Ministry of Health of the Czech Republic

JUDr. Radek Policar
deputy for legislation and law

In Prague on 4th December 2017
Č.j. MZDR 58046/2017

Position on the amendment to Act No. 378/2007 of Coll., on pharmaceuticals and amendments to some related laws (the Pharmaceuticals Act)

Dear Mr. Executive Director,

In response to your request from 22 November 2017 concerning the interpretation of Act No. 378/2007 of Coll., on pharmaceuticals and amendments to some related acts (the Pharmaceuticals Act) as amended by Act No. 66/2017 of Coll., effective 1 December 2017, I would like to say the following.

This act that comes into effect on 1 December 2017 will now include the obligation of the distributor of medicinal products "to ensure supplies of medicinal products for human use to the operators authorized to dispense medicinal products in quantities and time intervals adequate to the needs of patients in the Czech Republic. The distributor shall ensure supplies of a medicinal product based on the request of the operator authorized to dispense medicinal products within two workdays of such a request. In order to ensure availability of medicinal products on the market in the CR, the distributor has the right to ask a marketing authorization holder to provide medicinal products for human use in the scope of the distributor's market share and the marketing authorization holder must supply such medicinal products, i.e. fulfill its obligation stipulated in Section 33 (3, g, 3). The distributor's market share represents the market share achieved on the Czech market by the distribution of all medicinal products for human use in the calendar quarter prior to the last ended calendar quarter. Neither the distributor nor the marketing authorization holder is obliged to supply medicinal products to a party that has at least one financial debt over 30 days past due or if the sale of a medicinal product in the Czech Republic has been terminated or suspended. The distributor must proceed in compliance with the measure issued by the Ministry of Health in order to ensure the availability of medicinal products pursuant to Section 11(h) or Section 77 (d)."

The Ministry of Health believes that, in compliance with Section 33 (3, g, 3) of the Pharmaceuticals Act, it is mostly the obligation of the marketing authorization holder to ensure the supplies of a medicinal product. We see the distributor's right to ask the marketing authorization holder to provide medicinal products pursuant to Section 77 (1, d) of the Pharmaceutical Act as a safety net in the case that the marketing authorization holder did not fulfill its obligation.

In our opinion, this interpretation is in full compliance with the law of the European Union and practice in the European Union. According to the European Commission, Article 77 of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (hereinafter referred to as the "EU Directive") clearly shows that marketing authorization holders are free to decide whether to distribute medicinal products by themselves or through distributors. In its decision-making practice, the Court of Justice of the EU recognized that even the marketing authorization holders that have

a predominant position on the market may *"adopt measures that are justified and reasonable in order to protect their own business interests"* and allowed them to refuse supplies that are of "unusual nature" (see the judgment of the European Court of Justice regarding C-468/06 through C-478/06 *Syfait II,* Collection of Judgments 2008 I-07139, para 69-70).

We are of the opinion that if state authorities required marketing authorization holders to automatically supply medicinal products to distributors (in the scope of the market share of these distributors), it would compromise the fundamental freedom of the European Union, which is the free movement of goods. The free movement of goods means that there are no trading obstacles on the EU market, i.e. no tariff obstacles or measures having equivalent effect. Such obstacles in general mean *"any change in the trade of Member States that is able to hinder intra-Community's trade directly or indirectly, actually or potentially"* (see the judgement of the European Court of Justice regarding 8/74 *Dassonville* [1974] ECR 837, para 5). In this respect, hindering or restriction means any negative impact on the flow of goods by compromising the trading freedom of market participants (see the judgement of the European Court of Justice regarding 104/75 *DePeijper* [1976] ECR 613, para 13). The Ministry of Health believes that the application of Section 77 (1, h) of the Pharmaceuticals Act in the case that the marketing authorization holder meets its obligation arising from Section 33 (3, g, 4) of the Pharmaceuticals Act would compromise the trading freedom of market participants.

The Ministry of Health is of the opinion that neither the State Institute for Drug Control nor the Ministry of Health are legally authorized to determine or actually disclose the market shares of distributors within the meaning of the provision in question.

Sincerely,

Mgr. Jakub Dvořáček
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