It rings **a bell...**

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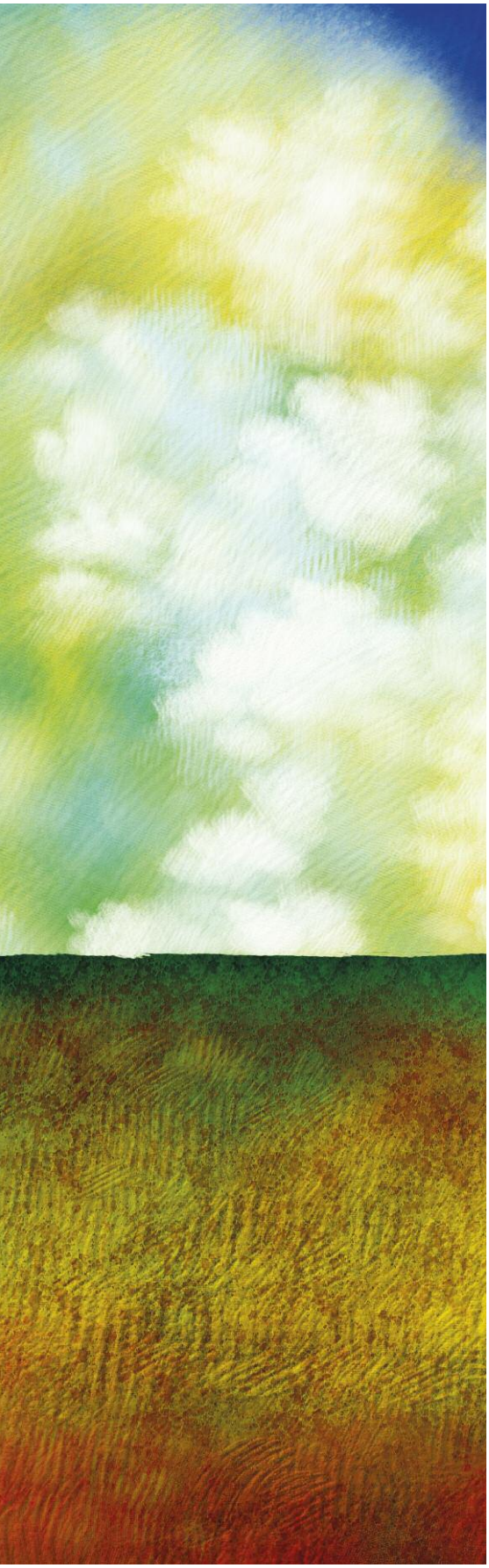

Polemic presented below concerns two publications that deal with Health Technology Assessment (HTA) in Poland:

1. "Pharmaceutical lobbying under postcommunism: universal or country-specific methods of securing state drug reimbursement in Poland?"; Piotr Ozierański, Martin McKee, Lawrence King; Health Economics, Policy and Law page 1-21, Cambridge University Press 2011;
2. "The politics of health technology assessment in Poland"; Piotr Ozierański, Martin McKee, Lawrence King; Health Policy 108 (2012) 178-193,

Articles by Ozierański et al. put Polish institutions and decision making system for pricing and reimbursement in Poland in a very bad light. This assessment is largely unfair and deprived of a reliable insight. Unfortunately, one can have reasonable doubts regarding the reliability of conducted surveys and the knowledge of the topic, which was a subject of the survey. What is more, the authors let themselves make recommendations for Poland without making comparative studies and without an in-depth analysis of changes that in recent years have taken place in Poland.

Firstly, it should be known that although Poland has not caught up with the most developed countries in terms of EBHC (Evidence Based Health Care), transparency and rationality in decision making for pricing and reimbursement yet, it is certainly a center of excellence in Central and Eastern Europe. Many countries look with envy at solutions adopted in Poland and the recommendations of the President of AHTAPol, the position of the Transparency Council (formerly the Consultative Council) and the reimbursement decisions of the Minister of Health are monitored and commonly taken into account abroad. It is worth remembering that 10 years ago Poland was a country full of appreciation for the reimbursement - decisions were made without any justification, without insight into the scientific evidence and without economic or financial analyses. Poland was a country which has repeatedly been pilloried by the European Commission for the lack of clear drug reimbursement criteria, thus fulfilling the provisions of EU Transparency Directive. Assessing the decision making system for reimbursement and pricing in Poland, it is worth to know in which direction and how fast we are going. While examining the reimbursement system in Poland, not only is good to know what HTA is, but also the knowledge of basis underlying basis of society debates as to the shape of HTA agencies in Poland as well as to decision making for pricing and reimbursement - which models from the world were taken into account, and which were rejected with full premeditation (by no means a British solution and the model of NICE were not and are not the best role model!).

Credibility of the surveys

The crucial point is credibility of the surveys, as it directly affects the objectivity of the conclusions. Unfortunately, one can have serious doubts and reservations about the fairness of the British team surveys. For example, from the first publication results, that none of the respondents has heard of Regulation No. 17/2007 of the President of the NHF, although the authors state that they specifically focused on therapeutic programs: "In this paper, we focus on Therapeutic Programmes as they are highly attractive for innovative drug companies"! The Regulation, which came into force as early as in 2007, was the first piece of legislation that governed decision making rules for reimbursement of therapeutic programs, fully meeting the requirements of the EU Transparency Directive. The Regulation has radically improved transparency and rationality of decision making process. This raises the question:

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Who were the interviewed persons? Were they random persons (and thus popular opinion in some societies was studied), were interviewed persons professionals in the field of drugs economy, thus did they have the expertise and overall view of the situation? The authors declare that the respondents were "major stakeholders", thus they were persons whose professional knowledge should not be questioned. Now, preliminary results of ongoing studies indicate that it is hard to find someone who is professionally engaged in the drug economy or HTA in Poland and who does not know the provisions of Regulation 17/2007. Selection of the sample, thus interviewed persons and their expertise, is essential to the credibility of the conclusions drawn by the authors from UK. What is more, declaration of the authors presented in the first publication that they carried out the search of relevant information in press seems untrue. There are hundreds of reports in the national press as well as in Polish and foreign specialist press that apply to regulations concerning granting of refunds under therapeutic programmes and Regulation 17/2007 of the President of the NHF. Building at least a basic search strategy, even a novice and inexperienced researcher can easily come across relevant media reports. All the more scientists with great achievements who should make a systematic search for the subject which they are "specifically focused on" should have found relevant information.

Objectivity of the conclusions

In both publications there were many conclusions that cannot be regarded as legitimate. The authors wrote that about 50% of drugs received positive recommendations for reimbursement, even though the cost-effectiveness ratios of these drugs are above the cost-effectiveness threshold enshrined in Polish law. Such conclusion is illegitimate

for a number of reasons. Firstly, the authors could not know risk sharing proposal that manufacturers submitted to the Ministry of Health together with analyses which were part of HTA report - HTA report, which presentation is required by law. Risk-sharing schemes reduce the effective price of the drug, and thus are essential for the final results of the cost-effectiveness evaluation. Secondly, in Poland large parts (unfortunately too large!) of the reviews evaluated by AHTAPol are blacked out, the authors were unable to have access to much information that is necessary to assess in an objective way the validity of a recommendation of the AHTAPol President.

Also, it is not clear what is the aim of raising the argument that "25% of the economic analysis is unreliable, and in 50% of cases some information is missing". If these issues are raised by AHTAPol it means that the agency does its job! AHTAPol acting as a light HTA agency for drugs properly captures the analyses of low quality and is an effective barrier to unreliable studies being directed to decision makers. In the case of deficiencies found in the analyses submitted to AHTAPol for appraisal, the agency calls for completion - it is also the most correct and expected behaviour, effectively carried out by the Polish HTA Agency. What is more, such proportions in other countries like in Australia, Great Britain, Netherlands and Scotland, that are leaders in implementation of EBHC worldwide, are similar.

Unfortunately, the most difficult task has British NICE, which operates in the mixed model, and actually close to heavy. Although employees of NICE use reviews provided by the manufacturers, they must often make their own de novo analyses. In many countries eg. SMC in Scotland, and PBAC in Australia, HTA agencies operate in a light model (just as the AHTAPol for drugs) and do not have problems which NICE has to face and do not spend huge amounts of public funds for health technology assessment. I think that UK could learn a lot and use models that work much better than the British ones. Without knowing the pros and cons of different HTA agencies worldwide operating in different models, objective conclusions cannot be drawn - especially if one does not see a broader perspective beyond the British Empire.

In fact, AHTAPol is not a politically independent institution. However, such conclusion adds nothing if is not compared with practice in other countries, and here especially British should first beat their breasts. The solution which was in force in Poland since 2009, when the Consultative Council was an advisory body to the Minister of Health, and AHTAPol was as advisory body to the Consultative Council, was much better than today. Amendment to the law on Basic Benefit Package (law on BBP) from 2009 which is in force today (by the way: the law on BBP is an act of a great importance which has being anticipated for many years), when the President of AHTAPol has become an advisory body to the Minister of Health and the Consultative Council has become an advisory body to the President of AHTAPol - so the significance of Consultative Council has meaningfully fallen - should be evaluated negatively. There has been observed a significant politicization of the process and dependence of AHTAPol on Ministry's influence.

British recommendations for Poland

It is good to read recommendation for Poland, that there is a need to prevent the departure of trained and experienced staff from AHTAPol or drug departments to work in a private sector. Although the problem of adverse selection in key areas of the health care system due to low wages has being raised for years, in fact it has not been resolved yet. The authors also raise the need for introduction of cooling-off period before employee, trained in the public sector, goes to work in a company. Such recommendation seems to be correct when it comes to employees who have held management positions- cooling-off period should be than a good practice. However, it cannot be in any way adjusted legally for ordinary employees - that would be harmful restriction of individual freedoms. The causes that underlie the adverse selection observed nowadays should rather be eliminated.

It is also good to read postulate of separating HTA from political influence. AHTAPol and the Transparency Council should not be, but unfortunately are, politicized. On the other hand, if we understand the separation of HTA from political influence - HTA in terms of health technology assessment - such problem in Poland does not exist today. AHTAPol plays a role of a gate keeper standing guard over the quality of analyses being directed to decision makers and generally fulfils its role well. However, this may change and the situation could dramatically get worse if we started using the British model and changed the light AHTAPol agency into heavy. Immediately, we could see political influence, not only in HTA reports, but also in the prioritization of topics for assessment – it should be stressed that in the case of politically light agency sensitive prioritization is not necessary at all.

Rightly the authors call for more openness to cooperation with patients' organizations and involvement of the public in the process of making value judgments and reimbursement decisions. I order to improve this, firstly good performance of the AHTAPol should be assured so adequate human resources should be properly allocated to the tasks. Unfortunately, even for AHTAPol for drug assessment in the light model it is very difficult to cope with tasks, thus taking into

account the voice of patients would be difficult today. Concerning transparency, obviously it should be a call for less black-outs in reports published by AHTAPol, so that only the information embraced by a trade secret would be hidden and such would not exceed 5% of a text.

Unfortunately, the other recommendations made by the authors do not deserve the attention because either Poland can be a model for other countries (eg. regarding the quality of analyses and clear criteria for the credibility of HTA, they are presented in a modern and stringent AHTAPol guidelines), or do not deviate from standards of developed countries (eg. adjusting the rules of resignation from employment in the public sector, or conflict of interest declaration). Also, development of HTA reports by pharmaceutical companies cannot be forbidden, what actually suggests statement of Mr. King quoted in press.

Similarly, it would be nonsense to forbid manufacturers and right holders to conduct phase III trial for registration. The problem is not to prohibit the sponsorship of studies and analyses, but to make quality standards public and have institutions guarding the quality of these studies. In the case of clinical trials, the rules of GCP (Good Clinical Practice) and adequate control of Registration Offices are used, as in the case of HTA, clear quality standards of HTA guidelines should be introduced and HTA agency operating in a light model should separate the wheat from the chaff. UK can only dream of a model in which operates Agency for Health Technology Assessment in Poland (AHTAPol). However, in order to see this, one must look at UK from the perspective of the world, rather than look at the world from the perspective of UK.

Ending

Although, there is still much to improve in the field of management of the basic benefit package in Poland, our country did not deserve for such a negative assessment that British authors presented internationally. Certainly, there is a need to improve transparency and rationality of decision making process for pricing and reimbursement. Agency for Health Technology Assessment in Poland as an advisory body to the Transparency Council should have other powers. The competences of advisory bodies to the Ministry of Health shall be raised and their political independence should be much greater. Since awareness of a need for change in the society of healthcare professionals in Poland is widespread, what was the point in writing articles that put our country in such a negative and unfair light?

Doubts about the methodology of the studies and their reliability, as well as recommendations made on the basis of sociological research, thus without reference to the different ways of systemic implementation of HTA or EBHC worldwide, raise fundamental questions. Have the authors aimed to know the objective truth, or look for a cheap sensationalism engaging in "tabloid science"? Have they strived for a fair assessment of pricing and reimbursement system in Poland, or have they taken an attractive for media topic with the accepted theses "to prove"? Soon the public should get answers to these questions.

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HTA Audit