

ROMANIA

Recent and planned developments in pharmaceutical policies 2022/2023

CHANGES IN PRICING

Starting with 01.01.2022 the MAH can apply for an **increase of price** anytime for the following products:

-the List of essential medicines (in order to be included in the List the product should be an originator, generic or biosimilar that had lost its patent and cumulatively meet the following conditions: the INN is included in the most recent WHO List of essential medicines and the INN is also included in the C Reimbursement List (which contain medicines included in the National Health Programs).

-immunological medicines and blood products or derived from human plasma, including vaccines;

-medicines for the management of coagulopathy that are included in the COVID-19 treatment Protocol (including Low Molecular Weight Heparin (LMWH));

Jan. 2022

Until the entry into force of the prices resulting from the 2023 revision (June 2023), the comparison with the generic/biosimilar/innovative reference price does not apply within the revision process or between two successive revisions, if the product is the only medicine on that INN, strength, pharmaceutical form, without taking into account the form of packaging.

Dec. 2022

For the 2023 revision of prices, including for all submission of new price approval in 2023, Hungary was excluded from the list of reference countries (due to the sharp depreciation of HUF)

2023

CHANGES IN REIMBURSEMENT

The reimbursement List has been revised several times:

- 76 new INN have been introduced in the Reimbursement List in 2022 vs. 56 in 2021;

- 91 INN subject to Managed entry-agreements as of 30.01.2023; A new Clawback policy will be implemented. As such, the new clawback policy is calculated and charged differently for type I (25% from the sales value) and type II (15%) medicinal products.

- Type I: originators
- Type II: generics/biosimilar

2022

July 2023

Special reimbursement framework for Zolgensma® (onasemnogen aeparvovec):

Although Zolgensma was assessed and received unconditional reimbursement inclusion in the List, given the excessive price, this medicine is reimbursed under a novel framework similar to a MEA (a negotiated price).

Further expansions of this type of inclusion in the List for other high priced medicines (e.g. gene therapies).

2022 – on going

OTHER CHANGES

Biosimilar switching and interchangeability:

For the first time in RO, in the new Framework Agreement between National Health Insurance House and healthcare providers it is stated that the initiation therapy must be done with a biosimilar. Also, the doctors have to switch 50% of their patients that receive the biological reference product on biosimilar.

June 2023

The price approval will be linked to the actual placing of the product on the market: 90 days to place the product on the market otherwise the price will not be approved.

April 2023

2022 – on going

The Catalogue of prices was 'cleaned' by the generic reference prices (GRP) that had no longer products placed on the market (GRP settled years ago). At the entry into force of the prices resulting from the 2023 revision (June 2023), the new GRP will be approved.

June 2023

Pilot project for vaccination in community pharmacies:

Since November 2022 a pilot project was initiated in the community pharmacies for vaccination against flu. In the future this will become a standard practice.

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:

- National register to report shortages: in place (since 2017 mandatory). There is a mandatory deadline for notification: 6 months in advance/ 12 months (for commercial reasons).
- Export ban: since January 2023 for some antibiotics. In force for 3 months (will expire in April)
- Regulatory measures: In order to mitigate some medicines shortages in August 2021 we approved the Order of the minister of Health that sets up rules for implementing art. 126a from 2001/83/EC Directive – the so-called "Cyprus clause" (Order no. 1540/2021). For those medicines the pricing policy is similar to the List of essentials medicines.
- Financial measures: see other measures (increases of prices)
- Stakeholder involvement: constant monitoring of possible shortages (patient associations, pharmacists etc.)
- Other: RO is involved in CHESSMEN Joint Action which aims to support the EU Member States in implementing proper structures, measures and tools to tackle the issue of medicine shortages.

2) Price increases:

- See changes in pricing section
- Possibility to index the maximal price with the inflation rate (EU rate for 2022 - 9, 2%) for medicines which prices are lower than 50 RON (~ 10 Euro).

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.):

- Task Force for assessing new measures to improve the pricing policy (2022 – on going)