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New rules on the regulation of medicine prices

Minister of Health's Order No. 703/2015 for the amendment and supplementation of the appendix to Minister of Health's Order No. 75/2009 for the approval of the Norms on the pricing of medicines for human use and for the amendment of Minister of Health's Order No. 245/2012 for the approval of prices to medicines for human use included in the National Catalogue of Medicines for Human Use Authorized for Marketing in Romania ("**Order No. 703/2015**") was published in the Official Journal of Romania, Part I, No. 396 of 5 June 2015.

Order No. 703/2015 brings important regulations on the endorsement of medicine price. The amendments and supplementations envisage, inter alia, new definitions, the extension of the category of medicines whose price is approved by the Ministry of Health, the establishment of two categories of national catalogues (lists) for the price of authorized medicines, new rules for the endorsement and application of the proposed prices, special limits for the prices of innovative medicines when the generic is launched and the maintaining of the currently authorized prices for another 90 days.

The Norms on the pricing of medicines for human use, as amended by Order No. 703/2015 (the "**Norms**") extend the category of medicines whose price is subject to the Ministry of Health's endorsement so as to include the OTC medicines which are prescribed and released in the social health insurance system and the national healthcare programs.

For the first time in Romania, two categories of national catalogues of medicine prices are established and defined, as follows:

- The National Public Catalogue of Prices (the "**Public Catalogue**"), which will include all maximal prices of medicines for human use valid in Romania and will be approved annually (as a rule) by order of the Minister of Health and posted on the website www.ms-preturi.ro; and
- The National Catalogue of Medicines for Human Use Authorized for Marketing in Romania ("**Canamed**"), which will include the maximal prices of the medicines used/sold by suppliers of medical services or medicines having a contractual relationship with the healthcare authorities; Canamed will also be approved by order of the Minister of Health and will be updated quarterly or whenever necessary, by including, amending or excluding the relevant prices.

Order No. 703/2015 provides that the prices of Canamed medicines must be smaller or equal to the smallest price of the same medicine from the countries used as benchmark, but it does not establish any other rules specifically applicable to Public Catalogue prices.

If the price is proposed in accordance with the Norms, the Ministry will issue an order for the approval of the price within 90 days as of the date when the applicant has submitted the full documentation. If the proposed price does not comply with the Norms, the Ministry of Health will issue and send to the applicant a decision on the rejection of the price proposal including the grounds of rejection and the price level established by the Ministry in accordance with the Norms. The applicant can refuse to accept the Ministry of Health's price, in which case the applicant can sell the medicines at the previously approved price, only up to the exhaustion of existing inventories, but not more than 6 months as of the date of the rejection decision.

If the applicant accepts the medicine price established by the Ministry of Health within 90 days as of the date when the rejection decision is sent, this price will be approved by order. If the Ministry's price is accepted after expiry of the said 90-day deadline, the final price will be approved at a level which complies with the Norms less 5% for a 12-month period.

According to the amended definition, "generic reference price" now means the maximum sale price of the generic medicine and of the innovative medicine for which there is a generic medicine with a price approved in accordance with the Norms. Generic reference price is approved by the Ministry of Health only once, on the date of the price application for the first generic medicine and accounts for 65% of the price of the relevant innovative medicine valid on the application date.

As of 2016, upon the price reanalysis made by the Ministry of Health, prices of (former) innovative medicines will be proposed by reference to the prices of these medicines in the relevant countries, but they cannot exceed the generic reference price aforementioned.

Finally, Article II of Order No. 703/2015 prorogues the validity period of the current National Public Catalogue of Prices (previously named "Canamed"), approved by Minister of Health's Order No.

245/2012, as further amended, by another 90 days after the date when the order is published, i.e., until 3 September 2015.

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Editors

Țuca Zbârcea & Asociații offers multidisciplinary services in relation to all relevant healthcare and pharma issues. The firm's **Pharmaceutical Law Practice Group** comprises lawyers specialising in regulatory matters affecting this industry, as well as in intellectual property, competition, litigation, taxation, advertising, mergers and acquisitions, consumer protection and nowadays, areas such as insolvency, restructuring, employment, work-out.

Țuca Zbârcea & Asociații mainly advises top international players in the pharmaceutical industry on matters of compliance with Romanian/EU legal requirements, as well as in relation to various matters such as pricing policies and reimbursement issues, clawback tax, promotional campaigns and advertising, disputes with the Ministry of Health and National Health Insurance House, public acquisition procedures, reimbursement/share-risk protocols, protecting the legal rights over the innovative medicines, clinical studies, sponsorship agreements or services agreements executed with healthcare providers, etc.

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