Scope of vignette:
- authorised products (with marketing authorisation)
- decision process about routine use (and not individual requests for reimbursement)
- **submissions** for P&R made by manufacturers

Green = related to/any special considerations for OMPs/UOMPs

Malta	**Standard reimbursement and HTA (critical appraisal) process for pharmaceutical products**
Overview of health system and P&R/HTA process	Tax based health system [1] Within the National Health System, the Directorate for Pharmaceutical Affairs (DPA) is responsible for developing and implementing equitable and sustainable Government pharmaceutical policies. [2] The Health Technology Assessment (HTA) Unit within the DPA assists in the decision making process regarding inclusion of new medicines on the Government Formulary List (GFL). The HTA Unit provides technical support to two committees (the technical committee GFLAC (Government Formulary List Advisory Committee) and the financial committee ACHCB (Advisory Committee for Health Care Benefits). The HTA Unit is involved in the pre and post committee procedures, and in creating technical reviews of the drugs being assessed. [3] The Pharmaceutical Pricing Unit within the DPA is responsible for contributing to fair pricing of medicines in the Government Health Services in concurrence with the Standard Operating Procedures, and calculating the Maximum Reference Price (MRP), External Reference Price (ERP) and Guidance Reference Price (GRP) according to the internal Standard Operating Procedure. [4]
Differentiation of rare disease treatments in the P&R system	None (HTA) (Following the publication of *L.N. 58 of 2018: Health Act (CAP. 528); Exceptional Medicinal Treatment Committee Regulations, 2018*, the committee named The Exceptional Medicinal Treatment Committee (EMTC) was set up. The objective of the EMTC is to assess requests for exceptional medicinal treatment in a consistent, transparent and sustainable way guided by strict criteria that include medicines for the treatment of Rare Diseases. [5])
Eligible medicines	All medicines that are indicated and utilised for any of the chronic diseases as listed in the Fifth Schedule of the Social Security Act Cap 318 Art 23 are eligible. [6]
Process	- Applications for new medicinal products or new indications are received at DPA, from either the Marketing Authorisation Holders (MAHs) or clinical consultants working within the Government Health Services - The applications consist of distinct forms for MAHs or and consultants, and are submitted together with all supporting documentation

Malta	Standard reimbursement and HTA (critical appraisal) process for pharmaceutical products
	- Upon receipt, an acknowledgment is immediately issued to the applicant confirming receipt - Requests are the validated in line with set entitlement criteria - The applicant is informed in writing whether the request has been accepted or not - If accepted, the request will be passed on to a reviewer for a thorough assessment of the medicine and preparation of a HTA - The place of the medicine being assessed is considered within an integrated care pathway encompassing the medical condition involved (i.e. the Government prioritises specific diseases areas e.g. oncology and diabetes. For these areas clinicians are invited to submit clinical pathways that will also include the role of the new medicine) - The report is then discussed by the two committees (the technical committee GFLAC and the financial committee ACHCB) - The HTA unit follows up the outcomes of the discussion and the final decisions are disclosed to the applicants - If the medicine is recommended for approval, the procurement section is notified to initiate the tendering procedure [3]
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	Yes, mainly clinicians in the submission, HTA process and at the committee level
Key domains in assessment	- Clinical-effectiveness - Cost-effectiveness
Evidentiary requirements	No leniency for OMPs
PROMs	Not applicable
Appraisal framework	In addition to the key domains, the following other key factors are included: • Introduction of medicinal product • Method of assessment • Field of application (information on disease/condition; epidemiology; comparative treatment) • Value of medicinal product indicated by the Clinical Chairman • Recommendations given by organisations for providing national guidance • Situation in other countries The Exceptional Medicinal Treatment Committee utilises a Schedule of Review Criteria for assessment of Exceptional Medicinal Treatment Requests in its processes where rare diseases and medicines with orphan status are included under the positive criteria. [5]
Reimbursement decision	GFLAC – technical recommendation ACHCB – financial recommendation

Malta	Standard reimbursement and HTA (critical appraisal) process for pharmaceutical products
	Minister for Health – final endorsement: approved or not approved If approved, the particular medicine will be available free of charge to patients in line with GFL policies.
Pricing process	Reference pricing: Maximum (MRP), External (ERP) and Guidance (GRP) Pricing computations are performed to create a reference price control during the procurement process of all the medicines, and are also included in the HTA of new medicines. Research of medicine prices is conducted from many EU countries falling within the bracket of +/-20 percentage points of Malta's Gross Domestic Product (GDP) per capita in Purchasing Power Standards (PPS) using EUROSTAT figures and the UK price. [4]
Managed entry agreements	Not applicable
Main challenges in appraising medicines for rare diseases (tick all that apply)	X Lack of good quality clinical data X Lack of real world data X Introducing value for money X Monitoring treatment efficacy X Managing budget impact X Lack of criteria/transparency of OMP P&R processes X Making arrangements to work for all stakeholders X Lack of long-term meaningful outcomes ☐ Other, please specify
Impact of special processes	Not applicable
Proposed policy change	Changes are planned to these processes, however, discussions are still ongoing.
Joint initiatives	DPA participates in various EU projects involving sharing of information related to pharmaceutical policies, pricing and reimbursement of medicine, between the participating member states. Collaborations include: - EUnetHTA and the HTA Network - The Pharmaceutical Pricing and Reimbursement Information (PPRI) network - The Network of Competent Authorities for Pricing and Reimbursement (CAPR)
SOURCES	
1	https://www.welcome-center-malta.com/the-maltese-health-care-system-explained/
2	https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/pharmaceutical-affairs.aspx
3	https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/assessment-unit.aspx

Malta	Standard reimbursement and HTA (critical appraisal) process for pharmaceutical products
4	https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/pharmaceutical-pricing.aspx
5	https://deputyprimeminister.gov.mt/en/pharmaceutical/Documents/Circulars/2019/circular_22_2019.pdf
6	https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/application-forms.aspx

Created in February 2019 by the IMPACT-HTA team with the support of the country experts. Last updated in November 2019.

Acknowledgments: We would like to thank Antonia Formosa, Director of Pharmaceutical Affairs at the Ministry of Health, for her time and valuable contribution in providing the information used to create and validate this vignette. This research is funded under the EC's Horizon 2020 Programme within IMPACT-HTA. Results reflect the authors' views. The EC is not liable for any use of the information communicated.

This vignette was compiled based on information provided by country experts and desk research. The information provided may be incomplete or contain inaccuracies. If you have any comments or updates, please email us at the following email addresses:

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