suggesting that these social relationships were in any measure improper, they might have been conducive to gaining privileged access to the AHTAPol. For example, a manager at a HTA firm asserted that "Officially, there are letters and meetings. But informal meetings [with AHTAPol staff] do happen. I wouldn't be melodramatic about them, though. The secret services which monitor the operation of the Agency [. . .] know about them."

The key element in building positive relationships with AHTAPol analysts was lucrative career opportunities. Notably, our interviews indicated considerable outflow of AHTAPol personnel to the pharmaceutical sector. An AHTAPol official explained the structural reason for this mobility pattern thus: "The AHTAPol educates high-quality experts who are soon captured by the pharmaceutical industry, which quadruples their pay and offers extra perks. They have gained experience. [. . .] These are brilliant

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people – doctors, pharamcologists, statisticians." Also, two senior Agency officials moved to domestic HTA companies and another one became the "Public Affairs and Policy Director" at a major multinational pharmaceutical company. Without implying any misconduct, we suggest that this mobility pattern might have created "coincidences of interests" [48] casting doubts over the use of insider information and connections when seeking and after finding employment in the pharmaceutical sector. An AHTAPol official recalled the move of one colleague thus: "X disappeared suddenly over one week [. . .] I remember hearing a rumour that X was going to take up an academic job. Later, it turned out that it was at [. . .] a powerful drug firm. This event did leave a nasty aftertaste." Consequently, an AHTAPol official complained: "If you know all AHTAPol's tricks of the trade, you are very useful for a drug company. [. . .] Unfortunately, we do not have a cooling-off period to wash out all this knowledge, information, relationships."

4.2.2. Establishing access to the Appraisal Committee

CC members' cooperation with drug companies was not unusual, given their long-standing, high-profile professional activity. However, it had important consequences for their role in drug evaluation. The relationships with drug companies reported every year in the "Register of benefits" [39] (Table 2) involved the transfer of cutting-edge knowledge to medical experts, primarily through sponsored participation at medical conferences [49,50]. As a Key Opinion Leader (KOL) in oncology described, "Without those stipends and grants, we wouldn't go anywhere. After all, no one else would pay for it." Firms also supported KOLs' research through requesting publications or providing money and data for their own projects. As the spokesperson for a drug company maintained, "Firms usually have funds for research devoted to their [KOLs'] therapeutic areas. [. . .] We can provide KOLs with scientific literature. These are absolutely basic types of activity for us." Furthermore, relationships with pharmaceutical firms were a way of putting money in the pockets of experts, particularly through "continuing medical education" [10]. As a KOL in psychiatry expounded, "If a drug company organises, for instance, a conference or a workshop for doctors, they [. . .] offer [me] employment as a lecturer, then this is additional income." Overall, while CC members displayed high standards of professional integrity, these relationships with drug companies contributed to "reaffirming" [50] their position in the medical milieu (p. 263), especially given that, as our interviews indicated, they were inadequately rewarded for providing their unique expertise to the AHTAPol.

Consultative Council members were required to fill in declarations of conflicts of interest [51] when assigned the leading role on a submission and at the beginning of a Council session. The declarations referred to paid lectures and other work, grants, employment, investment, patents, work as a court expert, and consultancy. However, the declarations did not include subtle attempts to build long-term positive relationships [10], succinctly described as "food, flattery and friendship" (p. 142), including sending seasonal cards, being invited to dinner or as guest speakers at conferences. The declarations attempted to include relationships of extended reciprocity [22,25,52,53] by asking about conflicts of interest regarding future employers. However, they did not cover relationships which could have existed long before experts' work in the CC and those which will be established long after the end of their term [cf. 11,24,25]. Crucially, as an AHTAPol official explained, "If someone decides not to disclose their relationships, there is no way we could establish the truth. [. . .] But as for now there seem to have been no problems in this respect. At least there has been no scandal."

The internal regulation of the CC [54] did not envisage drug companies' participation in CC sessions. As an AHTAPol official noted, "In general – though I don't know how it works in practice – all CC members agreed that the only form [of contact] that they want to see are documents" This was because "We would like to avoid a situation that they are having a discussion [. . .] [at a CC session] but its result is a foregone conclusion. For everyone has made up their mind, there have been informal discussions, someone has passed on something, this member is in agreement [with the applying firm] and he knows what to do. . ."

Against the background of formal regulations, there was substantial evidence of a postcommunist variant of the "permissive principle" [23] in handling CC members' conflicts of interest. Theoretically, the reporting of a conflict of interest should have precluded a CC member from playing a leading role in analysing a drug applying for reimbursement. However, reports from CC sessions demonstrated there were at least four exceptions to this rule (sessions 4/2008, 11/2008, and twice at the session 16/2008). As a manager at a HTA firm expounded, "It happens that the member who is most competent in a given area presents the drug to the rest of his colleagues. Meanwhile, he is the one most entangled in various events with firms. [. . .] Anyone who reads his analysis is aware that he might be entangled and looks at him with greater caution."

According to the internal regulation of the CC [54], the reporting of a conflict of interest could result in self-exclusion or exclusion from discussion and/or voting by other members. Reports from CC sessions held in 2007–2008 showed that the reporting of a conflict of interest never led to exclusion from discussion, because, as an AHTAPol official recounted, they "[M]ay have something important to say." However, CC members were excluded from voting in 55.6% of instances (45 out of 81) when reporting one or more conflicts of interest.

These results highlight a contradiction between attempts to control CC members' relationships with drug companies and the need to use their expertise, a pattern also identified in Western regulatory agencies [55]. Commenting on CC members' conflicts of interest, an AHTAPol official emphasised: "This is a considerable obstacle [. . .]. For these people are professionals, their opinions are highly penetrating, very reliable." Furthermore, "Having in mind the need to maintain a quorum, [they] started [. . .] to apply a liberal policy: 'Someone declared a conflict but let him take part in the discussion and voting because we have a clear situation.'"

Finally, our interviews suggested that some drug companies were determined to hold meetings with CC members outside the AHTAPol. As the public affairs director

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at a pharmaceutical company described, "We try to arrange [the meetings] [...] to present our arguments. They [CC members] can ask us questions, since these are very complicated issues, something may escape their notice, not everything is included in the characteristic of the medical product in the documentation submitted to the AHTAPol." While interviews with AHTAPol officials provided mixed evidence regarding the occurrence of such meetings, pharma's pressure to bypass the official regulations was undisputable.

In the following section, we analyse how the direct strategies of influence were supplemented by indirect ones.

4.3. Indirect strategies

Drug companies employed three major indirect strategies to influence the process of drug evaluation, relying on external experts, patient organisations, and elected politicians.

4.3.1. Co-opting external experts

The key external experts for the AHTAPol were national and regional consultants. Reports from CC sessions held in 2007–2008 demonstrated that they participated in discussing 26.5% (22 out of 83) drug-related issues considered by the Council. As an AHTAPol official recounted, "Consultants are invited [to participate in CC sessions], because it is thought they are the voice of the [medical] milieu, as well as the MoH, they know and are responsible for a given condition in this country."

For drug companies, national consultants were a vital source of "scientific authority" [50] supporting their products in the CC. According to a MoH official, "Consultants have immense power. They are authority for the Minister, the media and society. The firm can talk a lot but if the consultant says 'No', it can hardly do anything." The data published in the "Register of benefits" [...] suggested that to win sympathy of national consultants and thereby retain the possibility to obtain third party endorsements from them [26], multinational drug companies relied on essentially the same methods as with CC members.[4] A notable difference between CC members and consultants, however, was the relatively greater involvement of the latter in clinical trials; "the main form of rewarding and building long-term relationships with medical experts", according to a high-ranking MoH official [56].[5] Also, consultants were more engaged in the work of non-governmental organisations in the health-care sector. This activity might have been be utilised by drug companies as a channel of access (according to a partner at a law firm) or as an opportunity to provide favours to KOLs by funding these organisations. Even more importantly, some consultants "want to keep their relationships with the industry secret" noted an AHTAPol official. Paradoxically, the substantial differences in the level of detail provided by the consultants in the "Register" [39] may create the misleading impression that the most transparent consultants were the ones most entangled. This may, therefore, inadvertently disincentivise them to provide accurate data in the future.

Thus, while appreciating their expertise, an AHTAPol official complained: "In some areas, national consultants are deeply entangled in conflicts of interests and their opinion is suspicious." This perception, though shared by many of our interviewees, cannot be corroborated with quantitative data due to the differences in the accuracy of reports submitted in the "Register" [39]. Furthermore, assessment reports and recommendations published by the AHTAPol usually disclosed neither the names nor conflicts of interest of external experts advising on particular drugs.

Our interviews suggested that the implementation of two "transparency programmes" [9,45] regarding obtaining experts opinions (p. 160–161) faced practical difficulties. For example, as an AHTAPol official put it, "A great many consultants don't grasp the idea of conflict of interest. [...] We had a case of one professor. He declared he indeed collaborates, but does not take any money from the firm, [and] only [does it] for his clinic. [...] If it was not for the help of the firm in acquiring equipment, attending congresses, both he and his staff would not be present in global science."

However, to secure a necessary level of cooperation with external experts, the AHTAPol tended to adopt a "permissive principle" [23] towards their conflicts of interest. According to an AHTAPol official, "Although we can frequently see bias in opinions prepared by the experts, since their concept of good drugs suits that of the industry, we are determined not to lose all of them." This statement was to a certain extent supported by assessment reports, which offered, albeit in an unsystematic way, a minimal amount information on managing external experts' conflicts of interest. Though only two reports out of 55 (3.6%) mentioned exclusion of opinions provided by external experts due to their conflicts of interest, 30 reports (54.5%) were not clear on whether all external experts submitted declarations of conflicts of interest. Similarly, in 36 reports (65.4%) it was unclear whether external experts declared conflicts of interest, and in 44 reports (80%) it was unclear whether the AHTAPol utilised opinions provided by experts with conflicts of interest. As with the "Register of benefits" [39], the lenient approach to reporting conflicts of interest may have a demoralising effect on other experts [57].

Consequently, an AHTAPol official explained: "What is our greatest drama? The number of our credible experts is severely constrained. [...] If someone is a credible expert in, say, haematology, we cannot invite him each time we discuss an oncology drug, because he is more confident in certain drugs, less confident in others and does not have any contact with certain medicines as well."

Therefore, according to a person involved in the work of the AHTAPol, when selecting their external experts, "[CC members] make decisions based on connections, contacts and friendships. This milieu is very small. [...] [A]ll those professors from [names of specialities] know each other extremely well." Yet the trust-based approach may lead to "social closure" of a small group of medical experts [23]

[4] Aggregated in Web Supplement 2.

[5] Nevertheless, in contrast to the "Register of Benefits", reports from CC sessions showed that access to medical expertise was also facilitated through being invited to organise clinical trials (reported by four CC members as a potential conflict of interest in 2007 and 2008).

(p. 590–591). "Many of them have also been national or regional consultants [. . .]. So when someone proposes an expert, we can predict in advance that this person will have a close orientation and the same approach."

4.3.2. Stimulating endorsements by patient organisations

Patient organisations and members of the public could gain information about the agendas of forthcoming at CC sessions from the AHTAPol website [58]. Then, according to an AHTAPol official, "[A]ny patient organisation, anyone in general, may submit an opinion in writing. Those opinions are in one way or another made known to the Council." Furthermore, patient organisations could testify before the CC, often together with medical experts from their condition areas. As a representative of an association of patients with disease X described, "[T]he President of the AHTAPol [. . .] invited us in and said that the time starts running now – we have 5 min. Professor Y was discussing [. . .] the process of treating X, [. . .], then I, in the role of a patient, [described] how I see it, what is the application [of therapies], what is the need, how much it costs. [. . .] Then [. . .] the President of the AHTAPol thanked us, we also had a few questions, answered them and left." However, as an AHTAPol official observed, "The general trend is that the Council does not invite [patient organisations]. They do it occasionally, in touchy situations." This statement was reflected by reports form CC sessions. In 2007–2008, patient organisations gave testimonies with regard to 10.8% (9 out of 83) drug-related issues considered by the CC.

Our interviews revealed that the CC appreciated patient contributions. According to an AHTAPol official, "I think there is a need for such contacts, we have to consider various inputs, even though some of them are only emotional." Nevertheless, another AHTAPol official suggested that "anecdotal evidence" [19] was not prioritised by the CC: "They are one of the voices in discussion. We invite them to CC sessions to give them satisfaction." Equally important, though patient organisations invited to CC sessions were required to submit declarations of conflicts of interest [59], our interviewees were often concerned that in some condition areas patients' relationships with pharma were overly close [60]. An AHTAPol official asserted that "Patients suffering from [disease X] are awfully promoted by the industry, but I must say that [the leader of an association of carers whose children suffer from disease Y] [. . .] seemed very sensible. [. . .] I look at patient organisations with caution but I listen to them attentively."

Finally, it appears that patient organisations occasionally had a noticeable impact on decisions taken by the CC. As an AHTAPol official recounted, "I remember a very interesting discussion concerning drugs for [condition Y] [. . .] [T]he situation was that we had a negative verification analysis [drug assessment prepared by AHTAPol analysts] and consultants came [to the CC session] and people from an association [of carers] were also invited. [. . .] And at this moment [their] opinions [. . .] were very powerful."

4.3.3. Exercising political pressure

The institutional distance between the MoH and AHTAPol was relatively short, with the process of issuing recommendations being a key aspect of control [41–42]. Until 2009 a CC position had to be formally "accepted" by the Minister of Health prior to its publication, a procedure seen by some of our interviewees as highly controversial. This mechanism was replaced by issuing "AHTAPol recommendations" by the President of the AHTAPol, who considered a non-binding "CC position". These mechanisms of control were particularly important given the MoH's desire to avoid the risk of blame resulting from issuing reimbursement decisions not supported by positive recommendations. This naturally created opportunities for drug companies to influence the AHTAPol through the MoH [56]. As an AHTAPol official explained, "I think the MoH is more susceptible here [. . .]. Sometimes, there is political pressure on certain decisions, say, from various patient groups which accessed some places or organised media campaigns."

In practice, even though in the vast majority of instances the President agreed with the CC, the President could reject its opinions if they conflicted with those of the MoH on politically sensitive issues. For example, the AHTAPol President acceded to the wishes of the MoH when overruling a decision by the CC to reject changes in the area of so-called "nonstandard chemotherapy"[6] [61,62]. It appears that this allowed the Minister to show commitment to providing expensive novel drugs to a small fraction of cancer patients who otherwise would be treated only with standard therapies, even though the CC questioned the evidence base for this decision.[7] An AHTAPol official summarised: "The CC has been getting on well with [. . .] the President, but this does not exclude various difficulties [. . .]. The President is an official who has various dependencies, time pressures. . ."

Officials closely engaged in the work of the Council maintained that the Minister of Health did not influence the content of specific recommendations. "If there are any attempts of exerting pressure on the Council [. . .], they concern the timing and accuracy of the reports, but do not involve – at least to my knowledge – attempts of exerting pressure on the substance of the Council's decisions." However, the representatives of drug companies interviewed sometimes criticised the use of scientific evidence in the reimbursement process. An external affairs manager at a drug company argued: "These are often political decisions. They dig up dirt on drugs." Crucially, the Minister did have influence on broad policy directions. As an AHTAPol official recounted, in respect of the legitimisation of a change in the legal status of a sizeable group of therapeutic programmes [67], "The Minister [. . .] asked them to accept those changes *a priori*, without any analysis or research. The CC did a favour to the Minister and accepted this request."

[6] In the Polish reimbursement system, non-standard chemotherapy refers to oncology treatments that are not normally reimbursed but are administered only in exceptional circumstances through individual permissions given by the regional directors of the NHF.

[7] In two other instances, the President opposed the CC by issuing positive recommendations on a potentially highly expensive drug for cancer [63,64] and a rare disease [65,66].

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Table 3
Cost-effectiveness of drugs applying for reimbursement in the light of AHTAPol recommendations (2007–2011)[a,b]

	Positive recom. *N* (%)	Negative recom. *N* (%)	No position taken *N* (%)	Total *N* (%)
Highly cost-effective[c]	14 (12.3%)	13 (17.6%)	–	27 (14.2%)
Cost-effective[d]	12 (10.5%)	6 (8.1%)	–	18 (9.5%)
Close to exceeding the threshold of cost-effectiveness[e]	5 (4.4%)	6 (8.1%)	–	11 (5.8%)
Some estimates exceeding the threshold of cost-effectiveness[f]	5 (4.4%)	3 (4.1%)	–	8 (4.2%)
Not cost-effective[g]	23 (20.2%)	27 (36.5%)	1 (50.0%)	51 (26.8%)
Reimbursement conditional on cost-effectiveness or decreasing price[h]	36 (31.6%)	–	–	36 (18.9%)
Cost-effectiveness not specified[i]	19 (16.7%)	19 (25.7%)	1 (50.0%)	39 (20.5%)
Total	114 (100%)	74 (100%)	2 (100%)	190 (100%)

Source: Own calculations.

[a] We used AHTAPol recommendations supplemented by CC positions as data sources.

[b] We considered drugs on which recommendations issued by the AHTAPol were based on cost-effectiveness analysis, including cost–utility analysis. Consequently, we included recommendations stating that they are based on cost-effectiveness analysis, providing the values of ICER (Incremental Cost-Effectiveness Ratio) and/or ICUR (Incremental Cost–Utility Ratio), providing the cost of one QUALY (Quality-Adjusted Life Year) and/or LYG (Life-Year Gained), or stating that a drug is (not) cost-effective. To analyse cost-effectiveness of drugs evaluated by the AHTAPol, we utilised the following figures concerning GDP *per capita* in Poland: 27,803.7 PLN (2006), 30,872.8 (2007), 33,444.4 (2008), 35,214.3 (2009), 37,445.1 (2010) (obtained from http://www.eregion.wzp.pl/rachunek-regionalny/pkb-per-capita-regionu-jako-odsetek-pkb-per-capita-polski.html, accessed on January 15, 2012). As final calculations made by the Polish Main Statistical Office on GDP *per capita* become available towards the end of a calendar year, we analysed cost-effectiveness of drugs recommended by the AHTAPol in a given year, using the figure from the previous year.

[c] In line with WHO guidelines on cost-effectiveness, the AHTAPol considers drugs as highly cost-effective if the cost of one QUALY/LYG is less than one GDP *per capita*. We assume that a drug is highly cost-effective if at least one estimate does not exceed the threshold of one GDP *per capita*.

[d] In line with WHO guidelines on cost-effectiveness, the AHTAPol considers drugs as cost-effective if the cost of one QUALY is less than triple GDP *per capita*. We assume that a drug is cost-effective if estimates are greater that 1× GDP *per capita* but smaller than 70,000 PLN.

[e] We assume that a drug is close to exceeding the threshold of cost-effectiveness when at least one of estimates is higher than 70,000 PLN per 1 QUALY/LYG.

[f] A recommendation provides several estimates of cost-effectiveness, some of which exceed the threshold of cost-effectiveness.

[g] In addition to drugs with the cost of one QUALY exceeding triple GDP *per capita*, in a few cases we view medicines with a very high cost of treating one patient as not cost-effective (e.g. in rare diseases), even though the cost of one QUALY/LYG is not provided.

[h] A positive recommendation states that achieving cost-effectiveness or price decrease is a condition of reimbursement.

[i] The content of a recommendation does not allow for determining whether the drug exceeds the threshold of cost-effectiveness.

4.4. Outcomes of drug evaluation

We now explore whether the outcomes of drug evaluation met the interest of the public payer in reimbursing cost-effective drugs supported by sound pharmacoeconomic evidence. Fig. 1 shows that the proportion of positive recommendations was increasing over time. Given the diminishing scope for major therapeutic advances [10], this was in the interest of multinational drug companies and some patient groups. According to the public affairs director at a drug company, "There is growing pressure on the MoH created by positive AHTAPol recommendations. The queue of waiting drugs with positive decisions is growing longer." Consequently, "It is virtually impossible that the MoH will not introduce those therapies. Yet it will not happen automatically."

As indicated in Table 3, a substantial share of medicines positively recommended by the AHTAPol was cost-effective (or had to become less expensive or cost-effective) if they were to be reimbursed. However, only a slightly smaller proportion of medicines were not cost-effective or cost-effectiveness was not specified.

These policy outcomes need to be interpreted in the context of opportunity costs in the heavily underfunded Polish health-care system. An AHTAPol official provided a concrete example: "Life will always be chosen over palliative care. If we are going to prolong life with drug X for another 6 weeks or 3 months, maybe it will be better to use this money for a hospice or excellent palliative care, even half of this amount [of money would be sufficient]. But let this patient die in comfort, let them have a high quality of life without pain or nausea. [However,] [t]he answer is: 'Three months are on the average. But it may happen that he will live half a year. So what? Are we going to deny him these 3 months?' No, we won't deny it. But someone has to pay for it: people who need palliative care, [those who suffer from] dementia, rheumatism, paediatric [diseases]. These groups are very disadvantaged, in my view."

Crucially, the actual cost-effectiveness of many drugs recommended by the AHTAPol was highly uncertain, as demonstrated by the AHTAPol's frequent complaints about the poor quality of pharamcoeconomic data submitted by drug companies evidenced in Table 4. This entailed the risk of bias in favour of their interests, especially in the light of the outflow of highly qualified analysts to the pharmaceutical sector, which might have negatively affected the AHTAPol's capacity for thorough drug scrutiny [cf. 21,29,68].

The increasing number of positive recommendations resulted from an interplay of multiple factors affecting the outcomes of drug evaluations conducted by the AHTAPol, including the growing compliance of reimbursement applications with HTA guidelines issued by the Agency. Also, an AHTAPol official pointed to the "Diminishing role of the established thresholds of cost-effectiveness in adopting

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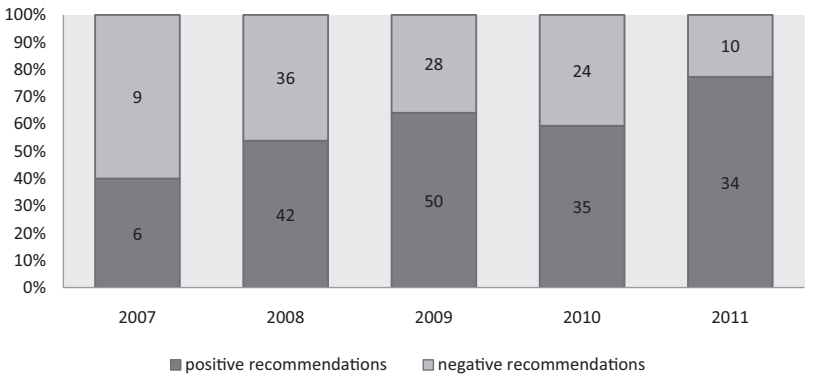

Fig. 1. Types of AHTAPol recommendations on the introduction of drugs to reimbursement (2007–2011)[a,b,c].
[a]It is necessary to explain our approach to counting AHTAPol recommendations. In several instances, one document issued by the AHTAPol in fact comprises more than one separate recommendation on drugs regarding different indications or reimbursement schemes. Similarly, the AHTAPol may recommend that a drug should not be reimbursed in one reimbursement scheme but in another. Therefore, the number of recommendations in our database exceeds the number of documents issued by the AHTAPol. [b]The figure excludes two recommendations from 2008 in which the AHTAPol took no position. [c]Numbers of recommendations are on the columns.
Source: Own calculations.

Table 4
AHTAPol's assessment of the credibility of "economic analyses" supporting drugs applying for reimbursement (2007–2011)[a,b,c].

	Positive recom. *N* (%)	Negative recom. *N* (%)	No position taken *N* (%)	Total *N* (%)
Neutral[d]	83 (49.7)	37 (34.6)	–	120 (43.5)
With limitations[e]	23 (13.8)	15 (14.0)	–	38 (13.8)
Not credible[f]	43 (25.7)	44 (41.1)	2 (100)	89 (32.2)
Outdated	4 (2.4)	–	–	4 (1.4)
Not supplied by applicant	14 (8.4)	9 (8.4)	–	23 (8.3)
Not analysed by the CC	–	2 (1.9)	–	2 (0.7)
Total	167 (100)	107 (100)	2	276 (100)

Source: own calculations.
[a] We used AHTAPol recommendations supplemented by CC positions as data sources.
[b] In AHTAPol's terminology, "economic analysis" is aimed at evaluating the relationship between clinical effects and the cost of medical technologies proposed for reimbursement.
[c] The categorisation presented in the table is inductive.
[d] A recommendation neither comments on the quality of "economic analysis", nor lists its limitations.
[e] A recommendation mentions a number of limitations of "economic analysis" but does not describe it as "not credible". It is important to stress, however, that some of the limitations are rather serious, including suspicions that the cost of the evaluated therapies may turn out to be significantly higher than suggested by the manufacturer.
[f] A recommendation explicitly refers to "economic analysis" as "not credible", "doubtful", "controversial", "debatable", "unclear", "displaying numerous deficiencies", "not useful for decision-making purposes" (or using similar terms).

recommendations."[8] [9] A key factor behind the rising number of positive recommendations was a growing tendency to issue conditional positions by the CC. These documents typically stressed clinical benefits offered by drug therapies, yet stated that the decision to reimburse them should be preceded by the fulfilment of technical or price-related requirements.[10] As an AHTAPol official explained, "This is a loophole which leaves open the possibility for further negotiations between the MoH and the drug company" and, if needed, shifted the blame for a negative reimbursement decisions to the uncooperative manufacturer. However, some conditional recommendations may be seen as an attempt of blame avoidance by the CC. According to a manager at a HTA firm, "Conditional recommendations are a nice way of avoiding responsibility for decisions [by the AHTAPol]." Pharma tended to use conditional recommendations as a strong argument to convince the MoH to enter price negotiations. However, some of these recommendations were negative in practice." Those drugs are extremely expensive and by no means cost-effective. The drug company does not have lobbying strong enough to receive a positive recommendation."

5. Discussion and recommendations

In this article, we have examined the political processes accompanying the evaluation of drugs by the Polish Agency for Health Technology Assessment. The main strengths

[8] See Web supplement 3. The time series is too short to support or refute this observation.
[9] This is no longer the case. The only cost-effectiveness threshold under the RA is 3× GDP *per capita*.
[10] See Web Supplements 4 and 5.

of our article include a rich and rigorously analysed qualitative dataset, corroborated with the statistical examination of available documentary data, but our analysis also has some limitations. While our typology of strategies employed to influence the drug evaluation process draws on the themes featuring prominently in numerous interviews with well-informed insiders, it is impossible to establish the extent to which these mechanisms are widespread. This is primarily due to "commercial and state secrecy" [25], which precludes investigating decisions about specific drugs. Furthermore, as our focus is on political mechanisms, we cannot make any claims about the scientific foundations of recommendations made by the AHTAPol.

We found that at the core of the politics of drug evaluation is the relationship between the MoH and the AHTAPol, characterised by political elites' desire to deflect blame for controversial reimbursement decisions, while retaining substantial control over the AHTAPol.

The non-binding yet politically profound character of recommendations created strong incentives for drug companies to exploit channels of access to the AHTAPol so as to maximise the chances of their drugs being positively recommended.

Two direct strategies of influence involved building relationships with a small circle of HTA analysts at the intersection of the public and private domains and with members of the Appraisal Committee. The nature of direct strategies – establishing social networks with a potential to foster sympathetic attitudes towards evaluated drugs – was similar to those used to influence regulatory scientists in the pre-2004 EU by [12,22,25]. However, these mechanisms seem to be particularly important in Poland due to the frequent contrast between formal rules and informal practices [46–48].

The indirect strategies relied on the basic types of third parties employed in relation to Western regulatory agencies [13,49,69,70] – KOLs in the medical milieu and patient organisations. What may be unique about Poland are the considerable opportunities for exerting influence through political elites, stemming from the short institutional distance between the MoH and the AHTAPol. Importantly, this channel of access increases the possible influence of KOLs and patient organisations, as they are highly effective in mounting pressure on the MoH [56].

The combination of the direct and indirect strategies generated a number of risks [71], summarised in Table 5, that may diminish the scientific authority of recommendations taken by the AHTAPol. More broadly, these risks may undermine the Agency's fundamental role as a "countervailing power" [25,72] to the pharmaceutical industry.

In terms of the outcomes of drug evaluation, AHTAPol recommendations have undoubtedly paved the way towards rational reimbursement policy-making, though their impact on reimbursement decisions taken by the Minister of Health was identified as relatively low in the first 3 years (2007–2009) [5]. However, the rising number of positive recommendations is a source of concern, given the frequent well-documented criticisms of newly launched drugs [10]. This is even more important because a substantial share of medicines positively recommended by the AHTAPol were reported as not cost-effective or were supported by dubious pharmacoeconomic evidence.

These policy outcomes were coupled with developments undermining the AHTAPol's capacity for thorough drug scrutiny: a substantial outflow of highly qualified staff to the pharmaceutical sector, frequent coincidences of interests of the mobile employees, and difficulties in expanding the organisational infrastructure of the Agency [9,29]. Therefore, part of AHTAPol's policy output may favour the interest of drug companies in profit maximisation over the state's interest in reimbursing cost-effective medicines based on sound scientific evidence. In claiming so, we do not imply a narrowly utilitarian understanding of HTA. When taking recommendations, especially on cancer and rare diseases, the AHTAPol must consider drug efficacy, safety, and availability of alternative therapies. Interactions between and relative importance of these factors should become the subject of a separate study.

We now discuss how the risks to drug evaluation are managed [73] by the new Reimbursement Act (RA) and other institutions. Alongside this, we formulate recommendations informed by our research, concentrating on regulations aiming to increase the "bureaucratic transparency" [74] of the reimbursement process, as this goal should be shared by all stakeholders [75]. One way of optimising this process is to adopt a cybernetic cycle of regulation [76] (p. 3): (1) setting standards based on authentic and inclusive consultations with stakeholders; (2) monitoring of compliance with the standards, combined with adequate sanctions for possible breaches; (3) rigorous enforcement of the agreed standards [cf. 73]. Regulations developed in this way may be revised and refined in subsequent regulatory cycles.

5.1. Professionalization of HTA

Professional codes of conduct, like the Ethical Code designed by the Polish Pharmacoeconomic Society, are typically viewed as a legitimate way to regulate HTA [77]. These regulations should pay particular attention to the transparency of interactions between HTA analysts and drug companies and between analysts from the public and private sectors. The regulations should be easily accessible to the public.

5.2. Restriction of job seeking and post public-payer employment

We urge the MoH to publish a comprehensive regulation of seeking alternative employment while still in public-payer organisations and after moving to the pharmaceutical sector [78]. This regulation, drawing on, for example, OECD guidelines [79], may be instrumental in preventing the (perception of) use of insider information and relationships for personal benefit (We must note that, having not scrutinised job contracts at the AHTAPol, we do not know to what extent these or similar procedures have been implemented).

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Table 5
Risks in drug evaluation and their possible consequences.

Nature of risk	Possible consequences
Risk # 1: Informal relationships between HTA analysts at the intersection of public-payer organisations and the pharmaceutical sector	Selective access to public-payer organisations based on personal connections
Risk # 2: Outflow of officials from public-payer organisations to the pharmaceutical sector	Loss of organisational memory; "coincidences of interest" resulting from seeking employment and then being employed in the pharmaceutical sector
Risk # 3: Cooperation between members of the Appraisal Committee and the pharmaceutical industry	Conflicts of interest; procedural difficulties in appraisal; selective access based on personal connections
Risk # 4: Cooperation between external experts and the pharmaceutical industry	Conflicts of interest; diminished credibility of external experts; "social closure" of experts engaged in drug evaluation
Risk # 5: Cooperation between patient organisations and the pharmaceutical industry	Diminished credibility of patient organisations; suboptimal patient participation in drug evaluation
Risk # 6: Pressure from political elites, especially on general directions of drug evaluation	Diminished political autonomy of the Appraisal Committee; political considerations outweighing scientific ones in drug evaluation

5.3. Disclosure and management of Appraisal Committee members' conflicts of interest

The Reimbursement Act redesigned the system for reporting and handling experts' conflicts of interest by replacing the "Register of benefits" [39] with two types of declarations. Declarations of the lack of conflict of interest, submitted on appointment to the TC and before every TC session, refer to membership in statutory bodies, stock ownership, and entrepreneurial activity in the pharmaceutical sector. Declarations of conflict of interest, submitted before every session, cover financial relationships with the pharmaceutical sector. The declarations concern both TC members and their family members. Declarations of the lack of conflict of interest will be verified by the Central Anticorruption Bureau. The provision of false information will entail legal sanctions.

On top of these changes, declarations of conflict of interest should incorporate "indirect interests" [80] or "non-personal pecuniary interests" [81] and distinguish between minor and major financial conflicts of interest [82]. Furthermore, the AHTAPol should specify a procedure on resolving doubts that may arise when providing information about conflicts of interests and correcting any inaccuracies [81]. Separately, the AHTAPol may set out regulations concerning receiving hospitality and gifts by TC members [81]. In applying any policies regarding conflicts of interest, policy-makers must recognise, however, that a radical "precautionary principle" [55] is not a feasible solution for the AHTAPol, given the dearth of alternative to the pharmaceutical industry sources of support for experts' research activity.

The RA secured the obligatory publication of, *inter alia*, assessment reports and reports from TC sessions. It must be noted, however, that initial reports from TC sessions [83] keep secret more information concerning conflicts of interests reported by its members than the analysed reports from 2007 to 2008.

We expect the newly implemented random selection of a team of TC members working on a submission to face practical problems, such as exclusion of members with the greatest expertise in specific clinical areas. Instead, we propose to increase the transparency of discussions leading to the selection of the submission team.

To minimise incentives for holding discussions with TC members outside the AHTAPol, voluntary meetings with drug companies might be considered within the procedure of receiving external clients [43].

5.4. Disclosure and management of external experts' conflicts of interest

The RA introduced obligatory declarations of conflicts of interest of external experts, with legal sanctions for the provision of false information. As with TC members, we recommend extending the list of conflicts of interest that are applied to external experts by "indirect" [80] or "non-personal pecuniary interests" [81].

In addition, there is still room for the improvement in the disclosure of information about external experts' conflicts of interests. Reports from TC sessions [83] now mention whether external experts have reported conflicts of interest and whether the TC has allowed them to testify. However, the reports should also include the types of conflicts of interest declared. Assessment reports must always state clearly whether external experts submitted declarations of conflict of interest and whether these were filled in correctly. It must also be evident what types of conflicts of interest were reported and whether opinions provided by experts reporting conflicts of interest were accepted by the AHTAPol. The criteria used in evaluating experts' conflicts of interest should be disclosed.

The possibility of "social closure" [23] in selecting external experts could be reduced by establishing an official list of experts advising the AHTAPol.

5.5. Institutionalisation of patient and public involvement

The AHTAPol should develop a comprehensive policy on patient and public involvement. It should detail the process of inviting guests to TC sessions, the rules of giving testimonies, reporting conflicts of interest, publishing written and oral comments and conflicts of interest.

In the long run, the transparency of patient and public involvement [84–86] might be enhanced by creating a register of individuals and organisations interested in contributing regularly to drug evaluation and willing to

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publically disclose their conflicts of interest [87]. The register could then become the basis for selecting members of a permanent advisory body, funded by the AHTAPol, comprising a range of condition areas, general patient associations, and members of the public.

5.6. Increased institutional distance between AHTAPol and MoH

The RA has increased the institutional distance between the MoH and the AHTAPol by prohibiting the overlap of positions between the Economic Commission at the MoH and the TC. Ensuring the representation of the MoH in the TC may, however, create opportunities for direct political influence on the TC.

Formal institutions alone seem to be insufficient to eliminate the risk of exerting political influence on the AHTAPol. Of equal importance is the gradual development of shared cultural norms stressing the autonomy of scientific drug evaluation [3]. This process may be facilitated by the application of techniques offered by the Programme on Negotiation at Harvard Law School [88] to resolve tensions arising between the MoH and the AHTAPol in relation to the reimbursement process.

Conflicts of interest

PO – none; LK – none; MM – has been a member of advisory boards for Merck & Co and Johnson & Johnson.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.healthpol.2012.10.001.

References

[1] Valesco-Garrido M, Kristensen FB, Nielsen CP, Busse R. Health technology assessment and health policy-making in Europe: current status, challenges and potential. Copenhagen: European Observatory on Health Systems and Policies; 2008.
[2] Lehoux P, Blume S. Technology assessment and the sociopolitics of health technologies. Journal of Health Politics Policy and Law 2000;25:1083–120.
[3] Lehoux P, Hivon M, Denis J-D, Tailliez S. Health technology assessment in the Canadian health policy arena: examining relationships between evaluators and stakeholders. Evaluation 2008;14:295–321.
[4] Will C, Moreira T. Introduction: medical proofs social experiments: clinical trials in shifting contexts. In: Will C, Moreira T, editors. Medical proofs, social experiments. Clinical trials in shifting contexts. Farnham: Ashgate; 2010. p. 1–15.
[5] Kolasa K, Schubert S, Manca A, Hermanowski T. A review of health technology assessment (HTA) recommendations for drug therapies issued between 2007 and 2009 and their impact on policymaking processes in Poland. Health Policy 2011;102:145–51.
[6] Charles River Associates. The implications of the pharmaceutical forum recommendations for CEE countries. London: CRA International; 2009.
[7] Wytyczne HTA. http://www.aotm.gov.pl/index.php?id=13 (accessed March 29, 2012); 2012.
[8] Draborg E, Gyrd-Hansen D, Poulsen PB, Horder M. International comparison of the definition and the practical application of health technology assessment. International Journal of Technology Assessment in Health Care 2005;21:89–95.
[9] Niżankowski R, Wilk N. From idealistic rookies to a regional leader: the history of health technology assessment in Poland. International Journal of Technology Assessment in Health Care 2009;25:156–62.
[10] Angell M. The truth about drug companies. How they deceive us and what to do about it? New York: Random House; 2005.
[11] Abraham J, Lewis G. Regulating medicines in Europe: competition expertise and public health. London: Routledge; 2000.
[12] Abraham J. The pharmaceutical industry as a political player. The Lancet 2002;360:1498–502.
[13] Ferner RE. McDowell ES. How NICE may be outflanked? British Medical Journal 2006;332:1268–71.
[14] The Lancet. Herceptin and early breast cancer: a moment for caution, 366; 2005. p. 1673.
[15] Abraham J. Sociology of pharmaceuticals development and regulation: a realist empirical research programme. Sociology of Health & Illness 2008;30:869–85.
[16] GSK. The use of health technology assessments (HTA) to evaluate medicines – key principles from GSK. http://www.gsk.com/policies/GSK-health-technology-assessments.pdf (accessed August 8, 2010); 2005.
[17] Banta D, Johnson E. History of HTA: introduction. International Journal of Technology Assessment in Health Care 2009;25:1–6 (Supplement 1).
[18] WHO. Cost-effectiveness thresholds; 2012 http://www.who.int/choice/costs/CER_thresholds/en/index.html (accessed May 15, 2012).
[19] Davis C, Abraham J. Rethinking innovation accounting in pharmaceutical regulation. Science, Technology & Human Values 2011;36:791–815.
[20] Spielmans GI, Parry PI. From evidence-based medicine to marketing-based medicine: evidence from internal industry documents. Journal of Bioethical Inquiry 2010;7:13–29.
[21] Abraham J. Drug trials and evidence bases in international regulatory context. BioSocieties 2007;2:41–56.
[22] Abraham J. On the prohibition of conflicts of interest in pharmaceutical regulation: precautionary limits and permissive challenges. A commentary on Sismondo (66:9, 2008, 1909-14) and O'Donovan and Lexchin. Social Science & Medicine 2010;70:648–51.
[23] Abraham J, Davis C. Drug evaluation and the permissive principle: continuities and contradictions between standards and practices in antidepressant regulation. Social Studies of Science 2009;39:569–98.
[24] Abraham J. Science politics and the pharmaceutical industry: controversy and bias in drug regulation. London: UCL Press; 1995.
[25] Abraham J. Partial progress: governing the pharmaceutical industry and the NHS, 1948-2008. Journal of Health Politics, Policy and Law 2009;34:931–77.
[26] Moynihan R. Key opinion leaders: independent experts or drug representatives in disguise. British Medical Journal 2008;336:1402–3.
[27] Abraham J. From evidence to theory: neo-liberal corporate bias as a framework for understanding UK pharmaceuticals regulation – response to Alison Edgely. Social Theory & Health 2007;5:161–75.
[28] Ustawa z dnia 12 maja 2011 o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych. Dz. U. Nr 122, poz. 696.
[29] Lipska I. The challenges for adapting HTA for use in Poland; 2009 http://www.aotm.gov.pl/index.php?id=5 (accessed March 27, 2012).
[30] Uchwała nr 56/16/2008 z dnia 28 października 2008 r. w sprawie finansowania sunitynibu (Sutent®) w leczeniu raka nerki zaawansowanego lub z przerzutami. http://www.aotm.gov.pl/assets/files/rada/uchwala_rk_aotm_56_16_2008_sunitynib_Sutent.pdf (accessed August 26, 2012); 2008.
[31] Dexter LA. Elite and specialized interviewing. Evanston: Northwestern University Press; 1970.
[32] Baggot R, Allsop J, Jones K. Speaking for patients and carers. Health consumer groups and the policy process. Basingstoke: Palgrave; 2005.

[33] Glaser BG, Strauss A. Discovery of grounded theory. Strategies for qualitative research. Chicago: Aldine De Gruyter; 1967.
[34] Sim J, Wright C. Research in health care: concepts designs and methods. Cheltenham: Nelson Thornes; 2002.
[35] Berry J. Validity and reliability issues in elite interviewing. PS: Political Science and Politics 2002;35:679–82.
[36] Strauss AL. Qualitative analysis for social scientists. Cambridge: Cambridge University Press; 2001.
[37] Geertz C. Thick description: toward an interpretive theory of culture. In: Geertz C, editor. The interpretation of cultures: selected essays. New York: Basic Books; 1973. p. 3–30.
[38] Rekomendacje i stanowiska. http://www.aotm.gov.pl/index.php?id=12 (accessed December 10, 2011); 2011.
[39] Rejestr korzysci. http://www.mz.gov.pl/wwwfiles/ma_struktura/docs/rejestr_korzysci_17112011.pdf (accessed December 10, 2011); 2011.
[40] AHTAPol. Archiwum. http://www.aotm.gov.pl/index.php?id=357 (accessed December 10, 2011); 2011.
[41] Hood C. The blame game: spin bureaucracy and self-preservation in government. Princeton: Princeton University Press; 2010.
[42] Hood C. The risk game and the blame game. Government and Opposition 2002;37:15–37.
[43] AHTAPol. Procedura Agencji Oceny Technologii Medycznych dotycząca przyjmowania klientów zewnętrznych z dnia 8 czerwca 2009 roku. http://www.aotm.gov.pl/assets/files/aktualnosci/10-06-2009/procedura-spotkan-w-AOTM0001.pdf (accessed October 5, 2011); 2009.
[44] Zarządzenie Nr 3/2010 Prezesa Agencji Oceny Technologii Medycznych z dnia 23 lutego 2010 r. w sprawie Komentarza podmiotu wnioskującego do oceny raportu w sprawie oceny leku lub wyrobu medycznego przygotowanej przez Agencje Oceny Technologii Medycznych. http://www.aotm.gov.pl/assets/files/aktualnosci/2010/24-02-2010/10.02.23_Zarzadzenie-3_2010_Komentarz_Producenta.pdf (accessed March 25, 2012); 2010.
[45] Wilk N. Doświadczenia pilotażu programow przejrzystości. http://archiwum.aotm.gov.pl/pliki/pub/pl/prezentacja_Norbert_Wilk.pdf (accessed August 23, 2009); 2008.
[46] Wedel J. The private Poland. New York and Oxford: Facts on File Publications; 1986.
[47] Wedel J. Clans, cliques and captured states: rethinking 'transition' in Central and Eastern Europe and the former Soviet Union. Journal of International Development 2003;15:427–40.
[48] Wedel J. Shadow elite. How the world's new power brokers undermine democracy, government and the free market. New York: Basic Books; 2009.
[49] Fishman J. Manufacturing desire: the commodification of female sexual dysfunction. Social Studies of Science 2004;34:187–218.
[50] Lakoff A. The anxieties of globalisation: antidepressant sales and economic crisis in Argentina. Social Studies of Science 2004;34:247–69.
[51] Załącznik nr 1 do Regulaminu Rady Konsultacyjnej Agencji Oceny Technologii Medycznych z dnia 29 marca 2011. Wzór – deklaracja konfliktu interesów. http://aotm.gov.pl/assets/files/rada/regulamin-29-03-2011/Regulamin_RK_AOTM_29032011_zal_1.pdf (accessed November 23, 2011); 2011.
[52] Oldani MJ. Thick prescriptions: toward an interpretation of pharmaceutical sales practices. Medical Anthropology Quarterly 2004;18:325–56.
[53] Sismondo S. How pharmaceutical industry funding affects trial outcomes: causal structures and responses. Social Science & Medicine 2008;66:1909–14.
[54] Regulamin Rady Konsultacyjnej Agencji Oceny Technologii Medycznych. http://aotm.gov.pl/assets/files/rada/regulamin-29-03-2011/Regulamin_RK_AOTM_29032011.pdf (accessed November 23, 2011); 2011.
[55] Lexchin J, O'Donovan O. Prohibiting or 'managing' conflict of interest? A review of policies and procedures in three European drug regulation agencies. Social Science & Medicine 2010;70:643–7.
[56] Ozieranski P, McKee M, King L. Pharmaceutical lobbying under post-communism: universal or country-specific methods of securing state drug reimbursement in Poland? Health Economics, Policy and Law 2012;7:175–95.
[57] Kuehn B. Report: FDA exerts too little oversight of researchers' conflicts of interest. Journal of American Medical Association 2009;301:709–10.
[58] AHTAPol. Plan pracy Rady Przejrzystości. http://www.aotm.gov.pl/index.php?id=11 (accessed March 28, 2012).
[59] Załącznik nr 5 do Regulaminu Rady Konsultacyjnej Agencji Oceny Technologii Medycznych z dnia 29 marca 2011. Wzór – deklaracja konfliktu interesów http://www.aotm.gov.pl/assets/files/rada/regulamin-08-06-09/regulamin_RK_AOTM_090608_zal_5.pdf (accessed March 28, 2012); 2009.
[60] Jakubiak L. Po czyjej stronie jest pacjent zrzeszony w "poprawnej medialnie organizacji. Rynek Zdrowia. http://www.rynekzdrowia.pl/Rynek-Zdrowia/Po-czyjej-stronie-jest-pacjent-zrzeszony-w-poprawnej-medialnie-organizacji,51978.html; 2010 (accessed March 10, 2010).
[61] Stanowisko Rady Konsultacyjnej nr 22/10/26/2009 z dnia 14 grudnia 2009r. w sprawie zmiany warunków realizacji świadczenia terapeutyczny program zdrowotny. Program leczenia w ramach świadczenia chemioterapia niestandardowa. http://www.aotm.gov.pl/assets/files/rada/rekomendacje_stanowiska/R43-chemioteriapia-niestandardowa/stanowisko_RK_AOTM_22_10_26_2009_TPZ_chemioterapia_niestandardowa.pdf (accessed February 15, 2010); 2009.
[62] Rekomendacja nr 43/2009 Prezesa Agencji Oceny Technologii Medycznych w sprawie zmiany warunków realizacji świadczenia gwarantowanego. Program leczenia w ramach świadczenia chemioterapia niestandardowa w zakresie programów zdrowotnych. http://www.aotm.gov.pl/assets/files/rada/rekomendacje_stanowiska/R43-chemioteriapia-niestandardowa/R_43.pdf (accessed February 15, 2010); 2009.
[63] Stanowisko Rady Konsultacyjnej nr 71/2011 z dnia 8 sierpnia 2011 r. w sprawie niezasadności zakwalifikowania świadczenia opieki zdrowotnej. Leczenie raka jelita grubego przy wykorzystaniu substancji czynnej bewacyzumab w ramach terapeutycznego programu zdrowotnego jako świadczenia gwarantowanego. http://www.aotm.gov.pl/assets/files/rada/rekomendacje_stanowiska/2011/R-71-2011-bewacyzumab/Stanowisko_RK_AOTM_71_2011_Avastin.pdf (accessed November 15, 2011); 2011.
[64] Rekomendacja nr 57/2011 Prezesa Agencji Oceny Technologii Medycznych z dnia 8 sierpnia 2011 r. w sprawie zakwalifikowania świadczenia opieki zdrowotnej. Leczenie raka jelita grubego przy wykorzystaniu substancji czynnej bewacyzumab jako świadczenia gwarantowanego w ramach programu zdrowotnego. http://www.aotm.gov.pl/assets/files/rada/rekomendacje_stanowiska/2011/R-71-2011-bewacyzumab/R_57_2011_Avastin.pdf (accessed November 15, 2011); 2011.
[65] Stanowisko Rady Konsultacyjnej nr 28/2011 z dnia 29 marca 2011 r. w sprawie zasadności zakwalifikowania świadczenia opieki zdrowotnej. Leczenie choroby Niemanna-Picka typu C z zastosowaniem substancji czynnej miglustat w ramach programu zdrowotnego, jako świadczenia gwarantowanego. http://www.aotm.gov.pl/assets/files/rada/rekomendacje_stanowiska/2011/R-28-2011-Zavesca/Stanowisko_RK_AOTM_28_2011_Zavesca.pdf (accessed November 15, 2011); 2011.
[66] Rekomendacja nr 20/2011 Prezesa Agencji Oceny Technologii Medycznych z dnia 29 marca 2011 r. w sprawie zakwalifikowania świadczenia opieki zdrowotnej. Leczenie choroby Niemanna-Picka typu C z zastosowaniem substancji czynnej miglustat (Zavesca®) w ramach programu zdrowotnego jako świadczenia gwarantowanego. http://www.aotm.gov.pl/assets/files/rada/rekomendacje_stanowiska/2011/R-28-2011-Zavesca/RP_20_2011_Zavesca.pdf (accessed November 15, 2011); 2011.
[67] Stanowisko Rady Konsultacyjnej nr 20/10/26/2009 z dnia 14 grudnia 2009 r. w sprawie zmiany warunków realizacji następujących świadczeń gwarantowanych, terapeutyczne programy zdrowotne. http://www.aotm.gov.pl/assets/files/rada/rekomendacje_stanowiska/R27-choroba-Gauchera/stanowisko_RK_AOTM_20_10_26_2009_TPZ_en_bloc.pdf (accessed February 15, 2010); 2009.
[68] Dychalska P. Urzędnicy czy praktykanci. Menedżer Zdrowia. http://www.termedia.pl/Urzednicy-czy-praktykanci,12,13548,0,0.html (accessed August 15, 2011); 2009.
[69] Healey D. Shaping the intimate: influences of the experience of everyday nerves. Social Studies of Science 2004;34:219–45.
[70] Moynihan R, Cassels A. Selling sickness: how the world's biggest pharmaceutical companies are turning us all into patients. New York: Nation Books; 2005.
[71] Hailey D, Juzwishin D. Managing external risks to health technology assessment programmes. International Journal of Technology Assessment in Health Care 2006;22:429–35.
[72] Light DW. Countervailing powers: a framework for the professions in transition. In: Johnson T, Larkin G, Saks M, editors. Health professions and the state in Europe. London: Routledge; 1995. p. 25–43.
[73] Hood C, Rothstein H, Baldwin R. The government of risk: understanding risk regulation regimes. Oxford: Oxford University Press; 2001.

Please cite this article in press as: Ozieranski P, et al. The politics of health technology assessment in Poland. Health Policy (2012), http://dx.doi.org/10.1016/j.healthpol.2012.10.001

[74] Hood C. What happens when transparency meets blame-avoidance? Public Management Review 2007;9:191–210.
[75] Kolasa K, Dziomdziora M, Fajutao L. What aspects of the health technology assessment process recommended by international health technology assessment agencies received the most attention in Poland in 2008? International Journal of Technology Assessment in Health Care 2011;27:84–94.
[76] Morgan B, Yeung K. An introduction to law and regulation. Text and materials. Cambridge: Cambridge University Press; 2007.
[77] Czech M. Etyka w farmakoekonomice. Czasopismo aptekarskie 2008;173:29–32 http://www.cza.pl/pdf/cza2008-05-s29-32.pdf.l (accessed March 12, 2012).
[78] Boyce G, Davids C. Conflicts of interest in policing and the public sector. Public Management Review 2009;11:601–40.
[79] Bertók J. Post-public employment: good practices for preventing conflict of interest. OECD Publishing; 2010.
[80] European Medicines Agency policy on the handling of conflicts of interests of scientific committee members and experts. European Medicines Agency. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf (accessed April 15, 2012); 2012.
[81] A Code of practice for declaring and dealing with conflicts of interest. National Institute for Health and Clinical Excellence. http://www.nice.org.uk/niceMedia/pdf/CodeofPracticeforDeclaringandDealingwithConflictsofInterest.pdf (accessed April 15, 2012); 2007.
[82] Kaiser J. Private money, public disclosure. Science 2009;325:28–30.
[83] Protokoły z posiedzeń Rady. http://aotm.gov.pl/index.php?id=586
[84] Facey K, Boivin A, Gracia J, Hansen HP, Lo Scazlo A, Mossman J, et al. Patients' perspectives in health technology assessment: a route to robust evidence and fair deliberation. International Journal of Technology Assessment in Health Care 2010;26:334–40.
[85] Gagnon M-P, Desmartis M, Lepage-Savary D, Gagnon J, St-Pierre M, Rhainds M, et al. Introducing patients' and the public's perspectives to health technology assessment. International Journal of Technology Assessment in Health Care 2011;27:31–42.
[86] Gauvin F-P, Abelson J, Giacomini M, Eyles J, Lavis JN. Moving cautiously: public involvement in health technology assessment community. International Journal of Technology Assessment in Health Care 2011;27:43–9.
[87] Abelson J, Giacomini M, Lehoux P, Gauvin FP. Bringing 'the public' into health technology assessment and coverage policy decisions: from principles to practice. Health Policy 2007;82:37–50.
[88] The Programme on Negotiation at Harvard Law School. http://www.pon.harvard.edu/?floater=99 (April 12, 2012); 2012.

Please cite this article in press as: Ozieranski P, et al. The politics of health technology assessment in Poland. Health Policy (2012), http://dx.doi.org/10.1016/j.healthpol.2012.10.001