

## NATIONAL CANCER CONTROL PROGRAMME

### Oral Anti-Cancer Medicines Model of Care Recommendations

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**National Cancer Control Programme Oral Anti-Cancer Medicines Model of Care  
Recommendations**

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## **Chairman's Foreword**

One of the advances in cancer therapy in recent years has been the development and widespread use of oral anticancer medicines (OAM) across a wide range of cancer types. OAM were viewed as “easier” and as more convenient than intravenous chemotherapy for patients. It is now recognised that increased vigilance is necessary throughout the multistep, multidisciplinary process from decision to prescribe through to monitoring of patients. These issues have been highlighted nationally and internationally. This guidance is the first in Ireland and seeks to address each step of the process of OAM use to improve safety and patient care.

A working group was established in 2014 to design a model of care for patients being treated with OAM. This report is the output of that working group. It has been a long journey and it is anticipated that the recommendations will further improve the safety of our patients on OAM. My thanks to all who have participated in the group.

Miriam O'Connor  
Chairman

## Executive Summary

The 2014 NCCP Oncology Medication Safety Review, (“the 2014 Review”) recommended the development of national guidance on the care of patients receiving Oral Anti-Cancer Medicines (OAM). A working group was established to advance this recommendation. The National Cancer Strategy 2017-2026 (1) recommended the development of a model of care for OAM.

The recommendations of this report relate specifically to the use of OAM in the treatment of cancer in adults; although they would be broadly applicable and address important gaps and concerns regarding safe use of these drugs in other areas and also in paediatrics.

Treating patients with OAM is a complex multistep, multidisciplinary process including the decision to treat, prescribing, dispensing and management of a patient on these medications. There is evidence of variation in the OAM model of care across the hospitals providing systemic anti-cancer therapy (SACT) services in Ireland. The OAM model of care has significant differences to that of parenteral SACT. The principal difference is that OAM are dispensed in the community and self-administered at home, while parenteral SACT is dispensed and predominantly administered in hospitals.

It is anticipated that additional safety challenges will emerge as new and potentially more complex OAM regimens are developed and it is therefore important to provide national guidance in this area.

The recommendations of this report focus on ensuring a safe OAM model of care. They incorporate the OAM recommendations of the 2014 Review and the National Cancer Strategy 2017-2026. These recommendations, when implemented in conjunction with the existing recommendations of the NCCP Oncology Medication Safety Review, seek to establish a safer OAM model of care. The NCCP OAM model of care recommendations are included in Appendix 1.

Broad support for change, across the health system, will be required to fully realise the recommendations of this report.

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The OAM Model of Care was agreed by the working group in March 2018 and was subsequently approved by both the NCCP Oncology Medication Safety Review Implementation Steering Group and the NCCP National Executive.



## Key Findings

The Group collated its findings from the literature review, survey of existing models of care nationally and internationally and expert knowledge of Group members. The Group identified a number of key findings in relation to ensuring a safe OAM model of care.

### Decision to treat

- The planning of SACT is undertaken in hospitals by consultant medical oncologists and haematologists.
- Patients who are prescribed OAM will need to manage their treatment at home.
- The suitability of this treatment in this context must be assessed for each patient by their oncology team.

These key findings highlighted the requirement for a recommendation on suitability assessment of patients who are to commence on an OAM.

### Prescribing

- SACT prescriptions are currently written by a consultant, specialist registrar or registrar based on the therapy plan devised by the medical oncologist or haematologist.
- There are a number of variations across hospitals in prescribing practice for OAM. These include different prescription formats and the point in the pathway at which the prescription is physically presented to the patient.
- It is necessary to bring consistency to these processes to reduce variation.

These key findings highlighted the requirement for safety standards for OAM prescribing, including prescriptions requiring dose modifications.

### Recommended information for inclusion on an OAM prescription

- The prescription should contain sufficient information to enable safe dispensing.

- The majority of OAM prescriptions are currently handwritten and use different formats. These are not structured to support the information recommended to enable prescription verification.

These key findings highlighted the requirement for recommendations on the information to be included on OAM prescriptions and the implementation of this within the national computer physician order entry system.

### **Prescription Verification of OAM**

- SACT prescriptions should be verified prior to dispensing and administration.
- It was noted that there is variation in the practice for the verification of OAM prescriptions. In some hospitals, prescriptions are verified by a pharmacist prior to being given to the patient<sup>1</sup> or forwarded to the community pharmacy for dispensing<sup>2</sup>; in other hospitals they are not.

These key findings highlighted the requirement for recommendations on pharmacist verification and review of OAM prescriptions by pharmacists.

### **Dispensing**

- At present, OAM are mostly dispensed by community pharmacists, with some being dispensed in the hospital setting.

These key findings highlighted the requirement for recommendations on the dispensing of OAM prescriptions and the need for specialised OAM training and education programmes for pharmacists.

### **Patient Review**

- Patients on OAM are assessed in a variety of settings in the hospital, including OAM clinics, out-patients departments and day wards.

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<sup>1</sup> In the case of high-tech prescriptions a copy is also sent to the community pharmacy

<sup>2</sup> Some hospital Pharmacy Departments dispense some OAM

These key findings highlighted the requirement for a recommendation on the review periods and review settings of patients on OAM.

### **Patient Education**

- Patients and their families/carers receive education on OAM treatment.
- There should be a standardised approach to patient education.
- Education encourages medication adherence and assists the patient in self-monitoring for adverse events at home.

These key findings highlighted the requirement for a recommendation on standardised patient education.

### **Communication Mechanisms**

- Communication regarding OAM treatment with the patient's GP and with their community pharmacy, is varied and inconsistent.
- Communication should ensure adequate sharing of information for the safe management of the patient's care.

These key findings highlighted the requirement for recommendations on standardised communication between healthcare providers to ensure safe management of patients on OAM.

### **Incident reporting**

- There is no centralised system for the recording or monitoring of incidents or near misses occurring in the community.
- Centralised reporting of incidents and near misses facilitates trend analysis and encourages learning from these incidents.

These key findings highlighted the requirement for a recommendation on centralised reporting of incidents or near misses.

# 1 Background

Systemic Anti-Cancer Therapy (SACT) involves the administration of medicine that often has a narrow therapeutic window and toxic side effects. SACT includes treatment administered both parenterally and orally; the latter being referred to as oral anti-cancer medicines (OAM). OAM have the same potential for risk as parenteral SACT in terms of treatment-related toxicities and potential for serious medication errors leading to patient harm. Quality and safety policies, such as those in place for parenteral SACT in Ireland, are less well defined for OAM (2). It is estimated that the number of patients receiving SACT for the treatment of their cancer will increase by 42%-48% between 2015 and 2025 (3).

SACT services<sup>3</sup> are delivered in 26 publicly-funded hospitals in Ireland<sup>4</sup> (Appendix 2). There are nine designated cancer centres, eight adult centres and one paediatric centre. Some of the cancer centres act as hubs for other hospitals i.e. satellite units or spokes, where medical oncologists and/or haematologists have sessional commitments and may not be on-site each day. These satellite units combine a mix of nurse-led and physician-supported care. All 26 hospitals are registered as Retail Pharmacy Businesses with the Pharmaceutical Society of Ireland.

The report of the National Cancer Control Programme (NCCP) Oncology Medication Safety Review (2) (“the 2014 Review”) was published in January 2014. This review was conducted across the 26 hospitals in Ireland involved in the administration of SACT in adults and children. The aim of the 2014 Review was to assess the medication policies and practices in day units nationally, from a patient safety and quality perspective so as to inform the development of national policies. Key recommendations from the 2014 Review that are relevant to OAM are provided in Appendix 3.

One of the recurring themes that emerged during the 2014 Review was the diversity, and sometimes absence, of processes for the management of OAM. A priority

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<sup>3</sup> For the purpose of this document, SACT services are used to encompass services from both consultant medical oncologists and haematologists.

<sup>4</sup> Cancer services are also provided in a number of private hospitals but services in the private sector are beyond the scope of this report.

recommendation of the 2014 Review, as detailed below, was the development of national guidance to manage OAM.

**Recommendation 80 of the NCCP Oncology Medication Safety Review**

A national guideline is required for the management of the prescribing and dispensing of oral chemotherapy. This guideline should include:

- Safe prescribing
- Prescription checking
- Prescription format
- Administration
- Service models for dispensing and supply
- Communication system between primary care and secondary care

The National Cancer Strategy 2017-2026 was published in July 2017. The strategy recognises that OAM, while prescribed in hospitals by specialists, are mainly dispensed in community pharmacies and administered in the patient's home. One of the Strategy's primary areas of focus is on the provision of optimal care to patients. The key elements of the Strategy relating to OAM are detailed in Appendix 4.

**Recommendation 23 of the National Cancer Strategy 2017-2026**

The NCCP will examine the model of care for patients receiving oral anticancer medicines and recommend steps to ensure that all patients receive such medicines in a safe and effective manner, with appropriate and proportionate supports, both in the hospital and community setting

This report signals the actions required to ensure a safe OAM model of care for patients receiving OAM as a component of their cancer treatment. The report findings are structured according to the following headings which highlight the key developments that will ensure a safe OAM model of care:

- Decision to Treat
- Prescribing of OAM
- Information for Inclusion on OAM Prescriptions
- Prescription Verification of OAM
- Dispensing

- 
- Patient Review
  - Patient Education - home administration of OAM
  - Communication Mechanisms
  - Incident Reporting

## 2 Methodology

A multidisciplinary OAM Working Group was convened by the NCCP in response to recommendation number 80 of the 2014 Review. The terms of reference and the membership of this group are included in Appendix 5 and Appendix 6 respectively. The working group met 14 times between 2014 and 2018.

The strategy of the working group was to:

1. Conduct a literature review to identify<sup>5</sup>:
  - OAM models of care in place internationally.
  - Strategies to improve safety in the OAM model of care in Ireland.
2. Undertake a survey of each hospital to establish the current model of care for OAM.
3. Document and compare the existing models of care for OAM and parenteral SACT utilising the findings of the 2014 Review and the hospital survey.
4. Develop recommendations to improve safety in the OAM model of care in terms of prescribing, dispensing and supervision of patients on OAM.

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<sup>5</sup> The literature review is available on request.

### 3 Model of Care for SACT Treatment

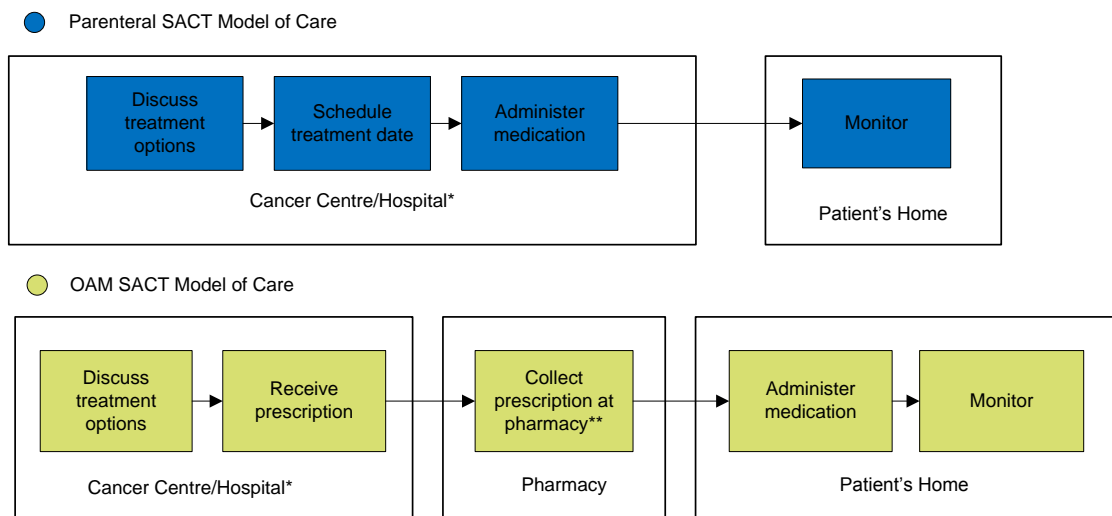
To examine the OAM Model of Care it was necessary to identify the generic SACT model of care and the differences between the models of care for parenteral SACT and OAM. The basic model of care for all SACT treatment is illustrated in Figure 1.



**Figure 1: SACT Model of Care**

There are additional elements in the model of care which are not included in the Figures below as these are key repeating elements and occur at multiple points and these are addressed in Section 3.10. These include patient education, patient review, prescription verification, funding, and risk management.

The working group identified the key differences between the parenteral SACT and OAM models of care as shown in Figure 2.



\*Normally as a day patient or out-patient

\*\*Prescriptions may be filled at a Cancer Centre/Hospital or Community Pharmacy

**Figure 2: Key Differences between the models of care for parenteral SACT and OAM**



### 3.1 Comparison of the Parenteral SACT and OAM Models of Care

The similarities and differences between the parenteral SACT model of care and the OAM model of care are detailed in Table 1.

**Table 1 Comparison of the parenteral SACT and OAM models of care**

Step in patient pathway	Current practice	Divergence between parenteral and OAM model of care
Decision to treat	The decision to commence on SACT is directed by consultant medical oncologist / haematologist. A therapy plan is created to guide that treatment. The therapy plan may be changed following patient review.	Patients on OAM require assessment to specifically determine their suitability for home management of treatment.
Patient Education	The patient is educated on the rationale, side effects and scheduling of the SACT treatment in the hospital by either the medical, nursing staff or both. Written information, including hospital contact numbers, are generally provided to the patient and an appointment for the next scheduled visit arranged.	Patients on OAM require additional education on adherence to treatment and administration at home.
Patient Review	Patients are reviewed at defined periods during their treatment in line with the treatment regimen to ascertain their suitability to continue on SACT treatment or requirements for a change to their treatment. These review periods vary depending on the treatment and may be prior to each cycle or at other pre-defined intervals. Patients may attend for unscheduled reviews due to complications of their treatment. During these reviews, the patient will be assessed for treatment side effects which may include some	<p>Parenteral SACT: Patient reviews take place where the parenteral SACT is administered, depending on the individual hospital's facilities.</p> <p>OAM: Patient reviews may take place in:</p> <ul style="list-style-type: none"> <li>• dedicated OAM clinics or in</li> <li>• haematology / oncology out-patients departments</li> <li>• haematology / oncology day ward</li> </ul>

Step in patient pathway	Current practice	Divergence between parenteral and OAM model of care
	laboratory tests to monitor for toxicity.	
Prescribing	The prescription for the patient's treatment is written by a consultant/SpR/registrar based on the SACT therapy plan devised by the consultant medical oncologist or haematologist, as appropriate.	<p>Parenteral SACT: Prescriptions are generally written electronically or on structured/ pre-printed order forms which include the data required for safe prescription verification, dispensing and administration</p> <p>OAM may be prescribed on one of two different prescription formats:</p> <ul style="list-style-type: none"> <li>(i) High-tech prescription format for those OAM which are listed on the High Tech arrangements of the Primary Care Reimbursement Service Community Drug Schemes</li> <li>(ii) Standard hospital out-patient/discharge prescription format which differ between hospitals. GMS cardholders are required to have standard hospital out-patient/discharge prescription formats transcribed to a GMS prescription format by their GP prior to dispensing.</li> </ul>
	SACT prescriptions may be written for one or more cycles depending on the period between clinical reviews.	In some instances a patient's GP may continue patients on hospital initiated OAM treatment between scheduled reviews in consultation with the treating consultant.
	Prescriptions may require modification following patient review and the results of monitoring tests (e.g. full blood count).	<p>Parenteral SACT: Prescriptions are verified and assessed by oncology pharmacists prior to dispensing and administration.</p> <p>OAM: Prescriptions may be given to a patient before the results of their monitoring tests are available. This requires that the patient is contacted</p>

Step in patient pathway	Current practice	Divergence between parenteral and OAM model of care
		<p>by phone once the results of their monitoring tests are available. This may happen before or after the prescription has been dispensed. The discussion with the patient depends on the results of their tests and may include instructions to:</p> <ul style="list-style-type: none"> <li>• Proceed with the dose on the prescription</li> <li>• Cease treatment</li> <li>• Proceed on a different dose. This may be organised without a new prescription being supplied to the patient.</li> </ul>
	Duration of validity of prescription	Prescriptions to be dispensed in a community pharmacy are valid for a maximum of 6 months from the date of prescribing <sup>6</sup> .
Prescription Verification	Prescription verification is carried out by oncology pharmacists in the majority of hospitals for all parenteral SACT prescriptions. There is variation in practice with regard to the oncology pharmacist prescription verification of OAM prescriptions.	OAM: Only some OAM prescriptions are verified by oncology pharmacists.
Dispensing	SACT is dispensed by a pharmacist for administration to the patient.	Parenteral SACT: All parenteral SACT is dispensed by the hospital pharmacy department and delivered to the location of intended administration (e.g. day ward / in-patient ward).

<sup>6</sup> SI 540/2003 Medicinal products (Prescription and Control of Supply) Regulation 2003

Step in patient pathway	Current practice	Divergence between parenteral and OAM model of care
		OAM: The majority of OAM are dispensed by community pharmacists with a limited number being dispensed in the hospital setting.
Administration	SACT is administered to the patient.	<p>Parenteral SACT: Administration of parenteral SACT is mainly in a hospital setting with suitably trained staff and supports. Patients proceed with treatment once the results of their monitoring tests (e.g. full blood count) are available and the patient has been deemed fit for treatment.</p> <p>OAM: OAM are administered by the patient at home with the patient or their carer responsible for the administration of OAM as prescribed. Some hospitals have patients on OAM attend for review<sup>7</sup> once they have their prescription dispensed and before commencing treatment.</p>
Funding	There are different funding mechanisms	<p>Parenteral SACT: Funding for parenteral SACT dispensed and administered in hospitals is via:</p> <ul style="list-style-type: none"> <li>• Hospital budgets for drugs administered in hospitals.</li> <li>• The Oncology Drug Management System (ODMS)<sup>8</sup> for specific high cost drugs administered in hospital.</li> </ul>

<sup>7</sup> Depending on local hospital processes, the patient may return to the hospital where the OAM is verified, counted and a further education of the patient takes place by an oncology nurse specialist in either the haematology oncology day ward or specific oral clinics or outpatient clinics within the hospital.

<sup>8</sup> <http://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/cdmp/odms.html>

Step in patient pathway	Current practice	Divergence between parenteral and OAM model of care
		<p>OAM: OAM approved for reimbursement by the HSE are dispensed in community pharmacies under the Community Drug Schemes including the High Tech arrangements of those schemes. There is no equivalent demand led funding stream for OAM dispensed in hospital. As a result, any OAM currently dispensed in hospital must be funded from the hospital's budget.</p>
Incident reporting	<p>Incident reporting is centralised through the Clinical Indemnity Scheme for incidents involving all medications dispensed in hospitals including both parenteral SACT and OAM.</p>	<p>OAM – there is no centralised system for reporting of incidents involving OAM dispensing and administration in the community setting.</p>

## 4 Findings and Recommendations

This section sets out the findings<sup>9</sup> and recommendations of the Working Group.

### 4.1 Decision to Treat

A consultant medical oncologist or haematologist makes the decision to treat a patient in conjunction with the patient and creates a therapy plan to guide that treatment. The therapy plan may be changed following patient review.

#### 4.1.1 Findings

- The 2014 Review recommended that the planning of SACT treatment should be undertaken in hospitals by consultant medical oncologists and haematologists, as appropriate (1).
- Patient suitability for treatment with an OAM should be considered when a decision is being made on the patient's therapy plan (4).

#### 4.1.2 Recommendation

OAM 1.	Patients who are to commence on an Oral Anti-Cancer Medicine require assessment to determine their suitability for home management of treatment.
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### 4.2 Prescribing of OAM

#### 4.2.1 Findings

- Prescriptions<sup>10</sup> may be written by the consultant medical oncologist or haematologist, SpR, registrar or registered nurse prescriber based on a therapy plan which has been written by the consultant. (2, 4-6).
- Prescriptions which incorporate repeat cycles do not take into account (5, 7):
  - Dose adjustments from cycle to cycle.
  - Dose delays.
  - Cessation of therapy.

<sup>9</sup> The findings have been informed by a literature review, a survey of existing models of care nationally and internationally and the expert knowledge of Group members.

<sup>10</sup> Current legislation governing prescribing means that prescriptions are valid for a maximum of six months.

- New treatment regimen superseding the OAM.
- In some circumstances, patients are contacted at home with regard to a modification of their prescription where that prescription has been issued in advance of test results being available.
- OAM prescriptions are mostly handwritten (2).
- Computerised Physician Order Entry (CPOE) and Pre Printed Orders using standardised templates are the preferred means to generate prescriptions (8-10).

#### 4.2.2 Recommendations

OAM 2.	Oral Anti-Cancer Medicines should be prescribed to the same safety standards as parenteral Systemic Anti-Cancer Therapy.
<p>OAM 3.</p> <p><i>This recommendation is based upon Rec. 47 of 2014 Review</i></p>	<p>The first cycle of a course of an Oral Anti-Cancer Therapy must be written by a consultant medical oncologist or haematologist, specialist registrar or registrar based on the consultant's written therapy plan.</p> <p>Subsequent cycles may be written by a consultant, specialist registrar (SpR), registrar or registered nurse prescriber following the consultant's written therapy plan.</p> <p>i. Oral Anti-Cancer Medicine prescriptions should be written for one cycle only except when a patient's scheduled review is longer than one cycle.</p> <p>Where the period between hospital reviews is greater than six months, a GP may write a follow up prescription following agreement on a written shared care plan with the consultant and in line with the consultant's therapy plan<sup>11</sup>. Communication between the prescribing consultant and the GP should outline the expected duration of therapy and the reason for the GP to refer for review prior to a planned review.</p>

<sup>11</sup> This is predominantly in haematological malignancies

OAM 4.	<p>Patients should not commence their treatment until the results of their monitoring tests are known.</p> <ul style="list-style-type: none"> <li>• Where a dose modification is required, a new prescription should be written.</li> </ul>
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## 4.3 Information for Inclusion on OAM Prescriptions

### 4.3.1 Findings

- The 2014 Review detailed the necessary information which should be included in a SACT prescription<sup>12</sup>.
- The information to be included on a prescription should be standardised to ensure that prescriptions contain sufficient information required to enable safe dispensing (2, 5, 11, 12). The working group defined a standard dataset for recommended information as described in Appendix 7.
- The majority of OAM prescriptions are handwritten using different formats that are not designed to support the inclusion of the information that is recommended to enable safe dispensing. These include:
  - High-tech prescription format for high-tech OAM. The current<sup>13</sup> high-tech prescription serves a number of purposes. It is the legal prescription as well as being part of the authorisation process for reimbursement.
  - Standard hospital out-patient prescription format. Formats of these prescriptions vary by hospital. In the case of patients holding medical cards, these prescriptions are subsequently transcribed to a General Medical Services (GMS) prescription by a patient's GP prior to dispensing.
- A national CPOE system is currently being implemented by the NCCP.
  - This system currently has constraints on the data that can be included on the printed prescription.

<sup>12</sup> Appendix 9 of the 2014 Review.

<sup>13</sup> There may be changes to the current high-tech prescription with the introduction of the PCRS high-tech hub.



### 4.3.2 Recommendations

<p>OAM 5.</p>	<p>All prescriptions for Oral Anti-Cancer Medicines should include the recommended information either as:</p> <ul style="list-style-type: none"> <li>• A standard Oral Anti-Cancer Medicine prescription template<sup>14</sup>.</li> <li>• Current prescription formats plus a treatment information document<sup>15</sup>.</li> <li>• Current prescription formats with the recommended information included as free text.</li> </ul>
<p>OAM 6.</p>	<p>The national computerised physician order entry should be configured to output the recommended information for inclusion on Oral Anti-Cancer Medicines prescriptions in line with OAM recommendation 5.</p>

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<sup>14</sup> Sample as detailed in Figure 3

<sup>15</sup> Sample included in Appendix 8. These are currently under development.

**ORAL ANTICANCER MEDICINE (OAM) Prescription DRAFT** Hospital Prescription Form Serial Number

*For dispensing pharmacist this prescription supersedes all previous OAM prescriptions* Dispense the required number of doses to complete one cycle per dispensing

HOSPITAL: Name		Address		Contact Phone no.	Fax No.
----------------	--	---------	--	-------------------	---------

<b>PATIENT DETAILS</b> (Apply patient label here or complete details)		Diagnosis: _____		<b>Nominated Pharmacy :</b>	
Patient Name		Diagnosis code: _____		Name:	
Patient Address		Patient Height _____ cm; Patient Weight _____ kg		Address:	
D.O.B.	Patient No.	Patient BSA _____ m <sup>2</sup> <input type="checkbox"/> Tick here if N/A		Phone:	
Consultant		Changes from Previous Prescription/ Deviation from Protocol / Additional Information:		Fax:	
GMS No.: _____ DPS No.: _____				GP:	
Protocol Name/ Clinical Trial Name:		Frequency of Patient Review:		Name:	
Course No.:		Allergies/Sensitivities/Contraindications:		Address:	
Code No.:				Phone:	
Prescription starts on cycle:				Fax:	

DRUG NAME (Approved): please print	Protocol Dose (per m <sup>2</sup> or per kg)	Patient Dose e.g.mg	Frequency e.g. per day	No. of Treatment Days	For non-continuous regimens				Planned Treatment start Date
					On Treatment		Off Treatment (rest days)		
					Day	Day	Day	Day	
	___per___								dd/ mm/ yy
	___per___								dd/ mm/ yy
	___per___								dd/ mm/ yy

Name	Prescribed by:	Hospital Pharmacist Review by:	Nurse Verification by:	Dispensing Pharmacist Name, Registration No., Date and Stamp to be endorsed on reverse of Prescription
Signature				
Registration number				
Date				

**Note**

- To Hospital: This form should be forwarded by fax to the appropriate High Tech Liaison Officer
- To Patient: This is your prescription. Please ensure that you bring it to your Pharmacy when you go to collect your medicine

**Figure 3: Sample OAM prescription format**

## 4.4 Prescription Verification of OAM

The National Cancer Strategy 2017-2026 advocates that all patients receiving OAM should have access to trained specialist pharmacists, in a hospital setting, who can advise them on how to take their medication correctly, the implications of misuse and possible side effects (1, 13, 14).

### 4.4.1 Findings

- The 2014 Review recommended that prescription verification policies should be in place for both parenteral SACT and OAM. It included minimum recommended pharmacist verification steps for anti-cancer medicine prescriptions.
- The Group found that standard pharmacy verification may or may not include the review of monitoring test results.
- The literature review shows that verification of OAM prescriptions by oncology pharmacists improves patient safety and decreases errors (4, 15-19).

### 4.4.2 Recommendations

<p>OAM 7.</p> <p><i>This recommendation is based on Rec. 59 of 2014 Review</i></p>	<p>All Oral Anti-Cancer Medicine prescriptions should be verified by an oncology pharmacist, who has demonstrated their appropriate competence and is locally authorised / accredited for the task<sup>16</sup>.</p>
<p>OAM 8.</p>	<p>Community pharmacists should have access to the recommended information, where relevant, to allow prescription review prior to dispensing.</p>

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<sup>16</sup> Minimum recommended pharmacy checks are detailed in Appendix 6 of 2014 Review.

## 4.5 Dispensing

Dispensing of OAM involves the complete process that occurs from receipt of the prescription, or request at the pharmacy, to the prescribed medicine being collected by the patient or their carer<sup>17</sup>.

Legislation requires that prescriptions are only dispensed in a retail pharmacy business. As noted previously, all 26 hospitals that provide SACT in Ireland are registered as retail pharmacy businesses.

### 4.5.1 Findings

- The literature review showed that many countries operate a hybrid model of dispensing shared between primary and secondary care (5, 13, 20, 21). See Table 2 for details.
- In the current OAM model of care in Ireland, OAM are dispensed in both community pharmacy and hospital pharmacy;
- The majority of OAM prescriptions are dispensed in community pharmacies.
- Most hospitals dispense some OAM. Lack of a hospital reimbursement mechanism for OAM dispensing is one of the barriers to hospital dispensing.
- Legislation<sup>18</sup> stipulates that the pharmacist should have due regard to the prescribed dosage with regard to the quantity dispensed from a prescription where the number of repeats only is specified.
- The first dispensing of OAM provides an important opportunity for in-depth counselling and consultation in the hospital setting (1).
- The benefits and challenges of different OAM dispensing locations were highlighted in the literature and discussed by the working group. The working group consensus from these discussions is presented in Table 3.
- Training and education programmes are recommended to be in place for community pharmacists (1, 14).
- All 26 hospitals are registered as Retail Pharmacy Businesses with the Pharmaceutical Society of Ireland (PSI).

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<sup>17</sup> PSI Guidelines on the Counselling and Medicine Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business, 2017

<sup>18</sup> Medicinal Products (Prescription and Control of Supply) Regulations 2015.

**Table 2: International practice – Model of Care OAM Dispensing Location**

<b>Model</b>	<b>OAM Dispensing Location</b>	<b>Country / Province</b>
1	Secondary care	Canada (British Columbia), England <sup>19</sup> , Wales
2	Primary care	Germany, Ireland <sup>20</sup>
3	Hybrid models – primary care and secondary care	Canada (Ontario), Australia, France <sup>21</sup>

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<sup>19</sup> This is currently under review due to the fiscal pressures and the increased requirement for staffing in secondary care due to increasing demand. Some hospitals in the UK have made arrangements for local outsourcing to community based pharmacies of hospital dispensing of OAM

<sup>20</sup> A small number of Irish hospitals dispense some OAMs for home administration.

<sup>21</sup> There are a small number of designated OAMs which are to be dispensed only in a hospital.

**Table 3: Benefits and challenges of OAM dispensing locations**

Factor	Model	Benefits	Challenges
<b>Safety</b> (2, 22-24)	Secondary Care	OAM dispensed under the supervision of oncology pharmacists with access to the information required to verify the prescription Ready access to the medical team to verify queries. Patient counselling can be completed on the same day that the patient attends for assessment.	Lack of adequate numbers of trained oncology pharmacists. Lack of standardised oncology training for pharmacists. Lack of adequate facilities/ infrastructure/staff resources to accommodate the volume of patients. Increasing use of OAM. Lack of access to the patient's non-cancer medication history. Communication with community pharmacists to ensure all patients' ongoing treatment is considered with regard to patient safety.
	Primary care	Community pharmacists generally have access to the patient's non-cancer medication history and can carry out full interaction check. Community pharmacist's role in patient counselling and education reinforces the information supplied to the patient by their SACT team.	Community pharmacist's lack of access to the required information to clinically verify the OAM prescription. Lack of oncology pharmacist verification of OAM prescription prior to patient discharge from hospital. Communication of required information to community pharmacists.
	Hybrid	Opportunity for holistic patient counselling on initiation of treatment and at key risk points in the patients treatment e.g. dose/frequency modification and treatment suspension/cessation Patients stabilised on treatment and on assessment intervals greater than one cycle can have prescriptions dispensed close to home.	Community pharmacists do not have access to the complete set of information required to clinically verify the OAM prescription Oncology Pharmacist verification of OAM prescription prior to patient discharge. Communication of required information to both community and hospital oncology pharmacists.

Factor	Model	Benefits	Challenges
Reimbursement(13, 22)	Secondary care	Potential savings through: <ul style="list-style-type: none"> <li>• Elimination of fees paid to community pharmacists</li> <li>• Reduction in wastage through hospital only dispensing of OAM</li> </ul>	Current reimbursement for OAM is through the Community Drug Schemes (CDS) including the High Tech arrangements of the PCRS CDS. Lack of dedicated funding for OAM dispensing in hospital. Lack of resources to support OAM dispensing in secondary care. Dispensing of prescriptions to patients attending private SACT services could remain in the community thus potentially negating some of the savings through reduction in wastage.
	Hybrid	Potential savings through reduction in wastage through hospital only dispensing of nominated OAM i.e. OAM which will be used for very small patient populations	Currently funded through the Community Drug Schemes. Secondary care dispensing will require a new funding model and resources
Patient	Secondary care	Patient counselling can be completed on the same day that the patient attends for assessment.	May decrease access for patients due to: <ul style="list-style-type: none"> <li>• Hospital location and dispensing hours</li> <li>• Patient geographical access to hospital.</li> </ul> May increase number of visits for patients: <ul style="list-style-type: none"> <li>• Not all patients will have a scheduled hospital visit per cycle.</li> <li>• Patients will need to return to the hospital for the cycles between assessments.</li> </ul>
	Hybrid	Providing consistent care regardless of geographical status Improved access allowing patients to be treated closer to home and to have a choice of provider	Variability in communication processes may lead to delays in information Difficulty accessing hospital personnel for queries

## 4.5.2 Recommendations

OAM 9.	<p>To facilitate appropriate counselling of the patient, the first cycle of Oral Anti-Cancer Medicines and the first cycle of a dose adjustment should be dispensed in a hospital setting where possible<sup>22</sup>.</p> <p>Subsequent cycles can be dispensed in the hospital or the community setting.</p> <ul style="list-style-type: none"> <li>• A funding model is required for Oral Anti-Cancer Medicines to be dispensed in hospitals which should consider the costs required to support this including but not limited to: <ul style="list-style-type: none"> <li>• Drugs</li> <li>• Staffing</li> <li>• Infrastructure</li> </ul> </li> </ul>
OAM 10.	<p>Only one cycle<sup>23</sup> of an Oral Anti-Cancer Medicine should be dispensed at a time. The quantity dispensed should not exceed the number of doses required to complete the cycle.</p>
OAM 11.	<p>Training and education programmes should be developed to support pharmacists, including community pharmacists, involved in dispensing Oral Anti-Cancer Medicines.</p>

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<sup>22</sup> Where a consultant deems that this is not necessary this approach may not be required for some patient cohorts, at the discretion of the consultant. This should be clearly defined locally following suitable risk assessment.

<sup>23</sup> A cycle is as defined in the treatment regimen or when the OAM is administered daily on a continuous basis, a cycle is equivalent to 28 days of treatment. Where a cycle is greater than 28 days and is not continuous, up to a maximum of 28 days of treatment should be dispensed at any one time.



## 4.6 Patient Review

### 4.6.1 Findings

- Patients are reviewed at defined periods during their treatment in line with the treatment regimen to ascertain their suitability to commence and continue on SACT treatment. These review periods vary depending on the treatment and may be prior to each cycle or other predefined intervals.
- Patients are reviewed by staff of the SACT service.
- Patients are reviewed in a variety of settings including OAM clinics, day wards and outpatient clinics (4, 6, 21, 25-27).
- Monitoring of patients is critical to help to identify problems and toxicities early.

### 4.6.2 Recommendation

OAM 12.	<p>Patients on Oral Anti-Cancer Medicine treatment should be reviewed by the SACT service staff in an appropriate location at the predefined intervals.</p> <p>This may be an Oral Anti-Cancer Medicine clinic, an outpatient clinic or a day ward.</p>
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## 4.7 Patient Education – home administration of OAM

### 4.7.1 Findings

- The 2014 Review documented that existing patient education practices were variable. International recommendations suggest that written and verbal information be supplied to patients (6, 7, 21, 28).
- There is concordance in the literature on the minimum education requirements for patients on OAM. See Appendix 9.
- Patients need to have a complete understanding of the relevant information as they are responsible for administration of their medicine at home.
- Medication adherence of OAM is required to provide the optimal response (29-31). Medication adherence is influenced by patient education, symptom management and monitoring by the health care team (26, 31, 32).

## 4.7.2 Recommendations

OAM 13.	Patients prescribed Oral Anti-Cancer Medicines should have access to standardised education <sup>24</sup> to support safe administration, safe handling, and management of side effects.
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## 4.8 Communication Mechanisms

### 4.8.1 Findings

- GPs normally receive communication with regard to patients' therapy plan from the treating consultant.
- Communication to community pharmacies from hospitals is not consistent and may include use of the postal service, email, phone calls or a combination of these.

### 4.8.2 Recommendations

OAM 14.	Information strategies should be developed to standardise communication between hospitals, community pharmacists and GPs.
OAM 15.	The SACT service within the hospital should ensure that community pharmacies have access to the following information: <ol style="list-style-type: none"> <li>1. The recommended information to enable safe dispensing of the prescription<sup>25</sup>.</li> <li>2. Contact information - hospital pharmacy or day ward personnel.</li> </ol>

## 4.9 Incident Reporting

### 4.9.1 Findings

- Hospital incident reporting is centralised through the Clinical Indemnity Scheme on the National Incident Management System (NIMS) platform.
- Community pharmacies do not have access to centralised reporting for:

<sup>24</sup>Appendix 9: Minimum Education Information Requirements for Patients.

<sup>25</sup>Appendix 7: Recommended information on OAM prescription and related dataset.

- Incidents involving OAM dispensing.
- Administration incidents, as self-reported by the patient or their family.
- The WHO Global Patient Safety Challenge on Medication Safety highlights that medication safety should be improved by strengthening the systems for reducing medication errors and avoidable medication-related harm (33).
  - The centralisation of incident reporting and/ or near-misses allows issues to be identified, quantified and then disseminated back to the health system so that avoidable patient harm can be minimised. (12, 34-36).

#### 4.9.2 Recommendation

OAM 16.	The NCCP should engage with key stakeholders to explore options for a centralised reporting system for incidents and near misses concerning Oral Anti-Cancer Medicines.
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## 5 Implementation of Recommendations

The majority of the recommendations contained in this guidance document are for implementation locally, in conjunction with the general recommendations of the 2014 Review report (2), to ensure the safety and quality of the OAM model of care.

The implementation of the recommendations within this report will require significant resources and a number of enabling steps to be approved and actioned by a wide group of stakeholders at a national level.

The group identified a number of actions which are required to support the implementation of the recommendations of this report:

- Development of a workforce plan in terms of:
  - Hospital prescription verification process.
  - Providing access for patients to the oncology pharmacist.
  - Hospital dispensing.
- Development of standardised documents:
  - To support communication between primary and secondary care.
  - To provide OAM specific treatment information documents.
  - Standard OAM prescription template.

## 6 Conclusion

This guidance on the safe use of OAM in the treatment of cancer was developed in response to a need for national recommendations in this area. This was highlighted as a priority recommendation of the 2014 Review in response to the variation in OAM management across the country.

The recommendations contained in this report aim to standardise the management of OAM nationally, within the specific context of patient safety and ensuring quality services.

The NCCP acknowledges the work of the OAM working group and would like to thank the hospitals who participated in the survey<sup>26</sup>.

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<sup>26</sup> The results of the survey are detailed in Appendix 10.

## Appendix 1. NCCP OAM Model of Care Recommendations

The recommendations of the report are detailed here:

**Table 4 Recommendations**

Number	Recommendation
OAM 1.	Patients who are to commence on an Oral Anti-Cancer Medicine require assessment to determine their suitability for home management of treatment.
OAM 2.	Oral Anti-Cancer Medicines should be prescribed to the same safety standards as parenteral Systemic Anti-Cancer Therapy.
<p>OAM 3.</p> <p><i>This recommendation is based upon Rec. 47 of 2014 Review</i></p>	<p>The first cycle of a course of an Oral Anti-Cancer Therapy must be written by a consultant medical oncologist or haematologist, specialist registrar or registrar based on the consultant's written therapy plan.</p> <p>Subsequent cycles may be written by a consultant, specialist registrar (SpR), registrar or registered nurse prescriber following the consultant's written therapy plan.</p> <ol style="list-style-type: none"> <li>i. Oral Anti-Cancer Medicine prescriptions should be written for one cycle only except when a patient's scheduled review is longer than one cycle.</li> <li>ii. Where the period between hospital reviews is greater than six months, a GP may write a follow up prescription following agreement on a written shared care plan with the consultant and in line with the consultant's therapy plan<sup>27</sup>.</li> </ol> <p>Communication between the prescribing consultant and the GP should outline the expected duration of therapy and the reason for the GP to refer for review prior to a planned review.</p>
OAM 4.	Patients should not commence their treatment until the results of their

<sup>27</sup> This is predominantly in haematological malignancies

	<p>monitoring tests are known.</p> <ul style="list-style-type: none"> <li>• Where a dose modification is required, a new prescription should be written.</li> </ul>
OAM 5.	<p>All prescriptions for Oral Anti-Cancer Medicines should include the recommended information either as:</p> <ul style="list-style-type: none"> <li>• A standard Oral Anti-Cancer Medicine prescription template<sup>28</sup>.</li> <li>• Current prescription formats plus a treatment information document<sup>29</sup>.</li> <li>• Current prescription formats with the recommended information included as free text.</li> </ul>
OAM 6.	<p>The national computerised physician order entry should be configured to output the recommended information for inclusion on Oral Anti-Cancer Medicines prescriptions in line with OAM recommendation 5.</p>
OAM 7. <i>This recommendation is based on Rec. 59 of 2014 Review</i>	<p>All Oral Anti-Cancer Medicine prescriptions should be verified by an oncology pharmacist, who has demonstrated their appropriate competence and is locally authorised / accredited for the task<sup>30</sup>.</p>
OAM 8.	<p>Community pharmacists should have access to the recommended information, where relevant, to allow prescription review prior to dispensing.</p>
OAM 9.	<p>To facilitate appropriate counselling of the patient, the first cycle of Oral Anti-Cancer Medicines and the first cycle of a dose adjustment should be dispensed in a hospital setting where possible<sup>31</sup>. Subsequent cycles can be dispensed in the hospital or the</p>

<sup>28</sup> Sample as detailed in Figure 3

<sup>29</sup> Sample included in Appendix 8. These are currently under development.

<sup>30</sup> Minimum recommended pharmacy checks are detailed in Appendix 6 of the 2014 Review.

<sup>31</sup> Where a consultant deems that this is not necessary this approach may not be required for some patient cohorts, at the discretion of the consultant. This should be clearly defined locally following suitable risk assessment.

	<p>community setting.</p> <ul style="list-style-type: none"> <li>• A funding model is required for Oral Anti-Cancer Medicines to be dispensed in hospitals which should consider the costs required to support this including but not limited to: <ul style="list-style-type: none"> <li>• Drugs</li> <li>• Staffing</li> <li>• Infrastructure</li> </ul> </li> </ul>
OAM 10.	Only one cycle <sup>32</sup> of an Oral Anti-Cancer Medicine should be dispensed at a time. The quantity dispensed should not exceed the number of doses required to complete the cycle.
OAM 11.	Training and education programmes should be developed to support pharmacists, including community pharmacists, involved in dispensing Oral Anti-Cancer Medicines.
OAM 12.	<p>Patients on Oral Anti-Cancer Medicine treatment should be reviewed by the SACT service staff in an appropriate location at the predefined intervals.</p> <p>This may be an Oral Anti-Cancer Medicine clinic, an outpatient clinic or a day ward.</p>
OAM 13.	Patients prescribed Oral Anti-Cancer Medicines should have access to standardised education <sup>33</sup> to support safe administration, safe handling, and management of side effects.
OAM 14.	Information strategies should be developed to standardise communication between hospitals, community pharmacists and GPs.
OAM 15.	<p>The SACT service within the hospital should ensure that community pharmacies have access to the following information:</p> <ol style="list-style-type: none"> <li>1. The recommended information to enable safe dispensing of the prescription<sup>34</sup>.</li> </ol>

<sup>32</sup> A cycle is as defined in the treatment regimen or when the OAM is administered daily on a continuous basis, a cycle is equivalent to 28 days of treatment. Where a cycle is greater than 28 days and is not continuous, up to a maximum of 28 days of treatment should be dispensed at any one time.

<sup>33</sup> Appendix 9: Minimum Education Information Requirements for Patients.



	2. Contact information - hospital pharmacy or day ward personnel.
OAM 16.	The NCCP should engage with key stakeholders to explore options for a centralised reporting system for incidents and near misses concerning Oral Anti-Cancer Medicines.

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<sup>34</sup> Appendix 7: Recommended information on OAM prescription and related dataset.

## Appendix 2. Location of publicly-funded units delivering systemic cancer therapy in Ireland

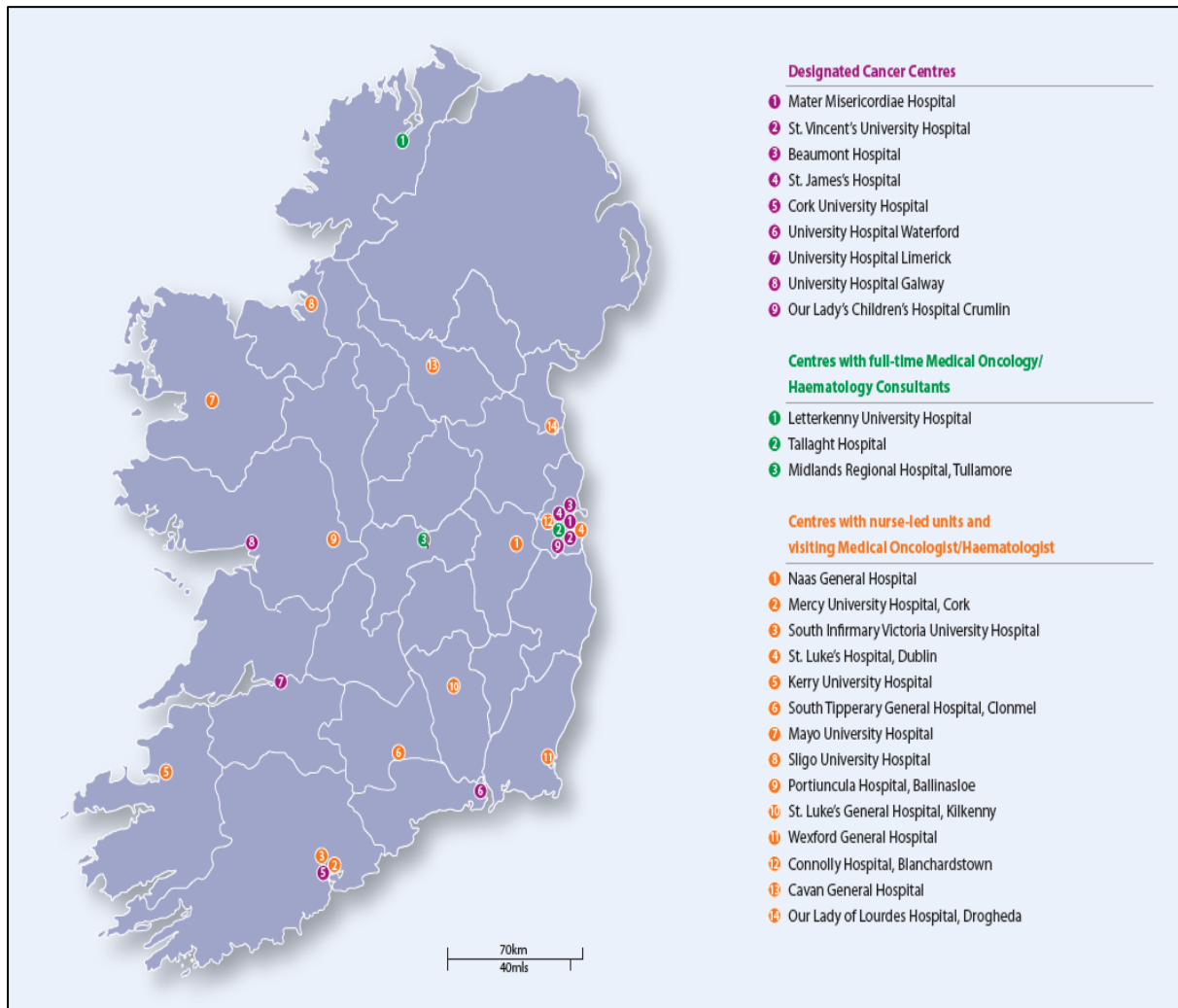


Figure 4: Appendix 2. Location of publicly-funded units delivering systemic cancer therapy in Ireland

## Appendix 3. NCCP Oncology Medication Safety Review: OAM Recommendations

The NCCP Oncology Medication Safety 2014 Review (2) contained 93 recommendations. There is variation in the implementation of some of the recommendations at hospital level due to resource and other issues. These are detailed in addition to their implementation status<sup>35</sup> in the NCCP Oncology Medication Safety Review: Final Implementation Status Report (11).

Table 5 below contains the recommendations and their implementation status across all 26 hospitals, which relate to the key risk points identified in the course of the literature review for the OAM guidance document.

**Table 5: NCCP Oncology Medication Safety Review – Key OAM recommendations and their implementation status**

Number	Recommendation	Status	Number <sup>36</sup>
<b>Prescribing</b>			
47	The first cycle of a course of systemic cancer therapy must be written by a consultant medical oncologist or haematologist, SpR or Registrar based on the consultant's written treatment plan. Subsequent cycles may be written by a consultant, Specialist Registrar (SpR) or Registrar.	Implemented	27*
56	A national computerised physician order entry system agenda should be developed by the NCCP and HSE IT	Underway	26
<b>Prescription Format</b>			
84	The NCCP will engage with the PCRS with regard to current of the High Tech prescription form	Underway	N/a
<b>Prescribing and Prescription Formats</b>			
50	Prescriptions/orders for all parenteral or oral chemotherapy must be written and should not be given as verbal or telephone orders. If a prescription/order is amended, the changes must be signed and dated on all copies of the prescription/order by	Implemented	25
		Not applicable	1

<sup>35</sup> The final implementation status update was completed on 17/11/2016.

<sup>36</sup> The number of hospitals implemented

Number	Recommendation	Status	Number <sup>36</sup>
	the physician before the treatment is administered or supplied by the Pharmacy Department. Electronic orders must be clearly attributed to the prescriber and all changes to the order must be maintained in an audit log.	Underway	1
<b>Prescribing, Pharmacist prescription verification, Administration</b>			
58	Hospitals should ensure that their chemotherapy prescription checking and administration policy includes: <ul style="list-style-type: none"> <li>• Both oral and parenteral chemotherapy</li> <li>• A description of the integrated multidisciplinary checking process and details of each team member's responsibility in this process.</li> <li>• The pharmacy verification practice where different levels of verification are in place.</li> </ul>	Implemented	15
		Underway	12
<b>Pharmacist prescription verification</b>			
59	All chemotherapy prescriptions should be checked by a pharmacist, who has demonstrated their appropriate competence and is locally authorised/ accredited for the task. Minimum recommended pharmacy checks are detailed in Appendix 6 of the 2014 Review Report.	Implemented	18
		Not started	1
		Underway	8
<b>Administration and Communication</b>			
33	All units should have written policies in place on information for patients on safe handling of cytotoxic drugs in the community including: <ul style="list-style-type: none"> <li>- Disposal information</li> <li>- Safe storage information</li> </ul>	Implemented	21
		Underway	6
<b>Patient Education and Communication</b>			
29	All units should have patient information on cancer e.g. cancer treatment, local support groups and support services.	Implemented	27*
30	Decisions to treat a patient with chemotherapy should involve the patient and carer on an informed choice basis.	Implemented	27*
31	Written information should be available for patients and carers for each treatment regimen on the hospital's agreed list.	Implemented	27*
32	There should be written information for patients and carers covering the action they should take, whom they should contact for advice, and the symptoms that should prompt this, with regard to treatment related side-effects of systemic cancer therapy.	Implemented	27*
<b>Patient Education</b>			
82	Structured education is required for patients and their carers in	Implemented	25

Number	Recommendation	Status	Number <sup>36</sup>
	relation to safe handling, administration and the identification and management of side-effects pertaining to their oral chemotherapy medications. A pre-treatment education checklist should be developed for patients on each oral chemotherapy agent.	Underway	2
<b>Patient Adherence and Monitoring</b>			
81	Monitoring of adherence to oral chemotherapy by medical/nursing personnel is recommended while patients are on their treatment.	Implemented	25
		Underway	2
<b>Communication</b>			
83	Patients on oral chemotherapy should have 24hr access to appropriately trained medical oncology staff.	Implemented	27*

\*Includes 26 hospitals, one of which submits separate reports for the Oncology day ward and the Haemato-oncology day ward.

## Appendix 4. National Cancer Strategy 2017-2026 (1): Key elements related to OAM

Page of strategy	Section/ Recommendation	Details
31	Section 3.5.2	Patients must be provided with the appropriate information to make informed decisions. Effective communication is highlighted as crucial to ensure understanding and to facilitate a partnership approach to care between patients and their healthcare providers. Patients must know what is happening, and the reason why it is happening, at each step of their care.
58	Section 7.3.2	Better integration between primary care and specialist care; and an expanded role for GPs in cancer care.
67	Recommendation 12	The NCCP will further develop the model of care for cancer to achieve integration between primary care and hospital settings at all stages in the cancer continuum, from diagnosis to post treatment care.
84	Section 10.4	Model of care for systemic cancer treatment.
84	Section 10.4	All patients receiving OAM should have access at the outset to trained, specialist pharmacists, in a hospital setting, who can advise them on how to take their medicine correctly.
84	Section 10.4	The development of dispensing protocols and training programmes for community pharmacists will aim to ensure that OAM are dispensed in a consistent, effective manner. Processes for information sharing, clinical handover and shared protocols for dispensing and checking prescriptions can ensure a common approach and standardise care between hospital and community settings.
84	Recommendation 23	The NCCP will examine the model of care for patients receiving oral anti-cancer medicines and recommend steps to ensure that all patients receive such medicines in a safe and effective manner, with appropriate and proportionate supports, both in the hospital and community setting.
127	Section 16.3.5	Pharmacists play an important role in the treatment of cancer patients, both in the hospital and the community, and greater support for community pharmacists is required to allow them to provide oral anti-cancer medicines and to counsel patients in a safe and effective manner.

## Appendix 5. Terms of Reference - NCCP OAM Working Group

### NCCP Oral Anti-Cancer Medication Working Group Terms of Reference

#### Membership

- 1) The composition of the Group will be determined by the NCCP.
- 2) The Chair of the Group will be appointed by and report to the Director of the NCCP.
- 3) Membership will be for the duration of the project.
- 4) Additional members may be co-opted to the group from time to time.

#### Objective

1. To develop recommendations on the safe prescribing, dispensing and administration of OAM for the treatment of cancer.  
This will be achieved by developing guidance on:
  - Safe prescribing of OAM.
  - Safe administration of OAM.
  - Safe service models for the dispensing and supply of oral Anti-Cancer medicines in primary or secondary care.
  - Communication mechanisms between primary and secondary care.
2. To present the findings and recommendations of the working group to the NCCP Oncology Medication Safety and Quality Review steering group.

#### Frequency of meetings

It is envisaged that the Group will meet approximately six times.

#### Secretariat

The Secretariat to the Group will be provided by NCCP.

## Appendix 6. Members of the NCCP OAM Working Group

Role of group	Name and professional title
NCCP	Ms Patricia Heckmann, Assistant National Director, NCCP & Chief Pharmacist Ms Terry Hanan, NCCP Nursing Development Coordinator Ms Anne Marie De Frein, NCCP Deputy Chief Pharmacist (joined the group in August 2017)
NCCP Medical Oncology Advisor	Prof. Maccon Keane, National Medical Oncology Lead, NCCP and Consultant Medical Oncologist at Galway University Hospital.
Consultant Medical Oncologist (ISMO representatives)	Dr Miriam O'Connor, Consultant Medical Oncologist Waterford University Hospital ( <b>Chair of the OAM Working Group</b> ) Dr Patrick Morris, Consultant Medical Oncologist, Beaumont Hospital.
Consultant Haematologist (IHS representative)	Dr Jeremy Sargent, Consultant Haematologist, Our Lady of Lourdes Hospital, Drogheda and Beaumont Hospital.
Nursing Representatives	Ms Clodagh McHugh, Beaumont Hospital (member of the group from May 2014 to Sept 2015) Dr Janice Richmond, Letterkenny General Hospital Ms Olive Burdett, Limerick (member of the group from May 2014 to May 2017) Ms Jo Ballot, St Vincent's University Hospital (member of the group from May 2014 to August 2017) Ms Liz O Connell, Tallaght Hospital Ms Hazel Murray, St Vincent's University Hospital (Joined the Group in August 2017)
Pharmacy Representatives	Ms Louise McDonnell, St. Vincent's Private Hospital, Dublin 4 Mr Bernard Duggan, Dargans Pharmacy, Dublin 1 (IOP representative from 2016) Ms Fionnuala King, (previously) St James Hospital (member of the group from May 2014 to Dec 2016) Ms Lisa Hammond, St. Vincent's University Hospital, Dublin 4 (joined the Group in January 2017) Mr Greg O'Lubhlai, Maxwells Pharmacy, Dalkey, Co. Dublin (joined the Group in October 2017)
Primary care reimbursement service	Mr Shaun Flanagan, Chief I Pharmacist, Corporate Pharmaceutical Unit, PCRS.

This report was drafted by Patricia Heckmann and Anne Marie De Frein on behalf of the NCCP OAM Working Group.

The report was finalised by the NCCP OAM Working Group on 22<sup>nd</sup> February 2018.



## Appendix 7. Recommended information on OAM prescription and related dataset

NOTE: The Working Group concluded that a number of approaches could be taken to ensure that prescription formats would meet the needs of:

- Prescribers to ensure safe prescribing.
- Pharmacists to ensure safe dispensing.

These approaches are underpinned by the recommended information for inclusion on OAM prescriptions which then could be implemented as:

- A standard OAM prescription template – sample as detailed in Figure 3.
- Current prescription formats plus a treatment information document. Sample included in Appendix 8<sup>37</sup>.
- Current prescription formats with the recommended information on it included as free text.

### Recommended dataset for OAM prescription

Recognising the safety concerns with the current available OAM prescription formats, the working group reviewed a variety of datasets for an OAM prescription based on the data fields in use or recommended in the following:

1. The current prescriptions e.g. high-tech prescription.
2. The prescription dataset recommended in the IMSN report (24).
3. The prescriptions used by individual hospitals providing SACT services.
4. The recommended dataset in Appendix 9 of the 2014 Review recommendations (2).
5. The proposed SACT dataset for the national CPOE system.

This dataset is detailed in Table 6 and will be utilised in the configuration of the national CPOE system. The implementation of the high-tech hub and changes to the High Tech arrangements of the PCRS community drug schemes in addition to efficiencies that may be gained through electronic implementation may result in changes to this dataset at implementation or in the future.

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<sup>37</sup> These are currently under development

**Table 6 Recommended information dataset on OAM prescription**

Data item name	Data Dictionary Data Element
Hospital name	
Hospital address	
Department contact no.	ONCOLOGY DEPARTMENT TELEPHONE NUMBER
Fax no.	ONCOLOGY DEPARTMENT FAX NUMBER
Patient name	
Patient address	PATIENT'S USUAL ADDRESS
DOB	PERSON BIRTH DATE
Hospital number	LOCAL HOSPITAL NUMBER E.G. MRN; BOARD NUMBER
Consultant Name	CONSULTANT NAME (INITIATING SYSTEMIC ANTI-CANCER THERAPY)
GMS / DPS / LTI Number etc	GENERAL MEDICAL CARD / DRUG PAYMENT SCHEME/ LONG TERM ILLNESS SCHEME NUMBER ETC
Diagnosis	PRIMARY DIAGNOSIS DESCRIPTION
Diagnosis code	PRIMARY DIAGNOSIS (ICD AT START OF SYSTEMIC ANTI-CANCER THERAPY)
Patient height	PERSON HEIGHT IN METRES at start of cycle
Patient weight	PERSON WEIGHT IN KG at start of cycle
Patient BSA	BODY SURFACE AREA CALCULATION at start of cycle
Changes from previous prescription	AN INDICATOR IF THE DOSE OF SYSTEMIC ANTI-CANCER THERAPY HAS CHANGED SINCE THE PREVIOUS PRESCRIPTION
Deviation from protocol /Additional Information	FREE TEXT TO CONVEY ANY ADDITIONAL INFORMATION FROM THE PRESCRIBER TO THE PHARMACIST
Frequency of patient review	HOW OFTEN THE PATIENT NEEDS TO BE REVIEWED
Allergies/Sensitivities/Contraindications	LIST OF PATIENT'S DRUG ALLERGIES/SENSITIVITIES/CONTRAINDICATIONS
Community Pharmacy	NAME OF COMMUNITY PHARMACY
Address	ADDRESS OF COMMUNITY PHARMACY
Phone	TELEPHONE NUMBER OF COMMUNITY PHARMACY
Fax	FAX NUMBER OF COMMUNITY PHARMACY
GP Name	GENERAL PRACTITIONER NAME
GP Address	ADDRESS OF GP PRACTICE
Phone	TELEPHONE NUMBER OF GENERAL PRACTITIONER
Fax	FAX NUMBER OF GENERAL PRACTITIONER
Protocol/Regimen name or clinical trial name	NCCP PROTOCOL NAME OR INDICATION OR CLINICAL TRIAL NAME
Course number	SYSTEMIC ANTI-CANCER THERAPY COURSE NUMBER
Code number	NCCP PROTOCOL CODE
Prescription starts on cycle	ANTICIPATED START DATE (SYSTEMIC ANTI-CANCER THERAPY DRUG CYCLE)
Total number of days in cycle	TOTAL NUMBER OF DAYS IN CYCLE INCLUDING REST DAYS
Cycle number	SYSTEMIC ANTI-CANCER DRUG CYCLE IDENTIFIER
Intended number of cycles	NUMBER OF SYSTEMIC ANTI-CANCER THERAPY CYCLES PLANNED
Drug name (approved)	SYSTEMIC ANTI-CANCER DRUG NAME

Data item name	Data Dictionary Data Element
Protocol dose (mg/m <sup>2</sup> or Kg)	THE DOSE AS MG PER METRE SQUARED OR KG OR AS RELEVANT IN THE PROTOCOL
Patient Dose	DOSE PATIENT IS TO RECEIVE IN MG
Frequency per day	THE NUMBER OF TIMES PER DAY THAT THE DOSE IS TO BE ADMINISTERED
No. of treatment days	THE TOTAL NUMBER OF DAYS THAT THE PATIENT WILL RECEIVE THE PRESCRIBED DOSES DURING THE CYCLE
"On" treatment days	INDICATE 'ON' TREATMENT DAYS DAY FROM AND DAY TO
"Off" treatment days	INDICATE 'OFF' TREATMENT DAYS DAY FROM AND DAY TO
Planned treatment start date	EXPECTED START DATE OF SYSTEMIC ANTICANCER THERAPY TREATMENT I.E. DATE PATIENT TO START TREATMENT ONCE GIVEN CONFIRMATION FROM THE HOSPITAL
Name	NAME OF PERSON VERIFYING THE PRESCRIPTION
Signature	SIGNATURE OF PERSON VERIFYING THE PRESCRIPTION
Registration Number	REGISTRATION NUMBER OF PERSON VERIFYING THE PRESCRIPTION
Date	THE DATE THE PRESCRIPTION IS WRITTEN
Prescribed by	THE NAME OF THE PRESCRIBER
Hospital Pharmacist review by	SIGNATURE REGISTRATION NUMBER AND DATE OF HOSPITAL PHARMACISTS REQUIRED
Nurse verification	SIGNATURE REGISTRATION NUMBER AND DATE OF HOSPITAL NURSE REQUIRED
Dispensing pharmacists	SIGNATURE REGISTRATION NUMBER AND DATE OF HOSPITAL PHARMACIST REQUIRED

### Defining a National OAM prescription template

The 2014 Review noted that prescribers consistently provided the basic information required to verify the clinical appropriateness of the prescription on parenteral SACT prescriptions but not on OAM prescriptions. The lack of structured formal prescriptions for OAM with the minimum dataset is a contributing factor to the safety concerns with OAM.

### Advantages of a designated OAM outpatient prescription

A designated national OAM prescription would:

- Be uniquely identifiable in its purpose encouraging all health professional to become familiar with the requirements for OAM prescribing.
- Facilitate consistent content and assure safer prescribing by prompting prescribers to document the minimum dataset required for safe and effective dispensing of OAM.
- Be used when prescribing all OAM from the Community Drugs Schemes.

- Ensure community pharmacists would be supplied with information recommended to enable safe dispensing.

Would eliminate the requirement for OAM prescribed on hospital prescriptions to be transcribed to GMS prescriptions.

### **Challenges to the design and implementation of a designated OAM outpatient prescription**

- A designated OAM discharge prescription would be in addition to the prescription formats currently in use.
- This prescription would have to be recognised as a valid prescription for reimbursement under the Community Drug Schemes.
- A nationally agreed list of OAM would have to be developed and maintained.
- The management of the prescription format to be used in the prescribing of OAM for non-cancer indications would have to be clearly communicated.
- Finalisation of OAM prescription format:
  - A number of iterations of the sample OAM prescription template were reviewed by prescribers and pharmacists. While reviewers recognised that this could be one approach to improve safety, it was also evident that the sample template did not allow for prescribing of all of the various dosing schedules associated with OAM.
- Implementation would require assessment of clinical risk on the introduction of a new prescription format, and associated training.

## Appendix 8. Proposed OAM Treatment Information Document Template

The intention of the OAM treatment information document is to supply supplementary information to the OAM prescription in order to ensure that the recommended information is available to a community pharmacist to enable safe dispensing.

The regimen specific treatment information documents will be based on the sample below, the recommended information for inclusion on OAM prescriptions as detailed in Appendix 7 and the data currently included on the current prescription formats.

This template will be an iterative document and will be updated to reflect feedback from key stakeholders including patients, carers, clinicians, nurses, pharmacists and others.

Regimen specific OAM treatment information documents will vary from the template due to the variety and complexity of OAM dosing schedules.

NOTE: The implementation of electronic versions of these forms may lead to redesign.

INSERT PATIENT DETAILS/LABEL HERE:

Full Name:	Day centre Phone Number:
Date Of Birth: ____/____/____	Liaison Nurse name & contact no.:
Consultant:	Hospital Pharmacist name & contact no.:
Hospital:	Main Hospital Phone Number:

This leaflet contains information on your medication

Please keep this document with your prescription and bring it to each hospital visit, GP visit and pharmacy visit.

<b>Name of Drug (s):</b>	
<b>Indication:</b>	
<b>NCCP Regimen Code:</b>	
<b>Accessible at:</b> <a href="http://www.hse.ie/cancer/nccpchemoregimens">www.hse.ie/cancer/nccpchemoregimens</a>	
<b>Dose &amp; Frequency of Drug:</b>	
<b>Cycle Duration (No. of days of treatment):</b> <b>One cycle is to be dispensed at a time.</b>	
<b>Anticipated No of cycles to be given:</b>	
<b>Frequency of Patient Review</b>	
<b>Information completed by:</b>	

For Cycle 1: The hospital will confirm your start date with you once your pre-treatment blood test results have been seen and your doctor has approved them.

For all other cycles: You will be given a start date by the hospital after review of your blood test results.

Please refer to the Patient information leaflets for the full list of potential side effects.

Your Community Pharmacist will counsel you on receipt of your medication. You may also be counselled by a member of staff at the hospital prior to starting this medication and/ or at any hospital visits you have.

Full Name:
Date Of Birth: ____/____/____
Consultant:

<b>CYCLE NO.</b>	<b>START DATE</b>	<b>HEIGHT (M)</b>	<b>WEIGHT (KG)</b>	<b>BSA (M<sup>2</sup>)</b>	<b>Change from previous prescription/ Deviation from regimen/ Additional Information</b>

## Appendix 9. Minimum Education Information Requirements for Patients

Treatment Details	Drug Name(s), Dose, Schedule Copy of the regimen Supportive care medication to be taken
How the medication is to be taken	No of tablets, no of times per day, start and stop dates Planned intervals between cycles With/ without food Medications/ Foods to avoid, What to do if a dose is missed What to do if they vomit after a dose
Safe Handling	Do not crush tablets or open capsules (unless instructed to do so) Safe Storage Safe Disposal of Vomit/ Excreta, Soiled Clothes Safe Disposal of Drug Containers/ Drug (in cases of early discontinuation)
Side effects	Expected side effects and how to manage them When to report side effect issues
Adherence	Promote importance of adherence Encourage patients to properly report compliance
Contact details (to include names and phone numbers)	Working hours Out of hours

## Appendix 10. OAM survey

A survey on the current OAM model of care in Irish publicly-funded hospitals was undertaken to supplement the Group's understanding of OAM services in Ireland. The survey was sent to all 25 hospitals involved in the prescribing of OAM in adults; 21 responses were received.

The survey findings highlight that in the hospitals who responded:

- 84% of hospitals supply patient information leaflets which include information related to the specific OAM prescribed.
- 84% of hospitals supply contact numbers for the hospital unit to patients and their carers.
- 74% supply a 9-5 hospital contact number for the community pharmacy to liaise with regarding any queries, 16% have a 24-hour number and 10% have no dedicated contact number.
- 45% of sites have a dedicated OAM clinic for commencement and review of patients on OAM.
- For those sites that do not have a dedicated OAM clinic, 83% of patients are seen in the day ward as day ward patients, 8% are seen in the day ward as outpatients and 9% are seen in the outpatient clinics.
- Many hospitals have implemented the recommendations of the 2014 Review (2) regarding prescription verification review: 90% of all OAM prescriptions are verified by a nurse and 60% by an oncology pharmacist.
- 58% of hospitals currently dispense some OAM to patients<sup>38</sup>.

The survey results were broadly in line with the findings of the NCCP Oncology Medication Safety Review: Final Implementation Status Report (11).

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<sup>38</sup> The 2014 Review had shown that a number of hospitals dispensed a limited range of OAMs but a significant number of hospitals dispensed some OAMs in exceptional circumstances e.g. unlicensed OAMs, OAMs on compassionate access programmes and clinical trials.



## Abbreviations

CDS	Community Drug Schemes (CDS) including the High Tech arrangements of the PCRS CDS
CPOE	Computerised Physician Order Entry
GMS	General Medical Services, provided by PCRS
GP	General Practitioner
NCCP	National Cancer Control Programme
OAM	Oral Anti-Cancer Medicines
PCRS	Primary Care Reimbursement Service
SACT	Systemic Anti-Cancer Therapy

## Glossary and Definitions

Cycle	A cycle is as defined in the treatment regimen or when the OAM is administered daily on a continuous basis, a cycle is equivalent to 28 days of treatment.
Cytotoxic	Any agent or process that is directly toxic to cells preventing their replication or growth. Chemotherapy and radiotherapy are forms of cytotoxic therapy
Dispensing	Primary care dispensing – community pharmacy Secondary care dispensing – hospital pharmacy OAM administration – supervision of care, education, toxicity management
High tech	The high tech arrangement of the Primary Care Reimbursement Service (PCRS) Drugs Scheme provides for the supply and dispensing of high tech medicines through retail pharmacy businesses as per prescriptions written in the hospital
OAM	Oral Anti-Cancer Medicines are defined, for the purpose of this document, as all drugs with direct anti-tumour activity that are administered by mouth for the treatment of cancer. It encompasses all drugs with direct anti-tumour activity and targeted therapies such as the tyrosine kinase inhibitors. It excludes hormonal therapy used to treat cancer.
Oncology Pharmacist	A hospital pharmacist who has demonstrated their appropriate competence and is locally authorised / accredited for the task(2)
Parenteral	All routes of administration of a medicine excluding oral e.g. subcutaneous, intravenous, intramuscular, intrathecal.
PCRS	The Primary Care Reimbursement Service (PCRS) is part of the HSE, and is responsible for making payments to healthcare professionals, for the free or reduced costs services they provide to the public
Prescription Verification	The key steps to be taken by a pharmacist, nurse or doctor when checking prescriptions for anti-cancer medicines <sup>39</sup> .
SpR	Specialist registrar

<sup>39</sup> The principles for prescription verification are included in Appendix 6 and 7 of the 2014 Review.

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