

# **Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines**

**British Oncology Pharmacy Association**

### Document Control

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Change History			
Draft	Date	Author/Editor	Summary of Change
1.1	21.09.09	Steve Williamson	Initial draft
1.2	07.10.09	David Thomson	Split document into 2 separate documents. General updates.
1.3 &1.4	07.10.& 20.10.09	Ewan Morrison & Mary McClean	Editorial comments, updates and changes to reflect UK perspective
1.5	7.11.09	BOPA committee	Incorporation of SFH and editing
1.6	14.11.09	Netty Wood	References & comments
1.7	18.12.09	Steve Williamson	Membership Consultation
1.8	8.1.10	Steve Williamson	Final Version
1.9	29.1.10	Steve Williamson	Reference to appendix in 3.1 removed (appendix now in supporting guidance)
Contributor			Section/Contribution
Scottish Oncology Pharmacy Practice Group (SOPPG)			SOPPG SOP for care planning and general comments
Joanne Robinson			Verification checklist
BOPA Committee			General comments
BOPA Members following consultation (names available on request)			Numerous comments and updates see consultation summary document.

### Information Reader Box

<b>Proposed Target Audience</b>	Oncology and Haematology Pharmacists, Provider Trust Chief Pharmacists, NHS Scotland Boards Directors of Pharmacy, Oncologists and Haematologists, PCT Prescribing Advisors, Cancer Networks, SHA, Welsh and NI Health board(s).
<b>Proposed Circulation List</b>	BOPA Members, FCP Members, Chief Pharmaceutical Officers for each home country, CAT, UKONS, Provider Trust Chief Pharmacists, NHS Scotland Boards Directors of Pharmacy, RCP, PCT Prescribing Advisors, Heads of Schools Pharmacy, RSPGB/PLB, NES Scotland, Paediatric Oncology Pharmacists
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## Contents

	Page
1. Scope of the standards	4
2. Limitations	6
3. Professional responsibilities	7
4. The BOPA Standards	8
5. References	9

## 1 Scope of the Standards

- 1.1 The Department of Health requires that all chemotherapy prescriptions should be checked and authorised by a pharmacist. The National Cancer Action Team report into the 'Quality and Safety of Chemotherapy Services' published in August 2009 states '*All chemotherapy prescriptions should be checked by an oncology pharmacist, who has undergone specialist training, demonstrated their appropriate competence and is locally authorised/ accredited for the task.*' The Scottish Government Health Department sets out its guidance in the Health Department Letter 2005 29 – Guidance for the safe use of chemotherapy. It states "*All prescriptions for chemotherapy must be verified by a suitably trained pharmacist in accordance with legislative requirements, national standards and guidelines*". In 2008 The National Confidential Enquiry into Patient outcome and Death (NCEPOD) report 'For better, for worse?' noted that there was only evidence of Systemic Anticancer Therapies (SACT) prescriptions being checked by a pharmacist in 53% of cases.
- 1.2 This document does not describe any novel clinical practice; it brings together established pharmacy practice and presents it in the form of standards. This will allow all Chemotherapy Services to assure themselves that their pharmacy policies, procedures and practices meet the required standard.
- 1.3 The document describes what key steps a pharmacist must take when checking prescriptions for anticancer medicines. For the purposes of this document this will be referred to as '**Verification**'. It is recognised that there are other terms in common use to describe this process e.g. 'clinical checking' or 'validation' etc.
- 1.4 This document is supplemented by a 'Supporting Guidance' document which provides more detailed guidance to assist pharmacists in undertaking each of the steps required for verification.
- 1.5 This document can be used alongside the performance criteria listed in 'PHARM56/ PHARM57: Verifying a prescription for chemotherapy against a protocol/ without using a protocol' listed on the Skills for Health website. Note Skills for Health is the Sector Skills Councils for Health. It is a UK-wide independent organisation, licensed by the Secretary of State for Education and Skills and funded through the four UK health departments. BOPA will seek to work with SFH on future standards.
- 1.6 This guidance applies to parenteral and oral administration of SACT including chemotherapy and non-cytotoxic medicines such as targeted therapies, antibody treatments and novel therapies, e.g. rituximab, sunitinib and lenalidomide.

- 1.7 Verification provides assurance that the prescribed treatment is tailored and correct for the patient and their specific disease. It provides a check on treatment accuracy and is essential to avoid medication errors. Cancer medicines must not be administered to, or taken by patients until an appropriately trained pharmacist has verified the prescription.
- 1.8 This document must be used in conjunction with local organisation/ Cancer Network/Health Board Policies on Medicines Management and safe use of SACT and the following national guidance documents:
  - Manual of Cancer Service Standards. Chemotherapy Measures DOH 2005 HSC 2008/001. Note this document will be replaced by new standards in mid 2010, Refer to new standards when available.
  - Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy: DOH 2008
  - HSE Information Sheet MISC615- Safe Handling Of Cytotoxic Drugs,9/03
  - National Patient Safety Agency (NPSA) Rapid Response Report. 'Risks Of Incorrect Dosing of Oral Anticancer Medicines.' 22Jan08.
  - Scottish Government Health Department HDL 2005(29) 'Guidance for The Safe Use Of Cytotoxic Chemotherapy'
  - Scottish Government Health Department CEL (2009) 21: Safe Administration of Intrathecal Cytotoxic Chemotherapy and CEL(2009)22: Safe Administration of Vinca Alkaloids.
  - Welsh and Northern Irish Cancer Standards.
  - COIN Chemotherapy Guidelines Clinical Oncology (2001)13:S211.The Royal College of Radiologists
  - The National Cancer Action Team report into the 'Quality and Safety of Chemotherapy Services' published in August 2009
  - PHARM56: Verify prescription for chemotherapy against a protocol available at <http://www.skillsforhealth.org.uk/>
- 1.9 Overall responsibility for the safe use of SACT and ensuring these standards are in place should sit with an appropriate senior clinical lead within each organisation, e.g. Head of Pharmacy; Lead Clinician for Chemotherapy or Trust Lead for Medicines Management.
- 1.10 Pharmacy staff verifying prescriptions for oral anticancer medicines should operate to the same safety standards used when verifying anticancer medicine prescriptions for all other routes of administration.
- 1.11 This document refers to pharmacists when describing verification, but it is recognised that suitably competent technicians may become involved in verification of chemotherapy. In this case governance leads must ensure these staff have documented competency and that clinical and corporate governance approval has been given for this professional role development.

- 1.12 It is considered good practice to document identified pharmaceutical care issues that need to be monitored with SACT as part of the verification process. A structured care planning template supports effective practice, electronic patient records or pharmacy section in chemotherapy notes are another options. This document should be available to the multidisciplinary team. The best place to undertake verification is at ward/ clinic level to optimise access to treatment plan(s), clinical notes and the multi-professional team.
- 1.13 SACT must be prescribed in the context of an approved protocol and prescribed on designated prescription forms (pre-printed) or electronically. Where e-prescribing takes place a rigorous validation process must be in place to ensure accuracy of calculated doses.
- 1.14 It is recognised that clinical capacity for pharmacists to verify chemotherapy prescriptions and deliver pharmaceutical care to cancer patients must be assessed as part of the chemotherapy service capacity. Clinical capacity is distinct from pharmacy capacity to prepare anticancer medicines. BOPA/ SCPG aim to develop and validate a pharmacy clinical capacity plan by October 2010.
- 1.15 Further work is ongoing in defining specific educational competencies outlining the knowledge and understanding that an appropriately trained pharmacist verifying a prescription must have. Note the supporting guidance to these standards includes a section on education and training.

## **2 Limitations**

- 2.1 It is recognised that the clinical role of pharmacy encompasses more than verification of individual treatment episodes. Pharmacy staff improve the risk management of anticancer medicines by medication review; patient education, clinical monitoring of patients receiving anticancer medicines; direct clinical care to anticancer medicine patients, e.g. prescribing and managing the introduction of new medicines.
- 2.2 Anticancer medicines are also used for non-cancer indications, e.g. methotrexate for rheumatoid arthritis, and pose similar risks to the patient. Guidance for verification of prescriptions of these medicines is outside the scope of this document. Pharmacy departments should consider if any of the standards listed can be applied to the verification of these medicines and other high risk medications.
- 2.3 It has been acknowledged that in many centres prescriptions for oral SACT / outpatient prescriptions may be checked in an area where there is not access to patient notes/ treatment plans (see standards 4.4 to 4.6) however Trusts should review practices to work towards compliance.

### **3 Professional Responsibilities**

- 3.1 Pharmacists verifying prescriptions are one part of the overall medicine management process for SACT and their supportive medicines. This document does not describe standards for the overall clinical monitoring of cancer patients. Pharmacists must define their responsibilities in areas where there is overlap to determine who has primary responsibility. Pharmacists must be aware of the clinical monitoring required for patients receiving chemotherapy and assure themselves a robust system for the monitoring of patients is in place within their organisation. This may vary between organisations.
- 3.2 Chemotherapy services are varied, it is recognised that there will be differences in pharmacists' responsibilities depending on the set up of their service. For example pharmacy may not prepare or not release anticancer medicines until the pharmacist has checked the full blood count. However as pre-prescribing and pre-preparation of chemotherapy becomes more widespread (to reduce waiting times and increase flexibility) there may be a requirement for drugs to be issued from pharmacy to a clinical area before full blood counts are known. In these circumstances pharmacists can still verify the prescription and allow the drugs to be released provided the organization has a policy in place clearly defining the process and identifying who is responsible for checking full blood count results.
- 3.3 When a pharmacist non medical prescriber (NMP) initiates a prescription this does not eliminate the requirement for a (second) pharmacist's role in verifying the prescription. NMPs must not be directly involved in verifying, dispensing and checking of prescriptions they have written. The Royal Pharmaceutical Society of Great Britain (RPSGB) state that NMPs must 'ensure separation of prescribing and dispensing whenever possible. Where a pharmacist is both prescribing and dispensing a patient's medication, a second suitably competent person should normally be involved in the checking process.'
- 3.4 Pharmacists verifying prescriptions for SACT must be able to recognise situations where they need to seek advice / support from appropriate sources, e.g. senior colleague and respond appropriately; in particular, where the complexity required exceeds their own personal level of competence or where there is reason for concern about the individual's suitability for the prescribed treatment.



## 4 The BOPA Standards

The key checks that an authorised pharmacist must undertake in order to verify any prescription for SACT prior to preparation and release are:

- 4.1 Check prescribers details and signature are present and confirm they are authorised to prescribe SACT
- 4.2 Ensure regimen has been through local approval processes e.g. clinical governance and financial approval and/ or is included on a list of locally approved regimens
- 4.3 On the first cycle check the regimen is the intended treatment as documented in a treatment plan, in the clinical notes or in the electronic record
- 4.4 Check regimen is appropriate for patient's diagnosis, medical history, performance status and chemotherapy history (using the treatment plan, clinical notes or electronic record)
- 4.5 Check there are no known drug interactions (including with food) or conflicts with patient allergies and other medication(s)
- 4.6 Check that the timing of administration is appropriate i.e. interval since last treatment
- 4.7 Check patient demographics (age, height and weight) have been correctly recorded on prescription
- 4.8 Check body surface area (BSA) is correctly calculated, taking into account recent weight. Note there should be local agreement for frequency of monitoring and checking patient's weight.
- 4.9 Check all dose calculations and dose units are correct and have been calculated correctly according to the protocol and any other relevant local guidance, e.g. dose rounding / banding
- 4.10 Check cumulative dose and maximum individual dose as appropriate
- 4.11 Check reason for and consistency of any dose adjustments, e.g. reduction(s) or escalations and ensure reason is documented.
- 4.12 Check method of administration is appropriate
- 4.13 Check laboratory values, FBC, U&E's and LFT's are within accepted limits if appropriate (see 3.2 above)
- 4.14 Check doses are appropriate with respect to renal and hepatic function and any experienced toxicities
- 4.15 Check other essential tests have been undertaken if appropriate
- 4.16 Check supportive care is prescribed and it is appropriate for the patient and regimen
- 4.17 Sign and date prescription as a record of verification

Ideally the verification and all pharmaceutical care issues should be documented within a structured pharmaceutical care plan / patient record. As a minimum significant care issues and interventions should be documented in the clinical notes or locally agreed system for recording.



## 5 References

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