



# LEGAL UPDATE



BEATOW PARTNERS

August 2015

HEALTH CARE SECTOR  
UPDATE

## INTRODUCTION TO THE AMENDMENT TO THE MEDICINAL PRODUCTS ACT

On July 1, 2015 the Ministry of Health of the Slovak Republic proposed to the Government of the Slovak Republic to adopt an amendment to the Act No. 362/2011 Coll. on Medicinal Products and Medical Devices, as amended (the **"Medicinal Products Act"**) also as the (the **"Amendment"**). The Amendment sets forth new obligations for the holders of the Human Drug Manufacturing License, holders of the License for the Wholesale Distribution of Human Drugs, holders of the License for the Provision of Health Care, holders of the Registration of Human Drugs and pharmaceutical companies (as defined in the Medicinal Products Act) (the **"Pharma Companies"**) to provide the National Health Information Center with an electronic report on its expenditures on advertising, marketing and monetary and in kind contributions for the previous calendar half year. The Amendment was approved by the Government of the Slovak Republic on the 173<sup>rd</sup> government session on August 26, 2015. The Amendment shall now be subject to the legislative procedure of the National Council of the Slovak Republic. The proposed entry into force of the Amendment is January 1, 2016.

## OBLIGATIONS ARISING FROM THE AMENDMENT

The Amendment proposes to introduce the following obligations:

- the Pharma Companies shall be obliged to provide the National Health Information Center with an electronic report on their expenditures on advertising, marketing and monetary and in kind contributions for the previous calendar half year; the Pharma Companies would be obliged to notify the aforementioned to the National Health Information Center no later than by January 31 and July 31 of the respective calendar year,
- the Pharma Companies shall be obliged to provide the National Health Information Center with information that they did not have any expenditures on advertising, marketing and monetary and kind contributions for the previous calendar half year in the case that they did not have any expenditures on advertising, marketing and did not directly or indirectly provide a health care worker or health care provider any monetary and kind contributions; the Pharma Companies would be obliged to notify the aforementioned to the National Health Information Center no later than by January 31 of the respective calendar year,
- a pharmaceutical company that secures the registration, categorization, marketing or procurement of buying or selling human drugs for holders of the License for the Provision of Health Care shall be obliged to provide the Ministry of Health of

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the Slovak Republic a list of holders of the License for the Provision of Health Care together with their registered seat, for which such pharmaceutical company carries out the aforementioned activities; such pharmaceutical company would be obliged to notify the aforementioned to the Ministry of Health by no later than by March 31, 2016,

III by removing the following psychotropic substance classified as Group II:

- Cannabidiol, CBD chemical name 2-(1R,6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl/-5-pentylbenzene-1,3-diol.

### SANCTIONS

Should the above mentioned obligations failed to be complied with, the Ministry of Health shall be entitled to impose a sanction in the amount of up to 10,000 EUR and up to three times this amount in the case of repeated violation.

### INTRODUCTION TO THE AMENDMENT TO THE ACT ON NARCOTIC DRUGS

On July 1, 2015 a Member of the Slovak National Parliament proposed an amendment to the Act No. 139/1998 Coll. on Narcotic Drugs, Psychotropic Substances and Preparations, as amended ("**Act on Narcotic Drugs**") also as the ("**Amendment to the Act on Narcotic Drugs**"). The Amendment to the Act on Narcotic Drugs shall now be subject to the legislative procedure of the National Council of the Slovak Republic. The proposed entry into force of the Amendment to the Act on Narcotic Drugs is January 1, 2016.

### PROPOSED CHANGES

The aim of the Amendment to the Act on Narcotic drugs is to update the Annex No. 1 of the Act on Narcotic Drugs the List of Narcotic Drugs and Psychotropic Substances Classified as Group I, II and

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