

Press release

In Bratislava, 30 March 2011

Is Decision Making in Drug Policy INDEPENDENT?

The pharmaceutical industry associated in SAFS has been trying to be a constructive partner to the Ministry of Health of SR regardless its political orientation, because we believe we share the common goal – rid the patient of suffering caused by illnesses. Transparency, predictability and independence of processes regulating the drug policy is very important for producers, distributors and pharmacists as well. It helps effective spending of state means, health system as such and last but not least the patients. Some measures, which form a part of the proposed amendment to Act on the Scope of Health Care, will cause the decision making about public resources in the amount of approximately EUR 1.5 billion (SKK 45 million) annually to become non-transparent and secret.

When the current government was formed in the summer of 2010 and transparency in spending public resources was discussed more, the pharmaceutical industry welcomed it. We select from the Program proclamation of the government, Chapter 1. Democratic state: The government of SR considers the following universal tools for curbing corruption:

- clear rules known ahead of time,
- decision making based on unbiased criteria (limiting subjective decision making),
- transparency of decision making processes allowing for public control (access to information, publishing information).

Currently the Amendment to Act No. 577/2004 Corpus Juris on the Scope of Health Care Covered by Public Health Care Insurance and on Reimbursement of Healthcare-Related Services, which should react to these challenges. However, the diction of the amendment to this Act has been convincing us on the contrary about moving away from the Government Proclamation. Therefore we would like to point out several facts.

The whole process of development and mainly the drug registration approval process within the national and as well European registration, is exemplarily transparent, widely accepted and incontestable. Approvals, whether within the State Institute for Drug Control (SIDC) or at the European level within the European Medicines Agency (EMA) are elaborated to the last detail. Members of these authorities fulfill criteria of independence (they are not the people who decide on the profit of participating parties, but experts). Their decisions are qualified and justified in detail, and as a consequence they enjoy a great degree of acceptance and respect. It is therefore natural that we require the same expert quality and independence in the payment reimbursement approval process as well, which ultimately closely relates to the recipient of health care – the patient.

Decision Making in Categorisation of Drugs, Medical Aids and Dietetic Foods

The amendment to Act No. 577/2004 Corpus Juris proposes to the Ministry of Health to exclude appointment, activity and decision making of the Categorisation Committee and Categorisation Council from administrative proceedings. Practically it would mean that entire activity of these advisory bodies, their meetings, minutes and all outputs, including recommendations, would be non-public and inaccessible to proceedings participants (and also to the public) in the future.

It is the subordination to administrative proceedings, publishing minutes from the meetings of the Categorisation Committee and Categorisation Council on internet, duty to produce a sound recording from their meetings and publishing voting of their members that secures at least minimum transparency and public control over drug categorisation (i.e. determination of price, patient payments and co-payments). The Prosecutor General's Office has also warned about the seriousness of this step within inter-ministerial comment procedure to the Amendment to Act No. 577/2004 Corpus Juris, according to which: „Expert assessment of the mater by the competent advisory body is in its content provision of evidence and therefore represents an inseparable part of the administrative proceedings of the Ministry on the Application.“

As a consequence of exclusion of activities of Categorisation Committee and Categorisation Council from administrative proceedings the decision making on public resources in the amount approximately EUR 1.5 billion (SKK 45 million) per annum will become non-transparent and secret. The only person at the Ministry of Health SR who will decide on these resources will be the Minister of Health. With respect to the above facts as well, it is inevitable to make the entire drug categorisation process transparent in the best possible way and under constant scrutiny and control of the public.

Public character of Categorisation Committee and Categorisation Council meetings is another crucial request of all the pharmaceutical industry in Slovakia, and that because of the above listed reasons. In spite of the fact that the Ministry of Health SR within preparation of the Amendment to the Act No. 577/2004 Corpus Juris publically declared and promised that meetings of these bodies would be public, the final version of the Amendment proposal to Act No. 577/2004 Corpus Juris does not stipulate the public character of meetings of these bodies, on the contrary, as was already mentioned above, their appointment, activity and decision making were excluded from the competence of administrative order, by which these bodies in relation to the public will function de facto and de jure away from any public control.

Conflict of Interest of Health Insurance Companies

Following a recent decision of the Constitutional Court SR health insurance companies are allowed to generate profit again (currently inter-ministerial comment proceedings in respect to the Act Amendment are taking place) and most probably upon meeting certain criteria they will be able to use it as they please. This fact may cause pressure on unavailability of modern innovative drugs and generate profit for insurance companies. Insurance companies can even independently decide on their profit through their representatives who are proper members of the Categorisation Committee and Categorisation Council.

On a simple example (in attachment to the Press release) we document it is visible even though producers lower the drug price, ultimately patient co-payment increases. We therefore propose this process on determination of payments for drugs is independent from business activities whether it is on the side of the pharmaceutical companies or on the side of health insurance companies. It should be in the competence of an independent expert and apolitical body, which will employ certified professionals from the area of medicine and pharmacoeconomics, whose independence will be confirmed and guaranteed. This is how it is solved in more countries of the EU, where similar bodies have been acting transparently and in public interest on a long-term basis (Great Britain, Germany, France, Holland, Sweden, etc.).

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