

The drugs don't work

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(Medical Xpress)—Drugs that do not represent value for money or are medically unproven may be increasingly reaching one of Europe's largest pharmaceutical markets, according to research undertaken by Cambridge sociologist Professor Lawrence King.

Professor King and colleagues Dr Piotr Ozieranski (University of Leicester) and Professor Martin McKee (London School of Hygiene and Tropical Medicine) found that multinational [drug](#) companies are deploying their massive financial resources to capture stakeholders at every stage of the process for the scientific recommendation of drugs in

Poland.

Through direct and indirect methods, many of which remain hidden from public view, some of the world's biggest pharmaceutical companies, as well as politicians, are exercising influence over the [drug evaluation](#) programme in Poland – which is overseen by the Polish Agency for Health Technology Assessment (AHTAPol).

Their ground-breaking findings are published in the December issue of *Health Policy*.

Professor King and his colleagues conducted more than 100 interviews with people on all sides of the process, as well drawing data from more than 270 scientific recommendations on drugs issued by the AHTAPol, which Poland's Minister for Health recently announced is in line to be replaced.

King said: "HTA (Health Technology Assessment) has traditionally been portrayed as a sophisticated scientific process providing quantifiable evidence-based recommendations for decision-makers, but our [sociological studies](#) have found that HTA is not 'pure science'; the drug industry is a key actor in the process of issuing recommendations.

"Our research is the first to look at HTA in Poland, the country with the largest [pharmaceutical market](#) in [Central Europe](#) and one which faces huge popular pressure at reimbursing [novel drugs](#) – as well as suffering from an underfinanced [healthcare system](#).

"The influence exerted by multinational drug companies calls into question the validity of Poland's HTA, given some of these conflicts of interest we've uncovered."

Among the conflicts of interest were conferences, paid for and

sponsored by pharmaceutical firms, in exotic locations such as Dubai. Drug companies also paid state experts to lecture, offered research grants and employed other incentives to win their hearts and minds. Other methods of interference included co-opting clinical experts, patient organisations and politicians to advocate drugs under consideration by the state authority.

The research showed that an increasing number of drugs were being recommended for reimbursement, even though more than 50% of the drugs were not deemed cost-effective at their current pricing. Furthermore, the AHTAPol found that for drugs positively recommended, the evidence supporting their cost-effectiveness was "not credible" in more than 25% of the cases, and was missing or lacking in more than 50% of the cases.

But perhaps one of the most worrying aspects of the team's findings was the scale of the brain drain from the AHTAPol to the private pharmaceutical sector, seen by King and his colleagues as one of the driving forces behind the ever-increasing number of recommendations for expensive and potentially ineffective drugs.

Dr Ozieranski said: "The most troubling finding from our research is the extent of privatisation of state expertise by the pharmaceutical sector. Our interviews and official data show the excellent experts, educated with public money, are almost immediately captured by the pharmaceutical industry – able to offer them a much better deal than the AHTAPol."

This loss of state expertise, coupled with the potential for 'insider knowledge' and personal connections being passed directly on to the biggest pharmaceutical companies, could be rectified by the installation of a 'cooling-off' period before state experts can jump ship to private jobs in the same sector, says King.

King and his colleagues were also concerned by examples of behind-the-scenes political interference, a problem not helped by the short institutional distance between AHTAPol and the Polish Government's Ministry of Health.

One interviewee, an AHTAPol official, said: "Sometimes there is political pressure on certain decisions, say, from various patient groups (often backed or created by the pharmaceutical companies) which accessed some places or organised media campaigns."

Another interviewee spoke of a Minister asking for a change in the legal status of a sizeable group of highly expensive reimbursed drugs – without any analysis or research.

Added Ozieranski: "Our research shows that political elites universally strive to retain control over the policy process while minimising their own accountability for controversial decisions."

However, despite the inherent problems in the HTA system in Poland, King and his colleagues maintain there is hope for the future, and hope their research can add to current debates around the provision of state-sanctioned drugs in Poland.

The authors highlight a few promising regulations introduced by the new reimbursement legislation in 2012. However, they note that not all improved standards for disclosure of conflicts of interests have not been implemented rigorously.

Drawing their conclusions, King and his colleagues suggest the following measures to improve transparency and increase the efficacy of new drugs reaching the marketplace:

- Broader use of professional codes of conduct for experts performing HTA
- Tighter regulation of job seeking and employment after leaving the public sector
- Comprehensive disclosure and management of experts' conflicts of interest
- Increased state support for patient and public involvement in HTA
- Well-defined institutional separation between HTA and political decision-makers

Added King: "We have offered a comprehensive set of recommendations aimed at improving the transparency of the HTA system in Poland, focusing on the effective disclosure and management of conflicts of interest – only very few of which seem to be ever reported, recorded or captured.

"Our research talks about the dilemmas that can be identified in any country using HTA to assist decisions about the reimbursement of new drugs, in particular the role of the drug industry in HTA."

Provided by University of Cambridge

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