Malta

Recent and planned developments in pharmaceutical policies 2023

CHANGES IN PRICING

Price updates (2023)
Prices used for reference price calculations are updated on a yearly basis.

External Referencing Pricing System (2023)
The External Reference Pricing system currently considers prices from a basket of EU countries falling within the bracket of +/-20 percentage points of Malta's GDP per capita in Purchasing Power Standards using EUROSTAT figures, together with the UK price. Following Brexit and the reduction in relevance of UK prices to the local scenario, discussions are in place on whether to keep considering the UK price when calculating External Reference Prices or not.

European Integrated Price Information Database (EURIPID) (2023)
EURIPID is a voluntary non-profit collaboration of national pricing and reimbursement authorities in mainly European countries through which national pricing and reimbursement authorities share national data on medicine prices and foster information and data exchange between the EU countries. The Directorate for Pharmaceutical Affairs is currently in advanced stages of discussions to join this collaboration which is expected to happen in 2023.

CHANGES IN REIMBURSEMENT

Biosimilar switching (2023)
The Ministry for Health is currently dealing with switching of biologics to biosimilars on a case-by-case basis and the necessary policy guidance is being provided accordingly. A longer-term policy on the efficient management of biologics and biosimilars on the Government Formulary List is also currently under discussion. Spurred by the EMA Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU, procurement specifications of biologics on the GFL are being amended to remove references to brands and thus improving competition.

Branded drug policy (2023)
A DH circular has been issued by the Chief Medical Officer aimed at improving the efficient uptake of generics has been issued in January 2023. Government Formulary List (GFL) medicines are mainly procured non-branded and procurement of branded items is limited to specific, justified cases such as certain categories of antiepileptics.

Budgetary measures (2023)
The financial allocation of budgeted funds for specific disease areas based on a prioritisation exercise emanating from suggestions by stakeholders and areas of unmet medical need. Proposals mentioned in the 2023 budget speech include:

- Extending entitlement of the Human Papillomavirus (HPV) vaccine to all boys born in the year 2000 and after.
- Introduction of new medicines on the GFL for the treatment of multiple sclerosis.
- Widening patients' entitlement who will benefit from medicines that treat diabetes and osteoporosis.
- Review and updating of the list of specialised nutrition formulas which are taken through intubation.
- Introduction of stimulating medicines for patients undergoing interventions involving third-party gamete donation.
- The introduction of a fund so that urgent cases of patients with suspected or diagnosed cancer are given the necessary treatment within a 12-week period as established in the patients' charter.
- Chemotherapy pumps for ambulatory administration of chemotherapy.

Introductions or modifications to the Government Formulary List (2021 – Present)

- 26/11/2021 – Voriconazole 200mg Vials for inpatient use.
- 30/12/2021 – Four-Factor Prothrombin Complex Concentrate (4F-PCC) for inpatient use.
- 17/03/2022 – Caffeine Citrate Solution for Infusion for inpatient use.
- 28/04/2022 – Extension of indication for pregabalin 75mg, 150mg and 300mg Capsules for inpatient and outpatient use in fibromyalgia and myalgic encephalomyelitis.
- 29/04/2022 – Extension of indication for Omalizumab 150mg Injections for inpatient and outpatient use in Severe Chronic Urticaria.
- 24/06/2022 – Non-Sedating Antihistamines Tablets and Oral Solution for inpatient and outpatient use.
- 06/07/2022 – Extension of indication for direct oral anticoagulants for inpatient and outpatient use in cardiac arrhythmias, and deep vein thrombosis and pulmonary embolism in malignancy.
- 19/12/2022 – Paxlovid® 150 mg/100 mg film-coated tablets.
- 22/12/2022 – Co-amoxiclav 625mg tablets to replace co-amoxiclav 375mg tablets.
- 22/12/2022 – Change in Gliptin (Dipeptidyl Peptidase 4 Inhibitor) from vidagliptin to sitagliptin 100mg tablets.
- 16/01/2023 – Change in concentration of chloral hydrate oral solution from 500mg/5ml to 143mg/5ml.motherapy Pumps that the patient can use in the comfort of their home, if and as prescribed by the treating consultant.

OTHER CHANGES

Pharmacist – Led Medicines Use Review (MUR) Service project (2022 – Present)
Following a new Pharmacy of Your Choice (POYC) service level agreement in 2022, a pilot Pharmacist – Led Medicines Use Review (MUR) Service project is currently being held. The objective of the MURs is to evaluate whether patients are using their medicines correctly, and to optimise treatment outcomes. Community pharmacists are expected to establish baseline of patients' understanding of:

- their chronic condition
- how optimal use of their medicines contributes to improved outcomes and quality of life
- the correct way to use or take their medicine/s
- the key clinical targets of their medicine/s regime
- the necessity of their adherence
- side-effects which may have had a negative impact on adherence
- medicine/s misuse

The Computer-Generated Prescription - Patients' Electronic Treatment Records real-time Update (2021 – Present)
The POYC Unit has developed an electronic program that enables easy access to the latest medication history of patients at the point of care in Primary Health Care Prescribing Clinics. This program is connected to the GFL, and doctors can select the patients' entitlement from a pre-existing drop-down Treatment List that includes items from the specific chronic treatment schedule. There are plans to expand this service to private doctors soon.

HTA Framework (2021 – Present)
The ESF funded project named "Capacity building to support the managed introduction of new medicines on the Government Formulary has been finalised, and DPA is currently considering the necessary updates to the way HTAs are produced following all the learnings and recommendations by the project partners.

HTA legislation (2022 – Present)
Following years of EU-funded project-based voluntary HTA cooperation (i.e. EUnetHTA joint actions), EU Regulation (2021/2282 on health technology assessment (HTA) came into force in January 2022 and will apply as of January 2025. Whilst DPA looks forward to the implementation of the HTA regulation, it is also expected that further capacity building will be necessary whilst considering the limited resources and expertise in a small member state like Malta.

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

The problem of medicine shortages seems to have intensified. Did you introduce new measures to tackle this recently?

- **High level discussions:** Parliament's health committee held an emergency meeting together with leading stakeholders from public and private entities to discuss the local shortage in medicines and to examine and understand what causes may be playing a role and how the situation compares to other countries.
- **Direct sourcing:** The Government has also directly sourced medicines from overseas when its local suppliers have been unable to satisfy contractual obligations, with any additional cost forked out by the government as a result of this direct procurement passed on to its domestic suppliers.
- **Revision of specifications:** Specifications of GFL drugs are continuously revised by the Formulary Management Unit at DPA to remain competitive and prevent out of stock situations.
- **Automated stock monitoring:** A new automated system to monitor stock levels in real time is in the near pipeline.
- **Stockpiling:** Stockpiling of medicines is being employed as a strategy to cope with the demand for medicines, especially over the winter season.
- **Emergency Response Unit (ERU) at CPSU**: On a public service level, the ERU at CPSU is tasked with purchasing products that are out of stock. An increase in the engagement of the ERU has been necessary due to the recent medicine shortages.
- **Medicines Intelligence and Access Unit (MIAU) at MMA:** On a national level, the MIAU is responsible for identifying reliable sources of medicines, as well as for using regulatory flexibilities and closely monitoring the European and local market for shortages of medicines. The MIAU continuously liaises with stakeholders and compiles and utilises medicines intelligence to to enable sourcing of medicines.
- **Brexit Derogation:** In order to maintain a high level of public health protection and avoid shortages of medicinal products the EC published Directive 2022/642, and therefore Directives 2001/20/EC and 2001/83/EC had to be amended to allow for exceptions for medicinal products supplied from the UK (excluding Northern Ireland) to Cyprus, Ireland, Malta, and Northern Ireland since these countries have traditionally relied on UK supply chains. The derogation will expire by December 2024 at the latest.

Do you have specific policies for price increases? Have you used or thought about price level freezing during this crisis situation?
There are no specific policies for price changes or increases that are actually used in practice. Prices of contracts are set in line with Public Procurement Regulations. Price level freezing during specific crises has not been considered.

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.)
N/a