

REPUBLIC OF ESTONIA MINISTRY OF SOCIAL AFFAIRS

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Your ref. 24.03.2024 / Our ref. 04.04.2024 No 1.4-2/792-2

Dear minister Dr. Arben Vitia,

Thank you for addressing me with enquiries regarding the pricing of medicinal products. More specifically you were asking for information about type of the prices and margins on medicines.

First of all I'd like to point out that the handling of medicinal products is regulated in the Estonian <u>Medicinal Products Act</u>. According to the Act, threshold values for mark-ups in wholesale and retail trade of medicinal products and the procedure for their implementation are established by a regulation of the Government of the Republic. Government has issued a regulation "<u>Threshold values for mark-ups in wholesale and retail trade of medicinal products and the procedure for their implementation</u>".

According to the regulation, in Estonia the price of medicines purchased from pharmacies is composed according to following criteria: the price set by the manufacturer of medicine + wholesale mark-up + pharmacy mark-up + VAT 9%. The limit rates of mark-up of medicines are established in the referred Government regulation. The criteria, that must be taken into account when establishing surcharges, are set out in the Medicinal Products Act as following:

- financial availability of medicines to end users that is characterized by the purchase of medicines compared to their prescription, the continuity of the use of medicines and the patients' OOP connected with the purchase of medicines;
- geographic availability of medicines to end users that is characterized by the number of licensed and marketed medicines, the number of wholesale and retail medicine companies, and the availability of medicine related assistance in permanently populated areas;
- risks related to the marketing of medicines that includes the risk of writing off purchased goods by handlers;
- weighted average markup percentage that indicates the price at which medicine packages are sold relatively more. The Ministry of Social Affairs prepares an <u>analysis</u> of the weighted average markup every year according to the data provided by wholesalers.

The principles of the current mark-up system of medicines in Estonia are as follows:

- markup limits, i.e. maximum allowed markups, have been established;
- handlers of medicines may also apply markups lower than the maximum;
- proportional (percentage of price of medicine) and fixed (amount in euros) markup limit is applied;
- the markup limit cannot be higher than 6.39 euros per package;
- markup for medicines of different price groups must create equal interest in handling medicines;
- the weighted average markup in the wholesale sale of medicines must be

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between 7-10% and in the retail sale of medicines between 21-25%;

there is no difference in applying the markups as regards to listed or not-listed medicines.

Please note that sometimes, especially in case of expensive patented medicines, managed entry agreements exist, with confidential discounts agreed between state and manufacturer.

You can find more information about the pricing of medicinal products from the webpage of the Estonian Health Insurance Fund: <u>https://www.tervisekassa.ee/en/people/pharmaceuticals</u> and <u>https://www.tervisekassa.ee/partnerile/ravimitest/soodusravimid</u>.

In case you have further questions, we would be happy to set up a virtual meeting with appropriate experts to share the insights into our system.

Yours sincerely,

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Riina Sikkut Minister of Health

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