

Pharma Flash

January 2020

New price rules of the Ministry of Health in the field of medicinal products

A new price rule of the Ministry of Health on the regulation of the prices of medicinal products and foods for special medical purposes came into effect on 1 January 2020. The rule entails the following changes in price regulation:

- it was established that “**another person placing an authorised medicinal product on the market**” places a medicinal product on the market in the Czech Republic within the meaning of the definition of this term under Section 3a (10) of the Act on Pharmaceuticals;
- **orphan medicinal products (unless they are also advanced therapy medicinal products)**, which can be used in inpatient and outpatient care and which are not reimbursed for outpatient care, will now always be subject to the regulation of the originator's price and of the maximum trade mark-up;
- **orphan medicinal products (if they are also advanced therapy products)** continue to be exempt from price regulation due to the application of a “specific contractual policy of health insurance companies”;
- **medicinal products** (including advanced therapy medicinal products) and **foods for special medical purposes** in the ATC group with the appropriate route of administration (i.e. those medicinal products that are set by price decision 1/19-FAR) are no longer subject to both maximum price and material price control;
- of advanced therapy medicinal products only those that have a so-called ‘**hospital exemption**’ continue to be subject to material price control;

- price regulation of individually prepared **medicinal products containing medical cannabis** is now stipulated in a special price rule (see below);
- the exception to the rule that the originator may increase the price subject to material control by a maximum of 3% during the calendar year will now also include **the radiopharmaceuticals 90Y, 186Re and 169Er**.

Related **price rule No. 2/2020/CAU**, on the regulation of the prices of provided health services, the setting of maximum prices of health services provided by dentists covered by public health insurance, and specific medical procedures also came into effect as of 1 January 2020.

A completely new special **price rule** is **Rule No. 3/2020/CAU**, on the regulation of the prices of individually prepared **medicinal products containing cannabis for medical use**. Under this rule, individually prepared medicinal products containing cannabis for medical use:

- are subject to **price regulation**, regardless of whether they are actually covered by public health insurance in a particular case or whether they are fully covered by the patient;
- have the **set final maximum price** of the originator, exclusive of value added tax.

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