



BEATOW PARTNERS

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2011 Drug Policy Reform
in Slovak Republic

BEATOW PARTNERS s. r. o.
law office
Panenská 23
811 03 Bratislava
Slovakia

Tel: +421 2 52 73 12 35
Fax: +421 2 52 73 33 29
info@beatow.com
www.beatow.com



LEGAL UPDATE

2011 DRUG POLICY REFORM IN SLOVAK REPUBLIC

Introduction

With effect as of 1 December 2011, a drug policy reform has been introduced by the Act No. 362/2011 Coll. on Drugs and Medical Devices and on amending certain laws and the Act No. 363/2011 Coll. on the Scope and Conditions of the Reimbursement of Drugs, Medical Devices and Dietary Foods covered by the Public Health Insurance and on amending certain laws, in the Slovak Republic (the “**Drug Policy Reform**”).

As a matter of courtesy, this newsletter highlights certain key changes to the Slovak health care system introduced by the Drug Policy Reform.

Measures to Mitigate Corruptive Practices

The Marketing Authorization Holders are explicitly prohibited, by any means whatsoever, to induce or influence the health care professionals at prescription of drugs, medical devices or dietary foods.

New duties of the Marketing Authorization Holders include, inter alia, the following:

- to submit to the Ministry of Health of the Slovak Republic (the “**Ministry**”) by 31 January of each calendar year, a report on the amount of its expenditures on the promotion, marketing and non-pecuniary considerations provided directly or indirectly to the health care provider in the previous year (the Ministry is obliged to publish

such report on its website without undue delay); and

- to provide to the National Centre for Medical Information (the “**National Centre**”) a list of health care professionals, who took a part in any events dedicated exclusively to professional and academic purposes, or in further education of health care professionals, funded directly or through a third person by the Marketing Authorization Holder (the National Centre is obliged to publish such list on its website without undue delay).

Sponsorship, direct or through a third person, of any event to the health care professional or the participation of the health care professional at any event, other than professional or academic event or further education of the health care professionals, is strictly prohibited.

At the same time, the health care professionals are required to notify the Ministry, on the quarterly basis, of the amount and purpose of any pecuniary and non-pecuniary income they obtained, including without limitation, any sponsorship of their participation at professional or academic event or of their further education.

Further, the following conduct has been explicitly banned:

- any promotional visit of the health care professional authorized to prescribe drugs during his/her business hours;
- any promotional supply, offer or promise of any donation or any pecuniary or material benefits, regardless of their value, to the health care professional authorized to prescribe or to

the health care provider authorized to issue drugs.

New Pricing System

The reference pricing system has become more stringent - the Slovak drugs prices will not exceed the second-lowest price from among the European Union countries (compared to the average of the six lowest prices of the respective medical products within the European Union member states used before 1 December 2011).

Categorization and Entry of New Generic Drugs to Market

With an aim to accelerate introduction of new drugs in the Slovak Republic, the periodicity of the categorization of the drugs increased so that at the present day, the categorization takes place on a monthly basis.

At the same time, to facilitate the monthly categorization, an electronic form of communication between the Marketing Authorization Holders and the Ministry has been introduced as a sole mean for the mutual communication in respect of categorization and official price fixing. Any Marketing Authorization Holder willing to participate in the categorization process before the Ministry must undergo the registration process for the electronic form of communication and have an individual appointed to represent it before the Ministry in the proceedings regarding categorization and official price fixing.

A new generic drug may be included into the list of categorized drugs only if its proposed price shall be at least by 30% lower than the price of the original drug.

It is expected that the newly introduced system of the categorization as well as the measures aimed to facilitate publishing of applications, motions, opinions and decisions in the process of the categorization on the website of the Ministry,

creates effective tools enhancing transparency in the Slovak health care system.

The new legal regulation has also introduced a categorization of special medical material – expensive medical devices (e.g. joint substitutes, cardio-stimulators, etc.) and stricter rules for assessment of the conflict of interests for the health care professionals, the employees of the Ministry and the members of categorization commissions and categorization councils, being the advisory bodies of the Ministry in the matters of categorization.

Availability of Categorized Drugs

Marketing Authorization Holder, product of which is included in the list of categorized drugs, has an obligation to ensure that such drug is available on the market in a sufficient quantity for the entire period, during which the drug is included in the list of categorized drugs. Sufficient quantity has been defined as a supply covering the estimated monthly consumption in the Slovak Republic. If the Marketing Authorization Holder fails to maintain this supply on the market for a period of 60 consecutive days, the Ministry is entitled to exclude such drug from the list of categorized medicines.

New Prescription Rules (Generic Substitution)

So-called generic prescription of drugs has been introduced, which provides for the obligatory prescription of the active substance instead of the particular drug by name (applies only to the active substances listed in the new legislation). Nonetheless, the health care professionals prescribing drugs have remained entitled to prescribe also the specific drug by stating its name.

Liberalization of Pharmacy Business

New legal regulation simplified the pre-requisites to be met in order to conduct business in the area of pharmaceutical care, where certain procedures and compliance requirements have been abolished or simplified.

Loyalty Systems in Pharmacies

As of 1 December 2011, pharmacies are allowed to provide discounts or other benefits to the patients. However, in-kind discounts or cash payments are still prohibited.

In case a pharmacy decides to grant discounts to the patients, it is mandatory obliged to provide a discount also to the health care insurance company at least up to 50% of the amount of discount granted to the patient.

For more information on the topic discussed in this issue of the BEATOW PARTNERS Legal Update, please contact Mr. Michal Delinčák at michal.delincak@beatow.com.

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