Chief Operating Officer Directorate
Healthcare Quality and Improvement

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Dear Colleagues

[REVISED] GUIDANCE FOR THE SAFE DELIVERY OF SYSTEMIC ANTI CANCER THERAPY

For Implementation: 1 July 2026

Background

1. Please note that this supersedes the information contained in CEL(2012) 30 and DL(2023)15.

2. Systemic anti-cancer therapy (SACT) includes but is not limited to cytotoxic chemotherapy, biological therapies, targeted therapy, immunotherapy, and advanced therapy medicinal products.

3. Cytotoxic chemotherapy is known to be potentially carcinogenic, mutagenic and is hazardous as defined by the Control of Substances Hazardous to Health Regulations 2002 (COSHH).

4. Treatment involving such medicines is required to be prescribed, dispensed, supplied and administered in accordance with the Medicines Act, 1968.

Purpose

5. The attached guidance, endorsed by the Scottish Cancer Strategic Board has been updated to reflect new knowledge, national guidelines and legislation on the safe delivery of SACT and now includes scope for management of parts of the SACT process in a risk stratified way.

6. The guidance covers all care settings including the patient's home.

DL(2025)14

26 June 2025

Addressees

For action
Chief Executives
Medical Directors
Directors of Nursing
Directors of Pharmacy
SACT Clinical Leads

For information
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Action

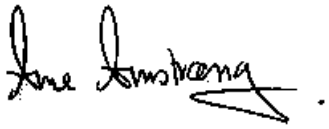
NHS Boards are:

- required to be able to demonstrate compliance in discharging their clinical governance responsibility by ensuring implementation and monitoring of this guidance
- required to participate in Healthcare Improvement Scotland's SACT Governance Framework to support quality assurance and demonstrate compliance
- required to work with their Regional Cancer Networks to develop action plans to address areas of non-compliance and share good practice
- advised that the Scottish Cancer Strategic Board will oversee progress against implementation of the guidance from 1 July 2026.

7. It is expected that NHS Boards, Regional Cancer Networks, the Managed Service Network for Children & Young People with Cancer, and Healthcare Improvement Scotland will work together to agree how best to take this guidance forward.

Yours sincerely

Professor Sir Gregor Smith
Chief Medical Officer for Scotland



Anne Armstrong
Interim Chief Nursing Officer for Scotland

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Table of Contents

Introduction

This guidance is intended to promote and assure the safe use of medicines to treat cancer in Scotland.

The Scottish Government's Cancer Strategy for Scotland 2023- 2033 states that 'safe and effective treatments are critical to improving outcomes for each person with cancer, improving overall quality of life and survival'.

Systemic Anti-Cancer Therapy (SACT) is required to be prescribed, dispensed, supplied, administered and disposed of in accordance with the Medicines Act 1968. This DL provides NHS Boards delivering SACT services with a framework for safe practice in the prescribing, preparation, administration and disposal of SACT to minimise the risk to patients receiving SACT and protect staff from occupational exposure to cytotoxic SACT.

Implementation of the guidance will be monitored by the NHS Board Lead Clinician for SACT who will report compliance with the DL to the NHS Board Chief Executive as part of their clinical governance procedures. NHS Boards are required to demonstrate compliance with the standards contained within this guidance document.

Scope

The scope of this document includes the use of any systemic therapy in the treatment of cancer, this may include, but is not limited to, cytotoxic chemotherapy, biological therapies, targeted therapy, immunotherapy, and advanced therapy medicinal products. It covers patients of all age groups receiving SACT, including clinical trials and any route of administration except intrathecal which is covered by the extant CEL 21 (2009). It excludes hormonal therapies.

It is recognised that radiopharmaceuticals are also used in the treatment of some cancers. These are highly specialised medicines and should be used under the control of healthcare professionals who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals. Radiopharmaceuticals are out with the scope of this guidance and are also covered by The Ionising Radiation (Medical Exposure) Regulations 2017, but the principles within the guideline should be considered in the development of local policies and procedures for these agents when used to treat cancer, based on risk assessment. Health Board SACT leadership must be aware of, and comfortable with, the governance of their use in cancer.

Background and Review Process

The Evolution of CEL 30 (2012)

NHS Scotland guidance for safe use of cancer medicines dates to HDL (2005) 29 guidance for the safe use of cytotoxic chemotherapy. The SACT treatment and service landscape evolved following this publication, with an increasing awareness of the need for robust governance and safety measures arising from the publication the NCEPOD Report – care of patients in England and Wales who died within 30 days of receiving systemic anti-cancer therapy (SACT) (2008). Better Cancer Care, published in 2008, set out a commitment to review the previous guidance for the safe use of cytotoxic chemotherapy. The initial work to update the HDL (2005) 29 guidance was undertaken accounting for the quality ambitions set out in Scotland's Quality Strategy (2010) that care will be safe, effective and person-centred,

and CEL 30 (2012) was published in July 2012. The original 2012 publication was externally peer reviewed through the National Cancer Action Team in England and Cancer Policy colleagues in the Welsh Assembly.

Updates to CEL 30 (2012)

Two refreshes of the CEL 30 (2012) guidance have now been undertaken; however, the revised and updated DL have the same purpose: to promote and assure the safe delivery of SACT in Scotland.

2023 Refresh – DL (2023) 15

With a view to reflecting the changing medicines environment over the previous decade, the first refresh of the CEL 30 (2012), was requested by the Scottish Government and undertaken under the auspices of the SACT Programme Board which reported directly to the National Cancer Recovery Group at that time. A Short Life Working Group was established to revise and update the previous version. DL (2023) 15 was published in June 2023.

2025 refresh – Adaptation to enable a risk stratified approach to SACT

The SACT landscape has changed significantly since the original publication of CEL 30 (2012), when cytotoxic chemotherapy was the mainstay of treatment and guidance was to manage all SACT in the same way. Many newer treatment options including targeted agents and immunotherapy are now used to treat cancer with differing risks associated with use both in terms of safe handling and tolerability. The Cancer Strategy for Scotland 2023-2033 recognises that cancer medicines account for the highest proportion of new medicines introduced within NHS Scotland annually and the consequent increasing pressure on SACT services to deliver treatments.

Recognising the evolution of clinical risk, the evidence base, and advances in pharmaceutical development, the Scottish Cancer Strategic Board commissioned a short life working group to undertake work to develop a robust process for managing SACT in a risk stratified way. The group updated specific targeted sections of DL (2023) 15 to ensure SACT governance processes are flexible enough to facilitate efficient and effective SACT service redesign without compromising patient safety. Central to this process has been the principles of realistic medicine, value-based health and care, clinical transformation, and improving patient outcomes over time with a clear aim of ensuring patient and professional confidence. This new iteration of the guidance brings a refreshed angle which will enable this risk stratified approach.

Clinical Management Pathways

In 2021, the Scottish Cancer Network (SCN) was established by Scottish Government, with one of the primary objectives being to explore the option for a ‘Once for Scotland’ approach in the development of Clinical Management Pathways. Clinical Management Pathways aim to build on existing regional Clinical Management Guidelines, bringing clinicians and Regional Cancer Networks together from across Scotland to agree national consensus on all elements of the patient pathway, from initial diagnosis through to recovery, living with cancer or end of life care.

It is recognised that if this programme is rolled out across all cancer services and tumour groups, there will be a period of transition in which some tumour groups will still be utilising existing Clinical Management Guidelines whilst they await the development and roll out of a Clinical Management Pathway. Therefore, the standards refer to Clinical Management Guidelines/Pathways interchangeably to allow for this transition period. Once a Clinical Management Pathway has been developed and approved for use by the regional networks across Scotland, any existing regional Clinical Management Guideline for that tumour group would become superseded. During the transition from CMG to CMP Health Boards will ensure ongoing update of existing Clinical Management Guidelines.

Process

This updated version of the DL was commissioned by the Scottish Cancer Strategic Board. A Short Life Working Group (membership in annex A) was established to revise and update the previous version of DL (2023) 15 published in June 2023. This working group comprised multi-professional stakeholders from the three Regional Cancer Networks and other relevant health professionals, alongside representation from the Scottish Government. A period of formal consultation was also sought with all persons named as ‘for action’ and ‘for information’ on page 1 alongside the membership of the Scottish Cancer Strategic Board. Feedback was received from across clinical and professional specialisms and the three regional cancer networks which informed this final published version.

Guidance

1. Clinical Governance, Quality and Risk Management

1.1 Clinical Governance

1.1.1 It is the responsibility of the NHS Board and the NHS Board Chief Executive to demonstrate compliance and ensure implementation of this guidance through discharging their clinical governance responsibilities. There must be an identified Governance Lead for SACT for each NHS Board at all times.

1.1.2 Effective clinical governance arrangements are in place for SACT services including the safe delivery of intrathecal SACT in line with CEL 21 (2009).

1.1.3 The NHS Board identifies a named Lead Clinician for SACT services who will be a consultant oncologist or haematologist, supported by nominated pharmacy and nursing leads.

1.1.3.1 It is a requirement that adequate time is assigned to fulfil the lead and supportive roles. NHS Boards will ascertain local requirements and will ensure sufficient time is allocated for job planning purposes.

1.1.3.2 In the absence of a named Lead Clinician for SACT services, the Lead Clinician responsible for Cancer Services (e.g. Clinical Director for Cancer Services or Associate Medical Director) will assume responsibility or identify a suitable deputy to ensure there is an identified Governance Lead for SACT

1.1.3.3 In Boards where children and young people (CYP) receive SACT, there is additionally a nominated Lead Clinician for CYP SACT Services, again supported by nominated pharmacy and nursing leads, to provide support to the NHS Board Lead Clinician for SACT services. Similarly, In the absence of a named Lead Clinician for CYP SACT services, the Lead Clinician responsible for Children and Young People's Cancer Services (for example Clinical Director or Associate Medical Director) will assume responsibility or identify a suitable deputy to ensure there is an identified Governance Lead for the CYP SACT service.

1.1.4 The Lead Clinician's accountability for the safe delivery of SACT services is clearly defined in the NHS Board's clinical governance structures. This includes clarity in respect of reporting to the relevant Board Executive Director with responsibility for clinical governance.

1.1.5 The Lead Clinician provides an annual report to the appropriate clinical governance group on the safe delivery of SACT in the NHS Board.

1.1.6 The Lead Clinician ensures that systems are compliant with current legislation, national standards and guidelines.

1.1.7 The roles and responsibilities of the Lead Clinician include ensuring that:

- systems are in place to develop, approve, implement, and regularly review policies and guidelines for the safe delivery of SACT across all care settings in the NHS Board, including SACT protocols and associated supportive treatment guidelines
- quality assurance processes are in place including demonstration of compliance with these standards through participation in Healthcare Improvement Scotland's (HIS) SACT Governance Framework
- an education and training programme for all staff involved in the delivery of SACT services is in place; and
- systems are in place for implementation of Clinical Management Guidelines/Clinical Management Pathways (CMGs/CMPs.
- all appropriate reporting and monitoring links within and across Board clinical governance processes and procedures from point of care to the Board are reflected in SACT assurance and governance considerations.

1.1.8 A co-ordinated regional or national approach to the development of CMG/CMPs and SACT protocols is in place to support a consistent approach to care delivery.

1.1.9 CMGs/CMPs and SACT protocols are readily available to all clinical staff involved in the delivery of SACT.

1.1.10 As part of the SACT Governance Framework, Healthcare Improvement Scotland (HIS) hosts a national external review group to conduct a review of board-level exception reports and action / improvement plans generated by the internal and external peer review audit cycle. This will generate a report for the Scottish Government.

1.2 A Risk Stratified Approach to Management of SACT

1.2.1 It is recognised that SACT is a term used to cover a diverse range of medicines with different risks in terms of toxicity profile and safe handling and preparation requirements.

1.2.2 It may be appropriate, following risk assessment, to manage some SACT regimens in alternative ways which should be clearly detailed in the SACT protocol

1.2.3 Where a risk stratified approach to SACT processes, (including prescribing, pharmaceutical verification, dispensing and administration), is proposed this must follow the national approach for SACT risk assessment, and be considered through the national assessment route.[1] Refer to appendix 1 for SACT process definition of terms.

1.2.4 Details of risk assessments for SACT protocols which have been nationally accepted as appropriate to follow a risk stratified approach should be available on a nationally governed platform for consideration of regional or board adoption through local governance groups.

[1] The work to form the National SACT Risk Stratification review group is underway and information on the National approach is anticipated to be shared with boards by end of Q3 2025

1.2.5 Local medicines governance processes will require review to reflect the risk stratified approach to management of SACT.

1.3 Education and Training

1.3.1 All staff involved in SACT services have appropriate skills, knowledge and training in their field of practice. Levels of SACT training should be stipulated within regional and/or local SACT governance processes including (but not limited to) for example: specialist SACT services, domiciliary SACT administration, SACT outreach clinics and provision of SACT outwith cancer specific services.

1.3.2 The Lead Clinician ensures the implementation of a programme of education and training. National methods of assessment for SACT theoretical and clinical competencies, such as the UKONS SACT passport and BOPA SACT verification passport should be utilised for appropriate staff involved in the delivery of SACT services.

1.3.3 The education and training to develop the competencies and skills required should be relevant to the specific role(s) within the SACT process, and will include some or all of the following:

- principles of safe use and relevant national guidance
- local policy and procedures on safe use
- principles of SACT relevant to area of clinical practice
- CMGs/CMPs and SACT protocols relevant to area of clinical practice
- process for the education and training of the MDT involved in prescribing, verification, administration, and management of adverse events for new SACT, at the point of introduction into practice
- consent and information giving
- toxicity assessment
- holistic assessment of patients receiving SACT
- prevention and management of adverse effects
- explicit training on selection and use of equipment including near patient preparation of appropriately risk assessed low risk SACT
- safe handling
- role specific awareness of how actions required for assurance and governance processes should be implemented

1.3.4 Evidence of this training is documented in each staff member's training record as relevant.

1.3.5 A system is in place for the quality assurance of education and training for all staff involved in the safe delivery of SACT which includes maintaining skills and competency assessment.

1.3.6 Guidance is provided for clinical staff working in non-cancer specialities who may have to care for patients receiving SACT.

1.4 Risk Management

1.4.1 The Lead Clinician ensures systems are in place to maintain adequate risk management of the SACT service in the NHS Board. This should be linked appropriately with NHS Board strategic and operational risk management procedures.

1.4.2 Capacity and workforce plans for SACT services are available and are reviewed and reported to senior managers and the appropriate NHS Board clinical governance group on a regular basis.

1.4.3 All clinical incidents of avoidable harm, such as adverse events and near misses involving SACT are documented, reviewed and learning shared to prevent future actual/potential harm. This should be undertaken in accordance with the National Framework

1.4.4 All deaths occurring within 30 days of administration of SACT are reported and reviewed as part of the NHS Board clinical governance arrangements.

1.4.5 Risk assessments are regularly undertaken to identify potential risks in the SACT service to enable steps to be taken to minimise avoidable harm. The risk register and action plan are reviewed at regular intervals and reported to the appropriate NHS Board clinical governance group as per Board risk management guidance.

1.4.6 The initiation/administration of SACT with an anticipated - risk of hypersensitivity/infusion related reaction or with potential for serious immediate adverse effects should only be at a time where there are appropriate measures in place to manage these events and any necessary escalation. Regional and/or board SACT governance processes should define risks for individual SACT drugs and regimens which may include when and where these can be administered.

1.4.7 In addition to NHS board clinical governance arrangements clinical incidents of avoidable harm and near misses involving children and young people's services are reported to, and reviewed by, the Managed Service Network for Children and Young People with Cancer (MSNCYPC).

1.5 Clinical Management Guidelines/Clinical Management Pathways

1.5.1 A CMG/CMP, as defined in the glossary, is in place for all common cancers. In paediatric cancer care, an approved clinical trial protocol or approved national Children's Cancer Leukaemia Group (CCLG) guideline may replace a CMG/CMP.

1.5.2 In rarer cancers, where there is no CMG/CMP, a SACT protocol is in place.

1.5.3 Development of CMGs/CMPs is be led by appropriate regional or national tumour specific Managed Clinical Networks (MCNs) or Pathway Boards and approved via local and regional clinical governance arrangements.

1.5.4 For children and young people, CMGs/CMPs or SACT protocols are approved via the MSNCYPC.

1.5.5 Policies and procedures are in place to manage individual requests for treatments not routinely available in line with NHS Board medicine governance processes and Scottish Government Health and Social Care policy.

1.6 SACT protocols

1.6.1 SACT protocols are in place for all SACT regimens in use. These can be digital or within an electronic prescribing and administration system but are readily available to all relevant healthcare professionals involved in a patient's care.

1.6.2 SACT protocols are evidence based and, where appropriate, in line with national guidelines.

1.6.3 SACT protocols are written in a clear and unambiguous manner and comply with the framework outlined in Appendix 2.

1.6.4 An approved clinical trial protocol or national paediatric guideline may be used in the absence of a SACT protocol.

1.6.5 Robust clinical governance systems are in place for the construction of protocols and associated prescriptions on electronic prescribing and administration systems. This includes:

- assigned responsibilities
- procedures for validation, double checking of entries, and the use of test prescriptions.

2. Decision to Treat, Consent and Information for Patients and Carers

2.1 Decision to Treat and Consent

2.1.1 The decision to initiate a new course of SACT is taken by a consultant oncologist/haematologist. For initial treatment this will be after discussion at a multi-disciplinary team (MDT) meeting, and in consultation with the patient or carer, where appropriate. It is advised that more than one haematologist or oncologist is present at an MDT to ensure consensus treatment decision.. In cases where initial treatment with SACT is prescribed in an emergency situation, prior to MDT discussion, the treatment plan is subsequently discussed and documented in the relevant MDT.

2.1.2 Selection of a SACT regimen, is the responsibility of the consultant oncologist/haematologist, considering the patient's wishes, co-morbidities, performance status and life expectancy, the CMG/CMP and SACT formulary choices available.

2.1.3 If patient specific circumstances require an alteration to the MDT plan (e.g. co-morbidities), or if there is a reason to vary from the CMG/CMP, this is explained and discussed with the patient and is clearly documented in the patient central records, letter to GP and on the SACT electronic prescribing record (consent form and treatment plan). Local/regional governance processes are followed to request access to non-approved SACT where appropriate.

2.1.4 The consultant oncologist/haematologist or appropriate deputy obtains written informed consent to treatment in accordance with national guidance and local policy.

2.1.5 Consent process is in line with HIS Guidance on consent for SACT.

2.1.6 The treatment decision, treatment intent (curative vs. non curative) and the proposed patient specific management plan, including planned assessment of treatment response, are documented in the patient's record and communicated to the GP within 14 days. This may be within 14 days of discharge following prolonged admission.

2.1.7 Relevant information summarising anticipated SACT toxicities, such as a copy of the consent form, are readily available to Emergency Departments and other providers of Unscheduled Care, ideally in the patient's Electronic Patient Record (EPR).

2.1.8 The performance status of the patient and any co-morbidities are documented in the patient's record.

2.1.9 For patients with poor performance status (ECOG PS 3 and 4) the rationale for treatment is clearly documented in the patient specific management plan and additional monitoring arrangements are in place including escalation to consultant level.

2.1.10 If patient's performance status is out with that recommended by the protocol the decision-making process is clearly documented.

2.1.11 The outcome of treatment and the decision to stop or change treatment is clearly documented in the patient record.

2.2 Information for Patients and Carers

2.2.1 There is provision of written and verbal information to patients receiving SACT and as a minimum the patient and/or carer receiving treatment is made aware of the following:

2.2.1.1 SACT protocol specific toxicities

2.2.1.2 signs and symptoms of extravasation for intravenous SACT

2.2.1.3 safe handling of SACT

2.2.1.4 information on what to do in the event of developing a toxicity including when, who, and how to contact the appropriate services

2.2.1.5 safe handling and disposal of patient waste.

2.2.2 A record of the information given to patients is documented.

3. Prescribing SACT

3.1 Prescribing

3.1.1 SACT can only be prescribed by an appropriately qualified, competent practitioner, as defined by local policy, and who meets the training and competency requirements to prescribe independently (see Appendix 1, Section 3).

3.1.2 SACT prescribers and reviewers, regardless of clinical setting, have access to all relevant clinical data, from electronic prescribing systems and other supporting clinical systems, to support safe and appropriate prescribing as defined by local or regional policy.

3.1.3 Clinical data used to support prescribing is collected within an appropriate timescale as defined by local or regional policy.

3.1.4 Where there are significant alteration options within a protocol, prescribing systems have separate regimens set up for these options.

3.1.5 The patient should be assessed for adverse effects at appropriate intervals as specified in the SACT protocol. This would routinely be at every cycle but may occur less frequently if the accepted risk stratified approach has deemed this appropriate. .

3.1.6 Adverse effects are graded using a recognised toxicity grading system, such as CTCAE or WHO criteria, and recorded in the patient record. Reasons for any dose adjustments or protocol amendments are also clearly documented within the patient's electronic record. In addition, systems are in place to ensure the patient is made aware of changes and any monitoring requirements.

3.1.7 Performance status is assessed prior to each prescribing episode of SACT and recorded in the patient's electronic prescribing record.

3.2 Prescriptions and Documentation

3.2.1 In secondary care cancer services SACT is prescribed using an electronic prescribing and administration system and complies with current legal requirements and local, regional, or national prescribing policy. Prescribing using a paper system is only undertaken in very limited circumstances, as defined by local policy, and needs to be readily accessible in the patient's record.

3.2.2 Where prescribing of SACT is taking place outwith specialist cancer services via an accepted risk stratified approach (see section 1.2) it should be on an appropriate primary care prescribing system which complies with current legal requirements and local, regional, or national prescribing policy. Records of SACT prescribed in primary care should be available to the cancer team leading the management of care on an accessible system such as the Emergency Care Summary (ECS). Similarly secondary care records relevant to the patient's care should be accessible or provided to the primary care team prescribing the SACT. Local processes may need to be developed to facilitate this.

3.2.3 All prescriptions are written in a clear and unambiguous manner and include the information contained in appendix 3 and in accordance with local or regional prescribing policies.

3.2.4 Where possible, there is a single SACT prescription for all medicines including all appropriate supportive care and hydration. Where additional supportive therapies are to be prescribed separately, this will be clearly indicated within the protocol, additional prescribing note on prescription or local/regional guidelines.

3.2.5 A prescribing episode may include prescribing multiple cycles of a regimen where an accepted risk stratified approach national protocol is available.

4 Pharmaceutical Verification, Preparation and Dispensing of SACT

4.1 Pharmaceutical Verification – refer to appendix 4 for key pharmaceutical checks.

4.1.1 All cycle 1 prescriptions for SACT are verified by a suitably trained registered pharmacist or pharmacy technician in accordance with legislative requirements, national standards and local or national policy prior to dispensing and release from pharmacy.

4.1.2 For cycle 2 onwards: “SACT cycles are verified by a suitably trained pharmacist or pharmacy technician in accordance with legislative requirements, national standards and local or national policy prior to dispensing and release from pharmacy.This would routinely be at every cycle, but where an accepted risk stratified alternative approach has deemed this appropriate – which may include frequency of verification or checks undertaken according to regimen specific factors – this should be detailed in the SACT protocol.

4.1.3 If any discrepancies are found during verification, appropriate procedures are followed to address these prior to sign-off, as defined within local policy.

4.1.4 In cancer specialist services verification of each prescription is recorded within the electronic prescribing and administration record according to local policy. In the exceptional circumstances in which a paper prescription is used, it is signed and dated manually (wet signature) as a record of verification or utilising advanced electronic signatures (AES).

4.1.5 Where an accepted risk stratified approach to prescribing and dispensing of SACT is taking place outwith specialist cancer services checks will be made by appropriately trained pharmacist or pharmacy technician as stipulated in the SACT protocol. Recording of checks should be considered as part of local implementation plans.

4.2 Aseptic Preparation and Dispensing

4.2.1 SACT will be supplied from a pharmacy-controlled facility. In addition to hospital aseptic and dispensary supplies, for SACT regimens where an accepted risk stratified approach has been approved community pharmacy and homecare are acceptable supply routes.

4.2.2 SACT is either, dispensed and labelled for the individual patient in a ready to administer form or, where appropriate after risk assessment, supplied as ward stock

e.g. subcutaneous or non-cytotoxic preparations. Where preparation out with pharmacy is risk assessed as appropriate, agreed written preparation guidance must be provided, and staff must use safe handling measures.

4.2.3 The preparation and dispensing of SACT complies with relevant legislative standards, national standards and guidelines.

4.2.4 In cancer specialist services staff preparing and dispensing SACT must confirm that pharmacy verification has taken place prior to release from pharmacy.

4.2.4.1 Where SACT is supplied from ward stock, staff administering the treatment must check that pharmacy verification has taken place prior to administration in line with the frequency specified in the SACT protocol.

4.2.5 Where dispensing of SACT is taking place via an accepted risk stratified approach outwith specialist cancer services appropriate checks as specified within the SACT protocol will be made by appropriately trained pharmacist or pharmacy technician as appropriate for the SACT regimen being dispensed prior to supply to the patient or carer.

4.2.6 Systems are in place to independently audit the aseptic service in line with NHS Scotland pharmacy aseptic audit programme for unlicensed facilities. The audit will be carried out by the MHRA (Medicines Healthcare products Regulatory Authority) for licensed facilities.

4.2.7 Non-conformance remediation plans, with priorities and timescales assigned, have to be agreed by the local Board and be in place to achieve full compliance with the audit standards.

4.3 Preparation and Labelling of Intravenous Vinca Alkaloids

4.3.1 When a vinca alkaloid is prescribed for administration in an adult or young people's unit, the prescribed dose is dispensed and supplied from the pharmacy-controlled facility ready to administer in a 50ml infusion bag.

4.3.2 When vinca alkaloids are prescribed for children or young people treated in a children's unit the prescribed dose is dispensed diluted and presented in a minimum 10ml syringe size.

4.3.3 For all vinca alkaloids dispensing labels are required to state, in addition to the standard information: "for intravenous use only – fatal if given by other routes".

4.4 Dispensing

4.4.1 Ready to administer SACT is dispensed in accordance with local policy and procedures that incorporate legal requirements, national standards and guidelines. As a minimum, local dispensing procedures must encompass information contained in Appendix 5.

4.4.2 When an oral suspension or liquid is dispensed the dose is measured using a suitable oral/enteral syringe.

Monitored dosage systems (MDS) are not routinely recommended when dispensing oral SACT. If it is necessary to use an MDS compliance aid, a risk assessment

performed to ensure that any risk to patients, carers and other health care professionals is managed appropriately.

4.4.3 Oral liquid preparations of cytotoxic SACT which do not have an EU or UK marketing authorisation are purchased from a MHRA licensed special manufacturer.

4.5 Issuing SACT for Self-Administration

4.5.1 Staff issuing SACT directly to patients/carers ensure that the patient/carer understands how and when to take their medicines and have been appropriately counselled.

4.5.2 If SACT for self-administration is being delivered directly to a patient's address local processes are in place to ensure all relevant information in relation to SACT is provided to the patient/carer as defined in section 2.2, and any changes made to dosing have been discussed (see 3.1.5).

4.5.3 Parenteral subcutaneous pre-filled syringes are supplied to patient with appropriate storage containers, safe-handling and waste disposal equipment, and training in correct usage provided.

4.5.4 The patient and/or carer is instructed on safe handling, storage, administration, spillage and disposal of SACT for self-administration, and is advised to return any unused SACT to pharmacy.

5 Administration

5.1 General Administration Issues

5.1.1 Policies and procedures are in place for SACT administration. and key checks are undertaken. This includes all routes of administration used within the NHS Board, .and are approved and reviewed as part of local medicines governance arrangements

5.1.2 SACT is administered in areas which are risk assessed as safe and appropriate for the treatment being administered.

5.1.3 Resuscitation equipment is accessible in clinical areas where SACT with an anticipated risk of immediately life-threatening reaction is administered. Annual risk assessment should be undertaken for all clinical areas administering SACT.

5.1.4 Staff who administer SACT have demonstrated an approved level of skill, expertise and experience as defined by local policy. They will be aware of potential side effects, administration related risks and their management relevant to area of clinical practice.

5.1.5 The patient's condition and clinical parameters are assessed using a recognised toxicity grading system within an agreed time frame prior to administration of SACT to ensure it reflects the most recent SACT review. The time frame for the toxicity assessment should be defined within regional and/or local SACT governance policy. Any clinically significant differences between the SACT review (3.1.5) and pre-

administration toxicity assessments are highlighted to the prescriber prior to administration.

5.1.6 The presence of a signed consent form must be verified before cycle 1 of a new SACT regimen is administered.

5.2 Pre-Administration Verification

5.2.1 The standard approach for parenteral SACT administration is two-person pre-administration checks of SACT medicines. Procedures exist for this which stipulate one of the checks is undertaken by the practitioner administering the SACT. The second checker is determined by board policy.

5.2.2 For accepted risk stratified SACT regimens the option of single nurse administration may be specified within the SACT protocol. Regional and/or board risk assessments may be undertaken to consider a single nurse check for these regimens. Single nurse administration should be in line with local guidance which may require local medicines governance processes to be reviewed.

5.2.3 The pre-administration checks independently confirm:

5.2.3.1 patient identity in line with local policy

5.2.3.2 patient name and CHI number match SACT prescription

5.2.3.3 correct date and time of administration

5.2.3.4 correct drug name, dose, volume bolus/infusion, diluent, route of administration and administration rate in relation to the prescription

5.2.3.5 expiry date and time will not pass before administration is complete

5.2.3.6 appearance and physical integrity of SACT

5.2.3.7 appropriate pre-medication and/or supportive therapies have been administered.

5.2.3.8 prescriber's signature and additional signature to indicate that pharmacy verification has been carried out.

5.2.3.9 checklist order reflects the order in which the SACT to be checked.

5.2.3.10 check for allergies

5.2.3.11 confirm venous access device patency.

5.2.4 If any discrepancies are found local procedures are followed to address these prior to administration.

5.2.5 Both the practitioner administering and the checker will sign the appropriate sections of the administration document as soon as is practical following the start of administration (this may be a digital signature). If intravenous SACT, administering practitioner is required to be SACT trained.

6 Extravasation

6.1 Minimising Risk of Extravasation

6.1.1 Policies and procedures for the administration of intravenous SACT include techniques which aim to minimise the risk of extravasation.

6.1.2 Patients and carers are made aware of the potential risk, signs and symptoms of extravasation and action they need to take if symptoms develop.

6.1.3 When a vinca alkaloid is administered in a 50ml infusion bag, a full risk assessment is undertaken locally to determine the most suitable method for intravenous infusion. The patient is closely monitored for signs of extravasation.

6.2 Treatment of Extravasation

6.2.1 A local extravasation procedure is in place to allow for the management of the suspected or actual extravasation and includes criteria for referral to specialist plastic surgical services.

6.2.2 Extravasation treatment kits and a copy of the extravasation procedures are readily available in areas where SACT is administered.

6.2.3 In the event of an extravasation, the patient, their consultant, and their GP are kept fully informed of ongoing management. The procedure requires to state how the GP is informed e.g. standard template letter or via electronic record.

6.2.4 All SACT extravasation injuries are documented in the patient's record and an adverse event report completed in accordance with local policy.

6.2.5 The patient is followed up and reviewed at regular intervals as appropriate to local guidance and level of injury.

7 Supportive Care During Treatment

7.1 Services delivering SACT have guidelines and protocols available for supportive treatment. These guidelines and protocols are readily available to all healthcare professionals and services who may be involved in the acute care of SACT complications, in particular neutropenic sepsis. A minimum list of the guidelines required is contained in Appendix 6.

7.2.1 Patient/care pathways for the management of complications of SACT are approved, regularly reviewed and updated as appropriate, by local clinical governance groups and are accessible to all relevant staff across the NHS Board area. This may include staff in NHS 24 Centres, NHS Board Out of Hours Centres, Emergency Care Centres and Acute Admission Units. The pathways include:

- optimum self-care prevention and management strategies for minor toxicities
- patient/carer information on what they are required to do in the event of developing a complication including when, who and how to contact relevant services

- signposts to guidelines and protocols for supportive treatment including Alert Cards advising of the signs and symptoms of neutropenic sepsis, and immunotherapy toxicities with details on how to access timely advice, 24 hours a day, every day, from an appropriate specialist and details of treat and transfer arrangements, if appropriate
- arrangements for communication with, and timely review by, appropriate specialist.

8 Alternative Models of SACT Delivery

8.1 If a location is being used on a regular basis for SACT delivery, then that location must comply fully with the requirements for an outpatient SACT delivery area.

8.2 The remainder of this section applies only to delivery of SACT out with a specialist cancer service in, for example, the rural general hospital, GP surgery, community hospital, or in the patient's home on an individual named patient basis or via dispensing services provided by community pharmacy or homecare suppliers, which may allow patients to remain at home or nearer to home while receiving treatment.

8.3 It is necessary for the overall clinical management of the patient to be led by the specialist cancer service.

8.4 Different models may be developed or utilised in the delivery of SACT out with the specialist cancer service through application of the risk stratified approach to SACT process. This could involve, but is not limited to; patient, carer or nurse administration in the patient's home or setting of their choice; centralised prescribing, verification and preparation at the specialist cancer service with administration in a facility closer to home but under the supervision and management of the specialist cancer service; an agreed process with other services that may include any of the following:

- Prescribing of SACT
- Pharmaceutical verification of SACT
- Monitoring and follow up of SACT
- Dispensing of SACT
- Administration of SACT

9 Safe Handling of Cytotoxic SACT

Cytotoxic medicines are hazardous as defined by the Control of Substances Hazardous to Health Regulations 2002 (COSHH). In relation to services delivering cytotoxic SACT the overriding health and safety principle is to minimise exposure and to prevent or minimise environmental contamination.

9.1 Minimising occupational exposure

9.1.1 Systems and procedures are in place to minimise occupational exposure in line with COSHH and establish safe handling as routine practice.

9.1.2 Personal protective wear and equipment, appropriate to the level of handling of cytotoxic SACT, is available to staff.Parenteral cytotoxic SACT is issued from a pharmacy-controlled facility in a 'ready to administer' form.

9.1.3 Local procedures specify that the cytotoxic SACT is not manipulated any way outside of a suitable environment within pharmacy premises. Policy outlines the action to be taken if the patient is unable to take the cytotoxic SACT in the form presented.

9.1.4 Systems are in place for the reporting of incidents involving accidental spillage and potential exposure to cytotoxic SACT.

9.2 Disposal

9.2.1 Systems and procedures are in place for the safe disposal of unused doses and all items contaminated with cytotoxic SACT.

9.2.2 Systems and procedures are in place for safe handling and disposal of patient waste potentially contaminated with cytotoxic SACT.

9.3 Spillages

9.3.1 Systems and procedures, including COSHH risk assessments, are in place to minimise the risk of spillage.

9.3.2 Cytotoxic spill kits are available and prominently displayed in all areas where cytotoxic SACT is stored or handled. Spillage kits are provided to patients self- administering liquid/injectable SACT.

10 Receipt, Transport and Storage of SACT

10.1 Systems and procedures are in place for the receipt of SACT into the pharmacy according to safe handling procedures, including product integrity checks and maintenance of temperature during transportation, where appropriate.

10.2 SACT is required to be stored securely and safely at appropriate temperatures in locations separate from other medicines and clearly marked for the storage of SACT only.

10.3 Systems and procedures are in place to ensure SACT is transported in a safe and secure manner. Transported products are required to be maintained within the cold chain for the duration of the transported period, where relevant, and sensitive products are not subject to any conditions which may affect product stability e.g. agitation/rough handling of monoclonal antibody products.

10.4 Reconciliation records are in place for the receipt of SACT in clinical areas.

Appendix 1 - Systemic Anti-Cancer Therapy (SACT) Process Definitions

Process	Definitions
1. Decision to Treat	The decision to treat a patient with SACT following the initial diagnosis, or the decision to change the SACT regimen, or to continue beyond the number of cycles originally planned should be made by a consultant oncologist/haematologist. Initial (first) treatment decision should be discussed at an appropriate Multidisciplinary Team Meeting (MDT) and there should be clear documentation of this.
2. Consent (Medical/ NMP)	Consent is the shared decision-making process by which a patient and physician come to an agreement on treatment. All patients receiving SACT should be fully informed of their treatment (including the potential toxicities) and must have given full written consent for the specified SACT regimen prior to treatment commencing. In Scotland the HIS SACT Consent framework defines process and standards to be followed.
3. Prescribing	Prescribing is the ordering of the use of a medicine (or other treatment) by someone who has the legal authority to issue prescriptions. Prescribing is a complex clinical skill that requires knowledge and understanding of disease, the patient's health and the medicines being prescribed. To prescribe medicines, practitioners must have a specific professionally registered qualification, and there is a Competency Framework for all Prescribers in place which the Royal Pharmaceutical Society publish on behalf of all regulators and professional bodies. To independently prescribe SACT there are additional training and competency requirements. **1. Medical prescribing of SACT:** a. Oncology: The Joint Royal Colleges of Physicians Training Board has acknowledged that there is an additional need to demonstrate competency, specific to the prescribing of SACT, in their Medical Oncology Speciality Training Curriculum for Systemic Chemotherapy. This was updated in 2023 (however this version does not specify SACT competencies, requiring referral back to the 2016 version). The curricula for both medical oncology and clinical oncology have mandated that competence in prescribing SACT be formally assessed https://www.rcr.ac.uk/sites/default/files/2016_curriculum_-_clinical_oncology_15_november_2016.pdf

	b. Haematology: The Haematology curriculum states that by the end of ST3 trainees should be able to 'document competency in chemotherapy prescribing'. Rough guide to Haematology July 2021.pdf (thefederation.uk) 2. **Non-medical prescribing of SACT:** Qualified Non-Medical Prescribers (NMPs) must have completed specific training to meet required competencies as defined in NHS Scotland SACT NMP framework. This includes SACT dose modifications and adding / removing supportive medicines, provided it falls within the NMP's area of competence. NMPs must ensure their practice complies with local policies when prescribing clinical trial medications, unlicensed medicines, off-label indications and controlled drugs.
4. Patient Assessment Prior to Treatment with SACT	Patients should be assessed for 'fitness for treatment' prior to the administration of SACT. Pre-treatment assessment (or review) can be carried out by an appropriately trained healthcare professional (referred to as '**SACT reviewers**') following a SACT protocol. The timeframe within which this can be completed prior to SACT administration should be defined by within SACT governance policies and / or individual SACT protocols. A SACT reviewer should work to a clear scope of practice defined within their clinical governing organisation policy to include: • The training / competency requirements • Definitions of the parameters of practice (this may include specific treatment areas or tumour group(s) and frequency of SACT prescriber reviews) • Clear mechanisms for escalation or referral back to SACT prescribers where the parameters of protocol are not met • A robust process for auditing practice. Reviews may take place by phone, video, face to face or electronically (using an approved app). A review will include an assessment of all pre-treatment parameters defined within the specific SACT protocol including: • Clinical assessment of the patient • Treatment toxicity assessment using common toxicity criteria (CTCAE) • Performance status using a recognised grading system • Blood and biochemical test results • Other critical tests e.g. cardiac assessment (ECHO, MUGA, ECG), pulmonary assessment (PFTs) etc • Monitoring of hypersensitivity reactions (at previous cycle)

	• Any other relevant information such as hospital admissions, GP attendance, new medications prescribed or purchased • Monitoring for response to treatment e.g. radiology reports (e.g. CT scan) or tumour markers (e.g. Ca125) SACT reviews will be recorded within the patient's clinical record with signature of the SACT reviewer. This can be electronic or wet signature as per SACT governance policy in place.
5. Pharmaceutical Verification of SACT	SACT pharmaceutical verification is undertaken by a suitably trained registered pharmacist or pharmacy technician (RPP) to ensure the safe use of SACT through identification, resolution and prevention of medicine-related problems. Verification ensures the SACT and all other medicines are prescribed legally and are clinically appropriate for the patient. Key pharmaceutical checks defined in appendix 4 of this guidance are undertaken to provide assurance that the prescribed treatment is appropriate for the patient's disease and their clinical condition, that doses are accurate and tailored for the individual patient and to reduce risk of medication errors.
6. Medicines Supply Routes	
a. Aseptic preparation of SACT	'Aseptic preparation of medicines' focuses on activity performed within an aseptic facility with pharmacy oversight, which operates under strictly controlled governance and regulatory arrangements. Aseptic preparation is defined as: reconstitution of an injectable medicine or any other aseptic manipulation when undertaken within NHS aseptic facilities to produce a labelled ready-to-administer presentation of a medicine, in accordance with a prescription provided by a practitioner, for a specific patient.
b. Non-aseptic dispensing within a pharmacy	The supply of an oral or ready to administer parenteral SACT, individually dispensed and labelled for the patient from a registered pharmacy premises.
c. Direct ward / clinical area supply	The risk assessed supply of SACT which is not labelled for a specific patient to a ward / clinical area for administration by a suitably qualified healthcare professional.
7. Administration	Patients should be assessed for "fitness for treatment" prior to the administration of SACT through the completion of a SACT review, as described above. Prior to administration on the day of treatment, a check should be undertaken to ensure the patient's current condition reflects the SACT review and there have been no significant changes which would affect fitness for treatment.

	Before administering any medicine, the person carrying out the procedure must be familiar with the advantages and limitations of the prescribed route and know the indications, contraindications and side-effects of the medicine they intend to give. The majority of SACT administration is undertaken by staff who have undertaken specific SACT administration training / competencies and have demonstrated an approved level of skill and experience as defined by SACT governance policy and stipulated in CEL30 (2012) DL 15. Staff will be aware of the potential side effects, administration related risk and their management. Prior to administering SACT an independent two-person check must be undertaken as standard, unless specifically defined within an approved SACT risk assessment form. This two-person check must include the person administering SACT and a second checker as defined by local policy. Where SACT is defined as low risk or SACT administration takes places in the patient's home or community setting, the patient or carer will be included in the checking process as the second checker. The process must ensure the health care professional confirms all key checks as defined in local policy. **Self-Administration or Administration by a Carer** In some circumstances, the patient or their carer may administer SACT. Patients and / or carers must be appropriately trained, confident and competent in the self-administration or administration technique. In addition, they must be provided with written or electronic supporting information and contact details, as well as appropriate safe-handling and storage advice and equipment as appropriate. **NOTE:** There is a requirement for local boards to have policies in place which define the roles, responsibilities, training and competency requirements for administration of medicines by health care professionals other than registered nurses and doctors.

Appendix 2 – SACT Protocol Framework

- the protocol name in full - sole use of an acronym to identify a protocol is minimised
- definition of the clinical condition(s) being treated including indication, line of therapy and any restrictions to eligibility (e.g SMC restrictions or NCMAG eligibility criteria)
- treatment intent – restricted to either ‘curable’ or ‘non-curable’
- usual baseline performance status required for treatment
- all SACT medicines by full generic name and, if appropriate by formulation and proprietary name
- dosing schedule for each medicine
- route, method and duration of administration
- maximum cumulative doses where applicable
- any pre-medication required
- diluents and appropriate infusion volumes
- ensure appropriate infusion line in use (when relevant)
- hydration schedules (when relevant)
- supportive therapy including, where appropriate, prophylaxis for the prevention of neutropenic sepsis
- concomitant radiotherapy & scheduling where relevant
- relevant critical tests – including haematology and biochemistry parameters and any other tests that need to be performed before SACT starts and during treatment
- special precautions and contraindications to treatment
- clinically significant medicines and food interactions
- expected toxicities / adverse effects
- extravasation risk
- recommendations for treatment delays or dose reductions based on relevant toxicities and/or haematology and biochemistry parameters
- where relevant, reference is made to policies for the management of toxicities
- decision points, including response assessment and advice on when patients are referred for review
- options for nationally supported risk stratified approach to prescribing, pharmaceutical verification, dispensing or administration where relevant
- reference source(s)

Appendix 3 – SACT Prescriptions

The following patient specific information is documented:

- name, date of birth, CHI number
- height, weight and body surface area where relevant
- diagnosis
- performance status
- relevant haematology and biochemistry results
- any other relevant critical tests
- calculated doses to be administered
- indication of any dose modifications made

Prescriptions are clear and unambiguous and include:

- the name of the SACT protocol
- all SACT medicines to be given including protocol doses
- the full generic name of each medicine and, where appropriate, the specific formulation and its proprietary name
- intervals between cycles
- maximum cumulative doses where applicable
- route, method and duration of administration
- where appropriate, diluents and infusion volumes
- hydration schedules if required
- pre-medication if required
- appropriate supportive therapy
- indication of concomitant radiotherapy where applicable
- cycle number and date of administration
- for SACT for self-administration - the start date and duration of each treatment cycle
- name of prescriber, signature* and date prescribed
- pharmaceutical verification signature* and date
- administration signatures*, date and time where relevant.

*within electronic prescribing and administration systems these details will be recorded electronically.

Appendix 4 - Key Pharmaceutical Checks

This list of pharmaceutical checks is not exhaustive but forms the basis of local policy and practice. For specific SACT regimens additional checks may be necessary or, conversely, some checks may not be relevant. In both these scenarios a risk assessment is completed and documented to determine which checks are required to maintain patient safety and quality of care (Refer to section 4.1 for risk stratified alternative approaches to pharmaceutical verification of SACT).

Prior to the first cycle of a new course of treatment, ensure that:

- the protocol has been through local approval processes
- the protocol is the intended treatment as documented in the patient's clinical record and is appropriate for the indication
- the appropriate regimen selection for a patient in accordance with CMGs/CMPs, local, regional and national guidance or as per individual patient treatment request.
- the protocol is appropriate for the patient's diagnosis, medical history, performance status and SACT history. The diagnosis includes pathology, staging, tumour markers and other relevant factors, as applicable, that determine eligibility for prescribed treatment.
- the patient has signed a SACT consent form for the new course of treatment

Prior to all cycles of treatment ensure that:

- there are no known medicine or food interactions or conflicts with patient allergies or previous adverse reactions
- the timing of administration is appropriate in relation to interval since last treatment
- patient demographics including age, height and weight are correctly recorded on prescription
- an appropriate body surface area (BSA) is correctly calculated where relevant, taking into account recent weight
- all dose calculations and dose units are correct and have been calculated correctly according to the protocol and any other relevant local guidance
- maximum cumulative dose and maximum individual dose is not exceeded, as appropriate
- reason for any dose adjustment is documented, and the dose adjustment is appropriate
- method of administration is appropriate
- relevant laboratory values are within accepted limits as defined in the SACT protocol
- other critical tests, including toxicity assessment, have been undertaken and recorded as defined in the SACT protocol
- doses are appropriate with respect to renal and hepatic function, performance status and co-morbidities and any experienced toxicities
- supportive care is prescribed, and it is appropriate for the patient and SACT protocol
- requirement for dose adjustment and/or prophylaxis, to minimise risk of neutropenic sepsis, as specified in the SACT protocol
- prescriber details and signature (written or digital) are present and confirm they are authorised to prescribe SACT

Appendix 5 - Dispensing Standards for SACT

Policies and procedures which incorporate legal requirements, national standards and guidelines are in place for:

Dispensing

- staff dispensing SACT can confirm that pharmaceutical verification has taken place prior to release from the pharmacy
- the exact amount of the treatment required is dispensed for the designated treatment/cycle duration, where there is deviation from this requirement, for clinical trials or if packs cannot be split, a risk assessment has to be performed to address any risks to patient safety
- the quantity of tablets/capsules/ sc syringes is double checked as part of the final check of the prescription
- the prescription is endorsed with the amount supplied for all strengths of products dispensed
- the dispensed items are checked by an appropriately trained member of staff to ensure:
- the correct medicine has been dispensed
- the correct dose, frequency, duration and dates of treatment as appropriate are detailed on the label
- the correct patient name is on the label
- the correct quantity of medicine to be dispensed has been calculated
- the correct quantity of medicine has been dispensed.

Labelling

- comprehensive directions for use are provided to patients supplied with SACT for self-administration
- SACT is never supplied and labelled ‘Take as directed’ unless the patient or carer is given additional explicit verbal and written information regarding dose, frequency of administration and duration
- A yellow label is attached to SACT to highlight type of medicine, and that cancer specialist advice should be sought if patient is admitted to hospital. For example, “This is an anti-cancer medicine. In the event of hospital admission/surgical procedure, discontinue this medicine until advice is sought from a cancer specialist”.

Appendix 6 - Supportive Treatments

Protocols for the following treatment related toxicities are developed locally or regionally/nationally and endorsed by local or regional governance groups. The detail of the content will reflect local practice.

- Neutropenic sepsis in line with Scottish Antimicrobial Prescribing Group Guidance and local guidelines or policy
- nausea and vomiting
- diarrhoea and constipation
- mucositis
- skin toxicity
- tumour lysis syndrome
- hypersensitivity reactions
- immunotherapy related toxicity
- vaccination advice (updated annually)
- pandemic management strategy
- bone modifying agents
- use of G-CSF
- bispecific antibody related toxicity
- CAR-T toxicity management (where relevant)

Appendix 7 - Clinical Governance Overview

Clinical governance is the process by which accountability for the quality of health care is monitored and assured. It should be supported through a culture where delivery of the highest quality of care and support is understood to be the responsibility of everyone working in the organisation – built upon partnership and collaboration within teams and between healthcare professionals and managers.

Clinical governance structures and processes assure Health Boards that this is happening – whilst at the same time empowering clinical and care staff to contribute to the improvement of quality as well as making sure that there is a strong voice of the people who use services.

Quality of care should be given the highest priority at every level within services. Delivery of effective clinical governance provides assurance to patients, clinical staff, managers, Directors and the Board that:

- Quality of care, effectiveness and efficiency drives decision making about the planning, provision, organisation and management of services
- The planning and delivery of services take full account of the perspective of patients and service users
- Unacceptable clinical and care practice will be detected and addressed.

Effective clinical governance is not the sum of all these activities; rather it is the means by which these activities are brought together into a structured framework and linked to strategic commitments to deliver safe, effective and person-centred care.

Clinical governance structures and processes should support staff in continuously improving the quality and safety of care. It will also ensure that wherever possible poor performance is identified and addressed. All health professionals are professionally accountable for their individual clinical and care decisions.

This DL is underpinned by the preceding clinical governance arrangements outlined through:

Clinical and Care Governance Framework NHS Scotland - blueprint for good governance: second edition November 2022 (link)

NHS HDL (2001) 74 Clinical Governance Arrangements. Scottish Executive (link)

NHS MEL (2000) 29 Clinical Governance. Scottish Executive (link)

NHS MEL (1998)75 Clinical Governance. Scottish Executive (link)

A National Framework for reviewing and learning from adverse events in NHS Scotland, Healthcare Improvement Scotland, February 2025 (Link)

DL (2024) 08 Framework Document for NHS Boards (link)

Annex A – Review Group Membership

Review SLWG Membership 2025	
Heather Dalrymple	Chair, National Clinical Lead, Cancer Medicines; Heathcare Improvement Scotland
Eve Thomson	Policy Manager, Cancer and Rehabilitation Unit, Scottish Government
North Cancer Alliance (NCA)	
Sarah Howlett	Lead Cancer Pharmacist, NHS Grampian
Katherine Cowie	Lead Cancer Pharmacist, NHS Tayside
Judith Jordan	Regional Lead Cancer Pharmacist, North Cancer Alliance
Beverley Brown	Advanced Nurse Practitioner, NHS Grampian
Emma Brown	Consultant Medical Oncologist, NHS Tayside
East of Scotland Cancer Network (SCAN)	
Judith Smith	Nurse Consultant, SCAN
Fionagh Ross	Lead Cancer Pharmacist, NHS Lothian
Helen Creedon	Consultant Medical Oncologist, NHS Lothian
West of Scotland Cancer Network (WoSCAN)	
Jennifer Laskey	Consultant Cancer Pharmacist and WoSCAN Lead Pharmacist
Nicky Batty	SACT Lead Nurse, NHS Ayrshire and Arran
Kelly Baillie	Lead Cancer Pharmacist, NHS Lanarkshire
Sharon Armstrong	Consultant Medical Oncologist & SACT Lead, NHS Greater Glasgow & Clyde
Fiona Cutler	Consultant Haematologist & SACT Lead, WoSCAN and NHS Ayrshire & Arran
Carla Forte	Lead Cancer Pharmacist, NHS Greater Glasgow & Clyde
Maureen Grant	Service Manager Oncology & Haematology, NHS Greater Glasgow & Clyde
Nicky Donnelly	Lead Nurse – Specialist Oncology Services, NHS Greater Glasgow & Clyde
Tracey Cole	Projects & Planning Manager, WoSCAN
Managed Service Network for Children and Young People with Cancer (MSNCYPC)	
Lesley Simpson	Paediatric Oncology Consultant, NHS Lothian
Carla Kierulff	Children's Cancer Research Nurse, NHS Grampian
Hugh Bishop	Paediatric Oncology Consultant, NHS Grampian
Scottish Cancer Network (SCN)	
Lisa MacLeod	Lead Pharmacist, Scottish Cancer Network

Annex B – Glossary

Advanced Therapy Medicinal Products	A novel class of medicines that are based on genes, tissues or cells. They can be classified into 3 main types: 1) gene therapy medicines, 2) somatic-cell therapy medicines, 3) tissue-engineered medicines
Adverse events	Any unfavourable, and unintended (including an abnormal laboratory finding), symptom, sign or disease temporarily associated with the administered treatment.
Audit	A method by which those involved in providing services assess the quality of care. Results of a process or intervention are assessed, compared with a pre- existing standard, changed where necessary then reassessed.
Biological therapies	Agents derived from biological sources designed to stimulate or restore the ability of the body's immune system to fight infection and disease. Examples used in cancer treatment include monoclonal antibodies, immunotherapy agents, and targeted therapies.
Bispecific Antibody (BsAb)	A type of cancer immunotherapy involving an engineered protein with dual-binding capability giving unique functions including recruiting and activating immune cells, interfering with receptor signalling and targeting drug delivery directly to specific cells, increasing treatment efficacy and reducing side effects.
CAR-T Therapy	A type of cancer immunotherapy where a patient's T cells (immune cells) are collected, then genetically modified to better recognise and attack cancer cells. These modified cells are then infused back into the patient to target and destroy the cancer
Carcinogen	A substance that causes or can help to cause cancer.
CHI Number	The Community Health Index (CHI) number is the unique patient identifier for NHS Scotland. Everyone who is registered with a GP practice in Scotland has a CHI number.
Clinical Governance Group	Clinical governance is the framework through which NHS organisations are accountable for continuously improving the quality of their services and safe-guarding high standards of care. SACT clinical governance groups within NHS Boards ensure that this true for SACT services.
Clinical Management Pathway	A Clinical Management Guideline (CMG)/Clinical Management Pathway (CMP) (see introduction) is a multi-professional document which promotes multi-professional provision of high-quality care by detailing appropriate management through all stages of the patient's journey – screening, diagnosis, staging, histopathology, investigations, radiotherapy, SACT, supportive treatment and follow up.
COSHH	Control of Substances Hazardous to Health Regulations 2002.
Course	In the context of this document, this is the total number of SACT treatments planned for one patient at a given stage in the clinical management plan. It is often spread over a number of weeks or months e.g. 6 cycles of SACT at monthly intervals will make up one course.
CTCAE	Common Terminology Criteria for Adverse Events.
Cycle	In the context of this document, each individual SACT treatment for a patient, the sum of which make up the course, e.g. 6 cycles of SACT make up one course.
Cytotoxic	Chemicals that are directly toxic to cells preventing their replication or growth.

Cytotoxic SACT	A group of medicines active against cancer but can also be used for non-malignant conditions. Also often referred to as cytotoxic chemotherapy. They are commonly classified according to their mode of action e.g. alkylating agents.
Dispensing	The activity of supplying a product in the appropriate form for a specific patient according to a prescription.
Episode	In the context of this document, each time a patient attends for treatment within a cycle.
Extravasation	Leakage of an intravenous medicine from the vein into surrounding tissues.
Guideline	A document containing best practice advice. May be used to develop specific local policies and procedures.
Immunotherapy	A type of cancer therapy that treats disease by activating or suppressing the immune system.
Intravenous	Given into a vein by injection or infusion.
Intrathecal	Injection into the cerebrospinal fluid bathing the spinal cord and brain.
Lead Clinician	For the purposes of this document the term lead clinician is used to indicate the named clinician within an NHS Board who has responsibility for SACT services and governance
Licensed Facility	A site is in possession of a Manufacturer's Specials Licence granted by the MHRA which allows the site to manufacture unlicensed medicines (specials).
Managed Clinical Network (MCN)	A linked group of health professionals from primary, secondary and tertiary care, working in a co-ordinated manner, unconstrained by existing professional and NHS Board boundaries, to ensure equitable provision of high quality, clinically effective, and patient centred services.
Managed Service Network (MSN)	Network of healthcare specialists from different NHS Boards working together in a co-ordinated manner unconstrained by existing professional and NHS Board boundaries, to ensure equitable provision of high quality, clinically effective, and patient centred services
MHRA	Medicines and Healthcare products Regulatory Agency; the UK medicines licensing regulatory authority.
Monitored Dosage Systems	A simple storage device for a patient’s medication. The dosage system is made up of multiple compartments, divided into the days of week and times of the day common for medicine taking.
Mutagen	A substance that can cause or increase the rate of genetic mutation.
Near Miss	An incident where the people involved came to no actual harm, but which could have had serious consequences.
National Cancer Medicines Advisory Group (NCMAG)	A health technology appraisal programme under Healthcare Improvement Scotland that provides advice to NHS Scotland on cancer medicines uses which are off-label (for purposes not specified in their official approval) or off-patent (generic or biosimilar versions of medicines). *Note - these uses are not in the remit of the SMC*.
Occupational Exposure	Risks encountered from exposure to potentially or actually hazardous substances in the workplace.
Off-Protocol	A treatment or protocol choice made based on individual patient need delineated by exceptional circumstances.
Pharmaceutical Care	A systematic approach applied by a registered pharmacist or pharmacy technician to ensure that the patient gets the right medicines, in the right dose, at the right time and for the right reasons.

Pharmaceutical Verification	A process by which a registered pharmacist or pharmacy technician ensures a prescription is clinically appropriate by reviewing relevant clinical parameters and all medicines being taken by the patient. The purpose is to identify, resolve and prevent medicine-related problems.
Policy	A plan of action adopted by a group or organisation.
Preparation	The manipulation of raw materials and components within the pharmacy to make a final product for dispensing or in anticipation of dispensing in accordance with a prescription.
Procedure	A document giving detailed instructions on how to carry out a task, based on good practice.
Quality Performance Indicator (QPI)	A proxy measure of quality care.
Records	A permanent written account of a process undertaken.
SACT Prescription	The prescription is used to order SACT medicines, authorise treatment and record their administration.
SACT Protocol	A written summary of all relevant safety and medicines governance guidance for use of a specific SACT regimen, including: indication/place in treatment pathway(s), SACT regimen details (as specified below), required critical tests, side effects and monitoring criteria, etc. (see Appendix 2).
SACT Regimen	The specific treatment course including all SACT drugs, doses, days of administration, treatment intervals and duration of treatment.
Scottish Medicines Consortium (SMC)	A health technology appraisal programme under Healthcare Improvement Scotland that provides advice to NHS Scotland on the clinical and cost-effectiveness of new medicines.
Systemic Anti-Cancer Therapies (SACT)	Encompasses biological therapies, immunotherapies, advanced therapy medicinal products and cytotoxic chemotherapy.

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