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Governing drug reimbursement policy in Poland: The role of the state, civil society and the private sector

Web Appendix 4 – Qualitative database

Contents

List o abbreviations

ADHD	Attention Deficit Hyperactivity Disorder
AHTAPol	Agency of Health Technology Assessment (*Agencja Oceny Technologii Medycznych*)
CC	Consultative Council (Polish: *Rada Konsultacyjna*) at the Agency of Health Technology Assessment
DDPP	Department of Drug Policy and Pharmacy (*Departament Polityki Lekowej i Farmacji*) at the Ministry of Health
EBM	Evidence-based medicine
EU	European Union
HTA	Health technology assessment
KOLs	Key opinion leaders in the medical milieu
MoH	Ministry of Health (*Ministerstwo Zdrowia*)
NHF	National Health Fund (*Narodowy Fundusz Zdrowia*)
NICE	National Institute for Health and Clinical Excellence (England and Wales)
QALY	Quality-Adjusted Life Year
PLN	Polish *złoty*, national currency in Poland
PR	Public relations
USD	United States Dollar

Introduction. The methodology of designing the appendix

This Web Appendix offers supplementary interview data concerning the findings presented in the article "Governing drug reimbursement policy in Poland: The role of the state, civil society and the private sector"

The list of topics covered in the Appendix follows the sequence of argument in the main body of the article. Most often, a topic in the Appendix refers to a finding analysed in up to four consecutive paragraphs in the article. Every topic starts with a brief introduction, summarising its contents, followed by a number of quotations.

The topics included in the Appendix are highly consistent with key themes established through the coding of the 109 interviews constituting our qualitative database. More exactly, these themes comprise high-level codes that were created after collapsing lower-level codes generated from research hypotheses or or emerging directly from the data..

The themes covered in the Appendix and in the main body of the article constitute a substantial part of the entire interview data set. In total, the article and the Appendix comprise statements made by 65 (out of 87) individuals from our sample and 86 (out of 109) interviews. Naturally, the perspectives of our key informants are the ones most represented. Nevertheless, we do not see it as a source of bias, as these statements are generally not contradicted by other interviewees. Also, they usually provide unique insights into exclusive knowledge about mechanisms of drug reimbursement.

As a rule, we excluded from the Appendix the themes that were not directly relevant for the main argument presented in the article. Furthermore, we excluded some sub-themes that could be relevant for the Appendix but were crucial for developing other publications. This is particularly the case with data concerning relationships between medical experts, patient organisations and multinational drug companies as well as the dynamics of "deniability" in drug reimbursement policy-making. However, quotations covered by these subthemes were

highly consistent with the main line of our argument. In addition, we excluded the themes which were very technical and therefore would not be easily accessible for an international reader without additional elaboration in the article.

In selecting individual quotations for each theme, we ensured that they reflect as many organisational perspectives as possible. When the interviewees disagreed on a particular issue, we paid attention to representing all contrasting viewpoints. It follows that we included even evidently deceptive statements by some interviewees and used them as a valuable source of data. In order to properly highlight negative evidence, we present it in separate subsections throughout the Appendix. We must also mention that we did not include the otherwise supportive quotations which might disclose the identity of an interviewee or other parties, especially in the context of ethically or legally dubious activities.

We included only quotations that are directly relevant for each theme. In so doing, we refrained from artificially inflating the number of quotations (and their length) by using data of poorer quality. A few quotations overlap with those utilised in the article but are presented in a more extensive form, without editing. In addition, a very limited number of particularly rich quotations appear simultaneously under more than one theme in the Appendix.

The length of individual quotations varies. Quotations coming from a small number of tape-recorded interviews are obviously longer and more evocative, whereas those transferred from hand-written notes are shorter and focus on key statements made by interviewees. Some quotations are edited. In principle, we removed fragments which were problematic in terms of anonymity, overly technical or irrelevant for a particular theme.

There are two limitations to the transparency of the data presented in the Appendix (and the article). First, we did not introduce an interviewee code so as to prevent well-informed insiders from identifying particular individuals by pulling together statements referring to a few themes. We expected that the interviewee code may constitute a real threat to

interviewees' anonymity, as we were aware that the publication of another article on informal mechanisms of drug reimbursement in Poland was followed by a "witch hunt" targeted at our informants. However, we would like to reassure the reader that, for example, quotations attributed to a "high-ranking Ministry of Health official" were in fact made by five different individuals. This is also the case with interviewees from the pharmaceutical sector, medical experts and representatives of patient organisations from particular condition areas. Second, for the same reasons we modified slightly the job titles of some of our interviewees. For instance, due to the small number of the Consultative Council members we merged them with other senior officials working for the Agency for Health Technology Assessment.

1. Conducting interviews

INTRODUCTION

This section illustrates the challenges that we faced in conducting interviews on mechanisms of power in the Polish drug reimbursement policy domain. While some interviewees, especially our key informants, were willing to share their insider knowledge relatively openly, others were often concerned about possible adverse reactions of their employers or other parties involved in the reimbursement process. Hence, a key issue in conducting interviews were reassurances about our commitment to protecting interviewees' anonymity.

QUOTATIONS

1.1. Challenges in conducting interviews

"You are investigating very murky areas." (high-ranking official, AHTAPol)

"The atmosphere surrounding this sector is very negative and fraught with controversies. Public knowledge about treatments and drugs is very limited. And drug companies are seen as offering expensive products and disregarding the public interest. This is all streaked with scandals, bribing doctors and setting unjust prices. Also, lobbying, particularly pharmaceutical lobbying has an unambiguously negative publicity in Poland." (freelance lobbyist)

"Drug companies are not trusted by the public, they are simply seen as firms which want to make money." (spokesperson, multinational drug company)

"In this moment, I am asking myself the question if this is really academic work what you are doing or if this is drug companies' intelligence to learn how we work... Convince me that you

do not have a big subsidy from a drug company which supports your research." (high-ranking official, AHTAPol)

"Why do you need to know all this? Why are you asking all these questions?" (manager, HTA firm)

"Various covert actions are taken [in the pharmaceutical sector]. They do not happen on the surface. You will find it difficult to study them." (representative, association of generic companies)

"This area is a minefield. Not many people will be willing to talk to you" (former high-ranking official, MoH)

"I think so [that some national consultants – senior ministerial advisors – have strong relationships with drug companies]. Yet I wouldn't like to elaborate on this topic, because it is too informal to be a subject of scientific inquiry. Maybe one of the [national] consultants will tell you more about it. Please ask consultants from areas with high competition on the market and controversies." (representative, professional association of medical professionals)

1.2. The role of anonymity in conducting interviews

"So you are going to use my statements as a synthesis, you are going to synthesise several [interviews], say, [to develop] an overview of the situation, with several or several dozen people? [...] I'm asking because this gives me more freedom to speak and present various mechanisms which do happen but about which I cannot say anything under my own name." (national consultant)

"I do hope that you will be writing very generally about the things I've told you. Remember that if anything happened, I will deny everything." (middle-ranking official, MoH)

"I have a lot to tell on this topic [drug reimbursement] but I would definitely like to avoid being cited. Let's agree that you will not cite me." (Member of Parliament)

"The things I am describing to you are the industry's tricks of the trade. I am speaking totally unofficially." (director, domestic public relations company)

"Add what I've just said to the description, without my name." (national consultant)

2. Initiating the reimbursement process

INTRODUCTION

This section provides more background on how the drug reimbursement process was initiated outside state organisations. In particular, it shows the significance of multinational drug companies in suggesting condition areas that were treated with highly expensive niche-buster drugs reimbursed within therapeutic programmes.

QUOTATIONS

"In general, this information [about the possible reimbursement of new drugs] comes from the bottom. [...] The Minister has small possibilities of creating his own ideas because he is no specialist but an official. [...] Obviously, the industry is the source of all this information. It's the company that sends the signal: 'We have it.'" (former high-ranking official, MoH)

"Given that the Minister [of Health] is an official, there is no need for him to know all of the areas of medicine. He does not [initiate the reimbursement process] himself. If there is a draft document, an appeal, a suggestion concerning the way of treatment or introducing a drug to reimbursement, he draws on expert opinions." (former high-ranking official, MoH)

"The problem with therapeutic programmes is that the NHF will not actually come up with anything on its own. This results in a very interesting mechanism: There is social pressure,

for instance, the television shows a sick child who desperately needs a very expensive drug, and there is pressure on the NHF to finance this drug. [...] Later, experts from the medical field say that it's precisely this drug that should be used because it will help a such and such patient group. As far as drug [therapeutic] programmes are concerned, professors from a given speciality are involved in their creation. And here a question needs to be asked whether these professors act in the interest of public finances or in the interest of patients or in the interest of a drug company, because we have different possibilities here." (journalist, daily paper)

"The most fundamental problem with drug policy – from my perspective [...] when I used to be there [the NHF] – is something which I call fashion. Someone has written or said somewhere that drug X […] is the best, the greatest one. Say, this is a cancer therapy. We administer it today and tomorrow there are no cancer cells and everything. And then we have a situation that every doctor would like to cure their patients, so there is nothing wrong than a doctor is so excited [*napalony*] about this direction. I don't know what to call it in a different way [...]: 'I'm so passionate, it must be this drug." (former high-ranking official, NHF)

"In the reimbursement process, the drug firm is [formally] an applicant only with regard to reimbursement lists. In therapeutic programmes, the firm can only act in a non-statutory – yet not necessarily illegal – manner. They can approach the Minister informally and say that there is a topic he should take up and that they have a nice drug." (former high-ranking official, AHTAPol)

"Therapeutic programmes are legal *terra incognita*. There is no formal procedure saying that the manufacturer approaches [the MoH or the NHF], what happens next, and how he is included in the process." (partner, multinational law firm)

"As for [therapeutic programmes], the entity eligible for proposing a drug for a programme is a drug company. The [...] service provider [the NHF] does not have such rights and capabilities. It is the NHF that, based on the proposal submitted by the firm, determining that the programme concerns a concrete and narrow group of patients, selects the programmes proposed by the firm. And to determine the description of the therapeutic programme, it invites authorities from a given area of medicine. And the programme is created on this basis." (former high-ranking official, NHF)

"[In therapeutic programmes] [t]here is no formal procedure saying that the manufacturer approaches [MoH or NHF], what happens next, and how it is included in the process." (partner, multinational law firm)

3. The importance of national consultants for drug companies

INTRODUCTION

This section provides additional background regarding the role of national consultants – key ministerial advisors in 84 areas of medical speciality – in the reimbursement process and their significance for multinational drug companies. It also explains that proposing the reimbursement of new expensive drugs, especially niche busters included in therapeutic programmes, allowed some consultants to build their individual position as medical experts as well as extend the power of their specialities.

QUOTATIONS

"Consultants have immense power. They are an authority for the Minister [of Health], the media and society. The firm can talk a lot but if the consultant says: 'No', it can do hardly anything. That is why consultants are in the very centre of firms' attention." (high-ranking official, MoH)

"They are an advisory body for the MoH and the NHF. Their opinions have a standardising quality. This is not the law, but important suggestions and recommendations. For drug companies, they way in which these recommendations are shaped is very important." (president, domestic lobbying firm)

"Each drug has its reviewer from CC as well as [national] consultants and, sometimes, members of patient organisations. Only after listening to expert opinions, and our internal discussion, which we sometimes continue through two sessions, we make our decision." (high-ranking official, AHTAPol)

"A consultant can recommend drugs that are rare and expensive. When such a drug is financed by the NHF, there needs to be an opinion provided by a consultant." (high-ranking official, MoH)

"As I picture this, if someone is the chair of a clinic, director of a hospital, or a professor, his relationships with the industry are very strong, intimate, so to speak. For he is the one who should notice this drug, give his opinion it, draw the MoH's attention. Essentially, their role is promoting new drugs. That is how they are introduced to the MoH's awareness." (high-ranking official, AHTAPol)

"For instance, we [the AHTAPol] lack specialists in [name of medical speciality]. That's why we always have to invite this particular national consultant. I have never ever heard him expressing a negative opinion about a drug. He is always the greatest enthusiast. I do not know why that is, but do not think he is such a devotee, so to speak, by nature. And the more enthusiastic the expert, the greater our scepticism and uncertainty. But [we] lack good arguments to challenge him. I have tried this one or two times and he asked me this simple question: "Are you a [specialist]?". And this shut me up. This is the authority and prestige of

a national consultant. He is a god-like figure. If we challenge them, we commit a faux pas and they feel insulted." (high-ranking official, AHTAPol)

4. "Blame games" between the MoH and the AHTAPol

INTRODUCTION

This section expounds the nature of "blame games" between the MoH and the AHTAPol, resulting from the key role of AHTAPol recommendations in legitimising reimbursement decisions taken by the Minister of Health. The MoH aimed to avoid reimbursing drugs not supported by positive AHTAPol recommendations in order to prevent unnecessary public scrutiny. This was associated with establishing a few institutional layers of control over the AHTAPol. On the other hand, the AHTAPol, particularly the CC, attempted to protect its independence from the MoH. While we did not identify strong evidence of MoH's direct interventions in relation to the issuing of individual recommendations, it influenced decisions taken by the AHTAPol in relation to broad policy directions. The profound political role of AHTAPol recommendations led to drug companies' strong desire to obtain positive recommendations.

QUOTATIONS

"The AHTAPol has a key role. It is supposed to reduce the grey sphere. It is supposed to reduce informal activities. It gives the decision-makers a justification [for a reimbursement decision]" (president, multinational drug company)

"The Minister can demonstrate with an AHTAPol 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." (partner, multinational law firm)

"The role of AHTAPol recommendations is unclear because it is the Minister of Health who is responsible for the shape of drug policy. His decisions cannot be bound by the Agency." (partner, multinational law firm)

"As of now, it has never happened that the Minister did not accept a recommendation. This is because we have appointed to the CC people whom we trust." (high-ranking official, MoH)

"The instances similar to X [a drug which was reimbursed despite a negative AHTA recommendations] are sporadic. I cannot imagine a drug receiving a negative recommendation from the Agency and then included by the Minister. [...] This would result in turmoil. That is why the Minister thinks: 'I don't want it.'" (external affairs manager, multinational drug company)

"If the Minister decided to reimburse a drug despite the negative recommendation, then difficult questions would follow immediately: "Who is behind it? Why did it happen?"' (external affairs manager, multinational drug company)

"We are determined to avoid the situation that a drug is placed on the [reimbursement] list despite the negative recommendation. As a rule, if the AHTAPol gives a negative recommendation, the drug is not reimbursed. In the past, it may have been different. But now it is the only right and safe solution. It shifts responsibility from the Minister to AHTA." (middle-ranking official, MoH)

"[T]he Ministry should [see] […] the Agency [as] [....] not just a fig leaf, which has to cover certain things, or [as] an excuse." (high-ranking official, AHTAPol)

"I think that this pressure [exerted by the MoH on the AHTAPol] does exist. When we look at the policy outcomes showing that AHTAPol is incapacitated by the MoH, the existence of this pressure becomes obvious. If 100% recommendations go along with the changes

proposed by the MoH, we can contend that this pressure is effective. I believe it is indeed very strong." (manager, domestic HTA firm)

"Now the Ministry [of Health] abuses us to cover up its mistakes. [They use us] to manipulate the legislation. They have made mistakes and crossed out this and that too hastily [from reimbursement schemes]. These [moves] were too indeterminate and now they [the MoH] are running to us to reactivate [certain things] or to introduce something that hadn't been there. The pressure [from the MoH] on the AHTAPol has increased, because the Ministry is fighting for its survival. There is a crisis situation in healthcare. This is like a volcano before explosion." (high-ranking official, AHTAPol)

"The Minister invited them [CC members] to the office and asked them to accept these changes [to a large number of therapeutic programmes] *a priori*, without any analysis or research. The CC did a favour to the Minister and accepted this request. And they have been regretting this decision ever since. This was a terrible mistake which rebounds on them all the time. But this is Poland. Unfortunately, mechanisms of this kind operate in this country." (high-ranking official, AHTAPol)

"I've heard a story, which cannot be verified, that in the case of drug X, the Minister of Health convened an extraordinary session of the CC saying that X must have a negative recommendation so that it can be removed from the reimbursement list [i.e. from open reimbursement]. [...] Sometimes the Minister needs a concrete recommendation." (partner, multinational law firm)

"Only a positive recommendations creates room for negotiation [with the MoH]." (external affairs manager, multinational drug company)

"We have to do everything to ensure that we receive a positive recommendation." (communications manager, multinational drug company)

"If a firm gets a positive recommendation, 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. That's why the AHTAPol is crucial for [drug] companies." (partner, multinational law firm)

"Firms do not 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." (key account manager, multinational drug company)

4.1. Negative evidence

"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 terms of credibility." (high-ranking official, NHF)

"After the creation of the AHTAPol to the reimbursement system it has become more difficult to introduce drugs to reimbursement. This place is the Mecca in the reimbursement process and the destination of drug companies' many pilgrimages. It simply has to be visited." (communications manager, multinational drug company)

"The AHTAPol is a big step forward. This Agency really evaluates the [reimbursement] applications. It will be present in the reimbursement process and should not succumb to political pressure. The AHTAPol can be a field of political games. The reimbursement [of a drug] can happen because of non-substantial reasons. The introduction of the AHTAPol have begun to bring reimbursement out of grey sphere. In the past, reimbursement was occurring in a covert way. But the AHTA constitutes the expert base [of the reimbursement process]." (president, multinational drug company)

"The final [reimbursement] decision is always up to the Minister. [...] Because, if someone would not like to bear responsibility, then it is best to shift it to a certain body. For this a large body, then it is not responsible for anything. Therefore, the minister does not evade responsibility." (high-ranking official, MoH)

"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." (high-ranking official, AHTAPol)

"I haven't hear about the Ministry [of Health] pressurising the AHTAPol to issue a recommendation going in a particular direction. The Minister wouldn't need to ask the Agency [to do this] [as the recommendation is not binding for the Minister]." (partner, multinational law firm)

5. Price negotiations with drug companies

INTRODUCTION

This section elaborates on the mechanisms of price negotiations between the MoH and multinational drug companies, particularly in relation to the most expensive niche-buster medicines applying for therapeutic programmes. It demonstrates the largely informal nature of interactions between representatives of the both sides. The evidence that does not support our argument suggests that this form of price negotiations might have led to obtaining price agreements more favourable for the MoH.

QUOTATIONS

"In therapeutic programmes, the rules [of price negotiations] are unclear and the process is not well organised. Now they belong to the MoH's sphere of competence but the influence of NHF still remains considerable." (corporate affairs director, multinational drug company)

"Price negotiations are not formalised and non-transparent, to put it mildly. [...] This is all informal and not described in the legislation. This is done sort of 'by the way'. […] The negotiations are not grounded in the legislation." (partner, domestic law firm)

"[Price] [n]egotiations can offer considerable opportunities for developing corrupt relationships." (former high ranking official, MoH)

"We do not formalise this process, because otherwise the negotiations would be illegal. There is no legislation permitting negotiations. We just use one article as the legal basis. This fiction works for everyone and that's why no one objects." (middle-ranking official, MoH)

"There is no procedure concerning therapeutic programmes, that is, those most expensive life-saving drugs. There is even no procedure of receiving external clients. The story goes on like this: The Minister calls [the firm] saying, 'You see, you have to come here tomorrow and, you know, we will talk.' And they have a chit-chat. It's not that there is one procedure concerning the whole area in which price-volume or risk sharing agreements emerge in a minimal form. But this is all done verbally. This is a gentlemen agreement. [...] This is the type of conversation you can have over coffee." (partner, multinational law firm)

5.1. Negative evidence

"We usually meet at the table several times. We either accept the price at some stage or go on with the negotiations." (high-ranking official, MoH)

"The negotiations are not entirely rigid, because they couldn't be done that way." (former high-ranking official MoH)

"First we have the initial offer form the reimbursement application, which is passed on together with information on prices in other countries and in the past. We then conduct our analyses. We receive an application after it has gone through the AHTAPol [...]. Price negotiations are mostly conducted with innovative companies [rather than generic firms] because these products are more expensive. We sit at the table, sometimes a few times. We are striving to arrive at a price that will not ruin the system. Innovative drugs are simply expensive. There is less and less drugs based on chemical synthesis but biotechnology drugs – created through molecular engineering – are more numerous. The truth is that is that sometimes they have little added value but are presented as extraordinary." (high-ranking official, MoH)

6. Criteria for taking reimbursement decisions

INTRODUCTION

This section explores a range of considerations involved in taking reimbursement decisions by political and bureaucratic elites at the MoH. In so doing, it presents both the general principles of drug reimbursement policy as well as more detailed criteria. It demonstrates a contrast between the perspectives of high-ranking MoH officials, who stress the role of Evidence Based Medicine and other stakeholders showing the limitations of the use of scientific evidence in reimbursement policy-making.

QUOTATIONS

6.1. General principles

"It is hard to evaluate something that does not exist in practice. The principles of drug policy – you have in mind those available on the MoH webpage – have not been implemented in

practice. It is difficult to list advantages and disadvantages of something that does not exist." (KOL, cardiology)

"There is no drug policy in this country! There is no drug policy because there is no health policy! So we do not have any vision of what can or cannot be financed from public funds. If this does not exist, then we cannot say that drug policy, which is part of health policy, is functioning. Drug policy does not function here also because we have opened a gigantic door saying 'Everyone can have everything.'" (high-ranking official, NHF)

"[Drug] [c]ompanies say that the MoH has a budget, not a plan. That is to say, they look at the amount of money at their disposal and think what they can afford. What they are not doing is defining their priorities in treatment areas." (American diplomat)

"I don't know if we support it or not, since I don't have the faintest idea of drug policy in this country." (high-ranking official, AHTAPol)

6.2. Detailed criteria

"There is a lot of talk about the Ministry's [of Health] policy, which is not always clear to us. [For example,] the issue of non-standard drugs [i.e. very expensive innovative therapies for small groups of patients, sometimes in off-label indications]. Who decides about it? There was a scandal [in this area]. The AHTAPol took a stand in this case but it was not very clear." (high-ranking official, AHTAPol)

"There are no clear criteria for taking reimbursement decisions. In the case of new expensive drugs we are not entirely sure why they enter reimbursement or not." (journalist, web-based magazine)

"[Reimbursement] criteria are very vague, very general. It's black magic for us. We don't know how it happens, how decisions are taken' (spokesmen, multinational drug company)

"Even when criteria exist, they are not applied, for instance with regard to official prices." (partner, domestic law firm)

"Theoretically, the reimbursement process is transparent but in reality the [reimbursement] decision is taken by one person [i.e. the Minister of Health] and it remains unknown why these decisions are as they are." (key account manager, multinational drug company)

"Politicians have the greatest impact on [reimbursement] decisions and experts are sidelined, so to speak. Sometimes, they are used as an alibi, sometimes they are just overtly ignored. Take the example of X [a drug whose introduction to reimbursement was associated with serious procedural irregularities]. The Minister Y makes a statement that it was him who took the decision [about the introduction of X to reimbursement]. [...] So no one is showing an expert who would say: 'Yes, [the reimbursement of] X was a purposeful decision, because research shows this and that. So the process of taking the decision is non-transparent. I don't know if this [introduction of drug X to reimbursement] was the effect of the meeting at that cafe or social considerations? How should I know it? No one shows me any substantive arguments." (journalist, daily paper)

"In fact, it remains unknown why [a certain reimbursement decision has been taken]. There are no arguments that would justify it." (Member of Parliament)

"How certain drugs are placed on the [reimbursement] lists is completely unclear for me." (American diplomat)

"This process is very secretive. It happens behind closed doors and its results are announced after many weeks. We don't know how and where decision is taken." (spokesperson, multinational drug company)

"The lack of clarity that we observe [in taking reimbursement decisions] may lead to lobbying scandals." (partner, domestic law firm)

"Drug policy in the area of drug reimbursement is characterised by may allusions, understatements, little transparency and gigantic lobbying." (former high-ranking MoH official)

"There are no clear criteria for taking reimbursement decisions." (journallist, web-based magazine)

"Reimbursement criteria are non-transparent. It is impossible to verify reimbursement decisions. There are no clear criteria and these decisions cannot be checked. In my opinion, these are political decisions." (partner, multinational law firm)

6.3. Negative evidence

"Our policy for a few years has been relative effectiveness. We compare drugs to one another based on their effectiveness. If it's not worth adding a drug to the reimbursement list, then we're sorry. We don't do this if the price is higher than drugs acting in a similar way." (high-ranking official, MoH)

7. The role of scientific evidence in taking reimbursement decisions

INTRODUCTION

This section illustrates an opposition between interviewees stressing the role of scientific evidence regarding primarily clinical and cost-effectiveness and those who pointed to problems related to utilising scientific evidence generated by drug companies to support their medicines applying state reimbursement.

QUOTATIONS

"Everyone is determined to introduce new allegedly breakthrough drugs to the market so that the patient pays a lot. But it turns out that they are not more effective than those already existing. And some of them have side effects as well." (journalist, web-based magazine)

"In practice, no one can verify the reliability of these [pharmacoeconomic] data [used to support reimbursement applications]. The effects of drugs can only be seen once they are applied on a daily basis. Sometimes firms hide some data. And here we have this lobbying... not lobbying but corruption of doctors or investigators. Everyone says that it is like this." (journalist, web-based magazine)

"HTA analyses play a very important role [in attempts aimed at entering drug reimbursement schemes]. They are evaluated by the AHTAPol. They comprise propositions, comparisons and evidence of cost-effectiveness. They are prepared in line with certain guidelines [...]. HTA is very hermetic knowledge. The most important centre for HTA is Cracow. They train experts in HTA. My impression is that HTA is used a bit optionally. [...] Sometimes, it is used not to allow a drug to enter reimbursement. This is not done religiously. NICE, from example, is a very prestigious institution, recognised all over the world. It is hard to imagine that evidence could be manipulated there. And [in Poland] these standards are sometimes applied and sometimes not. It all depends on the initial thesis. If the NHF does not want to reimburse [a drug] it will do anything not to let the AHTAPol allow it. There is pressure exerted on the AHTAPol." (freelance lobbyist)

"In half of the research results [submitted by drug companies] we deal with drugs whose effectiveness cannot be established. This makes our assessment so difficult. For instance, firms often misinform or over-interpret information concerning medical products. Data manipulation is very frequent in oncology. Firms use various statistical tricks and employ the best statisticians." (high-ranking official, NHF)

"What is more, what is important is [...] as far as rare diseases are concerned, is that drug companies very frequently act on the international stage to prevent the states from agreeing [the standards of] comparative research on drugs for rare diseases. If 16 people suffer from a disease in Poland, it is very difficult to conduct research on its [the drug's] effectiveness because there are too few people. But it can be done on the pan-European level. But drug companies do everything they can, because I have seen it [...], not to let this happen. [...] They are afraid of this." (Member of Parliament)

"Each drug has its weak spots. It always has strengths and weaknesses. For instance, there are always side effects." (external affairs manager, multinational drug company)

"These are often political decisions [AHTAPol recommendations]. They dig up dirt on drugs." (external affairs manager, multinational drug company)

"It [market access strategies employed by drug companies] covers both lobbying, creating reimbursement dossiers and pharmacoeconomic analyses." (key account manager, multinational drug company)

"That the firm comes with scientific evidence is far from enough. It is the ease of access to particular people that really counts." (communications manager, multinational drug company)

"I think that the AHTAPol makes mistakes more frequently than NICE. And I'm not saying this because I'm so smart. This is because NICE employs 500 people and the AHTAPol – 50. The Polish agency is a fresher and it has a slightly different role. But it is increasingly powerful. And people are expecting more from it." (external affairs manager, multinational drug company)

"There were one or two private [HTA] firms at the very beginning. Now they are springing up like mushrooms. And these are first-class firms, whom we trust. Because we know who they are. Sometimes half [of a HTA firm's] staff are our [former] analysts. They know who is who. […] [Apart from these established firms] [t]here are also firms which have just debuted on the market. [they have been around] [f]or a year or two. They are still learning. Very often, they write [HTA reports submitted as part of reimbursement applications] as drug companies dictate them. They are very easy to manipulate. Consequently, their reports are scrutinised very critically [by AHTAPol analysts], because their do not meet our criteria [i.e. HTA guidelines issued by the AHTAPol]. This is a struggle for survival on this market. They [HTA firms] compete against each other. [...] Sometimes, a drug firm chooses a not so good HTA firm and buys a [HTA] report for a lot of money, which is not prepared well. It [the report] does not consider all relevant literature, performs economic manipulations. It overestimates the number of potential patients with a given disease. [National] consultants estimate the number of patients in the country at 1,000 but they [the HTA firm] at 5,000. Or the other way round. The opportunities for manipulation are significant. But if they [HTA firms] make mistakes the mistakes favour their interests so that we [the AHTAPol] are encouraged to accept a drug." (high-ranking official, AHTAPol)

"I wouldn't fetishise this pharmacoeconomic analysis [a HTA report used to support a reimbursement application], because all drug companies are going to say that all we want to buy are their drugs. So it is easy to manipulate.... So these factors [possible manipulation of HTA reports] should be taken into account." (former high-ranking official, MoH)

"The AHTAPol is a very important institution, because it must be independent, it mustn't be lobbied etc. People need to be trained, sent abroad for various internships, training, scholarships. A database [of analyses] needs to be created. In general, a system must be built

and acquire certain rights. However, this hasn't been happening, unfortunately. Because we haven't got an institution, because it is as if virtual. Because like you can't create a university overnight, you can't create this institution in this way." (former high-ranking official, MoH)

7.1. Negative evidence

"If a drug technology is not supported by absolute facts there is no way to convince an official who has his head screwed the right way to reimburse it. In other words, there has to be some weight in it. If something costs a lot, to be reimbursed it needs to be supported by clinical and scientific data or a medical need or patients." (spokesperson, multinational drug company)

"Some time ago there was the Wild West [in the area of drug reimbursement]. We did not know what was happening. Let's say that deals were made under the table, so to speak. But now we have the AHTAPol. This is the first step. There is a positive or negative assessment of a drug. And this creates room for negotiating prices and other conditions of an agreement [with the MoH]." (communications manager, multinational drug company)

"A pharmaceoeconomic analysis [a HTA report used to support a reimbursement application] is something which should be used or should become a premise for funding from public finances." (former high-ranking official, MoH)

"The drug firm is only interested in presenting the drug in the best light possible. Therefore, it leaves out all that may be inconvenient or calculates economic coefficients in such a way that they reflect well on the drug. This needs to be verified, recalculated and compared [by the analysts]. It is the role of those people to analyse the applications and, having digested them, report the drugs to CC." (high-ranking official, AHTAPol)

"They [AHTAPol] are going to discover every manipulation [in pharmacoeconomic data submitted in reimbursement applications]. Establishing the AHTAPol created the chance of approaching this issue systematically. Of course, if someone manipulates so skilfully that it cannot be identified in clinical trials, the AHTAPol will not spot it because it draws on data that is already analysed." (high-ranking official, MoH)

8. The blockbuster and niche-buster strategies

INTRODUCTION

In this section, we offer additional evidence concerning the effectiveness of the two main pharmaceutical business models – the blockbuster and niche-buster strategies – in securing state drug reimbursement in Poland. Our interviewees were in agreement that niche-buster therapies were highly likely to enter therapeutic programmes (hospital therapies for narrow patient populations). In contrast, blockbuster medicines applying for open reimbursement (pharmacy drugs for large patient populations) were believed to be significantly less successful.

QUOTATIONS

"There are more and more 'me-too' drugs on the market. What characterises them is the lack of significant therapeutic benefits. They are not considerably better than already existing drugs." (key account manager, multinational drug company)

"Reimbursement lists [i.e. open reimbursement] are dominated by generic drugs. The MoH introduces them following the expiry of the patents on original drugs. That is why it is very difficult for innovative drugs to enter the reimbursement lists." (freelance lobbyist)

"Having in mind the size of the budget for open reimbursement, the introduction of innovative drugs to it was not as dynamic as in therapeutic programmes." (corporate affairs director, multinational drug company)

"[In open reimbursement] [i]t can happen that applying the drug will not be limited to strictly defined indications. As a result, 2,000 patients can change into 200,000. This will obviously ruin the budget. Especially drugs for chronic conditions may turn out to be Trojan Horses. If let inside, they can destroy all that has been build in the area of reimbursement. When decision makers are not able to estimate accurately the population of patients, they will be very cautious about introducing drugs to reimbursement. When new drugs enter reimbursement lists, no one really knows what will happen." (key account manager, multinational drug company)

"Clear indications and not so sizeable groups of patients are well perceived by decision-makers. This is especially evident in oncology drugs, which target genetically-determined cancers." (key account manager, multinational drug company)

"Patents for many blockbusters have already expired and firms whose significance was based on them are falling into decline. That is why drug companies try to diversify. The targeted therapies strategy can be compared to building a house on several thinner stilts instead of just a single fat trunk. For even if one of them is removed, the whole building will not collapse."(key account manager, multinational drug company)

"In more specialist treatments, drugs are unique in their kind. It follows that even if the therapeutic progress is minor, it is still visible. In the case of open reimbursement, it is difficult to prove that a new drug is superior to already existing drugs." (corporate affairs director, multinational drug company)

“Therapeutic programmes present a great opportunity. As far as the effectiveness of financing is concerned, they are much better than open reimbursement. It can be expected that the innovative character of a product will play an important role in convincing decision-makers. The chance of being introduced to a programme is quite high. This route is much more effective than open reimbursement.” (freelance lobbyist)

“That over the last ten years introducing specialist drugs to reimbursement has been easier than those widely applied becomes evident when we consider the growth of budgetary expenses on therapeutic programmes. It has been much more dynamic than in the case of open reimbursement.” (corporate affairs director, multinational drug company)

9. Interests of the postcommunist state and multinational drug companies in the field of drug reimbursement

INTRODUCTION

This section demonstrates that including niche-buster drugs for small and clearly defined patient populations allowed a high degree of control over reimbursement spending. On the other hand, the characteristics of these medicines, particularly a limited number of alternative treatments, provided drug companies with a strong argument in negotiations with the MoH.

QUOTATIONS

“[In open reimbursement] [i]t can happen that applying a drug won’t be limited to strictly defined indications. As a result, 2,000 patients can change into 200,000. This will obviously ruin the budget. Especially drugs for chronic conditions may turn out to be Trojan Horses. If let inside, they can destroy all that has been build in the area of reimbursement.” (key account manager, multinational drug company)

"The CC is usually convinced that a therapeutic programme enables strict control over indications and rules of using the drug. On the contrary, in open reimbursement there is a problem with treatment outside indications, broadening indications etc., which exposes the payer [the NHF] to high costs. [...] Therapeutic programmes often have registers of patients which, at least theoretically, should show over some time if a given technology is effective." (high-ranking official, AHTAPol)

"Constraints in spending are inherent in therapeutic programmes. The NHF tries to make sure that they do not become an excessive burden for the budget." (corporate affairs director, multinational drug company)

"Therapeutic programmes often have registers of patients which, at least theoretically, should show over some time if a given technology is effective' (high-ranking official, AHTAPol)

"Limitations in spending are inherent in therapeutic programmes. NHF tries to make sure that they do not become an excessive burden for the budget." (public affairs director , multinational drug company)

"Diminishing role of the established thresholds of cost-effectiveness in adopting recommendations [has contributed to the increasing number of positive AHTAPol recommendations]" (high-ranking official AHTAPol)

"Statistically, a drug prolongs life for three months. But there will be someone who will live three years longer. It is not surprising that patients want these drugs. For instance, in oncology therapies and in orphan diseases, these thresholds [of cost-effectiveness] [in taking recommendations] are less important." (corporate affairs director, multinational drug company)

"The CC assesses drugs which have received positive recommendations from other national agencies. Thus, they would like to avoid a situation when a drug receives a positive recommendation everywhere except for the AHTAPol. These situations become rarer with time." (corporate affairs director, multinational drug company)

"Cost-effectiveness is one thing and effectiveness is another. If there is a disease with no cure, it seems that the patients should be given something. [...] Sometimes there is political pressure on certain decisions, for example, from various patient groups who managed to reach certain places, did media campaigns." (high-ranking official, AHTAPol)

"Access to oncology drugs [reimbursed within therapeutic programmes has improved substantially over the last couple of years." (corporate affairs director, multinational drug company)

10. The importance of drug reimbursement for accumulation of political capital by elites

INTRODUCTION

In this section, we provide additional evidence on why reimbursing niche-buster drugs for narrow groups of patients served as a tool for maximising the accumulation of political capital by the leadership of the MoH. Quotations in this section obviously contrast with some of those presented in section #7, regarding the role of scientific arguments in accessing state-funded reimbursement schemes.

QUOTATIONS

"The Minister takes an inherently political decision – is a medical problem important or not?" (spokesperson, drug company)

"Reimbursement decisions have a political-scientific character. They are somewhat moral choices." (director, multinational pharmaceutical consultancy firm)

"Reimbursement decisions are to the same extent shaped by the media and public relations, national consultants and patients' associations, unless a strong political interest comes into play. Then it becomes a purely political decision." (partner, multinational law firm)

"You know, in my field, of all reimbursement applications concerning the class of drugs X the AHTAPol recommended positively [but] the Ministry [of Health] rejected [them] in the last moment using the pretext of unsubstantiated cancerogenity. And in the background there were financial issues and the meltdown of the state budget. And there was probably another group [of drugs] with a positive [AHTA] evaluation but not introduced to the [reimbursement] list by the Ministry. Such possibility exists because the AHTAPol issues a substantive decision, whether the drug is good or not, it should or shouldn't be [reimbursed]. But the ultimate decision is taken by the Ministry." (national consultant)

"The MoH is the Ministry of Public Relations. It is driven by the press and [the public] image. It is not an emotionally stable command centre." (partner, multinational law firm)

"The newspaper X wrote about disease Y and after just one week a relevant [therapeutic] programme appeared. They presented the programme which had already existed but had been not implemented." (former high-ranking official, MoH)

11. Interests of multinational drug companies and patients

INTRODUCTION

This section compares and contrasts the interests of patients form particular condition areas and multinational drug companies. It demonstrates that both sides are interested in

introducing innovative medicines to reimbursement. However, some interviewees saw drug companies' support for patient organisations as being often driven by the imperative of economic capital accumulation.

QUOTATIONS

"In Poland – as opposed to the West – there are considerable problems with access to drugs. As a result, although Polish patients also organise to provide themselves with group support, their main goal is lobbying to exercise their rights to health protection." (spokesperson, multinational drug company)

"Patients strive to get the drugs which drug companies want to sell, while the state tries to defend the budget." (president, domestic lobbying firm)

"Relationships between the industry and patients' associations have been and will be forever." (a high-ranking official, MoH)

"Our access to drugs is limited. [...] This activity [support for families with children suffering from ADHD] has been maintained. However, [...] since the very beginning we have wanted to secure access to drugs for our children. " (president, association of carers for ADHD patients)

11.1. Negative evidence

"And here I have a dilemma. Are [disease awareness] campaigns organised for commercial reasons? I'm not entirely sure that a commercial interest will energise a campaign. Engaging in pro-social activity, corporate sensitivity is motivated by an in-depth analysis of 'here and now' plus the prospects for development. What company engages its reserves in a campaign? First, it is on the market. Second, it is successful. Third, to be on the market and be successful, it needs to share. What is success? Success is premised on drugs, which are most

often reimbursed, that is, drugs which are paid for by the state budget and, partially, patients. So success is premised on patients and the state budget. A firm is reasoning this way: 'Now we have drug A. And in some time we are going to have drugs B, C, and D. Our social sensitivity involves showing decision-makers that the firm can afford to not only profit from the market but also share its success. A rational enterprise shows that it can share its success with the public payer and the patient. So pro-social activity is motivated more by long-term policy than concrete products. The firm is interested in the future, building relationships with decision-makers, its public image. It is more important than present profits (public affairs director, multinational drug company)

12. Drug reimbursement and inequalities in access to reimbursed drugs

INTRODUCTION

This section provides examples of inequalities in access to reimbursed drugs between condition areas.

QUOTATIONS

"[t]he health care budget in Poland *per capita* is two times smaller than in the Czech Republic or in Slovakia ... so not all [medical specialisations] can receive their share. And from our perspective [the interviewee's medical speciality] it is visible that some specialities are treated better, I think, because they have better pressure groups and they can make their problems heard and 'arrange' this issue for their for their specialities. [...] Disease X is not such a group because others are more numerous. And it doesn't hurt. So it is ignored. [...] Our cardiology is financed, to my mind, on the world-class level but the financing of all other

[specialities], maybe except for oncology, is far from sufficient, but don't cite my name in relation to this. But cardiology is overly financed." (national consultant)

"And I can see here an inconsistency [in drug reimbursement policy]. There are areas where innovative drugs are reimbursed. But they are not necessarily more effective or as effective [as already available therapies]. But in [my speciality] this is not the case. There has been no reimbursement since the introduction of drug X ten years ago. No new drugs. But it shouldn't be like this because in some aspects they give better effects in treatment." (national consultant)

"There are the very powerful oncology and cardiorogy lobbies. Also, the lobby of reumathologists has been emerging recently. They win vast sums of money to finance new, very expensive drugs." (high-ranking official, AHTAPol)

13. Drug reimbursement and opportunity costs

INTRODUCTION

This section offers additional interview evidence regarding examples of opportunity costs in the health care system that may be associated with the reimbursement of some classes of drugs, in particular for rare diseases.

QUOTATIONS

"Drugs that are associated with the heaviest lobbying often concern diseases which we cannot cure. Rheumatoid arthritis is a case in point. This disease can be treated with new, very expensive, very good biological drugs. And they help half of the patients. But treating one patient is very expensive. [...]. Another instance is a therapy which extends life for three months and is considered to be expensive. And it costs $30,000 per patient." (journalist, daily paper)

"We do not have any system for treating rare drugs [drugs for rate diseases]. Standard quotas [thresholds of cost effectiveness] are not applicable here. It's not known how these applications should be processed. Usually it is a matter of population size. If there are 10, 15, maybe 20 patients, then, when the costs are counted, this is around $1 million [PLN 3 million]. Then this is ok. But if we take haemophilia, the numbers are gigantic, it becomes problematic. And the Minister takes the decision either in agreement either the AHTAPol or against it. [...] [S]he [The Minister of Health] took this famous decision about treating rare disease, and we finance these drugs. But this problem is unsolved and it's growing. [...] The successes of medicine keep alive more and more of these children with enormous defects and with increasing costs of treatment. [...] These costs are unbelievably high. You could support the whole paediatric ward on [location name], equip it and support it over one year, spend the money that five or six children are using. The cost is 500-600-700 thousand euro per one child. But there is [the issue] of denying treatment – no one wants to discuss it." (high-ranking official, AHTAPol)

"We always deal with the problem of alternative costs. All right, let's buy this drug for 15 million [PLN, approximately $5 million in 2010] a year but who will be negatively affected by this decision? Who will not get their drugs as a result? Because we have a finite sum of money to spend and we are perfectly aware that it is public money that we spend. [...] From the point of view of a doctor, his natural instinct is to treat regardless of costs. [...] But we do not see the patient, though we defend the patient's interests institutionally. We have to see the interests of all patients, of whole society." (high-ranking official, AHTAPol)

"The successes of medicine keep alive more and more of these children with enormous defects and with increasing costs of treatment. [...] These costs are unbelievably high. You could support the whole paediatric ward on [location name], equip it and support it over one

year, spend the money that five or six children are using. The cost is 500-600-700 thousand euro per one child. But there is [the issue] of denying treatment – no one wants to discuss it." (high-ranking official, AHTAPol)

"Life will always be chosen over palliative care. This conflict is not recognised, [it is not recognised] that both things [pharmacotherapy for terminal cancers and palliative care] cost money. [...] If we are going to prolong life with drug X for another six weeks or three 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. The 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 three 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." (high-ranking official, AHTAPol)

"The key issue is funding and availability of specialists and time. For example, parental training, which we do theoretically instead of pharmacological treatment, takes 12 meetings, 1.5-2 hours each, which are led by two qualified specialists. And we have two options, really. Either the specialists do it for money, because their work is worth it, and then parents need to pay, or the National Health Fund will pay for it […] because we think it's worth it. However, many institutions don't do it. Psychotherapeutic treatment is extremely expensive everywhere in the world because it engages a lot of time of qualified personnel. Doing parental training requires 24 hours of my time. And assessing indications for pharmacological treatment, examining a child and writing a prescription takes one hour of my time. In reality,

pharmacological treatment is cheaper for the system. Let's not delude ourselves that [healthcare] systems are so interested in psychotherapy." (regional consultant)

14. Formal closedness of the policy process

INTRODUCTION

This section shows the constrained formal access of multinational drug companies to key state organisations involved in the reimbursement process. The interview material in this section runs largely counter to our argument about frequent informal interactions between representatives of drug companies and state officials.

QUOTATIONS

14.1. Formal access to the AHTAPol

"A thriving firm will certainly go to the AHTAPol itself. Firms access this place. They talk a lot and present their analyses." (freelance lobbyist)

"The AHTAPol is becoming a Mecca for drug companies. They have to visit its leadership and do all they can to ensure that the recommendation is positive." (communications manager, multinational drug company)

"These [formal] meetings are usually chaired by the President. They are official and minuted. They typically concern the state of the processing of the application. During these meetings drug firms smuggle additional information, concerning the drugs they are currently working on or the ones they are about to register." (high-ranking official, AHTAPol)

"We ask about the current situation, what is happening to the application, when the results may be expected." (external affairs manager, multinational drug company)

"There is no participation of [drug companies] at CC sessions. Our participation without the right to vote was indeed proposed. We wanted to listen to find out about reservations concerning our drugs. But this hasn't happened and won't happen. There is no discussion. X [a high-ranking AHTAPol official] wanted to introduce drug companies to the process to allow the AHTAPol to ask if it is in doubt." (external affairs manager, multinational drug company)

"There was a period when [...] staff were flooded with information from drug companies. [...] This had affected their work and we decided that these contacts end with me." (high-ranking official, AHTAPol)

"The door to the AHTAPol is locked." (external affairs manager, multinational drug company)

"When Minister X come into office, everything was cancelled, contacts between representatives of the Agency and drug companies were forbidden. [Currently,] they have the procedure of receiving external clients similar to the one in the Ministry. It goes on like this: During a meeting there are equal numbers of people representing both sides. It is crowded. The meetings are recorded. But what's key is that these meetings do take place. You can call, email them ask for a meeting to cover a specific issue. The meetings happen relatively quickly. Do they have any effect? I don't know." (external affairs manager, multinational drug company)

"If a decision [an AHTAPol recommendation] is negative and we totally disagree with it, we can send letters to all the people [involved] with arguments and counterarguments. Does anybody read them? I don't know. This is the only possibility of exerting influence available to us." (external affairs manager, multinational drug company)

14.2. Formal access to the CC

"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." (high-ranking official, AHTAPol)

"The CC tries to take decisions drawing on what has been said during the examination of an application at a CC session. We would like to avoid the situation that we are having a discussion here 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, and so on." (high-ranking official, AHTAPol)

"[W]e do not contact the industry. They [the industry] have changed the system lately. There are at least two or three firms which address individual applications to [Consultative] Council members and send technical materials so that [they – CC members] can familiarise themselves with the materials. However, this does not have much impact. Because this is or isn't read. Because the ultimate basis for a final recommendation will always be analyses prepared by [AHTAPol] analysts plus opinions issued by [national and regional] consultants and positions of CC members who know the topic." (high-ranking official, AHTAPol)

14.3. Formal access to the MoH

"Formal meetings concern the completeness of the [reimbursement] application, whether there is anything missing. There are also informal meetings aimed at building relationships." (freelance lobbyist)

"There are meetings with drug companies at the MoH. However, the Minister can't meet with a firm which comes all of a sudden. Meetings are scheduled in advance. Firms write applications and propose the topics. Most often, these are technical aspects of the processing

of reimbursement application. [...] If we've got the time, we meet them. The meetings are attended by the DDPP Director and the (Vice) Minister of Health. They are minuted. The minutes are sent to all interested parties, who can annotate their comments and reservations. I don't meet anyone apart from these [formal] meetings [organised within the framework of the procedure of receiving external clients]. We are very cautious against contacts with the industry which might be perceived as attempts of exerting influence." (high-ranking official, MoH)

"The reorganisation of internal procedures in the Ministry resulted in that the need for contact (with drug companies) has been minimised. The truth is that firms have positions regarding external contacts – government affairs, for example. They apply for meetings. [However,] [t]here isn't anything we couldn't do via normal correspondence. These meetings are quite troublesome for us because we need to engage a few people [in them]." (high-ranking official, MoH)

"For the MoH, the procedure of receiving external clients is designed to 'tick' these meetings off and gather information which is later put in somebody's desk." (external affairs manager, multinational drug company)

"Firms send letters asking for meetings but no one responds to them." (former high-ranking official, MoH)

"They suspect that we will be trying to introduce our 'message' [to apparently technical communication]. But we make our living out of it. They should listen to us and then make the right decision." (external affairs manager, multinational drug company)

"There is no way we can learn what happens with a [reimbursement] application. We can't call because such a conversation would be publicised and would result in data disclosure.

Only high-ranking officials X and Y can be contacted during the process of evaluating an application." (partner, multinational law firm)

"At the beginning of my work at X I was thinking why we were issuing all these policy statements without any effects on decisions. Only later did I realise that we actually create the reality in this way. What we are talking about becomes the norm accepted slowly by politicians." (representative, association of multinational drug companies)

"Even if we have urgent business, such as changing the packaging [of a drug], everyone [at teh MoH] is afraid to meet. They even don't want to speak over the phone." (lawyer, multinational law firm)

"The truth is that the MoH does not always react to formal letters." (communications manager, multinational drug company)

14.4. Formal access to state elites

"The Minister is always in a hurry and only has half an hour for a firm." (lobbyist, domestic lobbying firm)

"Although we have to wait so long for these meetings, they are attended by very kind young people, but not by the Minister of Health or the DDPP Director." (external affairs manager, multinational drug company)

"Drug companies love to have meetings with the Minister of Health. Consequently, if we have a meeting, the next application arrives just in a matter of days. They are queuing for a dozen weeks or months to for a meeting. This procedure [...] demonstrates the transparency of meetings between public officials and multinational drug companies. What happens is a drug company applies to the Minister in writing asking for a meeting and provides the topic. If we decide that we will receive them, they send us the specific list of topics – one, two,

three points as well as the names of their representatives and their positions. […] All meetings are recorded and archived. They are attended by the Vice-Minister responsible for drug Policy, three representatives of the DDPP and often there is also a representative of the Director General [of the ministry of Health]. We treat these meetings as lobbying meetings and as a result [...] the Director General can also send his representative. Consequently, there are four or five people representing the Minister of Health. The meetings are recorded and archived, which means that there are no talks outside the [meeting room]. So there is no possibility [...] to meet with a representative [in another room]. There wasn't [...] and won't be any possibility because it is not needed. These issues are important for the patients and the public finances and must be taken in a transparent way. (high-ranking official, MoH)

"The only person responsible for drug policy in [the Vice-Minister of Health]. [The minister] does not intervene. The Vice-Minister has a carte blanche. [...] And [the Vice-Minister] takes full responsibility for it. [The Minister] trusts [the vice-Minister's] and confirms [the Vice-Minister's] decisions. And [...] this eliminates any possibilities for by-passing [the procedure. It is not that if the firms cannot arrange something with [the Vice-Minister] they will go to the minister. The Minister hasn't meet with any firm since the start of [the Minister's] time in office. There is no such possibility." (high-ranking official, MoH)

15. Informal openness of the policy process

INTRODUCTION

This section shows the extent of formal access of multinational drug companies to key state organisations involved in the reimbursement process. The interview evidence in this section supports our argument about strong informal relationships between state officials and representatives of multinational drug companies.

QUOTATIONS

15.1. Informal access to the AHTAPol

"Drug companies always exert strong pressure on establishing personal contact." (high-ranking official, AHTAPol)

"Firms sponsor conferences for which we are frequently invited." (high-ranking official, AHTAPol)

"I have just received an invitation for a conference on medical technologies. I have noticed two representatives of drug companies on the tentative list of the speakers. So why have I got there? Why so suddenly? The only reason for this is that I [work for the AHTAPol]. They have not invited me because of my other professional roles. For them I [am a person who works for the AHTAPol and] can be useful in many ways. This is like taming." (high-ranking official, AHTAPol)

"Of course, firms have plenty of opportunity to contact the AHTAPol President during various outings and conferences." (partner, multinational law firm)

"Participation in various conferences attended by people from the AHTAPol, the MoH, the Health Committees in Parliament is needed and appropriate. I guess that nowadays a conference may be the best place to establish contact with decision makers. Obviously, it is difficult to arrange something important, since walls have ears there. But what we can do is sell key information to decision makers. This is an important part of the lobbying process."(external affairs manager, multinational drug company)

"A lot depends on his [an AHTAPol official] willingness to meet with one or another person. This is all based on relationships. Some people have greater capabilities than others. If a firm

lacks them, it translates into limited access. And I am not even talking about 'fixing' here, but just about simple access." (communications manager, multinational drug firm)

"That the firm comes with scientific evidence is far from enough. What really counts is the ease of access to particular people. These[informal] meetings can obviously affect the drug's chances of being reimbursed." (communications manager, multinational drug firm)

"That the AHTAPol and commercial HTA firms are one social milieu is an open secret. Yet this topic is not publically discussed, it's not placed on the media agenda." (corporate affairs director, multinational drug company)

"[T]hey [AHTAPol analysts and HTA companies] have strong relationships. These people graduate from the same medical academies and departments. Quite often, they have common teachers, supervisors, professors." (high-ranking official, AHTAPol)

"All prestigious HTA companies [...] and the AHTAPol originate from the same community. And I'm talking about both ATHAPol and commercial firms. These are several dozen people who know each other very well. They have functioned in this small milieu for many years, studied together, formed a pressure group. Their paths have diverged with time but their work overlaps. When an AHTAPol analyst receives a HTA report, he can tell that it has been prepared by a so and so. It's not that this report will get a better mark. This analyst will simply know that this report will be good, reliable. And on the other hand, he knows where the author makes silly mistakes. It works. These are former colleagues. It is much easier to read and rate a colleague's report. You trust your colleague more than a stranger on the street. You have to consider the human factor." (external affairs manager, multinational drug company)"

"It all depends on contacts that are permitted or the most widespread. Officially, there are letters and [formal] 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." (manager, domestic HTA firm)

15.2. Informal access to the CC

"Firms approach us informally. For instance, during a conference the medical manager of the firm whose drug had been rejected asked me if it made sense to struggle any longer. And I said to him: 'It's your business, you should do so. You should improve the application, provide us with better arguments.' I do not think it was pressure. It was this sort of discussion you have when you stand with a glass of wine and talk." (high-ranking official, AHTAPol)

"[Firms establish relations with CC members] not only officially but also unofficially." (external affairs manager, multinational drug company)

"That's certain. [about attempts at establishing informal access to CC members]" (corporate affairs director, multinational drug company)

"Firms try such actions. Some – this depends on the culture of a firm – attempt such actions. Of course, having received these documents [additional materials in support of a reimbursement application] we familiarise ourselves with them or not. This depends on the situation, how big is the pile of these materials. But generally we try and at least have a look at what this is about. Overall, it can be said that 95% of these materials are intended to additionally demonstrate advantages of a given medical technology." (high-ranking official, AHTAPol)

"Sometimes these [drug firms' representatives] who know me, try very hard [to meet me]. I remember that a year ago I had a call from the firm producing a drug for X. They wanted to

discuss it over dinner. But if there are firms I have cooperated with for years, [..] I tell them: 'I'm at the AHTAPol at the moment, so going to congresses with you or suchlike actions are out of question, since those tie my hands at the Agency and I don't want this.'" (high-ranking official, AHTAPol)

"Firms have access to CC members. They have cooperated. They have been in relationships with drug companies. [Those] professors are on the market. They give lectures, for example. So they can be reached." (partner, multinational law firm)

"There is a firm which has received multiple negative recommendations concerning their product. But they keep sending letters to CC members asking them to consider this as well, to consider something new." (high-ranking official, AHTAPol)

"No, this is my prevention. I give those people a clear message, that even if their drug will be assessed soon, then, may God forbid, they don't try to [exert pressure] on me." (high-ranking official, AHTAPol)

"We try to arrange [the meetings with CC members] to present our arguments. Some of them agree, we do this officially, in a larger group to avoid suspicion of exerting influence. The majority of them agree. 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." (corporate affairs director, multinational drug company)

"Some CC members wouldn't like to meet, even though they know the person from a drug company very well. There is, however, a group that would eagerly talk about the drug which will be assessed on the next [CC] session. Overall, I think the majority of [CC] members agrees to meet." (corporate affairs director, multinational drug company)

15.3. Informal access to the MoH

"If the door to the MoH is closed, the industry searches around and tries to find a place to enter." (partner, multinational law firm)

"It was my colleague's first day at work and he couldn't open the [code-protected] door [leading to the DDPP]. When he was waiting there, a pharmaceutical lobbyist appeared suddenly, entered the code and invited my puzzled colleague in." (former middle-ranking official, MoH)

"Actually, people who no longer work for the MoH know this code [to the door leading to the DDPP]. It's no big secret. And some people are let inside because they are recognised. The door is there only for cheap effect. Or people remember this code. I know a story about a lobbyist who 'got lost' in the DDPP. He saw something on a desk. But what did it get him? Maybe found out the stage of processing the application. But this is an old story. Sometime ago there was a big mess in the DDPP." (partner, multinational law firm)

"[The procedure of receiving external clients] does not correspond with the reality. The key issue is to establish a very high threshold in terms of formalising the contacts. But 'Rabbitt's friends and acquaintances'[1] come in whenever they please. This is pure cronyism. The register of meetings is a method for making contacts more difficult and improving the situation of those who are in friendly relationships with decision-makers. Those who don't have informal relationships need to have to cringe at the doorstep. This is what happens in the MoH. A half a year of waiting for a meeting. What can you say after half a year? What is the point? Unfortunately, this does not strengthen transparency." (manager, domestic HTA firm)

[1] The interviewee refers here to a Polish saying about "Rabbit's relatives and acquaintances" (*krewni i znajomi królika*), inspired by "Winnie the Pooh". It is used to describe nepotistic and clientilistic practices in the public and private sectors.

"You wouldn't believe me if I told you that I don't know anybody from a drug company. Exactly. Sometimes, I meet them privately outside price negotiations. This is not illegal. I think people representing public institutions and drug companies should know each other." (middle-ranking official, MoH)

"When Minister Z come into office, he was obsessed with various scandals and created [a ministerial advisory body]. It was meant to be anonymous and secret services were supposed to check if there were any leaks concerning the names [of members of the advisory body]." (journalist, web-based magazine)

"[A ministerial advisory body] was supposedly secret but its composition leaked to the market." (former high-ranking official, MoH)

"The [lobbying] scandal with the main role played by X [high-ranking MoH official] is a fact. He went too far. The [court] trial is ongoing; those who are guilty have not been convicted yet. I don't want to slander him. I don't know whether corruption took place but it is possible that it did. I don't have such knowledge. But I must admit that he was a good [official title]. During his term we could come to the MoH, enter the DDPP, sit at one of the offices and tell the officials: 'Listen, here are materials that you might find useful.' Now it is not possible. I approve of anticorruption measures but what we have now is a gross exaggeration." (external affairs manager, multinational drug company)

15.4. Informal access to state elites

"Participation in various conferences attended by the people from the AHTAPol, the MoH, the Health Committees in Parliament is both needed and appropriate. I guess that nowadays a conference may be the best place to establish contact with decision-makers. Obviously, it is difficult to arrange something important, since walls have ears there. But what we can do is to

sell key information to decision makers. This is an important part of the lobbying process." (external affairs manager, multinational drug company)

"I have been in this business for so many years. [...] And I said I would not stoop as low as to sign in on those waiting lists and allow them to record me [during the meetings]. If someone wants to do this as a form of prevention, this is beneath my dignity. We used to go to the MoH very often and I think it should always be like this. We would meet frequently on informal occasions and discuss regulations. The same issue was with Members of Parliament. The would call me and say: 'Please, come. I have got something I do not understand.' They were not ashamed to ask us about various things. We would meet in the lobby or go to a canteen and sit, and talk." (representative, association of multinational drug companies)

"If a certain issue is likely to have negative political resonance, it can be brought to the [Minister's] Political Cabinet. We can say that [the Vice-Minister] can make a decision that threatens [the Minister]. We can talk with the cabinet members about the political consequences of certain steps for decision-makers." (lobbyist, domestic lobbying firm)

"Experts have influence on drug reimbursement but they must have influence on the Minister of Health in the first place. I don't know exactly who these people are. I don't know how exactly they advise [the Minister]. They are not formally employed at the MoH. These are, for example, former Ministers of Health. They can influence [the Minister's] decisions. But this possibility exists because they are close to her. (partner, multinational law firm)

16. "Ritualistic" use of formal institutions

INTRODUCTION

This section aims to explain reasons behind the contrast behind drug companies' formal and informal access to the reimbursement process. It provides additional support for the argument

regarding the "ritualistic" use of formal institutions by state elites. Our interviews demonstrate that restrictive formal consultations institutions are largely aimed at improving the public image of the MoH. At the same time, selective informal access is offered to a group of friendly drug companies.

QUOTATIONS

"The problem is that the more closely you want to follow the [reimbursement] process, the more you enter the grey sphere of relationships with state authorities." (partner, multinational law firm)

"The Polish law is like web: a horsefly will squeeze through yet a bee will bog down." [...] [formal regulations are] [m]uch ado about nothing. What they practically mean is that the 'relatives' and 'acquaintances' will meet outside [state organisations], while others are muzzled and can't communicate." (former high-ranking official, AHTAPol)

"The regulations limiting the formal access and discussions improve the competitive situation of firms with informal access." (manager, domestic HTA firm)

"I don't believe in declarations made by the MoH regarding the alleged limiting of contacts with drug companies. I receive plenty of information that they can access the MoH in various ways. On the declarative level, the MoH obviously has a justification for the general public but this is not true." (journalist, daily paper)

"Formal regulations concerning contacts with firms are prohibition. The higher the dams, the greater the pressure. Firms have to get there somehow or otherwise the headquarters will do away with them." (former high-ranking official, MoH)

"The lobbying law is stupid. In reality, it is an anti-lobbying law. It results in that it is easier to corrupt people. The legislation has introduced a requirement to develop detailed reports from meeting with lobbyist. Minister X wrote that he had no meetings with anyone. These regulations have become routinised [i.e. no one treats them seriously]." (high-ranking official, MoH)

"This [the procedure of receiving external clients] hits the hardest the firms that want either to act transparently or are afraid to act non-transprently. But this [the excessive formalisation of drug companies' access to the MoH] is just evasion. It does not work. What it does it creates massive bureaucracy. These [MoH] officials are obviously afraid to meet drug companies. I don't think that an official meeting with a firm creates a problem. It often happens that firms are the most reliable source of information. I think they can afford to do economic analyses [to provide scientific evidence for a reimbursement application]. An official like a journalist has the right to meet several sides." (journalist, daily paper)

"...[high-ranking MoH officials] are afraid that [they] will get fired or it will be [insinuated] that they do this and that. [...] quite simply, after the scandal with X [high-ranking official involved in irregularities in introducing a drug to reimbursement], which did happen, they are afraid that they will lose their posts and it will be grilled by the media, so there is absolute silence [in the MoH] and the regulation [...] [establishing the procedure of receiving external clients] is to... A regulation [has been introduced] that they [MoH officials] must meet in pairs or trios with people from the outside [i.e. representatives of the pharmaceutical sector]. So it is totally trendy because they want to have peace and quiet [at the MoH]. Because, you see, since they implemented this regulation there has been no scandal regarding drugs at the MoH. There is simply silence, because no one is talking about anything there. Ok, they have

buried the problem because there are no discussions on this subject [contacts with the pharmaceutical industry." (director, domestic pharmaceutical market consultancy)

"The [tape] recorder is always on the table. It is very uncomfortable for the firms. Generally, these discussions are very bizarre. Many people from the West are amazed at this procedure and claim it has nothing to do with good manners and a culture of contacting people." (middle-ranking official, MoH)

17. The role of social capital in informal lobbying

INTRODUCTION

This section explains why social capital in the form of personal relationships with politicians, bureaucrats and medical experts is a key precondition of effective informal lobbying.

QUOTATIONS

"A very important player in the pharmaceutical market [...] told me once that the pharmaceuticals is a very interesting and profitable sector. But the prevalent form of business relations is that it is a 'wining and dining industry. As a very rich man, he is a bit distanced from it. But this captures the nature of this [pharmaceutical lobbying]. This is, in my view, the essence of this lobbying. Pharmaceuticals are an extremely relational industry. This relationality is evident in the sphere of marketing, contacts with doctors, presidents and contacts with KOLs. The latter group decides whether a given group of drugs is reimbursed or not. The relationality also affects relationships with decision-makers. There are always attempts to establish personal contact. It is always a concrete representative of the firm and a concrete person from the Ministry of Health, a concrete national consultant. These are the features that distinguish the pharmaceutical sector and pharmaceutical lobbying form other

forms of lobbying. My fellow lobbyists form Washington confirm that this is an extremely relational industry. ” (freelance lobbyist)

There are formal meetings regarding the completeness of a reimbursement application. [...]. There are also informal meetings are used to build relationships. [...] [with decision makers].” (freelance lobbyist)

“A lot depends on his [official X’s] willingness to meet with one or another person. This is all based on relationships.” (communications manager, multinational drug company)

“Drug companies always exert strong pressure on establishing personal contact.” (high-ranking official, AHTAPol)

“Some [lobbyists] have greater capabilities than others. If a firm lacks them, it translates into limited access. [...] [This] can obviously affect the drug’s chances of being reimbursed.” (communications manager, multinational drug firm)

“Lobbying is about selling your contacts. [...] If there’s money, Rabbit’s friends will always turn out.”[2] (former high-ranking official, MoH)

“Limiting drug companies’ access to the MoH results in that people with contacts are extremely valuable.” (partner, multinational law firm)

“They [freelance consultants] know the right people and they know whom to talk.” (partner, multinational law firm)

[2] The interviewee refers here to a Polish saying about “Rabbit's relatives and acquaintances” (*krewni i znajomi królika*), inspired by “Winnie the Pooh”. It is used to describe nepotistic and clientilistic practices in the public and private sectors.

"Regulations limiting formal access and discussions improve the competitive situation of firms with informal access." (manager, domestic HTA company)

17.1. Negative evidence

"It is true that relationships are important in pharma [i.e. the pharmaceutical sector]. A lot depends on them. A balance needs to be achieved in these relationships. How a relationship looks like depends on a person. A personal relationship is not the most important one. What is more important is a substantive relationship. This is what's key. I always try to create the best positive impression regarding the substantive aspect. This is what creates real value. Of course, it is not that non-substantive relationships are not maintained with medics, KOLs, professors. If I go dining with a KOL, we are not talking only about substantive issues. This is not specific to the pharmaceutical sector, though. It concerns any form of relationships." (account director, public relations company)

"Obviously, the relationship [between medical experts and] the pharmaceutical industry is very intimate, very close. Because the two sectors need each other. I can see no possibility for separating these contacts because they [the two sides] need contact each other. Firms regularly organise training, events, congresses, booths. Each side tries to manipulate the other. This is purposeful. Because if I as a [national] consultant I'm trying to introduce a new technology, new drug, new diagnostic instruments to the market, I will be negotiating with these people [i.e. the pharmaceutical industry] to acquire information, to acquire other possibilities, including [a] negotiation [position]. The intelligence is used by both sides. This is normal. The only thing is that it should happen according to the law or ethics. It has to be like this. [...] We depend on each other." (high-ranking official, AHTAPol)

18. The role of informal lobbying in securing access to political elites and bureaucrats

INTRODUCTION

This sections supplements the explanation of the contrast between drug companies' formal and informal access to the policy process offered in section #16. The interview evidence shows that extensive informal access depends on successful informal lobbying drawing on personal relationships between drug companies' representatives and state officials. Conversely, the lack of sufficiently strong personal relationships translates into limited access to the policy process.

QUOTATIONS

"Every occasion is good to exert pressure. If you submitted an [reimbursement] application you use all possible ways to lobby." (associate, domestic law firm)

"There is a great deal of personal, direct contact among those people [middle-level bureaucrats and representatives of drug companies]." (Member of Parliament)

"A lot depends on [an official's] willingness to meet with one or another person. This is all based on relationships. [...] And I am not even talking about 'fixing' here, but just about simple access." (communications manager, multinational drug company)

"Some firms are successful [in securing access to the MoH leadership]. This is done on the basis of contacts. Contacts among colleagues and friends are crucial." (representative, chamber of commerce representing multinational drug companies)

"Meetings are also held outside the Ministry, for example, at conferences attended by people acting on behalf of drug companies. They are attended by consultancy firms which are not

lobbyists [officially]. These are contacts within social circles [*układy towarzyskie*] and within this framework they act in the interest of those [drug] firms. Mr X has a consultancy firm and knows the Minister. The drug companies utilise his company. What I have in mind here are some advisory, consultancy and law firms. Contacts and acquaintances are of particular importance. What counts are relationships (*układy*) between colleagues and friends, prior business activity. The Minister is going to meet his friends" (lobbyist, domestic lobbying firm)

"Some companies simply have a lot of pull with the MoH. They don't have to go around." (partner, multinational law firm)

"If you do not have connections, you have to stay in the queue and your contacts are impeded." (manager, domestic HTA firm)

"Those who do not have impeded contacts meet leisurely in the evening with ministerial advisors and [Ministry] officials." (manager, domestic HTA firm)

"If the door to the MoH is closed, the industry searches around and tries to find a place to enter." (partner, multinational law firm)

18.1. Negative evidence

"The sectoral code of conduct [code of marketing practice developed by an association of innovative drug companies] was developed not so long ago. It needs to be contrasted with a high level of corruption in Poland. A firm present on stock exchange in the US is subject to scrutiny of the Securities and Exchange Commission (SEC). Consequently, the firm does not want to mess with SEC. We have restrictive rules in the Polish system and possible violations are dealt with by the Main Pharmaceutical Inspectorate." (communications manager, multinational drug company)

19. The reimbursement policy domain

INTRODUCTION

This section supplements the picture of the drug reimbursement policy domain. It focuses on its following characteristics:

- Size.
- Educational and professional background of its representatives.
- The nature of social interactions.
- Social mobility patterns.
- Relationships between the drug reimbursement policy domain and other policy domains.
- Coincidences of interest displayed by some individuals active in the drug reimbursement policy domain.

QUOTATIONS

19.1. Size

This social milieu [people dealing with reimbursement] is very small." (high-ranking official, AHTAPol)

"Pharmacy is a bit hermetic milieu. This is so for several reasons. If someone starts dealing with it [i.e. pharmaceuticals], they don't leave this field. It is an interesting sector, you can't get bored here. People start specialising and this makes possible exit even more difficult. Secondly, this is a very narrow milieu. For example, firms that deal with public affairs and public relations in the context of health is very few." (account director, domestic public relations company)

19.2. Educational and professional background

“Only people who know a lot about drugs can lobby. Who else could do it?” (lobbyist, domestic lobbying firm)

“Only medical education allows for speaking with decision-makers who are doctors themselves.” (account director, domestic public relations company)

“They all studied at the same medical schools, which are not so numerous in Poland, they are about the same age. [...] Doctors work for pharmaceutical companies, the MoH and hospitals’” (journalist, weekly magazine)

“People dealing with drug reimbursement constitute a very hermetic social milieu. The vast majority of people dealing with pharmaceutical lobbing are ex-doctors, pharmacists, microbiologists. They study for five-six years. These are very difficult studies but not particularly helpful in terms of broadening horizons. They work very hard, spend a lot of time studying and have very little time to get interested in other things, such as politics or economy.” (freelance lobbyist)

“The pharmaceutical sector has a very strong scientific background, especially in the area of biotechnology drugs. Firms are relying primarily on medics. These are the people who rule.” (freelance lobbyist)

“People from this sector are medics, biologists, chemists... They represent medical sciences. They are not experts in politics or lobbying. At a certain moment there was a tendency to employ outsiders in this sector. My friend who is a lawyer moved from the tobacco [sector] to a drug company. He was working there for six months but he couldn’t find himself. [...] He did not achieve success as a pharmaceutical lobbyist.” (freelance lobbyist)

19.3. Interactions

“Doctors know each other and maintain their friendships.” (lobbyist, domestic lobbying firm)

“In this medical milieu, everyone knows everyone.” (journalist, weekly paper)

“We all know each other. We know who works where and who moved where.” (communications manager, multinational drug company)

“I am from this milieu [name of medical speciality], so no matter if I am the [national] consultant or not, we all know each other and I have always been respected here.” (national consultant)

[Question: In the milieu of people dealing with [disease] X, do all people know each other]. Of course.” (national consultant)

“As of now, it has never happened that the Minister [of Health] did not accept a recommendation. This is because we have appointed to the CC people whom we trust.” (high-ranking official, MoH)

“Cardiologists always stick together.” (freelance lobbyists)

“People [involved in drug reimbursement] know each other very well.” (representative, chamber of commerce associating multinational drug companies)

“‘It was not long ago when people all went together for vodka and hung around with tarts.” (key account manager, multinational drug company)

“[Pharmaceutical lobbyists] have regular contacts with the MoH and the NHF. They are known and respected there.” (account director, domestic public relations company)

"There are people who maintain some distance while being on certain [official] posts. It's not the case that everyone goes to drink vodka with anyone. Lobbyists can get this impression because its them who buy this vodka." (journalist, weekly paper)

"I know they have strong relationships [analysts working for the AHTAPol or HTA firms]. These people graduate from the same medical academies and departments. Quite often, they have common teachers, supervisors, professors. They are fluent in English, statistics, economy and other more esoteric specialisations such as QALY." (high-ranking official, AHTAPol)

"There were one or two private [HTA] firms at the very beginning. Now they are springing up like mushrooms. And these are first-class firms, whom we trust. Because we know who they are. Sometimes half [of a HTA firm's] staff are our [former] analysts. They know who is who [in the area of drug reimbursement]." (high-ranking official, AHTAPol)

19.4. Closed circuit

"Today, many people who finish their work at the MoH [...] start working for the [pharmaceutical] industry. But they still have colleagues who work at the MoH. And later they move on from the industry to another place [in the sector]." (journalist, weekly paper)

"People dealing with drug reimbursement constitute a very hermetic social milieu." (free-lance lobbyist)

"Just look at my career path. I initially worked for [firm] X, then for Y, later for Z, and now I am looking for another job. But all the time I have been moving within the same milieu. These are the same people. I have been meeting the same people all the time." (communications manager, multinational drug company)

19.5. Social insulation

"I am currently considering moving to another environment which would offer new challenges or to remain in the pharmaceutical sector. Although it may be a little stuffy here, I have put a lot of effort to learn the rules of the game, which are unlike in any other sector. This area has certain additional rules which are informal and nontransparent. No matter where you work, the same rules apply. This is not like in free commerce. [...] I think it is difficult to move to even close sectors, such as Fast-Moving Consumer Goods or cosmetics, which have, for instance, similar rules concerning accessing journalists. The pharmaceutical sector requires gigantic creativity because of the limitations. We always have to plot how to go around them. We try to go around this wall." (communications manager, multinational drug company)

"[Pharmaceuticals] is the sector which is difficult to enter and leave." (communications manager, multinational drug company)

19.6. Coincidences of interest

"[The wife of an MoH official] was a vice-president of a drug company." (high-ranking official, MoH)

"[R]elationships between officials and the pharmaceutical business [...] do exist, but are indirect and thus it is difficult for a lay observer to see them." (manager, domestic HTA firm)

"There is a situation where a relatively high-ranking official for many years has had a partner who holds a top position in the pharmaceutical sector." (Member of Parliament)

"This official [whose partner holds a top position in the pharmaceutical sector] has access to extensive sensitive information. And her partner's professional role comes down to advising a drug company based on instant access to information. This situation is bizarre. Yet the

superiors at the MoH do nothing about it because this relationship is informal." (former middle-ranking official, MoH)

20. Exchange of favours

INTRODUCTION

This section details the mechanism of extended reciprocity involved in informal lobbying taking place between members of social circles populating the drug reimbursement policy domain. It demonstrates why informal persuasion within cliques may be a more effective method of influence than corruption.

QUOTATIONS

"There are very few people who can afford to escape the national health system and seek treatment in another country. And information concerning the decision-makers' relatives who are seriously ill is found out by the drug companies. [...] And this allows the firms to influence Members of Parliament, officials, people who are influential in a given area. They 'selflessly' offer drugs costing several thousand dollars. And this is a matter of life and death. [...] Imagine that you are a Member of Parliament and your brother or sister is seriously ill. Are you going to refuse [a favour] to a drug company?" (high-ranking official, MoH)

"The issue of interpersonal relationships is crucial in lobbying. What's key is the unique 'chemistry'. Either it's there or not. It can mean a variety of things: charm, appeal, and, most importantly, friendship and favours. Suppose, your mum is very ill and someone helps you 'arrange' a good hospital. You will surely react positively, if this person asks you to read some paperwork. The path of mutual favours is incomparably more important than bribes. Bribes create discomfort for both sides. What they mean is they humiliate the receiver. The exchange of favours is a debt everyone takes on but eagerly pays off. You do something

positive. As a result, an emotion, connection emerges. If someone helped you cheat on an important test [at school] even twenty years ago, you will be willing to help them out against all the odds." (president, domestic lobbying firm)

"Politicians always desperately want to get something in return from us. They have to be convinced that they will benefit from this. So when it comes down to taking a decision, the other side has to have a political interest in it." (representative, chamber of commerce associating multinational drug companies)

"Someone from a drug company suggested that I should create a foundation which could focus on any health-related issue [...]. This conversation clearly suggested that money wouldn't be a problem at all, they will obviously provide it. [...] Their goal was to access someone with extensive political contacts, because at that time I already had such contacts. It's important for them to influence decision making circles using such soft methods." (Member of Parliament)

"At the beginning of the 1990s, doctors were longing for trips. And the state system was completely unaware of the threat. Public officials, too, attended congresses, which is now unthinkable. The general atmosphere was that there was almost open corruption. Leisure trips and bonuses were commonplace. This mechanism became ingrained in a healthy tissue." (former high-ranking official, MoH)

21. Kompromat

INTRODUCTION

This section offers examples of how discrediting information may be used to extort favourable policy decisions from members of social circles involved in reimbursement policy-making. While the mechanism of kompromat is the opposite of extended reciprocity

involved in exchange of favours (see section #20), it also relies on informal relationships within cliques.

QUOTATIONS

"[On limited disclosure of official information regarding medical experts' conflicts of interest] I believe the goal here is to pacify the drug evaluation process. This information translates into great power, particularly it allows [political elites] for manipulating people on whom they have collected dirt. This mechanism is similar to that used by communist secret services in relation to their secret collaborators. The message is clear: 'If you want to make money peacefully, just do your job.' Thus, instead of ensuring the impartiality of recommendations, the declarations are *de facto* an instrument employed to mute potential opponents." (manager, domestic HTA firm)

"You know, I don't want to speak loudly about that [using patient organisations as a lobbying tool by drug companies] to avoid becoming the object of black public relations. It is not difficult to stimulate one or two manipulated articles about a callous official." (former high-ranking official, MoH)

"People who become Ministers and Vice-Ministers of health come from the Healthcare system. Drug companies get them by the balls. And then all sorts of dirt can be found, as in the case of X [a ministerial advisor]. If someone is not obedient, they can be 'killed'." (high-ranking official, MoH)

"Anyone who has a high position in this country can expect that they will be subject attempts aimed at creating negative opinion about them. Any X has its enemies. You can make enemies anytime. It is possible that Y (a high-ranking official) has both fans and enemies" (high-ranking official, AHTAPol)

"Experts and doctors also become subject of lobbying. X [a KOL in rheumatology] [...] is not liked by the doctors. Drug companies have attempted to destroy X using journalists." (journalist, daily paper)

22. Effectiveness of informal lobbying

INTRODUCTION

This section demonstrates how our interviewees evaluated the effectiveness of informal persuasion as a primary method of lobbying employed by multinational drug companies. The interview material demonstrates that the only category of interviewees denying the effectiveness of informal lobbying were high-ranking MoH officials.

QUOTATIONS

"Our major problem is that when we were a young democracy in the 1990s and a young market, there was a lot of incompetence involving public officials as well as the firms. Firms did really stupid things and this affects us even today. We have large problems with the image, since we are perceived as corrupt and as swindlers." (spokesperson, multinational drug company)

"There was a time when firms were rapped over the knuckles for their unethical actions." (key account manager, multinational drug company)

"Decision making in the area of drug reimbursement is premised on personal contacts." (partner, multinational law firm)

"These totally informal relationships very often influence the policy process." (Member of Parliament)

“Trust plays the key role. If you know someone very well, you trust him or her and you have more confidence that you will not hit a landmine” (key account manager, multinational drug company)

“If you’re asking me what type of lobbying is most effective, I’ll tell you that this is direct conversation.” (spokesperson, multinational drug company)

“I know a case where an application was considered twice by the [a ministerial advisory body]. Now let’s assume that the person who prepares documents for the X [...] maintains friendly relations with the pharmaceutical firm [which submitted the application]. To what effects can it lead? Interestingly, when the application was considered for the first time, the decision was negative, while the next time it was positive.” (former middle ranking official, MoH)

“Whether these mistakes are intentional or happen through an oversight is hard to tell. ... It’s difficult to catch anyone red-handed. You can always go for coffee with someone.” (former middle ranking official, MoH)

“Actions taken by the drug industry are slippery. New therapies are arranged quietly, not transparently, in an unknown way, unethically. The way this is done is not ok. This is not arranged in a way that is understandable for society, which sees that material benefits may come into play. That’s why it’s best to stay away from this market. There is a marked difference between the pharmaceutical market and the IT market. Not everyone has got to have a mobile phone but we will all be sick someday. The drug market is unique because it concerns every one of us. Everyone has some interest in it.” (account manager, multinational public relations company)

22.1. Negative evidence

"We are not defenceless against it [drug companies' pressure]. Our response is formalised procedure which are aimed at eliminating corrupt actions. The decision-making process is split into phases. Decisions are taken collegially at the subsequent steps. Another response is the verification of research, scientific evidence by people who deal with it. What I have in mind here is the ATHAPol." (high-ranking official, MoH)

"As far as the pharmaceutical industry is concerned, they all know each other, they have shared interests. There is fierce competition for control over the market […] but they also respect certain rules. There is a code of marketing practice, which has been accepted by firms form association X. They play fair as far as possible." (high-ranking official, AHTAPol)

23. Patient organisations access to the reimbursement process and lobbying methods

INTRODUCTION

This section illustrates the extent of patient organisations' access to key state organisations involved in the drug reimbursement process. In addition, it provides examples of lobbying methods utilised by patient organisations and evaluates their effectiveness in influencing drug reimbursement policy. Most of our interviewees conceded that patient organisations enjoyed broad access to the policy process (certainly broader than drug companies) and were relatively effective in securing the desired policy outcomes.

QUOTATIONS

"This is a new, active stakeholder [i.e. patient organisations]. They want to influence drug reimbursement." (president, multinational drug company)

"I think there is a need for such contacts [with patient organisations], we have to consider various inputs, even though some of them are only emotional." (high-ranking official, AHTAPol)

"[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 [Consultative] Council. Most often this is not *in extenso* [...] but rather a summary prepared by [AHTAPol] analysts." (high-ranking official, AHTAPol)

"We demanded [the class of drugs X] to appear on the reimbursement list [...]. We managed to cause an AHTAPol [i.e. a CC] session and there professor X and I gave testimonies." (representative, association of patients with diabetes)

"[T]he President of the AHTAPol [...] invited us in and said that the time starts running now – we have five minutes. 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." (representative, association of patients with diabetes)

"We had meetings on the Vice-Minister [of Health] level, in a parliamentary committee, etc. And we played a part in that the AHTAPol considered drug X as one that was needed, recommended it [for reimbursement] and financial resources were identified [to cover its cost]." (president, association of ADHD carers)

"It was difficult to arrange a meeting [at the MoH]. We first sent an official letter. We supported it with a phone call, possibly an email. We were striving to establish [contact]. It happened that the Minister X has an assistant who, say, organised this meeting, set the date.

[...] We engaged many experts, the most prominent specialists in ADHD, who could talk, so that they would be authorities for the Vice-Minister. And I'll tell you that this was really important. It is the doctor that can evaluate whether an illness has a long-term character and what the diagnosis is. He is a much greater authority." (president, association of ADHD carers)

"And I'll tell you that there were meetings in Seym and Senate (lower and upper chambers of parliament) [...] there was also the Health Committee of Seym. It was debating on this topic for over an hour. And minister X said that the issue of reimbursing drugs for ADHD is one of few issues where the main source of pressure [...] on the MoH and the NHF to finance or reimburse [drugs] are civil society organisations. It was a very important statement, I believe, because it often happens that it is only the drug company and the evaluating experts. And in our case there was social pressure." (president, association of ADHD carers)

"An association, as any other group, can send their opinions and questions." (high-ranking official, MoH)

-"... sometimes I also ask them for support. There was a case one year ago. I protested against them [some pharmacotherapy changes proposed by the MoH] and also asked the patients' association to express their opinion on this issue. We had this type of cooperation." (national consultant)

"There is no formal obligation [to cooperate with patients]. However, I very much like cooperating with them." (national consultant)

"They ask me for help or intervention or sometimes invite me to their meetings." (national consultant)

"They may organise press conferences or collect signatures under appeals which demand including drugs on the reimbursement list." (journalist, daily paper)

"They [patient organisations] are visible in the media. They perform very well in terms of the image." (partner, multinational law firm)

23.1. Negative evidence

"They are one of the voices in discussion. We invite them to CC sessions to give them satisfaction." (high-ranking official, AHTAPol)

"The general trend is that the Council does not invite [patient organisations]. They do it occasionally, in touchy situations." (high-ranking official, AHTAPol)

"It was difficult to arrange a meeting [at the MoH]. We first sent an official letter. We supported it with a phone call, possibly an email. We were striving to establish [contact]. It happened that the Minister X has an assistant who, say, organised this meeting, set the date. [...] We engaged many experts, the most prominent specialists in ADHD, who could talk, so that they would be authorities for the Vice-Minister. And I'll tell you that this was really important. It is the doctor that can evaluate whether an illness has a long-term character and what the diagnosis is. He is a much greater authority." (president, association of ADHD carers)

"It's not me who wants to contact patient organisation but the opposite. [...] For example I receive an invitation to a conference. Or they ask me to evaluate a project for which they want to get funding from the EU or the Ministry of Health and they want to have an expert's opinion. [...] If I have the time, I meet these request and if I haven't got the them, I don't." (regional consultant)

24. Importance of patient organisations for drug companies

INTRODUCTION

This section explains why patient organisations are key allies of multinational drug companies striving to introduce their products to state-funded drug reimbursement schemes. In particular, it highlights the significance of lobbying through patient organisations for pharmaceutical companies lacking strong personal relationships with state officials.

QUOTATIONS

“We can in advance say what they [patients] will demand. We can be 99% sure that this will be enthusiastic support of a new drug.” (high ranking official, AHTAPol)

“For drug companies, mobilising patients is the most effective solution.” (president, domestic lobbying firm)

“This story is told by the man who has a name and a history. He can enter the land of happiness provided that the official takes one decision.” (president, domestic lobbying firm)

“Sometimes there is a case of one patient which focuses a whole range of issues [and] can lead to winning money for the whole therapeutic group.” (president, domestic lobbying firm)

“If we want something from decision makers, they instantly adopt a negative attitude. But if twenty or thirty people send letters or hold a demonstration, this is a completely different matter. For these are potential voters.” (key account manager, multinational drug company)

“Associations are created in ‘expensive’ conditions such as oncology or asthma.” (journalist, web-based magazine)

25. Methods of controlling patient organisations by drug companies

INTRODUCTION

This section elaborates on the types and effectiveness of methods utilised by drug companies to control patient organisations.

- Establishing patient organisations.
- Money transfers.
- Providing medical information.
- Control over lobbying activity.

QUOTATIONS

25.1. Establishing patient organisations

"Creating pressure and expectations is a classic method employed by drug companies. This happened in the case of [drug] X for kidney cancer. The reimbursement application was immediately followed by the appearance of the patients association and even a journalist suffering from kidney cancer. It happened so suddenly. It could not have been a coincidence." (former high-ranking official, AHTAPol)

"There is a great deal of patients' associations purposefully established by drug companies." (journalist, daily paper)

"Some patients' associations are established for a business, particularly reimbursement, purpose." (communications manager, multinational drug company)

"In 2005, [...] we [several carers' associations from various regions of Poland] had our first meeting. I don't know who financed this [...]. I guess it was one of drug companies using a

contact [...] Someone simply barged in on this milieu, and provided the list of people from all over the country who were interested in this topic [...] I guess it was a marketing agency." (president, associations of carers for ADHD patients)

"[Some] [p]atients' associations have been created to introduce new products to the market. The drugs are sometimes needed and sometimes are supposed to replace those that are already on the market." (former high-ranking official, MoH)

25.2. Money transfers

"If the firm pays the association, it can also draft its statue. In this situation, it is doubtful whether the association would express patients' authentic needs. Of course, both sides have similar interests. But it may turn out that another firm has similar drugs." (communications manager, multinational drug company)

"Patients' associations are a weak actor and an easy prey for drug companies." (key account manager, drug company)

"And when they [the drugs] had been registered, I don't remember how exactly, the contact [with the drug producer] was established. We had the contact with the drug company because it was the applicant [for reimbursement] and we were talking about what was happening, what the procedure was. They kept us informed and even made a donation. But this information was very valuable because we had the same interest – if the drug costs [approximately] €75, then many parents can't afford it." (president, association of ADHD carers)

25.3. Providing medical information

"Parents are told that this medicine is super effective and will greatly improve their children's state. Though all the signs are that this is not true. And those people, clinging to this fresh hope, contact each other and develop the organisation." (Member of Parliament)

"I would say that over the last 10-15 years there has been no revolution in treating long-term conditions, such as diabetes [or] other diseases. Drug companies introduce the concept of 'innovative' and 'old-fashioned' drugs, but this is an improper concept. A more valid distinction is between effective and ineffective drugs." (national consultant)

"When 100% of this information utilised by the association is sponsored by the firm, even doctors find it difficult to assess its credibility, not to mention the patients." (journalist, daily paper)

"We should be crystal clear about it. Those people are indoctrinated and they will pass on what they were led to believe." (national consultant)

"If an association is sponsored by one firm, it may be suspected of manipulating facts concerning the effectiveness of drugs and discrediting competitors." (communications manager, drug company)

25.4. Control over lobbying activity

"They [drug companies] think this way: 'Since we want to lobby effectively for our product, we will prepare a letter which will be distributed among the association's members to save them the trouble of writing it. We will also develop an appeal list which you will just sign.'" (former high-ranking official, MoH)

"Everything that is published in the press is manipulated. You will not find out how it is in reality. Letters written by people suffering from X are a mystification. This serves the interests of just one firm." (president, domestic lobbying firm)

"In 2005, [...] we [several carers' associations from various regions of Poland] had our first meeting. I don't know who financed this [...]. I guess it was one of drug companies using a contact [...] Someone simply barged in on this milieu, and provided the list of people from all over the country who were interested in this topic [...] I guess it was a marketing agency." (president, associations of carers for ADHD patients)

25.5. Negative evidence

"It is difficult to establish an association and make it an active actor. The key thing is to have authentically involved people. […] No communicational actor can control, mobilise patients, make them look credible." (director, domestic public relations firm)

"We search for existing associations and support them in their media activity." (director, domestic public relations firm)

"They [drug companies] engage in charitable activity. The association form X [name of city] received once or twice [approximately] €2.500, we received [money] to develop our infrastructure and things like that. Once €750 and once €1000. This is not, as I say, the main source of our founding. Sometime ago [a postal company] supported us with €4.000, 'cause we have help line so that a parent can call us." (president, associations of carers for ADHD patients)

"We can provide patients with educational leaflets. We can organise a conference for them. Sometimes it happens that we are approached by associations which tell us: 'Give us money

for statutory purposes!" We can distribute badges, educational materials concerning this condition. But we cannot discuss drugs with them because they are not doctors. We can arrange a speaker, an external expert […]. We sign a contract with him, receives money for it. But this presentation concerns not our drug but the disease." (communications manager, multinational drug company)

"Firm X pays particular attention to ethical aspects [in dealing with patient organisations]. We present yearly reports detailing our donations. There is not financing 'under the table.' But there are many associations with unclear sources of funding." (key account manager, drug firm)

"We stick to ethical rules. When you work for a [drug] firm you can feel the tension between fight [for reimbursement] and a ban on referring do drugs even indirectly [i.e. ban on direct-to-consumer advertising].[...] We can always explain that what we are doing is a campaign concerning a disease and rising public awareness. (communications manager, multinational drug company)

26. The effectiveness of using patient organisations as a third party

INTRODUCTION

This section offers additional evidence regarding the high effectiveness of patient organisations as a third party acting on behalf of multinational drug companies.

QUOTATIONS

"The media prominence of the drug was very important. If there are vocal protests, the MoH has to react. It was visible in the case of a drug for kidney cancer." (corporate affairs director, multinational drug company)

"It's great for a company when the material is broadcasted during prime-time news releases. It shows a pretty girl who suffers a lot and loves to paint. The only thing that is missing is the drug. This drug is there. It can be purchased. So why don't do it? [...] A lot is said about poor children and how difficult their fate is." (president, domestic lobbying firm)

"I remember that patient organisations were pressing [for reconsidering a drug by the AHTAPol]. And we have to remember that they are often subsidised by drug companies." (high-ranking official, AHTAPol)

"These media reports serve as a propaganda machine which builds the social awareness of the need of a certain drug. This in turn creates pressure on decision makers aimed at reimbursing this drug." (high-ranking official, MoH)

"I think the MoH is more susceptible here [i.e. to patient organisations acting as a third party] [...]. Sometimes, there is political pressure on certain decisions, say, from various patient groups which accessed some places or organised media campaigns." (high-ranking official, AHTAPol)

"Strong pressure from the media is very important. This was evident in the case of drug X for kidney cancer." (corporate affairs director, multinational drug company)

"There was an association which wanted to maintain a higher price for insulins produced by so-called innovative companies, although the domestic producer had offered an innovative insulin for a lower price." (former high-ranking official, MoH)

"They come to us and ask to include this drug in reimbursement. But they don't ask for other equally good drugs produced by other companies." (high-ranking official, MoH)

26.1. Negative evidence

"Very often – maybe unjustly – some associations are accused of simple, plain lobbying on behalf of drug companies."' (former high-ranking official, MoH)

"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." (high-ranking official, AHTAPol)

"By looking at the associations' name it's difficult to tell if there is a drug company behind it. But when they come and talk to us they turn out to be in favour of just one solution. And based on this I conclude that they are sponsored by drug companies." (high-ranking official, NHF)

27. Extent of relationships between medical experts and drug companies

INTRODUCTION

This section details the extent of relationships between multinational drug companies and two key categories of medical experts involved in the drug reimbursement process – national consultants, who submitted draft therapeutic programmes to the MoH, and CC members, who issued recommendations for the Minister of Health regarding the reimbursement of new drugs.

QUOTATIONS

27.1. CC members

"A geneticist or a philosopher do not prescribe drugs, because what they do is research. So what can they obtain from the industry? Maybe something once or twice a year. Firms can offer or sell them hardly anything. That is why from the perspective of drug companies those are not the types of people worth investing in. On the other hand, in the CC you also have an endocrinologist or oncologist. They are constantly under pressure, particularly if they are first class clinicians who prescribe very expensive drugs." (high-ranking official, AHTAPol)

"Our professional roles are highly diverse. […] [If a CC member] focuses on medical procedures, […] [his] conflicts of interests have been occasional. [He] [doesn't] […] deal with drugs, because they are on the peripheries of […] [his] practice. On the other hand, there are internists who deal with drugs all the time and they have conflicts of interests." (high-ranking official, AHTAPol)

"It can be expected that very experienced doctors have more conflicts of interest than those less experienced." (high-ranking official, AHTAPol)

"It is obvious that CC members like all KOLs have relationships with the industry. Almost all of them are active doctors so that they meet medical representatives on a daily basis. Even a pharmacologist has contacts with the pharmaceutical sector through his academic work." (corporate affairs director, multinational drug company)

"We are active in a different therapeutic area than members of the CC. But if someone is, say, a nephrologist, they must have contacts [with drug companies]." (corporate affairs director, multinational drug company)

27.2. National consultants

“In X [name of speciality] every doctor, not only a professor, every doctor accepts invitations to give lectures, write articles, participate in advisory bodies, lead on clinical trials, and they are rewarded for this. It happens all over the world, including Poland.” (national consultant)

“This situation is not unique to the medical market and to Poland. Every doctor has some relationships with the pharmaceutical industry, because they are invited to congresses, receive drug samples or pens, some gadgets. Now all of this is legitimised, but these relationships do exist everywhere in the world.” (national consultant)

“Naturally, [I cooperate with drug companies].” (regional consultant)

“It is obvious [that drug companies try to contact me]. I have radically limited these contacts especially recently. In general, I try to limit these contacts especially at work. I can contact [drug companies] during an outing, when I’m going for a conference. You know, any conference in the world couldn’t take place without sponsors. And the natural sponsor is the drug industry. And I can see no reason not to exchange opinions or talk. Even more so because there is a great many of brilliant people in this industry.” (national consultant)

28. Transfers of cultural capital

INTRODUCTION

This sections provides additional examples of the transfer of cultural capital, in the form of various forms of research support, from multinational drug companies to medical experts taking part in the evaluation of drugs considered for state reimbursement.

QUOTATIONS

"Some of them [CC members] go to four or five sponsored congresses a year. They have a few 'champions' of this sort. Their relationships with the industry are more intimate, so to speak." (high-ranking official, AHTAPol)

"It is said that firms pay doctors for prescribing drugs. It may be the case that in the past firms exceeded the rules of hospitality. [...] They were far too open-handed in helping doctors. There is nothing wrong in sending doctors to congresses. This is indeed very positive. If there is a 'number one event' every doctor would like to be there. But not everyone can afford it. What needs to be covered is the flight, stay, congress fee. Top knowledge is disseminated at these congresses. And the same is true for seminars and workshops. And in the past firms were helping doctors too eagerly. A firm's budget is not made of rubber. We can send two, three, five people to a cardiology congress. In the past, firms offered doctors far too much than necessary. The hospitality was abused. Firms simply overdid." (spokesperson, multinational drug company)

"Congresses during which therapies are presented are very important. KOLs attend these conferences. Conferences are the most basic method of establishing relations with KOLs." (account director, domestic public relations company)

"Obviously, it [receiving research support from drug companies] always entails some form of indoctrination [..]. For instance, in psychiatry there is always a disproportion between pharmacological treatment and the amount of information on psychotherapy. [...] Firms supply you with materials, books, invite for conferences, lectures. However, to do psychotherapy training you need to enrol on your own and pay PLN 300-400 [$100-$150] for training on a Saturday. My training in psychotherapy, I counted it the other day, has cost me PLN 40,000 [$15,000], from my own money. No institution dealing with psychotherapy has reimbursed me with these expenses. And this concerns the majority of clinical psychologists.

It follows that to gain knowledge on behavioural ADHD you need to go and pay but to get knowledge on pharmacological ADHD you can go for a conference or training organised by a drug company, on a Saturday, for free. You can have dinner as well. Yet for a psychotherapeutic conference you need to get your own sandwiches. Simple as that. This is a general problem, which has been diminishing, I think, in line with doctors' growing affluence. […] It is not that I cannot go for a conference because this is my monthly salary. It has changed, now a doctor can train himself or herself for their own money. It is a matter of decision, not capabilities." (regional consultant)

"I don't know what you mean by 'cooperation' [with drug companies]. We have some contact every day. They come here [clinical hospital] everyday, because it is their job. But cooperation? They come, inform us about various things, present various issues related to their products, or inform us. They also fund trips to various congresses and training of this sort. Without those stipends and grants, we wouldn't go anywhere. After all, no one else would pay for it. And they cover the costs. And if we invite some guests [they also cover the cost]. Or they finance some of our congresses or scientific-educational get-togethers." (regional consultant)

"Innovative companies have access to knowledge and this is what KOLs as scientists and clinicians are primarily interested in." (spokesperson, multinational drug company)

"Low salaries force doctors to enter deals with drug companies. These don't have to be vulgar bribes. It can be a conference trip, even in Poland, which a junior doctor can't afford to pay. And in exchange it is expected that he prescribes a given drug. I agree this is a pathology, but it is stressed that doctors don't earn much and if they want to improve their qualifications, they need money. (KOL, oncology)

"Generally, everyone is tainted. No one is without sin here." (KOL, oncology)

"Drug companies [...] for a long time have enabled Polish doctors' contact with scientific life, especially when a trip for an international conference was out of their reach." (regional consultant)

"We provide KOLs with publications from various journals." (account director, domestic public relations company)

"We can ask a scientist to prepare a publication for a specific topic and we obviously provide him with the relevant literature." (spokesperson, multinational drug company)

"Medical representatives provide KOLs with various materials such as publications form various journals." (director, domestic public relations company)

"Firms have funds for research related to their [KOLs'] therapeutic areas. We can ask a scientist to prepare a publication for a specific topic and we obviously provide him with the relevant literature. Alternatively, if they want to study something not as a clinical trial, they also turn to a drug company. These are absolutely basic types of activity for us." (spokesperson, multinational drug company)

"Sometimes, they buy us books or facilitate access to other sources of information such as various journals." (regional consultant)

"In terms of the disadvantages, I have already told you about shifting stress or the amount of information towards pharmacological treatment. Sometime ago, there was an imbalance in the provision of information. This has changed after a few scandals. Now there is a requirement to disclose negative results. […] But these are marketing strategies. It is hard to expect that a drug company whose [product's] primary effect is obesity will organise a conference on obesity." (regional consultant)

"There is no doubt that the pressure [on KOLs] exists. The industry is so rich, so powerful... I imagine This type of pressure is very strong and can take various forms: bringing equipment, books, help with getting a good start. If professors at clinics have promising PhD students and want to send them somewhere to have an internship, they surely rely on the industry's help, their contacts, laboratories. They do so if they want to build a research team. This is how it is done. [...] And then we can learn how powerful and influential professors of medicine are in this country. They create large empires. These are very rich people. But the appearances that everything looks so simple, neat, elegant. These are horrible things, but this is the truth." (high-ranking official, AHTAPol*)*

28.1. Negative evidence

"There are many benefits and problems [regarding cooperation with drug companies]. The benefits are evident. Drug companies – albeit now to a lesser extent – for a long time have enabled Polish doctors' contact with scientific life, especially when a trip for an international conference was out of their reach. An average fee at a medical conference of the European type is approximately €800, you see. This is a doctor's monthly pay, without the [cost of] the travel and hotel. Without firms' sponsoring this was impossible. Now it no longer exists. The affluence of the Polish system has changed. It is a matter of the exchange rate to dollar and euro. However, for example, ten years ago subscribing to ten scientific journals was simply impossible because the cost of yearly subscription was a yearly budget of an institution and a Polish hospital didn't have money for it. A Polish hospital usually does not have money for salaries or energy, and subscribing to scientific journals, buying books or subscribing to online access to medical data bases [is impossible]. I do not know a hospital director who would do such things, since there is simply no money for this. And this is a very important, valuable thing." (regional consultant)

"[Can KOLs access negative opinions about drugs?] Today? There is the 'Enter' button on your computer [i.e. keyboard]. It is not a problem whatsoever. I had a lecture yesterday about a drug which will be introduced and I accessed information which will be published only next week, because it is already on the Internet. Of course! [these sources of information are credible for doctors] However, it is much more difficult to access them. Separately, promotional materials are prepared by drug companies based on objective articles which are favourable for them. They are bound in a nice way. Nonetheless, a rank-and-file doctor finds it difficult to understand a scientific article, the whole process of reaching a conclusion. To fully understand what's going on the whole process needs to be scrutinised. [...] [so that it becomes possible to establish] [whether] [...]information provided is factual or whether it is suspicious […]. Then based on this information firms create promotional materials which reach doctors." (national consultant)

29. Transfers of economic capital

INTRODUCTION

This section shows further examples of the transfers of economic capital – taking the form of diverse financial incentives – from multinational drug companies to medical experts taking part in the evaluation of drugs considered for state reimbursement.

QUOTATIONS

"Drug firms sponsor opinion leaders in the medical milieu." (former high-ranking official, MoH)

"They [KOLs] are a group whose financial relationships are relatively well determined. If they act or make statements in favour of a given firm, they are rewarded. What comes into

play are scientific project, scientific initiatives for which they take money." (public affairs director, multinational drug company)

"KOLs are used to working with [drug] firms. They have it in their blood. [...] Professors are invited to disease awareness campaigns. Their role is to participate at a conference, give an interview. Sometimes a professor will prepare a 15-minute lecture where he shows some old lousy slides. Some of them can't even make a presentation in Power Point. Or the lecture is very sophisticated but the target audience are journalists, who are struggling to understand it.[..] It [making conference presentations] doesn't cost them [KOLs] a lot of work." (key account manager, multinational drug company)

"In my opinion, KOLs are used to cooperating with firms. They are finding it very difficult to get out of some habits. They still remember the times of Eldorado, when there were no ethical rules. They used to receive watches, laptops, a dog for the wife." (key account manager, multinational drug company)

"Clinical trials are main the form of rewarding and building long-term relationships with KOLs." (high-ranking official, MoH)

"KOLs hugely benefit from clinical trials." (high-ranking official, NHF)

"The recruitment of a patient to a clinical trial can bring the investigator even €5,000. Everything depends on the importance and the rarity of the disease. If the trial concerns sclerosis multiplex, for one included patient the investigator can receive several thousand euro. This is a gigantic business." (high-ranking official, AHTAPol)

"Members of the CC are KOLs in their fields so lectures are something absolutely natural. If they organise lectures, they are paid for it. It's difficult to expect that they will do it as an act of charity." (external affairs manager, drug company)

"We do not know what happens to that money [money flows between the drug company and the investigator in a clinical trial]. Does the hospital receive it? We have no idea. But this is an open secret. How the principal investigator divides this money [from a clinical trial] is only his business. Whether he takes 90% and gives 10% to his assistants. Or he can give 20% to his assistants, who actually designed the project, 10% to the hospital and transfer the rest to his private account in Switzerland." (high-ranking official, AHTAPol)

29.1. Negative evidence

"When we invite experts for our conferences, we pay them a fee. It has to be commensurate with the amount of work and market conditions. If it does not reach the maximum amount, we can reimburse the expert for the costs of travel form another city. He draws on our materials concerning, say, clinical trials. Thus, during the conferences he says that he is discussing our product or explains that his presence here is thanks to the firm." (communications manager, multinational drug company)

"If a drug company is organising, for instance, a conference or workshops for doctors, they turn to me and offer employing me as a lecturer, then this is additional income. Then I need to decide whether I want to make money on a Saturday or stay at home." (regional consultant)

"I'm not hiding it that I'm very eagerly invited [to speak at conferences sponsored by drug companies]. I have always been and even more so now because I'm a national consultant. But now I have stopped accepting invitations because, first, I have too many duties, and, second, I have resigned from product presentations, that is, those in which I'm talking about a particular drug, even if I'm doing this objectively..." (national consultant)

"Trips to exotic places [sponsored by drug companies] probably still happen. There are some legal limitations, though [on how they should be organised]. I don't have detailed knowledge

on this issue. This is not an effective business solution, in my view. A trip should be aimed at acquiring knowledge and passing it on [to other doctors, e.g. at a clinic]. It would be naive to claim that these trips don't happen. Relationships are one thing but at the end of the day a firm is interested in its financial results. In this context, trips to tropics are not effective, because doctors don't get much out of them. This is the other side of the story. For a doctor, time is money. They want to learn something about therapies, drugs. I believe that common sense helps in organising these trips. I don't think that innovative firms – these are the ones we work for – believe that this is an effective business solutions, especially with regard to building relationships [with medical experts]. Holidays is doctors' private matter. Offering trips is an intrusion into privacy. For sure, sometimes there are trips for a lecture and a holiday. However, as far as I know, it is usually a four-day conference and one day for sightseeing." (account director, domestic public relations company)

30. Increase in scientific capital

INTRODUCTION

This section demonstrates how the transfers of cultural and economic capital from drug companies translate into increased scientific capital – or prestige – of medical experts advising state organisations in the drug reimbursement process.

QUOTATIONS

"A clinical trial, especially a multicentre one, is a real treat for professor X. By taking part in it, he can meet big names from France, the US and the UK. This is extremely valuable, since his peers in Poland look up to him when his name appears next to those foreign names in 'The Lancet' or 'British Medical Journal.'" (journalist, weekly magazine)

"Firms can support PhD students, research staff working for a given professor. He is then credited with their successes." (key account manager, multinational drug company)

"Cooperation with a drug company is aimed at pursuing research, earning money and increasing one's prestige." (account manager, multinational public relations firm)

31. The role of social capital in building relationships with medical experts

INTRODUCTION

This section offers additional evidence concerning the role of social capital in building relationships between drug companies and medical experts. With few exceptions, our interviewees maintained that the transferring cultural and economic capitals also involved long-term and trust-based contacts with medical experts.

QUOTATIONS

"[In the pharmaceutical sector] [t]his relationality [i.e. key role of personal relationships] is visible in marketing actions, contacts with doctors-presidents and contacts with KOLs. The latter decide whether a certain group of medicines will be reimbursed or not." (freelance lobbyist)

"In the pharmaceutical sector, stakeholder mapping is crucial. We have to be able to do this even while asleep. Firms know precisely which KOLs may support their products." (freelance lobbyist)

"Achieving Key Opinion Leaders' support is vital. We do need to have permanent relationships with them. This is the essence of pharmaceutical lobbying." (freelance lobbyist)

"Established relationships allow me to call a national consultant or the president of a medical society. And I tell them that we have an interesting idea and would like to talk. Drug companies have been working with KOLs for many years. They have to know them. We have to know them. The most important thing is to get them interested in the topic or campaign. They will happily sign anything related to broadening access to a new group of drugs, they want to see the effectiveness of treatment being increased and the access for patients in the queue [for procedures involving drugs] being improved." (account manager, public relations firm)

"I am well perceived on the market and many firms would like to have me on board. This results from many years of experience and cultivating relationships." (communications manager, multinational drug company)

"I truly learnt how important relationships with concrete people are when I was suddenly sacked by my firm just before the launch of the campaign I had prepared. Then one of the key opinion leaders engaged in developing the campaign called me and asked where I was. I explained what had happened and he said that in these circumstances he had no choice but to quit from this initiative. For he was cooperating with the person, not with the firm. I must say that I have been maintaining this relationship till today." (communications manager, multinational drug company)

"The drug company has its own KOLs and public relations agencies have theirs. The firm simply knows whose opinions are necessary or desirable. ... The drug firm often tells us that we should consider concrete people in the campaign. On the other hand, as an experienced agency we can suggest cooperation with a given expert." (account manager, public relations firm)

"Suppose that the firm enters a new area, say oncology. It obviously has brilliant people inside, but this is a new area and so they will be starting from the scratch. They will have to who works with whom and why. That is why firms employ people with established relationships. It is better to employ someone who knows these relationships." (key account manager, multinational drug firm)

31.1. Negative evidence

"It is true that relationships are very important in pharma. Indeed, very much depends on them. But one needs to strike a proper balance in these relationships. How a relationship looks like depends on a particular person. The personal relationship as such is not the most important thing, though. The substantive relationship is more important, yes, it is definitely crucial. I'm always determined to show the substance of the issue correctly. This is precisely what creates an added value. Obviously, it is not that we do not maintain personal, non-substantive relationships with key opinion leaders, professors, and medics. If I go to dinner with a key opinion leader, we're not talking business at that time. But this is not unique to pharma. This is characteristic of relationships in general." (public relations director, domestic public relations firm)

"It is obvious that they [drug companies] try to contact me. But I have limited my contacts recently. I generally try to reduce these contacts at work. I can contact them at a seminar or when I go for a conference somewhere. You know, no conference anywhere in the world could happen without sponsors. And the drug industry is a natural sponsor. I can see no reason why opinions could not be exchanged there, why we could not talk. Even more so because the industry has a lot brilliant, civilised people." (national consultant)

"Z [A prominent medical expert working for the Agency], because of his position at [institution Y], had dealings with virtually every drug company [...], either through

recommending drugs, going to congresses, advising on various issues. He knows everyone in the drug industry, certainly all people from the top [*wierchuszka*]. But so what? He is a professional, a very competent person. His opinions are very penetrating, exceptionally reliable. [...] [Also,] [h]e is already retired. And retirement gives a degree of comfort in this country but not everyone can use it properly..." (high-ranking official, AHTAPol)

32. Insufficient support from the state for medical experts

INTRODUCTION

This section offers additional evidence showing how insufficient state support for medical experts contributes to their structural dependence on multinational drug companies.

QUOTATIONS

"I have recently spoken to a national consultant. He complained that he should be attending congresses and visiting clinics in the country but the state does not provide him with funding. So they sometimes take money from drug companies. It is obviously very hypocritical of politicians to eagerly criticise relations between national consultants and the industry, whereas they give them no money." (president, domestic lobbying firm)

"A national consultant is a very prestigious post which entails multiple responsibilities. It is my strong conviction that national consultants are largely underpaid for their work. They are paid by the MoH at the end of the year and it is not uncommon that they use their own money to carry out many tasks. This situation results from the financial crisis and budgetary problems." (high-ranking official, MoH)

"After all, we are cut off from access to the literature. The AHTAPol does not subscribe to journals even such as "The Lancet" or "British Medical Journal". CC members are obviously

unwilling to pay for the relevant articles form their own purse. But at the end of the day it is AHTA which should provide those publications on their desk." (high-ranking official, AHTAPol)

"What they receive for work at CC is really symbolic. [...] These are really ludicrous sums when we have in mind the level of specialisation and preparation of CC members." (high-ranking official, AHTAPol)

"National consultants are employed by the MoH. What they earn is ludicrous. And these people are the organisers of their sectors [areas of medical speciality]. To maintain his position, a consultant must have money, which he receives form drug companies." (high-ranking official, MoH)

33. Exclusivity of drug companies' relationships with medical experts

INTRODUCTION

This section details how our interviewees perceived the strength of ties linking some medical experts to particular drug companies. The prevalent view among our interviewees was that it is uncommon that multinational drug companies establish exclusive relationships with medical experts.

QUOTATIONS

"Firms want to keep KOLs by themselves, because they have invested so much money in them, for instance, in promoting them in the media." (director, domestic public relations firm)

"Professors can be divided into two types – supportive and unsupportive [of our drugs]. They are either 'ours' or 'theirs'. Those who are unsupportive work for our competitors. By that I

mean giving lectures, doing research, being reviewers, taking part in conferences sponsored by the firm." (key account manager, drug company)

"It is important to maintain stable relationships with KOLs. They are invited to conference and international conferences, what also comes into play is work for drug companies, primarily in clinical trials and this is what binds a [national] consultant with a drug company." (freelance lobbyist)

33.1. Negative evidence

"Sometimes it is in the interest of the drug company that a KOL cooperates only with them. But rarely can these people afford to work only with one firm. They have a high position, they are authorities. Also, this attitude results from progress in medical research. It may turn out that in six months' time a new targeted therapy would be introduced and the drug which is considered to be the best today will lose its place." (account manager, public relations company)

"I think that competition is a permanent element in our relationships with KOLs." (communications manager, multinational drug company)

"Firms obviously compete for KOLs' attention. They use various methods to bind KOLs to themselves." (key account manager, multinational drug company)

"[National] [c]onsultants can meet various firms. These are professors, they have their own experience, knowledge..." (partner, multinational law firm)

"It is uncommon that a very important KOL cooperates only with one firm. This would be unfavourable. When you consider competing drugs, it is uncommon that one product is decidedly better than the other. It all comes down to the nuances. KOLs support them

somewhat arbitrarily by showing their own preferences." (corporate affairs director, multinational drug company)

34. Extent of medical experts' independence from drug companies

INTRODUCTION

This section provides different perspectives regarding a possible impact of relationships with drug companies on medical experts' advice offered to state organisations. Overall, medical experts stressed their own independence but were more sceptical about their colleagues.

QUOTATIONS

"It all depends [whether KOLs cooperate with one or many drug companies]. Some represent the position favourable only for one company because this is closer to their convictions. [On the other hand,] [t]here are also experts whose scientific views correspond with the interests of many firms, even those displaying scientific contradiction. So there is a whole spectrum of [KOLs'] attitudes between the two extremes: on the one end, stressing one's scientific independence and, on the other, extensive cooperation and shared interests with drug companies. A KOL engages socially, medially and scientifically. Their all scientific and non-scientific activity reflects initiative coming from business" (public affairs director, multinational drug company)

"You know, I have been thinking about it for a long time, because I sometimes observe those presentations [at medical congresses], not only in Poland but also abroad. They are very emotional, saying how wonderful a drug is. And I always wonder to what degree this is [...] induced by gratification or [results from] deep internal conviction. Like I say, this does not concern Poland only. Sometimes, when I listen to acknowledged professors singing praises of a medicine during a meeting organised by the firm, I keep saying to myself: 'Gosh, I

would never sell myself like this for any money. I had thought that it was a matter of financial influence until I had a chat with one opinion leader – not a Polish one – who was singing praises of one drug which he had started [taking] and induced depression in himself, which is described as a side effect of this drug. Notably, this drug was registered but now, due to a high number of depressions, it has been withdrawn and disappeared. This convinced me that this is not the case... that this enthusiasm is not caused by relevant gratification but this is a man's internal conviction." (national consultant)

"Obviously, firms have the opportunity to influence, because if you are preparing a lecture and ask them for scientific materials, they will very happy to send you several hundred of their materials, where there is a mass of articles describing very positive events. And it can be even be done in an objective way. But in this way you can expect to have a hundred concerning positives. But the hundred of negatives you have to find on your own, if you can be bothered. If you can, you arrive at an objective picture. But if you can't and choose the easy way... Because for every topic you can find both positive and negative information. And this is a matter of selecting information and making up your own mind. If you draw on positive information, you will have one thing. If you draw on negative information, you will arrive at a completely different position. It is a matter of establishing your own opinion on a given topic." (national consultant)

"I think that competent and independent people work for the AHTAPol but in the CC the situation is a bit worse. There are indeed a few people in the CC who are closely related to the pharmaceutical industry. And here the decisions are not fully reliable, at least this is my perception. The procedures that have been developed are not bad but there are a few issues." (Member of Parliament)

"It is very easy to 'bribe' CC members and the industry knows how to do it. There is no slightest doubt that they are manipulated. If someone receives an offer to attend a congress, say, in Hawaii, where the firm covers all the costs, including a visit in an entertainment or a tourist centre, he will go there. And [then] for a year he will be obediently declaring the conflict of interest and will not participate in discussion concerning the drug of this firm. But this trip to Hawaii is very profitable for him. Anyone would like to go to Hawaii or Chile for a trip sponsored entirely by a drug company, including a visit to a theme park or a tourist centre. They are all exposed to it." (high-ranking official, AHTAPol)

"During my stay at the office, there was a problem with drug X: some national consultants were expressing themselves unreasonably. They did it publically, during press conferences. They were cited by serious media." (former high-ranking official, MoH)

"In some areas, national consultants are deeply entangled in conflicts of interests and their opinion is suspicious." (high-ranking official, AHTAPol)

"We need to select KOLs viewed as independent. Only their opinion matters." (lobbyist, domestic lobbying firm)

"If a consultant went to Hawaii and it was sponsored by a drug company, he comes back and evaluates this drug, it is highly unlikely that the assessment will be negative. This person writes workbooks or guidelines, or teaches. He is a medical authority. And he benefits financially through trips, congresses or the like, or indeed in cash, or through clinical trials which a drug company organises at his [clinic]." (journalist, web-based magazine)

34.1. Negative evidence

"I am perceived as an objective lecturer [...] it's not that on Monday I will tell that the pill A is the best, on Tuesday that pill B, and an Wednesday that pill C, but I have my own balanced

opinion, which can indeed show that a given drug is better, that is, has an advantage in this and that. However, it will be evident that this is my opinion based on the data and not on [...] who is standing behind my back as a sponsor. There are differences. One drug is better, another is worse. Obviously, there is a game played by the industry, because if they know that I am convinced about the effectiveness of a drug, then I am invited by these who have this drug and not those who haven't. This introduces bias to communication." (national consultant)

"At the beginning [of my career], yes [I was suggested to say which drug is 'good' at a sponsored lecture]. But for some time now the organisers have known that this is pointless in my case. [...] At the beginning, I was part of a pool of lecturers. When I was invited, [this pressure was exerted] many times, virtually every time. [...] This is not arranged in writing. It is always a chat. 'Listen, say about this drug but not the other drug.' Or: 'I don't want you to talk about that drug. Then I reply: "Man, it's me who decides what I'm talking about. If you want someone to tell what you want, write a text and hire a journalist from a news programme – he will do it better than me.'" (national consultant)

"I can tell you that after several situations at the beginning of my career [attempts of exerting informal pressure] ended because I have always had the same [negative] response and it was obvious that making such offer was a waste of time." (national consultant)

35. Effectiveness of institutions for managing medical experts' conflicts of interest

INTRODUCTION

This section offers contrasting perspectives on the effectiveness of institutions for managing the conflicts of interest reported by members of the CC, the key expert advisory body in the

drug reimbursement process. While some interviewees stressed the effectiveness of these institutions, the dominant position stressed multiple barriers to their proper enforcement.

QUOTATIONS

"This [conflicts of interest reported by CC members] is a considerable obstacle [for the CC] [...]. For these people are professionals, their opinions are highly penetrating, very reliable. They have been dealing with these topics all the time." (high-ranking official, AHTAPol)

"Firms have access to Council members. Those professors have cooperated, they give lectures. They've had relationships with firms." (partner, multinational law firm)

"Having in mind the need to maintain a quorum, [CC members] 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.'" (high-ranking official, AHTAPol)

"That there are few members present and some of them have conflicts of interests has a fatal influence on their work. For if there is no quorum, they cannot vote. Sometimes it happens that of the six people present, three have a conflict. This is the end because they cannot take any decision. They just discuss current matters. Or if they have an issue at the end of the session and some of our colleagues have to catch a train, they have to drop it automatically because there is no quorum. Situations when there are many conflicts of interest but few members do block our work." (high-ranking official, AHTAPol)

"Luckily, there is this one-year dividing line [in declarations of conflicts of interest submitted by CC members]. Otherwise they would have to exclude X [a CC member] from the outset. Because of his position at [institution X] had dealings with virtually every drug company in this country, either through recommending drugs, going to congresses or advising them on various issues. (high-ranking official, AHTAPol)

"We will never find out. At least in the CC. It is always the case that at the beginning of a CC session the first item on the agenda [concerns declarations of conflict of interest]. They receive questionnaires listing all firms whose products are analysed and evaluated on the day. Every firm is listed. If someone has had deals with a firm, they declare it. There are various thresholds – lectures, trips, or shares. [...] Then they vote if they want to exclude [members with conflicts of interest] or not. Such a person is not asked to leave [the room where the session is taking place] because this would be awkward. If someone decides not to disclose his or her relationships, there is no way we could establish the truth. We have no agency that would investigate this. But people have been declaring honestly. But as for now there seem to have been no problems in this respect. At least there has been no scandal." (high-ranking official, AHTAPol)

"And what if a declaration does not reveal the truth? It [a declaration of conflicts of interest] is a minor threat [for those who might not reveal their conflicts], I believe." (partner, multinational law firm)

35.1. Negative evidence

"[CC members leading on a given topic] [...] are selected based on their speciality. In the CC there is a nephrologist, a cardiologist, a pharmacologist [...], probably two oncologists... . If someone is a nephrologist it is more likely that they will assess drugs that are related to the excretory system, the circulatory system, kidneys. Oncologists are given oncology drugs." (high-ranking official, AHTAPol)

"[T]hey [CC members] can say that they have a conflict of interest, since we have these declarations, and because of too close cooperation with a firm, they cannot evaluate this drug." (high-ranking official, AHTAPol)

"I remember that he [a CC member] once got a drug used in [disease name] because the person who knows this topic very well had various lectures for this firm and they [the CC] would like to avoid a situation of conflict of interest. It is better when a person supposed to objectively analyse a drug does not have conflicts of interest." (high-ranking AHTAPol official)

"At the beginning of every CC session, the Chairman of the CC asks about causing the lack of objectivity. This concerns primarily typical financial conflicts of interests, for example, lectures. CC members are KOLs in their areas of speciality, so a lecture is absolutely natural. They are national consultants, KOLs for firms, doctors from their regions. They should not be cut off from this. This person gives a lecture and takes money form the sponsor. It is hard to expect that they will do it charitably. Later [at a CC session] this parson may abstain from contributing to the discussion. What also comes into play are conference trips, lectures, writing reports. There are situations where firms call them [CC members] all the time, pester them. This was particularly the case at the very beginning [of the functioning of the AHTAPol]. Firms were introducing a typically sales, promotional message [to their communication with CC members]. This should be reported as a conflict of interest and described as an attempt of immoral influence on CC members. It shouldn't be accepted." (external affairs manager, multinational drug company)

"It happens that the member who is the 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." (manager, domestic HTA firm)

"I must tell you that I'm amazed at the honesty and reliability of people who deal with it both in the CC and analysts who prepare initial reports. These people are indeed independent and

are striving to be as objective as possible, always, in relation to each case and they declare conflicts of interest on paper. If someone has had a lecture for a firm, travelled, been gratified in one way or another, they are excluded from discussion, they do not take part in voting. Sometimes they are let speak because they are specialists in a given field. [...] But they don't vote. This is the rule. It should be like this." (high-ranking official, AHTAPol)

36. Directions of social mobility between the state and the pharmaceutical sector

INTRODUCTION

This sections supplements the evidence concerning the prevalent direction of social mobility in the drug reimbursement policy domain. All our interviewees agreed about the high extent of outflow of cadres form state organisations to the pharmaceutical sector.

QUOTATIONS

"I have been working in the DDPP for two years. When one person leaves, I will be the employee with the longest work history there." (middle-ranking official, MoH)

"After two years they move to a pharmaceutical company. This is the present career model." (freelance lobbyist,)

"It only has been recently when X left us and moved to a pharmaceutical company which offered him a sky-high contract. They simply bought him, with all his qualifications, abilities and experience. We felt very sorry, since it was so unexpected, but what can we do about it? People are only people." (high-ranking official, AHTAPol)

"There were one or two private [HTA] firms at the very beginning. Now they are springing up like mushrooms. And these are first-class firms, whom we trust. Because we know who

they are. Sometimes half [of a HTA firm's] staff are our [former] analysts." (high-ranking official, AHTAPol)

"Some of these people [state officials] ends up in the industry very quickly. A good employee spends very little time in the Ministry." (former high-ranking official, MoH)

"A former [high ranking ministerial official] had worked at a pharmaceutical company, then for a long time at the MoH and then lost his job because many officials were fired." (journalist, weekly paper)

"Note that cadres flow only from the MoH to drug companies and there is no movement in the reverse direction." (journalist, weekly paper)

"Nowadays, the exchange rate is lower among directors, and higher among ordinary employees." (representative, association multinational drug companies)

"From time to time, I advise pharmaceutical companies drawing on my experience at MoH." (former high-ranking official, MoH)

"There is something resembling the 'revolving door'. The flow of cadres is very high. But there is no room for proper lobbying. The most effective firms are those who have departments dealing with drug reimbursement. Its boss has been the same for ten years. In addition, there are people who used to worok for the MoH or the NHF for two or three years. This is notorious. They studied biotechnology, for example. [When working for state organisations] [t]hey received substantial preparation in HTA through workshops, conferences or internships in leading institutions abroad. And after two years or so they move to a drug company. This is the present career model. And all this is related to the relationality of this sector." (freelance lobbyist)

36.1. Negative evidence

“The AHTAPol has been germinating on the basis of commercial HTA firms from Cracow [i.e. the firms provided some personnel for the AHTAPol].” (former high-ranking official, MoH)

37. Determinants of the “Fire Exit” syndrome

INTRODUCTION

This section elaborates on the key determinants of the high extent of outflow of state cadres to the pharmaceutical sector:

- Low salaries
- Difficult working conditions in state organisations.
- Limited prospects for career advancement in state organisations.

We did not identify any disagreement about the determinants of the “Fire Exit” syndrome.

QUOTATIONS

37.1. Low salaries

“I earn around half the average pay [in Poland]. On the other hand, I’m working with therapeutic programmes worth [yearly] more than one million times my monthly salary. Isn’t it absurd?” (middle-ranking official, MoH)

“This is a structural problem. The cap on earnings in public offices is subject to top-down regulations for the whole state sector.” (high-ranking official, National Health Fund)

“A pharmacoeconomist has to have colossal knowledge about medicines, microeconomics and very advanced statistics. If someone goes to a drug company with this knowledge, [...]

his [monthly] earnings start from $7000, whereas at the AHTA [...] he earns up to $700-1000. [...] I think they should act as sort of a special force in a sense that they decide about billions of dollars and they should be rewarded [properly]. ” (Member of Parliament)

“There are a few very bright doctors there [in the AHTAPol] [...] Some of them work quarter-time at a hospital to get some additional money in the evenings. It is like this. If someone is married with kids and comes from the province and wants to live in Warsaw, he needs to work extremely hard. [...] I think they should earn two or three times more than now, if they are supposed to concentrate only on this [i.e. work for the AHTAPol].” (high-ranking official, AHTAPol)

“In Poland, there is very few people with advanced knowledge about drug registration or reimbursement. In the UK, for example, they have vast human resources to deal with it. [In Poland] People work in the MoH two years after graduation and earn $1000, And later this amount is doubled as soon as they join a drug company. I’ve never heard about people coming from drug companies to the Ministry [of Health].” (high-ranking official, MoH)

“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. They were learning that [pharmacoeconomics]. There was a visit to NICE, analysts are sent for workshops. These are brilliant people, doctors, pharamcologists, statisticians.” (high-ranking official, AHTAPol)

“An awful lot of money is involved [in transferring state officials to the pharmaceutical sector]. And I regret that very much. We are fully aware that the AHTAPol trains excellent analysts who are bought by private companies. They are simply bought. They are offered a three-four times higher salaries. And these people go there [to the pharmaceutical sector]. This outflow does exist.” (high-ranking official, AHTAPol)

"What they [CC members] receive for work at the CC is really symbolic. [...] This is like voluntary work. [...] This has been working only based on the good will and enthusiasm of these people." (high-ranking official, AHTAPol)

37.2. Difficult working conditions

"I worked in the Ministry [of Health] for less than three years. This was a big failure because nothing could be done. I quit because was fed up with fighting with the system. I left this job. At the beginning, I was very enthusiastic but then I was 'cured'. Around the same time several other people left. Those people left but they are still in the system. Some of them moved to the AHTAPol, but the others went mainly to drug companies. Those people have the choice. And they have got the experience. They went to the MoH for a reason." (former middle-ranking official, MoH)

"This is incredibly hard work [for AHTAPol analysts and CC members] They need to sit on it, count, verify [analyses submitted by drug companies]. This is gigantic work. [...] It is so unfair that you offer high-quality expertise whose someone else will take away and sell." (high-ranking official, AHTAPol)

37.3. Limited prospects for career advancement

"My friend [currently at a drug company, formerly an MoH employee] used to think that she was doing a really good job and didn't understand why the Ministry was being criticised. Now she has told me that a quarter of the Ministry's activities does not serve any purpose." (external affairs manager, multinational drug company)

"The AHTAPol definitely lacks the necessary prestige. [...] I know the Western standards, particularly the British ones, very well, and that is why I reiterate that the Agency of this class should [offer] [...] proper salaries for the analysts and fees for CC members." (high-ranking official, AHTAPol)

"From all over the MoH we [the Department of Drug Policy and Pharmacy] are grilled by the media most often." (high-ranking official, MoH)

"In the Ministry of Foreign Affairs, after ten years an official has prestige, international contacts. They participate in important issues and this compensates for low salaries. In the MoH, officials fight with hospitals, drug firms and patient organisations. This is hard and unrewarding work." (freelance lobbyist)

"Those officials face high stress levels and are kicked around." (lobbyist, domestic lobbying firm)

38. Consequences of the "Fire Exit" syndrome for the state

INTRODUCTION

This section explains key consequences of intensive mobility form the state to the pharmaceutical sector:

- The depletion of valuable types of state expertise.
- Limited capacity for developing coherent pharmaceutical policy.
- Negative selection of state cadres.
- Diminished loyalty of officials to the state.

We did not identify any disagreement regarding the negative impact of the "Fire Exit" syndrome on state capacity.

QUOTATIONS

38.1. Drainage of state expertise

"In the DDPP [MoH department dealing with drug policy] we have a problem with doctors. The only doctor is the Director. In addition, there are two pharmacists. The other employees are lawyers like myself. The situation is very daunting in terms of who works here. Let's not delude ourselves – lawyers do not have practical knowledge [about drugs].We obviously rely on HTA but we need someone inside who is able to provide information instantly, not after one month, because we need to wait for a reply [from the AHTAPol]. What we need is internal experts" (middle-ranking official, MoH)

"X [former high-ranking AHTAPol official] was ideally informed about drug prices and sales. [...] He is now working for [a higher education institution] and has close relationships with the industry. Quite simply, X is now earning two-three times more than [we could offer]. However, X was extremely useful. X was able to recall the numbers instantly. X was invaluable as far as statistical information is concerned. Yet he had better offers. And the AHTAPol will keep losing such people." (high-ranking official, AHTAPol)

38.2. Limited capacity for developing coherent pharmaceutical policy

"In the DDPP there is no continuity." (partner, multinational law firm)

"This constant fluctuation results in that we lack highly qualified specialists who would be able to develop this policy." (high-ranking official, AHTAPol)

"This constant fluctuation results in that we lack highly qualified specialists who would be able to develop this [drug reimbursement] policy. People come and are gone in a year or two." (high-ranking official, AHTAPol)

"[At the MoH] there is a great many of young people. But they don't know our problems, they do not know the sector." (representative, association of multinational drug companies)

38.3. Negative selection of state cadres

"They have too few people and not always the best people, because it is very hard to keep them in public administration." (American diplomat)

"Those people [former MoH officials who moved to the pharmaceutical industry] have received substantial preparation in HTA through workshops, conferences or internships in leading institutions abroad." (freelance lobbyist)

"I'm dissatisfied with my contact with the MoH. This is because of the constant staff turnover, the learning curve of new officials and the lack of follow up of ideas of the predecessors. The MoH is an institution acting between extremes, whose intellectual perspective is limited by the political calendar. When there is a power shift, the new team will start a new revolution. The main minuses include incompetence, the lack of proper work organisation, instability of tasks and the bureaucratic apparatus, appalling communication (for example, there is no possibility of web-based contact on many levels of the hierarchy) and delays following redundancies or annual leave of an employee. I don't know about any positives." (KOL, cardiology)

38.4. Diminished loyalty of state officials

"We haven't got pharamcoeconomists in Poland, this class haven't developed yet. [...] We employ people who – it very often happens that – they already come with this goal: 'I will work a year or two, learn and then move to the industry. These people are very vulnerable to various pressures because they want to find a good job afterwards. So if they are paid very little, they just accept it that they will work here for a few years and then quickly go to the industry because here in the Agency [the AHTAPol] they are paid so badly." (Member of Parliament)

"This Department [the DDPP] is like a blossoming orange tree. Some oranges are ready to be plucked, the others are ripening and their fate is a foregone conclusion." (high-ranking official, MoH)

"People go to [work for] the MoH for various reasons. They view it as an investment in themselves, a way of developing contacts." (external affairs manager, multinational drug company)

"Those people are very vulnerable to various pressures because they want to find a good job afterwards." (Member of Parliament)

"I am young and can wait. For two years, I have been learning how all this functions. But I need to have self-respect. I know that my situation on the job market is rather comfortable." (middle-ranking official, MoH)

"We have the choice [to either stay in state organisations or to move to the pharmaceutical industry]." (former middle-ranking official, MoH)

"Only an idiot would accept money. We should look at the broader context. ... There are more subtle methods of influence than paying people. What counts for them is not only the present, but also the future." (middle-ranking official, MoH) "The quality of our training surpasses any commercial offers. During two years we can teach them a lot more than on various other training schemes." (high-ranking official, MoH)

"He [a high-ranking AHTAPol official] disappeared suddenly over one week [...] I remember hearing a rumour that he was going to take up an academic job. Later it turned out that it was […] a powerful drug firm. This event did leave a nasty aftertaste." (high-ranking AHTAPol official)

"It only has been recently when X [an ex AHTAPol high-ranking official] left us and moved to the pharmaceutical company which offered him a sky-high contract. They simply bought him, with all his qualifications, abilities and experience." (high-ranking official, AHTAPol)

"X [an ex AHTAPol high-ranking official] quitted in a very bad style. He disappeared suddenly over one week and presented us all with the *fait accompli*. I remember hearing a rumor that he was going to take an academic job. Later it turned out that it was not the academia but a powerful drug firm. Sadly, he did not warn us in advance. This event did leave a nasty aftertaste in AHTA." (high-ranking official, AHTAPol)

"Many ex decision makers establish their own firms. And they search for contracts from drug companies which owe them something. For the pharmaceutical firms, this situation is like a skeleton in the closet." (key account manager, multinational drug company)

"I know that what often emerges during job interviews at drug companies is a question about 'flexibility'. But it does not refer to working hours but to ethical flexibility – to what degree this person is going to let him- or herself be utilised." (high-ranking official, NHF)

"Cadres are being drained from public administration. This is a very difficult problem. This may be in need of a legal regulation. It is rather disturbing when someone who was responsible for drug policy [at the MoH] ends up in a drug company whose medicines he previously recommended. It does not necessarily mean corruption. The quality of cadres is another problems. Citizens do not love wall-paid officials. But well-paid officials guarantee that that the issue [i.e. state interests] is protected." (Senator – Member of the Upper Chamber of Parliament)

38.5. Negative evidence

"Those who stay at the MoH are – like ourselves – *udarniks* and desperados. [...] Money is not the only thing that counts for us. We have always been in Europe" (high-ranking official, MoH)

39. Consequences of the "Fire Exit" syndrome for drug companies

INTRODUCTION

This section illustrates two primary consequences of the widespread employing of former state officials for by multinational drug companies: improved access to informational and social capital. The vast majority of our interviewees viewed the "Fire Exit" syndrome as contributing significantly to increasing the power of multinational drug companies.

QUOTATIONS

39.1. Access to informational capital

"[Someone who worked on reimbursement in a state organisation] is extremely valuable: he knows a lot, he has contacts. He has the idea of the reimbursement mechanism. So from the point of view of firm X, he is so valuable not because he is so hard-working, but because he has contacts which he acquired, say, in the MoH." (journalist, weekly paper)

"What is crucial for firms is knowledge about procedures, such as submitting and processing reimbursement applications. [Thanks to ex-officials] the company does not have to hire firms which analyse the applications for them." (high-ranking official, NHF)

"I know the [reimbursement] process, I know how it works and I'm able to tell what may happen to the application." (former middle-ranking official, MoH)

"Ex officials know how to move smoothly within the MoH, whom they should talk to or address a letter to. Though I try very hard, I don't know this, because I didn't work there." (external affairs manager, multinational drug company)

"What do firms want from a rank-and-file official? Information. This official will not change anything by himself, since decisions are taken at the top" (former middle-ranking official, MoH)

"If it were for competence, it [the mobility of state officials to the pharmaceutical sector] would not be a problem." (former high-ranking official, MoH)

"Obviously, I can call my friend and ask whom I should talk to. In this sense, her help is useful because she can direct me to her friends who are not my friends."(lobbyist, domestic lobbying firm)

"Sometimes our clients strongly believe they should target the Minister. But the truth is their proposition may get lost somewhere [even though they speak with the Minister]. The main conclusion is that lower-ranking officials are very important." (lobbyist, domestic lobbying firm)

"I have access to confidential information, for example drug companies' pricing strategies so that I know how much a drug costs. It means that I know their spending on production, marketing, administration etc. [...] And we really know how much these drugs cost. This is really important information." (middle-ranking official, MoH)

"[Former state officials] are a major advantage for drug companies. These are highly educated people, lawyers, sometimes with doctorates. There are firms which count on acquiring some [insider] information." (high-ranking official, NHF)

"When does lobbing happen? I don't know when lobbing happens. All I know is just an anecdote. A very hot period is just before reimbursement lists [with drugs from open reimbursement] are about to appear [i.e. be updated by the MoH]. Sometimes, someone gets lucky when making a phone call to the MoH and hears something like this 'We are very busy right now because we have just received the list'. This means that the list will be published, say, in two days' time." (director, domestic pharmaceutical market consultancy)

39.2. Social capital

"[Ex-MoH bureaucrats] become 'contact points' in their companies. They can naturally call their colleague from the MoH and ask how her day was." (partner, domestic law firm)

"[Transfers of MoH officials] [are] an important phenomenon. Do you know X [a former moH official now working as a lobbyist for a multinational drug company]? Luckily, I don't have such dilemmas. I'm just a lawyer, an advisor. I can work for the Ministry [of Health] and then for the industry. [...] The exchange rate of officials is high. Sometimes they are useful for drug companies. They can tell how the procedure, how reimbursement looks like in practice. Such a person is a big bonus for a [drug] company. Interpersonal contacts do matter. It is much easier to call to the MoH and [...] arrange a meeting." (former middle-ranking official, MoH)

"X [A former high-ranking MoH official] used to keep some firms' reimbursement applications in a drawer. After leaving MoH he started working for the firms whose applications he didn't keep there." (lobbyist, domestic lobbying firm)

"A powerful pharmaceutical firm tried to hire me. [...] They contacted me through an international headhunting agency and proposed a managerial post related to dealing with the company's external stakeholders. [...] They assured me that I would be very pleased with my contract. [...] They were obviously trying to win me over using the argument of high

earnings. [...] people having similar posts to mine have also been cornered in this way. [They] were offered a monthly pay starting somewhere in the region of €10,000. Having in mind our ludicrously low salaries, this is a great temptation. However, it is not impossible that if I had small children, the desire to have a large house and a new car, I would have broken down. [...] All in all, I must admit that I'm quite proud to have become hunted in this way. Why did they want to recruit me? Because I can be useful. [Though the post I was proposed] has virtually nothing to do with my background. This is lobbying. This shuts my mouth. Becaus then I sign a declaration of loyalty and I can only represent the firm's interests." (high-ranking official, AHTAPol)

"The way HTA firms recruit their employees depends on the position. As far as analysts are concerned, the experience of work at the MoH is not necessary. People with this kind of experience are not numerous and they typically end up at [drug] firms. Quite simply, firms can offer them better contracts. As for managerial posts [in HTA firms], previous work experience in the MoH is inevitable. The recruitment process is not based on public job advertisements. Rather, it is primarily premised on personal contacts." (manager, domestic HTA firm)

"These people [former state officials currently employed by drug companies] just sit there and do practically nothing. They are paid for being on stand-by." (key account manager, multinational drug company)

"A firm is reasoning this way: 'Let's employ someone who knows other people from the MoH. Though he is only a pawn, he has certain insider information which may be useful in bringing some things closer, speeding [things] up, getting knowledge about the competition. This employee is 28 years old and has worked in the MoH for three years. This is a transactional method. It is a very important element of strategies pursued by the

pharmaceutical industry. Firm find ex state employees very useful. This has nothing to do with [proper] lobbying. This is insider information. We have someone there with whom we used to sit at the same desk and drink tea. And this person says that our application is ok, and theirs [another company's] will not pass, since it is 'incorrect' It has "deficiencies". This is fixing, in my opinion. This is economic intelligence." (freelance lobbyist)

"There were major problems with drug X. This was a very unpleasant affair. Y [an official allegedly involved in the assessment of the drug] quit [the AHTAPol] just overnight without telling us anything about it. This is a skeleton in the cupboard. This did leave a very nasty aftertaste. [...] Y was offered enough money to resign from [Y's post]. If you know all the AHTAPol's tricks of the trade, you are very useful for a drug company. They knew exactly what they were buying. Unfortunately, we do not have a cooling-off period to wash out all this knowledge, information, relationships. This put us in a very bad situation. But there are no legal grounds to forbid [officials from taking such steps]. (high-ranking official, AHTAPol)

39.3. Negative evidence

"The way we treat former MoH employees depends on a person, really. If they behave as usual, we treat them normally. If they are trying to manipulate us, we treat them differently. It all depends on whether the firm brainwashed them. (high-ranking official, MoH)

"X [former AHTAPol official who suddenly moved to a drug company] is enormously valuable for that firm [X's current employer]. But X does not exist for the Agency. X doesn't exist anymore. We don't talk about X. […] The firm is aware of it. Anyway, they haven't had any new submissions recently. However, sooner or later there will be new drugs [submitted by the firm]. This [mobility of state officials to the pharmaceutical sector] complicates our life and makes it difficult." (high-ranking official, AHTAPol)