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# Accreditation Programme for Oral Systemic Anti-Cancer Therapies (SACT) Counselling by Pharmacy Staff

May 2015

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Version 5.0



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### Adaptated from:

The Royal Marsden NHS Foundation Trust Oral Chemotherapy Training

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### Contributions

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### Acknowledgments

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This document aims to standardise the counselling of oral SACT and accreditation for pharmacy staff across LCA Trusts, and to support transferability of skills.

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## 1 Scope of Document

This document is designed for use by all registered pharmacists and pharmacy technicians working within a Trust that is part of LCA, who require accreditation to be added to the register for competency of counselling of oral systemic anti-cancer therapy (SACT). Each Trust will have a local verification procedure, and it should be noted that this accreditation determines **competency** to counsel SACT, not procedural. The trainee will need to comply with local processes in order to fit the needs of the local service. This oral accreditation includes counselling of all oral SACT, including traditional cytotoxics (e.g. capecitabine, methotrexate, vinorelbine); non-traditional cytotoxic medications or novel targeted therapies such as tyrosine kinase inhibitors (e.g. imatinib and gefitinib); and teratogenic medicines. It does not include hormonal or anti-hormonal therapies (e.g. abiraterone, enzalutamide).

The procedure does not authorise a pharmacist or pharmacy technician to counsel oral cytotoxic medications used for non-malignant indications.

## 2 Background

The British Oncology Pharmacy Association (BOPA) recognised the risks associated with the management of oral chemotherapy and issued a position statement on 'The safe practice and pharmaceutical care of patients receiving oral anti-cancer medicines'.

In January 2008, the National Patient Safety Agency (NPSA) issued a Rapid Response Report entitled 'Risks of Incorrect Dosing of Oral Anti-cancer Medicines'. The report highlighted the potential for fatal outcomes if incorrect doses of oral anti-cancer therapy are prescribed, dispensed or administered. The NPSA indicated there were three deaths and over 400 patient safety incidents concerning oral anti-cancer therapy between November 2003 and July 2007.

Many oral SACT medicines are very expensive (up to £200 per dose) and it is important that wastage is kept to a minimum. Pharmacy staff can work with patients in order to minimise wastage. For example, where oral SACT is a continuous treatment and the medicines are supplied in a 30 day pack and the patient returns to clinic every 4 weeks, the patient may accumulate supplies at home. Pharmacy staff can ask patients about the supplies they have at home and either amend supply quantities at this visit or reschedule the next visit for five weeks instead of four.

This accreditation has been designed so that pharmacy staff handing the oral anti-cancer medicine to the patient (or carer) ensures the patient understands the following:

- why they are taking the treatment
- how and when to take the medicine including 'gaps' of treatment
- patient has been told about any dose modifications and understands why this is necessary
- what to do if a dose is missed
- what to do in the event a dose is vomited
- common side effects and what action to take if they occur
- how to obtain further supplies
- handling precautions and storage conditions
- to return any unused oral anti-cancer medicines to the hospital pharmacy
- ensure wastage is minimised, particularly for high cost oral anti-cancer medicines
- need to inform their healthcare team if they are taking prescribed/over the counter medicines/supplements
- specific advice regarding safe crushing of tablets or opening of capsules (if applicable).

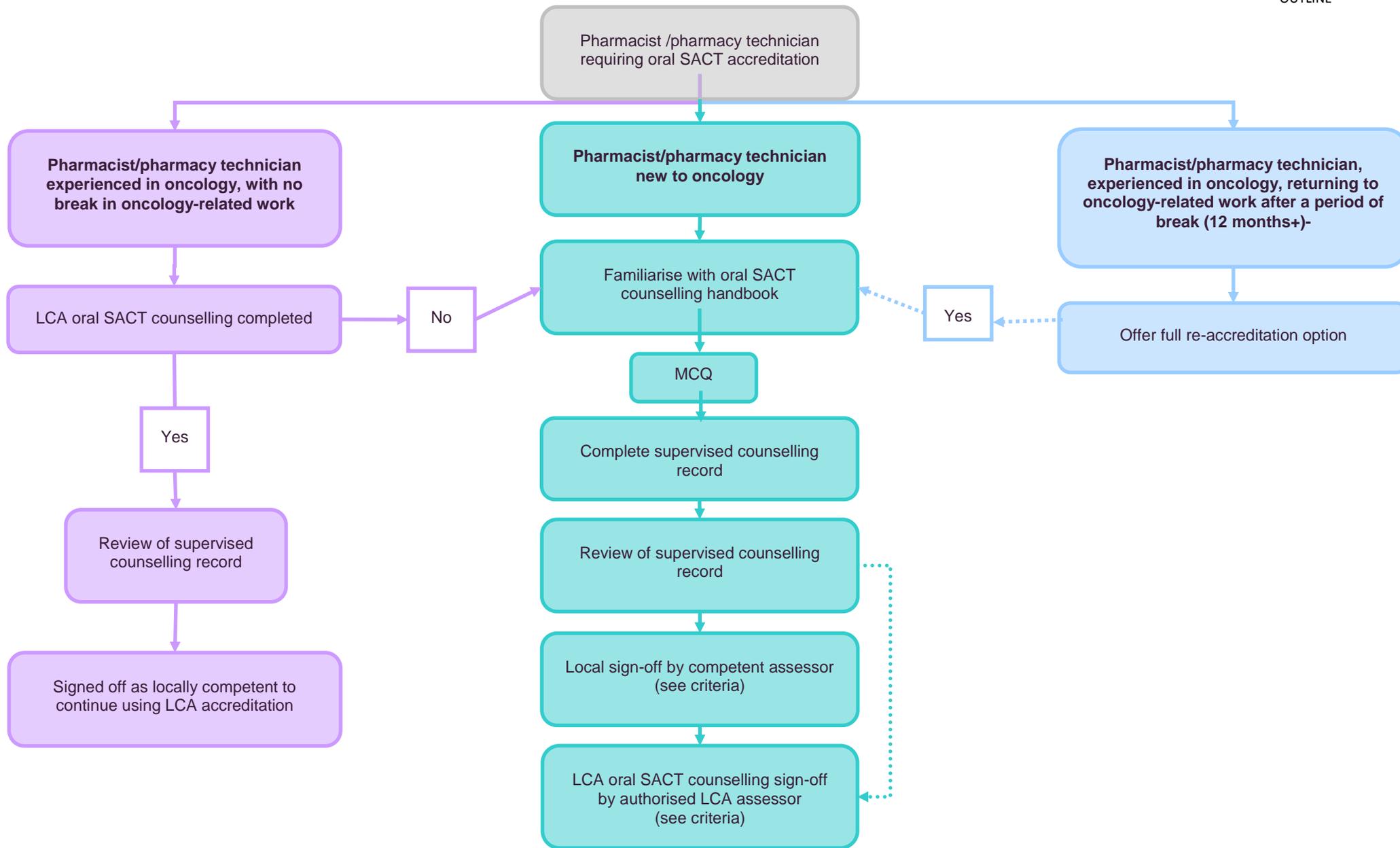
### 3 Outline

This document will outline the process of accreditation required for pharmacists and pharmacy technicians when starting his/her accreditation in the oncology setting. It is designed to be used in conjunction with the oral SACT Counselling handbook for pharmacy and nursing staff that will aid the pharmacist and pharmacy technician to support patients receiving oral SACT. Updates to the handbook, including the latest medicine monographs, can be found on the LCA website [www.londoncanceralliance.nhs.uk](http://www.londoncanceralliance.nhs.uk)

This accreditation will allow staff to move between LCA Trusts more fluidly; it is only valid when accompanied by the accreditation record for the local area where the accreditation was signed off. The individual pharmacist or pharmacy technician is responsible for maintenance and recordkeeping of this accreditation. It can be held electronically or on paper.

To improve the quality of patient healthcare records kept by the Trust, once the patient has received the counselling according to the counselling checklist:

1. The electronic system should be annotated: 'Patient counselled on their first (or subsequent) cycle using the LCA checklist by (name)'
2. A copy of the checklist should be retained or uploaded onto the electronic system.
3. The patient should be given a 'Taking your oral anti-cancer medicine' information sheet.



## 4 Accreditation Pathway

The following needs to be completed in order to be signed off for the LCA Oral SACT Counselling Accreditation:

Pharmacists or pharmacy technicians new to oncology should complete the full local and LCA accreditation – the LCA accreditation will be an enhanced step to the local accreditation and therefore not additional workload.

Oncology-experienced pharmacists and pharmacy technicians who do not have LCA accreditation, but have local accreditation, should continue with the LCA accreditation and/or new Trust's local accreditation in order to be added to the local oral SACT counselling register.

Oncology-experienced/senior oncology pharmacy staff already counselling patients may not need to complete the training, but enter the LCA accreditation at the annual re-accreditation stage. This can be decided locally by the site lead.

The recommended route is to continue with the LCA accreditation to reduce re-accreditation burden. The local accreditation route is usually reserved for small DGH hospitals where the balance between operational sign-off and LCA-wide accreditation needs to be made.

A pharmacist or pharmacy technician who does not have the LCA oral SACT counselling accreditation and has not completed an LCA Trust local accreditation, will need to complete the full LCA accreditation process.

## 5 Suggested Local Accreditation

All LCA Trusts must cover the local accreditation outlined below.

### Trainee responsibilities

Trainee must:

- undergo local induction
- read LCA accreditation programme
- familiarise themselves with the oral SACT counselling handbook and how to access/use this document
- complete MCQ (questions will be available in advance but must be answered in a test setting)
- complete local supervision with an authorised assessor

### Assessor responsibilities

Authorised assessor must:

- facilitate local supervision of the trainee
- review MCQ and supervised counselling record of the trainee

### Definition of terms

Trainee	a pharmacist/pharmacy technician undertaking the programme
Supervisor	a pharmacist/pharmacy technician who has successfully completed the accreditation
Assessor	pharmacist/pharmacy technician approved by local Trust to assess accreditation programme

## 6 Accreditation Checklist

The checklist below details the requirements for both local and LCA accreditation/sign-off. A pharmacist or pharmacy technician can be assessed as competent to counsel patients on oral SACT by designated assessors, identified by the Chief Pharmacist of each Trust. LCA will hold a list centrally of accredited assessors for each Trust, for reference.

<b>Trainee name:</b>		<b>Date:</b>
<b>Job title:</b>		
<b>KNOWLEDGE</b>		
Familiar with oral SACT counselling handbook and how to access/use this document  Completed the MCQ test (Pass mark 80%)	Assessor's details: Name:  Signature:  Job Title:	
<b>COUNSELLING RECORD</b>		
Record of supervised oral SACT counselling completed to LCA criteria (see supervised counselling record)	Assessor's details: Name:  Signature:  Job Title:	
<b>LOCAL REGISTER</b>		
Pharmacist or pharmacy technician's name added to the local register for counselling of oral SACT	Assessor's details: Name:  Signature:  Job Title:	

If the above has been successfully completed, please ensure the LCA assessor for your Trust is given the paperwork to review and assess for LCA counselling competency. The assessor must ensure a copy is retained for Trust records in the trainee's personal file. The trainee should also keep a copy for their professional practice. The trainee has responsibility for maintaining competence through regular practice and update knowledge base.

## 7 Training Sessions

### 7.1 MCQ test

The test will provide pharmacy staff with the essential theoretical knowledge required to underpin practice. The test must be completed before undertaking supervised practice. The expectation is a minimum score 80% is a pass. Any less than the minimum score will constitute a fail and the trainee expected to re-take the test. If a maximum of three attempts are made, the trainee will be referred to their line manager for an action plan.

### 7.2 Supervised counselling record

The required number to qualify for LCA accreditation is detailed below. Individual Trusts will make the decision as to whether an adjusted number of these are required for local accreditation. If, however, fewer than the required number of prescriptions is used for local accreditation, the pharmacist or pharmacy technician will be required to complete further records if they move to another LCA Trust where the accreditation is in use. Once the individual has been signed off, the pharmacist or pharmacy technician is able to fluidly move between the LCA Trusts. Details of the local accreditation process for pharmacists and pharmacy technicians with an LCA accreditation can be found in section 5.

- Stage 1: **Watch one** – Trainee should observe their assessor undertake one patient counselling before attempting themselves
- Stage 2: **Do three** – Trainee should counsel three patients under direct supervision of an accredited pharmacist or pharmacy technician (the supervisor may provide prompts if key aspects are omitted)
- Stage 3: **Teach one** – to your assessor, counsel one patient still under direct supervision and without any prompting

A minimum of three supervised assessments will take place against the counselling record with the trainee using the checklist. A mixture of encounters should be completed – for example first cycles, swallowing difficulties and dose changes. If a range of encounters are not possible within a reasonable time frame, then role play assessments should be carried out. The trainee will receive immediate feedback from the supervisor/assessor. If a greater number of attempts are required to consolidate competence and confidence or deemed necessary by the assessor, please photocopy additional supervised counselling records.

See [Appendix 3](#) for the supervised counselling record template.

**Both theoretical and practical assessments need to be completed in order pass the competency training.**

## 8 Re-accreditation

Re-accreditation needs to be completed after a period of 12 months from the date of addition to the register. This is the responsibility of the individual pharmacist or pharmacy technician, and failure to do this will result in being removed from the oral SACT counselling register. Please see below for the re-accreditation procedure:

- Familiarise themselves with oral SACT counselling handbook (for changes/updates) and read the training slides for essential counselling elements (on the LCA website), and sign to indicate this has been completed.
- Complete one supervised record – Teach one – to your assessor, counsel one patient still under direct supervision and without any prompting (using the supervised counselling record)

## 9 References

British Oncology Pharmacists Association. Position statement on the care of patients receiving oral chemotherapy. *Pharmaceutical Journal*; (2004) 272: 422-423

National Patient Safety Agency (NPSA) Rapid Response Report. '*Risks of incorrect dosing of oral anticancer medicines*'. [www.npsa.nhs.uk/patientsafety/alerts-and-directives/rapidrr/risks-of-incorrect-dosing-of-oral-anti-cancer-medicines](http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/rapidrr/risks-of-incorrect-dosing-of-oral-anti-cancer-medicines)

## 10 Suggested e-learning

BOPA e-learning centre [www.bopawebsite.org](http://www.bopawebsite.org)

- Webinar/Current issues with Oral Anti-cancer Medicines

CPPE – An open learning programme for pharmacists and pharmacy technicians – [www.cppe.ac.uk](http://www.cppe.ac.uk)

- E-learning portfolio/Cancer in relation to pharmacy practice

## Appendix 1 MCQ test

1. What are the usual side effects of capecitabine, erlotinib, sunitinib and vemurafenib?
  - a. Skin rash
  - b. Diarrhoea
  - c. Infection/fever
  - d. A and b
  - e. All of the above
2. Which of the following is/are considered benefits of oral anti-cancer therapy?
  - a. An increase in oral anti-cancer therapies will result in an over capacity of IV infusions on day units
  - b. The perception exists that patients prefer oral therapy
  - c. Reduced complications from IV access (infections and blood clots)
  - d. All the above are true
  - e. Only b and c
3. Which of the following are TRUE about patient preference for oral therapy?
  - a. Although oral monotherapy may avoid the inconvenience of a hospital visit, many combination therapies include parenteral therapy, and therefore require a hospital visit anyway
  - b. Most oral anti-cancer therapies regimens are simple for the patient to manage
  - c. Oral anti-cancer therapies will shift some aspects of managing oral anti-cancer treatment to the patient; not all patients are suitable
  - d. All of the above
  - e. Only a and c above
4. Which of the following is/are TRUE about concordance to oral anti-cancer therapy?
  - a. Directly ask the patient
  - b. Patient diaries, pill counts
  - c. Concordance to oral therapies is generally very good, as illustrated by the excellent long term concordance to imatinib therapy
  - d. All of the above
  - e. Only a and b above
5. The risk of exposure can be minimised when handling oral anti-cancer therapies:
  - a. No touch technique for carers/healthcare professionals – either using gloves or popping the medicine out of a blister pack
  - b. The patient can touch the tablets/capsules as they are taking the therapy
  - c. The patient should wear gloves
  - d. A and b
  - e. A and c
6. Which patient information sheets and/or disposables should be given to a patient unable to swallow capecitabine with a jejunostomy?
  - a. Dissolving oral anti-cancer tablets safely and an oral anti-cancer pack (containing 10 x gloves/10 x aprons/10 x masks/ 1 yellow waste bag)
  - b. Oral/enteral syringes
  - c. Giving an anti-cancer medicine through a feeding tube and an oral anti-cancer pack (containing 10 x gloves/ aprons/mask/1 yellow waste bag)
  - d. A and b
  - e. B and c

7. When should a patient/carer be given instructions how to take the anti-cancer medicine?
- Each cycle
  - First cycle
  - Second cycle if not understood at first cycle
  - Only b
  - B and c
8. A patient has oral anti-cancer tablets/capsules left over from the previous cycle, should they?
- Flush/throw them away
  - Return to the hospital pharmacy
  - Re-use or re-schedule if a high cost drug
  - All of the above
  - Only b and c
9. Which of the following statements is correct about commonly prescribed medicines which interact with oral anti-cancer therapies?
- Procarbazine interacts with food
  - Erlotinib interacts with proton pump inhibitors and should be separated in time
  - St. John's wort can affect the effectiveness of many targeted medicines
  - All of the above
  - Only a
10. Which of the following is TRUE about oral anti-cancer therapies?
- Includes traditional chemotherapy, targeted agents, teratogenic medicines
  - Should not be handled by anyone who is pregnant or planning a pregnancy
  - Wash hands after taking
  - All of the above
  - Only b and c

MCQ answer sheet	
Please circle one answer per question. A score of at least 80% on the MCQ is required.	
1. a b c d e	6. a b c d e
2. a b c d e	7. a b c d e
3. a b c d e	8. a b c d e
4. a b c d e	9. a b c d e
5. a b c d e	10. a b c d e

## Appendix 2 LCA oral SACT counselling checklist

Oral anti-cancer patient and carer education checklist	
<p><b>Prior to first cycle</b></p> <p>This checklist must be completed with the patient/carer at the point of handing the medication to the patient either in conjunction with or following a pre-treatment consultation</p>	Tick if discussed with the patient/carer
<b>Instructions for taking</b>	
Explain how and when to take the medicine including any treatment breaks	
If the patient is unable to swallow tablets or capsules or has a feeding tube, please refer to oral SACT counselling handbook for information on how to dissolve or open capsules (if appropriate for the oral anti-cancer medicine)	
Missed doses can be taken if near to the scheduled time. Otherwise, do not try and catch up or double the next dose. Wait until the next dose is due.	
In case of vomiting after taking a dose, do not repeat the dose and take the next dose at the normal time. If this occurs again, contact the chemotherapy team/24 hour advice line.	
Check patient aware of side effects and has received written information. Any side effects should be reported to their chemotherapy nurse or doctor.	
If the patient is taking any prescribed/over the counter medicine/supplement – the patient should inform their medical team.	
Return any unused oral anti-cancer medicine to the hospital pharmacy. Do not flush or throw them away (for high cost drugs see counselling handbook).	
<b>Storage and handling</b>	
The oral anti-cancer medicine should not be handled by anyone who is pregnant or planning a pregnancy (unless taking on the advice of medical team).	
If the carer is giving the anti-cancer medicine, they should not handle the medicine directly but wear gloves or push the medicine out of the blister pack (if applicable) directly into a medicine pot.	
Store the tablets/capsules in the container provided.	
Store the tablets/capsules in a secure place, away from and out of sight of children.	
Wash hands thoroughly after taking/giving the oral anti-cancer medicine.	
Check the patient understands how to take the treatment, by asking them to repeat back their instructions.	
<b>Written information provided</b>	
Taking an oral anti-cancer medicine patient information sheet	
Diary for taking oral anti-cancer medicine (if applicable)	
For swallowing difficulty only – give relevant factsheet if appropriate for the oral anti-	

cancer medicine and an oral anti-cancer pack with disposables (e.g. oral/enteral syringes)		
Dissolving oral anti-cancer tablets safely		
Opening oral anti-cancer capsules safely		
Giving an oral anti-cancer medicine through a feeding tube		
Giving an anti-cancer syringe by mouth		
<b>Patient name</b>	<b>Counselled/educated by</b>	
<b>Hospital number</b>	<b>Pharmacist/Pharmacy technician/Nurse/Interpreter</b>	
<b>Signature and date</b>	<b>Signature and date</b>	

**Before all subsequent cycles:**

- Check the patient understood the checklist above and repeat if necessary
- Check any side effects experienced with their previous cycle were discussed with their medical team
- If a dose adjustment has been made, check the patient is aware why their dose has been changed and how many tablets/capsules they should now take
- Check they had no problems taking their previous cycle
- Check the patient understands how to take the treatment, by asking them to repeat back their instructions

**Please retain a copy and/or endorse the prescription/electronic patient record as evidence counselling took place at each cycle.**

## Appendix 3: LCA Oral SACT Supervised Counselling record for Pharmacy Staff

Oral SACT Supervised Counselling record for Pharmacy Staff					
Introduction					
For each supervised practice the trainee must: <ul style="list-style-type: none"> <li>– Introduce self to patient and carer</li> <li>– Patient correctly identified (name, DOB)</li> <li>– Explains purpose of counselling</li> <li>– Follow the points below:</li> </ul>	Tick if discussed/completed (comments overleaf)				
	Watch one	Under Supervision			Teach one
1		2	3		
<b>1. Prior to first cycle:</b>					
<b>a) Instructions for taking</b>					
Explain how and when to take the medicine including any treatment breaks.					
If the patient is unable to swallow tablets or capsules or has a feeding tube, please refer to oral SACT counselling handbook for provision of a relevant factsheet and an oral anti-cancer pack and disposables, if appropriate for the oral anti-cancer medicine.					
Missed doses can be taken if near to the scheduled time. Otherwise, do not try and catch up or double the next dose. Wait until the next dose is due.					
In case of vomiting after taking a dose, do not repeat the dose and take the next dose at the normal time. If this occurs again, contact the chemotherapy team/24 hour advice line.					
Any side effects should be reported to their chemotherapy nurse or doctor					
If the patient is taking any prescribed/over the counter medicine/supplement, the patient should inform their medical team.					
Return any unused oral anti-cancer medicine to the hospital pharmacy. Do not flush or throw them away (for high cost drugs refer to counselling handbook).					

<b>b) Storage and handling</b>					
The oral anti-cancer medicine should not be handled by anyone who is pregnant or planning a pregnancy (unless on the advice of your medical team).					
If the carer is giving the anti-cancer medicine, they should not handle the medicine directly but wear gloves or push the medicine out of the blister pack (if applicable) directly into a medicine pot.					
Store the tablets/capsules in the container provided.					
Store the tablets/capsules in a secure place, away from and out of sight of children.					
Wash hands thoroughly after taking/giving the oral anti-cancer medicine.					
Check the patient understands how to take the treatment, by asking them to repeat back their instructions.					
Taking an oral anti-cancer medicine information sheet, manufacturer's leaflet and chemotherapy alert card given to patient.					
Able to assess patient/carer's ability to self-medicate: <ul style="list-style-type: none"> <li>• ability to take medication correctly and monitor side effects</li> <li>• judge when to interrupt treatment and call the hospital if required</li> </ul>					
Provides opportunity for questioning/discussing through interaction.					
<b>2. Before all subsequent cycles</b>					
Check the patient understood the checklist above, and repeat if necessary.					
Check any side effects experienced with their previous cycle were discussed with the medical team.					
If a dose adjustment has been made, check the patient is aware why their dose has been changed and how many tablets/capsules they should now take.					
Check they had no problems taking their previous cycle.					
Check the patient understands how to take the treatment, by asking them to repeat back their instructions.					

Supervised No.1 – Drug      Cycle No      Type of encounter (e.g. first cycle, swallowing difficulty, dose adjustment)

<b>Trainee comments</b>		
<b>Assessor comments</b>		
<b>Assessor name</b>	<b>Assessor signature</b>	<b>Date</b>

Supervised No. 2 – Drug      Cycle No      Type of encounter (e.g. first cycle, swallowing difficulty, dose adjustment)

<b>Trainee comments</b>		
<b>Assessor comments</b>		
<b>Assessor name</b>	<b>Assessor signature</b>	<b>Date</b>

Supervised No. 3 – Drug      Cycle No      Type of encounter (e.g. first cycle, swallowing difficulty, dose adjustment)

<b>Trainee comments</b>		
<b>Assessor comments</b>		
<b>Assessor name</b>	<b>Assessor signature</b>	<b>Date</b>

Supervised (Teach one) – Drug      Cycle No      Type of encounter (e.g. first cycle, swallowing difficulty, dose adjustment)

<b>Trainee comments</b>		
<b>Assessor comments</b>		
<b>Assessor name</b>	<b>Assessor signature</b>	<b>Date</b>

## Appendix 4: London Cancer Alliance ACCREDITATION Certificate for oral SACT counselling

Name of pharmacist/pharmacy technician ..... & GPhC number: .....

Base Hospital: .....

Level of Practitioner: .....

LCA Accredited to counsel patients on oral SACT for the following specialist areas:

- Solid tumour
- Haemato-oncology
- Paediatric oncology

This pharmacist/pharmacy technician is competent/not competent\* to counsel oral SACT according to the specialties detailed below across the LCA network

Name (Block capitals): ..... (List of assessors held centrally by the LCA)

Signature of Trust LCA-approved assessor: .....

Date of accreditation: ...../...../.....

*\*This certificate is only valid in conjunction with completed supervised counselling record which should be presented for review when requested*

*\*\*This certificate is valid for a period of twelve months from the date of accreditation. Re-accreditation is required in order to maintain LCA-accreditation*

## Appendix 5: London Cancer Alliance RE-ACCREDITATION Certificate for oral SACT counselling

Name of pharmacist/pharmacy technician ..... & GPhC number: .....

Base Hospital: .....

Level of Practitioner: .....

### Self-Declaration:

- I wish my name to remain on the local register for counselling patients on oral SACT prescriptions
- I have successfully completed a minimum of one assessed patient counselling
- I declare that I remain competent to counsel patients on oral SACT prescriptions
- I have read the training slides and am familiar with the oral SACT counselling handbook

Signature of pharmacist/pharmacy technician: ..... Date: ...../...../.....

This pharmacist/pharmacy technician is competent/not-competent\* to continue to counsel patients on oral SACT according to the specialties detailed below across the LCA network

Solid tumour                       Haemato-oncology                       Paediatric oncology

Name (Block capitals): ..... (List of assessors held centrally by the LCA)

Signature of Trust LCA-approved assessor: .....

Date of re-accreditation: ...../...../.....

*\*This certificate is only valid in conjunction with completed supervised prescription log which should be presented for review when requested*  
*\*\*This certificate is valid for a period of twelve months from the date of accreditation. Re-validation is required in order to maintain LCA-accreditation*

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