Ministry for Health

Department for Policy in Health

Directorate for Pharmaceutical Affairs

Data Protection and Retention Policy

SCOPE

1. This Policy is aimed at regulating the retention, maintenance and disposal of documentation, both personal and other, within the Directorate for Pharmaceutical Affairs, as provided for in the terms of requirements emanating from legal provisions in such other acts as the Public Administration Act chapter 497 and directives emanating therefrom, and in accordance with the principles of data protection legislation, and the National Archives Act (Cap. 477).

BACKGROUND

2. The General Data Protection Regulation (GDPR) (EU) 2016/679 puts forward the principle that personal and sensitive personal data, should not be retained for periods that are longer than necessary. In this context, the Directorate for Pharmaceutical Affairs will be putting forward a retention policy for all records collected and processed, with the purpose of ensuring compliance to the Regulation and to ensure that no resources are utilised in the processing and archiving of data which is no longer of relevance.

OBJECTIVES

3. This policy aims to achieve the following objectives:

    - Regulate the retention and disposal of the various types of records within the Directorate for Pharmaceutical Affairs while adhering to the Data Protection principle that personal data should not be retained for a longer period then necessary; as per Article 5 (e) of the GDPR.
    - Dispose of unnecessary documentation that is no longer relevant and is taking up useful storage space: stated in Article 17 of the GDPR.
    - Promote the digitisation of documentation as may be reasonably possible in order to minimize the use of storage space required to store documentation, as well as to promote a sustainable use of paper and printing consumables.

THE DATA SUBJECT RIGHTS

4. Data subjects are entitled to know, free of charge, what type of information the Directorate for Pharmaceutical Affairs holds and processes about them and why, who has access to it, how it is held and kept up to date, for how long it is kept, and what the Unit is doing to comply with data protection legislation.

    The GDPR establishes a formal procedure for dealing with data subject access requests. All data subjects have the right to access any personal information kept about them by the Directorate for Pharmaceutical Affairs, either on computer or in manual files. Requests for access to personal

information by data subjects are to be made in writing using the Request for Access to Personal Data by Employees, and sent to the Data Protection Officer of the Directorate for Pharmaceutical Affairs. The data subject identification details such as ID number, name and surname have to be submitted with the request for access. In case we encounter identification difficulties, the data subject may be required to present an identification document.

ADMINISTRATION

5. Documentation is held and recorded by the administration office at the Directorate for Pharmaceutical Affairs. This policy is therefore applicable to all such documentation. It will be the responsibility of the relevant Head of the Directorate for Pharmaceutical Affairs and any other deputy, supervisor or administrator who may be delegated to ensure that all provisions of this policy are adhered to.
6. All staff that create, maintain, process and store records mentioned hereunder are responsible to perceive and implement the instructions given in this policy.

7. The Directorate for Pharmaceutical Affairs, following appropriate consultation and direction, is authorized to modify this policy as deemed appropriate from time to time to ensure compliance with state laws.

DOCUMENTATION HELD WITHIN THE DIRECTORATE FOR PHARMACEUTICAL AFFAIRS

8. As part of its operating requirements the Directorate for Pharmaceutical Affairs requests, keeps and maintains a wide range of documentation including personal data. The type of data that is being utilised by Directorate for Pharmaceutical Affairs may be listed as follows:

- Human Resources records
- Requests for introductions onto the Formulary by Marketing Authorisation Holders
- Requests for introductions onto formulary by clinicians
- Medicinal product summary sheets
- Requests for reference prices
- Health technology assessment and related documents
- Exceptional medicinal treatment requests
- Ombudsman cases
- Documents related to EU collaborations
- Travel documents
- Purchasing records
- EU Funding applications
- EU projects
- Movement of file register
- Inventory records

SECURITY OF DOCUMENTATION

9. Documentation is maintained in an accessible but secure location with adequate access provided to officials who have the clearance level to access the relevant documentation. In the case of documents with sensitive personal data with higher clearance levels, access control protocols are fully adhered to, to ensure that only those that have the required security clearance have access to such documentation.
10. In the case of personal data, the GDPR also stipulates that only those required to process personal data should have access to personal records.
11. Personnel who are found to be in breach of these security protocols, and thus in breach of the GDPR, will be subject to disciplinary action as per Article 33 Clause (5) of the GDRP.

MANUAL VS ELECTRONIC RECORDS

12. In terms of retention periods, it needs to be pointed out that the same retention period will apply for both electronic (if applicable) and manual data.

RETENTION PERIOD

13. The Retention schedule (on the following document) outlines the retention requirements for the various categories of documentation within the Directorate for Pharmaceutical Affairs:

Key	Unit /Dept	Category	Records Type	Description	Retention Period	Remarks	Action required by the National Archives (when retention period expires)
1	Department for Policy in Health	Directorate Pharmaceutical Affairs- Human Resources	Human Resources Records	Attendance and Absence Records; Sick leave Certificates; Application forms for enlistment, calls, and positions; Telework, Career break and reduced hours application forms; Continued Professional Education allowance, Qualification allowance application forms; Applications for training opportunities; Training records	According to existing Retention Policy for HR Documents issued by OPM.	None	According to existing Retention Policy for HR Documents issued by OPM.
2	Department for Policy in Health	Directorate Pharmaceutical Affairs- Free Medical Treatment	Requests for introductions onto the Formulary by Marketing Authorisation Holders	Applications to the Superintendent of Public Health for the inclusion of new medicinal products or new indications onto the Formulary, known as T01 form	Ten (10) Years from Evaluation	L.N 58 of 2009- Availability of Medicinal Products within the Government Health Services Regulations; EU Council Directive 89/105/EEC - Transparency Directive	A random sample of five (5) applications from every year is to be transferred to the National Archives for permanent preservation.

3	Department for Policy in Health	Directorate Pharmaceutical Affairs- Free Medical Treatment	Requests for introductions onto the Formulary by Clinicians	Submission to the Superintendent of Public Health for the inclusion of new medicinal products or new indications onto the Formulary, known as T02 form.	Ten (10) Years from Evaluation	L.N 58 of 2009- Availability of Medicinal Products within the Government Health Services Regulations; EU Council Directive 89/105/EEC - Transparency Directive	A random sample of five (5) applications from every year is to be transferred to the National Archives for permanent preservation.
4	Department for Policy in Health	Directorate Pharmaceutical Affairs- Free Medical Treatment	Medicinal Product Summary Sheets	Summary of the medicinal product referred to the committees for inclusion onto the Formulary.	Indefinite	None	To be kept indefinitely by the originating office.
5	Department for Policy in Health	Directorate Pharmaceutical Affairs- Free Medical Treatment	Requests for Reference Prices	Applications for the calculation of reference prices of medicinal products	Three (3) years	None	Not required for permanent preservation by the National Archives

6	Department for Policy in Health	Directorate Pharmaceutical Affairs	Health Technology Assessment and related documents	Comprehensive evaluation and assessment of existing and emerging medical technologies in regard to their medical, economic, social and ethical effects.	Ten (10) Years from evaluation and assessment.	None	A random sample of five (5) applications from every year is to be transferred to the National Archives for permanent preservation.
7	Department for Policy in Health	Directorate Pharmaceutical Affairs	Exceptional Medicinal Treatment Requests	Applications for provision of medicinal treatment when the treatment is not on the Formulary or is not according to Government Formulatory List policies	Seven (7) years retention period starts from the application date	L.N.58 of 2018- Exceptional Medicinal Treatment Committee Regulations, 2018 and obligations that might exist under other legislation	A random sample of five (5) applications from every year is to be transferred to the National Archives for permanent preservation.
8	Department for Policy in Health	Directorate Pharmaceutical Affairs	Ombudsman cases	These records are a **copy of the investigations** which is then sent to the Commissioner for Health within the Parliamentary Ombudsman.	Ten (10) years from date of completion	Ombudsman retention policy in place	Not required for permanent preservation by the National Archives
9	Department for Policy in Health	Directorate Pharmaceutical Affairs-Eu Collaborations	Documents relating to EU collaborations	Surveys, meeting minutes, working documents, reports	Ten (10) years	None	Transfer to the National Archives for Permanent Preservation.

10	Department for Policy in Health	Directorate Pharmaceutical Affairs-Financial Documents	Travel documentation	Travel files, expense statements, GA27 forms, other related forms, invoices and receipts.	Ten (10) years	This is a **copy**. The travel report is sent to International Affairs & Policy Development Directorate	Not required for permanent preservation by the National Archives
11	Department for Policy in Health	Directorate Pharmaceutical Affairs-EU Programmes	EU Funding applications	**Copy** of the Applications for EU funded projects or programmes. Original records are kept in the Ministry Registry.	Three (3) years after end of programming period. This is not the original documentation.	The retention period of documentation is established according to Planning & Priorities Coordination Division (PPCD) instructions	Not required for permanent preservation by the National Archives
12	Department for Policy in Health	Directorate Pharmaceutical Affairs-Eu Programmes	EU Projects	**Copy** of the Documentation relating to projects utilising EU Funding. Original records are kept in the Ministry Registry.	Three (3) years after end of programming period.	The retention period of documentation is established according to Planning & Priorities Coordination Division (PPCD) instructions	Not required for permanent preservation by the National Archives
13	Department for Policy in Health	Directorate Pharmaceutical Affairs-Others	Movement of files registers	Track record of movement of paper files	Ten (10) years	None	Not required for permanent preservation by the National Archives

14	Department for Policy in Health	Directorate Pharmaceutical Affairs-Others	Inventory Records	Records of fixed tangible assets including furniture and office equipment	Indefinite	None	Not required for permanent preservation by the National Archives
15	Department for Policy in Health	Directorate Pharmaceutical Affairs-Financial Documents	Purchasing records	Invoices and receipts.	Five (5) years	None	Not required for permanent preservation by the National Archives

IMPLEMENTATION OF THE RETENTION PERIOD

14. The implementation of the said retention periods come into effect as from 19th November 2019 and cover all data held at the Directorate for Pharmaceutical Affairs. The first step will be to dispose of old documents dating back decades held within the premises according to procedure and timeframes listed in this policy. Every file destroyed shall be documented by the staff to keep a track record. Eventually officers responsible for data listed in the retention schedule will, following approval by the management team, dispose of such data according to the given timeframes.

CONCLUSION

15. This retention policy is intended towards achieving a good working balance between the retention of useful information and the disposal of data which is no longer required and is being unnecessarily archived. Data that needs to be destroyed will be disposed of in an efficient manner to ensure that such information will no longer be available within the Directorate for Pharmaceutical Affairs. Data Protection Controllers, Heads, and DPOs will be made aware of the noted retention periods and will instruct all relevant personnel to follow the indicated procedures accordingly.

It is to be noted that anonymised data do not fall within the parameters of this Retention Policy, since they do not constitute identifying personal data

The Data Protection Officer of the Directorate for Pharmaceutical Affairs may be contacted at:

Address:
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St. Luke's Hospital,
Guardamangia

E-mail: dpo@dpa.gov.mt
Telephone: 25955232

The Information and Data Protection Commissioner

The Information and Data Protection Commissioner may be contacted at:
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