Standards for Pharmacy Verification of Prescriptions for Cancer Medicines

British Oncology Pharmacy Association

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Endorsed by:

ROYAL PHARMACEUTICAL SOCIETY

Contents

1. The Purpose of the BOPA Standards

- 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 Chief Executive Letter 30 (2012) – Guidance for the safe delivery of systemic anticancer therapy. It states *"All prescriptions for SACT are verified by a suitably trained pharmacist in accordance with legislative requirements, national standards and local policy prior to dispensing and release from pharmacy".*

- This 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.

- 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.

2 The scope of the BOPA standards

- 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.

- 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.

- 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.

- It is noted that SACT medicines dispensed as part of a clinical trial may be classed as investigational medicinal products (IMPs) and additional checks are needed according to the clinical trial protocol and GMP guidelines.

- 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:
  - Royal Pharmaceutical Society Professional Standards for Hospital Pharmacy July 2012
  - Manual of Cancer Service Standards. Chemotherapy Measures DOH 2011
  - Dispensing and Supply of Oral Chemotherapy and SACT in Primary Care. Royal Pharmaceutical Society January 2011
  - 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 CEL (2009) 21: Safe Administration of Intrathecal Cytotoxic Chemotherapy and
  - Scottish Government Health Department CEL 30 (2012) – Guidance for the safe delivery of systemic anticancer therapy
  - Northern Irish Chemotherapy Service Standards.
  - Welsh Cancer Standards 2005 WHC (2005)051 Cancer Services in Wales: Publication of National Cancer Standards and the implication for Commissioners and Providers, through the Cancer Networks, 2009 (Sarcoma Services), 2010 (Rehabilitation of Adults with Cancer) and Northern Irish Cancer Standards.
  - 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/

3 Putting the Standards into Practice

- The BOPA Standards have been updated to reflect the changing nature of SACT use. There are now increasing numbers of fixed dose continuous SACT therapies that do not require the same level of checking as cytotoxics since they pose a lower risk to patients. The BOPA standards have been simplified to seven core steps with associated secondary steps to be applied as appropriate depending on configuration of local services.

- Local teams should review their pharmacy verification practice and clearly document in local policy where the different levels of verification are required, e.g. for IV chemotherapy all secondary steps may be needed or for fixed dose continuous oral SACT only the core steps are needed.

- 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.

- SACT must be prescribed in the context of an approved protocol and prescribed via electronic prescribing system. The 2011 English Cancer Standards, measure 11-3S-139 states: '*There should be a database driven, electronic prescribing platform for chemotherapy'.* Similar directives exist for Scotland and Wales.

- A rigorous validation process for e-prescribing must be in place to ensure accuracy of calculated doses. These systems must have on-going maintenance and have suitable arrangements for supervision of their use by appropriately qualified staff. Where electronic systems are not yet available/commissioned SACT must be prescribed on designated prescription forms (pre-printed regimen specific).

- It is considered good practice to document identified pharmaceutical care issues that need to be monitored with SACT as part of the verification process, particularly for IV chemotherapy. This can be in a structured care planning template, as part of the electronic patient records or in the chemotherapy notes.

- Clinical capacity for pharmacists to verify chemotherapy prescriptions and deliver pharmaceutical care to cancer patients must be monitored as part of the chemotherapy service capacity.

- BOPA has defined specific educational competencies outlining the knowledge and understanding that an appropriately trained pharmacist verifying a prescription must have.

- More detailed guidance to assist pharmacists in undertaking each of the steps required for verification is available in 'Supporting Guidance' document.

4 Professional Responsibilities

- 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.

- Pharmacists verifying prescriptions are one part of the overall medicine optimisation process for SACT. This document does not describe standards for the clinical monitoring of patients receiving SACT. Pharmacists must define their responsibilities in areas where there is overlap to determine who has primary responsibility.

- 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 in services where chemotherapy is prescribed and prepared in advance of critical blood results being known it is acceptable for drugs to be released from pharmacy before full blood counts are known, provided the organisation has a policy in place clearly defining the process and identifying who is responsible for checking full blood count results before administration.

- If a pharmacist prescriber (NMP) initiates a prescription a pharmacist is still required to verify the prescription. The Royal Pharmaceutical Society of Great Britain 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.*'

- 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.

- 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 organisation's governance leads must ensure these staff have documented competency and that clinical and corporate governance approval has been given for this professional role development.

5 Limitations

- 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 and direct clinical care to anticancer medicine patients, e.g. prescribing and managing the introduction of new medicines.

- 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.

- 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. This may be appropriate depending on the complexity of the regimen, see section 5.2 below)

5 The BOPA Standards

1. **Check the Prescription**: Has the drug or regimen been prescribed in line with legislation and local prescribing policy?
   - Check the prescriber's details and signature are present and confirm they are authorised to prescribe SACT as appropriate
   - Check that the prescription is clear, legible, unambiguous and includes all details required for dispensing, labelling and administration
2. **Check the Prescription Against the Protocol and Treatment Plan:**

   This will include as appropriate/relevant:
   - Ensuring the 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
   - Where there is access to either clinical notes, treatment plan or electronic record on first cycle check the regimen is intended treatment and is appropriate for patient's diagnosis, medical history, performance status and chemotherapy history
3. **Check Patient Details**
   - Check patient demographics (age, height and weight) have been correctly recorded on prescription as appropriate
4. **Check Administration Details**

   This will include as appropriate/ relevant:
   - Checking there are no known drug interactions (including with food) or conflicts with patient allergies and other medication(s)
   - Checking the timing of administration is appropriate i.e. interval since last treatment and/or start and stop dates for oral chemotherapy
   - Checking appropriate supportive care is prescribed
   - Checking method of administration is appropriate
5. **Check Calculations:** Are the BSA and dose calculations correct?
   - 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 as appropriate
   - Check prescribed dose is in line with previous dose reductions
   - Check body surface area (BSA) is correctly calculated if needed for dose calculation. There should be local agreement for frequency of monitoring and checking patient's weight.
6. **Check Laboratory Results as appropriate**:
   - Check laboratory values, FBC, U&E's and LFT's are within accepted limits if appropriate
   - Check doses are appropriate with respect to renal and hepatic function and any experienced toxicities
   - Check other essential tests have been undertaken if appropriate
7. **Sign and date prescription as a record of verification**

Document Control

Title	BOPA: Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines: Version 2.3
Author / Editor	Steve Williamson, Consultant Pharmacist in Cancer Services Northumbria HCFT/ North of England Cancer Network
Owner	BOPA.

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 Maclean	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
2	3.12.12	Steve Williamson	Draft Version 2
2.2	11.03.13	Steve Williamson	Changed following consultation to members
2.3	02.04.13	Steve Williamson/ Helen Flint	Final version reviewed by committee

Information Reader Box

Proposed Target Audience	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).
Proposed Circulation List	BOPA Members, FCP Members, Chief Pharmaceutical Officers for each home country, 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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