PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Brief: Malta 2021

Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series

Commissioned by the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection

Gesundheit Österreich GmbH

PPRI Pharma Brief: Malta 2021

Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series

Authors
Stefan Meli (Directorate for Pharmaceutical Affairs, Ministry for Health)
Sylvana Magrin Sammut (Directorate for Pharmaceutical Affairs, Ministry for Health)

Reviewers
Jennifer Farrugia (Directorate for Pharmaceutical Affairs, Ministry for Health)
Antonia Formosa (Directorate for Pharmaceutical Affairs, Ministry for Health)

Guardamangia, 08th June 2022

Commissioned by the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection

Gesundheit Österreich GmbH

Suggestion for citation: Meli Stefan, Magrin Sammut Sylvana (2022): PPRI Pharma Brief: Malta 2021. Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series. Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), Vienna

P4/33/4493

Owner, editor and publisher: Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), Stubenring 6, 1010 Vienna, Austria, Tel. +43 1 515 61, websites: www.goeg.at and https://ppri.goeg.at

This report contributes to the implementation of the 2030 Agenda for Sustainable Development, in particular to Sustainable Development Goal (SDG) 3 "good health and well-being" and its target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

About PPRI Pharma Briefs

This concise report on the pharmaceutical pricing and reimbursement policy framework in Malta is part of the series of PPRI Pharma Briefs launched by the Pharmaceutical Pricing and Reimbursement Information (PPRI) Secretariat in 2019.

PPRI networks

The PPRI network is a collaboration of **pharmaceutical pricing and reimbursement authorities** of 50 – mostly European – countries (as of 2022) as well as international and European institutions (e.g. European Commission, OECD, World Health Organization). The aim of this network is to facilitate exchange between public officials, supported by scientific evidence and a common understanding of pharmaceutical policy issues. Under the framework of PPRI, further regional PPRI networks (e.g. in Central Asia) and thematic PPRI networks (e.g. on medical devices) have been established. PPRI networks are coordinated by the PPRI Secretariat which is hosted at the Pharmacoeconomics Department of the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG).

PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI contributes to the international scientific evidence base, in particular in the areas of (comparative) **pharmaceutical systems research** and pharmaceutical policy analysis, by providing country information that is usually not published in other literature. This is of interest for policy-makers who want to cross-learn and benchmark as well as for researchers who perform policy analyses and require contextual information on national pharmaceutical systems.

PPRI country information

Well-established publications that offer pharmaceutical pricing and reimbursement information on a single PPRI country are the **PPRI Pharma Profiles** that are available as in-depth reports as well as short reports, see https://ppri.goeg.at/ppri_pharma_profiles. Furthermore, one-page graphical abstracts are provided in the **PPRI Posters**, see https://ppri.goeg.at/ppri_posters.

The new series **PPRI Pharma Briefs** responds to the interest and needs expressed by policy-makers and technical experts in public authorities responsible for the pricing and reimbursement of medicines to read concise reports of the pharmaceutical policies in other countries.

The PPRI Pharma Briefs draw upon the information and data that have been provided by the PPRI network members, in addition to literature and relevant documents, such as legal provisions.

For requests and comments, please contact ppri@goeg.at.

Key data at a glance

General and economic data

Population (2020)	516,100
Country size (2021)	316 km²
Gross domestic product / GDP (2020)	GDP per capita: USD PPP 28,746
Health expenditure / HE (2020)	HE per capita: € 3,378.54 USD PPP 3,820.00 HE in % of GDP: 13.29% Public HE as % of total HE: 75.52%
Pharmaceutical expenditure / PE (2020)	PE per capita: €567.74 USD PPP 641.87 PE in % of HE: 16.803% Public PE as % of total PE: 43.68%

GDP = gross domestic product, HE = health expenditure, PE = pharmaceutical expenditure, PPP = Purchasing Power Parties, USD = United States dollars

Sources: Population – NSO World Population Day 2020 [1,2]; Country size – NSO Environment Statistics 2006 [2,3]; Gross domestic product – OECD [4]; Health expenditure – OECD Health Spending [5]; Pharmaceutical expenditure – OECD Pharmaceutical Spending [6] and OECD Country statistical profile: Malta [4]

Provision of pharmaceuticals

Community pharmacies (14.12.2021)	230
Dispensing doctors	0
Wholesale (2021)	Number of wholesale companies: 84
Pharmaceutical industry	Number of companies (manufacturers): 27 Number of companies (importers): 20 Research-based companies: N/a

Sources: Community pharmacies – pharmacy.com.mt [7]; Wholesale companies – Malta Medicines Authority [8]; Manufacturing/importing companies – Malta Medicines Authority [9]

Pharmaceutical market

Pharmaceutical market	€ 196m
Medicines (2021)	8,173 medicines authorised (counted including different pharmaceutical forms and dosages) 763 medicines (counted including different pharmaceutical forms and dosages) included in the outpatient reimbursement list (December 2021)
Generic market shares	N/a (value and volume – reimbursement segment)

Sources: Pharmaceutical market value – The Pharmaceutical Industry in Figures (2021), EFPIA [10]; Authorised medicines – Medicines Database, Malta Medicines Authority [11]; Reimbursed outpatients medicines – Government Formulary List (Out Patients List), Directorate for Pharmaceutical Affairs [12]

Pharmaceutical pricing (2021)

Price regulation	No, this applies for reimbursable and non-reimbursable outpatients and inpatients medicines.
Pricing authorities	**Outpatient and inpatient**: There are no pricing authorities as pharmaceutical pricing is not regulated in Malta. For new medicines on the Government Formulary List (GFL), a Maximum Reference Price is calculated by the Pharmaceutical Pricing Unit at the Directorate for Pharmaceutical Affairs. For other medicines on the GFL, price control is achieved by procuring through a tendering system.
Key pricing policies	**External price referencing**: In place, for reimbursable outpatient and inpatient medicines in the public sector. In place on a voluntary basis in the private sector. **Value-based pricing**: Not in place **Price negotiations**: In place, for some reimbursable outpatient and inpatient medicines with no competition. **Managed-entry agreements**: This is used for some reimbursable outpatient and inpatient medicines, particularly high-cost items. These are mostly financial schemes. **Tendering**: This is used for the vast majority of reimbursable outpatient and inpatient medicines. **Cost-plus pricing**: Not in place **Generic price link**: Not in place **Biosimilar price link**: Not in place
Pricing in the supply chain	**Wholesale**: No **Pharmacy**: No. In common practice, retail community pharmacies set retail prices of medicines at a mark-up of +20% on the wholesale prices recommended by wholesale distributors. **Value-added tax**: 0% for medicines (standard VAT 18%)

Source: VAT rate - Fifth Schedule of the Value Added Tax Act (Chapter 406 Laws of Malta), Office of The Commissioner for Revenue [13]

Pharmaceutical reimbursement (2021)

Reimbursement authorities	**Outpatient:** Ministry for Health **Inpatient:** Ministry for Health
Reimbursement lists	**Outpatient:** Outpatients Formulary List **Inpatient:** Hospital Formulary List (GFL)
Reimbursement criteria	**Outpatient and Inpatient**: Inclusion decisions are based on health technology assessments prepared by the Directorate of Pharmaceutical Affairs at the Ministry of Health. As per Legal Notice 58 of 2009, criteria for inclusion on the GFL shall consider: • Registration status of the medicinal product in Malta. • Whether the medicinal targets of one of the 87 conditions for which free outpatient medical aid may be accorded, as specified in the Fifth Schedule of the Social Security Act • Diagnostic and other requirements or costs for the prescription, use and monitoring of the medicinal product • Value, extent and relevance of the information and evidence available, particularly in terms of innovation, therapeutic effectiveness and improvement, safety, efficacy, impact on quality of life, availability and versatility of medicinal product, cost-effectiveness, comparison to other available medicines and other treatment modalities • Cost and economic evaluation As per the Health Act (Cap. 528) of 2013, inclusion on the list of benefits provided directly or indirectly by the public healthcare system shall be based on:

	• international evidence • health technology assessments • consultation with relevant stakeholders • capacity within the public health system • social and epidemiological considerations • affordability and sustainability
Co-payments for medicines	**In the public sector:** No co-payments in the in- and outpatient sector **In the private sector:** In the private sector some people may have private health insurance which may include full or co-payments depending on the case.
Demand-side measures to enhance the uptake of off-patent medicines	**Reference price system:** No **Prescribing by International Non-Proprietary Name (INN):** Mandatory unless: (i) prescription involves a biological product, (ii) prescriber deems it medically necessary to prescribe a specific brand. **Generic substitution:** Allowed (unless prohibited by the prescriber in a specific case)

Source: Reimbursement lists - The Government Formulary List, Directorate for Pharmaceutical Affairs [14]; Reimbursement criteria - Legal Notice 58 of 2009 [15] and the Health Act (Cap. 528) of 2013 [16]; Demand side measures - Subsidiary Legislation 458.49: Prescription and Dispensing Requirements Rules [17]

Key technical terms are defined in the glossary in Annex 2.

Summary

The entity responsible for the regulatory framework for pharmaceuticals and pharmaceutical activity in Malta is the Malta Medicines Authority [18]. Amongst other activities, the Malta Medicines Authority is responsible for regulating the entrance of medicines onto the Maltese market as stipulated in the Medicines Act [18].

Pharmaceutical pricing and reimbursement fall within the remit of the Ministry for Health and involves a multi-stage process that includes various entities within the Ministry. The Superintendent of Public Health (SPH) is legally responsible for implementing regulations related to the introduction of medicines onto the Government Formulary List (GFL), as stipulated in Legal Notice 58 of 2009 which describes regulations related to the availability of medicines within the Government Health Services [15]. Two consultative committees recommend which medicines should be included on the GFL based on presented evidence from HTAs. These are the Government Formulary List Advisory Committee (GFLAC) - a technical committee, and the Advisory Committee for Health Care Benefits (ACHCB) - a financial committee.

Production and presentation of HTAs falls within the remit of the Directorate for Pharmaceutical Affairs (DPA), which forms part of the Department for Policy in Health [19]. As per the Health Act (Cap. 528) of 2013, the Department for Policy in Health, which in turn falls under the responsibility of the Chief Medical Officer, is responsible for providing advice on Government health policy to the Minister for Health [16].

Medicines which are included on the GFL and are therefore provided free of charge by the Government Health Service, are centrally procured by the Central Procurement and Supplies Unit (CPSU). This is done via a price-driven tendering process where the cheapest offer that fits a set of technical specifications is opted for so as to promote competition in line with EU public procurement regulations. There are exceptions to this rule where prices of some medicines may also be negotiated in cases where industry stakeholders fail to participate in tenders or where there is no competition. Financially based managed entry agreements are also in place for some high-cost items. Price control is also achieved by means of Maximum Reference Prices which are determined during the HTA process based on a system of external reference pricing, and as decided by the GLFAC and ACHCB. These are set in the published tenders as an upper limit for bidders. The above applies for both outpatient and inpatient medicines included in the public sector.

Both wholesale and community pharmacy remunerations are unregulated in Malta. In common practice, retail community pharmacies set retail prices of medicines at a mark-up of +20% on the wholesale prices recommended by wholesale distributors. The standard VAT rate is 18%. However, in Malta this does not apply to medicines as the VAT rate for medicines is 0% [13].

The Government of Malta provides medicines free of charge via the public health system. From a reimbursement policy perspective, the provision of free medicines is legally mandated in the Fifth Schedule of the Social Security Act which specifies 87 chronic conditions, for which free medicines can be provided by the Government Health Service on an outpatient basis [20]. Certain medicines

are also provided free of charge as a form of social assistance to means tested patients as per the Second Schedule of the same Act. Reimbursed medicines need to be listed on the GFL, which is the positive reimbursement list and comprises two lists, namely, the Hospital Formulary List and the Out-Patients Formulary List [14]. The GFL lists the international non-proprietary name of medicinal products (INN), the dosage form and strength, and other information such as entitlement and the category of physicians who can prescribe a particular medicine. The Out-Patients Formulary List is intended for use by the Pharmacy of Your Choice (POYC) scheme and by government pharmacies [12,14].

Both the Hospital Formulary List and the Outpatients Formulary List are managed by the Formulary Management Unit (FMU) at the Directorate for Pharmaceutical Affairs [21].
Applications for new medicines to be included on the GFL are received from Marketing Authorisation Holders (MAHs) or from clinical consultants by DPA. After vetting, the HTA Unit at DPA prepares HTAs and presents them to the GFLAC. The remit of the GFLAC is to recommend approval of the inclusions of drugs onto the GFL to the ACHCB on the information presented in the HTA, as compared to other drugs within the context of a clinical pathway. The GFLAC also recommends a maximum reference price, as guided by the HTA. The ACHCB in turn advises the Minister for Health on whether the drug should be included onto the GFL or not, basing their recommendation on considerations related to budget impact, sustainability, and capacity within the context of the national public health system. The Minister for Health then gives final endorsement for the inclusion of a medicine onto the GFL. This process applies both for inpatient and outpatient medicines.

The Maltese national healthcare system does not include any form of co-payment and all medicines listed in the Government Formulary List are 100% reimbursed to entitled patients. In the private sector, payments are either 100% out-of-pocket, or they may be fully or partially reimbursed depending on the private health insurance policy coverage.

As stipulated in Subsidiary Legislation 458.49: Prescription and Dispensing Requirements Rules, prescribing by INN is mandatory unless the prescription involves a biological product, or the prescriber deems it medically necessary to prescribe a specific brand [17]. Generic substitution is allowed unless prohibited by the prescriber [17].

Keywords

Pricing, reimbursement, pharmaceutical policies, pharmaceutical system, Malta

Summary in local language

L-entità risponsabbli għall-qafas regolatorju għall-farmaċewtiċi u attivitajiet relatati f'Malta hijja l-Awtorità dwar il-Mediċini [18]. Fost attivitajiet oħra, l-Awtorità dwar il-Mediċini għandha r-responsabbiltà li tirregola d-dħul ta' mediċini ġodda fuq is-suq Malti kif inhu stipulat fl-Att dwar il-Mediċini [18].

L-ipprezzar ur-rimbors tal-farmaċewtiċi jaqa' taħt ir-risponsabbiltà tal-Ministeru tas-Saħħa, u jinvolvi proċess b'ħafna stadji li jinkludi entitajiet varji fi ħdan il-Ministeru. Is-Suprintendent tas-Saħħa Pubblika (SPH) huwa/hija legalment risponsabbli għal l-implimentazzjoni tar-regoli rrelatati ma' l-introduzzjoni tal-mediċini fuq il-Lista Formularja tal-Gvern (GFL), skond kif inu sstipulat fl-Avviż Legali 58 ta' l-2009 li jiddeskrivi r-regolamenti dwar id-disponibbiltà ta' prodotti mediċinali fis-Servizzi tas-Saħħa tal-Gvern [15]. Żewġ kumitati konsultattivi jirrakkomandaw liema mediċini għandhom jiġu nklużi fuq il-GFL abbażi ta' evidenza ppreżentata mill-HTAs. Dawn huma l-Kumitat Konsultattiv dwar Lista Formularja tal-Gvern (GFLAC) - kumitat tekniku, u l-Kumitat Konsultattiv dwar i-Benefiċċji tas-Saħħa (ACHCB) - kumitat finanzjarju.

It-tħejjija u l-preżentazzjoni ta' l-HTAs taqa' taħt ir-responsabbiltà tad-Direttorat għal l-Affarjiet Farmaċewtiċi (DPA), li jifforma parti mid-Dipartiment għall-Politika tas-Saħħa [19]. Skond l-Att Dwar is-Saħħa (Kapitolu 528) ta' l-2013, id-Dipartiment għall-Politika tas-Saħħa, li taqa' taħt ir-responsabbiltà ta' l-Uffiċjal Mediku Ewlieni tal-Gvern (CMO), huwa nkarigat illi jgħati pariri dwar il-kwistjonijiet kollha rrelatati mal-politika tas-saħħa tal-Gvern lill-Ministru tas-Saħħa [16].

Il-mediċini li huma inklużi fuq il-GFL, u li allura huma pprovduti bla ħlas mis-servizzi tas-saħħa, huma akkwistati mis-*Central Procurement and Supplies Unit* (CPSU) permezz ta sistema ta' *tenders* fejn il-prodott bl-iktar prezz baxx, iżda li jaqbel ma' l-ispeċifikazzjonijiet tekniċi, jiġi mgħażul. Dan sabiex tiġi promossa l-kompetizzjoni f'konformità mar-regolamenti tal-UE dwar l-akkwist pubbliku. Hemm eċċezzjonijiet għal din ir-regola fejn il-prezzijiet ta' xi mediċini jistgħu ukoll jiġu nnegozjati fejn ikun hemm nuqqas ta' parteċipazzjoni f'*tender*. Ċerti mediċini għoljin jiġu akkwistati permezz ta' *managed entry agreements* finanzjarji. Il-kontroll tal-prezz jinkiseb ukoll permezz ta Prezzijiet ta' Referenza Massimi (*Maximum Reference Prices, MRPs)* li huma ddeterminati matul il-proċess HTA abbażi ta' sistema ta' pprezzar ta' referenza esterna, u kif jiġi deċiż mill-GLFAC u l-ACHCB. Dawn jiġu stabbiliti fit-*tenders* ippubblikati bħala limitu massimu għall-offerenti. Dan kollu jgħodd għall mediċini li jintużaw ġewwa l-isptar, kif ukoll għall dawk li jintużaw barra, fis-settur pubbliku.

Ir-rimunerazzjonijiet fl-ingrossa, kif ukoll dawk fl-ispiżeriji tal-komunità f'Malta mhumiex irregolati. Fil-prattika komuni, l-ispiżeriji tal-komunità jistabbilixxu l-prezzijiet tal-mediċini b'żieda ta' +20% fuq il-prezzijiet bl-ingrossa rrakkomandati mid-distributuri bl-ingrossa. Ir-rata tal-VAT normali hija ta' 18%, iżda f'Malta din ma tapplikax għall-mediċini billi r-rata tal-VAT għall-mediċini hija ta' 0% [13].

Il-Gvern ta' Malta jipprovdi mediċini b'xejn lill-pazzjenti bħala parti mis-sistema tas-saħħa. Millat ta' politika ta' rimbors, l-għotja ta' mediċini bla ħlas hijja mħarsa fil-liġi, speċifikament fil-

Ħames Skeda ta' l-Att Dwar is-Sigurtà Soċjali li tisspeċifika l-erbgħa w tmenin marda u kundizzjoniji li dwarhom tista' tingħata għajnuna medika mis-Servizzi tas-Saħħa tal-Gvern barra mil l-isptar bla ħlas [20]. Ċerti mediċini huma mgħotijja bla ħlas bħala forma t'assistenza soċjali lil pazjenti li jkun sarilhom eżami tal-mezzi skond it-Tieni Skeda ta' l-istess Att Dwar is-Sigurtà Soċjali. Biex mediċina tkun tista tigi pprovduta b'xejn lill-pazzjenti bħala parti mis-sistema tas-saħħa, jeħtieġ li din tkun miżjuda fuq il-GFL, li hijja lista ta' mediċini li jistgħu jigu rrimborsati. Din hija maqsuma f'żewġ listi; il-Lista tal-Formularju ta' l-Isptar u l-Lista tal-Formularju tal-Pazjenti Esterni [14]. Il-GFL telenka l-isem internazzjonali mhux proprjetarju tal-mediċini (INN), il-forma ta' dożaġġ u l-qawwa, u informazzjoni oħra bħall-intitolament u l-kategorija ta' tobba li jistgħu jippreskrivu l-mediċina partikolari. Il- Lista tal-Formularju tal-Pazjenti Esterni hija maħsuba għall-użu mill-iskema tal-Ispiżerija tal-Għażla Tiegħek (POYC) u mill-ispiżeriji tal-gvern [12,14].

Kemm il-Lista tal-Formularju ta' l-Isptar kif ukoll il-Lista tal-Formularju tal-Pazjenti Esterni huma ġestiti mit-Taqsima tal-Ġestjoni tal-Formulari (FMU) fid-Direttorat għall-Affarijiet Farmaċewtiċi [21].

L-applikazzjonijiet biex mediċini ġodda jiżdiedu fuq il-GFL jiġu mibgħuta lid-DPA mingħand d-detenturi ta' l-awtorizzazzjoni għal tqegħid fis-suq (MAHs) jew mingħand konsulenti kliniċi. Wara eżaminar preliminarju, l-Unità ta' l-HTAs fi ħdan id-DPA tipprepara l-HTAs u tippreżentahom lill-GFLAC.

Il-mandat tal-GFLAC hu illi jirrakomanda l-approvazzjoni ta' l-inklużjoni tal-mediċini fuq il-GFL lill-ACHCB, u li tibbaża dawn ir-rakkomandazzjonijiet fuq l-informazzjoni mil l-HTAs li jkunu ġew ippreżentati li tinkludi wkoll paragun ma mediċini oħrajn f'kuntest ta' perkors kliniku. Il-GFLAC għandu wkoll il-kariga li jirrakomanda press massimu ta' referenza, skond kif ikun ġie ggwidat mill-HTA. L-ACHCB imbgħad tgħati parir lill-Ministru tas-Saħħa dwar jekk il-mediċina għandiex tidħol fil-GFL jew le, u tibbaża r-rakkomandazzjonijiet tagħha fuq l-impatt li jista jkollha l-mediċina fuq il-baġit, is-sostenibilità tagħha u l-kapaċità tas-sistema tas-saħħa. Wara dan il-proċess, biex il-mediċina tiġi inkluża fil-GFL, ikun meħtieg illi l-Ministru tas-Saħħa jgħati approvazzjoni finali. Dan il-proċess japplika kemm għal mediċini li jkunu ħa jintużaw ġewwa l-isptar, kif ukoll għal dawk li jkunu ħa jintużaw minn pazjenti esterni.

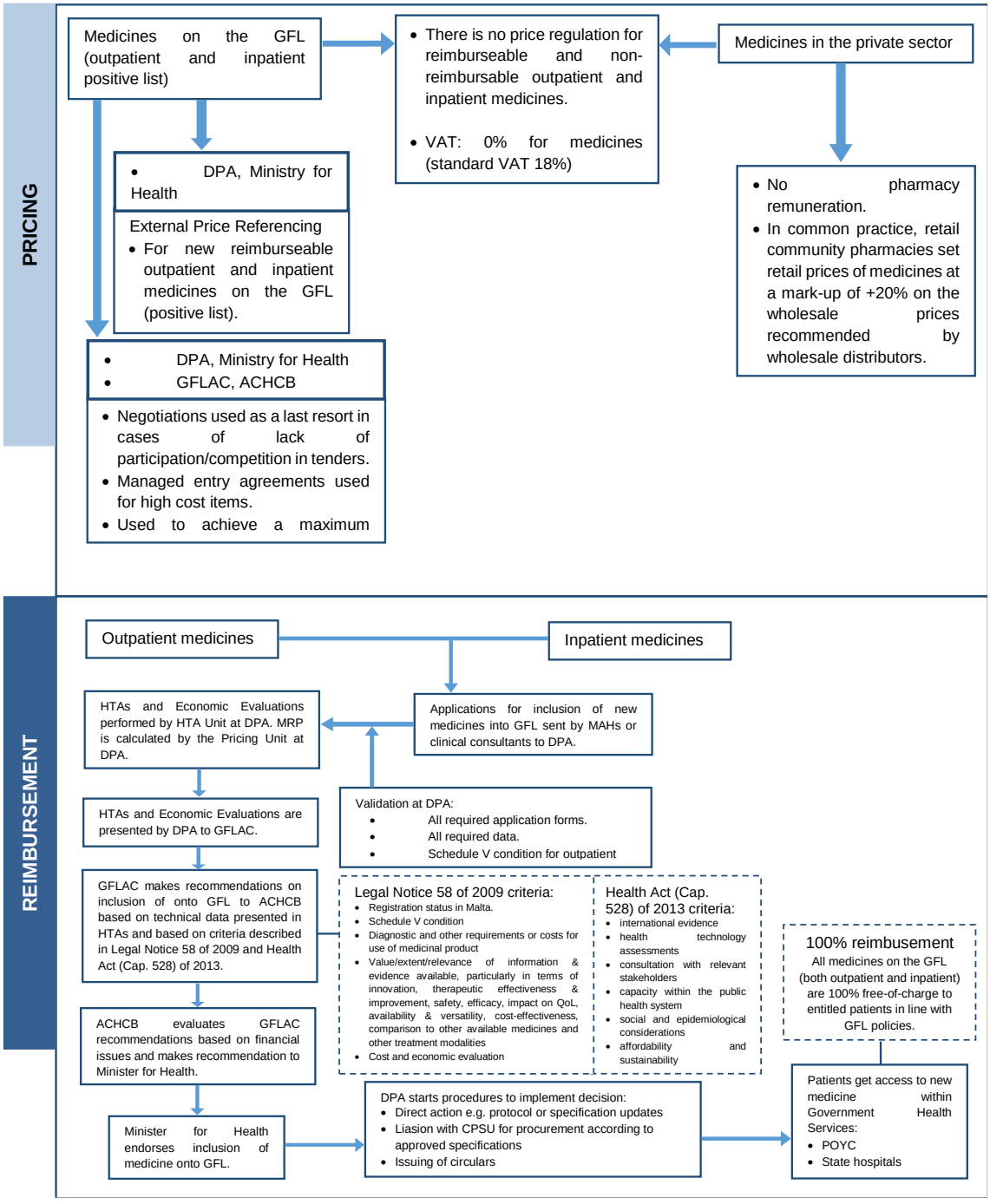
Is-sistema tas-saħħa f'Malta ma' tinkludi l-ebda forma ta' kopagament u l-mediċini huma pprovduti totalment b'xejn għal kull min hu intitolat. Fis-settur privat, il-ħlas jista jsir kollu kemm hu mill-pazjent, jew jista jkun kopert parzjalment jew totalment skont il-kopertura tal-polza t'assigurazzjoni privata.

Kif inhu sstipulat fil-Leġislazzjoni Sussidjarja 458.49: Regoli Dwar Il-Ħruġ Ta' Riċetti U Dispensa Ta' Mediċini, huwa obbligatorju illi r-riċetti jiġarġu skond l-isem internazzjonali mhux proprjetarju (INN), sakemm ir-riċetta ma tkunx waħda għal prodott bijoloġiku, jew sakemm min jikteb ir-riċetta ma jidhirlux li tkun ħtieġa medika illi l-ħruġ tar-riċetta ssir għal prodott ta' marka

speċifika [17]. Is-sostituzzjoni ġenerika hijja permessa, ħlief f'sitwazzjonijiet fejn din ġiet ipprojbita minn min kiteb ir-riċetta [17].

Graphical summary

Pharmaceutical pricing and reimbursement policies in the inpatient and outpatient sector



1 Framework

Pharmaceutical policy in Malta is not laid out in one single policy document, but rather, in several pieces of legislation. The key legal documents to this regard are the Medicines Act (Cap. 458), Legal Notice 58 of 2009 (Availability of Medicinal Products within the Government Health Services Regulations), the Health Act (Cap. 528) and the Social Security Act (Cap. 318) [15,16,20].

The key competent authority for regulatory affairs involving pharmaceuticals and pharmaceutical activity, including marketing authorisation, pharmacovigilance and inspections is the Malta Medicines Authority [23]. The Medicines Authority acts on behalf of the SPH as the Licensing Authority as per Subsidiary Legislation 458.39 (Delegation to Medicines Authority Order) [21]. The Medicines Act lays out the functions and responsibilities of the Licensing Authority on matters relating to the regulation of medicines and pharmaceutical activity [23].

From a market access perspective, the Malta Competition and Consumer Affairs Authority (MCCAA) aims to achieve fairer and more affordable medicine prices on the private market and cooperates with the Medicines Intelligence and Access Unit at the Malta Medicines Authority as well as medicine distributors to this regard. The MCCAA adopts a strategy of benchmark comparisons with medicines in 12 other reference countries via its Office for Consumer Affairs [24]. This provides the information upon which price reductions are based. This, together with collaborations with government entities ensures increased access, fairer prices, and sustainability [25].

With regards to pricing and reimbursement perspective, different entities within the Ministry for Health are responsible for different aspects of the process. The Chief Medical Officer is responsible for the health services provided to the public through the Ministry for Health. This includes the provision of free medical aid, including pharmaceuticals, within the National Health Service [26]. The Chief Medical Officer is also responsible for the development of pharmaceutical policies, the determination of entitlement to public health care services and the issuing of recommendations for new initiatives, also as guided by HTAs [26]. DPA is responsible for the receipt and vetting of applications for inclusion onto the GFL form MAHs or from clinical consultants. DPA is also responsible for calculating the Maximum Reference Price, for the production of HTAs and for presenting them to GFLAC, and for drawing up technical specifications for procurement. It is also responsible for the management of the GFL. GFLAC and ACHCB act as advisory committees for inclusion of medicines onto the GFL; the former basing their decision on evidence presented in HTAs and the latter on budget impact, sustainability, and capacity within the context of the national public health system. The Minister for Health is then responsible for final endorsement.

Medicines being considered for outpatients' use within the Government Health Services must target one of the 87 conditions listed in the Fifth Schedule of the Social Security Act (Article 23 of Chapter 318 of the Laws of Malta) [20]. Since this schedule describes only the chronic conditions for which free medicines can be provided by the National Health Service on an outpatient basis, this does not apply for inpatient medicines.

2 Pricing

Pricing at manufacturer price level

In the private sector, the pricing system operates on a voluntary basis and involves a system of external reference pricing which takes the average price of a medicine across a number of countries. According to the MCCAA, price data is sourced from 12 reference countries, and the method of processing this is subject to the terms of a voluntary agreement between the Government and the local pharmaceutical stakeholders [24]. There have also been recent instances where consultations between various stakeholders including local distributors, the Malta Medicines Authority, the MCCAA and the Parliamentary Secretary for Consumer Rights, Public Cleansing and Support for the Capital City led to voluntary agreements on price reductions of medicines in Malta [25].

In the public sector, a Reference Price to be paid for a medicine that will be supplied for free is calculated using a system of external reference pricing which includes prices from a basket of 11 EU countries falling within the bracket of +/- 20% of Malta's GDP per capita in Purchasing Power Standards using EUROSTAT figures (Cyprus, Czech Republic, Estonia, Hungary, Italy, Lithuania, Poland, Portugal, Slovakia, Slovenia, Spain), as well as the UK price [27]. In the case of new medicines to be included in the GFL, a Maximum Reference Price (MRP) is calculated by the Pharmaceutical Pricing Unit at DPA and is included in HTAs which are then presented to the advisory committees, GFLAC and ACHCB, for their recommendation of inclusion onto the GFL or otherwise [27]. This MRP is then used during tenders in a price-driven procurement process by CPSU, where the cheapest option considered suitable as per the approved technical specifications is opted for.

External Price Referencing applies to both inpatient and outpatient medicines and also to medicines already on the GFL. Reference prices are valid for 6 months and revisions are carried out as required if the 6-month period has elapsed. The External Reference Price (ERP) is the average price of the basket of countries. If prices are not found in a minimum of 3 countries within the basket, the ERP is called Guidance Reference Price (GRP).

Managed-entry agreements are also conducted for certain high-cost medicines. Price link policies are not in place in Malta.

Procurement

In Malta, procurement of pharmaceuticals on the GFL occurs via a centralized process. Hospitals do not carry out their own procurement of pharmaceuticals. The Government procurement entity in Malta for pharmaceuticals and medical devices is the Central Procurement and Supplies Unit within the Financial Management and Control Unit at the Ministry for Health.

Procurement of medicines in the public sector mostly consists of a price-driven system which is based on tenders. The cheapest option that fits the technical specifications in the tender is opted for and the tender value is published. This promotes competition in line with EU public procurement regulations. There are exceptions to this rule where prices of some medicines may also be negotiated as a last resort in cases where industry stakeholders fail to participate in tenders or

where there is no competition. Managed entry agreements are also in place for some high-cost items. Public procurement in Malta is regulated by Legal Notice 352 of 2016 (Public Procurement Regulations, 2016 - Arrangement of Regulations) and Legal Notice 350 of 2016 (Emergency Procurement Regulations, 2016 - Financial Administration and Audit Act (Cap. 174)) [28-30]. The process of public procurement is managed via the web-based Electronic Public Procurement System for all calls for tenders which aims to increase efficiency, transparency and security in public procurement whilst also respecting the legal principles mandated by legislation [31].

In Malta pharmacists play a substantial role, both in pricing and reimbursement, and in procurement. Pharmaceutical policy, HTA production, pricing, exceptional medicinal treatment requests and government formulary management tasks are performed nearly in their entirety by pharmacists at DPA. With regards to procurement, pharmacists at DPA, state hospitals and POYC engage with CPSU to discuss and manage issues related to stock management, technical specifications for procurement of both currently procured medicines and new ones, customer demands and medicine shortages. Pharmacists also occupy key roles in various decision-making committees which influence pricing, reimbursement and procurement decisions, including the GFLAC, the ACHCB, the Exceptional Medicinal Treatment Committee (EMTC), the Advisory Committee on Immunisation Policy (ACIP) and the Antibiotics Committee.

Pricing in the supply chain

Pricing of medicines is not regulated and a system of free pricing is in place. In common practice, retail community pharmacies set retail prices of medicines at a mark-up of +20% on the wholesale prices recommended by wholesale distributors.

The standard VAT rate is 18%. However, in Malta this does not apply to medicines as the VAT rate for medicines is 0%.

The hospital price corresponds to the wholesale price. However, hospital pharmacies may only sell medicines to outpatients when they are not available in community pharmacies, and in these cases, a 15% mark-up is applied.

3 Reimbursement

In Malta, outpatient and inpatient medicines that are on the Government Formulary List may be given free of charge to entitled patients. These are dispensed from Government Health Service stocks which may be present at state hospital pharmacies, as is the case for inpatient medicines and certain outpatient medicines, or at community pharmacies via the Pharmacy of Your Choice (POYC) scheme in the case of most outpatient medicines.

Reimbursement for outpatient medicines

Free outpatient medicines are given for the treatment of one of the eighty-seven chronic conditions for which free medicines can be provided by the Government Health Service on an outpatient basis as per the Fifth Schedule of the Social Security Act based on the presence of a medical condition and not on financial means [20]. The 87 conditions can be seen listed on the Outpatients Formulary list [12]. Patients who fall within a low-income bracket as determined by a means test are given a form of social assistance as per the Second Schedule of the same act [20]. This entitles them to certain essential medicines, medical devices, and dental and optical services. The reimbursement system does not operate as an insurance and patients do not need to ask for funding. They may obtain a prescription (free of charge from Government Health Service doctors, or paid for from their private doctors), and collect their medicines at regular intervals from the community pharmacy of their choice via the POYC scheme.

The POYC scheme distributes Government Health Service stocks of pharmaceuticals and certain medical devices to local community pharmacies [32]. In this decentralized system, patients are able to pick up their free medicines for chronic conditions on an outpatient basis from their local community pharmacies, thus avoiding the need to overload hospitals and health centres [32].

Applications for inclusion of medicines onto the GFL are considered by two consultative committees. GFLAC is the technical committee whilst ACHCB is the financial committee. The GFLAC is composed of a chairperson, two pharmacists who are also public officers, two clinicians from amongst the medical consultants who are public officers, a patient representative, a legal advisor who is a public officer and two economic advisors [15]. The ACHCB is composed of the Permanent Secretary in the Ministry, as Chairman, the Chief Medical Officer to Government, as Deputy Chairman, the Lead Chairperson of the Chairpersons Committee, a nurse, a pharmacist, an allied healthcare professional, a person who has the warrant to practice as advocate in Malta representing the Ministry, a representative of the Minister responsible for Finance, a representative of the Consumer Protection Department, a representative of the Central Procurement and Supplies Unit and an officer appointed by the Minister to act as secretary [16].

As per Legal Notice 58 of 2009, the GFLAC shall make a recommendation to the ACHCB on the inclusion of medicines onto the GFL. As per this same Act, their recommendations shall be based on the following [15]:

- Registration status of the medicinal product in Malta.
- Whether the medicinal targets of one of the 87 conditions for which free outpatient medical aid may be accorded, as specified in the Fifth Schedule of the Social Security Act.
- Diagnostic and other requirements or costs for the prescription, use and monitoring of the medicinal product.
- Value, extent and relevance of the information and evidence available, particularly in terms of innovation, therapeutic effectiveness and improvement, safety, efficacy, impact on quality of life, availability and versatility of medicinal product, cost-effectiveness, comparison to other available medicines and other treatment modalities.
- Cost and economic evaluation.

As per the Health Act (Cap. 528) of 2013, the ACHCB shall make a recommendation to the Minister for Health on the inclusion onto the GFL of medicines suggested by GFLAC based on international

evidence, health technology assessments, consultation with relevant stakeholders, capacity within the public health system, social and epidemiological considerations and affordability and sustainability [16].

The Minister for Health is then responsible for final endorsement.

The reimbursement system does not involve any co-payments since all medicines in the positive list are 100% reimbursed to entitled patients in line with entitlement criteria and GFL policies [20]. Patients will need to obtain a prescription and may get this free of charge from Government Health Service doctors, or at a fee from their private doctors.
The Government Health Service provides coverage which is nearly universal in its scope. It features no form of co-payment, cost-sharing or direct upfront payments, be it for medicines or for medical services for entitled patients. For patients who are not entitled to free medication in Malta, only medicines prescribed during hospital stays and the three days following discharge are provided free of charge.

Despite such universal coverage, out of pocket spending on pharmaceutical and healthcare remains quite high in Malta due to the widespread use of private primary care [33]. According to the 2019 Country Health Profile for Malta authored by the OECD, in 2017 Malta registered the joint fourth highest level of out-of-pocket spending in the EU: more than twice the EU average (34.6 % vs the EU average of 15.8 %) [4]. Medicines make up a large share of out-of-pocket spending in Malta, second only to spending on outpatient care [4]. In Malta, outpatient care is delivered both via public entities and via private GPs or specialists [4]. Cultural and societal preferences, the ability to select specific providers, the ability to access medicines not provided by the public system and the avoidance of long waiting lists present in the public sector have been suggested as reasons for the high rate of out-of-pocket spending on healthcare in Malta [34]. Despite the high level of spending on private healthcare, the level of unmet medical needs remains low in Malta [34].

Reimbursement for inpatient medicines

With regards to the inpatient sector, medicines pass through the same centralized process of assessment through GFLAC and ACHCB based on HTAs, and procurement via CPSU. Funding is also centralized as for outpatient medicines. State hospitals do not perform approval, funding, or procurement as this is all centralized via the Ministry for Health. The difference, as compared to medicines intended for outpatient use, is that whilst inpatient medicines are still subject to specific entitlement criteria and GFL policies, they do not need to target one of the eighty-seven chronic conditions mentioned in the Fifth Schedule of the Social Security Act.

Medicines approved for use in the inpatient setting are included on the Hospital Formulary List following the same approval procedure and criteria described for outpatient medicines, with the exception of need for a Fifth Schedule condition as described above [35]. As of September 2020, 1,287 medicines have been included in the Hospital Formulary List. The Hospital Formulary List is also managed and coordinated by the FMU within the DPA. Procurement is all centralized and hospitals can only procure what is on the hospital formulary list.

There is no co-payment for medicines in the inpatient sector either. All medicines listed in the Government Formulary List are 100% reimbursed to entitled patients in line with GFL policies.

Agreements

Details on MEAs in place in Malta are scarce as these agreements are all of a confidential nature. Such agreements are in place for some high-cost outpatient and inpatient medicines that are still under patent. The MEAs in place in Malta are of a financial nature and normally take the form of simple discounts, price-volume agreements or bundling agreements. Prices and content of these MEAs are confidential.

Demand-side measures

There is no reference price policy for reimbursements in which identical or similar medicines are clustered and reimbursed at the same set amount. Doctors within the Government Health Service do not operate under any budget caps and are free to prescribe drugs according to the criteria set in the Government Formulary List to entitled patients.

As stipulated in Subsidiary Legislation 458.49: Prescription and Dispensing Requirements Rules, prescribing by INN is obligatory unless the prescription involves a biological product, or the prescriber deems it medically necessary to prescribe a specific brand [17]. Generic substitution is allowed on a voluntary basis, unless prohibited by the prescriber [17].

Biosimilar substitution at pharmacy level is not allowed. However, 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 provided accordingly. A longer-term policy on the efficient management of biologics and biosimilars on the Government Formulary List is also currently under discussion. Furthermore, policy documents related to branded medicines for specific patient populations and also individual exceptional medicinal treatment requests are also in advanced stages.

4 Developments

General

Recent years have seen a number of major reforms in the public health system in Malta. A significant milestone was the introduction of the POYC scheme which enabled patients to obtain their free medicines from a community pharmacy of their choice, resulting in increased accessibility to medicines [32]. Since 2013, there has been a concerted effort by the Government to eradicate the problem of out of stock medicines. Amongst other initiatives, there has been an increase in funding allocation towards the procurement of medicines and an overhaul of the procurement system with the setting up of a new centralized storage facility.

A recent initiative that has been introduced with significant positive impact on patient access was 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. This initiative started as an oncology fund and has now been extended to other fields such as diabetes, cardiology, osteoporosis and psychiatry. Other recent initiatives include measures which have been taken to improve patient access, including the further addition of new chronic conditions in the Fifth Schedule of the Social Security Act that enable patients to be entitled to medicines on an out-patient basis. These include benign prostate enlargement, severe atopic dermatitis, hidradenitis suppurativa and chronic spontaneous urticaria. Efforts are underway to increase these conditions covered further in the coming years, e.g. osteoporosis.

From a legislative point of view, there have also been developments in recent years, the 2013 Health Act laid down the basic structure of public health entities within the Ministry for Health, namely the Department for Policy in Health, the Department for Health Services and the Department for Health Regulation as well as the role of the ACHCB and health technology assessments within the process of introduction of medicines onto the formulary [16]. Legal Notice 58 of 2018, introduced the legal obligation for the Government Health Services to consider approval of Exceptional Medicinal Treatment (EMT) requests, which are defined as medicines which are not on the GFL, are on the GFL but not being requested according to their criteria, are branded or are requested to treat a rare disease [36]. This brought about the introduction of a set of criteria for decision-making in EMTs, as well as a shift in decision-making responsibility from the Director at DPA and the Chief Medical Officer, to a newly formed EMT Committee appointed by the Minister for Health [36].

In 2019 there has also been a drive in capacity building within DPA. Several courses were launched at DPA via the European Social Fund, in collaboration with the Institute for Medical Technology Assessment at Erasmus University, Rotterdam. These focused on increasing knowledge of health economics and health technology assessments within the staff at DPA in order to strengthen local HTA processes. In 2020, DPA launched several projects and policies, including the Horizon Scanning project and the Branded Medicinal Products Policy. The Horizon Scanning project aims to improve strategic and financial planning and decision-making throughout the Ministry for Health by providing timely, early intelligence on potential new medicines currently under development.

DPA is also in the final stages of preparation of the Branded Medicinal Products Policy which will map out procedures involved for the switching of brands of medicines on the GFL in drugs where brand changes can have serious consequences, as well as entitlement procedures for specific populations. DPA are also working on a long-term policy on the efficient management of biologics and biosimilars on the GFL.

DPA are also spearheading the revamping of an internal IT infrastructure with the aim of moving from disconnected IT systems to a new multi-user solution based on secure web-enabled technology. This system has been integrated with the robotic system at Mater Dei Hospital which in 2021 will perform the dispensing of medicines in wards.

On an international front, in 2017, Malta co-founded the Valletta Declaration Group together with Cyprus, France, Italy, Greece, Portugal, and Spain [37]. The first seven countries were subsequently joined by Ireland, Romania, Slovenia, and Croatia. The Valletta Declaration Group is a cross-border pharmaceutical market access collaboration that focuses on discussing legal and political means to increase transparency on pharmaceutical pricing and to facilitate joint procurement initiatives, as well as information exchange on medicinal products, on policies for the use of medicines and good practices issues including biosimilars, advanced therapies, reference pricing, shortages and reimbursement [37].

5 References

1. Population, Migration and Crime Statistics Unit. *Glossary*. [homepage on the Internet]. Valletta: National Statistics Office; 2021 [cited 2021 Dec 14]. Available from: https://nso.gov.mt/en/News_Releases/Documents/2021/07/News2021_122.pdf.

2. Communication department of the European Commission. *About the EU: living in the EU*. Brussels: European Union; 2021 [cited 2021 Dec 14]. Available from: https://europa.eu/european-union/about-eu/figures/living_en#size

3. National Statistics Office. *Environment statistics 2006*. [homepage on the Internet]. Valletta: National Statistics Office; 2006 [cited 2020 Sep 14]. Available from: https://nso.gov.mt/en/publicatons/Publications_by_Unit/Documents/B3_Environment_Energy_Transport_Agriculture_Statistics/Environment_2006.pdf

4. OECD. *State of health in the EU: Malta - country health profile 2021*. [homepage on the Internet]. Paris: OECD; 2021 [cited 2021 Dec 14]. Available from: https://www.oecd-ilibrary.org/docserver/cd4b1ed7-en.pdf?expires=1641553767&id=id&accname=guest&checksum=5A556DFB1ECAEB87F971D0F8A72BE7E2

5. OECD. *Health spending*. [homepage on the Internet]. Paris: OECD; 2021 [cited 2021 Dec 14]. Available from: https://data.oecd.org/healthres/health-spending.htm#indicator-chart

6. OECD. *Parmaceutical spending*. [homepage on the Internet]. Paris: OECD; 2021 [cited 2021 Dec 14]. Available from: https://data.oecd.org/healthres/pharmaceutical-spending.htm

7. pharmacy.com.mt. *Pharmacies, clinics & health professionals directory*. [homepage on the Internet]. pharmacy.com.mt; 2021 [cited 2021 Dec 14]. Available from: http://www.pharmacy.com.mt

8. Malta Medicines Authority. *Authorised wholesale dealers in Malta*. [homepage on the Internet]. San Gwann: Malta Medicines Authority; [updated 2021 Jul 07; cited 2021 Dec 14]. Available from: http://www.medicinesauthority.gov.mt/file.aspx?f=455

9. Malta Medicines Authority. *List of licencesed manufacturers-importers*. [homepage on the Internet]. San Gwann: Malta Medicines Authority; [updated 2020 Oct 22; cited cited 2021 Dec 14]. Available from: http://www.medicinesauthority.gov.mt/file.aspx?f=454

10. EFPIA. *The pharmaceutical industry in figures - Key data 2021*. [homepage on the Internet]. Brussels: EFPIA; 2021 [cited 2021 Dec 23]. Available from: https://www.efpia.eu/media/602709/the-pharmaceutical-industry-in-figures-2021.pdf

11. Malta Medicines Authority. *National products*. [homepage on the Internet]. San Gwann: Malta Medicines Authority; [updated 2021; cited 2021 Dec 14]. Available from: http://www.medicinesauthority.gov.mt/Exports/Local/AdvancedSearchResultsLocal.xls

12. Directorate for Pharmaceutical Affairs. *Out-patients formulary list.* [homepage on the Internet]. Guardamangia: Directorate for Pharmaceutical Affairs; [updated 2021 Dec; cited 2021 Dec 23]. Available from: https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/formulary/formulary.aspx

13. Ministry for Justice, Culture and Local Government. *Value added tax act (cap. 406.), 1999.* Valletta: Ministry for Justice, Culture and Local Government; 1999.

14. Directorate for Pharmaceutical Affairs. *The government formulary list.* [homepage on the Internet]. Guardamangia: Directorate for Pharmaceutical Affairs; [updated 2021 Dec; cited 2021 Dec 23]. Available from: https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/formulary/formulary.aspx

15. Ministry for Justice, Culture and Local Government. *L.N. 58 of 2009, Availability of medicinal products within the government health services regulations, 2009.* Valletta: Ministry for Justice, Culture and Local Government; 2009.

16. Ministry for Justice, Culture and Local Government. *Health act (cap. 528.), 2019.* Valletta: Ministry for Justice, Culture and Local Government; 2013

17. Ministry for Justice, Culture and Local Government. *Subsidiary legislation 458.49: Prescription and dispensing requirements rules.* Valletta: Ministry for Justice, Culture and Local Government; 2006.

18. Malta Medicines Authority. *Mission and objectives.* [homepage on the Internet]. San Gwann: Malta Medicines Authority; [updated 2021 Dec; cited 2021 Dec 23]. Available from: http://www.medicinesauthority.gov.mt/missionobjectives?l=1

19. Directorate for Pharmaceutical Affairs. *Health technology assessment unit.* [homepage on the Internet]. Guardamangia: Directorate for Pharmaceutical Affairs; [updated 2021 Dec; cited 2021 Dec 23]. Available from: https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/assessment-unit.aspx

20. Ministry for Justice, Culture and Local Government. *Social security act, (cap. 318.).* Valletta: Ministry for Justice, Culture and Local Government; 1987.

21. Directorate for Pharmaceutical Affairs. *Formulary Management Unit.* [homepage on the Internet]. Guardamangia: Directorate for Pharmaceutical Affairs; [updated 2021; cited 2021 Dec 23]. Available from: https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/formulary.aspx

22. Ministry for Justice, Culture and Local Government. *Subsidiary legislation 458.39: Delegation to medicines authority order.* Valletta: Ministry for Justice, Culture and Local Government; 2004.

23. Ministry for Justice, Culture and Local Government. *Medicines act, (cap. 458.).* Valletta: Ministry for Justice, Culture and Local Government; 2003.

24. Malta Competition and Consumer Affairs Authority. *Annual Report 2020.* [homepage on the Internet]. Blata l-Bajda: Malta Competition and Consumer Affairs Authority; [updated 2021; cited 2021 Dec 23]. Available from: https://mccaa.org.mt/media/6963/2020-annual-report-mccaa_one-page.pdf

25. Malta Competition and Consumer Affairs Authority. *Price reductions on 29 medicines.* [homepage on the Internet]. Blata l-Bajda: Malta Competition and Consumer Affairs Authority; [updated 2019 May 08; cited 2021 Dec 23]. Available from: https://mccaa.org.mt/Section/Content?contentId=4011

26. Office of the Chief Medical Officer. *Chief medical officer.* [homepage on the Internet]. Guardamangia: Office of the Chief Medical Officer; [updated 2021; cited 2021 Dec 23]. Available from: https://deputyprimeminister.gov.mt/en/CMO/Pages/Chief-Medical-Officer.aspx

27. Directorate for Pharmaceutical Affairs. *Pharmaceutical pricing unit.* [homepage on the Internet]. Guardamangia: Directorate for Pharmaceutical Affairs; [updated 2021; cited 2021 Dec 23]. Available from: https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/pharmaceutical-pricing.aspx

28. Ministry for Justice, Culture and Local Government. *L.N. 352 of 2016, Public procurement regulations, 2016.* Valletta: Ministry for Justice, Culture and Local Government; 2016.

29. Ministry for Justice, Culture and Local Government. *L.N. 350 of 2016, Emergency procurement regulations, 2016.* Valletta: Ministry for Justice, Culture and Local Government; 2016.

30. Ministry for Justice, Culture and Local Government. *Financial administration and audit act (cap. 174.).* Valletta: Ministry for Justice, Culture and Local Government; 1962.

31. Department of Contracts. *Electronic public procurement system (ePPS).* [homepage on the Internet]. Floriana: Department of Contracts; [updated 2021 Dec; cited 2021 Dec 23]. Available from: https://www.etenders.gov.mt/epps/home.do

32. Pharmacy of Your Choice Unit. *About us.* [homepage on the Internet]. Guardamangia: Pharmacy of Your Choice Unit; [updated 2021 Dec; cited 2021 Dec 23]. Available from: https://deputyprimeminister.gov.mt/en/poyc/Pages/About%20Us.aspx

33. Azzopardi-Muscat N, Buttigieg S, Calleja N, Merkur S. *Malta: health system review, 2017*. [homepage on the Internet]. Brussels: European Observatory on Health Systems and Policies; 2017 [cited 2021 Dec 28]. Available from: https://www.euro.who.int/__data/assets/pdf_file/0009/332883/Malta-Hit.pdf?ua=1

34. European Commission. *Country report Malta 2019*. [homepage on the Internet]. Brussels: European Commission; 2019 [cited 2021 Dec 28]. Available from: EU Malta: https://ec.europa.eu/info/sites/info/files/file_import/2019-european-semester-country-report-malta_en.pdf

35. Directorate for Pharmaceutical Affairs. *Hospital formulary list*. [homepage on the Internet]. Guardamangia: Directorate for Pharmaceutical Affairs; [updated 2021 Dec 30; cited 2021 Dec 30]. Available from: https://deputyprimeminister.gov.mt/en/pharmaceutical/Documents/GFL/hosp_gfl_dec_2021.pdf

36. Ministry for Justice, Culture and Local Government. *Exceptional medicinal treatment committee regulations, (S.L.528.08)*. Valletta: Ministry for Justice, Culture and Local Government; 2018.

37. South EU Summit. *Valletta declaration*. [homepage on the Internet]. South EU Summit; [updated 2021; cited 2021 Dec 30]. Available from: https://southeusummit.com/about/valletta-declaration/

6 Annex

Annex 1: Stakeholders

Role	Name in local language (Maltese &/or English)	Website(s)
Competent authority for marketing authorisation of medicines	Malta Medicines Authority	http://www.medicinesauthority.gov.mt/
Competent authority for pricing of medicines	Direttorat għall-Affarijiet Farmaċewtiċi (Directorate for Pharmaceutical Affairs)	https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/pharmaceutical-affairs.aspx
Competent authority for reimbursement of medicines (outpatient)	Direttorat għall-Affarijiet Farmaċewtiċi (Directorate for Pharmaceutical Affairs)	https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/pharmaceutical-affairs.aspx
Public payer(s) for outpatient medicines	Ministeru għas-Saħħa (Ministry for Health)	https://deputyprimeminister.gov.mt/
Public payers for inpatient medicines	Ministeru għas-Saħħa (Ministry for Health)	https://deputyprimeminister.gov.mt/
Patients organisations	e.g. • National Patients' Organisation – Malta • Malta Health Network	• N/a • https://www.maltahealthnetwork.org/
Consumers organisations	• Għaqda tal-Konsumaturi (Consumers' Association Malta) • Association of Consumer Rights	• http://camalta.org.mt/ • http://www.acrmalta.com/
Pharmacy associations	• Kamra tal-Ispiżjara (Malta Chamber of Pharmacists) • Malta Association of Hospital Pharmacists	• https://spizjara.org/ • http://www.mahp.org.mt/
Industry associations	Pharmaceutical Research Based Industry Malta Association	N/a
Wholesale association	Association of Medical Representatives- Malta	https://amrcommitteemalta.wixsite.com/amrmalta

Source: Websites as per above table

Annex 2: Glossary

claw-back	A policy where funds already paid by public payers to pharmaceutical companies, wholesalers or pharmacists have to be paid back to the third party payers under certain conditions (e.g. if a certain threshold is exceeded).
community pharmacies	Health care facilities which dispense medicines (prescription-only medicines and/or non-prescription medicines, reimbursable and/or non-reimbursable medicines) to outpatients.
co-payment	Insured patient's contribution towards the cost of a medical service covered by the health insurance. Can be expressed as a percentage of the total cost of the service (percentage co-payment), as a fixed amount (prescription fee) or a deductible.
cost-plus pricing	Pricing policy that determines a medicine price by taking into account production costs, promotional expenses, research & development, administration costs, overheads and a profit that is considered 'reasonable'.
discount	A price reduction granted to specified purchasers under specific conditions prior to purchase.
dispensing fee	A fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up.
external price referencing	The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
free pricing	Pricing policy, in which governments allow pharmaceutical companies to determine the price of the medicine they launch.
generic substitution	Practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (e.g. branded or unbranded generic), often containing the same active ingredient(s).
Health Technology Assessment (HTA)	A multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.
INN prescribing	Requirements for prescribers (e.g. physicians) to prescribe a medicine by its International Non-Proprietary Name (INN), i.e. the active ingredient name instead of the trade name.
managed-entry agreement (MEA)	An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms and are usually classified into financially-based and performance-based MEA.

marketing authorisation	A licence issued by a medicines agency approving a medicine for market use based on a determination by authorities that the medicine meets the requirements of quality, safety and efficacy for human use in therapeutic treatment.
mark-up	Percentage of the purchasing price added on to get the selling price.
pharmaceutical expenditure	Total expenditure on pharmaceutical and other medical nondurables. This comprises medicinal preparations, branded and generic medicines, patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives and other medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices.
policies	Instruments, tools and approaches that allow policy-makers to achieve defined objectives.
price link policy	Practice of setting the price of a medicine (e.g. a generic or a biosimilar) in relationship to the price of another medicine (e.g. originator, biological reference medicine), usually at a certain percentage lower.
pricing (price setting)	Act of determining the medicine price which is either taken by a pharmaceutical company (free pricing) or is the competence (responsibility) of a competent authority (price control).
price negotiation	A pricing procedure, in which medicine prices are discussed and agreed (e.g. between manufacturer and third party payer).
price regulation (price control)	Pricing policies where government authorities set the price of a medicine and/or indirectly influence it (e.g. statutory pricing, price negotiations, public procurement).
procurement	A process to purchase goods and services (e.g. medicines) that involves many steps and many stakeholders based on national, or supranational, regulation, policies, structures and procedures.
reference price system	A reimbursement policy in which identical medicines (ATC 5 level) or therapeutically similar medicines (ATC 4 level) are clustered (reference group). The third party payer funds a maximum amount (= reference price), while the patient must pay the difference between the reference price and the actual pharmacy retail price of the medicine, in addition to any co-payments.
reimbursable medicines	Medicines which are eligible for reimbursement. Expenses of reimbursable medicines may be fully covered by third party payers, or only partially (a specific percentage).
reimbursement	Coverage of the expenditure by a third party payer (e.g. social health insurance/National Health Service).
reimbursement list	A list that contains medicines with regard to their reimbursement status. It may either include medicines eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list).
tendering	Any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous.

value-based pricing	Policy of authorities to set the prices of a new medicine and/or decide on reimbursement based on the therapeutic value that a medicine offers, usually assessed through health technology assessment (HTA) or economic evaluation. In a full-fledged VBP, the pricing and reimbursement systems are integrated, and the price and reimbursement decision is taken jointly based on a value assessment.
wholesale	All activities consisting of procuring, holding, supplying or exporting medicines, apart from supplying medicines to the public.

Source: Glossary of Pharmaceutical Terms