

A Protected Distribution System of Medicinal Products Introduced in the Czech Republic

On 24 September 2019, the Parliament approved an amendment to the Act on Pharmaceuticals which, among others, following a proposal raised by deputy Pawlas, modifies the existing obligations to ensure supplies of medicinal product supplies in the distribution chain and newly introduces so-called protected distribution system. The amendment is expected to enter into effect on 1 December 2019, depending on when it is officially published.

Redefinition of the obligations of the marketing authorization holder (“MAH”) and of the distributor

The amendment is based, to certain extent, on the existing legislation regulating the obligations of the MAH and of the distributor to ensure supplies of medicinal products supplies in the distribution chain, which was introduced

in April 2017. However, the existing legislation has been described as legally unenforceable, even by the Ministry of Health.¹ Therefore, the amendment aims to newly define the rights and obligations of the MAH and of the distributor to ensure that they are enforceable; in particular, the amendment no longer refers to the market share of distributors. The amendment thus introduces so-called protected distribution system which is triggered once a distributor voluntarily decides to assume a public service obligation.² The marketing authorization holder will then be obliged to supply medicinal products to such distributor. And the distributor will then be obliged to supply these medicinal products exclusively to pharmacies in the Czech Republic.

A detailed description of the newly introduced rules compared to the existing rules is provided in the tables below.

MAH's obligation to supply the distributor

	Current legislation (from 1 April 2017)	New legislation (expected from 1 December 2019)
Distributor entitled to request supplies from MAH	Any distributor.	A distributor that has provided MAH with a written representation that it requires medicinal products to ensure the provision of healthcare to Czech patients (i.e. no export).
Eligible medicinal products	Any medicinal products.	Any medicinal products.
Quantity of mandatory supplies	Distributor's market share in the calendar quarter preceding the latest completed quarter. No market share data available; calculation unclear.	Average 2-week demand coming to the distributor from operators entitled to supply medicinal products – i.e. basically pharmacies, including hospital pharmacies. Calculation unclear.
Exemptions	<ul style="list-style-type: none"> – Distributor is in delay with payment for more than 30 days. – The placing on the market of the medicinal product has been interrupted or terminated. 	<ul style="list-style-type: none"> – Distributor is in delay with payment for more than 30 days. – The placing on the market of the medicinal product has been interrupted or terminated. – SUKL has fined the distributor for an unlawful export during the past 2 years.

¹ See the statement of Deputy Health Minister Filip Vrabel available at: https://www.mzcr.cz/dokumenty/nametek-filip-vrabelproti-emergentnimu-sys-temu-broji-tikdo-se-boji-o-zisky_15884_1.html.

² The justification for deputy Pawlas' proposal clarifies that the proposal “introduces a protected distribution system that will ensure the availability of medicinal products to patients in any pharmacy in the Czech Republic. Under the protected distribution system, the marketing authorization holder (manufacturer) supplies medicinal products to the distributor who has undertaken, as part of the voluntarily assumed public service obligation, to supply the medicinal products thereby obtained to operators authorised to supply medicinal products in the Czech Republic. Such distributor maintains the stock of medicinal products thereby obtained in sufficient quantity to be subsequently able to supply pharmacies within 2 working days of receiving the order. The medicinal products thereby obtained will only serve patients in the Czech Republic, as distributors are expressly forbidden by law to export these medicinal products abroad.” See Parliamentary Print 302, Chamber of Deputies, 8th term, available at: http://www.psp.cz/sqw/historie_sqw?o=8&t=302.

Pharma Flash

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Distributor's obligation to supply pharmacies

	Current legislation (from 1 April 2017)	New legislation (expected from 1 December 2019)
Distributor obliged to supply pharmacies	Any distributor.	A distributor that has provided MAH with a written representation that it requires medicinal products to ensure the provision of healthcare to Czech patients (i.e. no export). Distributor may supply medicinal products supplied by MAH under this regime only to operators entitled to supply medicinal products – i.e. basically pharmacies, including hospital pharmacies.
Eligible medicinal products	Any medicinal products.	Any medicinal products.
Delivery deadline	2 working days from the pharmacy's order.	2 working days from the pharmacy's order.
Exemptions	<ul style="list-style-type: none"> Pharmacy is in delay with payment for more than 30 days. The placing on the market of the medicinal product has been interrupted or terminated. 	<ul style="list-style-type: none"> If the pharmacy is in delay with payment for more than 30 days, the price for the ordered medicinal product must be paid no later than at the moment of the delivery. The placing on the market of the medicinal product has been interrupted or terminated.

Health Minister: the new legislation should not be applied

Health Minister Adam Vojtěch, who disagreed with the adoption of the amendment, has literally stated during its discussion in the Chamber of Deputies that *“we will not have to fully apply the draft in the form in which we will approve it because we have a governmental amendment to the Act on Pharmaceuticals, which introduces so-called ‘emergency system’. The first reading of the draft is already awaiting us and I think it will introduce clear rules for the distribution of medicines in the Czech Republic that will be transparent, will really be a benefit, so I think it will not be an issue if the draft is approved in the form as actually approved by the Chamber.”*³

The Health Minister here refers to the draft of another amendment to the Act on Pharmaceuticals introducing so-called emergency system of medicinal products supplies according to the Slovak model.⁴ That draft, on which the Ministry of Health has been working for more than a year and which is currently being discussed by the Parliament, foresees the introduction of completely new supply obligations in the distribution chain, which are fundamentally different from those introduced by the above amendment. The question is, however, in what form and whether the emergency system will be introduced in the Czech Republic at all.

³ See Stenographic record from the 34th session of the Chamber of Deputies of the Parliament of the Czech Republic of 24 September 2019. Available online at: <http://www.psp.cz/eknih/2017ps/stenprot/034schuz/s034173.htm>.

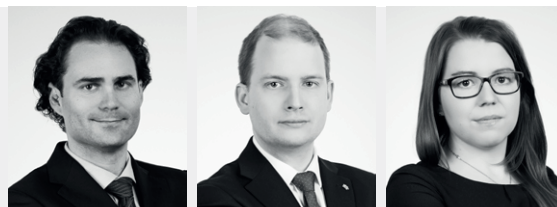
⁴ See Parliamentary Print 581, Chamber of Deputies, 8th term, available at: http://www.psp.cz/sqw/historie_sqw?o=8&t=581.

Authors:

Václav Audes | Partner

František Neuwirth | Associate

Vlad'ka Laštůvková | Junior Associate



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PRAGUE

Florentinum, Reception A
Na Florenci 2116/15
110 00 Prague 1
Czech Republic
Tel.: +420 255 000 111

BRNO

Titanium Business Complex
Nové sady 996/25
602 00 Brno
Czech Republic
Tel.: +420 545 423 420

BRATISLAVA

Zuckerman del Centre
Žižkova 7803/9
811 02 Bratislava
Slovak Republic
Tel.: +421 232 113 900

PILSEN

Nepomucká 144
326 00 Plzeň
Czech Republic
Tel.: +420 371 005 320

OLOMOUC

Salm Palace
Horní náměstí 371/1
779 00 Olomouc
Czech Republic
Tel.: +420 581 000 310

OSTRAVA

Poděbradova 2738/16
702 00 Ostrava
Czech Republic
Tel.: +420 596 110 300