

# **Ministry for Health**

## **Pharmacy of Your Choice Unit**

### **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 Pharmacy of Your Choice Unit (POYC), as provided for in the terms of requirements emanating from legal provisions in such acts as the Public Administration Act (Chap. 497) and directives emanating therefrom, and in accordance with the principles of data protection legislation, and the National Archives Act (Chap. 477).

#### **BACKGROUND**

2. The GDPR puts forward the principle that personal data and sensitive personal data should not be retained for periods that are longer than necessary. In this context, the Pharmacy of Your Choice Unit will be putting forward a retention policy for all data and documentation that it collects and processes, 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:
  - a. Regulate the retention of and disposal of the various types of documentation whether held in manual or automated filing systems within the Pharmacy of Your Choice Unit, while adhering to the Data Protection principle that personal data should not be retained for a longer period than necessary, as per Article 5 (e) of the GDPR;
  - b. Dispose of unnecessary documentation that is no longer relevant and is taking up useful storage space as per Article 17 of the GDPR;
  - c. 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. The data subject is entitled to know, free of charge, what type of information the Pharmacy of Your Choice Unit holds and processes about him 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 Pharmacy of Your Choice Unit, 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 Form](#), and sent to the Chief Executive Officer of the Pharmacy of Your Choice Unit. The data subject identification details such as ID number, name and surname must be submitted with the request for access. In case we encounter identification difficulties, you may be required to present an identification document.

## **ADMINISTRATION**

5. Documentation is held and recorded by the Pharmacy of Your Choice Unit. This Policy is therefore applicable to all such documentation. It will be the responsibility of the Chief Executive Officer, as Data Controller, or any delegates 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 Pharmacy of Your Choice Unit, 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 PHARMACY OF YOUR CHOICE UNIT**

8. As part of its operating requirements the Pharmacy of Your Choice Unit requests, keeps and maintains a wide range of documentation including personal data. The various types of documentation utilised by the Pharmacy of Your Choice Unit may be categorised as follows:
  - Applications for Schedule V
  - Applications for MAS Approvals
  - Patients' POYC Applications
  - Applications for over 70 home deliveries
  - Change in Pharmacy Applications
  - Audit Section Stock take reports / Pharmacy files (1 per pharmacy)
  - Invoices at POYC Stores (both from the Central Processing and Supplies Unit (CPSU) and to Pharmacies)
  - Return Notes for collection of medicines
  - External transfer notes for redistribution
  - Monthly External returns
  - Daily / urgent summations
  - Delivery Logbooks
  - Batch recall
  - Files containing JIT (Just In Time) / urgent orders / pick lists / stock movements
  - Deviation reports
  - BMR (Batch manufacturing Record)
  - Partial Manufacturing Area Temperature logs
  - Partial Manufacturing Area Deviations records
  - Partial Manufacturing Area GRN's (Goods Received Notes)

- Seal Record numbers
  - Delivery Sheets
  - Orders sent to CPSU (hard copies)
  - Invoices for stationery supplied to pharmacies
  - Delivery notes from / to MDH
  - Copies of Orders related to Partial Manufacturing Area
  - Daily statistics
  - Staff meeting minutes
  - Printed Emails
  - Stock adjustments
  - Transfers from PMA to Stores (IMAINQ to IMAINI)
  - Dangerous Drugs Control Card applications and expired returned Control Cards
  - Records of goods that expired or were damaged at POYC
  - Records of expired goods to be boarded out
  - Cleaning Logs
  - Temperature logs for storage areas
  - Van Storage Temperature Logs
  - Coeliac Vouchers and Receipts
  - Creditors / Suppliers Invoices
  - Pharmacy files
  - Coeliac Operator Files
  - Tax deductions and Tax Files
  - iSTK- (IStock-an electric stock management system) transactions
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 GDPR.

## **MANUAL VS ELECTRONIC RECORDS**

12. Retention policies apply to manual records. For electronic records, data may be retained for longer to comply with GDPR Article 9, Clauses (h), (i) and (j) and the Social Security Act Cap. 318, Article 23 and Fifth Schedule, Part II. Historical data is retained for statistical purposes but only a limited number of persons have access to it through an access key (pseudonymized).

## **EXEMPTIONS**

13. In cases where the retention of particular documents is essential such as where court cases are instituted, requests are still pending or in other serious cases of importance such as audits on the Pharmacy of Your Choice Unit, the retention period shall be suspended as deemed appropriate by the management team at the Pharmacy of Your Choice Unit.

## **RETENTION PERIOD**

14. The retention schedule hereunder outlines the retention requirements for the various categories of documentation within the Pharmacy of Your Choice Unit:

<b>Key</b>	<b>Unit / Department</b>	<b>Category</b>	<b>Record Type</b>	<b>Description</b>	<b>Retention Period</b>	<b>Remarks</b>	<b>Archival Action (When Retention Period Expires)</b>
1	Pharmacy of Your Choice Unit	POYC Stores	Invoices at POYC Stores	Invoices for medicines transferred from Central Procurement and Supplies Unit to POYC Stores.	Five (5) years	According to EU Directive 2001/83/EC, Article 80.	Not Required for permanent preservation by the National Archives.
2	Pharmacy of Your Choice Unit	POYC Returns Section	Return Notes for collection of medicines	A list showing type and amount of medicines that are to be returned from a community pharmacy to POYC.	Five (5) years	According to EU Directive 2001/83/EC, Article 80.	Not Required for permanent preservation by the National Archives.
3	Pharmacy of Your Choice Unit	POYC Returns Section	External transfer notes for redistribution	A list showing type and amount of medicines that are to be transferred from one community pharmacy to another through the POYC Returns Section. It is compiled by POYC.	Five (5) years	According to EU Directive 2001/83/EC, Article 80.	Not Required for permanent preservation by the National Archives.
4	Pharmacy of Your Choice Unit	POYC Stores	Daily Summations	A sum total is generated for each medicine according to route / van on a daily basis.	Five (5) years	According to EU Directive 2001/83/EC, Article 80.	Not Required for permanent preservation by the National Archives.
5	Pharmacy of Your Choice Unit	POYC Stores	Urgent Summations	A sum total is generated for each medicine as sent by courier / out-of-route.	Five (5) years	According to EU Directive 2001/83/EC, Article 80.	Not Required for permanent preservation by the National Archives.

6	Pharmacy of Your Choice Unit	Preparation Area	Delivery Logbooks	A record of the date and time of each delivery to a community pharmacy takes place duly signed by the POYC delivery person and the pharmacist present in each community pharmacy.	Five (5) years	Internal Policy	Not Required for permanent preservation by the National Archives.
7	Pharmacy of Your Choice Unit	Responsible Person Office	Batch Recalls	A detailed record of any medicines that are recalled when POYC is instructed by the Central Processing and Supplies Unit (CPSU).	Five (5) years	According to EU Directive 2001/83/EC, Article 80.	Not Required for permanent preservation by the National Archives.
8	Pharmacy of Your Choice Unit	POYC Stores	Files containing Just in time (JIT)	Lists showing type and amount of medicines supplied from POYC to a community pharmacy.	Five (5) years	According to EU Directive 2001/83/EC, Article 80.	Not Required for permanent preservation by the National Archives.
9	Pharmacy of Your Choice Unit	Responsible Person Office	Deviation Reports	Records of deviations from Standard Operating Procedures involving pharmaceuticals at POYC. If for some reason, Standard Operating Procedures are not followed to the letter, a report in a standardized format is drawn up and filed.	Ten (10) years	According to EU Directive 2001/83/EC, Article 80. (ca. ten (10) reports per year).	Records are to be transferred to the National Archives for permanent preservation.

10	Pharmacy of Your Choice Unit	Partial Manufacturing Area (PMA)	Batch Manufacturing Records	Detailed records of repackaging of medicines at POYC.	Five (5) years	According to EU Directive 2001/83/EC, Article 80.	Not Required for permanent preservation by the National Archives.
11	Pharmacy of Your Choice Unit	Partial Manufacturing Area (PMA)	Temperature Logs	Daily records of ambient temperature at POYC Partial Manufacturing Area.	Five (5) years	According to EU Directive 2001/83/EC, Article 80.	Not Required for permanent preservation by the National Archives.
12	Pharmacy of Your Choice Unit	Partial Manufacturing Area (PMA)	PMA Transfer Notes	Records of transfer of medicines from Partial Manufacturing Area to POYC Stores	Five (5) years	Internal policy	Not Required for permanent preservation by the National Archives.
13	Pharmacy of Your Choice Unit	Partial Manufacturing Area (PMA)	PMA Goods Received Notes	Records of transfer of medicines from POYC Stores to the Partial Manufacturing Area for repackaging.	Five (5) years	According to EU Directive 2001/83/EC, Article 80.	Not Required for permanent preservation by the National Archives.
14	Pharmacy of Your Choice Unit	Preparation Area	Seal record numbers	All medicines that are transferred from POYC to community pharmacies are sealed at POYC. The unique numbers on the seals are recorded. The seals are broken by the pharmacist in charge when s/he receives the boxes.	Six (6) months	Internal policy	Not Required for permanent preservation by the National Archives.

15	Pharmacy of Your Choice Unit	POYC Stores	Orders sent to Central Procurement and Supplies Unit (CPSU).	Records of medicines ordered by POYC from the CPSU.	Six (6) months	Internal policy	Not Required for permanent preservation by the National Archives.
16	Pharmacy of Your Choice Unit	Logistics	Van Storage Temperature Logs	Daily records of ambient temperature of vans used for delivery of medicines.	Six (6) months	Internal policy	Not Required for permanent preservation by the National Archives.
17	Pharmacy of Your Choice Unit	Logistics	Invoices for stationery supplied to pharmacies.	Invoices for stationery supplied to pharmacies by POYC.	Six (6) months	Internal policy	Not Required for permanent preservation by the National Archives.
18	Pharmacy of Your Choice Unit	Partial Manufacturing Area	Delivery notes from / to MDH	Records of transfer of medicines from POYC Partial Manufacturing Area to Mater Dei Hospital Clean room for repackaging and vice-versa	Six (6) months	Internal policy	Not Required for permanent preservation by the National Archives.
19	Pharmacy of Your Choice Unit	Various sections	Daily statistics	Sections are monitored through daily statistics (Management of Stock and Operations, Information and Communication Technology, Finance and Accounting Management, POYC Services, Human Resources Management).	One (1) year	Internal policy	Not Required for permanent preservation by the National Archives.



20	Pharmacy of Your Choice Unit	Medicines Approval Section (MAS)	Applications for Schedule V	Application forms for the main document entitling patients to free medicines. These are physically submitted to POYC or sent via email by consultants or delegates and subsequently printed. These are retained in case the electronic record needs to be verified or rectified.	One (1) year from the date an application is processed at Pharmacy of Your Choice Unit.	Internal policy	A random sample of one hundred applications (100) from each year is to be retained and transferred to the National Archives for permanent preservation. Any different versions of the forms is to be represented in the sample.
21	Pharmacy of Your Choice Unit	Medicines Approval Section (MAS)	Applications for Medicines Approval Section Protocol Regulated Medicines Permit	Application forms for the MAS Permit. These are physically submitted to POYC or sent via email by consultants or delegates and subsequently printed. These are retained in case the electronic record needs to be verified or rectified.	One (1) year	Internal policy	Not Required for permanent preservation by the National Archives.

22	Pharmacy of Your Choice Unit	Medicines Approval Section (MAS)	Patients' POYC Applications	Application forms in paper format for joining the POYC Scheme. These are retained in case the electronic record (a database) needs to be verified or rectified.	One (1) year	Internal policy. Applications are all in hard copy. Their data is then inputted in a database.	A random sample of one hundred applications (100) from each year is to be retained and transferred to the National Archives for permanent preservation. Any different versions of the forms is to be represented in the sample.
23	Pharmacy of Your Choice Unit	Medicines Approval Section (MAS)	Application for Delivery of Pharmaceutical Stock to +70 Patients' Homes	Application forms for delivery of stock to a patient's home instead of his / her pharmacy of choice. Currently restricted to patients who are over the age of 70 or have mobility issues.	One (1) year	Internal policy	A random sample of one hundred applications (100) from each year is to be retained and transferred to the National Archives for permanent preservation. Any different versions of the forms is to be represented in the sample.

24	Pharmacy of Your Choice Unit	Medicines Approval Section (MAS)	Consent Form for a Change in Pharmacy	Through this form, the patient declares that s/he wants to change the community pharmacy of choice and the new pharmacy approves this transfer. Some applications are signed by the legal carer/guardian in case of underage patients and patients with mental/physical health issues.	One (1) year	Internal policy	Not Required for permanent preservation by the National Archives.
25	Pharmacy of Your Choice Unit	Finance	Staff Meeting Minutes	Minutes of all meetings	Thirty (30) years	Government Department Policies	Records are to be transferred to the National Archives for permanent preservation.
26	Pharmacy of Your Choice Unit	All sections	Printed emails	All printed emails that are sent or received. Normally, this correspondence originates from pharmacies to POYC Orders Section (to order medicines for their patients and possible replies).	One (1) year	Internal policy. Correspondance may include patient details. These emails are printed to facilitate workflow.	Not Required for permanent preservation by the National Archives.
27	Pharmacy of Your Choice Unit	POYC Stores	Stock adjustments	Physical records of electronic adjustment of stock to reflect actual quantity of medicine in POYC stores	Two (2) years	Medicines Authority Audits	Not Required for permanent preservation by the National Archives.

28	Pharmacy of Your Choice Unit	Drug Control Card Section	Application Forms and Returned White Control Cards	Application forms for White Drug Control Card that may be attached to a previous expired card.	Two (2) years	Internal policy	Not Required for permanent preservation by the National Archives.
29	Pharmacy of Your Choice Unit	POYC Stores	Expired and Damaged at POYC	Records of medicines that expired or were damaged while at POYC (not in community pharmacies).	Ten (10) years	Internal policy	Not Required for permanent preservation by the National Archives.
30	Pharmacy of Your Choice Unit	POYC Stores	Expired goods to be boarded out	Lists of medicines that are to be boarded out and subsequently destroyed in a safe manner.	Ten (10) years	Internal policy	Not Required for permanent preservation by the National Archives.
31	Pharmacy of Your Choice Unit	All sections	Cleaning Logs	Standardised sheets recording the regular cleaning of POYC premises.	Three (3) years	Medicines Authority Audits	Not Required for permanent preservation by the National Archives.
32	Pharmacy of Your Choice Unit	POYC Stores	Temperature Logs	Records showing the daily temperatures of all areas where medicines are stored within POYC.	Three (3) years	Medicines Authority Audits	Not Required for permanent preservation by the National Archives.
33	Pharmacy of Your Choice Unit	POYC Stores	Van Storage Temperature Logs	Records showing the storage compartment temperature of vans for each trip	Three (3) years	Medicines Authority Audits	Not required for permanent preservation by the National Archives.

34	Pharmacy of Your Choice Unit	Finance	Coeliac Vouchers and Receipts	Physical records of Financial transactions associated with the National Coeliac Scheme.	Ten (10) years	Malta Finance Laws	Not required for permanent preservation by the National Archives.
35	Pharmacy of Your Choice Unit	Finance	Creditors / Suppliers Invoices	POYC Financial Transactions	Ten (10) years	Malta Finance Laws	Not required for permanent preservation by the National Archives.
36	Pharmacy of Your Choice Unit	Finance	Pharmacy Files	Financial transactions between POYC and Community Pharmacies	Ten (10) years	Malta Finance Laws	Not required for permanent preservation by the National Archives
37	Pharmacy of Your Choice Unit	Finance	Coeliac Operator Files	Financial transactions between POYC and private operators of the National Coeliac Scheme.	Ten (10) years	Malta Finance Laws	Not required for permanent preservation by the National Archives
38	Pharmacy of Your Choice Unit	Finance	Tax Deductions and Tax Files	Tax deductions applied by POYC to Community Pharmacies	Ten (10) years	Malta Finance Laws	Not required for permanent preservation by the National Archives
39	Pharmacy of Your Choice Unit	POYC Stores	iSTK Transactions	Records of transfer of medicines between POYC Stores and CPSU, between POYC Stores and Community Pharmacies and between POYC PMA and POYC Stores.	Five (5) years	According to EU Directive 2001/83/EC, Article 80. iSTK is a multi-dimensional inventory and management software.	Not required for permanent preservation by the National Archives

## **IMPLEMENTATION OF THE RETENTION PERIOD**

15. The implementation of the said retention periods shall come into force as from 30<sup>th</sup> November 2019 cover all data held at the Pharmacy of Your Choice Unit. The first step will be to dispose of old documents dating back, 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**

16. 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 Pharmacy of Your Choice Unit. 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 Pharmacy of Your Choice Unit** may be contacted at:

Address:

Pharmacy of Your Choice Unit

St. Luke's Hospital

Guardamangia PTA 1010

E-mail: [dpo.poyc@gov.mt](mailto:dpo.poyc@gov.mt)

Telephone: 22481800

### **The Information and Data Protection Commissioner**

The Information and Data Protection Commissioner may be contacted at:

Level 2, Airways House,

High Street,

Sliema SLM 1549

Email: [idpc.info@gov.mt](mailto:idpc.info@gov.mt)

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