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The politics of health technology assessment in Poland

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ABSTRACT

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

1. Introduction

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

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

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

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

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

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

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

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

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

2. Background

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

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

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

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