Opinion: More accountability needed in how drugs are priced and reimbursed

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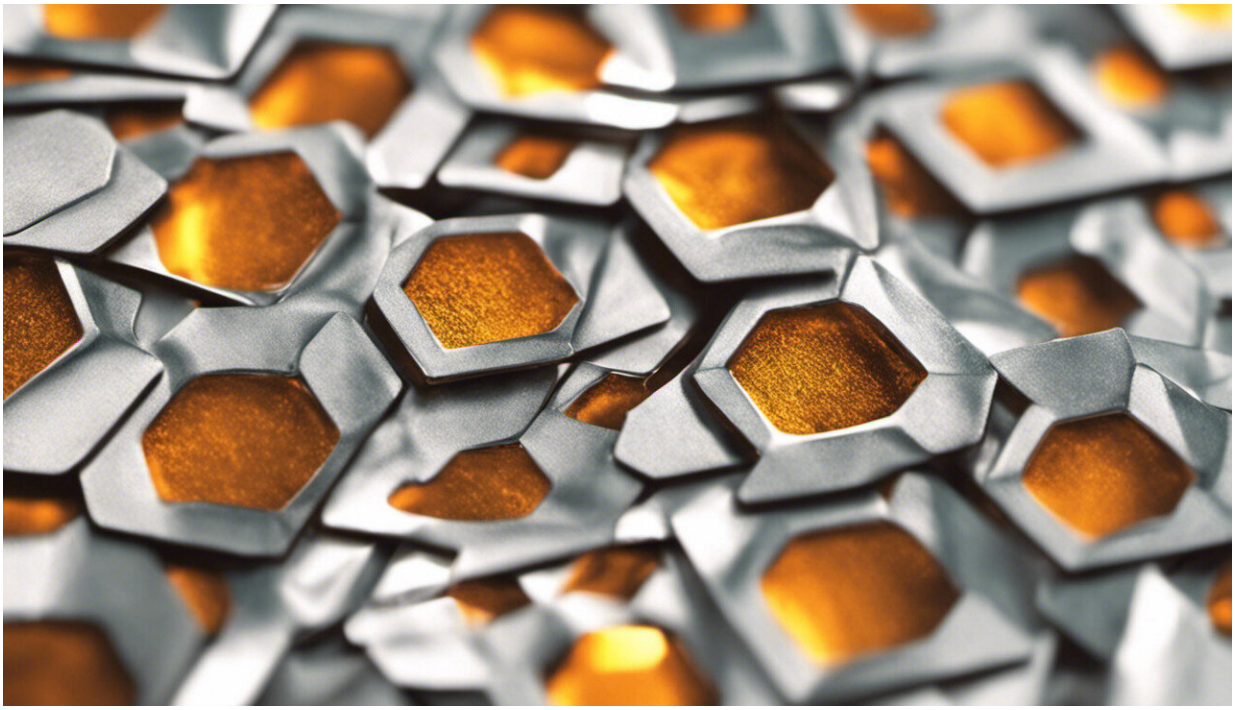

Credit: AI-generated image (disclaimer)

Approving new medicines that hit the market is the responsibility of the EU, but it is left up to individual member states to decide which ones they wish to subsidise. New prescription medicines can be very expensive and few patients could afford novel drugs for cancer and especially rare conditions if they had to pay out of their own pockets.

But, thanks to state subsides, what most EU patients pay is only a fraction of the original price, be it in the form of a flat prescription fee (as happens in England) or various levels of patient co-payment depending on the patient and the medicine (as happens in Poland).

The case of Poland is interesting. In recent years, it has adopted many institutional innovations that seek to ensure it makes sound pricing and reimbursement decisions. However, in new research we've published in the British Journal of Sociology we found that Poland's pricing and reimbursement system (P&R) still lacks transparency and accountability, which allows informal social actors to evade regulations that govern conflicts of interest.

EU member states use complex policy instruments to determine how much they are willing to pay the pharmaceutical industry for its products (pricing) and which medicines are to be prioritised and made accessible to patients (reimbursement). Given the steeply increasing prices of new medicines, P&R has a considerable impact on budgets. In combination with finite health budgets (and often decreasing in real terms), P&R is associated with important "opportunity costs" and ethical dilemmas, as brilliantly portrayed in Andrew Wishard's documentary, The Price of Life.

It has long been recognised that P&R decisions need to be based on sound evidence about drug efficacy, safety, cost-effectiveness and likely impact on health budgets. This has resulted in the increasing role of expert advisory bodies such as the National Institute of Health and Care Excellence (NICE) in the UK, carrying out scientific evaluations of medical, economic and ethical considerations associated with the public funding of new drugs. Politicians and civil servants involved in the process must also use clear criteria for making their decisions.

The Polish paradox

Poland has been at the forefront of central European countries in embedding the principles of these scientific assessments into its P&R system. For example, Poland was quick to establish its Agency for Health Technology Assessment and Tariff System, while no equivalent body exists in the neighbouring, and more economically advanced, Czech Republic.

Nevertheless, Poland's P&R has suffered from persistent irregularities, including lobbying scandals as well as strong corporate and political pressures on the agency it set up. These seem to be part of a general pattern of informal dealings in the healthcare sector, including the cherry-picking of winners in public tenders, nepotism and informal payments to doctors. Importantly, those involved in these dealings typically remain unaccountable.

Revolving door in other countries. Credit: Dan4th Nicholas, CC BY

Mechanisms of 'deniability'

Drawing on more than 100 interviews with insiders in Poland's system, we identified four mechanisms that amount to what political anthropologist Janine Wedel calls "deniability".

- We found evidence of blurred boundaries between institutions involved in the policy process. This allowed policymakers, for example, to shift blame for controversial reimbursement

decisions to bureaucratic or expert advisory bodies.

- Some of the key stakeholders played roles in different sectors – public institutions, the pharmaceutical sector or civil society organisations, and sometimes all at the same time. While these "coincidences of interest", to use another term coined by Wedel, could reasonably be seen as controversial, they tended to escape the definitions of "conflict of interest" included in formal regulations.
- Playing multiple roles allowed stakeholders to maximise their influence by choosing the most convenient hat depending on the situation. For example, some legal advisers acted as "objective" commentators of reimbursement policy while representing pharmaceutical companies in the process.
- We identified evidence of activity of elite cliques. Members of these informal groups were able to coordinate their resources and influence while officially representing different organisations.

The last few years have seen the introduction of more comprehensive rules governing conflicts of interest. This includes publishing increasingly detailed protocols from sessions of the Polish agency's main expert advisory body and introducing toughened conflict of interest requirements for top ministerial medical advisers. Whether these improvements address the problem of limited accountability depends on whether policymakers are willing to act on the spirit rather than the letter of regulations, among other things.

These problems are clearly not limited to Poland. For example, in the US and the EU alike, concerns have been expressed over the revolving door between drug regulators and the pharmaceutical sector as well as some senior clinicians acting as seemingly independent third parties on the industry's behalf. There have also been criticisms of the activity of some contract research organisations playing roles in multiple arenas ranging from organising clinical trials to delivering public relations services to

drug companies.

What can be improved?

There are no easy solutions to the issues we have identified. One important way of addressing "coincidences of interest" is by introducing a comprehensive cooling off period for public officials leaving state institutions. This issue can also be addressed by continually reviewing conflict of interest policies, especially declarations submitted by those consulted in the drug evaluation process, to make sure they reflect emerging forms of collaboration with the pharmaceutical industry.

High ranking officials should also commit to building a culture of transparency by following conflict of interest disclosure declarations. There is also a big role to be played by journalists in the context of holding policymakers, civil servants and other stakeholders to account. And there is much for others in the EU to learn about what – and what not – to do, from Poland.

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