

ESTONIA

Recent and planned developments in pharmaceutical policies 2022/2023

CHANGES IN PRICING

A review of wholesale and retail mark-up regulation: an analysis carried out in Q II-III, preparation of proposals as of Q IV. The current regulation dates back to early 2000s with the same threshold values and price groups.

2023

A law amendment discussed in the parliament to decrease the **VAT from 9% back to 5%** (a rate used before the 2008 economic crisis) for specific cancer medicines bought from donations. No final decision yet.

2023

CHANGES IN REIMBURSEMENT

On-patent **biologics and JAK-inhibitors** which were initially reimbursed via inpatient/hospital list are transferred to outpatient list. Process for some indications (e.g. asthma, RA, AD) still ongoing.

From 2022

As an extraordinary measure the state allocated **800 000 €** to the Tartu University Hospital Children's Foundation to finance the purchasing of medicines for **children with rare diseases** (not financed by the EHIF).

28 Feb 2023

Review of the existing guideline for economic evaluation of pharmaceuticals.

2023

OTHER CHANGES

The **Estonian National Medicines Policy 2030** – a comprehensive policy document with an implementation plan and relevant indicators. Also includes priorities on the European pharmaceutical strategy.

3 Jan 2023

The two main work streams are:

- 1) access, availability, affordability and
- 2) rational use and raising public awareness.

In the area of pricing and reimbursement the focus will be on:

- regulation on pharmaceutical pricing (mark-ups review) and fair competition in wholesale and retail market,
- more flexible reimbursement for medicines without a MA in Estonia,
- decrease OOPs for vulnerable groups (OTC and Rx).

SPECIAL TOPIC:

Developing and implementing pharmaceutical policies in view of the current challenges (soaring inflation, medicine price increases, increasing no. of medicine shortages)

1) Medicine shortages:

- Reporting of shortages: MAH obliged to report **2 months ahead** of the expected supply disruption. The number of notifications is going up (in 2022 359 notifications, a 24% increase compared to pre-Covid-19 time). Information is uploaded in the national register of medicinal products. The State Agency of Medicines sends notifications about shortages to all subscribers of its online information letter.
- Since 2020 wholesale companies with a market share of more than 10% (in Estonia 2 companies) must report their inventory on a weekly basis (in the state of emergency on a daily basis (during workdays)).
- National stockpiles: In 2021 the **Estonian Stockpiling Agency** was established who is tasked to manage the emergency supplies of vital products, including a **2-month supply** of medicinal products sold in community pharmacies (165 products, ensured by contracts not by a physical reserve). In 2022 a contract for 104 medicinal products was concluded and in 2023 Jan an additional tender was organised. The conditions needed to be made more flexible in the second tender due to the lack of offer on some products.
- Export bans: the State Agency of Medicines has currently banned the parallel export of **18 medicinal products** (9 relate to the shortages of Ozempic). The biggest number of bans were during Covid-19 crisis (around 40) but otherwise the trend is **relatively stable**.
- Regulatory measures: no changes
- Financial measures: no changes
- Stakeholder involvement: during Covid-19 crisis **good will agreements** between the Ministry of Social Affairs and 7 larger wholesale companies to hold 2-month stocks covering 800 APIs. Limited in time (only during the official state of emergency).
- Other: **named patient basis reimbursement to cover shortages/or market withdrawals** of reimbursed pharmaceuticals (->increased bureaucracy for doctors, patients and EHIF). 2021-2022 it has affected haematology/oncology (interferons, etoposide), schizophrenia (haloperidol), depression (bupropion), migraine (zolmitriptan), antithrombotic (enoxaparin).

2) Price increases:

- Out of **250 reference price groups**: in 2021 there was a **price increase in 2%** of the price groups; in 2022 the relative indicator was **3,6%**.
- EHIF has **price agreements for 605 medicinal products**: in 2021 the price increased for ca **0,3%** products, in 2022 the **increase was 10-fold (3%** of products).
- The above-mentioned tendency is continuing for both indicators and affects more older APIs with lost or inexistent competition. The patient numbers are small or/and well established.
- We have had cases where the price increase is requested for products with no or much more expensive alternatives. We have no other option than to accept the price increase if the prices in the reference countries allow it. If not, we must set the price at the level of the reference country and the price increase burden will be borne by the patient OOP.

3) Introduction or discussion of other measures related to current challenges (high inflation rates, budget caps, high-priced medicines, introduction of production sites in Europe, etc.):

- No updates