

NCCP GUIDANCE DOCUMENT

Retention and Disposal of Systemic Anti-Cancer Therapy (SACT) prescriptions and compounding worksheets

Version	Date	Amendment	Approved By
1	11/01/2017	Version 1	NCCP following consultation
2	11/11/2019	Reviewed. References updated	NCCP

All comments and feedback are welcome at oncologydrugs@cancercontrol.ie

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1 Background

Each hospital supplying cancer services should have a policy in place defining the retention time and disposal method for Systemic Anti-Cancer Therapy (SACT) prescriptions and worksheets. This should be developed in line with the HSE National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs)(1).

The underlining principle is that all documentation should be retained for a sufficient period to satisfy the appropriate legislative requirements or national recommendations or standards where there is no relevant legislation in place. Where documentation may be covered by more than one recommendation, the default recommendation is that which requires the longest retention period. Where it is appropriate, records should be retained on a computer database.

This guidance has been produced by the NCCP in response to requests from a number of hospitals providing SACT services and should be read in conjunction with the HSE Standards and Recommended Practices for Healthcare Records Management (2), each Hospital’s local policy in addition to relevant legislation.

The recommendations are intended as a guide based on the information available at the time of publication and broad consensus of best practice. The recommendations may alter as national recommendations, standards and legislation dictates.

The recommendations cover the retention and disposal of SACT prescriptions¹ and SACT worksheets. Other documentation e.g. Quality Control documents, unlicensed medicines documentation, blood products documentation is beyond the scope of this document. Please refer to local hospital policy for more details on these areas.

¹ For the purpose of this document SACT prescriptions includes prescriptions or “orders” for SACT and related supportive care

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2 Healthcare Records/ Medical Records

HSE Standards and Recommended Practices for Healthcare Records Management (2), states that medication prescriptions form part of the patient’s Healthcare Record.

These records are subject to retention as per the HSE Standards and Recommended Practices for Healthcare Records Management (2) and the National Hospitals Office code of practice for healthcare records management, part 5: retention and disposal schedule (3). The relevant sections are included in appendix 1.

Note: There are specific recommendations relating to all types of records relating to children and young people which are also included in Appendix 1 (3).

See Section 6 for recommendations on clinical trials.

3 SACT Prescriptions Dispensed to Take Home

Prescriptions may be dispensed by a hospital pharmacy department for a patient to take home. These patients may be inpatients or attending a day ward or outpatients department. A copy of the prescription should be retained in the patient’s healthcare record as per the National Hospitals Office code of practice for healthcare records management (2).

The key regulation covering the retention of dispensed prescriptions is the Medicinal Products (Prescription and Control of Supply) Regulations 2003 – S.I. 540/2003 (as amended) (4). These regulations state that:

A person keeping open shop for the dispensing or compounding of medical prescriptions in accordance with the Pharmacy Acts, 1875 to 1977 shall preserve for a period of two years from the relevant date

(a) the register kept under paragraph 1 (of the S.I.);

(b) in the case of a health prescription, the duplicate copy thereof and in the case of any other prescription, the prescription

See Section 6 for recommendations on clinical trials.

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4 SACT Prescriptions Administered in Hospital

SACT prescriptions written in hospitals, for the purpose of hospital administration, are sometimes managed as orders versus prescriptions.

In those hospitals managing these as prescriptions then the retention requirements would be the same as those detailed in Section 3.

In those hospitals managing these as orders then the retention requirements would be defined locally. The NCCP recommend that the requirements detailed in Section 3 would be applied at a minimum. A copy of the order should be retained in the patient’s healthcare record as per the National Hospitals Office code of practice for healthcare records management (2). The relevant areas are highlighted in appendix 1.

See Section 6 for recommendations on clinical trials.

5 SACT Compounding Worksheets

In the absence of specific Irish legislation or standards the NCCP recommends that EU GMP guidelines are followed (5).

Appendix 4 of the EU GMP guidelines state that documentation must be kept for one year after expiry of the batch to which it relates or at least five years after certification of the batch by the Qualified Person, whichever is the longer.

See Section 6 for recommendations on clinical trials.

6 Clinical Trials

Healthcare Records for patients who have participated in clinical trials must be retained for 20 years as detailed in:

- The HSE Standards and Recommended Practices for Healthcare Records Management (2) and the National Hospitals Office code of practice for healthcare records management, part 5: retention and disposal schedule (3). The relevant sections, 12a and 12b, are included in appendix 1.
- EudraLex - Volume 10 Clinical trials guidelines. 2016 (3) and
- E.U. COMMISSION DIRECTIVE 2005/28/EC (6, 7).

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Pharmacy Department copies of prescriptions for patients who have participated in clinical trials must be retained for 5 years after the end of the trial as detailed in EudraLex Vol 10 clinical trials guidelines (7, 8). Note HSE Standards and Recommended Practices for Healthcare Records Management (1), states that medication prescriptions form part of the patient's Healthcare Record.

Compounding worksheets for investigational medicinal products, must be kept for at least five years after the completion or formal discontinuation of the last clinical trial in which the batch was used (7).

7 Disposal

All of the above documentation should be destroyed with due diligence to the requirements for confidential waste.

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8 References

1. HSE. National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). 2016.
2. HSE. Standards and Recommended Practices for Healthcare Records Management. 2011(3).
3. HSE. National Hospitals Office Code of Practice for Healthcare Records Management Part 5: Retention and Disposal Schedule 2012;3.
4. Medicinal Products (Prescription and Control of Supply) Regulations (SI 540/2003), (2003).
5. EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines. 2016.
6. EudraLex - Volume 10 Clinical trials guidelines. 2016.
7. EU. COMMISSION DIRECTIVE 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products. 2005.
8. EU. DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. 2001.

9 Other reading

- PSI Guidelines on the Keeping of Records in Respect of Medicinal Products when Conducting a Retail Pharmacy Business. Version 3 April 2019. Available at: <https://www.thepsi.ie/Libraries/Folder Pharmacy Practice Guidance/1 11 Guidelines on the Keeping of Records.sflb.ashx>
- How to keep proper pharmacy records — a downloadable good practice guide. Pharmaceutical Journal. 2013; 290: 621.
- SPS UK. Recommendations for the retention of Pharmacy Records. November 2019. <https://www.sps.nhs.uk/articles/retention-of-pharmacy-records/>
- Beaney A. Quality Assurance of Aseptic Preparation Services: Standards, Part A. 5th Edtn.: NHS Pharmaceutical Quality Assurance Committee, Royal Pharmaceutical Society; 2016.

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Appendix 1 National Hospitals Office code of practice for healthcare records management, part 5: retention and disposal schedule(3)

Reference	Types of Healthcare Record	Retention Period	Derivation	Final Action
HCR10	Children and young people (all types of records relating to children and young people) Records created under Childcare Acts	Retain until the patient's 25th birthday or 26th if young person was 17 at the conclusion of treatment, or 8 years after death. If the illness or death could have potential relevance to adult conditions or have genetic implications, the advice of clinicians should be sought as to whether to retain the records for a longer period To be retained in perpetuity (forever)		Destroy under confidential conditions
HCR12a	Clinical trials of investigational medicinal products – healthcare records of participants that are the source data for the trial	For trials to be included in regulatory submissions: 20 years. It is the responsibility of the Sponsor/someone on behalf of the Sponsor to inform the investigator/institution as to when these documents no longer need to be retained	European Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.	
HCR12b	Clinical trials of investigational medicinal products – healthcare records of participants that are the source data for the trial	For trials which are not to be used in regulatory submissions: 20 years	Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use	Destroy under confidential conditions
HCR37	Oncology (including radiotherapy)	25 years. NB Records should be retained on a computer database if possible. Also consider the need for permanent preservation for research purposes		Destroy under confidential conditions