

Critical opinion on the study entitled: **“Pharmaceutical lobbying under postcommunism: universal or country-specific methods of securing state drug reimbursement in Poland”** by Ozieranski, McKee, King; Health Economics, Policy and Law; Cambridge University Press 2011.

The main issues causing high uncertainty and bias in the study:

1. RESPONDENTS

Uncertain who they were and how they were selected; questioning accidental “people from the street” about very specific and highly sophisticated issues seem to be wrong – the respondents must have been “accidental” if they did not know about the decree 17/2007 of the President of NHF in Poland (with further amendments) and do not know about the bill for new reimbursement law (highly suspicious!);

2. LEGAL ACTS

The authors did not find any information not in media, nor in databases as well as got no clue from the interviewed respondents about essential legal acts (mentioned in item 1 above) regulating therapeutic programs and out-patient drugs coverage, which correspond with Transparency Directive of EU; it is a very basic issue (sic!) for such a study; it rises high suspicion of not being systematic in the approach but also to be insufficient in preparation to the questioning and the study itself (“fieldwork 02.2009 till April 2010”!);

3. TRANSFORMATION

Poland has been changing very quickly towards EBHC (especially in the area of reimbursement and pricing) in the last 10-12 years; lack of notification of the essential fact of the observed “object” constantly changing was not recognized and omitted by the authors;

4. On page no. 6 one can find two fake statements:

- A. *“At the time of writing, there were no detailed legal regulations concerning the development of therapeutic programmes. “Therapeutic programmes are legal terra incognita.” (2). Our reconstruction of the policy process, based on the reading of scattered fragments of legislative acts and the interview data, suggests the existence of considerable space for effective pharmaceutical lobbying”*
- B. *“However, rarely can such a recommendation provide undisputable scientific arguments for reimbursing drugs, given the nature of clinical and pharmacoeconomic data submitted by drug companies (Sismondo, 2008; Spielmans and Parry, 2010).”*

It is misleading and definitely not true! It shows that the whole study as well as “major stakeholders” and search for information in media and legal acts was fake or very far from scientific standards.

AND MORE

“The role of EBM is further diminished by the incomplete implementation of the EC Transparency Directive (89/105/EEC).” Quite opposite it is constantly growing and the picture of Poland drawn by the authors certainly is unfair.

“In Poland, only the first requirement is occasionally met while the main object of criticism is reimbursement criteria applied by the MoH. “[They] are very vague, very general. It’s black magic for us. We don’t know how it happens, how decisions are taken.” (6).” It is very unfair, especially if authors specifically focus on area therapeutic programs (as declared in the publication) – from 2007 management of this area in Poland fulfills Transparency Directive requirements with high extend!

5. Comments to page no. 12 put Poland in a bad light and to me it is very unfair; actually problems and issues presented on the page 12 refer to all European and highly developed countries; in my opinion it is even more unfair as Poland is a country of reference in the region of CEE and even more could be a paragon for a few western countries.

The publication as a whole has put Poland in bad light. That hurt image of Poland as a country and good name of people who have fought for transparency and rational in reimbursement and pricing policy there.

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