

Pharma Flash

January 2019

New Health Ministry Price Regulations for Medicinal Products

On 1 January 2019 **price regulation 1/2019/FAR**¹ of the Ministry of Health entered into effect. The regulation introduces in particular the following changes:

- The **maximum mark-up will be reduced** in the 7th band and in the 8th band to 4% and to 2% respectively; the surcharge in these bands will be increased. After the change the maximum mark-up amount will be regulated as follows:

Band	Base from (CZK)	Base up to (CZK)	Rate	Surcharge (CZK)
1	0.00	150.00	37%	0.00
2	150.01	300.00	33%	6.00
3	300.01	500.00	24%	33.00
4	500.01	1,000.00	20%	53.00
5	1,000.01	2,500.00	17%	83.00
6	2 500.01	5,000.00	14%	158.00
7	5,000.01	10,000.00	4%	658.00
8	10,000.01	9,999,999.00	2%	858.00

- The price regulation now expressly deals with **discounts and bonuses**. If in connection with the supply of a reimbursed medicinal product a discount or bonus is granted and if it is possible to unambiguously determine their amounts and allocate them to a **particular individual item in a tax document** (invoice) already at the date of taxable supply – regardless of whether such a discount or bonus is provided or obtained at the date

of taxable supply or at a later date –, then such a discount of bonus **will be reflected in the unit price**.

- **Changes are made to definitions of terms** used in the price regulation. In particular, the new term “**other person placing a registered product on the market**” is being introduced, the meaning of which is a distributor who places medicinal products on the Czech market but who is not a marketing authorization holder for these products and does not supply these products to the marketing authorization holder for these products. This new term will also be included, among others, in the definition of the **manufacturer’s price**.

In contrast to the original intention announced by Deputy Health Minister Filip Vrabel² no cap on the distributors’ mark-up was introduced, i.e. the maximum mark-up was not divided into separate caps for distributors and pharmacies. The maximum mark-up thus remains shared between distributors and pharmacies. The Czech Chamber of Pharmacists expressed their disappointment in this connection³.

Also, on 1 January 2019, the related **price decision 1/19-FAR**⁴ of the Ministry of Health entered into effect. This decision changes the list of ATC groups which are not subject to a maximum price regulation.

The **State Institute for Drug Control** issued a notice⁵ on the discussed price regulation and price decision which covers primarily the new list of “deregulated” ATC groups.

¹ Price regulation of the Ministry of Health 1/2019/FAR of 12 December 2018 on the regulation of prices of medicinal products and food for special medical purposes; available at: http://www.mzcr.cz/Odbornik/dokumenty/cenovy-predpis-1/2019/far_16489_1953_3.html.

² See https://www.mzcr.cz/dokumenty/namestek-filip-vrubelproti-emergentnimu-systemu-broji-tikdo-se-boji-o-zisky_15884_1.html.

³ See <https://www.lekarnici.cz/Media/Tiskove-zpravy/Do-noveho-cenoveho-predpisu-ministerstva-zdravotni.aspx>.

⁴ Price decision of the Ministry of Health 1/19-FAR of 12 December 2018 which sets out a list of ATC groups which are not subject to a maximum price regulation; available at: http://www.mzcr.cz/Odbornik/dokumenty/cenove-rozhodnuti-1/19/far_16490_1953_3.html.

⁵ See <http://www.sukl.cz/leciva/cenovy-predpis-ministerstva-zdravotnictvi-1-2019-far-a>.

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