Attack is not always the best defence. A reply to Krzysztof Landa

We appreciate Mr Landa's interest in our research on the Polish drug reimbursement system. Regrettably, however, his article in the last issue of "Menedzer Zdrowia" misrepresents our publications, contains multiple errors and is framed as personal attack. We must therefore correct Mr Landa's misconceived argument, thereby providing an accurate explanation of our research concerning key part of Poland's health policy

Our research

Before we address Mr Landa's criticism let us outline key findings from our sociological study of the Polish reimbursement system.

Our first article, "Pharmaceutical lobbying under postcommunism. Universal or country-specific methods of securing state drug reimbursement in Poland?", analyses methods of influence used by drug companies to secure the reimbursement of extremely expensive drug therapies in therapeutic programmes. Drawing primarily on 109 in-depth interviews with representatives of major stakeholders in the reimbursement process, we identified two key lobbying methods: informal persuasion based on exchange of favours and endorsements by seemingly independent third parties - some patient organisations, leaders of opinion in the medical milieu (KOLs) and journalists. Supplementary lobbying methods involve using parliament and ministries, as well as diplomatic pressure.

It is worth noting that the validity of our findings was publically confirmed by Ms Helena Brus, a healthcare expert, who for many years held top positions in pharmaceutical giants such as Merck or GSK. In an interview published in *Tygodnik Powszechny*, Ms Brus stated that "This is an interesting work and consistent with the facts".

The second article, "The Politics of Health Technology Assessment in Poland", focuses on the process of issuing recommendations by the Agency for Health Technology Assessment (AHTAPol). In addition to over 100 interviews, it employs a documentary database of an unprecedented size: 276 recommendations and 55 assessment reports, the "Register of Benefits" and 26 reports documenting sessions of the Consultative Council. On this basis, we found that The Ministry of Health often uses AHTAPol recommendations as a "fig leaf" covering controversial reimbursement decisions. We show that drug producers employ direct and indirect strategies to influence the process of issuing recommendations. The direct strategies involve building relationships with a circle of health technology assessment analysts and experts working for the Agency. The indirect strategies employ KOLs, patient organisations, and political elites to endorse policy positions favourable to drug companies.

Equally important, the article shows 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” or otherwise lacking in more 50% of the cases.

The findings from both articles received positive comments at conferences in Poland and the UK. We also emphasise that they are consistent with research on new forms of corruption in the pharmaceutical sector conducted independently by Dr Paulina Polak of the Jagiellonian University. It is unfortunate that Mr Landa did not present the nature of our research, attacking instead its randomly selected aspects. As we demonstrate below, his criticism does not hold water.

Basics of social science

The first strand of Mr Landa’s criticism is methodological in nature. To begin with, he expresses doubts about the construction of our sample of interviewees. Our methodology is explained in the articles and therefore we see no need to repeat these points here. What should be stressed, though, is that our sampling method accurately reflected the characteristics of our topic, research questions and social characteristics of potential interviewees. In so doing, it followed procedures of purposive and snowball sampling commonly used in similar research settings. What is unusual about our sample, however, is its unprecedented size. It is fair to say that samples in similar studies consist of 20-50 interviewees. Therefore, our sampling strategy not only meets but also exceeds criteria used to judge the quality of social science research.

Furthermore, Mr Landa unjustly refers to our interviewees as “accidental people”, lacking knowledge about the workings of the Polish reimbursement system. We recruited and present the views of knowledgeable interviewees representing diverse organisational perspectives. We can see that the broad categories of interviewees used in the articles may sound less authoritative (e.g. a high-ranking MoH official vs a Vice-Minister of Health responsible for drug policy) but our ultimate ethical obligation was to protect their anonymity. Nevertheless, it should be clear for any reader with in-depth knowledge of the reimbursement system that insights reported in the two articles could only have been provided by well-informed individuals occupying top-level positions.

We must note here that Mr Landa shows a lack of elementary knowledge about social science research. For example, he conflates surveys with in-depth qualitative interviews, two fundamentally different research methods. Similarly, he does not recognise the difference between purposive, snowball and random sampling and is unfamiliar with the principles of anonymising interviews.

Secondly, Mr Landa criticises us for a selective focus. Specifically, he stresses that we do not offer a comprehensive discussion of Regulation no. 17/2007 of the President of the NHF. In saying so, Mr Landa is oblivious to the fact that any properly designed research should be driven by specific questions. In our case, we were interested in methods used by the multinational pharmaceutical industry to influence pharmaceutical policy in Poland. This research question is determined by contemporary sociological research conducted in Western countries; a limited amount of practically oriented studies available to health policy makers in Poland; and the public’s interest in improving the transparency and accountability of policy decisions worth billions of euro.

Our research focus is also supported by a long history of disregard for formal rules in the area of pharmaceutical policy, highlighted by the European Commission, NIK (see especially more recent reports on the organisation of clinical trials) and even the pharmaceutical industry and the Ministry

of Health. A key example is the lack of publication of reports from sessions of the Consultative (Transparency Council) after 2008 (reports from January 2012 cannot be seriously considered due to the amount of text that has been blacked out). It follows that to understand Polish reimbursement system we should not focus on the apparently excellent formal regulations but rather on their practical implementation, especially interactions with informal rules. Therefore, a sociological analysis of reimbursement regulations was a more pressing research problem than legal or historical studies, which can of course be undertaken in the future.

Paradoxically Mr Landa himself contradicts methodological good practice by making a series of statements supported neither by his original research nor existing literature. For example, he does not show which countries admire Poland's reimbursement system; how NICE is dependent on British politicians. Tellingly, Mr Landa cites our first article incorrectly and using a different referencing style than the second one.

Let's put things straight

Apart from making unsubstantiated claims about methods, Mr Landa misunderstands or manipulates some of our findings.

Mr Landa is wrong in claiming that we sought to paint a one-sided picture of Polish healthcare. Quite the opposite, we developed a balanced evaluation of some aspects of its part, that is, the reimbursement system. In this context, we stress the outstanding quality of analysts, members of the Consultative Council and national consultants, as well as the AHTAPol's contribution to develop a rational reimbursement system. Therefore, it is unfair to say that we represent a biased perspective of the "british empire" (sic).

Regarding more detailed issues, as explained in the article in analysing drug cost-effectiveness we summarised publically available AHTAPol recommendations, which must be taken into consideration by the Minister of Health (we indicated the share of documents stating whether the AHTAPol considers drug to be cost-effective or not). Nowhere did we claim that we analysed confidential data submitted by drug manufacturers.

Furthermore, contrary to Mr Landa's statement, we did mention that the AHTAPol contacts drug companies using the "procedure of receiving external clients". It must be noted, however, that the possibility of submitting comments to assessment reports was fully formalised by the Reimbursement Act, while our research concerns the period before 2012. That is why in exploring the credibility of pharmacoeconomic data we took into account the results of final appraisal included in recommendations, which should then be passed on to the Minister of Health in due course. Is Mr Landa thereby implying the existence of possibilities of "improving" a recommendation which has already been issued? (We are not referring here to a fairly common – and sometimes also controversial – procedure of reissuing recommendations based on requests submitted by the Minister of Health) If this was the case, we would be dealing with an informal procedure lacking grounds in the legislation.

Finally, we must point out that Mr Landa makes two false statements about our research. First, nowhere in the articles do we write that any of our interviewees did not hear about the regulation

17/2007. Secondly, we do present our findings in the international context and use research conducted in countries such as the UK or Canada to inform our recommendations.

Issue of the style

It is unfortunate that Mr Landa masks the lack of substantive arguments with an aggressive style ("tabloid science", "cheap sensationalism") and attempts to patronise us ("mr Piotr", "mr King"). In the light of Mr Landa's apparent lack of competence in social science research, his assessment of our work as "utterly hopeless, abusing the rules of science" is highly inappropriate. What's even worse, he uses demagogical patriotism to defend well-documented failings of the Polish reimbursement system.

Ways forward

Should we be happy with the current process of drug evaluation? To help in answering this question we might put our previously cited findings in a different context. Would we recommend a hospital director to procure expensive pieces of medical equipment knowing that half of them were not representing good value for money at their current pricing? How confident would we be in our recommendations knowing that half of them were based on dubious, incomplete or outdated analyses? And if the director listened to us, would it be safe to say that his hospital was a "centre of excellence", to use Mr Landa's description of Poland's reimbursement system?

These are important questions, particularly in the light of existing plans to replace the AHTAPol with a new agency. We are pleased to see that Mr Landa agrees with our recommendations concerning the need to increase the distance between the AHTAPol and the Ministry of Health, introduce a cooling-off period for former public officials and enhance the transparency of reports and recommendations developed by the AHTAPol. We disagree, however, with his assertion that existing regulations of conflicts of interest are sufficient. Our research demonstrates, for example, that they do not distinguish between minor and major conflicts and tend to be poorly implemented. Also, it seems rational that rank-and-file state employees should be subject to employment-seeking regulations outside the public sector, though perhaps less stringent than in the case of senior officials. This is because, as our research suggests, even junior officials may be a source of invaluable insider knowledge and connections in the lobbying process orchestrated by the drug industry. Finally, some of Mr Landa's recommendations are self-contradictory. For example, he laments insufficient cadres in the AHTAPol but at the same opposes the introduction of a "heavy" agency.

Most importantly, we believe that a "heavy" agency – or at least its carefully selected elements – should indeed be seriously considered as an alternative to AHTAPol. The most obvious advantages of this model, supported by sociological research on the public sector (e.g. Janine Wedel), include the following.

- Increased public oversight and transparency of the development of HTA recommendations
- More intensive cooperation with the academia, increased patient and public involvement
- Expanding highly-trained research cadres with enhanced opportunities for professional advancement in other areas of healthcare, state institutions and the academic sector

The new agency should be protected from political and industry interference, based on the to-date experiences with the functioning of the AHTAPol. And, like other drug regulatory agencies, it could be funded largely based on fees paid by drug manufacturers. Regrettably, initial proposals in this direction were removed from the draft of the reimbursement act. Fundamentally, when considering alternative models of HTA agencies, we should not be primarily interested, as Mr Landa does in his article, in their direct costs. Quite the contrary, we should focus particularly on the quality of the HTA process as it translates into the spending of an incomparably larger reimbursement budget.

In addition to concrete institutional solutions a significant culture shift is needed. This includes greater appreciation of social science research conducted from an outsider perspective. In the UK and the US, dedicated research groups are commissioned to conduct multi-million euro evaluations of individual practices, hospitals, national and local quality improvement initiatives, or entire policies. The resulting recommendations are treated seriously both by medical professionals and policy makers, particularly when negative findings are reported.

All in all, we have addressed all of Mr Landa's criticisms. His article serves to validate our research as it confirms some of our concerns regarding the monopolisation of policy making by a narrow social circle.