Drug pushing in the New Europe

September 23 2011

Meds. Credit: Carbon NYC from Flickr

An investigation by academic researchers has revealed how backroom deals and discreet pressure by pharmaceutical corporations are determining which drugs are delivered to hospital patients in Poland.

The study, which is described by one of its authors as a “warning for the New Europe”, was led by sociologists at the University of Cambridge, UK. It calls for an overhaul of Poland’s drugs reimbursement system – the process by which government effectively signs off new drugs for use – and suggests that flaws in the system allow some treatments to be employed for therapeutic programs even though their effectiveness is not guaranteed.

The fact that pharmaceutical corporations lobby decision-makers in an effort to ensure that their products are taken up by national health programmes is well-documented in countries such as the UK. Less clear

is how far this is happening in the former Eastern Bloc states which entered the European Union in 2004, and whether it is properly acknowledged and controlled.

The new research, published in the journal, *Health Economics*, Policy and Law, identifies serious loopholes in the drugs reimbursement system used by the Polish government, arguing that it leaves companies with too much room to influence the final decisions taken by the Ministry of Health. Interviews the researchers conducted with industry insiders revealed that companies commonly try to buy the favour of key policy-makers, or "outflank" them by winning over expert advisors and pressure groups.

Dr. Lawrence King, from the Department of Sociology, University of Cambridge, said: "This may be part of a broader syndrome of the prominence of informal institutions in post-communist policy-making, rather than something which is unique to Poland. For the New Europe, this could be a warning."

Reimbursement is usually the final hurdle for a company trying to get its drug on to the market and is typically determined by government. Final checks about the product's cost-effectiveness and efficacy are made before a decision is taken about how the manufacturer will be paid. This means that flawed reimbursement systems can lead to the wrong drugs being sanctioned for use by health service providers, resources being wasted and, potentially, patients not getting access to the treatments they need.

Poland was chosen for the study because it is the largest pharmaceutical market in Central and Eastern Europe and an important player in influencing the balance of power in the pharmaceutical sector. The researchers focused on a major state reimbursement schemes that funds free therapies, used by hospitals to treat rare diseases and certain types

of cancer. Typically it means funding innovative and emerging drugs rather than generic treatments.

Between February 2009 and April 2010, the team carried out 109 in-depth interviews with people involved with this policy – among them government officials, drug company representatives, national consultants and representatives from patient groups. They also reviewed existing legislation, policy documents, official reports and media articles. Two specific disease awareness campaigns in Poland were also tracked by the researchers.

They found a lack of regulation in Poland concerning the development of therapeutic drug reimbursement programmes, and of the way in which drug companies approach ministers. One lawyer they spoke to described reimbursement as “legal terra incognita“, while others described the process of decision-making as akin to “black magic”.

In addition, the study found that the Polish Agency for Health Technology Assessment (AHTA), which recommends drugs to the Minister of Health, rarely has conclusive data from the drugs companies about their products. One official told the team: “In half of research results, we deal with drugs whose effectiveness cannot be established.”

These factors conspire to create loopholes which pharmaceutical companies can then exploit. While the Polish Ministry of Health does have a formal consultation procedure for receiving clients, those who use it described it less as a means of access, and more as a technique used to muzzle “unfriendly” manufacturers.

Meanwhile, informal deals are taking place outside the system, the study found. Companies build up relationships with key decision-makers by offering them mutual favors, such as support for sick relatives, or lucrative positions in the industry. In one case referred to in the paper, a

cardiology drug was accepted for reimbursement even though the scientific evidence supporting it was doutbful. Later, the press discovered that the decision had been taken after the relative of a high-ranking ministerial official had a new flat “arranged” by the drug company.

Where pharmaceutical companies cannot access ministers directly, the researchers found that they attempt to reach expert national consultants instead. The state offers little renumeration for these expert scientists’ work, which enables drug firms to offer their own financial support, or the consultants access to trials and medical knowledge that will help them to raise their academic profile.

Similarly, firms also help out patient groups whose cause matches the treatments they are trying to sell. In extreme cases, they even manufacture them. One former official in the AHTA told the researchers about a case in which a reimbursement application for a kidney cancer drug was submitted. Almost simultaneously, a patients’ association lobbying for precisely this kind of treatment appeared on the scene. “It could not have been a coincidence,” the interviewee is reported as having said.

Other informal lobbying methods are also identified in the paper. The researchers spoke to newspaper journalists who had been telephoned by drugs manufacturers wanting to “order an article” in the paper. They also encountered cases where firms had approached different ministers in an attempt to exert indirect pressure on the Ministry of Health, or, in the case of international pharmaceutical corporations, asked their own governments to exert diplomatic pressure on Polish decision-makers.

The paper notes that while some of these methods resemble techniques long-since recognised in western Europe and the US, they are exaggerated in Poland by the imbalance between the economic resources

of drug companies, and those of other players such as patient groups or consultants.

In response, the researchers recommend comprehensive reform of the current system in Poland, which would involve more effective regulation of consultations between the Ministry of Health and drug companies, and a beefing up of financial and organisational support for third parties, so that they can adopt a genuinely independent role. The authors also recommend strengthening the AHTA as a check and balance against the Ministry, and measures making the Ministry's own considerations more transparent, so as to decrease "the opacity of pressures from other ministries or states."

More information: The full paper, Pharmaceutical lobbying under postcommunism: universal or country-specific methods of securing state drug reimbursement in Poland? is published in the latest issue of *Health Economics, Policy and Law.*

Provided by University of Cambridge

Citation: Drug pushing in the New Europe (2011, September 23) retrieved 23 June 2024 from https://medicalxpress.com/news/2011-09-drug-europe.html

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