

# **Systemic Anti-Cancer Therapy Care Pathway**

**Guidelines on the Safe Use of Oral  
Anti-Cancer Medicines**

**Pathway of Care**

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## 1.0 BACKGROUND

On 22<sup>nd</sup> January 2008 the National Patient Safety Agency (NPSA) issued a Rapid Response Report alerting all healthcare staff involved in the use of oral anti-cancer medicines of potentially fatal outcomes if incorrect doses of oral anti-cancer therapy are prescribed, dispensed or administered. This outlined actions the NHS and independent sector must undertake.

Standards for dealing with adult systemic chemotherapy are clearly defined in the NHS Cancer Standards (Chemotherapy QSIS Standards). The overriding principle of this document is that oral anti-cancer medicines are managed to at least the same standards as IV chemotherapy/ IV anti-cancer medicines.

This document provides guidance for **all** organisations and staff involved in the prescribing, dispensing, supply, administration and monitoring of oral anti-cancer medicines in Kent and Medway Cancer Collaborative. This includes all secondary care, primary care and the independent sector.

## 2.0 DEFINITION

For the purposes of this document the term 'Oral Anti-cancer Medicine' is used to refer to all drugs with direct anti-tumour activity, orally administered to cancer patients, including traditional cytotoxic chemotherapy such as capecitabine, hydroxycarbamide, chlorambucil and small molecule treatments such as imatinib, erlotinib, sunitinib and other agents such as thalidomide or lenalidomide. It does *not* include hormonal or anti-hormonal agents such as tamoxifen and anastrozole but does include abiraterone and enzalutamide.

## 3.0 SCOPE

This document is aimed at staff delivering oral anti-cancer medicines for patients with malignant disease. All local policies must be developed by a multi-professional team and comply with the scope of this document. The governance of the Network Guidelines for the Safe Use of Oral Anti-cancer Medicines will be managed according to the agreed Network Chemotherapy and local chemotherapy group structure.

It is the responsibility of all staff involved in the delivery of oral anti-cancer medicines to ensure they follow the individual Trust policies and guidelines relating to adverse incident reporting and investigation reporting. Staff must also be aware of all Trust policies and guidelines relating to risk management, use of unlicensed medicines and infection control.

It must be noted that some oral anti-cancer medicines are also used for non-cancer indications, e.g. methotrexate for rheumatoid arthritis, and pose similar risks to the patient. It is recommended that organisations undertake a risk assessment and the principles of this guidance applied as appropriate.

These guidelines must be used in conjunction with national chemotherapy standards as detailed in the Quality Surveillance Team (QST) website, see <https://www.qst.england.nhs.uk/>

## 4.0 PRESCRIBING OF ORAL ANTI-CANCER MEDICINES

The prescribing of oral anti-cancer medicines should be carried out and monitored to the same standards as those for parenteral (IV) chemotherapy.

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## 4.1 Who Can Prescribe

Prescribing of the first and subsequent cycle of oral anti-cancer medicines is undertaken by either a haematologist or oncology specialist at Consultant/ SAS/SPR level who has been assessed as competent and whose name appears on the Trust's approved list of prescribers.

**Non-medical prescribers** may prescribe the second and subsequent course of oral anti-cancer medicines provided they have acquired approval from their organisation and are working within an agreed clinical management plan (supplementary NMPs) or following a treatment plan (independent NMPs) (Peer Review standard 3C-137).

**Prescribing oral anti-cancer medicines in primary care** must only be undertaken within agreed shared care guidelines. The clinical lead for oral anti-cancer medicines (see [section 10.0](#)) must be involved in the approval for use of all shared care guidelines. Shared care guidelines should consider the following areas in addition to the usual clinical management issues of shared care:

- Assessment of patient's suitability to self-administer
- Assessment of patient's home environment
- Prescribing of anti-cancer treatments
- Arrangements for pharmacist prescription verification
- Dispensing anti-cancer medicines
- Checking clinical parameters including blood counts before administration (and ideally before dispensing)
- Assessing the patient is fit to receive chemotherapy
- Self-administration of the chemotherapy
- Delivery, storage and disposal arrangements
- Managing side effects and/or adverse events
- Emergency contact(s)
- Follow up arrangements

## 4.2 Initiating Treatment

All prescribers initiating treatment for oral anti-cancer medicines must:

- Assess the patient's suitability for oral treatment including ability to swallow tablets or capsules
- Assess patient's ability to comply with the proposed drug/ regimen
- Obtain consent from the patient following local Trust protocol
- Provide verbal and written information about their oral anti-cancer therapy (this information should include contact details for specialist advice)
- Ensure appropriate communication to patient's GP and referring consultant about the medicines, ensuring the GP is clear on the role they play in managing the patient. *note : caution must be taken if trusts issue copies of 'prescriptions' to GPs as there is a risk of inappropriate continuation of medicine. It must be stated on any written communication where appropriate that 'This medication is NOT for continuation by primary care'.*
- Ensure patients are appropriately counselled on the use of their medicines. This should include informing the patient that they should stop their oral anti-cancer medicine if they are admitted to hospital until they have been reviewed by the oncology / haematology team. *Note this information may be provided/ reinforced by pharmacist /nurse according to local policy.*

See [section 5.2](#) for standards on writing prescriptions for oral anti-cancer medicines.

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## 4.3 Inpatient Prescribing

### Inpatient Prescribing (New Patients)

In-patient prescribing for new patients must be to the same standards as prescribing for day-case and out-patients and must only be initiated (decision to treat and initially prescribed) by those prescribers defined in [section 4.1](#). All chemotherapy prescriptions must be prescribed on the KMCC networked chemotherapy electronic prescribing system (EPS). The details of any 'pick-up internal' (TTO / medicines to take home) medication, which (may) include(s) oral SACT should then be transcribed onto the in-patient drug chart with a note to refer to the chemotherapy EPS for full details of the regimen. The record of administration for 'pick-up internal agents' will be made on the in-patient chart. The in-patient chart should contain the same detail as is found on the EPS, i.e. the dose, frequency, intended start date and duration of treatment, and where applicable stop date, and proprietary name if relevant. Start and stop dates should also be indicated on the inpatient record of administration. If oral SACT has been included as an 'internal' agent (drug to be given within the hospital) on the EPS, then reference should be made to this on the drug chart, **but** the record of administration should be made on the EPS. This scenario would only occur on an oncology or haematology in-patient ward except in exceptional circumstances. All intended deviations from protocol, such as dose modifications, should be clearly identified as such, on the Chemotherapy EPS as well as on the drug chart.

### Inpatient Prescribing on Admission (currently on treatment)

Patients admitted to hospital wards on oral anti-cancer medicines are at risk from uncontrolled prescribing. A detailed medication history must be taken on admission, including:

- Prescribing centre, named oncology / haematology consultant and clinical nurse specialist
- Indication for oral anti-cancer therapy
- Drug(s) and dose(s), frequency of administration, e.g. daily, weekly, continuous or cyclical
- Intended start date, duration of treatment, intended stop date for each cycle of treatment and date of next cycle
- Any supportive medications, e.g. anti-emetics

*Note: where possible, the original prescription for oral anti-cancer medicine should be accessed.*

The patient's original prescriber should countersign the drug chart (if they are available) or clinical staff must contact the chemotherapy unit to confirm medication history and treatment plan.

If the original prescriber is not available, details of the chemotherapy regimen from the EPS for the current cycle of treatment should be obtained, and the information transcribed onto the in-patient drug chart as outlined above by a prescriber as defined in [section 4.1](#) or by a member of the Trust Acute Oncology Team trained and competent to prescribe SACT. In order to support staff involved in the prescribing of oral anti-cancer medicines, there must always be available in the organisation a trained oncology pharmacist who is able to provide oncology pharmacy advice to clinical staff.

Other reference sources for cancer medicines should be available during and out-of-hours for information on special precautions, guidance for monitoring, expected toxicities, contraindications, potential interactions and medications to be avoided. This may include the out-of-hours service and the chemotherapy trained nurses on an in-patient ward as well as the KMCC SACT protocols available on the KMCC website.

The patient's current medical condition must be assessed to ensure suitability for continued treatment with the medicine.

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Where possible, the patient's own medication should be utilised for the remainder of the cycle, thus minimising the risks associated with prescribing inappropriate / incorrect dose or duration of treatment. All inpatient prescriptions for oral anti-cancer medicines must be checked by an appropriately trained (ideally oncology trained) pharmacist.

### **On discharge**

If continuing supply of the oral anti-cancer medicine is required, it must be prescribed on the EPS by a prescriber as defined in [section 4.1](#) and must be checked by a trained oncology pharmacist prior to dispensing. Details on any doses dispensed and administered to the patient whilst an in-patient must be made available to the oncology pharmacist.

Details of the chemotherapy prescription should be sent to the GP endorsed "This medication is not for continuation by primary care".

NB: Oral SACT should be prescribed and dispensed by the patient's usual treatment centre. If, in exceptional circumstances, treatment is prescribed and delivered elsewhere, this should ONLY be done in liaison with the patient's oncology team. On discharge, where relevant, details of any oral anti-cancer medicines prescribed and dispensed should be communicated to the patient's usual oncology treatment centre.

## **4.4 Hospital Outpatient Prescribing**

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All oral anti-cancer medicine prescriptions must be prescribed on the electronic prescribing system (see [section 5.2](#)), with the exception of those drugs which have undergone a risk assessment and been deemed suitable for dispensing in primary care. In these exceptional circumstances the drug may be prescribed on an FP10 (HNC). See [section 6.4](#) for further information.

## **4.5 Prescribing for External Healthcare Organisations**

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All prescribers who write prescriptions for oral anti-cancer medicines for patients who will have the medicines administered in organisations external to their Trust, e.g. nursing homes, hospices, prisons, and children's homes must ensure that the external organisation has access to the specified regimens and protocols. In the case of organisations such as prisons where medications are re-prescribed by the prison's medical officer in accordance with their own procedures it is recommended that the organisation ensures regimens and protocols are always obtained before re-prescribing.

## **4.6 Repeat Prescriptions**

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Oral anti-cancer medicines must not be prescribed by repeat prescription.  
 N.B. Dispensing in instalments may occur in certain circumstances.

## 5.0 PROTOCOLS, SACT REGIMENS ON THE ELECTRONIC PRESCRIBING SYSTEM (EPS) AND TREATMENT PLAN

### 5.1 Protocols and SACT Prescriptions on the EPS

All oral anti-cancer medicines must be prescribed within the context of a written protocol and prescribed on the chemotherapy EPS. A Network Chemotherapy protocol and EPS regimen should be used wherever possible; if this is not possible, the KMCC policy for the management of algorithm deviations should be followed. Full details of the specific SACT protocol should be contained within patient's notes, with a copy of the protocol if it is not easily accessible. Access to protocols should be available on all wards where oral anti-cancer medicines are routinely administered or where patients receiving oral anti-cancer medicines may be admitted (e.g. emergency admissions wards). Protocols must contain:

- Definition of the clinical condition being treated and therapeutic intent
- Names (approved) of all medicines to be given
- Dosing schedule for each medicine
- Maximum individual dose where applicable
- Maximum cumulative doses where applicable
- Supportive therapy
- Any tests that need to be performed before chemotherapy starts and during treatment
- Recommendations for dose modifications for adverse reactions
- Number of cycles or review period
- Common drug interactions
- Reference(s) source

Details of anti-cancer drug protocols can be found on the Kent and Medway Cancer Collaborative Website under Network Chemotherapy Prescription Proformas or within the KMCC document management system. Prescribers must have access to these documents at the point of prescribing. Protocols for anti-cancer medicines dispensed within the community are also available on the Kent and Medway Cancer Collaborative website. Where anti-cancer medicines are dispensed by a homecare company, Trusts should ensure the homecare company has access to the chemotherapy protocol and this should be described within local policies.

N.B. If a KMCC SACT protocol is not available on the KMCC website, then the SACT regimen on the EPS should be used for reference (a programme of work is in being undertaken to create a full set of PDF SACT protocols; prior to the creation of these, the chemotherapy prescription met the requirements of a chemotherapy protocol).

Prescriptions must contain the following information:

- Patient details including, height, weight and surface area
- Protocol / regimen name
- Drug names (generic and, in some cases where relevant, proprietary name), and doses (both as mg/m<sup>2</sup> or per kg and the final calculated dose or as a fixed dose)
- Frequency of administration (and timing where relevant)
- Number of days or doses to be dispensed (expressed in words and figures e.g. for three (3) days not 3/7 – abbreviations are **not** to be used)
- The intended start date and exact duration of treatment including either stop date or the word 'ONLY' to indicate that the medicine is not continuous, e.g. capecitabine start on 1/1/08 for 14 days ONLY

N.B. For continuous treatment – the intended review date can be found on the action sheet).

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N.B. On the rare occasion where an oral anti-cancer drug is to be dispensed from a community pharmacy, a copy of the protocol should be attached to the FP10 (HNC) prescription (a copy of the Trust proforma should not be issued as this may result in a patient receiving the supply twice). See [section 6.4](#) for further information on dispensing in primary care. It is recommended that the FP10 (HNC) should be endorsed with a reference number to correlate with the Kent and Medway protocol number in the section of the KMCC website “protocols for anti-cancer medicines dispensed within the community”.

## 5.2 Treatment Plan

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The chemotherapy action sheet, located within the patient’s chemotherapy notes details the treatment plan. This action sheet may be in the form of an Electronic Action Sheet on KOMs. The following should be included within the action sheet:

- Diagnosis
- Treatment intent
- Clinical trial (if applicable)
- Total number of cycles or number until review
- Number of cycles before review
- Details of chemotherapy regimen
- Details of tests
- Review date
- Deviations from standard protocol (e.g. dose modifications).

*Note: Deviations from the standard protocol should be communicated to the patient’s GP and referring consultant.*

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## 6.0 DISPENSING AND SUPPLY OF ORAL ANTI-CANCER MEDICINES

Acute Trust pharmacy departments dispensing oral anti-cancer medicines should operate to the same safety standards used when preparing and dispensing parenteral (IV) chemotherapy. Dispensing of oral anti-cancer medicines may be undertaken by homecare companies. Trusts, within their policies, should ensure that homecare companies have policies and procedures in place relating to the dispensing of oral anti-cancer medicines and that the principles and safety standards outlined in this document are met.

All pharmacy staff involved in the dispensing of oral anti-cancer medication must have access to the agreed regimen protocols for the regimens in use. Note: the BNF is **not** recommended as a primary source of anti-cancer drug prescribing information.

Where anti-cancer medicines are dispensed by a homecare company, Trusts should ensure the homecare company has access to the chemotherapy protocol and this should be described within local policies.

All prescriptions for oral anti-cancer medicines should be validated (checked and authorised) by an appropriately experienced oncology pharmacist either prior to or at the point of dispensing.

All prescriptions for oral anti-cancer medicines **MUST** be computer generated on the Chemotherapy EPS Pharmacists **must not** accept prescriptions handwritten on out-patient prescriptions. . The only exception is for FP10(HNC) prescriptions as set out in [section 4.4](#).

Where practical, pharmaceutical care plans should be put in place to identify the key issues that need to be monitored with the oral anti-cancer medicine/ regimen.

It is recognised that it may not be possible to ensure that all oral prescriptions are validated (checked and authorised) by a trained oncology pharmacist. Trusts must therefore ensure that appropriate training on the safety aspects of oral anti-cancer medicines is provided to pharmacy staff involved in dispensing and supply of these medicines. This must be undertaken as part of induction process for new staff and repeated every two years for all staff involved in dispensing and supply of oral anti-cancer medicines.

In order to support staff involved in the dispensing and supply of oral anti-cancer medicines, there must always be available in the organisation a trained oncology pharmacist who is able to provide oncology pharmacy advice to dispensary staff.

**Note:** Trained oncology pharmacists are those who are deemed competent to check and authorise IV chemotherapy prescriptions and are competent to provide pharmaceutical care to cancer patients.

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## 6.1 Standards for Dispensing

- ➔ The pharmacist must ensure the directions on the prescription are clear and unambiguous and include, where relevant, the intended period of treatment, including start and stop dates for short term or intermittent treatment.
- ➔ The exact quantity of tablets/capsules required must be supplied unless a risk assessment of a particular drug/ pack size/type identifies it as not suitable to be split. Wherever possible, only packs that match usual dosing and cycle length requirements or that can be safely split will be purchased.
- ➔ The quantity of medication to be dispensed must be subject to a second independent check and the quantity dispensed should also be double checked unless a sealed pack is supplied.
- ➔ Ideally, a different member of staff should final check the prescription from the pharmacist who clinically screened the prescription.
- ➔ All patients must receive the manufacturer's Patient Information Leaflet, with their oral anti-cancer medicines.
- ➔ Pharmacy staff must not break or crush tablets, capsules must not be opened. If the dosage is half a tablet, the patient must be counselled and given instructions on how to administer the dose.
- ➔ Queries about difficulties in taking the solid oral form should be directed to a specialist oncology / haematology pharmacist. Where there are difficulties swallowing tablets / capsules, and where it is available, use of a suspension or solution is preferred and a suitable preparation should be obtained from an NHS hospital pharmacy or commercial compounding/manufacturing facility with appropriate safe-handling facilities. It must be noted that in many cases there are no liquid alternatives, in these cases refer back to original prescriber.
- ➔ Use of multi-compartment compliance aids (e.g. 'dosette' boxes) are not recommended and should only be used where absolutely necessary as identified in a risk and adherence assessment which must be undertaken and documented in the patient's notes.
- ➔ Label directions must be clear and unambiguous and include where relevant; the intended period of treatment; start and stop dates or the number of days expressed as '**for X days ONLY**' to indicate that the medicine is not continuous (for short term or intermittent treatment); an appropriate indication of the need for safe handling. Any ambiguities must be referred back to the validating pharmacist.
- ➔ An additional label should be added stating "*No further supply should be obtained from your GP*"
- ➔ An additional label should be added stating "*oral anti-cancer medicine – only to be re-issued by oncology / haematology*"
- ➔ An additional label should be added stating "*On admission to hospital, stop this medicine and discuss immediately with oncology/ haematology team*".

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## 6.2 Supply to In-Patients

Oral anti-cancer medicines should not be kept as stock or temporary stock items on the ward. Supply of oral SACT to in-patients should be made in line with standards set out in [section 6.0](#) and [6.1](#).

Wherever possible, patient's own medicines must be used. Oral anti-cancer medicines should not be ordered without checking with the patient and/or carer that patient own supplies are not available.

All anti-cancer medicines must be dispensed and labelled to include the following information:

- Patient name
- Generic drug name and in some cases, where relevant, proprietary name.
- Strength of tablets or capsules, or concentration of oral liquid
- The number of tablets / capsules in the container, or volume of liquid
- Administration instructions
- Length of treatment, including stop date as appropriate
- Storage conditions
- Caution: Cytotoxic Drug (as appropriate)
- Name and address of pharmacy department
- In addition, all legal requirements for dispensed medicines

N.B. Patients should be advised to return any unused oral anti-cancer medication that they may have at home to the hospital pharmacy or chemotherapy ward.

## 6.3 Supply to External Healthcare Organisations

Trusts supplying oral anti-cancer medicines to external organisations who will take responsibility for administering the medicines, e.g. Nursing homes, prisons, children's homes must ensure that the medicines are labelled as in 6.2 above and the external organisation has access to the specified regimens protocols and these contain the details laid out in [section 5.1](#). Prescribers are responsible for ensuring pharmacies supplying the medicines know the medicines will be administered in an external organisation.

## 6.4 Dispensing in Primary Care

It is **NOT recommended** that oral anti-cancer medicines are dispensed by community pharmacies unless a risk assessment has been undertaken and an appropriate framework has been developed to ensure the principles and safety standards outlined in this document are met, ideally this should include a service level agreement. An example where a framework may be developed is a community pharmacy located within an Acute Trust site. Areas for consideration in the framework include:

- Suitability of drug/regimen, i.e. assessment of potential toxicity of the drug(s) and complexity of the regimen (more than one drug, pulsed schedule, variable dose)
- Availability of drugs (wholesaler or direct)
- Origin of prescription, primary or secondary care (the use of FP10(HP) prescriptions may be a barrier to the recommendation for regimen specific computer generated prescriptions)
- Requirement for specialist clinical oncology pharmacy advice
- Requirement for Shared Care documentation
- Training requirements for primary care pharmacists
- Remuneration issues
- Handling and disposal of cytotoxic drugs (COSHH)
- Out of hours support

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## 7.0 PATIENT EDUCATION AND MEDICATION COUNSELLING

Prior to the first cycle of treatment all patients (and carers if they assist the patient with administration of medication) should be seen and counselled/ educated by an appropriately trained chemotherapy nurse, pharmacist, or pharmacy technician using the checklist below ([section 7.1](#)). After counselling/educating the patient, the pharmacist, pharmacy technician or nurse should make a note on the annotation page of the EPS or in line with Trust process.

### 7.1 Summary of Counselling Checklist Prior to Starting Oral Anti-Cancer Treatment

The healthcare professional should ensure:

- The patient understands that the medicine has been prescribed only for them and should not be given to anyone else.
- The patient understands that the medicine should be stored in a safe place away from children and should not be handled by anyone else (unless it is being given by a carer, see below)
- That if a carer is administering the medicine they are aware that they should not handle the tablets or capsules directly (they should be tipped or pushed out from the blister pack directly into a medicine pot)
- The patient (or relative/ carer) understands how and when to take the medicine (in particular, if there are breaks in treatment they know when this should be and how long it should be for)
- The patient understands any specific directions (relating to food, fasting etc.)
- They know what they should do if they miss a dose.
- They understand what to do if they vomit a dose.
- They understand what the side effects of treatment are and what they should do if they experience them. In particular they know who they should contact. (Note. Patients must be able to access the same 24 hour telephone advice service provided for iv chemotherapy and be given a Hand Held Record for Chemotherapy identifying their “key worker”).
- They know how and where to obtain further supplies.
- They understand what they should do with left over tablets.
- They understand how they should dispose of medicine spoons, syringes or measures if used for cytotoxic medication.
- They understand the role of their GP and the role of the hospital multi professional team.
- They are able to take their medicine in the dosage form supplied.
- If the patient is unable to swallow tablets or capsules, they have been referred to the oncology pharmacist and given the appropriate advice.
- They understand that they should inform the healthcare team if they are taking over the counter medications/ supplements.
- If a patient treatment diary is available it has been completed by a nurse or pharmacist

Before issuing any further supplies, pharmacy staff or other healthcare professionals should ensure:

- Patients were seen and counselled/educated as described above prior to their first cycle of treatment
- They fully understand how and when to take their medicines
- The patient had no problems taking their first cycle of treatment. For example they had no problems swallowing the medication or with vomiting
- That if a dose reduction has been made, the patient is aware why their dose has been changed and how many tablets / capsules they should take and when

If at any stage it becomes apparent that the patient does not have a full understanding of how to take their medicine or if there are any concerns regarding compliance, the patient should be referred back to the cancer specialist.

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## 8.0 ADMINISTRATION AND HANDLING

The administration of oral anti-cancer medicines on Trust premises should be carried out and monitored to the same standards as those for parenteral (IV) chemotherapy. i.e. oral anti-cancer medicines should be administered by appropriately qualified clinical staff who are competent to follow the same safeguards and checks as when administering IV anti-cancer medicines. There should be a log of who these staff are within the organisation.

Clinical staff administering oral anti-cancer medicines on non-oncology/ haematology wards to in-patients should contact members of the patient's specialist team for information and advice about the oral anti-cancer medicine.

Trusts' administration of medicines policies must be complied with (particularly in relation to when a second check is required).

Staff administering oral anti-cancer medicines must have access to the specified regimens protocols.

When in-patients are self-administering their oral anti-cancer medicines, the responsibility for administration lies with the patient and their carer. The health care professional's role is to support patients to take their medication correctly and as safely as possible and that records are maintained.

### 8.1 Clinical Checks Prior to Dispensing and/or Administration of Oral Anti-Cancer Treatment

Before oral anti-cancer medicines are dispensed and administered, the patient must be clinically reviewed by an appropriately qualified and competent clinical staff member who will:

- Ensure that the patient's medical condition and blood parameters support ongoing treatment.
- Check results of all investigations, blood parameters and specific drug calculations specified within the treatment protocol / local guidelines.
- Document that administration of the medicine(s) can proceed in the patient's chemotherapy / medical records (ideally the EPS) and patient held records (if used).
- In the case of inpatients receiving their medications over a period of days, the above checks must be done before the first dose is given in hospital and then during treatment according to the parameters specified in the written protocol.

## 9.0 WASTE DESTRUCTION

Clinical staff administering oral anti-cancer medicines to patients in Trust premises must be familiar with the Trust's procedures for safe handling of cytotoxic medicines and disposal of waste.

Patients must be given advice on how to safely store their oral anti-cancer medicines and told where and how to return unused medicines for disposal.

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## 10.0 GOVERNANCE AND AUDIT

Each organisation should nominate a clinical lead for oral anti-cancer medicines. This would normally be the Head of the Chemotherapy Service to ensure consistency of standards. The clinical lead must work with Trust Management, Lead Clinician for Cancer, Chemotherapy Lead, Chief Pharmacist and Lead Oncology Pharmacist, and Lead Cancer Nurse to ensure these standards are enforced.

Organisations must have in place policies covering all aspects of prescribing (including the use of electronic prescribing of SACT), dispensing and administering oral anti-cancer medicines, making reference to the standards for IV SACT.

Overall responsibility for safe use of oral anti-cancer medicines and implementation of local policy should lie either with the Head of Cancer Services or Head of Medicines Management (usually Chief Pharmacist) for each organisation.

Adherence to local policy should be audited on an annual basis to ensure the policy is still relevant to the service provided.

Organisations must ensure they have a robust system for recording clinical incidents and near misses with oral anti-cancer medicines. It is recommended that incidents be reported using the existing clinical governance framework within the Trust. Errors relating to oral anti-cancer medicines must be reviewed by the Network Chemotherapy Advisory Group as part of their role in reviewing chemotherapy errors.

## 11.0 REFERENCES

- ◆ British Oncology Pharmacists Association (BOPA). Position statement on the care of patients receiving oral chemotherapy. *Pharmaceutical Journal* 2004; 272:422-423
- ◆ Cancer Measures, Department of Health 2004 [www.CQUINS.nhs.uk](http://www.CQUINS.nhs.uk)
- ◆ Department of Health; The NHS Cancer Plan 2000 [www.dh.gov.uk](http://www.dh.gov.uk)
- ◆ Department of Health; Implementing care closer to home providing convenient quality care for patients, a national framework for pharmacists with special interests 2000
- ◆ Department of Health (2001) Reference guide to consent for examination or treatment <http://www.dh.gov.uk/assetRoot/04/01/90/79/04019079.pdf>
- ◆ Dispensing of Oral Chemotherapy in the Community; A viability assessment' BOPA Position Statement May 2007
- ◆ Guidelines on the Handling and Disposal of Pharmacy Waste. NHS Pharmaceutical QA Committee, September 2002
- ◆ Health and Safety Executive (2003) Safe handling of cytotoxic drugs. HSE Information Sheet MISC615.
- ◆ Joint Council for Clinical Oncology (JCCO). Quality Control in Cancer Chemotherapy. Managerial and Procedural Aspects. 1994
- ◆ National Patient Safety Agency (NPSA) Rapid Response Report. 'Risks Of Incorrect Dosing of Oral Anti-cancer Medicines.' 22nd January 2008. Available at <http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/rapidrr/risks-of-incorrectdosing-of-oral-anti-cancer-medicines/>
- ◆ Oral Chemotherapy Safety Practices at US Cancer Centres: questionnaire survey: Weingardt S et al: *BMJ* 2007; 334:407
- ◆ Royal College of Nursing (1998) The Administration of Cytotoxic Chemotherapy – Clinical Practice Guidelines.
- ◆ Scottish Executive 'Guidance For The Safe Use Of Cytotoxic Chemotherapy' HDL 2005(29)
- ◆ The Calman Hine Report; A policy framework for commissioning cancer services
- ◆ The safe and secure handling of medicines: a team approach. A revision of the Duthie Report (1988). Royal Pharmaceutical Society of Great Britain, 2005.
- ◆ White Paper 2006 Our Health, our care, our say; [www.dh.gov.uk](http://www.dh.gov.uk)

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## 12.0 ACKNOWLEDGEMENTS

Acknowledgement must be given to the Scottish Executive 'Guidance For The Safe Use Of Cytotoxic Chemotherapy' HDL 2005(29), The Royal Marsden NHS Foundation Trust, Procedure and Checklist for Counselling / Education Patients on Oral Anti-cancer Chemotherapy, and particularly to the North of England Cancer Network Standards for the Safe Use of Oral Anti-cancer Medicines on which this guidance is based.

## 13.0 PERSONNEL AND CONTACT INFORMATION

A comprehensive, up to date list of contact details can be found on the KMCC website via the following link:  
<http://www.kmcc.nhs.uk/about-us/kent-and-medway-cancer-collaborative/>

## 14.0 GLOSSARY

Acronyms in common usage throughout KMCC documentation

BNF	British National Formulary
BOPA	British Oncology Pharmacist Association
CNB	Cancer Network Board
COSHH	Control of substances hazardous to health regulations.
CYP	Children & Young People (in relation to the IOG)
DCCAG	Diagnostic Cross Cutting Advisory Group
DOG	Disease Orientated Group (NSSG/TSSG/TWG)
DVH	Darent Valley Hospital
DGT	Dartford and Gravesham NHS Trust
EK	East Kent
EKHUFT	East Kent Hospitals University Foundation Trust
EPS	Electronic Prescribing System
FP10(HNC)	Prescriptions issued by hospital doctors for dispensing in the community
GP	General Practitioner
HoP	High Level Operational Policy
IOSC	Improving Outcomes: A Strategy for Cancer
IV	Intravenous
K&C	Kent & Canterbury Hospital, Canterbury, (EKHUFT)
KMCC	Kent & Medway Cancer Collaborative
KMCRN	Kent & Medway Cancer Research Network
KOMS	Kent Oncology Management System
LSESN	London & South East Sarcoma Network
MFT	Medway Foundation Trust
MTW	Maidstone & Tunbridge Wells NHS Trust
NHS	National Health Service
NMP	Non-medical prescriber
NPSA	National Patient Safety agency
NOG	Non Surgical Oncology Group <i>(Permanent oncologist sub group of the DOGs with a specific responsibility for chemo/rad pathways and advice to the DOG, Network and GEOGRAPHICAL LOCATIONS on new drugs)</i>
PoC	Pathway of Care <i>(Network agreed disease site specific clinical guidelines)</i>

QEQM	Queen Elizabeth the Queen Mother Hospital, Margate (EKHUFT)
QoL	Quality of life
QSIS	Quality service information system
QST	Quality Surveillance Team
RAT	Research and Trial Group <i>(Permanent sub-group of the DOGs with a specific responsibility for taking forward the clinical trials agenda)</i>
RMH	Royal Marsden Hospital
RNOH	Royal National Orthopaedic Hospital
SACT	Systemic Anti-Cancer therapy
SACT regimen	Systemic Anti-cancer prescription on the electronic prescribing system
SACT protocol	Systemic Anti-cancer protocol on KMCC website
TTO	Treatment to take home
QVH	Queen Victoria Foundation Trust Hospital East Grinstead
UCLH	University College Hospital London
WHH	William Harvey Hospital, Ashford (EKHUFT)
WK	West Kent

## 15.0 DOCUMENT ADMINISTRATION

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<b>Principle author</b>	Caroline Waters
<b>Co-author(s)</b>	Bryony Neame
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### Revision History

Date of revision	New Version Number	Nature of Revision	Author
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October 2020	V6	Reformatted	R Patel