

PRESS RELEASE**In Bratislava, 4 May 2011****SAFS: We are in favour of clear rules**

The Health Care sector has recently prepared and publically presented several legislative intentions: in September 2010 and in February 2011 two different proposals of amendment to Act No. 577/2004 Corpus Juris on the Scope of Health Care and in March 2011 a completely new wording of the Drug Act. These two acts are the key acts equally for patients and doctors, and also for pharmaceutical industry and other involved participants.

SAFS considers alarming the fact that new legislation in the health care sector is prepared lately without dialogue and communication with external environment, which we consider to be the basic condition not only of transparency, but also democracy in general. It is desirable for Act amendments in the health care sector to be prepared with quality and to bring order and legal security into the system for all participating parties.

We appreciate the effort of the sector to prepare new legislative standards in order to comply with actual needs of regulators, providers and patients. The result of this effort has a very inconsistent effect and there were many comments filed with respect to the proposals. There were about 400 comments filed in relation to the Amendment to Act No. 577/2004 Corpus Juris on the Scope of Health Care, out of which 182 were crucial and in relation to the new wording of the Drug Act more than 1,000 comments, out of which 407 were crucial.

Could these proposals have been of higher quality?

Immediately after the new government of Iveta Radičová assumed the government office we were trying for open communication and transparency in the process of preparation of new legislation. In the area of drug policy, which relates to us most, there were many substantial problems, which have not been solved in the long-term at all, or were solved only inconsistently and hurriedly and such solutions after all brought up only chaining and growing of problems. However, the new legislation in the health care sector is being prepared without a dialogue, which we consider the basic condition not only for transparency, but democracy at all.

In the Slovak Republic, which is found on a democratic principle, the act proposals should be prepared publically and in cooperation with all parties involved. There are currently enough examples from other sectors, where they follow such principle – e.g. Transport Act, Act on Mortgages under preparation, etc.

The proposed acts had a potential to improve transparency and professionalism of drug policy in such a way as to invest tax payers' money into their health in the most effective way. SAFS wishes to be a partner at creating such serious changes. We respect that it is not possible to synchronise requirements of all parties. It is more important that the proposals prepared are of good quality and they bring order and legal security into the system for all parties involved.

Examples of specific critical proposed changes (comments) from SAFS:

Breaking access of Slovak patients to modern innovative drugs

One of the most pressing issues of the proposed amendment to Act No. 577/2004 Corpus Juris is the Access of new innovative drugs to the Slovak market. The amendment proposes a reimbursement from the health care insurance, which cannot exceed 25 %, unless the drug has the price set at least in two countries out of five with equal or similar GDP per capita as in Slovakia. Thus another barrier implementation is concerned (related to price referencing according to the second lowest price of EU-27) to entry of modern original drugs for the Slovak patients. Such access worsens competitions and is in breach with its fundamental principles.

If such approach were applied now already, then out of 31 original oncology drugs, which are currently in the market, 5 would not exist in the market at all, or would be available with a socially unbearable co-payment and 13 drugs would get to the patient on average by 15 months later.

Compulsory lowering of prices by more than 10 % represents another barrier for entry to innovations with categorisation of every new indication, or by more than 30 % with cancellation of request for prescription restrictions.

Health of Slovak patients in danger with respect to limiting drug availability

Setting reference drug price as the second lowest within the entire EU can negatively result in endangering Access to drugs for Slovak patients. Extremely low price level of drugs in the SR will accelerate so-called re-exports, which at current rules vary between 10 – 15 %. These re-exports mean that lowering drug prices to the second lowest price in the EU will induce increase in exports of cheap Slovak drugs and consequently some drugs will not be available to the Slovak patients. Benefit of low drug prices in Slovakia will paradoxically be reaped

by private distribution companies and their target countries and not the Slovak patients. The Slovak patients will be left only with empty racks in pharmacies and unrealisable prescriptions in the hands, as shown in the case of Greece, which implemented a similar principle for setting drug prices (*E. Sukkar, Greek regulator blames low prices for medicine shortages, Scrip 24 February 2011*). In Greece some vital drugs for oncology patients and insulin for diabetes patients became unavailable.

SAFS therefore suggested to define conditions in the Act of parallel export of drugs in the same way as is in the case of parallel import. The amendment to Act No. 577/2004 Corpus Juris under preparation (at this time also subject of inter-ministerial comment procedure) implements great financial fines and compulsory delisting of the drug from the drug categorisation list for even short-term unavailability in the market – specifically already in such case, when the drug is not available in the Slovak market for 15 consecutive days.

Transparency of decision-making processes

Meetings of the advisory bodies of the Ministry of Health (Categorisation Committee and Categorisation Council) form the basis of the entire decision-making process. If they are taken out from the administrative procedure, there will be room for non-transparency of the entire categorisation process. Moreover, in the decision-making bodies there are representatives of the health insurance companies, who are in conflict of interest, because they decide among other things about their profit. The greater the profit for the insurance companies, the greater the demands on the patient co-payments. SAFS is not interested to become a member of the advisory bodies in drug categorisation – we are interested in professional level of these bodies and without any suspicion whatsoever of possible conflict of interest.

SAFS appreciates the meeting of the Prime Minister with the representatives of the health associations and alliances, which took place on Friday 29.4.2011 at the Office of the Government at the presence of the Minister of Health. Mrs. Prime Minister welcomed the SAFS proposal on transparency of the categorisation process and together with the Minister of Health promised that this problem can be solved easily. SAFS is prepared to cooperate on making the new “rules of the game” in drug policy the best quality.

Attachments to the Press Release:

Attachment No. 1: Terminological dictionary (explanation of selected terms)

Attachment No. 2: Information on SAFS

In case you need any additional information, please contact:

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Attachment No. 1:**TERMINOLOGICAL DICTIONARY**

INDICATION – List of diseases or difficulties, with which the drug can be used or for which it was approved by the authorized institutions for use.

PRESCRIPTION RESTRICTION – Restriction determined by the MH SR based on the recommendation of the Categorisation Committee for drugs, which make doctor's specialisation more precise, who can prescribe the given drug in such manner, so it can be reimbursed from the health insurance.

DRUG PRICE REFERENCING – Process of drug price comparison in the Slovak Republic with other EU member states.

RE-EXPORT (PARALLEL DRUG EXPORT) – Represents export of the registered drug by a different company than is its producer, or holder of registration decision. It is used when the drug price in various states of Europe is significantly different – the drug is bought in the “cheap“ country and sold in the “expensive“ one.

“**ADMINISTRATIVE PROCEDURE**“ – Procedure set by law on administrative procedure (Act No. 71/1967 Corpus Juris - Administrative Order), according to which the so called “administrative bodies“ on the rights and obligations of the Slovak citizens and if no other Act stipulates any other modification of process (examples: tax or construction). Even in these cases the basic obligations of the bodies and citizens are kept, as stipulated by the Act on administrative procedure, and special laws stipulate only some deviations typical for the given area. The central government body is also the Ministry of Health of the SR, which should abide by laws in effect in all proceedings and interactions, which relate to laws and obligations of citizens. Any other procedure is unlawful and even unconstitutional.

CATEGORISATION COMMITTEE – The full name is Categorisation Committee for Drugs. It is an advisory body of the MH SR, which professionally secures drug categorisation. It has 11 members and consists of representatives from the MH SR (3), health insurance companies (5) and doctors (3).

CATEGORISATION COUNCIL – The full name is Categorisation Council for Drugs. It is an advisory body of the MH SR, which solves appeals against decisions of the Categorisation Committee for Drugs. It has 11 members and consists of representatives from the MH SR (3), health insurance companies (5) and doctors (3).

DRUG CATEGORISATION – The process, in which reimbursements for drugs from public health insurance are determined. By its means the MH SR controls drug consumption. Within categorisation it is determined which drugs are to be reimbursed fully, which partially and which not at all. Thus categorisation determines the amount of patient co-payment and conditions for drug prescription, i.e. which doctor (general practitioner or specialist) and what illness (indication) he can prescribe the drug for.

DECISION MAKING IN CATEGORISATION – The Ministry of Health SR decides in the first level within categorisation proceeding, but the Minister acts and signs pursuant to the law. The Minister of Health decides on the second level on the appeals against decisions of the Ministry of Health, but in this case he acts on his own behalf as the head of the central state administration body (Ministry). Members of the advisory bodies of the Categorisation Committee and Categorisation Council will not vote on proposals of categorisation decisions as up until now according to publically expressed opinions of the Ministry of Health of the SR, but will instead only submit professional advice to the Minister, while it will solely depend on the personal judgment and consideration of the Minister, whether he will abide by it or not.

ORIGINAL/INNOVATIVE DRUG – An original drug is a result of 10 -15 year-work of researchers. The active ingredient is protected by a patent according to the valid legislation in the given country. Before the pharmaceutical company received registration and may introduce the drug to the market, it must perform many pre-clinical and clinical tests. Long-term experience and procedures in research work and study of new drug effects, the highest standard in production tested by years, and reputation of research based pharmaceutical companies are a guarantee that the patient receives modern treatment respecting current levels of scientific knowledge.

GENERIC DRUG – Generic drug contains the same active molecule as the original drug. It arrives to the market after the original drug loses patent protection. Prices of generic drugs are lower because during their development neither high investments into research were necessary nor clinical studies as with original drugs.