New rules on medicine price formation

4 September 2015

In brief

The Law regulating pharmaceutical activity has been amended to include new rules on medicine price formation.

In detail

Under the amendments, as of 1 October 2015 the 15% profitability requirement is removed from the delivery price of medicines manufactured by domestic producers.

A new mechanism has been established on the mark-up of medicines. The mark-up rates vary with the prices registered in the National catalogue of manufacturers' prices for medicines.

To this aim, medicines and other pharmaceutical products have been classified into five categories, according to their prices, with the following mark-up thresholds set:

- up to 40% for medicines with prices of up to 30 Moldovan lei (of which 15% for businesses which import / distribute medicines, and 25% for pharmacies);
- up to 32% for medicines with prices between 30.01

- and 60 Moldovan lei (of which 12% for businesses, and 20% for pharmacies);
- up to 26% for medicines with prices between 60.01 and 120 Moldovan lei (of which 10% for businesses, and 16% for pharmacies);
- up to 21% for medicines with prices between 120.01 and 240 Moldovan lei (of which 8% for businesses, and 13% for pharmacies);
- up to 16% for medicines, with prices over 240
 Moldovan lei (of which 5% for businesses, and 11% for pharmacies).

The provisions on the thresholds above will enter into force on 1 April 2016.

In addition, the Law provides for a two-stage implementation, as follows:

 As of 1 October 2015, businesses which import / distribute medicines will

- adjust mark-ups, as required by the Law.
- Pharmacies will continue to charge a 25% mark-up until 1 April 2016. As of this date, pharmacies will be required to use the differential markup thresholds, as stipulated by the Law.

[Source: Law no. 150 of July 30, 2015 amending and supplementing Law no. 1456-XII of May 25, 1993 on pharmaceutical activity, Official Gazette no. 241-246 of August 28, 2015]

The takeaway

The price profitability requirement has been removed for domestic manufacturers of medicines.

A differential mark-up mechanism has been established for medicines, in accordance with their prices.

The Law will be implemented in two stages, starting 1 October 2015 and 1 April 2016.



Tax and Legal Alert

Let's talk

For a deeper discussion of how this new legislation might affect your business, please contact:



Mihaela Mitroi Partner Mihaela.Mitroi@ro.pwc.com



Alexandru Munteanu Manager, Attorney-at-law Alexandru.Munteanu@ro.pwc.com



Tatiana Stavinschi Manager <u>Tatiana.Stavinschi@ro.pwc.com</u>



Lilia Tapu Manager <u>Lilia.Tapu@ro.pwc.com</u>

PricewaterhouseCoopers Moldova 37, Maria Cibotari Street Chisinau, Republic of Moldova Tel:+ (373 22) 25 17 00 Fax:+ (373 22) 23 81 20