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Some thoughts regarding reimbursement act of 12 may 2011

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Health care costs and drug reimbursement are tightly intertwined. For more than decades healthcare costs have grown faster than our national economy. Constant cost growth threatens politicians and undermines the existence of the publicly funded National Public Fund (NHF). It is not surprising then, that the Polish Ministry of Health has decided to introduce a new bill regarding drug reimbursement, called " Act of 12 May 2011 on the reimbursement of medicinal products, special purpose dietary supplements and medical devices" effective from 1 January 2012.

The project was not discussed with the medical community and was riddled with loopholes, limits, exclusions, and is full of ambiguous clauses. In addition, in the first version of the bill, articles 48 and 129b defined the penalty, for physicians and pharmacists, respectively, on top of the refund for undue reimbursements paid by the Fund including statutory interest counted from the date of the refund. These penalties were due in several cases, especially when the prescription was: incompatible with the beneficiary's rights; not justified by medical documentation; and in conflict with the registered indications. The act generously waived the penalty when the prescription was forged: "The provision of ... shall not apply in the case where the prescription ... has been counterfeited..." (sic !). Following the announcement of the act in the end of 2011, the Supreme Medical Chamber started a nationwide protest of doctors together with pharmacists that forced the legislators to promptly amend the act in January 2012. Although penalties for physicians have been lifted some ambiguous clauses still remained in the act.

The purpose of this commentary is to discuss the most sensitive articles of the act in the hope that this may help future legislators. The comments represent the author's personal opinion and do not necessarily reflect the viewpoint of the Polish Pharmacoeconomical Society. The former Minister of Health accused all protesters of criticism based on bad will making this work sensitive to the unjustified accusation of ties with the pharmaceutical industry (see below: conflict of interest).

The law is written on 40 pages and contains 86 articles. It starts with the definitions which are severely limited. There is an absence of important terms relating to reimbursement policy such as: "clinical efficacy", "practical efficacy", "rationalization analysis" (i.e. analysis indicating the source of funds for a drug to be reimbursed – see below). In addition, certain definitions are far from accurate – for example, generic is: "...a medicine containing the same active ingredient and having the same indications and the same route of administration in the absence of differences in pharmaceutical form".

The bill begins with a puzzle: "...The total reimbursement budget is no more than 17% of the total public funds assigned for to guaranteed benefits in the Fund's financial plan" (art. 3). Why 17% ? In 2010 the NHF spent 19 % on drugs, which indicates a heavy cut of 2% on drugs reimbursement for the year 2012. No explanation is provided regarding the 17% figure, and without a definite mathematical approach it is difficult to understand the steps that will be taken when the NHF will exceed the 17% threshold. The act specifically addresses this issue: "... the amount in excess shall be assigned to the given limit group...The applicant... return to the Fund an amount which is proportionate to the share of the reimbursement costs of the drug..". However the calculation for payback due to overspending is highly sophisticated – the appropriate formulae are: KZi = Siunorm*KP*G*0.5;

Sinorm = Si/∑Si and Si = G2i/∑g2i * C2i/C2L.

In Chapter 3, Article 10.3 contains a definition stating the lists of drugs excluded from the reimbursement, represents the highest level of inaccuracy: "…The following cannot be reimbursed: a medicine … in clinical conditions in which it is possible to effectively replace that medicine…by changing the patient's lifestyle". On one hand this clause implies that physicians are likely to treat patients who do not required treatment; on the other hand it allows the cashier of the Fund to deny reimbursement in case of, for example, conditions such as type 2 diabetes where a strict diet and exercise are the best treatment options. As everybody knows the population of type 2 diabetics is enormous and therefore cost savings for the Fund may be significant. Such an article raises the suspicion that the law opens an "umbrella" for the Fund and not for the patient contrary to government announcements.

However, the umbrella does not cover the Ministry of Health as several own goals are apparent. Here is the most important (article 33): "The minister responsible for health … shall revoke … the reimbursement decision for a drug… in the case of finding the absence of the declared therapeutic efficacy".

The entire act is dumb on the subject of an assessment regarding a lack of therapeutic efficacy. It is not a subject that one should slide over. The Pharmaceutical Law contains an extensive list of conditions regarding the efficacy of a drug which must be fulfilled by the applicant in order to register a given indication. None is listed for the administrators to revoke the reimbursement for a given drug. It is not mentioned who is responsible for such assessment. In the Polish version of the act there is a hint that it is the Minister himself/herself. Neither is the administrative way to appeal against such decisions indicated.

The reimbursement could also be denied by administrative decision, when the obligation of the annual volume of supplies by producers is not met. In this case, it is not only the pharmaceutical manufacturers that feel the repercussions, but patients are punished as well.

Article 12 describes the intentions of the Minister of Health: "In the view of the need to obtain the best possible health effects within the framework of the available public funds … the Minister… issues … reimbursement decision and the decision setting the official sales price with consideration given to the following criteria". One criterion and perhaps the most important one is point no 4: "the clinical and practical efficacy". The point is that conjunction "and" is used. In that case, if it is used in the same manner as logic or mathematics, both conditions (clinical efficacy and practical efficacy) must be fulfilled in order to secure reimbursement. However, "and" could be also used as the grammatical conjunction, similarly it is used in everyday day language, novels or fairy-tales. It is difficult to accept the idea that the new law is a fairy-tale however either way - the statement in criterion no 4 is ambiguous.

Assuming that in the act "clinical efficacy" is "efficacy" and "practical efficacy" describes "effectiveness" the problems connected with the application for reimbursement become apparent, as efficacy and effectiveness must be shown together. Dura lex, sed lex. It won't be easy, for an applicant, a candidate for reimbursement, to demonstrate both efficacy and effectiveness at the same time. It is quite possible that latter condition could be fulfilled but only by a small number of candidates. The difference between these two, efficacy and effectiveness could be best exemplified by the Black's et al alendronate study (Black et al.: Randomised trial of effect of alendronate on risk of fracture… Lancet 1996;348:1535). In this study, 2027 women (aged 55-81) randomly received placebo or alendronate for 36 months with two inclusion criteria: low bone mineral density and vertebral fracture. However, the exclusion criteria are of interest. These were: peptic ulcer disease (bleeding or 2> ulcers in last 5 yrs), dyspepsia, abnormal renal function, major medical problem precluding participation for 3 years, severe malabsorption, uncontrolled hypertension, myocardial infarction, unstable angina, disturbed thyroid or parathyroid function and the use of hormone replacement therapy. In other words, only exceptionally healthy women received the studied drug. The chances that one can meet such women in the practice are like 1 to 508 since 2,027 women were recruited among 1 030 000 questioned (see Black et al.). There was no comparison between the population used to establish efficacy and the population likely to be met in clinical practice and therefore solely efficacy and not effectiveness was shown.

Finally, the most ambiguous article is number 28, clause 7, point b in which so-called "rationalization analysis" is required by the Ministry of Health

to justify application for reimbursement. When the addition of a particular drug to the reimbursement list would increase the total reimbursement costs, the applicant is obliged to provide the solution that will result in a release of public funds which will compensate for the increased total reimbursement costs. The idea is fantastic for the National Health Fund, as it will ensure there is a fixed budget on reimbursement, and perhaps this may explain the mysterious 17% figure discussed earlier.

In summary, the new act as explained in the introduction was extremely needed and there are many articles in the new act that represent solid knowledge and real help for patients and physicians. However, if the new law is expected to change the pharmaceutical market, making it more friendly to patients and pharmaceutical producers, many articles require further discussion and clarification.

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