Directorate for Pharmaceutical Affairs

Structure, Functions and Responsibilities

The Directorate of Pharmaceutical Affairs has the mission of developing and implementing equitable and sustainable pharmaceutical policies for the National Health Services in Malta. In addition, it promotes excellence in patient care by adding value to individual patient care through assuring safe, rational and cost-effective use of medicines to all.

The Directorate is sub-divided into 8 units and currently employs 19 officers.

- The Formulary Management Unit establishes, maintains and periodically reviews the Government National Formulary for pharmaceuticals in the Government Health Service; and provides advice and technical assistance in the establishment of technical specifications. This unit sets service-wide protocols governing prescribing and the rational use of medicines; and issues circulars related to formulary management.
- The Pharmaceutical Pricing Unit contributes to fair pricing of medicines in the Government Health Service in concurrence with the Standard Operation Procedures emanating from Maltese legislation. This unit calculates the Maximum Reference Price (MRP), External Reference Price (ERP) and Guidance Reference Price (GRP) according to the internal Standard Operating Procedure. It monitors and follows drug prices across EU countries.
- The Health Technology Assessment Unit performs validation of applications for new medicines onto the formulary. Through the use of Health Technology Assessments (HTAs), this unit analyses information and evaluates clinical evidence regarding requests for introducing new medicinals or new indications of existing medicines on the government formulary intended for discussion and recommendation by the two consultative committees: the Government Formulary List Advisory Committee (GFLAC) and the Advisory Committee for Health Care Benefits (ACHCB).
- The Exceptional Medicinal Treatment Unit assesses requests on a named-patient basis for exceptional medicinal treatment in a fair, equitable and transparent manner in accordance with L.N. 58 of 2018 Exceptional Medicinal Treatment Committee Regulations, 2018. Reviews are then presented to the appropriate authorities for their consideration based on the evidence presented.
- European Collaborations: DPA participates in various EU networks and initiatives relating to Pharmaceutical Policy including EUNetHTA, HTA Network, PPRI network and The Network of Competent Authorities for Pricing and Reimbursement (CAPR). DPA establishes contacts with Pricing and Reimbursement Agencies and Authorities in the various EU countries and communicates through networking and sharing of information with the other EU peers involved in pharmaceutical policy.

- The Pharmaceutical Strategy and Policy Unit formulates, monitors and evaluates pharmaceutical policies to be implemented in the Government Health Service within the framework of a National Health Policy and international pharmaceutical practices. A horizon scanning system was set up in 2020 with the aim of performing horizon scanning activities within the context of pharmaceutical policy. This will be used to improve strategic and financial planning and decision-making by providing timely, early intelligence on new medicines which are not yet licensed. Horizon scanning is the process which allows the identification of new and emerging medical products by systematic analysis of pipeline health technologies, typically before they reach the market, and before the HTA process.
- The Medication-use Evaluation Unit monitors drug utilisation and patient outcomes following treatment. This process is conducted on medications on the Government Formulary List, newly introduced drugs and non-formulary drugs currently being approved through the Exceptional Medicinal Treatment Policy.
- The Pharmaceutical Professions Management Unit demands continuous collaboration with the Directorate for Human Resources within the Ministry for Health and with the Administrative/Technical heads of the different pharmaceutical entities with regards all issues related to the pharmaceutical professions.

An administration office supports all the above sections.

General Description of the Categories of Documents Held

- Policy documents and related working documents
- Studies, reports, interim reports and related documentation
- DH Circulars
- Standard Operating Procedures
- Human Resource documents
- Databases relating to free medical treatment
- Dossiers relating to free medical treatment

Contact Details of the FOI Office of the Directorate for Pharmaceutical Affairs

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