MEDICINES ACCESSIBILITY IN A NATIONAL HEALTH SERVICE

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This dissertation is dedicated to my fiancée, Mireille, and my family for their love and support.

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Abstract

Access to medicines is a critical factor in maintaining public health. Inadequate accessibility is often a result of gaps within the public health system. Addressing these deficiencies can improve health outcomes and enhance patient satisfaction. This study aims to address the gaps in the Maltese public healthcare system by introducing a reimbursement policy. A literature review was conducted to compare the Maltese healthcare system with international models. Insights informed the design of two focus group discussion guides: one to investigate views on which reimbursement policy and methodology would be suitable for Malta, taking into consideration personalised and innovative medicine (Focus Group A) and another to examine barriers to accessibility and ethical aspects (Focus Group B). Both guides were validated by five pharmacists, with face validity assessed by a linguistic expert. Focus Group A included experts from six pharmaceutical stakeholder entities, and Focus Group B consisted of participants from six patient representative groups. The data collected underwent PESTLE and SWOT analyses. Analysis results were used to design a reimbursement policy, subsequently validated through Focus Group C, consisting of five experts from pharmaceutical stakeholder entities. Results suggest the reimbursement policy could reduce wastage, improve patient satisfaction, and improve sustainability compared to the government formulary system. While beneficial, respondents in Focus Group A (N=10) indicated that patients might resist the transaction to a reimbursement system (n=8). Focus Group B (N=6) emphasised preventing medicine shortages due to the significant negative impact. In conclusion, implementing a reimbursement model in a small market such as Malta faces multiple barriers, both politically and from patients, especially when transitioning from a government formulary system. Pilot studies are recommended to assess patient response and the impact of the reimbursement model on accessibility.

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List of Abbreviations

ADHD.....Attention Deficit Hyperactivity Disorder

AI.....Artificial Intelligence

CED.....Coverage with Evidence Development

CPSU.....Central Procurement & Supplies Unit

DPA.....Directorate of Pharmaceutical Affairs

EMT.....Exceptional Medicinal Treatment

ERP.....External Reference Pricing

FDG.....Focus Group Discussion Guide

FREC.....Faculty Research Ethics Committee

GDP.....Gross Domestic Product

HTA.....Health Technology Assessment

IRP.....Internal Reference Pricing

ISPOR.....International Society for Pharmacoeconomics and Outcomes Research

MCC.....Malta Chamber of Commerce

MEA.....Managed Entry Agreement

MHN.....Malta Health Network

MMA.....Malta Medicines Authority

MoU.....Memorandum of Understanding

OOP.....Out-of-Pocket

PDSA.....Plan-Do-Study-Act

PESTLE..... Political, Economic, Social, Technological, Legal and Environmental.

PLR.....Performance Linked Reimbursement

POYC.....Pharmacy of Your Choice Unit

PPRI.....Pharmaceutical Pricing and Reimbursement Information

SWOT.....Strengths, Weaknesses, Opportunities, and Threats

UREC.....University of Malta Research and Ethics Committee

WHO.....World Health Organisation

Chapter 1
Introduction

1.1 Overview

National health services aim to ensure sustainable and equitable access to medicines (Chattu et al, 2023). This is a critical factor in maintaining public health, and an understanding of existing reimbursement models is necessary to address gaps in the national health system (Shukar et al, 2021; Bomhof et al, 2023; Chattu et al, 2023). The fee-for-service model is an example of a financial-based model where the sole focus is the financial value of the product (Beck da Silva Etges et al, 2023; Trotta et al, 2023). Value-based reimbursement models focus on the benefits provided to the patient (Jommi et al, 2020; Maddox et al, 2020; Teisberg et al, 2020; Gondi et al, 2022; Beck da Silva Etges et al, 2023; Shenfeld, 2024). In a Value-based reimbursement model the reimbursement amount is tied to the benefits provided by the pharmaceutical which includes the improvement in patient quality of life and increase in patient survival rate, while accounting for the price of the medicine (Jommi et al, 2020; Teisberg et al, 2020; Beck da Silva Etges et al, 2023; Shenfeld; 2024). This encourages the use of medicines that are found to be the most beneficial (Maddox et al, 2020; Teisberg et al, 2020). To implement a value-based reimbursement model, an understanding of the economic benefit of the direct and indirect effects of the medicine is needed (Jommi et al, 2020).

1.2 Managed Entry Agreements

Managed Entry Agreements (MEA), which are also known as risk-sharing agreements, are agreements that aim to improve public access to new pharmaceutical (in which cost effectiveness and health technology assessment (HTA) results are inconclusive) while dividing the risks associated with the public coverage of the pharmaceutical (Andersson et al, 2020; Dabbous et al, 2020; Gamba et al, 2020; Neyt et al, 2020; Zampirolli et al, 2020; Thanimalai et al, 2021; Mitkova et al, 2023; Trotta et al, 2023). The risks of introducing a new pharmaceutical are shared between different

stakeholders, which include the health care payers and manufacturers (Andersson et al, 2020; Dabbous et al, 2020; Gamba et al, 2020; Neyt et al, 2020; Zampirolli et al, 2020; Thanimalai et al, 2021; Trotta et al, 2023). MEAs can be divided into two main types, which are: financial-based and health outcome/performance-based agreements (Dabbous et al, 2020; Neyt et al, 2020; Trotta et al, 2023).

Financial-based agreements focus solely on the financial aspect of a pharmaceutical. (Dabbous et al, 2020; Neyt et al, 2020; Trotta et al, 2023). Such an agreement can take the form of price-volume agreements, which can have a maximum sales volume or a budget (Dabbous et al, 2020; Neyt et al, 2020; Trotta et al, 2023). If the budgetary ceilings are exceeded, the manufacturer usually provides a discount or rebates on pharmaceuticals that exceeded the predetermined limit (Dabbous et al, 2020; Neyt et al, 2020; Trotta et al, 2023).

Health outcome-based agreements can be subdivided into two categories, which are performance-linked schemes and coverage with evidence development (CED) (Dabbous et al, 2020; Ciulla et al, 2024; Trotta et al, 2023). CEDs rely on future studies to provide data that fills the gaps (Dabbous et al, 2020; Ciulla et al, 2024; Trotta et al, 2023). While this is simple in concept, in practice, there have been difficulties in acquiring the desired evidence (Dabbous et al, 2020; Ciulla et al, 2024; Trotta et al, 2023). CED have several disadvantages, such as the lack of utility in treatments that require extended periods to produce a significant beneficial effect on the patient (Dabbous et al, 2020). In such patients, it may be more ethical to switch the patients to an already proven treatment (Dabbous et al, 2020). CEDs have an administrative burden, as evidence is to be collected and examined (Zeitler, 2022). The specifics on who will collect the required evidence and the deadline for the collection of evidence would need to be decided at the start of the agreement, and failure to do so can cause a breakdown of the CED (Zeitler, 2022).

Patients on treatments that are part of a CED agreement may also suffer from an increased burden, as the patients may be required to submit themselves to related tests (Carter et al, 2019). Patient consent is not always obtained to conduct such tests (Carter et al, 2019). The requirement of patient consent is determined on the following factors: feasibility in obtaining consent from all of the patients, patient response to unconsented tests or analysis, whether the tests are already being done as part of the clinical treatment, whether the act of requesting consent from the patient will cause them harm or discomfort, and whether the data collected will be anonymised (Carter et al, 2019). Another disadvantage of CEDs is the divergence of funds into treatments that may not prove beneficial or cost-effective, unlike the mainstream treatments (Dabbous et al, 2020). Restricted CED agreements can be implemented to reduce the risks associated with CED agreements, but it would be questioned if it is fair for the specified population to receive access to innovative medicines with limited evidence while others are not given the same privilege (Dabbous et al, 2020). The restricted access to a medicine related to restricted CED agreements can facilitate data gathering by limiting the treated population to the population found at the data gathering sites, and this population would have improved patient safety as the attending healthcare professionals are more experienced with patients on treatments with limited evidence (Lakdawalla et al, 2024). CEDs have the disadvantage that the payer is not reimbursed until the required evidence has been submitted (Dabbous et al, 2020). If the submitted evidence is insufficient, the patient will not be reimbursed (Dabbous et al, 2020). To mitigate the risk of the patient not being reimbursed, there are escrow agreements (Dabbous et al, 2020). In an escrow agreement, the sales generated will be kept frozen in a bank, and it will be given to the manufacturers or healthcare insurance, depending on how the CED agreement is concluded (Dabbous et al, 2020).

Another type of health outcome-based agreement is performance-linked reimbursement (PLR), which bases the reimbursement amount on the clinical outcome of the patient (Kim et al, 2020). Manufacturers that enter a PLR agreement have confidence in their product's ability to improve the patient's quality of life, as the manufacturers are taking a risk of a low reimbursement amount if the product underperforms (Kim et al, 2020). A PLR agreement can be used to increase the market share of a new product (Kim et al, 2020). For example, Novartis agreed to cover the cost of an osteoporosis treatment if the patient suffered a fracture within 1 year of starting zoledronic acid (Kim et al, 2020). In return, more patients were shifted to zoledronic acid by the national health service (Kim et al, 2020).

1.3 Reference Pricing

Another price mitigation tool is reference pricing which can be divided into are internal reference pricing (IRP) and external reference pricing (ERP) (Holtorf et al, 2019; Verghese et al, 2019; Iravani et al, 2020; Costa & Santos, 2022; Frank et al, 2022; Sullivan et al, 2022; Babaie et al, 2023).

1.3.1 External Reference Pricing

ERP also known as international reference pricing is the practise or policy of making use of the prices of pharmaceuticals in one or more countries: to decide on a maximum copayment amount, to have a base price during negotiations, to put a cap on market prices, to adjust the copayment amount after the medicine has been added to the reimbursement list and/or to change the price of the pharmaceutical after the initial launch (Holtorf et al, 2019; Verghese et al, 2019; Iravani et al, 2020; Frank et al, 2022; Sullivan et al, 2022; Babaie et al, 2023). ERP is not a resource-intensive practice, and ERP does not require a high degree of pharmacoeconomic expertise to implement when compared with other price control methods (Sullivan et al, 2022). Given this, it can be integrated

into a system relatively fast when compared to other tools (Sullivan et al, 2022). ERP is ineffective in managing the prices of pharmaceuticals when used on its own, and it is suggested by the World Health Organisation (WHO) to use ERP in conjunction with other tools such as HTA (Verghese et al, 2019; Sullivan et al, 2022; Babaie et al, 2023). An ERP can also be hindered by the data available from the selected reference country basket, as information regarding rebates and discounts may not be disclosed (Frank et al, 2022; Sullivan et al, 2022). The countries selected for the reference country basket are determined by a variety of factors including the country's similarity in socioeconomic situation to the country implementing the ERP, which is measured via the Gross Domestic Product (GDP) per capita, geographic proximity, data availability and health insurance's structure (Verghese et al, 2019; Frank et al, 2022; Babaie et al, 2023). A country that applies ERP would also need to consider the reference countries' currency, as the fluctuation in the currency can affect the conversion between currencies; as such, the policy makers need to determine which conversion rate is used in the ERP (Frank et al, 2022). There is no standard rule on when ERP should be revised for a product (Sullivan et al, 2022). Given this, countries need to develop their system on when a medicine should be revised (Sullivan et al, 2022). While the use of ERP was found to reduce prices of medicines in the short term, the long-term effects are not well studied (Holtorf et al, 2019; Sullivan et al, 2022). Even so, ERP is theorised to cause unintended consequences (Holtorf et al, 2019; Sullivan et al, 2022). One such consequence, is the delay or prevention of the introduction of medicines into low-income countries, this is to avoid a lower reference price for the product which can hinder their profits in higher income countries (Iravani et al, 2020; Frank et al, 2022; Sullivan et al, 2022; Babaie et al, 2023). Consequently, patient inequality in access to medicines becomes more prevalent in low-income countries (Iravani et al, 2020). ERP may cause a decrease in the production of

new medicines and active ingredients due to diminished profits, which subsequently decreases the investments made in research and development (Holtorf et al, 2019; Iravani et al, 2020; Frank et al, 2022; Sullivan et al, 2022).

1.3.2 Internal Reference Pricing

In contrast to ERP, IRP makes use of locally authorised products as the base to regulate the price of a new product (Verghese et al, 2019; Rangchian et al, 2020; Costa & Santos et al, 2022). The prices of local products can be used to determine price caps for medicines based on their pharmaceutical groups and to also decide a reimbursement amount for medicines while allowing for at least one fully reimbursed medicine for each pharmaceutical group country (Verghese et al, 2019).

IRP, in comparison to ERP, has easier access to the required pricing information as it does not require data from other countries. It was found that at times the switch from an ERP system to an IRP system causes a marked decrease in the cost of medicines, while also improving the population's satisfaction in the healthcare system (Rangchian et al, 2020). In IRP, medicines can be grouped into reference groups, which can be determined by the medicines' therapeutic class, indications, health outcomes, efficacy and safety (Verghese et al, 2019; Rangchian et al, 2020).

There are multiple ways in which the IRP can control the price of medicine through the use of the reference group's data (Costa & Santos et al, 2022). Portugal had used the average of the five cheapest medicines in each reference group to calculate the average price, which is used as a benchmark for new medicines (Costa & Santos et al, 2022). After October 2017, the Portuguese IRP policy was updated so that the IRP is the minimum value between the most expensive generic medicine available and the average of the five cheapest medicines (Costa & Santos et al, 2022). This change decreased the

IRP for 36% of the reference groups, which mainly consisted of medicines with minimal competition from other similar or bio-equivalent products (Costa & Santos et al, 2022). Rangchian et al (2020) conducted a study where the following four models of calculating the IRP were analysed: the mean price of the reference group, the median price of the reference group, the minimum price of the reference group and the mean price of the three minimum prices from the reference group. It was found that when the IRP was based on the mean price of the reference group or the median price of the reference group, it was affected by outlier prices (Rangchian et al, 2020). When the IRP was based on the minimum price of the reference group and the mean price of the three minimum prices from the reference group, outlier prices did not produce a prominent effect on the IRP (Rangchian et al, 2020). Rangchian et al (2020) concluded that the IRP based on the mean price of the three minimum prices from the reference group was the most beneficial policy as it reduced medicine prices while also providing a competitive and flexible environment. This IRP policy also reduces the risk of the drug supply chain suffering from disruption or a decrease in medicine quality. IRP as a cost containment tool is more effective on medications used to treat chronic conditions and that have an extended duration of use, when compared to medicines used to treat acute conditions or are used for a limited duration (Rangchian et al, 2020; Costa & Santos et al, 2022). The price reduction was greater in medicines that had alternative medicines belonging to the same therapeutic class (Rangchian et al, 2020). IRP in a copayment method also incentivises the use of generic medicines over branded ones, as these carry a lower out-of-pocket (OOP) cost (Rangchian et al, 2020; Costa & Santos et al, 2022). If the medicine or the therapeutic class of the medicine is sparse with generics, there is less competition, and ergo, it would have a lower cost containment effect (Costa & Santos et al, 2022). Manufacturers might also not decrease the prices of their branded medicines to mitigate

the loss of sales, and the manufacturers may even increase their prices to make up for the loss of profit by depending on the patients loyal to their brand (Costa & Santos et al, 2022). If there is an increase in the price of branded medicines, it can result in manufacturers increasing the cost of their generic medicines as an attempt to increase their profit margin. (Costa & Santos et al, 2022). IRP was also found to reduce the overall consumption of medicine (Costa & Santos et al, 2022). While this can be interpreted as a decrease in patient accessibility to medicine due to their inability to purchase at the price set by the IRP, it can also be a result of patients ceasing excessive or unneeded purchasing of medicines, which has the positive effect of reducing medicine wastage (Costa & Santos et al, 2022). If the price of branded medicines decreases, it can create an entry deterrent to generic medicines, as branded medicines would be able to take up a larger share of the profit generated within the reference group; this would also result in less competition within the reference group (Costa & Santos et al, 2022). While IRP can have a price containment effect, it is suggested to use this tool in conjunction with other tools such as price caps to have an optimal price reducing effect, especially in medicine groups in which there is low competition (Rangchian et al, 2020; Costa & Santos et al, 2022).

1.4 Health Technology Assessment

HTA is a multidisciplinary system that evaluates the value of the health technology at different points of its lifecycle (Fontrier et al, 2022; Huang et al,2022; Sehmi & Wale, 2022; Büssgen & Stargard, 2023; Falkowski et al, 2023). The criteria on which the health technology is evaluated and the degree to which the information generated by the HTA is used by a healthcare system vary from country to country (Fontrier et al., 2022; Sehmi & Wale, 2022; Fontrier et al, 2024). Criterions for an HTA includes the clinical value of the medicine, cost effectiveness, ethical issues, cultural issues, social issues, and both direct and indirect consequences of the health technology

(Drummond et al., 2022; Falkowski et al, 2023; Muir et al, 2023; Vanier et al, 2024). The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) had assigned a special task force to further expand what can be used to calculate a technology value; from this, they had developed the ISPOR value flower (Figure 1.1) (Muir et al, 2023).

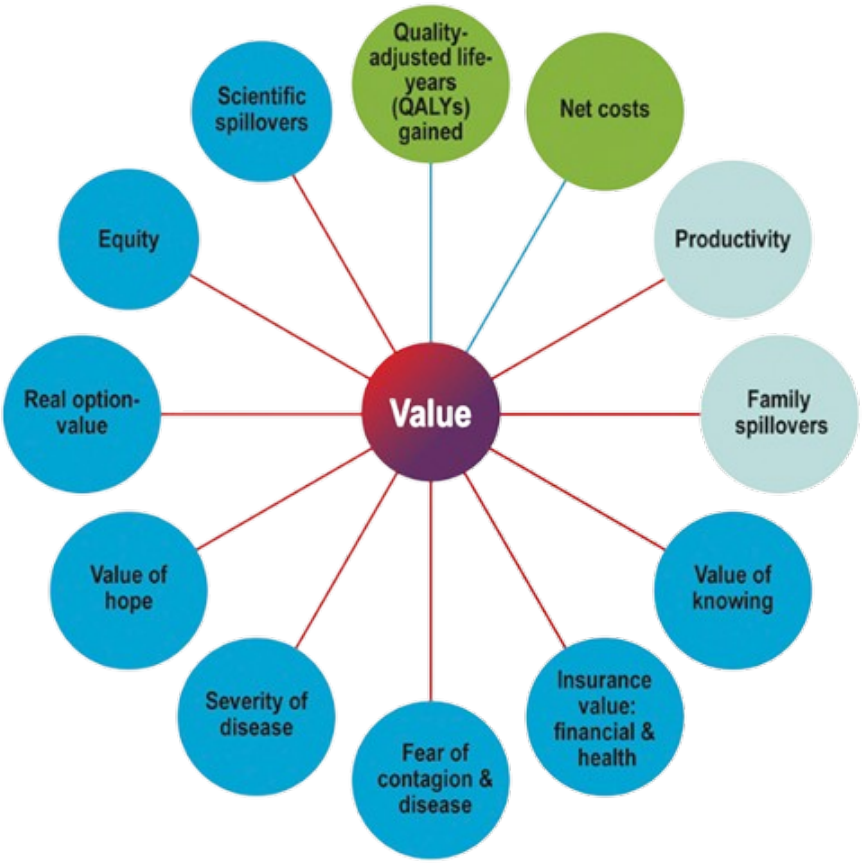

Figure 1.1 ISPOR Value Flower

Taken from: Neumann PJ, Garrison LP, Willke RJ. The History and Future of the "ISPOR Value Flower": Addressing Limitations of Conventional Cost-Effectiveness Analysis. Value in Health. 2022;25(4):558–65. https://doi.org/10.1016/j.jval.2022.01.010.

Note: Green circles: core elements of value

Cyan circles: common but inconsistently used elements of value

Blue circles: potential novel elements of value

Blue lines: value element in the traditional payer perspective

Red lines: value element also included in the societal perspective

These technological assessments and advancements in this field encourage innovation that aids in safeguarding the public while also assessing their cost per benefit (Stühlinger, 2020; Büssgen & Stargard, 2023; Desmet et al, 2024). Policy makers use HTAs assessments and appraisals to estimate the value of the medicine during price negations and allow them to make informed decisions on how to allocate their budget in a way that promotes an effective, high-quality, and equitable health system (Wang et al, 2020; Fontrier et al, 2022; Huang et al, 2022; Sehmi & Wale, 2022; Büssgen & Stargard, 2023; Falkowski et al, 2023; Vanier et al, 2024). HTAs may also consider the patients' preferences, which aids in improving the patients' satisfaction with the health system (Vanier et al, 2024). To achieve these higher levels of patient satisfaction, along with improved innovation, the HTAs need a certain level of transparency and accountability (Bullement et al, 2019; Falkowski et al, 2023; Fontrier et al, 2024). Understanding the reasoning behind an HTA's decision-making analysis aids pharmaceutical companies in their development process, and it empowers the patient by giving them insight into their medicine (Bullement et al, 2019; Falkowski et al, 2023; Fontrier et al, 2024). The information generated by the HTAs is being harmonised through data sharing initiatives such as the European Network for HTA, which also reduces duplication of work (Cowie et al, 2022; Falkowski et al, 2023; Desmet et al, 2024). The European Union (EU) seeks to further improve the harmonisation among member states through the HTA Regulation 2021/ 2282 (Desmet et al, 2024; Fontrier et al, 2024). This collaboration aims to harmonise the methodology for the HTAs conducted within the EU while also implementing the concept of joint scientific conclusions and joint clinical assessment (Desmet et al, 2024). Other data sharing initiatives, such as the International Decision Support Initiative, support low-income countries in their healthcare-related decision-making process and promote universal health coverage (Falkowski et al, 2023). HTA

bodies, while they can support government and policy makers, can be independent of governmental structures or incorporated within the government structure (Drummond et al, 2020; Fontrier et al, 2022; Fontrier et al, 2024). It has been found that HTA bodies that are integrated into the government structure are more transparent than the private HTA bodies due to their increased focus on societal perspectives (Fontrier et al, 2022). While the private HTA bodies have a higher degree of independence in comparison to their integrated counterparts (Fontrier et al, 2022). These HTA bodies are usually one of seven types of entities: health organisations, research institutions, HTA-research institutions which have specialised departments for HTA activities, national HTA agencies, insurance organisations, governmental organisations, and medicine regulations with HTA functions (Fontrier et al, 2022). HTAs in and of themselves can be divided into three models, each focusing on the priorities of their respective national health system (Fontrier et al, 2022). These models are the clinical and cost-effectiveness model, the comparative clinical benefit assessment model and the value-based assessment model (Fontrier et al, 2022). While there is a push towards the implementation of a value-based assessment model, there are difficulties in maintaining consistent assessment of the elements throughout different syndromes and indications (Muir et al, 2023). Traditional cost-effective analysis has the benefit of being easy to reproduce and serving as a standardised form of analysis between syndromes and indications (Muir et al, 2023). The standardised format of traditional cost-effective analysis limits the analysis's ability to capture the additional value benefits which can be found in a value-based analysis (Muir et al, 2023). Any type of HTA analysis timely manner can lead to delays in the launch of a pharmaceutical product, leading to the loss of years and lower quality of life (Büssgen & Stargardt, 2023; Fontrier et al, 2024). This delay can be attributed to the requirement for additional evidence in order to prove that the product is more clinically beneficial

when compared to cheaper competitors (Cowie et al, 2022). HTAs aim to assess the product on its long-term benefit (Cowie et al, 2022). However, given that the clinical trials are typically carried out over a shorter period of time, this negatively affects the HTAs ability to determine the impact on the quality of life and mortality in the long-term, which can cause further delays (Cowie et al, 2022). Delays will lead to the use of older molecules, which may have a lower therapeutic value, and the use of such molecules could lead to an increase in healthcare expenditure (Büssgen & Stargardt, 2023). Patient might also feel the need to pay OOP to obtain better treatments, which increases their financial burden (Büssgen & Stargardt, 2023). Manufacturers also suffer from this delay as it would minimise their profits and shorten the amount of time available for them to recuperate the finances spent during the development process (Büssgen & Stargardt, 2023). Manufacturers may attempt to start the process of having their product accepted to a reimbursement formulary before their product is granted a marketing authorisation to minimise the loss of profits caused by the HTA (Büssgen & Stargardt, 2023). However, as the product is not already approved by the National Competent authority, there is a risk that it would not be approved or that the dossier would need to be significantly updated (Büssgen & Stargardt, 2023). Harmonisation of HTA procedure and criteria for when a product undergoes an HTA also reduces the delay caused by the procedure (Drummond et al, 2022). As HTAs aim to reduce expenses for the healthcare industry, manufacturers face a choice of being subjected to HTA, which may require them to lower their prices, or they must adapt to a smaller market size (Büssgen & Stargardt, 2023). This can also lead to withdrawals of medical products, as seen in Germany, which had reported an increase in withdrawal rates after the implementation of the German HTA system (Büssgen & Stargardt, 2023). Access to care is not always considered during an HTA, which can result in decreased access to mitigate the cost of the medicine (Büssgen &

Stargardt, 2023). Randomised trials are considered the gold standard in HTAs, but the time needed to do such a trial is costly and time-consuming, which can delay access (Vanier et al, 2024). Accelerated HTA procedures can be initiated after conducting non-randomised studies; they can be enacted when urgent access is needed for a product. (Vanier et al, 2024). Considerations such as the justification for the accelerated procedure and results used are analysed to preserve patient safety (Vanier et al, 2024).

1.5 Payment systems

Financing of healthcare systems can be divided into two main systems, multi-payer systems or single-payer systems (Petrou et al, 2018; Donnelly et al, 2019). These systems are not mutually exclusive, as hybrid payer systems have been implemented in certain cases, such as in the United States (Donnelly et al, 2019).

1.5.1 Single Payer Systems

National health systems with a single payer system (also known as the national health insurance system) are characterised by the financing of the system through a single entity; the government (Fox & Poirier, 2018; Petrou et al, 2018; Donnelly et al, 2019; Cai et al, 2020). Single payer systems aim to provide universal coverage through a single all-encompassing benefit package, which makes private insurance redundant (Cai et al, 2020; Markowitz & McLeod-Sordjan, 2021). Another element of single payer systems is the universal negotiations of reimbursement amount and medicine prices (Cai et al, 2020). Compared to multiplayer systems, it was found that single payer systems reduce expenditure of the healthcare system due to a simplified administrative process (Cai et al, 2020). Depending on the single payer system, it can also cause a reduction in the price of medicine and medical equipment, the rate of fraud and the waste of medicines (Cai et al, 2020). This cost reduction can be further enhanced through the reduction of disagreements between different providers, which have different aims, such as those

which are for profit and those that are not (Markowitz & McLeod-Sordjan, 2021). Single payer systems, while typically succeeding in providing universal coverage for the basic needs, are usually unable to provide much beyond that, such as private rooms in a hospital (Fox & Poirier, 2018). A patient who wants these additional benefits would have to do so through a private insurer (Fox & Poirier, 2018).

1.5.2 Multi-Payer systems

Multi-payer systems are health systems which are financed through more than one entity, which can include the government (Petrou et al, 2018; Donnelly et al, 2019). This usually involves private insurance, which is financed via individual premiums that the government can pay (Donnelly et al., 2019). Multi-payer systems aim to improve quality through the competition of private purchasers (Petrou et al,2018). However, it was found that when this was applied in the EU and Russia, there was no significant increase in quality (Petrou et al, 2018). Multi-payer systems generate more inequity between patients, as it has been found that patients who had a private insurer had a lower frequency of tumours compared to the patients solely on public benefits (Petrou et al, 2018). Compared to single payer systems, multi payer systems require a more complex system to collect funds as each payer would need to implement their fund collection system, which results in a higher overall cost of the healthcare system (Petrou et al, 2018). As multi-payer systems are more market-oriented, they can provide more patient-specific packages that better cater to their needs (Petrou et al, 2018). Insurances in a multi-payer system can also mitigate risks through risk adjusters (Petrou et al, 2018). Risk adjusters are a timely, resource-heavy process in which resources are redistributed among patient pools to mitigate risk and the related costs (Petrou et al, 2018). While risk adjusters allow for better allocation of resources, even an optimum readjustment will result in unmet objectives (Petrou et al, 2018).

1.6 Generic and Biosimilar Medicine Adoptability

Generic medicines are defined as medicines that have the same qualitative and quantitative composition of the active substance while remaining bioequivalent to the reference product (Spanou et al, 2019; Hussain, 2023). This bioequivalence may need to be determined via bioequivalence studies; however, an exception known as the bio waiver exists for medicines that are categorised as the biopharmaceutics classification system Class I or Class III.[1] Generics of parenteral medicines can also be exempted from submitting bioequivalent studies granted that they are administered intravenously or in the case of the other parenteral routes they must prove that the medicine has the same type of solution, contains the same concentration of the same active ingredients and have the same excipients in the similar amounts to the reference product.[2] While biosimilars are medicines with a biological medicine as the reference product, they must show that the biosimilar is similar in terms of structure while having no significant clinical differences in their immunogenicity, efficacy and safety profile (Spanou et al, 2019). Due to the complexity of the manufacturing process of biological products and the natural variability, generics are not possible as these factors do not allow for the formation of a replica of the reference product (Spanou et al, 2019). Adoption of the generic and biosimilar medicines leads to lower healthcare spending as they are more cost-effective (Spanou et al, 2019; Hussain, 2023). Improvement in cost-effectiveness leads to improved patient access both in the private sector and from the healthcare system (Hussain, 2023). The lower spending in the healthcare system allows for funding of other programs, which

[1] European Medicines Agency (EMA). ICH M9: Biopharmaceutics Classification System-based Biowaivers [Internet]. Amsterdam: EMA;2020 [cited 2025 May 01]. Available from URL: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-m9-biopharmaceutics-classification-system-based-biowaivers-step-5_en.pdf

[2] European Medicines Agency. Guideline on the Investigation of Bioequivalence (EMA). [Internet]. London: EMA;2010 [cited 2025 May 01]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-bioequivalence-rev1_en.pdf

can further enhance the patient's quality of life (Hussain, 2023). The decrease in prices of medicines is exacerbated by competition between manufacturers, which leads to further improvement in patient access (Hussain, 2023). Generics have impacts outside of the national borders they are authorised (Ferrario et al, 2020; Hussain, 2023). The introduction of a generic in a country can lead to its availability in developing countries, which have a smaller budget than developed countries, and generics play a factor in managing epidemics through the increased availability on a worldwide scale (Ferrario et al, 2020; Hussain, 2023). However, there is concern that if the generics or biosimilars have a low uptake, manufacturers might withdraw this low-profit product (Hussain, 2023). Biosimilars are more at risk of being withdrawn as they have a much lower uptake than new generics (Hussain, 2023). These low uptakes of biosimilars can be mitigated by allowing pharmacists to substitute originator medicines with their biosimilar or generic (Spanou et al, 2019; Ferrario et al, 2020). This substitution may introduce a nocebo phenomenon to both patients and healthcare professionals due to a negative perception of generics and biosimilars (Spanou et al, 2019; Car et al, 2024). This is caused by a decrease in the expectation of the medicine which can lead patients to not adhere to the treatment which can result in a discontinuation of treatment, and it can cause patients to drop out of clinical trials which will cause a false negative effect on the safety profile (Spanou et al, 2019; Car et al, 2024). A study by Faasse et al (2016) showed in their observational study that patients who took a brand-labelled medicine found their headaches to be treated more effectively while having fewer adverse effects than the generic labelled medicine. Using a single-blinded functional magnetic resonance imaging study, Fehse et al (2015) also showed that patients responded more to the branded labelled aspirin than the generic labelled aspirin, even though both were placebos. This nocebo phenomenon is not as conclusive as what is found in other studies, such as when Reimers et al., 2017, found

that patients who were switched from the branded levetiracetam to the generic levetiracetam remained seizure free, showed equal of fluctuations of serum levetiracetam to those patients on the branded levetiracetam, and they were not switched back to the branded levetiracetam. This lack of nocebo phenomenon was found in other studies using levetiracetam, such as the open-label study by Fanella et al (2017), the substitution study by Bosak et al (2017) and the Greek open-label study by Markoula et al (2017) (Spanou et al., 2019). The nocebo phenomenon extends to healthcare professionals as it was found that physicians are concerned when switching or prescribing generic products to their patients (Spanou et al, 2019). This can increase healthcare expenditure as physicians would be more likely to switch patients from the generic medicine to the originator medicine (Spanou et al, 2019). Elderly patients were found to be more at risk for the nocebo phenomenon as they are likely to be subject to polypharmacy; as such, a change in the tablets' colour or shape can result in increased anxiety, which would make them more prone to adverse events (Spanou et al, 2019). These nocebo phenomena can be mitigated through a diverse range of strategies, such as through communication strategies which promote empathy and positive reinforcement from the pharmacist, and providing the reason for the substitution by focusing on the active ingredient, rather than on the brand (Car et al., 2024). Focus on the price difference should be avoided in the communication strategy as this can suggest a negative connotation to the patient (Car et al., 2024). To strengthen this communication strategy, it is suggested that healthcare professionals are trained so that these soft skills can be strengthened, and they can increase their knowledge of the nocebo phenomenon (Car et al., 2024). To increase the smoothness of any substitution, the involvement of a nurse could be highly beneficial as they critical role in the patient's care and, as such, could aid in communicating the substitution of the organisation to a generic (Car et al, 2024). The nurse would also assist

in providing a more personalised approach to the information provided, which would improve the patient's satisfaction (Car et al, 2024). Involving the patient in the decision-making process is highly advised as this would make them aware of the decisions made and it would give them a voice for their treatment (Car et al, 2024). Follow-ups after the substitution are also recommended as this can be used to address any adverse events they might experience (Car et al, 2024).

1.7 Drug Intelligence

Drug intelligence is wisdom and information generated through the analysis and evaluation of data-driven information and finds (Muscat, 2020). The generated information can be implemented in a health system to facilitate effective, tactical, and practical decision-making, which can improve access to medicine (Muscat, 2020). Artificial Intelligence (AI) can further strengthen the impact of drug intelligence in improving medication management (Allam, 2025). AI can also streamline workflows such as inventory management (Allam, 2025). This is due to its ability to make predictions on the demand for a medicine, which aids in minimising surplus inventory while reducing the risk of shortages (Allam, 2025). AI can improve responsiveness when faced with the destruction of the supply chains by aiding the management of the disruption by providing solutions and improving the visibility of the supply chain (Allam, 2025). AI's forecasting capacity can be an early warning for pharmacists regarding future possible shortages (Pall et al, 2023; Oualikene-Gonin et al, 2024; Allam, 2025). This empowers pharmacists to act before the shortage is announced by the drug manufacturers and, as such, safeguard patient accessibility to medicine through rationing of medicines (Pall et al, 2023). This also gives pharmacists time to find an alternative medicine and to discuss with physicians alternative treatments that they can prescribe (Pall et al, 2023; Allam, 2025).

1.8 Pooled Procurement

Pooled Procurement is implemented by multiple organisations outside of Malta, such as the Global Drug Facility, the President's Emergency Plan for AIDS Relief and the Global Fund (Parmaksiz et al, 2022). This type of procurement has the advantage of addressing issues of limited technical capacity, limited human resources, assuring high-quality procurement of high-quality medicine, lack of or insufficient incentives for manufacturers to supply, affordability and the lack of supply of specific medicines (Parmaksiz et al, 2022). These issues are addressed via a technical and human resource efficient process which incentivises supply through an increase in supplier competition (Parmaksiz et al, 2022). This procurement style was prominent during the Covid-19 pandemic due to the alignment of goals between organisations (Parmaksiz et al, 2022). A variation of the pooled procurement style is the multi-winner tender, which was designed to tackle the disadvantages which single-winner tenders are predisposed to (Németh et al, 2023). Disadvantages of single-winner tender are the loss of long-term maintenance of a competitive pharmaceutical industry, the lack of a secure, continuous supply of medicines and the lack of coverage for conditions with a small patient population (Németh et al, 2023). Multi-award tenders require more planning to implement than single-award tenders, but they have already been applied in some European Countries, including Germany (Németh et al, 2023). Multi-award tenders award a percentage of the market share depending on the rank awarded to the bidder (Németh et al, 2023). This aims to reduce the risk of a supplier forming a monopoly and reduce the risk of shortages through the acquisition of multiple suppliers (Németh et al, 2023).

1.9 National Health Insurance Scheme

A national health insurance scheme is a form of pooling financing aimed at achieving financial protection and aid in achieving universal coverage (Cuadrado et al,

2019). These aims are obtained by combining health risks into a single fund to which the population makes a payment; this practice is known as risk pooling (Cuadrado et al, 2019). This delinking of financial contribution from the health needs would allow for effective resource pooling, which can be applied to the population (Cuadrado et al, 2019). Through this pooling of funds, the health system would also improve the efficiency of the system and strengthen stewardship (Cuadrado et al, 2019). A similar system was originally implemented in Germany in 1883, and it was named the Health Insurance Act (Krankenversicherungsgesetz) (Busse et al, 2017). It is called the Bismarck model, which was a multi-payer system that collected funds into multiple social health insurance funds (Schut et al, 2023; Tsiachristas et al, 2023). The Bismarck model is often compared with the Beveridge health system, which is a single-payer system (Busse et al, 2017; Schut et al, 2023). These models are not mutually exclusive, as a model with elements from both can be implemented, and this was done to tackle challenges of an ageing population and introduce new diagnostic and therapeutic technologies (Busse et al, 2017; Shishkin & Sheiman, 2023). To govern such a system, the government would need to decide on important factors such as: who can provide drug insurance, who receives which insurance, how the insurance is paid for and how the selection of conditions and medicines covered are made (Pantoja et al, 2022). These decisions are made based on achieving the following objectives: ensuring universal access to essential medicines, the access to medicines is equitable, OOP payments for crucial medicines is either eliminated or reduced, reducing the expenditure needed on healthcare through measures such as negotiating better prices and ensuring that medicines are used appropriately (Pantoja et al, 2022). In such a system, a mandatory public insurance can be made available, and it is supplemented with private insurance, which can be either non-profit or for-profit (Pantoja et al, 2022). Another option is that the private insurance substitutes the public insurance while also having a

mandatory basic insurance made available (Pantoja et al, 2022). A system that has a public insurance supplemented by a private insurance can better reduce costs and improve the quality of the system through competition (Pantoja et al, 2022). This system carries the risk that a "two-tiered" system might emerge as patients who can afford private insurance would pick over the public insurance, resulting in increased costs and reduced quality (Pantoja et al, 2022). The choice of medicines covered can be made by one body or a mix of the government, independent bodies that the government has allocated this authority or by the private insurance companies (Pantoja et al, 2022). While the decision made by the government is more likely to ensure equitable access and prevent payments that could put patients into poverty, it can be affected by corruption or political interest (Pantoja et al, 2022). To reduce this risk, HTA agencies are employed to assist or conduct the decision-making process for which medicines are covered by the insurance (Pantoja et al, 2022). As HTA agencies focus mainly on cost containment, this could lead to a decrease in the availability of non-essential medicines (Pantoja et al, 2022). In the case of private insurance companies, they would be concerned about profit; their choices of medicines covered could lead to reduced coverage, shifting of costs to the government or an increase in OOP payments (Pantoja et al, 2022). Though insurance may cause an increase in medicine consumption, this increase positively influences pharmaceutical innovation (Pantoja et al, 2022; Fan et al, 2023). The increase in medicine consumption encourages and allows pharmaceutical companies to conduct new drug research and, as such, increase the number of patent applications (Fan et al, 2023). Health insurance is also used to facilitate the recruitment of patients for clinical trials and further encourage new clinical trials (Fan et al, 2023). Another benefit of a health insurance system is optimising antimicrobial use (Obadare et al, 2024). It had been found that after implementing a health insurance system, the prescribing amounts of antibiotics were

close to the WHO-recommended value, which indicates that an insurance system improves antimicrobial stewardship (Obadare et al, 2024).

1.10 Maltese National Health System

The Maltese National Health system serves around a population of half a million, which is funded via its tax-based system.[3] This system currently serves around half a million patients, and involves the public sector in providing access(Muscat, 2020).[3] While the cover in Malta is supposed to be universal, patients still have OOP payments.[3] In 2020, it was found that 30% of healthcare expenditure was OOP, and 28% of the OOP expenditure was related to pharmaceuticals, which was also the second highest OOP expenditure (Figure 1.2).[3] This was the second highest OOP cost, just under the Outpatient medical care, which was 42% of OOP expenditure(Figure 1.2).[3] This can be attributed to the cost of acute conditions, which may not be covered by the public health system.[3] While patients received 3 days worth of medicine following release from the hospital, if the treatment goes beyond 3 days, they may face OOP expenditure (Muscat, 2020).

[3] European Observatory on Health Systems and Policies (EOHSP). Malta: health system summary 2024 [Internet]. Brussels: EOHSP; 2024 [cited 2025 May 01]. Available from URL: https://eurohealthobservatory.who.int/publications/i/malta-health-system-summary-2024

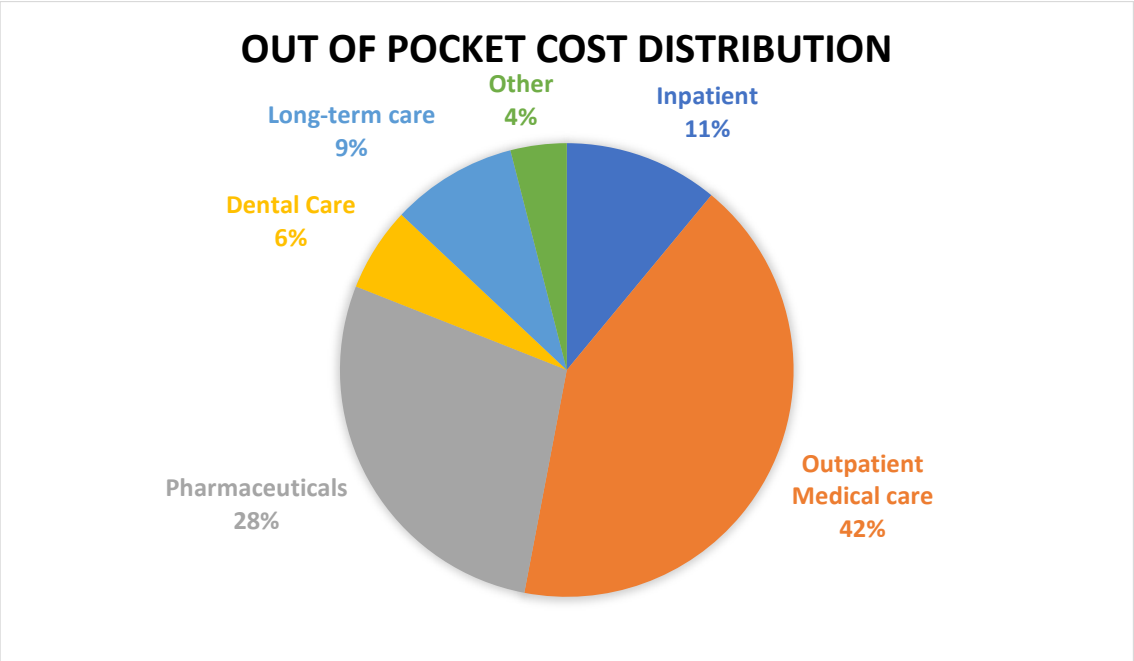

Figure 1.2 The 2020 Pocket cost distribution in Malta

The 2020 percentages of OOP cost distribution in Malta were taken from: European Observatory on Health Systems and Policies (EOHSP). Malta: health system summary 2024 [Internet]. Brussels: EOHSP; 2024 [cited 2025 May 01]. Available from URL: https://eurohealthobservatory.who.int/publications/i/malta-health-system-summary-2024

Patients may acquire medicines without OOP costs due to the Social Security Act Cap 318 Article 23 and the amendment of this act – Act No. I of 2012 and the Fifth Schedule to the same Act.[4] The schedule is also referred to as Schedule V, which covers 83 conditions.[4] Patients diagnosed with one of the listed conditions would be entitled to medications allocated to that condition as listed in the Government Formulary List.[4] Schedule V is not affected by any factor other than the patient's diagnosis; this includes the patient's age or income.[4] New applications for most of the conditions can only be made by consultants.[4] The exception lies in hypertension treatment and cholesterol treatment, as a health centre doctor can also apply for these conditions.[4] Patients entitled

[4] Pharmacy of Your Choice (POYC). Schedule V [Internet]. Pietà: POYC; 2023 [cited 2025 May 01]. Available from URL: https://poyc.gov.mt/en/schedule-v-r/schedule-v/

via the Schedule V may collect their medicines from any of the 226 pharmacies that participate in the Pharmacy of Your Choice (POYC) scheme. [4] Entitled patients would be able to collect 56-day supply of medicine, granted that they do not fall in the list of medicines mentioned in Subsidiary Legislation 31.18 Drugs (Control) Regulations. Usually, a 28-day supply of these medicines can be provided, provided that the other legal requirements mentioned are met, such as the presentation of a valid control card and a prescription for narcotic and psychotropic drugs.

1.10.1 Procurement for the Maltese National Health System

Procurement for the medicines and medical devices used in the Maltese national health system is done by the Central Procurement and Supplies Unit (CPSU).[5] CPSU is allocated a budget to achieve this goal, and they aim to maximise the use of the budget (Muscat, 2020).[5] CPSU achieves this through a public tendering process in which the cheapest eligible bid would be awarded the tender (Muscat, 2020). This process promotes fairness and competition between bidders, which leads to the procurement of higher quality medicine while minimising the cost of the medicines (Muscat, 2020). This is a form of pooled procurement which can be used to tackle the difficulties of a small market size, which is a characteristic of Malta (Muscat, 2020; Parmaksiz et al, 2022).

1.11 Rationale for the research

Improving access to medicine in Malta is a multifactorial challenge that has a substantial impact on public health. To tackle this challenge, the international scenario was examined to examine the tools and policies used to mitigate medicine accessibility.

[4] Pharmacy of Your Choice (POYC). Schedule V [Internet]. Pietà: POYC; 2023 [cited 2025 May 01]. Available from URL: https://poyc.gov.mt/en/schedule-v-r/schedule-v/
[5] Central Procurement and Supplies Unit (CPSU). L-Missjoni Taghna [Internet]. San Ġwann: CPSU; 2023 [cited 2025 May 01]. Available from URL: https://cpsu.gov.mt/dipartimenti/missjoni/

This study aims to use a reimbursement model to improve medicine accessibility and foster a more patient-centred approach in treatments.

1.12 Aims and Objectives

This study aims to develop a reimbursement model for Malta, which promotes the accessibility of medicines while remaining sustainable.

The objectives are:

•To identify and review international drug reimbursement policies in relation to the local scenario.

•To identify the Strengths, Weaknesses, Opportunities, and Threats associated with the implementation of a reimbursement model in Malta.

•To propose and validate a reimbursement policy for Malta.

Chapter 2
Methodology

2.1 Overview

An in-depth literature review was conducted to collect information regarding reimbursement models. The following databases were used to achieve this: HYDI, Google Scholar and PubMed. Articles were filtered so that only articles published in peer-reviewed journals after 2019 were used. Health system reviews were also used to supplement the data collected. The data collected was then used to produce two (2) focus group discussion guides (FDG), which focused on two (2) aspects of reimbursement. One (1) guide focused on which reimbursement policy and methodology is suitable for Malta, while the second FDG focused on the ethical aspects of reimbursement. The guides were validated by one (1) linguistic expert and five (5) pharmacists. During the validation they were asked to grade each question on a 5-point Likert scale where one (1) is the lowest score and five (5) is the highest score on the following categories: "Clarity and Relevance", "Comprehensiveness", "Engagement and Motivation" and "Consistency and Bias". The validators were also asked to grade the overall FDG on a 5-point Likert scale, where one (1) is the lowest score and five (5) is the highest score, on the following categories: "Usability" and "Overall Effectiveness". An average percentage score was calculated, where a score of 15% would indicate that all participants gave a rating of 1 and a score of 100% would indicate that all participants gave a rating of 5. Areas with a percentage score of 50% or lower were focused on as they required significant amendments. The scores and comments given by the validators were used to improve the focus group discussion guides. Consent to participate in the dissertation was obtained from the following organisations: Action for Breast Cancer Foundation, ADHD Malta, Caritas Malta, CPSU, the Directorate of Pharmaceutical Affairs (DPA), the Pharmacy department of Mater Dei Hospital, the Malta Chamber of Commerce (MCC), the Malta Dementia Society, the Malta Health Network (MHN), the Malta Medicines Authority, the

POYC Unit and Step Up for Parkinson's. Ethics approval was sought after the organisations consented to participate in the study and the validated FDGs were completed. After the ethics approval, the organisations were divided into two groups, which were labelled Group A and Group B. Group A consisted of CPSU, DPA, and MCC. MMA, Pharmacy Department of Mater Dei Hospital and POYC. Group B consisted of Action for Breast Cancer Foundation, ADHD Malta, Caritas Malta, the Malta Dementia Society, MHN, and Step Up for Parkinson's. Each group participated in a focus group or interview, depending on their availability. Group A were questioned using the FDG that focused on which reimbursement policy and methodology is suitable for Malta, and Group B was questioned using the FDG that focused on the barriers to medicines accessibility and ethical aspects of a reimbursement system. The data collected underwent a Political, Economic, Social, Technological, Legal, and Environmental (PESTLE) analysis to examine the macro-environmental factors of a reimbursement model. Afterwards, the data was put through a Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis. Following the SWOT analysis, the information was used to draft a reimbursement policy that aims to provide increased accessibility to innovative and personalised medicines while improving the quality of medicines provided, increasing sustainability, and maintaining a highly ethical mindset. The drafted policy underwent a validation via Focus Group C, which included participants who originate from DPA, the Pharmacy unit of Mater Dei, MCC, and MMA. Focus Group C was given a validation tool which contained eight (8) 5-point Likert-scales in which they were asked to grade the policy on the follow categories: "Exploitability", "Clarity", "Consistency", "Applicability", "Sustainability", "Feasibility", "Comprehensiveness", and "Pharmacist Response." An average percentage score was calculated where a score of 15% would indicate that all participants gave a rating of 1 and a score of 100% would indicate that

all participants gave a rating of 5. Areas which had a percentage score of 50% or lower were focused on as they required significant amendments. The policy was amended as per the validators' comments and scores.

2.2 Literature Review

The literature review made use of the following databases: HYDI, PubMed, and Google Scholar. Outside of these databases, the Health System reviews found in the Health System in transit were used as grey literature. During the literature review, the following key phrases were used: "Reimbursement Model", "Insurance Model", "Value-based Pricing", "Outcome-based Reimbursement", "National Health System", and "Health Technology Assessment." The articles chosen had to meet the following inclusion criteria: published between 2019 and 2024 and sourced from peer-reviewed journals. Articles which did not mention the pharmaceuticals were excluded. The included articles were then reviewed for information regarding reimbursement policies, forms of pricing and the pharmacoeconomic effect of the models or tools used. During the review, articles that were not focused on pharmacoeconomics were removed.

2.3 Focus Group Discussion Guide

The data collected from the in-depth literature review was used to develop two (2) focus group discussion guides. The guides consisted of a set of questions accompanied by sub-questions, which facilitated a more detailed exploration of the primary topic. Examples of reimbursement models and pricing models were included in the guide if the participants needed more information. Definitions of personalised medicine, single-payer model and multi-payer model were included so that a standard definition is given to the participants. The two FDGs were labelled as Guide A and Guide B. Guide A focused on which reimbursement policy and methodology is suitable for Malta, taking into consideration recent advances such as personalised and innovative medicine, and it had

six (6) questions. The questions focused on: the access to personalised medications, the participants' thoughts on a reimbursement system instead of the current system, which reimbursement model would be considered for which medications, how would reimbursement amount/price of product be set, the use of a single-payer and multi-payer system and the expected response to a reimbursement system. In guide A, there is a 5-point Likert scale where one (1) is a negative response and five (5) is a positive response on the expected patient response to a reimbursement model. Guide B focused on the barriers to accessibility and ethical aspects of a reimbursement system, and it had five (5) main questions. The questions focused on: the patient barriers in the current national health system, the priorities of the patients in a reimbursement system, the effects of socioeconomic situations, the reimbursement model which would benefit patients the most, and the need for convenient dosage forms. The guides were validated by one (1) linguistic expert and five (5) pharmacists. The validators were given an evaluation questionnaire to grade the guides (Appendix 1). The evaluation questionnaire contained a 5-point Likert scale where one is the lowest score and five is the highest score on the following categories: "Clarity and Relevance"," Comprehensiveness", "Engagement and Motivation" and "Consistency and Bias". The evaluation questionnaire contained another set of 5-point Likert scales, where one is the lowest score and five is the highest score, in which the overall guide was evaluated on the following categories: "Usability" and "Overall Effectiveness". The validators were asked to suggest amendments to the guides. An average percentage score was calculated for each question and an overall overview of the guide. Areas which had a percentage score of 50% or lower were focused on as they required significant amendments. The guides were updated in line with the scores and comments given by the validators.

2.4 Focus Group Recruitment

The focus group participants were selected through convenience sampling. In Focus Group A, participants from the DPA, CPSU, the Malta Medicines Authority, the Pharmacy unit of Mater Dei and members from the Malta Chamber of Commerce were recruited. In focus group B, participants from Malta Health Network, ADHD Malta, Caritas Malta, Malta Dementia Society, Action for Breast Cancer, and Step Up for Parkinson's were recruited. Permission was obtained from the relevant department of each organisation so that members of their organisation can participate.

2.5 Ethics Approval

Ethics approval was obtained after the organisations consented to their participants' involvement in the focus group. The consent email from each organisation, validated focus group discussion guides, proposal, and protocol were submitted to the University of Malta Research and Ethics Committee (UREC). The UREC self-assessment had indicated that the research was only to be submitted for records, and there was no need for review from the Faculty Research Ethics Committee (FREC) (Appendix 2).

2.6 Focus Groups

The participants were contacted to schedule a focus group. If a participant was not able to attend a focus group, another focus group was set up to accommodate them. One-on-one interviews were also used due to scheduling conflicts. A consent made as per the University of Malta standards was designed. In the consent form, participants are asked for their permission to record the focus groups and ensuring that participants are volunteering their participation while having the option to leave the dissertation at any time of their choosing. Participants were informed that the dissertation follows the General Data Protection Regulation. Each participant was given a consent form to sign before the focus group, confirming that they agree that the session will be recorded, and

while the participants will not be mentioned by name, they may be mentioned by their position and current organisation.

2.7 Analysis of Focus Group Data

The data collected from the focus groups underwent a PESTLE analysis to identify factors and the macro-environmental context that the factors fall under. The factors are divided into five (5) categories, which are: Political, Economic, Social, Technological, Legal and Environmental (Furuncu, 2025). Factors designated as high impact are expected to affect major parts of the policy and its implementation. Medium impact factors are expected to either influence moderate or specific aspects of the policy and its practical implementation. Low impact factors are predicted to have a limited potential to influence policy or affect the implementation. The results from the PESTLE analysis and the data collected from the focus groups were used to conduct a SWOT analysis. The SWOT analysis has four (4) categories: Strengths and Weaknesses, which are internal factors, and Opportunities and Threats, which are external factors (Furuncu, 2025).

The scores from the Likert scale found in Guide A were analysed to predict the patient response to a reimbursement model. The data highlighted the areas in which a reimbursement policy could have difficulties, and the areas in which it needs to be efficient in providing access.

2.8 Policy Drafting and Validation

The data gathered from the SWOT analysis was used to draft a reimbursement policy. The policy was drafted to improve accessibility and maintain equity. The policy was divided into five (5) main sections, which are: “Purpose of the Policy”, “Terms, definitions and abbreviations”, “Implementation procedures”, and “Policy Review.” The Policy was validated via focus group C. Focus group C consisted of members from the

DPA, the Pharmacy unit of Mater Dei, and MMA. Focus group C was given a validation tool which contained six (6) 5-point Likert-scales in which they were asked to grade the policy on the follow categories: “Exploitability”, “Clarity”, “Consistency”, “Applicability”, “Sustainability”, “Feasibility”, “Comprehensiveness”, and “Pharmacist Response.”

2.9 Policy Validation Analysis and Amendments.

An average percentage score was calculated, where a score of 15% would indicate that all participants gave a rating of 1 and a score of 100% would indicate that all participants gave a rating of 5. Areas which had a percentage score of 50% or lower were focused on as they required significant amendments. The comments and other data provided by the focus group underwent a PESTLE analysis and then a SWOT analysis. The results of the analysis and the suggestions from the validators were used to amend the policy. Areas with a percentage score of 50% or lower were focused on as they required significant amendments.

Chapter 3
Results

3.1 Structure of Results Chapter

The results consisted of 1) the validation of the focus group discussion guide, 2) the data collected from focus group A, 3) the data collected from focus group B, 4) the drafted reimbursement policy which was based on the data collected from focus group A and B, 4) the data collected from focus group C, and 5) the improved reimbursement policy following the validation with focus group C.

3.2 Focus Group Discussion Guide Validation

FDG A and FDG B were validated by five (5) pharmacists and one (1) linguistic expert to ensure face and content validity. The six (6) questions of FDG A gained the following overall scores (rounded to the nearest whole number): Q.1 86%, Q.2 92%, Q.3 93%, Q4 93%, Q.5 88% and Q.6 88%. The percentage score for the overall evaluation of FDG A, which was calculated by totalling the score for "Usability" and "Overall Effectiveness" and calculating the percentage total score out of the total score of 60, came out to 93% (Appendix 3). FDG A was amended and improved based on the feedback from the validation.

FDG B consisted of five (5) questions. FDG B underwent the same validation process as previously explained for FDG A. The following scores (rounded to the nearest whole number) were obtained: Q.1 96%, Q.2 94%, Q.3 95%, Q.4 98% and Q.5 92%. The percentage score for the overall evaluation of FDG B was 95% (Appendix 4). FDG B was amended and improved based on the feedback from the validation.

3.3 Focus Group A Results

Focus group A consisted of stakeholders and experts in the pharmaceutical field who gave their insight on reimbursement models and the current Maltese healthcare model. The participants highlighted that the current healthcare system in the country

suffers from delays in accessing novel medicines compared to other member states. One participant stated that it takes around ten years after the medicine has been introduced into the market before becoming available in the Maltese formulary. The experts acknowledged that the presence and advancements of AI are pressuring healthcare systems to advance at a faster rate and to increase the availability of personalised medicines. It was acknowledged that while the introduction of innovative and personalised medicines is challenging, they are most cost-effective despite their increased price when compared to traditional treatments. The cost-effectiveness was attributed to reduced hospitalisation and sick leaves, which results in higher productivity on a national level. A participant put forth a multi-award tender system (which is already in use) to improve access to novel medicines while reducing the risk of shortages. A reimbursement system that provides access to originator medicines or a variety of brands was suggested to be highly beneficial in improving patient quality of life while improving patient treatment by increasing the consistency of brands used and giving access to an alternative when the current treatment fails. Means testing, cost-utility analysis and the production of a bill showing the expenditure of the treatment given for the patient were recommended to prevent waste and ensure that patients are prioritised depending on their needs while remaining sustainable. Participants agreed that medicines, depending on the demand needed and cost, would require a different approach to add a medicine to a reimbursement policy. Private insurances were considered, especially given that Malta has one of the lowest health insurance rates in the European Union. As a cost containment measure, a participant suggested that medicines that have a level of cost effectiveness would be considered for first-line treatment, while more expensive but more advantageous options would not be offered unless the cost-effective options have failed. Patients not eligible

for the more novel and advantageous product would only be reimbursed for the amount provided for the cost-effective product.

Participants expressed that patients would have a negative reaction to the introduction of the reimbursement policy in Malta (n=9;69%) (Figure 3.1). Participants stated that patients have had a negative experience with a previous attempt at a government reimbursement measure. The primary reason given for the expected adverse reaction from patients was the interpretation that patients would view reimbursement systems as a detrimental factor to their healthcare benefits when compared to the current POYC system. To mitigate the negative perception, suggestions were made to avoid terms such as "reimbursement" and "co-payment". Other terms, such as "government assistance", were suggested. Patient education on the policy was highlighted as an effective method to improve patient perception of a reimbursement model.

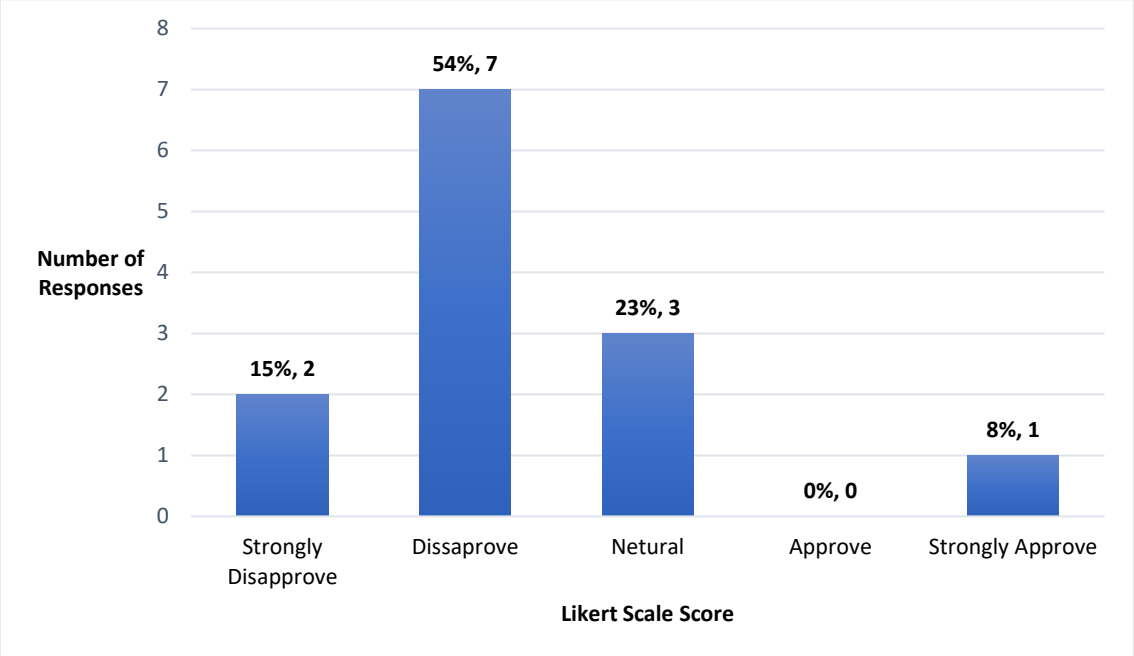

Figure 3.1 Focus Group A Likert Scale on the perceived patient response to a reimbursement system (N=14). The scores are represented as follows: 1 = Strongly Disapprove, 2 = Disapprove, 3 = Neutral, 4 = Approve, and 5 = Strongly Approve.

All participants agree that a pilot study is necessary to ensure patient accessibility while assessing the strain on the healthcare system. The use of a single-payer system would streamline patient education, thereby aiding in improving accessibility and patient perspective, as the lack of complexity is stated to make it easier to educate patients on the policy.

3.4 Focus Group B Results

Participants stated that while the Maltese healthcare system is currently highly beneficial to patients, it is not without its shortcomings. The healthcare system causes bureaucratic navigational issues to patients, ranging from finding the correct type of physician to understanding the forms needed to acquire their entitled benefits. The participants highlighted the difficulties and delays in accessing a specialised physician, such as a psychiatrist, through the Maltese healthcare system. Ergo, patients would either have delayed treatment or visit a private physician, which incurs OOP. Participants stated that patients may not always know what is available on the formulary, which has caused some patients to suffer OOP due to the physician's recommendation of a non-formulary brand or medicine. In conditions in which the brand can significantly impact the treatment, patients are more likely to need to pay OOP in the Maltese healthcare system, as the current system is unable to guarantee the brand's availability. Patients with Attention Deficit Hyperactivity Disorder (ADHD) were highlighted as a patient group that is highly affected by the brand of the medicines they use, ergo, likely to suffer from high OOP costs. The participants mentioned that some patients rely on the Malta Community Chest Fund to afford non-formulary medicines. According to the focus group participants, there are significant discrepancies between the options available on the formulary for certain conditions and those available on the market. The negative impact of the limited selection of medicines is further exacerbated by the outdatedness of the

medicines available, which increases the likelihood of OOP expenditure due to the need for more effective medicines found in the private market. The lack of variety of medicines was suggested to contribute to therapeutic nihilism in elderly patients, which increases the pharmacoeconomic cost of medicines. Participants pointed out that the current system invites a substantial amount of wastage. The wastage is multifactorial, encompassing issues such as medicines expiring within the system and patients continuing to take their entitled medication even after they are no longer prescribed these medicines.

The participants were asked to prioritise elements of a healthcare system; the majority's priority was the prevention of shortages (n=5). The remaining participant's priority was access to a variety of medicines (n=1). The second priority for most of the participants was access to innovative medicines (n=4). The remaining participants' second priority was access to more convenient medicines (n=2). The third priority for the participants was equally divided between access to a variety of medicines (n=3) and access to more convenient medicines (n=3). The least prioritised aspects were access to more innovative medicines (n=4) and access to more convenient medicines (n=2) (Figure 3.2).

To achieve the patient representative group priorities, the participants had suggested the use of a voucher system, which would allow patients to purchase the cheapest available medicine needed without OOP costs while giving the option of purchasing more expensive generic or branded products with reduced OOP costs.

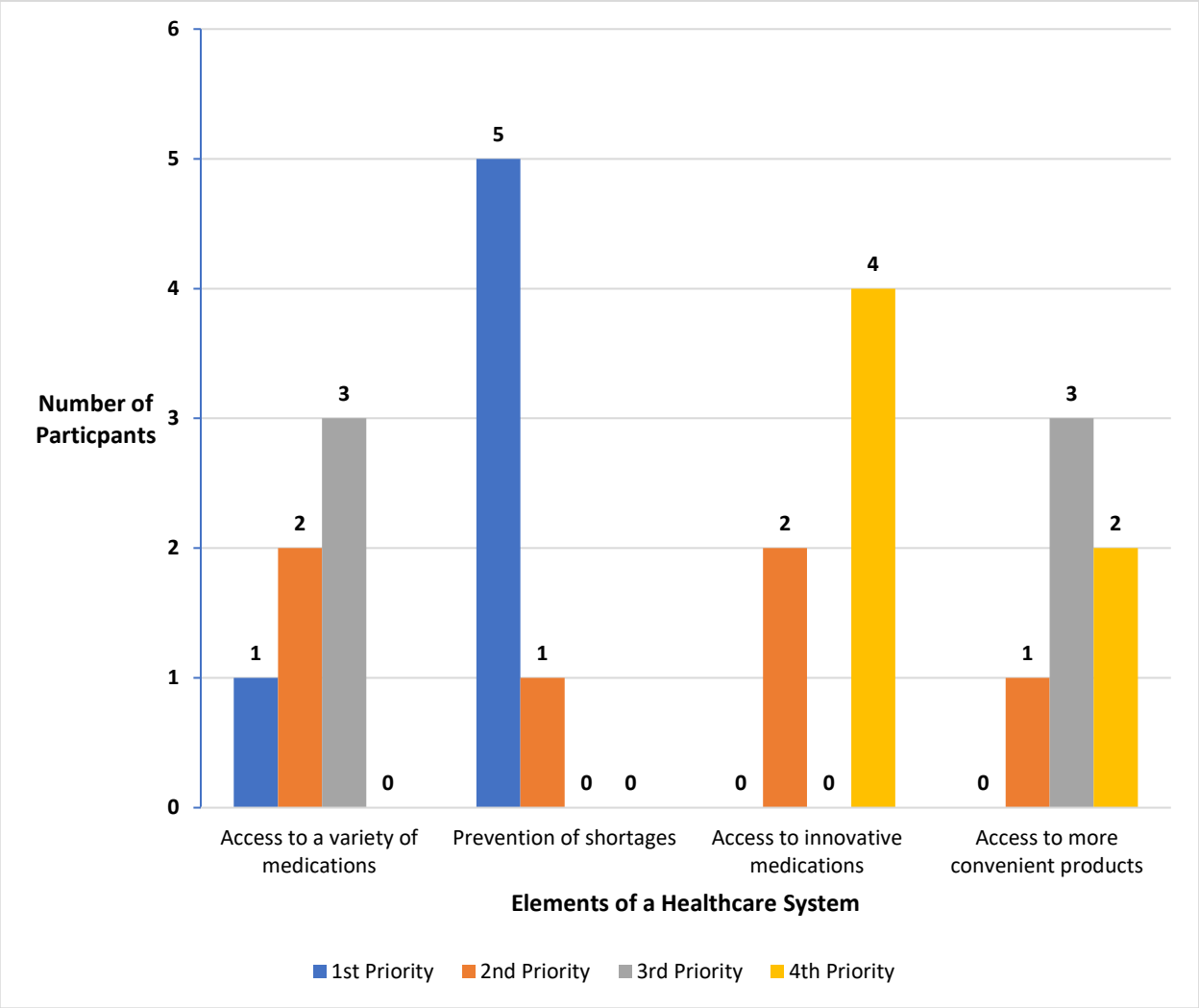

Figure 3.2 Focus Group B prioritising the elements of a healthcare system (N=6)

3.5 Focus Group A and B PESTLE analysis

The data provided from both focus groups A and B underwent a PESTLE analysis, and the following table, highlighting key factors for each category, was produced (Appendix 5).

The analysis indicated that political, economic, and legal factors have the highest impact on a reimbursement policy. Social and technological factors were found to have a medium impact. The least impactful factor was the environmental factor.

3.6 Focus Group A and B SWOT analysis

The data provided from both focus groups A and B , and the PESTLE analysis (Appendix 5) underwent a SWOT analysis, and the following table highlighting both the internal factors and external, was produced (Table 3.1).

Table 3.1 Focus Group A and B SWOT analysis

ANALYSIS OBJECTIVES	
To assess the strengths, weaknesses, opportunities, and threats in the implementation of a new healthcare reimbursement system.	
Internal Factors	
Strengths (+)	Weakness (-)
Political Stability (Political)	Government Budget (Political)
Healthcare Financing (Economic)	Regulatory Environment (Political)
Stakeholder Support (Political)	Government Policy (Political)
	Patient Awareness (Social)
External Factors	
Opportunities (+)	Threats (-)
Digitalisation of Healthcare (Technological)	Inflation and Cost of Living (Economic)
Private Sector Competition (Economic)	Public Sentiment (Political)
Access and Equity (Social)	Intellectual Property Laws (Legal)
Environmental Policies (Legal)	EU laws surrounding reimbursement and pricing (Legal)
Public Health Outcomes (Social)	

The results of the SWOT indicated four (4) weaknesses, of which the majority were categorised as Political factors (n=3). While there are only three (3) strengths

identified, five (5) opportunities were found with the implementation of the reimbursement system.

3.7 Policy Design

The data collected from focus groups A and B, along with the PESTLE analysis (Appendix 5) and the SWOT analysis (Table 3.1), were used to design a reimbursement policy that improves access to medicines (Appendix 6). Focus was given to empower patients and allow them to purchase branded medicines with reduced OOP cost. To ease the financial burden incurred by the policy, guidance was given on how to introduce novel medicines. Guidance on the implementation phase of the policy was based on pilot studies that would start with selected medicinal groups. The data collected from the pilots would be analysed and implemented into future pilot studies to further streamline and improve the policy while improving its real-world practicality.

3.8 Policy Validation

The initial Policy was validated on “Exploitability”, “Clarity”, “Consistency”, “Applicability”, “Sustainability”, “Feasibility”, “Comprehensiveness” and “Pharmacist Response”. The average percentage scores in order of the above factors are 52%, 68%, 72%, 64%, 68%, 64%, 56% and 56%. The participants' scores can be found in Table 3.2. The participants gave the policy an average overall score of 63%.

Table 3.2 Policy Validation Scores

	Pharmacist 1	Pharmacist 2	Pharmacist 3	Pharmacist 4	Pharmacist 5
Exploitability	3	3	3	1	3
Clarity	2	5	5	3	2
Consistency	3	5	5	3	2
Applicability	2	5	3	4	2
Sustainability	3	5	4	3	2
Feasibility	4	5	2	3	2
Comprehensiveness	4	5	2	1	2
Pharmacist Response	3	3	2	4	2
Total Overall Score	24	36	26	22	17
Total Overall Percentage Score	60%	90%	65%	55%	43%

3.9 Policy PESTLE analysis

The data provided from the policy validation underwent a PESTLE analysis, and the following table, highlighting key factors for each category, was produced (Appendix 7).

The analysis indicated that from the factors found, all the political factors, all of the economic factors and one (1) of the social factors have the highest impact on the implementation and effectiveness of the policy. The two (2) remaining social factors, all

of the technological and all of the legal factors, were found to have a medium impact. The least impactful factor was the environmental factor.

3.10 Policy SWOT analysis

The data provided from both the validation and the PESTLE analysis (Appendix 7) underwent a SWOT analysis, and the following highlighting both internal and external factors, was produced (Table 3.3).

Table 3.3 Policy SWOT analysis

ANALYSIS OBJECTIVES	
To assess the strengths, weaknesses, opportunities, and threats in the implementation of the draft policy	
Internal Factors	
Strengths (+)	Weakness (-)
Standardised procedures (Legal)	Budgetary constraints (Economic)
Health Technology Assessments (Economic)	Technologically Challenging (Technological)
Negotiations (Economic)	Bureaucratic Obstacles (Political)
Digital infrastructure (Technological)	
Reduced Wastage (Environmental)	
External Factors	
Opportunities (+)	Threats (-)
Controlled Scaling (Economic)	Budget Overruns (Economic)
Improve Patient Trust (Society)	Non-Compliance (Legal)
Improve Patient Adherence (Society)	Patient Dissatisfaction (Society)
Expand Coverage (Political)	

3.11 Policy Amendments

The data collected from the policy validation (Table 3.2), the PESTLE analysis (Appendix 7) and the SWOT analysis (Table 3.3), were used to improve the policy in

terms of “Exploitability”, “Clarity”,” Consistency”,” Applicability”,” Sustainability”,” Feasibility”,” Comprehensiveness” and “Pharmacist Response.”

Focus was given to close loopholes and to improve clarity by providing more details within the policy. Cross-resistance with other entities was also considered to reduce the implementation cost and reduce the confusion and training needed, as it would be a system that users (healthcare professionals or patients) would be familiar with. Suggestions were made to focus on the medicines to implement the system on medicines which are not already provided by the current system without OOP costs. To ensure that the policy acts as intended, it was suggested that the Plan-Do-Study-Act (PDSA) tool be used. The policy is currently in the Plan stage, and more details for the Do stage were suggested to ensure adequate data collection. It was suggested that a unit would be dedicated to the implementation and management of the policy. In the event there is a problem with the system, it was suggested that either pharmacies would have a way to log the medications reimbursed in an offline manner, or an IT specialist would be available to attend to unexpected issues or there would be a support team that would guide pharmacies on best to proceed or a mix of the aforementioned suggestions.

Chapter 4
Discussion

4.1 Context

The findings of this research highlight the difficulties patients may face accessing their medicines through the healthcare system. After identifying the need for improvements of the current healthcare system, recommendations to meet the identified unmet needs were made through the drafting of a reimbursement policy. The drafted policy underwent validation and was further improved using the feedback acquired. While further improvement may be required, it acts as an indicator of unmet patient needs. It offers possible recommendations on how to improve the current Maltese healthcare system.

4.2 Barriers to accessibility

Barriers to accessibility were found to be a multifactorial issue. Bureaucratic obstacles were highlighted, ranging from complicated healthcare systems to difficulties accessing the required physicians. These issues were exacerbated by patients' age, lack of familial support and limitations caused by their afflicted condition. An example of this is elderly Parkinson's patients who are required to be viewed by a specialist. These specialists have a long waiting time before they can be seen through the public health system, and elderly Parkinson patients require transport, which may not always be easily accessible depending on the severity of their Parkinson's, familial support and current physical fitness. To address these issues, the recommendation is for the system to be simplified and to have guides that patients can use to easily understand the healthcare system and the requirements. Other recommendations, include improving access to physicians by having physicians dedicated to reviewing patients so they could renew their prescribing or having physicians visit elderly homes to further improve patient quality of life.

The current Maltese healthcare system is dependent on a tendering system operated by CPSU, which procures medicines for the entire public healthcare system. This system of a central procurement entity can mitigate the disadvantage of Malta's small population by collecting medication for the majority of the population in a single order and reduce the cost of acquiring medicines through a tender. However, this method of acquiring medicines has the drawback of preventing patients from acquiring specific branded medicines, non-formulary medicines or recommended medicines which they are not entitled to without aid from other entities or without incurring OOP costs, which could be unaffordable to patients or reduce patient quality of life due to the increased financial burden. Some examples of these areas of inaccessibility include the accessibility to branded medicines such as Zexitor ® (metformin 500mg or 1000mg prolonged release tablets), which are preferred by some patients due to their gentler effects on the stomach.

Patients in the Maltese healthcare system are currently entitled to the government-supplied medical treatments without OOP costs through the Social Security Act Cap 318 Article 23 and the amendments of this act (Act No. I of 2012), and the Fifth Schedule of the Social Security Act.[4] The medicines to which patients are entitled to are dependent on their chronic condition.[4]This limitation of the healthcare system has caused medications with multiple indications that apply to multiple chronic conditions to be offered to a select group of patients through this act. Empagliflozin is an example of this, as only diabetic patients are currently eligible to receive this medicine through this act. In contrast, patients with cardiac conditions, who can benefit from its cardioprotective properties, are required to make OOP payments to gain access to this medicine. To mitigate this shortcoming, the eligibility for a product would be tied to its indication

[4]Pharmacy of Your Choice (POYC). Schedule V [Internet]. Pietà: POYC; 2023 [cited 2025 Apr 16]. Available from URL: https://poyc.gov.mt/en/schedule-v-r/schedule-v/

instead of patient eligibility being tied to their chronic conditions. Eligibility criteria, such as treatment failure, can be placed on expensive or non-first-line treatments.

As all the treatments given by POYC are collected by the CPSU, in the event of a shortage of a POYC medicine, the CPSU would need to place an urgent request for the product. This can lead to delays in the procurement of the product. In a reimbursement system where the private stock is used to provide for the patient, the risk of shortages is mitigated through the presence of multiple suppliers. While competition between the private suppliers can aid in keeping the price per unit low, it may not be as cost-effective as a tender. The lack of pricing regulation in Malta further increases the risk of higher prices for private stock.

The current tendering system is subject to an increased risk of changes in brand medicines when compared to the private market. While generics are bioequivalent to the originators, the change in brands can confuse patients, especially those who are illiterate. The change in brand can hinder patient communication with healthcare professionals, as patients sometimes relay a description of the tablet or capsule when they are unable to pronounce the name of the medicine. In some cases, a change in brand can have a negative impact on the treatment outcome, such as in hypothyroidism treatment, as changes in the brands of levothyroxine can affect the patient's thyroid levels. The policy aims to improve this by providing a set reimbursement amount for each medicine, which assists patients in purchasing branded medicines through a copay system. While this might improve access and reduce the risk of shortages, a system that makes use of private stock can increase the cost of the system as the price is controlled through competition between different brands and not through the tendering system.

As the current Maltese healthcare system only allows the patient to collect from one chosen pharmacy at a time, as the chosen pharmacy needs to be supplied with an adequate government stock of medicines, this limits the patients' ability to collect medicines. If their chosen pharmacy is unable to supply the required medicines, there is no simple way for the patients to acquire their medicines without incurring OOP costs. If patients can freely acquire their medicines from any pharmacy, competition between pharmacies increases, leading to increased service quality while minimising patient costs.

4.3 Overview of Proposed Policy

The proposed policy aims to improve accessibility through a reimbursement system. It also focuses on cost containment through negotiations with the medicine providers to prevent high prices on the market, which would increase OOP costs.

To ensure these OOP costs are minimal, medicine pricing regulations would need to be implemented in Malta. This requires new legislation for Malta and possibly a new entity or unit to oversee this regulation. Lessons could be taken from other countries which make use of pricing tools, including HTAs, reference pricing and value-based pricing. This would involve significant studies on the impact that the pricing regulation would have in Malta, which can negatively affect patient accessibility through declining interest from Marketing Authorisation Holders due to lower profit margins. In place of pricing regulation, the policy offers some guidelines and advice to aid in ensuring that the proposed products are offered at an acceptable price, and this would incentive other products to decrease their price closer to the reimbursement amount, as it would increase the quantity of their sales.

In the policy, medicines were divided into two categories: legacy medicines and novel medicines. Legacy medicines were defined as medicines whose active

pharmaceutical ingredients have been available on the market for an extended period and have had their patent expire. Novel medicines were defined as newly developed medicines that offer new therapeutic benefits for patients. A distinction was made as legacy medicines are likely to have generics available and have had more time to prove their therapeutic benefits, while allowing sufficient time for any safety risks that were not detected during clinical trials to become known. These factors make legacy medicines easier to introduce into the scheme due to their lower prices when compared to novel medicines and due to having more evidence supporting their therapeutic benefits and safety profile. Novel medicines, due to the recency of their development, may not have as much evidence as legacy medicines, which makes it harder for HTAs to be carried out on novel medicines and makes it more difficult to determine their value. Negotiations on the pricing of novel medicines are more critical when compared to legacy medicines. If the novel medicines do not have sufficient evidence, testing centres may be required to gather evidence that can either support or go against the use of this medicine. While the population of Malta limits the amount of data that can be gathered, the small geographical area of Malta means that there is no need for a large quantity of testing centres, and a single centralised centre can be used for multiple novel medicines.

The policy underlines what is required for pharmacies to participate in the reimbursement system. This mainly includes the ability to use the licensed software and a way to scan the barcode or unique identifier code (which is subject to the Falsified Medicines Directive). Pharmacies that participate in the scheme must make available the cheapest alternative to their patients while it is readily available. This ensures that patients do not incur OOP costs needlessly. Additionally, providing such a medicine would be beneficial to the pharmacy as this may encourage the patients to come back to said pharmacy.

The policy uses the Social Security Act and Schedule V to determine patient eligibility to join the reimbursement system. To summarise, any patient who is diagnosed with a condition listed in Schedule V is entitled to free medicines through the POYC system. The other way in which patients can get medicines is through the pink card, which is given to elderly patients as a form of social security, in which they are entitled to some free medicines which are not part of the Schedule V. In the case the patient needs full coverage for a medicine which is not given by this policy or the current care system, the Exceptional Medicinal Treatment (EMT) unit has an application form and process which can be used to grant access to these medicines.[6]

The policy currently allows for the dispensation of a 28-day supply to patients and prevents patients from collecting another 28-day supply until their current supply is close to completion. The pharmacist uses the official program to log down what the patient has collected, and the patient notification system would send an automated SMS to the patient. The SMS provides the following information:

- the medicines that the patient has claimed
- the number of medicines claimed (per unit dose)
- the total amount that will be reimbursed to the pharmacy
- A call to action that prompts the patient to use the listed contact number if the medicines are not claimed by the patient

The primary purpose of this SMS is twofold: firstly, to reduce waste of medicines by informing patients of the monetary value of the medicines provided. Through this understanding, patients would understand the significance of the monetary loss associated

[6] Directorate for Pharmaceutical Affairs (DPA). Exceptional Medicinal Treatment Policy [Internet]. Pietà: DPA; 2025 [cited 2025 May 01]. Available from: https://pharmaceuticalaffairs.gov.mt/en/units/exceptional-medicinal-treatment/

with wasted medicines, leading to less wastage of medicines by patients. Secondly, the call to action aims to encourage patients to report fraudulent activity, which reduces the exploitability of the policy.

Pharmacies in the scheme would be paid the reimbursement amount via a monthly back transfer. The reimbursement amount would depend on the number of medicines dispensed on the system in the previous month. As the patient can collect their medicines from any pharmacy in the scheme, competition between pharmacies would increase. The increased competition encourages pharmacies to provide better services to increase sales. Improvements that can be seen are increased services from the pharmacist, such as increased point-of-care testing.

During the implementation phase, a pilot would be carried out to target a gap in patient accessibility. During the implementation phase, cross-functional collaboration would be encouraged to minimise the resources needed to implement the policy and minimise the confusion that can occur due to changes in the healthcare system through minimisation of the changes needed to implement the policy.

The PDSA method would be used throughout the policy pilot phases to ensure continuous improvement of the policy. The following key performance indicators will be used to make quarterly reports: patient satisfaction, adverse event reports, patient adherence, medicine shortage frequency and duration. The policy will undergo biannual analysis, in which the data collected would be used to suggest amendments to the policy.

The policy requires a memorandum of understanding (MoU) to be sought with the representatives of the pharmacies. This would ensure the pharmacies cooperation and further strengthen the policies' ability to improve patients medicine accessibility.

Following the signing of the MoU the policy will be subject to said MoU and amendments may be required so that it conforms to the MoU.

4.4 Potential Benefits of the Reimbursement Policy

The primary benefit of the policy is the improvement of public health through addressing the gaps in the healthcare system, as patients would have access to a wider variety of medicines, which allow for a higher degree of personalisation of treatment. The policy aims to use private stock to supply patients, which would limit the amount of wastage in the system. Wastage could also be reduced by informing patients of the monetary value of the medications they are receiving. The policy aims to allow patients to copay for medicines, provided that the medicine they collect has the same active ingredient, dose, and dosage formulation as the medicine listed in their entitlement. This would empower patients to have a larger part in their treatment plan. It would reduce the risk of shortages for patients as they would have access to a larger variety of brands. As the patient selects their brand, there is a lower risk of variance in brands than in a tender system. This would reduce the risk of patient confusion in their treatments due to a change in the brands of their medicine. This would also reduce confusion between patients and healthcare providers regarding a patient's treatment plan, especially for patients experiencing polypharmacy and elderly patients.

4.5 Expected Patient Response

Despite the expected benefits of the policy, a negative patient response cannot be excluded. The negative response is primarily anticipated due to the current culture and societal norms. Investments must be made to educate patients and present the policy in a way that is more acceptable to patients. Words such as “reimbursement” were suggested not to be used when presenting the policy to the public. To improve the response, an analysis of which patient group would have the most positive response can be used to

determine which medicines should be entered into the policy first. As the public becomes more accustomed to the concepts of the policy, more medicines can be entered into the policy system, ergo, more patients would join the system.

4.6 Limitations

Despite the variety of perspectives taken into account during the study, it is limited by the sample size used to gain this perspective. A large representative sample of the population would provide a more accurate result in the stakeholders' perception, which would aid in identifying and addressing the stakeholders' concerns with a reimbursement system. A large sample size would allow a more accurate perception of the public's opinion regarding a reimbursement system, which could show the individual patient population's perception regarding a reimbursement system. The different patient population perspectives aid in identifying the current gaps in the healthcare system, which may require additional solutions other than a reimbursement system.

A feasibility study of the reimbursement system, while beneficial, was not feasible in this study. A feasibility study would give insight into the monetary strain the reimbursement system would have on a country's budget. While a reimbursement system has been implemented in multiple countries, given the small population size of Malta, challenges such as attracting Marketing Authorisation Holders to the country may present themselves due to this characteristic of Malta.

A pilot study could determine the impact the policy would have on patient medicine accessibility, along with identifing loopholes and shortcomings in the policy. Without an accurate assessment of the reimbursement system, the implementation could be hindered while also impeding patient accessibility. The current system is dependent on patient reporting and audit findings to determine the fraudulent use of the system. A

pilot study could identify fraudulent use of the system, which is less likely to be detected through an audit. The audit structure can be designed based on the findings of the pilot study to ensure that the most probable noncompliant use of the system is detected.

The study was not able to gather enough information on how the implementation of the policy would possibly affect other units within the healthcare system. This can lead to delays in the implementation, depending on the effect of the policy on other units in the healthcare system. This information is critical to ensure that other units within the healthcare system facilitate the implementation rather than hinder it. This could reduce the overall cost of implementation of the reimbursement system by using the already existing structure in place, while possibly aiding the other units.

4.7 Future Studies

It is recommended that future studies on how public health in Malta changes after the implementation of a reimbursement system be carried out. A study on public health could divide patients into different patient groups depending on the indication being treated and age. Such a study should take into account whether there were any changes in accessibility and take into consideration what treatment the patient would be on if they were still on the previous healthcare system.

A study on how patient perspectives on a reimbursement system change over time is recommended. This would highlight how patients react to changes in the healthcare system and indicate how patients become desensitised to certain systems. The study could also consider how effective the implementation strategies are at improving the patient response to a change in the healthcare system.

4.8 Conclusion

The study indicated that a reimbursement system is likely to benefit patients and the healthcare system. It is expected to improve the sustainability of the healthcare system while also improving patient accessibility to medicine. Despite the overall beneficial effects of a reimbursement system, patients could be expected to resist during the initial implementation phase. The resistance was attributed to previous experiences with similar systems and to fear that the new system would decrease the benefits offered to patients.

To reduce the misconception that the system would reduce patient benefits, education on the new system would have to be offered to both patients and healthcare professionals. Consideration should be given for health professional communication training, which could further improve the patient response. In addition, healthcare professionals may have a closer relationship with the patient than educators, which would allow for a more tailored explanation for the patients.

The main measure to improve patient response is a slow implementation phase coupled with education to both healthcare professionals and patients. This slow phase would give patients time to see the benefits of the reimbursement system. While also allowing more time for patient education to improve patient perception on the reimbursement system.

The reimbursement system is expected to facilitate the introduction of novel medicine and later personalised medicines into Malta. This would lead to improvements in patients' treatment outcomes and improvement in their quality-of-life years. The shift from a one-size-fits-all to a personalised approach, while likely to be more expensive than traditional treatment, may still have a cost-saving effect. The cost-saving effect can be attributed to the reduction in hospitalisations and the decrease in need for additional

treatments as a result of progression, flare-up or resistance to treatment from their condition. Other contributors include a reduction in recovery time, which would decrease the cost for hospital stays and improve the patients' productivity, which in turn has an economic benefit to the individual and society. Patients' participation in the labour force may improve due to the halting of debilitating effects of their condition, potentially avoiding the need for home health aides or nursing home admissions. Finally, personalised medicines may decrease the frequency or need for certain diagnostic tests, which would reduce waiting times for patients and costs in terms of diagnostic tests done. This would also minimise potential risks associated with the diagnostic test, such as increased risk of infection, and this would improve patient economic contribution as they would need to take less time out of their day to undergo diagnostic tests.

The suggested reimbursement system is expected to reduce the frequency of patients changing the brand of their medicine. The reduced frequency in changing brands of medicine reduces the risk of decreased treatment efficacy or failure due to the variance between brands. The reduction of changes between brands of medicines would also reduce confusion in patients due to changes in brands, especially in the elderly and/or patients who experience polypharmacy. In this system private pharmacy stock would be used, reducing the risk of waste compared to the current healthcare system. This system would promote competition between pharmacies while possibly increasing their profit through increased foot traffic.

To conclude, while the implementation of a reimbursement system faces multiple challenges from different fronts, its implementation or partial implementation is expected to benefit patients through increased accessibility and the country through improved public health and productivity.

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Appendices

Appendix 1

Validation Questionnaire

Dear Participant,

My name is Michael Cini, and I am a second-year Doctor of Pharmacy student currently working on my thesis titled Medicines accessibility in a national health service.

Firstly, I would like to thank you for your help in validating the questioning tools. Your perspective and insights will help me refine and validate these tools.

Additionally, please be assured that this study will follow the General Data Protection Regulation (GDPR) to ensure the privacy and security of all participants' information.

Below you will find a Likert scale ranging from 1 to 5, where 1 represents a poor score and 5 represents a perfect score. These scales will be used to grade the questions and the overall questionnaire based on the specified criteria. Feel free to also reword questions on the questioning tool using the tracked changes feature of word.

To help guide you, please find the guiding questions for each criterion below.

For individual questions:

1. **Clarity and Relevance**
    a. Are the questions clear and easily understandable?
    b. Do the questions effectively address the topic or objective of the tool?
    c. Are there any questions that seem confusing or ambiguous?
2. **Comprehensiveness**
    a. Do the questions cover all necessary aspects of the topic?
    b. Is there any critical area or detail that you feel is missing?
    c. Are there any redundant or unnecessary questions?
3. **Engagement and Motivation**
    a. Did the questions engage you and keep your interest throughout?
    b. Were there any questions that felt repetitive or disengaging?
4. **Consistency and Bias**
    a. Were the questions consistently phrased and free from bias?
    b. Did you notice any questions that seemed leading or unfair?

For Overall Questionnaire:

1. **Usability**
    a. How easy was it to navigate and use the questioning tool?
    b. Were there any difficulties or challenges in answering the questions?
    c. How would you rate the overall user experience?
2. **Overall Effectiveness**
    a. Do you feel that the tool effectively achieves its intended purpose?
    b. How confident are you in the validity of the responses generated using this tool?

Validation Tool A

The following is the validation criteria for Questioning Tool A, which focuses on the finer details of access and reimbursement. The goal of this tool is to gather information on the characteristics that a reimbursement model for Malta should have.

Question 1

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Question 2

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Question 3

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Question 4

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Question 5

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Question 6

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Overall Questionnaire

1. **Usability**

1	2	3	4	5

2. **Overall Effectiveness**

1	2	3	4	5

Additional Comments

_____
_____
_____
_____
_____

Validation Tool B

The below is the validation criteria for Questioning tool B which focuses on the ethical and patient aspects. The goal of this tool to gather information on any ethical issues the reimbursement model might have and how to address them. Additionally, it aims to gather information on how to make the reimbursement model more patient-focused.

Question 1

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Question 2

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Question 3

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Question 4

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Question 5

1. **Clarity and Relevance**

1	2	3	4	5

2. **Comprehensiveness**

1	2	3	4	5

3. **Engagement and Motivation**

1	2	3	4	5

4. **Consistency and Bias**

1	2	3	4	5

Overall Questionnaire

1. **Usability**

1	2	3	4	5

2. **Overall Effectiveness**

1	2	3	4	5

Additional Comments

Appendix 2

Ethics Approval

The status of your REDP form (MED-2024-00392) has been updated to Acknowledged

Inbox ×

form.urec@um.edu.mt 26 Nov 2024, 14:48

to me

Dear Michael Cini,

Please note that the status of your REDP form (MED-2024-00392) has been set to *Acknowledged*.

This status change was accompanied by the following explanation/justification: *Dear applicant, Your research ethics application has been received. This does not mean that your application has FREC ethical approval and may be subject to an audit review. The FREC number generated by submission for records only cannot be used as proof of ethical approval. As indicated in the Research Ethics Review Procedures, submissions which have no self-assessment issues are kept for record and audit purposes only, so research may commence. Kindly note that FREC will not issue any form of approval as the responsibility for the self-assessment part lies exclusively with the researcher. Please note that SCPD generally requires review. If you have any questions or doubts or require any further clarification you can contact the MED FREC secretary. Regards, MED FREC*

You can keep track of your applications by visiting: https://www.um.edu.mt/research/ethics/redp-form/frontEnd/.

This email has been automatically generated by URECA. Please do not reply. If you wish to communicate with your F/REC please use the respective email address.

Appendix 3

Validation results for FDG A

	Pharmacist 1	Pharmacist 2	Pharmacist 3	Pharmacist 4	Pharmacist 5	Linguistic Expert	Total
Question 1							
Clarity and Relevance	3	5	5	3	4	5	25
Comprehensiveness	3	5	5	5	3	5	26
Engagement and Motivation	4	5	5	5	4	4	27
Consistency and Bias	4	3	5	5	3	5	25
Totals	14	18	20	18	14	19	103
Percentage Total Score	70%	90%	100%	90%	70%	95%	86%
Question 2							
Clarity and Relevance	4	4	5	5	5	4	27
Comprehensiveness	4	5	5	5	5	4	28
Engagement and Motivation	4	5	5	5	5	3	27
Consistency and Bias	4	5	5	5	5	4	28

	Pharmacist 1	Pharmacist 2	Pharmacist 3	Pharmacist 4	Pharmacist 5	Linguistic Expert	Total
Totals	16	19	20	20	20	15	110
Percentage Total Score	80%	95%	100%	100%	100%	75%	92%
Question 3							
Clarity and Relevance	4	5	5	5	5	4	28
Comprehen siveness	4	5	5	5	5	5	29
Engagement and Motivation	4	5	5	5	5	3	27
Consistency and Bias	3	5	5	5	5	4	27
Totals	15	20	20	20	20	16	111
Percentage Total Score	75%	100%	100%	100%	100%	80%	93%
Question 4							
Clarity and Relevance	5	4	5	5	5	4	28
Comprehen siveness	4	4	5	5	5	4	27

	Pharmacist 1	Pharmacist 2	Pharmacist 3	Pharmacist 4	Pharmacist 5	Linguistic Expert	Total
Engagement and Motivation	4	5	5	5	5	3	27
Consistency and Bias	5	5	5	5	5	4	29
Totals	18	18	20	20	20	15	111
Percentage Total Score	90%	90%	100%	100%	100%	75%	93%
Question 5							
Clarity and Relevance	4	5	5	5	3	3	25
Comprehen siveness	5	5	5	5	5	3	28
Engagement and Motivation	5	4	5	5	5	3	27
Consistency and Bias	5	5	5	5	3	3	26
Totals	19	19	20	20	16	12	106
Percentage Total Score	95%	95%	100%	100%	80%	60%	88%

	Pharmacist 1	Pharmacist 2	Pharmacist 3	Pharmacist 4	Pharmacist 5	Linguistic Expert	Total
Question 6							
Clarity and Relevance	5	5	5	4	3	4	26
Comprehensiveness	4	5	5	5	3	4	26
Engagement and Motivation	4	5	5	5	4	4	27
Consistency and Bias	3	5	5	5	4	4	26
Totals	16	20	20	19	14	16	105
Percentage Total Score	80%	100%	100%	95%	70%	80%	88%
Overall Questionnaire							
Usability	4	5	5	5	5	4	28
Overall Effectiveness	4	5	5	5	5	4	28
Totals	8	10	10	10	10	8	56
Percentage Total Score	80%	100%	100%	100%	100%	80%	93%

Appendix 4

Validation results for FDG B

	Pharmacist 1	Pharmacist 2	Pharmacist 3	Pharmacist 4	Pharmacist 5	Linguistic Expert	Total
Question 1							
Clarity and Relevance	5	5	5	5	5	5	30
Comprehensiveness	5	5	5	5	5	5	30
Engagement and Motivation	4	5	5	5	5	5	29
Consistency and Bias	4	2	5	5	5	5	26
Totals	18	17	20	20	20	20	115
Percentage Total Score	90%	85%	100%	100%	100%	100%	96%
Question 2							
Clarity and Relevance	4	5	5	5	5	5	29
Comprehensiveness	4	5	5	5	5	5	29
Engagement and Motivation	5	3	5	5	5	5	28
Consistency and Bias	3	4	5	5	5	5	27
Totals	16	17	20	20	20	20	113
Percentage Total Score	80%	85%	100%	100%	100%	100%	94%

	Pharmacist 1	Pharmacist 2	Pharmacist 3	Pharmacist 4	Pharmacist 5	Linguistic Expert	Total
Question 3							
Clarity and Relevance	4	4	5	5	5	5	28
Comprehensiveness	4	5	5	5	5	5	29
Engagement and Motivation	4	5	5	5	5	5	29
Consistency and Bias	4	4	5	5	5	5	28
Totals	16	18	20	20	20	20	114
Percentage Total Score	80%	90%	100%	100%	100%	100%	95%
Question 4							
Clarity and Relevance	5	5	5	5	5	5	30
Comprehensiveness	4	5	5	5	5	5	29
Engagement and Motivation	4	5	5	5	5	5	29
Consistency and Bias	4	5	5	5	5	5	29
Totals	17	20	20	20	20	20	117
Percentage Total Score	85%	100%	100%	100%	100%	100%	98%

	Pharmacist 1	Pharmacist 2	Pharmacist 3	Pharmacist 4	Pharmacist 5	Linguistic Expert	Total
Question 5							
Clarity and Relevance	4	5	5	5	5	3	27
Comprehensiveness	5	5	5	5	5	3	28
Engagement and Motivation	5	5	5	5	5	3	28
Consistency and Bias	4	5	5	5	5	3	27
Totals	18	20	20	20	20	12	110
Percentage Total Score	90%	100%	100%	100%	100%	60%	92%
Overall Questionnaire							
Usability	4	4	5	5	5	5	28
Overall Effectiveness	4	5	5	5	5	5	29
Totals	8	9	10	10	10	10	57
Percentage Total Score	80%	90%	100%	100%	100%	100%	95%

Appendix 5

PESTLE analysis of Focus Groups A and B

PESTLE Analysis for the Implementation of a Reimbursement Model in Malta			
Factor	**Sub-factor**	**Details**	**Impact (High/Medium/Low)**
Political	Government Policy	The model needs to align with the government's initiatives related to health spending.	**High**
	Political Stability	Changes in the government could affect priorities for healthcare reforms	**High**
	Stakeholder Support	Political Stakeholders would have to create laws or amend current policies for a reimbursement model.	**High**
	Regulatory Environment	Changes in pricing regulations can affect both public and private sector healthcare professionals.	**High**

Factor	Sub-factor	Details	Impact (High/Medium/Low)
Political	Public Sentiment	Public Support is required for the transition to a reimbursement model. Resistance from patients can affect the implementation of a reimbursement model.	**High**
Economic	Government Budget	The design of the reimbursement model might increase the strain on the government budget.	**High**
	Inflation and Cost of Living	Cost of living and inflation rate influence the affordability of the model.	**High**

Factor	Sub-factor	Details	Impact (High/Medium/Low)
Economic	Healthcare Financing	The amount of funds generated through taxes and other government initiatives influences the amount of budget available.	**High**
	Private Sector Competition	Increasing involvement from the private sector, including health insurance companies, can support the model or undermine the public health policy.	**High**

Factor	Sub-factor	Details	Impact (High/Medium/Low)
Social	Access and Equity	The model must allow equitable access to avoid exacerbating health disparities.	**Medium**
	Public Health Outcomes	Changes in the healthcare system can lead to improvements in public health outcomes. Inefficiencies in the model can lead to a negative impact on public health outcomes.	**Medium**
	Patient Awareness	Changes in the healthcare system can alienate or confuse patients, especially given that patients are not used to a reimbursement model.	**Medium**

Factor	Sub-factor	Details	Impact (High/Medium/Low)
Technological	Innovation in Medicine	High-cost medicines can impact the sustainability of the model	**Medium**
	Digitalisation of Healthcare	Digitalisation of prescriptions can improve the efficiency of a reimbursement model.	**Medium**
Legal	Intellectual Property Laws	Patent protections reduce the availability of generics, which will be crucial to the affordability and accessibility of medicines.	**High**
	EU laws surrounding remuneration and pricing	The model must comply with EU Law regarding transparency and drug pricing.	**High**

Factor	Sub-factor	Details	Impact (High/Medium/Low)
Environmental	Environmental Policies	Environmental polices around pharmaceuticals and waste can have a direct or indirect impact on the reimbursement system.	**Low**
	Supply Chain Challenges	Environmental factors such as weather can disrupt the supply chain and affect medicines accessibility.	**Low**

Appendix 6

Draft Policy

MEDICINES ACCESSIBILITY PROGRAM POLICY

1. Purpose of the Policy

The policy aims to provide an overview of how the government assists in the purchase of medicines. The policy indicates how (i)the subsidised amount is chosen for each medicine, (ii) medicines are subsidised, (iii)new medicines are added to the program, and (iv) a patient enters the program.

2. Terms, definitions and abbreviations

Falsified Medicine Directive (FMD): the harmonised European measures that aim to prevent falsified medicines from entering the legal supply chain and reaching patients.

Health Technology Assessment (HTA): A multidisciplinary and systematic evaluation of the properties of a health technology, which is used to guide the use of said technology.

Legacy Medicine: Medicines that have been available on the market for an extended period and are no longer covered by a patent.

Marketing Authorisation Holder (MAH): The licence holder of a medicine

Medical Association of Malta (MAM): the Maltese doctors' professional association and trade union.

Managed Entry Agreements (MEA): Risk-sharing agreements which are made between manufacturers and payers.

Novel medicines: Newly developed medicines which have a unique therapeutic benefit.

Reference Countries: Countries which are used for reference pricing.

Value-Based Agreements (VBA): an agreement between the manufacturer and payer in which the cost of the product or service is determined based on the clinical performance of the product or service.

3. Policy statements

3.1 Introductory Process

Medicines are classified into two categories: legacy medicines and novel medicines. The process for requests is dependent on which category the medicine falls under. The process is as follows:

Legacy medicines

1. Requests submitted to introduce a medicine are examined based on related medical guidelines. The request is then discussed with the Medical Association of Malta (MAM) to determine the average frequency of prescribing.
2. Market research is carried out in the local market and reference countries when possible.
3. A Health Technology Assessment (HTA) of the product is carried out.
4. The cheapest generic on the market, which can supply for 28 days (on the lowest dosage regimen), is evaluated to see if it meets the budgetary requirements while meeting the patient's needs.
5. If the product is not within budget or the analysis shows that there is room to negotiate for a cheaper price, discussions should be opened with the Marketing Authorisation Holder (MAH) to negotiate for an acceptable price.
6. If the product price meets the budgetary criteria, it is added to the program.

Novel medicines

1. Requests submitted to introduce a novel medicine are examined based on related medical guidelines. The request is then discussed with the MAM to determine the medication need.
2. Carry out market research in the local market and reference countries when possible.
3. Carry out an HTA of the product.
4. The data collected from the market research and HTA is used as the basis for negotiations with the MAH. Considerations are made for managed entry agreements or value-based agreements based on the data found.
5. If an acceptable offer based on budgetary constraints and priorities is reached, then the medicine is added to the program.

3.2 Community Pharmacy entering reimbursement system

Pharmacies that are entered into the reimbursement system require the following:

- Software from an authorised provider
- A scanner that can scan the barcode and/or FMD unique identifier.

Any registered pharmacy is duty-bound to comply with any investigator or auditor.

3.3 Registering patients into the reimbursement system.

Any eligible participant can be entered into the system by a licensed physician through the web portal.

3.4 Adding medicine to the patient's profile

Medications can be assigned to patients by their physician through the patient's profile on the web portal. Medications that do not require a specialist or an exemption can be added by a licensed physician as deemed necessary. The physician must specify the following when adding a medicine:

- The indication for the treatment
- The duration of treatment
- The strength of the medication
- The frequency of dosing
- The timing of dosing

If any of the above are changed during the patient's treatment, the physician is required to be updated at the earliest.

Physicians may receive comments or queries from patients or other healthcare professionals through the portal. These are required to be answered at the earliest.

3.5 Exceptional Cases

If it is determined that a patient can only take a certain branded medicine or a certain dosage form, the physician must provide reason and evidence for this decision. Some examples include patient allergy or risk of patient non-adherence due to pre-existing conditions. The requests are viewed by the entity responsible for the policy. The entity must then present its reasons for its decision. In the event this was a new type of request, then the reasons must be documented to have a standardised approach.

3.6 Dispensing of Medicines

Patients may go to any pharmacy participating in the scheme to collect their medicines. Patients may only buy up to 2 months' supply at a time and must wait till their supply is nearing completion before collecting another 2 months' supply. At the pharmacy, the pharmacist logs what the patient has bought on the official system, and once these are logged, the patient receives an automated SMS showing:

- the medicines that the patient has claimed
- the number of medicines claimed (per unit dose)
- the total amount the patient had been reimbursed
- A contact number that can be used if the medicines are not claimed by the patient

3.7 How reimbursement is issued to pharmacies

Pharmacies are paid the reimbursement amount via a monthly bank transfer. The reimbursement amount is determined by the medications dispensed on the system in the previous month.

4 Implementation procedures

The reimbursement policy will be implemented in a stepwise fashion through pilots of therapeutic medicinal groups. During the pilots, the responses and complaints from all involved are recorded to improve the implementation of future studies. The effects on the budget are taken into consideration along with changes in patient accessibility.

Appendix 7

PESTLE analysis of the initial policy

Factor	Sub-factor	Details	Impact (High/Medium/Low)
Political	Government-driven initiative	The Policy requires government support to ensure smooth implementation	**High**
	Involvement of Regulatory Bodies	Regulatory bodies' assistance would be needed to ensure the policy runs effectively.	**High**
	Budgetary Allocation	The Policy might divert budget allocation from other initiatives	**High**
Economic	Budgetary Constraint	The amount of budget available is tightly bound to the breadth of the implementation model.	**High**
	Price Negotiations	Price negotiations act as a price mitigation strategy for the cost of medicines reimbursed.	**High**
	Monthly Reimbursements	These monthly reimbursements would aid in supporting local community pharmacies by increasing their revenue.	**High**

Factor	Sub-factor	Details	Impact (High/Medium/Low)
Social	Improved Public Health	Improved medical access would lead to improved health outcomes, which would lead to an overall improvement in public health.	**High**
	Increased Public Engagement	The SMS systems would increase public engagement with the system and, as such, aid in improving the system.	**Medium**
	Increased focus on patients' needs	The policy takes into account allergies, non-adherence risks and other risks that could affect patient accessibility.	**Medium**
Technological	Electronic and Digital Tools	Specific tools are required for the implementation of this system, including web portals and scanner programs.	**Medium**
	Increased Reliance on Digital Infrastructure	The use of web portals increases the pharmacies' dependence on digital infrastructure. .	**Medium**

Factor	Sub-factor	Details	Impact (High/Medium/Low)
Technological	Automated SMS	Automated SMS notification enhances real-time communications and alert patients to any fraudulent behaviour related to their reimbursement.	**Medium**
Legal	Standardised Documentation	Decisions made regarding the medicines must be documented in a standardised manner.	**Medium**
	Inspection and audits	Inspections and audits must be carried out to ensure the system is not abused.	**Medium**
Environmental	Waste Reduction	The electronic system reduces the amount of paper used. The system also shows the amount reimbursed to make patients aware of the value of the medicines and, as such, avoid wastage of medicines.	**Low**

Factor	Sub-factor	Details	Impact (High/Medium/Low)
Environmental	Stock Waste	As there is no separation between stock for reimbursement and private stock, there is less risk of medicines expiring.	**Low**

Appendix 8

Dissemination of Results

Abstract accepted for the University of Malta Research Expo 2025 : Cini M, Anastasi A, Serracino-Inglott A. Medicines Accessibility In A National Health Service

Medicines Accessibility In A National Health Service

Patient accessibility to medicine is a vital factor in improving and safeguarding public health. In the 2022 European Federation of Pharmaceutical Industries and Associations Patient Waiting to Access Innovative Therapies indicator survey Malta had the longest delay (average of 1351 days) in providing access to innovative medicines. This study aims to develop a reimbursement model for Malta, which reduces this delay in accessibility while remaining sustainable. An in-depth literature review was conducted to compare medicine reimbursement policies in the international scenario and the local scenario. The compiled data was used to develop two questionnaires, each focusing on an aspect of a reimbursement system: pharmacoeconomic aspects (Focus Group A) and ethical aspects (Focus Group B). These questionnaires were applied to their respective focus group, and a SWOT analysis was carried out on this data. The SWOT analysis was used to draft a reimbursement policy, which was validated through Focus Group C. The data from the focus groups indicated a desire for improved access to both innovative medicines and dosage forms. It was expressed that personalised and innovative medicine will be able to reduce healthcare expenditure despite their higher cost. Streamlining and robustness of the systems were also emphasised. The study demonstrated a need to improve access to personalised and innovative medicine. There are currently strategies in place, but further investment is needed. The strategies need to take into consideration the patient and pharmacist response for easier implementation.

Abstract accepted for the 83rd FIP World Congress of Pharmacy and Pharmaceutical Sciences 2025, Copenhagen, Denmark, September 2025: Cini M, Anastasi A, Serracino-Inglott A. Medicines Accessibility through a Reimbursement Model in a National Health Service

Title

Medicines Accessibility through a Reimbursement Model in a National Health Service

Background Information

Medicines accessibility is a critical challenge for healthcare systems, as lack of equitable access to medicines can significantly impact public health. Systems where medicines are provided by the government through tax funded programs may struggle with sustainability, access to newer medicines, and consistent access to the same brand of medicines. A reimbursement model could address these issues while empowering patients. This study explores the potential of a reimbursement system to improve medicines accessibility in a country with a small market.

Purpose

The aim of this study is to develop a reimbursement model applicable to countries with small markets. The objectives are: (i) to identify and review international drug reimbursement policies, (ii) to analyse the strengths, weaknesses, opportunities, and threats (SWOT) associated with implementing a reimbursement model in countries with a small market, and (iii) to propose and validate a reimbursement policy.

Method

An extensive literature review was conducted to gather information on international drug reimbursement policies. The data collected was used to design guidelines for two focus groups: one investigating views on which reimbursement policy and methodology is

suitable for small market countries, taking into consideration recent advances such as personalised and innovative medicine (Focus Group A) and the other taking into consideration barriers to medicines accessibility and ethical aspects (Focus Group B). These guidelines were validated by five pharmacists. A linguistic expert was consulted to ensure face validity. Focus Group A consisted of experts from six different pharmaceutical stakeholder entities, and Focus Group B consisted of participants from six patient representative groups. The data collected underwent political, economic, social, technological, legal, and environmental (PESTLE) and SWOT analyses. Analysis results were used to design a reimbursement policy, which is validated through Focus Group C, consisting of experts from pharmaceutical stakeholder entities.

Results

The results showed that the introduction of a reimbursement system is beneficial in reducing wastage, improving patient satisfaction, and increasing sustainability compared to a government formulary system. However, respondents in Focus Group A (N=10) indicated that patients might have a negative response to transitioning from a government formulary system to a reimbursement system (n=8). Focus Group B (N=6) emphasized the importance of preventing shortages, as this can have the highest negative impact. For example, ADHD patients may require access to specialised medicines, with some patients expressing willingness to pay extra for this access. Additionally, both focus groups identified that clear communication and education about a potential reimbursement system is essential to mitigate resistance and ensure smooth implementation.

Conclusion

The study found that implementing a reimbursement model in a country with a small market faces multiple barriers, both politically and from patients, especially when transitioning from a government formulary system. Education and communication about

the reimbursement system will be paramount to its success. Pilot studies are recommended to evaluate patient response, equity, sustainability, and how the reimbursement model would interact with a pricing authority. These studies will help refine the model and address any potential issues before full implementation.

Topic Area

Social and Administrative Pharmacy

Addenda

Addendum 1

Reimbursement Policy

MEDICINES ACCESSIBILITY PROGRAM POLICY

1. Purpose of the Policy

The current Maltese healthcare system suffers from gaps in access to medicines and accessibility. Patients in the current healthcare system can either obtain medication at no cost through the healthcare system or purchase it at full retail price from a private retailer. This situation has created a need for an intermediary option that allows patients to buy medications not covered by the formulary at a reduced price. Moreover, discrepancies between clinical prescribing and formulary eligibility further complicate continuity of care. The policy aims to improve patient access to medicines while reducing their out-of-pocket expenses.

Before implementing this policy, a memorandum of understanding will be sought with the pharmacy representatives. The policy will be subject to this memorandum and updated as needed.

The policy aims to provide an overview of how the government assists in the purchase of medicines. The policy indicates how (i) a medicine is added to the scheme, (ii) how medicines are dispensed in the scheme and (iii) how pharmacies receive the reimbursement amount.

To reduce bureaucratic obstacles in the administration of the policy, it is suggested that the reimbursement scheme be overseen by one entity, which will be referred to as the Policy Owner.

2. Terms, Definitions and Abbreviations

Exceptional Medicinal Treatment (EMT): medicinal treatment which is not covered by an existing policy on the Government Formulary List.[1]

Falsified Medicine Directive (FMD): the harmonised European measures that aim to prevent falsified medicines from entering the legal supply chain and reaching patients.[2]

Health Technology Assessment (HTA): An assessment that summarises information about medical, economic, social and ethical issues related to the use of a health technology.[3]

Legacy Medicine: Medicines that have generics, biosimilars, or are licensed through the well-established use legal basis (10a) from the directive 2001/83/EC.[4]

Marketing Authorisation Holder (MAH): The licence holder of a medicine

Managed Entry Agreements (MEA): Risk-sharing agreements which are made between manufacturers and payers.

Novel medicines: Newly developed medicines which have a unique therapeutic benefit.

Reference Countries: Countries which are used for reference pricing.

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[1] Directorate for Pharmaceutical Affairs (DPA). Exceptional Medicinal Treatment Policy [Internet]. Pietà: DPA; 2025 [cited 2025 May 03]. Available from: https://pharmaceuticalaffairs.gov.mt/en/units/exceptional-medicinal-treatment/

[2] European Commission. Falsified Medicines [Internet]. Brussels: European Commission; 2025 [cited 2025 May 03]. Available from: https://health.ec.europa.eu/medicinal-products/falsified-medicines_en

[3] European Commission. Overview of Health Technology Assessment [Internet]. Brussels: European Commission; 2025 [cited 2025 May 03]. Available from: https://health.ec.europa.eu/health-technology-assessment/overview_en

[4] European Commission. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [Internet]. Brussels: European Commission; 2001 [cited 2025 May 03]. Available from: https://eur-lex.europa.eu/eli/dir/2001/83/oj/eng

Value-Based Agreements (VBA): a possible form of MEA agreement in which the cost of the product or service is determined based on the clinical performance of the product or service.

3. Policy Statements

3.1 Introductory Process

Medicines are classified into two categories: legacy medicines and novel medicines. The process for requests is dependent on which category the medicine falls under. Requests can be submitted by (i) the Marketing Authorisation Holder (MAH) or (ii) a physician. The overall process is as follows:

1. Requests submitted to introduce a medicine into this scheme are examined based on related medical guidelines. The request is then discussed with a group of experts who can aid in determining the impact of a medicine on both public and individual levels. The expected frequency of prescribing is also determined.
2. Market research is carried out in the local market and reference countries when possible.
3. A Health Technology Assessment (HTA) of the medicine is carried out, except on medicines that are already available in the government formulary.
4. Prices are assessed, and a maximum reference price is established.
5. The approved maximum reference price cannot be exceeded.

3.2 Pharmacy joining the reimbursement scheme

1. Pharmacies can apply to join the scheme through the physical or electronic submission of the application form. The application form will request the following business identifiers
    - Name of Pharmacy
    - Pharmacy Licence Number
    - Pharmacy Address
    - Business Phone Number of the Pharmacy Licence Holder
    - Business Phone Number of the Managing Pharmacist
    - Business Email Address
    - IBAN account number

A copy of the Pharmacy Licence must be given with the application form. In the event of discrepancies between the licence and given information, proof of pending or accepted variations is required.

2. As part of the application, it is expected to read and understand the terms and conditions. After doing so, they need to sign the application form to indicate that they agree to the terms and conditions of the scheme. The terms and conditions aim to hold pharmacies responsible for any fraudulent activity, ensure cooperation with auditors and investigators, and ensure pharmacies provide medicines which do not incur out-of-pocket costs to the patients, provided that these medicines are currently not experiencing a shortage.
3. If a pharmacy is approved to join the scheme by the Policy Owner, it will be provided with the software that will be used to register for the scheme.

4. Along with the software, an instruction manual for the software is given. If more information is needed, requests can be made for training sessions on the program.

3.3 Registering patients into the reimbursement scheme.

1. Patients can be entered into the scheme through a web portal by an authorised prescriber.
2. A patient's eligibility is determined by the Social Security Act CAP 318 Article 23 and the amendment of this act - Act No. I of 2012 and the Fifth Schedule to the same Act.[5]
3. A request to enter a patient into the scheme is examined by the Policy Owner, who determines if a request is (i) to be approved, (ii)approvable pending further information, or (iii) to be rejected.
4. If the patient is accepted into the scheme, any overlapping medicine entitlement is revoked.

3.4 Adding medicine to the patient's profile

Medications can be assigned to a patient's profile by an authorised prescriber through the care system. The authorised prescriber must specify the following when adding a medicine:

- The indication for the treatment
- The duration of treatment
- The strength of the medication
- The frequency of dosing

[5] Government of Malta. Healthcare Entitlement [Internet]. Valletta: Government of Malta; 2025 [cited 2025 May 8]. Available from: https://www.gov.mt/en/Life%20Events/Pages/Healthy%20Living/Healthcare-entitlement.aspx

- The timing of dosing

If there are any changes to the above must be reflected in the patient's profile; the authorised prescriber must update the details in the patient's profile so that the reimbursement remains valid for the patient.

3.5 Removing a medicine from a patient's profile

When a medicine is no longer needed by a patient, the approved prescriber can remove it from their profile through the web portal. When removing the medicine, the practitioner must select the applicable reason/s from below for the removal of the medicine:

- Lack of Effectiveness
- Occurrence of serious side effect/s
- Other

If lack of effectiveness is selected, the following information would be requested:

- Parameters used to determine the lack of effectiveness

If occurrence of serious side effect/s is selected, the following information would be requested:

- Description of side-effect/s
- Frequency of side-effect/s
- Severity of side-effect/s

If other is selected, the authorised prescriber would be asked to describe the reason and to provide any related details.

Once the authorised prescriber removes the medicine from the patient profile, they will no longer be able to collect it from the pharmacy. The patient would also be informed of the removal through an automated SMS system.

3.6 Exceptional Cases

If it is determined that a patient can only take a particular medicine, the authorised prescriber is advised to inform the Policy Owner through the official channels. The requests are divided into normal and urgent requests. The classification is determined by the Policy Owner, and it would be based on the negative impact associated with the delay of the request. Non-urgent requests are to be reviewed weekly, while urgent requests are to be reviewed within 48 hours of receiving the request. Non-urgent requests are to be reviewed by a committee consisting of the Chairperson of the Policy Owner, two (2) pharmacists and two (2) clinicians. Urgent requests are to be reviewed by a committee consisting of the Chairperson of the Policy Owner, one (1) pharmacist and one (1) clinician. If the request is accepted, the patient's entitlement is updated so that the medicine can be purchased without out-of-pocket costs for the patient. The process, comments from the committee and decisions are documented throughout.

3.7 Dispensing of Medicines

Patients will select a main pharmacy from which they will collect their medicines through the submission of a form. Once selected, the pharmacy will be added to the patients' profile, and they may only collect medicine from their main pharmacy, except in exceptional circumstances. In exceptional circumstances, such as shortages of a medicine, a pharmacist may update the patients' profiles to allow them to collect medicines from another pharmacy for one month. In the event the patient wishes to permanently change their main pharmacy, they would be requested to fill in a form, which

would be sent to the Policy Owner. The request to change the main pharmacy is to be processed within 7 days of request submission.

Patients may only be dispensed up to a 28-day supply and must wait until their supply is nearing completion before collecting another 28-day supply. This is ensured through the software, which allows the pharmacists to see all previous dispensations to said patient. The software used would also alert pharmacists if the patient is exceeding the maximum supply allowed for the patient. If the patient requires a supply that exceeds 28 days, then a request is to be made to the Policy Owner with any related evidence. The request is to be reviewed within a week of submission by the policy owner. The patient can buy any brand they wish as long as it contains the active ingredient, dose and dosage formulation of a medicine listed in their entitlement. If the product costs more than the reimbursement amount provided the patient would have to pay the remaining amount. At the pharmacy, the pharmacist logs what the patient has bought on the official system, and once these are logged, the patient notification system would send an automated SMS to the patient showing the below:

- the medicines that the patient has claimed
- the number of medicines claimed (per unit dose)
- the total amount that will be reimbursed to the pharmacy
- A call to action that prompts the patient to use the listed contact number if the medicines are not claimed by the patient

3.8 How reimbursement is issued to pharmacies

Pharmacies are paid the reimbursement amount via a monthly bank transfer. The reimbursement amount is determined by the medications dispensed on the system and the related reimbursement amount.

4 Implementation Procedures

The reimbursement policy should undergo a Plan-Do-Study-Act (PDSA) testing. During the Do stage, it will be implemented in a stepwise fashion through pilots of therapeutic medicinal groups. The order in which the therapeutic medicinal groups are introduced is determined by the Policy Owner. The order of the therapeutic medicinal groups would be chosen by the Policy Owner, depending on budgetary impact, current accessibility, expected impact of the policy and expected patient response.

The following key performance indicators will be used to make quarterly reports: patient satisfaction, adverse event reports, patient adherence, medicine shortage frequency and duration. During the pilots, responses and complaints from all parties involved are recorded to inform the implementation of future studies. Each year, 10% of claims are selected via random sampling and are audited to ensure compliance with the system.

5 Policy Review

The policy shall be reviewed biannually by the entity responsible for the policy. The policy amendments will consider the findings from audits, key performance indicators and any other relevant data.