

HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

1. Please provide a bird's eyes view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

Malta's healthcare economy is made up of both the public healthcare system and the private healthcare system.

The public healthcare system is managed by the Ministry for Health and Active Ageing, while the private healthcare system comprises various market players, including private hospitals, clinics and pharmacies, as well as medicinal product manufacturers, importers, distributors and wholesalers, whose licensing and authorisations are mainly regulated by the Malta Medicines Authority.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

Malta's public healthcare economy is financed exclusively through general taxation, and the national healthcare system (which provides almost universal coverage) is funded by the government and is free to eligible patients. Medicinal products may be placed on the national formulary list in terms of the Availability of Medicinal Products within the Government Health Services Regulations (Subsidiary Legislation 458.31 of the Laws of Malta). When applying for placement of these products on the national formulary, the applicant must specify the estimated unit cost, the total cost per patient (annually or per treatment course), the estimated number of patients who would require the product and the price being charged to other European Union Member States for the same product. In terms of the regulations, any decision on the inclusion of a medicinal product on the national formulary list and the reference price to be paid for such product by the government is taken through a single administrative procedure. The applicant is also able to request an increase in price, but this increase must first be approved by and justified to the Superintendent of Public Health. In terms of the same regulations, the government has the power to request that the price being charged is reviewed according to the exigencies of the government or to impose a price freeze. Products on the formulary list are provided free of charge to eligible patients.

In the private healthcare sector, reimbursement to patients for certain medical procedures may be covered by insurance plans, but this depends on the insurance provider and is not standardised. Typically, patients are required to pay for services or products obtained outside of the public sector as out-of-pocket fees, due immediately upon receipt of the service or product. However, the private sector is free to determine its own patient payment plans.

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?
<p>The key regulator for healthcare financing and reimbursement is the Ministry for Health and Active Ageing. This Ministry is tasked with the provision of free public healthcare services in Malta, regulating all healthcare services and developing and implementing policies related to public health.</p> <p>The private healthcare sector, on the other hand, operates under a free-market pricing policy. Pricing of medicines, medical devices and other medical products and procedures in the private sector is not fixed or monitored by the government, but it is the stakeholders in the sector that determine pricing (eg, the manufacturer or the distributor depending on the arrangement between them).</p>
4. Has there been a change with healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?
<p>According to <i>State of Health in the EU: Malta Country Health Profile 2023</i>, published by the Organisation for Economic Co-operation and Development (OECD), health spending in Malta grew at the highest rate in the EU in real terms over the last decade.</p> <p>According to the same source, while total expenditure on health in Malta increased to 10.7 per cent of GDP in 2020 (up from 9.1 per cent in 2019) in response to the Covid-19 pandemic, this was slightly lower than the EU average of 10.9 per cent of GDP. However, the methods through which such financing and reimbursements take place has not changed following Covid-19.</p>
5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?
<p>All Maltese citizens and EU residents with a European Health Insurance Card (EHIC) and all residents covered by social security legislation or humanitarian exemption can access the healthcare system. Medical service suppliers or providers are required to be licensed when undertaking licensable activities (such as importation or wholesale of medicinal product). The conditions for admission vary depending on the licence being sought and the subject matter in question. For example, a different licensing regime applies to manufacturers of medical cannabis compared to manufacturers of other medicinal products.</p>
HEALTH INSURANCE FINANCING AND COVERAGE
6. How are health insurance carriers financed? How are premiums determined?
<p>Health insurance companies are largely financed by the premiums paid by their insured and the investments made by the insurance undertaking.</p> <p>Premiums to be paid are determined based on the policies taken out by the patient. Treatments are often categorised in the following manner:</p> <ol style="list-style-type: none">1. inpatient treatment (hospital stays of one or more nights);2. day patient treatment (no overnight stays); or

3. outpatient treatment (treatment received from a medical practitioner which does not require a stay in hospital either as an in-patient or day-patient).

7. How is coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in person medical appointments and telemedicine appointments?

Insurance carriers are regulated by the Malta Financial Services Authority. Insurance carriers are free to define the coverage that they offer, and the carrier can choose to differentiate between in-person appointments and telemedicine appointments. As mentioned above, treatments are often categorised in the following manner:

1. inpatient treatment (hospital stays of one or more nights);
2. day patient treatment (no overnight stays); or
3. outpatient treatment (treatment received from a medical practitioner which does not require a stay in hospital either as an in-patient or day-patient).

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

Services provided by hospitals and ambulatory settings in the public healthcare sector are financed by the government and are free of charge to the patient (in public healthcare centres). However, a significant portion of the population elects for private general practitioners (GPs). In the private sector, these services are typically funded through fixed or flat pricing per treatment and the patient would be required to pay for these services as an out-of-pocket expense after receipt of the service.

9. How are the prices of such services determined? How is economic efficiency controlled?

The private sector, which mainly provides primary and ambulatory care, operates in a free market where prices are not determined or regulated by the government. If a person goes to a private GP, there will be no reimbursement by the government.

The prices in the public sector for such services are determined by the government and the marketing authorisation holder at the point in time that the service is procured by government (through public tendering). Eligible patients would receive these services free of charge as these are funded through general taxation and national insurance payments.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

In the private sector, services are typically paid for by the patient as an out-of-pocket fee after receipt of the services. There are certain medical services and procedures which may be covered by insurance providers, but this will depend on the provider and the service being offered.

In the public sector, these services are covered by the government and are free of charge to the patient at the point of service provision.

11. How are the prices of such services determined? How is economic efficiency controlled?

In the private sector, physicians, therapists, laboratories and other service providers are free to determine their own pricing methods. Typically, pricing is provided on a fixed/flat pricing per treatment category/indication basis. Furthermore, insurance providers will typically have a schedule of reasonable fees that the provider is willing to cover and if a service cost more than the value that is found in that schedule, the provider will only cover the patient up to the amount stated in the schedule.

In the public sector, services are covered by the government and the patient receives such services free of charge. The services are carried out in public healthcare centres or public hospitals, and the physicians, therapists, laboratories and other service providers are employed and paid by the government (generally as salaries based on national salary scales as opposed to fee-for-service). Practitioners are free to practice in both public and private healthcare sector.

PHARMACEUTICALS AND MEDICAL DEVICES

12. How are pharmaceuticals and medical devices financed and reimbursed?

Medicinal products found on the national formulary list are provided to patients free of charge at the point of administration or collection. Marketing authorisation holders are compensated by the government at the point of the government's procurement (generally through public procurement processes) of the product. The government also operates a scheme known as the Pharmacy of Your Choice Scheme (POYC), which allows eligible patients to obtain medicinal products forming part of this scheme free of charge: these products will be delivered to the pharmacy requested by the patient. Patients who are entitled to the POYC scheme are outlined in the Social Security Act (Chapter 318 of the Laws of Malta).

In the private sector, patients are typically required to pay for pharmaceuticals and medical devices themselves, either directly or through insurance coverage if applicable to the products or devices in question.

13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?

As stated above, the price of the pharmaceutical and medical device in the public sector is determined by the marketing authorisation holder when applying to have the products included on the national formulary list. The Pharmaceutical Pricing Unit (one of the functional units within the Directorate for Pharmaceutical Affairs) is responsible for:

- contributing to fair pricing of medicines in the Government Health Services;
- calculating the maximum reference price (MRP), external reference price (ERP) and guidance reference price (GRP) according to the internal standard operating procedure.

This unit calculates these prices to assist and serve as a reference price control during the procurement process of all the medicines. The prices are also included in the process of internal studies conducted for the purposes of health technology assessments of new medicines proposed for introduction onto the government formulary list.

In the private sector, the marketing authorisation holder, distributor or importer of the product or device typically determines the price to be charged to patients.

LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT

14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.

In the public healthcare sector, there are several cases that are litigated before the Public Contracts Review Board, whose function is to hear and determine complaints submitted by any person having or having had an interest in obtaining a particular public supply, public service or public works contract. Many of these cases relate to the pricing of medicinal products and devices, and the competitive advantage (or disadvantage) that interested persons may have in their bid.

RECENT DEVELOPMENTS AND TRENDS

15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes, or trends for healthcare financing and reimbursement and briefly indicate how these may foreseeably affect the medical sector in the near future.

Malta's main public hospital is currently experiencing a severe bed shortage and overcrowding issue. The government is working towards identifying additional premises to expand the provision of national healthcare services throughout the island in order to alleviate the pressure that is being put onto the public healthcare system as a result of this issue.

Malta's *National Health Systems Strategy for 2023–2033* (published in September 2024) also highlights how Malta's rapidly changing sociodemographic landscape, and the existing and anticipated significant technological and medical developments, have required the country to be more responsive and flexible to meet the needs of patients, as well as the population. We therefore expect there to be a greater emphasis placed on improving and developing the telemedicine sector, as well as the online/internet pharmacy space over the next few years.