



IMSNI Briefing Document on Oral Anticancer Medicines (OAM)

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This document is intended as a “best practice” guideline and is not to be regarded as a document offering definitive legal advice in relation to the subject matter

About the IMSNI

The Irish Medication Safety Network (IMSNI) is an independent group of pharmacists and other specialists working in the acute sector, whose principal aim is to improve patient safety with regard to the use of medicines through collaboration, shared learning and action.

The following is a position paper from the IMSNI on the prescribing and dispensing of Oral Anticancer Medicines (OAM) in Ireland. This paper proposes a safer environment for OAM prescribing and dispensing in Ireland.

Executive Summary

Traditionally cancer therapy has involved the use of intravenous products, prepared and administered by specialist staff in hospitals. In recent years many new oral anticancer medicines (OAM) have become commercially available and these offer many advantages to patients and to the health care services. Inherent in the use of these medicines are risks to patient safety. Safety strategies, such as double or triple checks are core features of the system for parenteral (e.g. intravenous) chemotherapy management; however few of these features are incorporated into the management systems for oral chemotherapy¹.

In 2008, the National Patient Safety Agency (NPSA) in the UK issued an alert outlining serious patient safety incidents involving oral anticancer medicines. In response, minimum standards were enforced in the UK to ensure that OAM are managed to the same strict standards as injected therapy¹. Similar strategies are in place in many other healthcare systems such as the US, Australia and Canada^{2,3,4}. In contrast, guidance on the management of OAM in Ireland is lacking.

In 2009, Hammond *et al* undertook research study to evaluate the current systems for OAM prescribing and dispensing in Ireland, representing the only national research on this subject. The findings from the study determined wide variations in practices for both the checking and dispensing of prescriptions for OAM. The current system for prescribing and dispensing OAM is primarily on the High Tech Drugs Scheme (HTDS) facilitated by dispensing through community pharmacies. Of the pharmacists surveyed, 64% (n=230) felt that they did not have sufficient information available to them to safely dispense prescriptions for OAM. In addition, 74% felt that the current Irish system of prescribing and dispensing OAM placed patients at risk. A review of 100 oral anticancer prescriptions from two national cancer centers revealed that only 16% of the prescriptions contained sufficient information to allow an accurate clinical check to be undertaken in a community pharmacy setting to ensure safe dispensing. This was directly related to the absence of specialised reference sources. This landmark study concluded that the current system of prescribing and dispensing of OAM in Ireland afforded the opportunity for risks relating to this group of medicines, thus exposing patients to safety risks. This was directly related to the fact that OAM are not managed to the same strict standards as parenteral anticancer medicines.⁵

In response to this report, the Irish Medication Safety Network (IMSNI) established an OAM working group to devise risk reduction strategies to improve the safety of patients receiving OAM in Ireland. To determine the common components of OAM international best practice, the working group critically evaluated interventions in other jurisdictions for their applicability

to the Irish Healthcare system. A number of strategies with significant potential to reduce patient harm were identified and explored as potential risk minimization strategies. In summary, these included the need for the introduction of a national prescription for OAM and a robust method of clinical verification for all OAM prescriptions by specialist pharmacists. In addition, it was identified that the site of dispensing for OAM prescriptions merited review.

Recommendation from the IMSN OAM Working Group

The number of oral anticancer agents available, particularly the targeted therapies, is likely to increase substantially in the near future. Risks to patients are known to be increased if non-specialist practitioners prescribe, dispense or administer these oral medicines and bypass the normal safeguards used for injectable anti-cancer medicines¹.

The IMSN working group recommends that clinical verification and dispensing of all OAM prescriptions should take place in the hospital where the patient's clinical information is available, and where treatment is undertaken.

OAM prescriptions should be verified by pharmacists with specialist chemotherapy knowledge (*specialist pharmacists*) to ensure patient safety^{1,4,6,7}. Doctors, pharmacists and nurses must prescribe, dispense, administer and monitor oral anti-cancer medicines to the same standard as injected (parenteral) chemotherapy¹.

The requirement for verification of all OAM prescriptions by specialist pharmacists and dispensing from hospital pharmacies will present challenges in terms of human resources and drug costs, and allocation of specific resources will be necessary. The resources for OAM are currently in primary care therefore reallocation to the secondary care/acute sector would be required.

Definitions

OAM:

For the purpose of this document the term “oral anticancer medicine” includes those drugs with direct anti-tumour activity. Targeted therapies such as the kinase inhibitors are also included (appendix 1).

This guidance is primarily intended to promote the safe use of the medicines listed to treat cancer. Where the use of these medicines is for non-cancer treatment (e.g. methotrexate in rheumatoid arthritis) a risk assessment should be undertaken and the guidance applied as appropriate. Use of this term does not include hormonal or anti-hormonal therapy used to treat cancer.

A number of agents (e.g. thalidomide and lenalidomide) are currently subject to some degree of regulatory control for the purpose of pregnancy prevention due to teratogenic side-effects. They are included on this list as the controls in place do not necessarily provide the information identified as being required for the safe management of OAMs.

BNF:	British National Formulary
BOPA:	British Oncology Pharmacy Association
BSA:	Body Surface Area
DoHC:	Department of Health & Children
GMS:	General Medical Scheme
HAI:	Haematology Association of Ireland
HCP:	Health Care Professional
High-Tech:	High Tech scheme is an Irish reimbursement scheme for specific listed drugs
IMSN:	Irish Medication Safety Network
ISMO:	Irish Society of Medical Oncology
NCPP:	National Cancer Prevention programme
NPSA:	National Patient Safety Agency (UK)
PCRS:	Primary Care Reimbursement Scheme
PPS:	Personal Public Service
PSI:	Pharmaceutical Society of Ireland
SACT:	Systemic Anti-Cancer Therapies
SHPA:	Society of Hospital Pharmacists of Australia
SmPC:	Summary of Medicinal Product Characteristics

Background

Traditionally cancer therapy has involved the use of intravenous products, prepared and administered by specialist staff in hospitals. In recent years many new oral anticancer medicines (OAM) have become commercially available. The use of oral anticancer medicines offers many advantages to patients and health care services; however these medicines also pose risks to patient safety. In 2008, the National Patient Safety Agency (NPSA) in the UK issued an alert outlining serious patient safety incidents involving oral anticancer medicines. In response, minimum standards were enforced in the UK to ensure that OAM are managed to the same strict standards as injected therapy¹. In contrast to the stringent standards that have been put in place in the UK¹ and other jurisdictions^{2,4} guidance on the management of OAM in Ireland is lacking. The majority of OAM in Ireland are dispensed by community pharmacists, often with little or no experience in this area, without access to clinically relevant patient details and specialist reference sources.

Hammond *et al* carried out a research project to assess the risks to patient safety within the current Irish system of prescribing and dispensing of OAM.⁵ Hammond concluded that the current system of prescribing and dispensing OAM in Ireland is unsafe for patients. Both community and hospital pharmacists recognise that there are risks with the current system and suggestions to address these risks to patient safety were proposed. Seven key recommendations were made in the research project, which were then narrowed down into four main options. In response to the results of this research, the IMSN established an OAM working group with the aim of giving direction for the safe and effective management of OAM in Ireland. The IMSN working group set about evaluating the recommendations made by Hammond *et al* with regards to their benefits and limitations, feasibility as well as financial implications.

The findings of Hammond *et al* show that up-to-date national guidance on the management of OAM is required. National standards for OAM management need to be designed and implemented to ensure oral anticancer therapy is managed to the same standards as injected anticancer therapy. These patient safety standards will enable the safe and effective management of OAM through consistent and controlled management of prescriptions for OAM throughout the country.

Having examined the available evidence it is the opinion of the IMSN OAM working group that the following risk reduction strategies should be given priority:

1. A national prescription for OAM
2. Specialist pharmacists performing clinical verification (with or without dispensing)
3. Provision of information to community pharmacists to enable them to undertake clinical verification of OAM prescriptions.

Options to Reduce the Risks Associated with the Management of OAM

Option 1: Implementation of a National Oral Anticancer Prescription (Appendix 2)

Background:

OAM are generally part of complicated treatment schedules, which can be cyclical in nature and based on patient factors such as

- diagnosis
- weight
- body surface area
- renal and liver function
- bone marrow reserve
- occurrence of toxicities
- treatment protocols
- performance status

a) Standard OAM Prescription

The first weakness in the current system is that OAM may be prescribed on a number of different prescription forms and that they may be dispensed under one of a number of schemes. The scheme allocated depends on both the patient's medical card status and reimbursement status of the drug, which in turn is determined by the Department of Health and Children (DoHC). Schemes include the High Tech Drugs Scheme, General Medical Scheme (GMS) and the Drug Payment Scheme (DPS). The current prescription forms are not designed specifically for OAM and there are no fields on the forms to document the information that is essential in the prescribing, clinical verification and dispensing of OAM (appendix 3).

b) Eliminate Transcription

A second weakness is the transcription step which must take place when an OAM is not listed on the High-Tech scheme and the patient's drug access is via the GMS. The hospital prescription will be presented to the GP for transcription onto a GMS prescription form. The risks inherent in the transcription process e.g. from a hospital prescription to a GMS form are well known.⁵ The current process requires the GP to accept responsibility for generating a prescription when the decision to treat and the information about the risks associated with that decision are not necessarily available to him/her. The GP is dependant on the transfer of information from the hospital to provide context on the task they are requested to undertake. It could be argued that as non-specialists in cancer care, it is not appropriate that they are required to undertake this unnecessary and risk-laden extra step. It is important to note that within most cancer centres in Ireland, local policy dictates that only Haematology/Oncology Registrars and Consultants are authorised to prescribe chemotherapy.

The implementation of a National OAM prescription form (Appendix 2) along with a designated list of OAM that should be prescribed on it (Appendix 1) would eliminate these weaknesses in the current system. The OAM would then be prescribed by a specialist in the hospital setting on the designated form.

c) Prevent/ Prohibit Repeat Prescribing

In the interest of patient safety, the IMSN OAM working group recommends that, repeat prescriptions should not be issued for OAM. There are a number of reasons for this recommendation:

1. Dose adjustments are frequently made from cycle to cycle.
2. Dose delays may be introduced but the prescription dispensed as is, due to lack of information available to the community pharmacist.
3. Cessation of therapy may occur before completion of all cycles due to for example toxicities or disease progression.
4. New treatment regimen may be commenced.

If any of the above events occur, the community pharmacist could inadvertently continue to dispense the medication at the original dose, unless the necessary information is volunteered by the patient or carer. It is safer that prescriptions for OAM are for single dispensing only.

Benefits:

- A national prescription for OAM will be easily recognisable and allow all health care professionals to become familiar with its layout and the range of information contained.

- The standardised prescription design will facilitate consistent content. The dataset transferred will enhance the information available to safely dispense OAM.
- A specific prescription for OAM will prompt prescribers to document the information required for safe and effective dispensing of OAM.
- Prescription legibility, identified as a problem by community pharmacists in Hammond *et al's* research, could be addressed by requiring that the prescriber print in block letters with one letter per a pre-printed box (see appendix 2).
- No significant costs anticipated to develop/ implement such a strategy.
- The new oral anticancer prescription would ensure use when prescribing *any* OAM listed in appendix 1, not just those OAM currently listed on the High Tech Drug scheme e.g. chlorambucil. This would enable prescribers and pharmacists to develop familiarity with safe dispensing of OAM.

Limitations:

- While a new OAM prescription design means a more complete dataset would be available to the community pharmacist for clinical verification, essential data such as renal, hepatic and bone marrow function would still not be available. This data is utilised when undertaking clinical verification of parenteral chemotherapy prescriptions.
- A defined list of OAM is required which requires national approval (see appendix 1).
- When new OAM are licensed, they would need to be allocated efficiently to the defined list as per the current system.
- The prescribing and reimbursement model adopted for the current High-Tech scheme would most likely be retained. The new oral anticancer prescription would have to be recognised as a valid prescription for reimbursement under the Primary Care Reimbursement scheme (PCRS).

While this is a standalone option it could also be integrated into option 2 and 3 below.

Option 2: Involvement of Specialist Pharmacists in the Management of Oral Anticancer Medicines

Background:

Clinical verification of an OAM prescription is a complex process, reliant on specific information being available in order to accurately check and safely dispense OAM. This includes access to clinically relevant patient details including laboratory results, specialist reference sources and local treatment protocols. Appendix 4 gives a detailed seventeen point guide on the necessary steps involved in accurately and safely verifying an OAM prescription.

Verification provides assurance that the prescribed treatment is tailored and correct for the patient and their specific disease. It provides a check on treatment accuracy and is essential to avoid medication errors. Cancer medicines must not be administered to, or taken by patients until an appropriately trained pharmacist (specialist pharmacist) has verified the prescription.^{4,7}

The specialist pharmacist in the hospital setting has ready access to patient specific factors (listed in option 1) all of which are all essential to the clinical verification process.

Specialist pharmacists may be involved at two levels of OAM management:

- a) Clinical verification of prescriptions only with community pharmacy dispensing
- b) Clinical verification and drug dispensing within hospitals

Both options are discussed separately below. The National Cancer Action Team report into the 'Quality and Safety of Chemotherapy Services' published in August 2009 states 'All chemotherapy prescriptions should be checked by an oncology pharmacist, who has undergone specialist training, demonstrated their appropriate competence and is locally authorised/ accredited for the task. This applies to oral as well as parenteral treatments'. The pharmacist carrying out the verification of the OAM prescription should have appropriate training, knowledge and skills in cancer chemotherapy.^{6,7}

The Scottish Government Health Department sets out its guidance in the Health Department Letter 2005 29 – Guidance for the safe use of chemotherapy. It states, "All prescriptions for chemotherapy must be verified by a suitably trained pharmacist in accordance with legislative requirements, national standards and guidelines".⁸

Another internationally accepted standard for defining the role of a Specialist Cancer Pharmacist is available from the Society of Hospital Pharmacists of Australia (SHPA) 2007.⁴ SHPA state that the oncology pharmacist must have adequate education and training in clinical oncology pharmacy practice. The oncology pharmacist should ideally have postgraduate qualifications in clinical pharmacy. They must possess up-to-date clinical oncology knowledge and be capable of exercising independent, responsible clinical judgement. The oncology pharmacist must maintain a minimum of 20 hours continuing education points per year within the field of oncology pharmacy practice.

In Ireland, the last National Guidance on Chemotherapy was published in 1996 and did not discuss these matters in any detail.⁹ In light of the increasing complexity and toxicity profiles of OAM, the IMSN working group recommends that a similar standard to BOPA/SHPA should be adopted in Ireland.

(a) Clinical Verification of Oral Anticancer Medicines prescription by specialist pharmacists

In 2008 the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report 'For better, for worse?' noted that evidence of Systemic Anticancer Therapies (SACT) prescriptions being checked by a pharmacist existed in only 53% of cases.¹⁰

In Ireland, Hammond *et al* in 2009 found that only 21% and 11% of OAM prescriptions written in the day centres and outpatient departments of Irish hospitals respectively were consistently clinically verified by a pharmacist. Furthermore, only 16% of OAM prescriptions originating in two cancer centres contained sufficient information to allow them to be clinically verified by a community pharmacist using reference sources readily available to them such as the BNF and SmPC.⁵

The process involved in clinical verification of an OAM prescription has been outlined in a recently published document by the British Oncology Pharmacy Association (BOPA) (appendix 4).⁷

The IMSN OAM working group recommends that all OAM prescriptions should be clinically verified by a specialist pharmacist. The prescription should be signed and the Pharmaceutical Society of Ireland (PSI) registration number of the pharmacist undertaking the verification should be included. The written authorised treatment protocol and patient specific treatment plan should then be communicated to the patient's Community Pharmacist prior to the initial dispensing, and thereafter if any changes in treatment were made.

Benefits:

- Appropriately trained oncology/haematology pharmacists (Specialist Pharmacists) with access to clinically pertinent patient details, specialist reference sources, local treatment protocols and the prescribing team would ensure that OAM prescriptions are clinically verified. The community pharmacist could then dispense the oral anticancer medicines

safely, in the knowledge that the essential patient safety step (clinical verification) has occurred.

- The same standards that are currently employed for parenteral anticancer therapy could be applied to OAM as recommended by the NPSA Rapid Response Report.¹
- It is disruptive and time consuming for community pharmacists to have to contact the prescribing doctor in order to clarify or amend a prescription. The process of verification in the hospital setting will ensure these inefficiencies are eliminated, facilitating a more streamlined safer process for the patient.
- Facilitation of more timely and appropriate clinical interventions by healthcare professionals in the same institution
- The availability of contact details for a specialist pharmacist on each prescription will facilitate ease of contact between the community pharmacist and the specialist pharmacist. This key recommendation was identified by community pharmacist's feedback in Hammond *et al's* 2009 research.⁵

Limitations:

- The clinical verification of prescriptions for OAM will require increased specialist pharmacist resources in the hospital. In addition to clinical verification, this role will encompass development and maintenance of OAM protocols, transfer of information across the secondary-primary care interface, and responding to OAM enquiries from primary care HCPs. Corresponding infrastructural resources will be required.
- OAM prescriptions may originate from many different locations within the hospital setting e.g. out-patient clinics, discharge prescriptions, day ward clinics. There will have to be a major restructuring of hospital systems to ensure that all OAM prescriptions can be verified before the patient presented it to a community pharmacy.
- Close liaison and cooperation from all members of the healthcare team will be required to ensure that all OAM prescriptions written in hospital would be sent to the specialist pharmacist for verification before being given to the patient.
- The involvement of specialist pharmacists in verifying OAM prescriptions may result in extending the duration of the patient's hospital visit.
- Data protection issues will need clarification.

(b) Dispensing of Oral Anticancer Medicines from Hospital Pharmacy Departments

Benefits:

- As patients are already attending hospital for medical review, dispensing from the hospital pharmacy facilitates seamless care.
- Hospital Pharmacists already have access to information such as diagnosis etc (detailed on page 8 under background of option 1) and this information is necessary for the verification of parenteral chemotherapy. Few changes would be required to include verification of OAM prescriptions in this system.
- Any data protection concerns are eliminated as in-hospital dispensing removes the need for transfer of data.
- It is easier to get access to prescribers to clarify or correct any ambiguities or mistake on a prescription within the hospital.
- Hospital pharmacies can readily dispense from clinic visit to clinic visit. They are ideally positioned to respond in real time, to changes in a prescription due to toxicity or disease progression, without the risk of patients having an excess supply of an obsolete treatment regimen at home.
- Pharmacists are specialists in medicines management and drug knowledge. The benefit to patients of being counselled by a specialist pharmacist with additional expertise ensures a better patient understanding of their drug therapy.
- Currently, any of the approximately 1,600 community pharmacies in Ireland may stock and dispense oral anticancer medication to patients. The economies of scale gained by dispensing from hospital pharmacy departments are indisputable (reduced wastage, enhanced stock management, streamlined systems and processes).
- A preliminary analysis of the PCRS data (appendix 5) available suggests that the current primary care fees, if reallocated, would either be cost neutral or could generate cost savings. More detailed analysis of updated PCRS data will be required to better undertake a cost benefit analysis.

Limitations:

- Existing staffing levels within Irish hospitals will not support the implementation of this recommendation. Currently the resources both fiscal and personnel for the dispensing of OAM are in primary care. There would have to be a transfer of these resources into hospitals for this recommendation to be implemented.
- Currently a complete record of the patient's full medication history is unavailable in either primary or secondary care. There is a requirement for the information to be communicated from primary to secondary care as well as from secondary to primary care

to allow for screening of potential problems such as drug-drug interactions and adverse effects.

- Hospital dispensing may impact negatively on the level of re-imburement community pharmacists receive in patient care fees.
- Patients may find it more convenient for prescriptions to be dispensed from their community pharmacy.
- OAM are sometimes prescribed outside the Medical Oncology/Haematology specialities e.g. thalidomide in dermatological conditions. Despite the change in indication, these drugs still pose identical risks to the patient. Guidance for verification of prescriptions of these medicines is outside the scope of this document.

Option 3: Provision of information to Community Pharmacists to enable them to undertake clinical verification to international standards

Background:

Traditionally community pharmacists use references such as the BNF and the SmPC to undertake a clinical review of any prescription. However, these references do not give detailed advice about OAM. It is essential to have access to medicines information resources and treatment protocols specific to the oral anticancer regimens. Ideally, this should be in the form of written anticancer treatment protocols. However, community pharmacists do not have easy access to these or other specialist references that would be available in the hospital setting. Therefore, to undertake the clinical verification of OAM prescriptions, community pharmacists would need to be provided with sufficient information as specified in the BOPA standards.⁷ This would be in the form of patient specific treatment plans and standardised national treatment protocols.

There are no published clinical verification or OAM standards in Ireland. In the UK, in response to the risks of incorrect dosing of OAM highlighted by the 2008 NPSA Rapid Response Report, the NPSA set minimum standards for the management of OAM.¹ They directed immediate action be taken by both the NHS and the private sector, with this action to be completed by the 22nd July 2008, six months after the rapid response report was issued. Doctors, nurses and pharmacists were made aware that the prescribing, dispensing and administration of oral anticancer medicines should be carried out and monitored to the same standard as injected therapy. The NPSA Minimum Standard Recommendations required that:

- Healthcare organisations should prepare local policies that describe the safe use of these oral medicines.
- Treatment should be initiated by a cancer specialist.
- All OAM should be prescribed only in the context of a written protocol and treatment plan.
- Non-specialists who prescribe or administer on-going OAM should have ready access to appropriate written protocols and treatment plans including guidance on monitoring and treatment of toxicity.
- Staff dispensing OAM should be able to confirm that the prescribed dose is appropriate for the patient, and that the patient is aware of the required monitoring arrangements. This would be achieved by having access to the written protocol and treatment plan from the initiating hospital and advice from a pharmacist with experience in cancer treatment in that hospital.
- Patients should be fully informed and receive verbal and up-to-date written information about their oral anticancer therapy from the initiating hospital. This information should include contact details for specialist advice, which can be shared with non-specialist practitioners. Written information including details of the intended oral anticancer regimen and treatment plan including monitoring arrangements should be given to the patient.

Benefits:

- There would be no change to current prescribing, dispensing and reimbursement of OAM in Ireland.
- Supplying community pharmacists with information on the patient's treatment plan and other relevant information would facilitate them to undertake an accurate clinical verification.
- By having access to the treatment plan, the community pharmacist could use this to reinforce the patient's understanding of their treatment and of their monitoring plan.
- Patient / Community Pharmacist relationship unchanged.
- Potential drug interactions with the patient's concomitant medications would be readily identified.
- Liaison with the community pharmacist would also allow for pre-ordering of OAM, avoiding delays for patients commencing treatment.

Limitations:

- To reduce the potential for error, national standardised protocols would have to be developed. This would require the involvement of a number of special interest bodies e.g.

NCPP, HAI and ISMO. The IMSN OAM working group notes that individual Irish hospitals at present find it difficult to standardise treatment plans among their own consultants.

- The community pharmacist will be required to correlate the OAM prescription with the national treatment protocol to confirm that they are verifying the patient's treatment correctly. This will require a unique identifier that links the prescription to the protocol.
- Hospital treatment protocols are generally compiled by specialist staff experienced in the management of cancer. They often include complicated treatment schedules that may not be readily comprehensible to non-specialist staff. All community pharmacists would require access to and completion of adequate standardised national training to meet the requirements as set out by BOPA (appendix 4) in order to safely dispense OAM.
- Many hospitals do not yet have treatment protocols for all OAM. This would involve increased resources to develop and maintain these protocols.
- Resources, from a staffing and informatics perspective, would be required to compile and keep national protocols updated.
- Local policies would have to be developed that clearly outline who is responsible for the transfer of the information to the community pharmacy and whether it is their responsibility to seek it.
- There are many logistical requirements to be considered in ensuring that the community pharmacist is forwarded all the relevant information in a timely manner either electronically or otherwise.
- Data protection issues would need to be clarified.
- Even if a community pharmacist is given a patient treatment plan, this may not be enough to allow for a full clinical verification. The BOPA guidelines outline that additional information such as a full diagnosis or a patient's BSA are required to check a dosage calculation. In the absence of widespread use of electronic patient records, patients' diagnosis and BSA are currently only available in paper format within the hospital medical notes. In addition, as primary and secondary care information systems are not integrated, community pharmacists do not currently have access to electronic laboratory results

Conclusion

Traditionally cancer therapy has involved the use of intravenous products, clinically checked, prepared and administered by specialist staff in hospitals. In recent years many new oral anticancer medicines (OAM) have become commercially available and these offer many advantages to patients and to the health care services. Inherent to these medicines are risks to patient safety as the normal safeguards used for injectable anti-cancer medicines are bypassed. Guidance on the management of OAM in Ireland is lacking and the number of oral anticancer agents available, particularly the targeted therapies, is increasing and likely to increase substantially in the near future.

The IMSN OAM working group identified and prioritised a number of strategies with significant potential to reduce patient harm with respect to oral anticancer medicines. These included a national prescription for OAM, specialist pharmacists performing clinical verification (with or without dispensing), and provision of information to community pharmacists to enable them to undertake clinical verification of OAM prescriptions.

Having considered the benefits and limitations of each option, the IMSN working group recommends that clinical verification *and* dispensing of OAM prescriptions take place in the hospital where the patient's clinical information is available, and where treatment is undertaken.

OAM prescriptions should be verified by pharmacists with specialist chemotherapy knowledge (specialist pharmacists) to ensure patient safety^{1,4,7} Doctors, pharmacists and nurses must prescribe, dispense, administer and monitor oral anti-cancer medicines to the same standard as injected (parenteral) chemotherapy¹.

Allocation of specific resources is necessary before this could occur. The exact cost of this change is outside the scope of this document. However, an overview of costs of OAM to the High tech scheme to date, together with the significant upward trend of these costs since 2007 (see Appendix 5), would indicate that this change could be done in a cost neutral fashion.

Review of:

- the 2008 High Tech scheme figures;
- an estimated number of dispensing per year;
- an average number of cycles and
- the current patient fee per month

suggests that the cost of OAMs in primary care is equivalent to approximately 20 specialist pharmacists' salaries, at IMPACT mid point of senior pharmacist scale. In Ireland, approximately 40 hospitals (between public and private) are currently involved in prescribing OAM.

This option will present many challenges to the system. The resources for OAM are currently in primary care therefore reallocation to the secondary care/acute sector would be required. However, while our recommendation will impact on current processes in place for dispensing OAM, it appears it could be done with reallocation of monies already in the system rather than requiring further investment.

The primary consideration of the group is to address the lack of governance surrounding current practices to improve the safety of patients who are prescribed oral anticancer medicines (OAM). Notwithstanding the challenges involved, we consider that for the reasons outlined above, our recommendation that **clinical verification and dispensing of OAM prescriptions take place in the hospital** is by far the best way to achieve this.

Appendices

Appendix 1

For the purpose of this document the term “oral anticancer medicine” is taken from the NPSA Rapid Response Report: Risks of incorrect dosing of oral anti-cancer medicines.¹ The term OAM includes those drugs with direct anti-tumour activity such as those listed in table 1:

Bexarotene	Idarubicin	Tegafur/Uracil
Busulfan	Lenalidomide	Temozolomide
Capecitabine	Lomustine	Thioguanine
Chlorambucil	Melphalan	Topotecan
Cyclophosphamide	Mercaptopurine	Treosulfan
Estramustine	Methotrexate	Thalidomide
Etoposide	Mitotane	Tretinoin
Fludarabine	Procarbazine	Vinorelbine
Hydroxycarbamide		

Table 1: OAM with direct anti-tumour activity

In addition targeted therapies that affect cancer biological pathways such as the kinase inhibitors listed in table 2 are included:

Dasatinib	Gefitinib	Nilotinib
Erlotinib	Imatinib	Sorafenib
Everolimus	Lapatinib	Sunitinib

Table 2: OAM that affect cancer biological pathways

Our use of this term does not include hormonal or anti-hormonal therapy used to treat cancer.

The above guidance is primarily intended to promote the safe use of the medicines listed to treat cancer. Where the use of these medicines is for non-cancer treatment, a risk assessment should be undertaken and the guidance applied as appropriate.

This list is not exhaustive and may not include medicines introduced into clinical practice after this document was drafted (May 2010).

Appendix 2

OAM PRESCRIPTION

Hospital Name: _____ **Consultant Name:** _____
Hospital Address: _____

PATIENT DETAILS

Name:		GMS Number:	
Address:		Telephone Number:	
		Diagnosis Code:	
Hospital Medical Record Number:		Height (cm)	
		Weight (kg)	
Date of Birth:		Round height and weight to the nearest whole number	
		Body Surface Area (BSA)	

OAM PRESCRIPTION – NON REPEATABLE

DRUG NAME					
Dose <small>(mg/m², mg/kg etc. if relevant)</small>	Calculated Dose <small>(mg)[†]</small>	Frequency	Start Date	Duration* <small>(State exact number of days of dosing)</small>	Cycle Length [‡] <small>(State exact number of days)</small>
DRUG NAME					
Dose <small>(mg/m², mg/kg etc. if relevant)</small>	Calculated Dose <small>(mg)[†]</small>	Frequency	Start Date	Duration* <small>(State exact number of days of dosing)</small>	Cycle Length [‡] <small>(State exact number of days)</small>
DRUG NAME					
Dose <small>(mg/m², mg/kg etc. if relevant)</small>	Calculated Dose <small>(mg)[†]</small>	Frequency	Start Date	Duration* <small>(State exact number of days of dosing)</small>	Cycle Length [‡] <small>(State exact number of days)</small>

†Consider tablet strength(s) available and prescribe doses to correspond appropriately
 For example: For Sumatriptan 50mg * days 1 – 28; ‡ 42 days

Dose Reduction from Previous Prescription(s): Yes No
 Explanation If Yes: _____

PRESCRIBER INFORMATION

Print Name: _____ Bleep/Contact #: _____
 Signature: _____ Registration #: _____ Date: _____

SPECIALIST PHARMACIST CHECK

Print Name: _____ PSI Registration #: _____
 Signature: _____ Date of Dispensing: _____

Appendix 3

Information that the IMSN working group consider essential in the prescribing of OAM:

- Drug and dose per patient factor (e.g. mg/kg, mg/m²)
- Patient weight, height, body surface area (BSA), where relevant
- Calculated patient dose
- Frequency of administration
- Intended start date
- Duration of treatment
- Intended stop date, where relevant
- For drugs for which a variety of schedules are in common use it is especially important that the intended schedule is unambiguously stated specified on every prescription (Capecitabine for example, may be given 2 weeks on treatment and 1 week off, 3 weeks on and 1 week off, 2 weeks on and 2 weeks off or continuously)
- All intended deviations from protocol, such as dose modifications, should be clearly identified as such
- Patient name and two other unique identifiers (e.g. hospital number, date of birth)
- Drug allergies
- Prescriber's name, signature and the date of writing

Appendix 4

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Issue Date: 8th January 2010.⁷

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

1. Check prescriber's details and signature are present and confirm they are authorised to prescribe SACT.
2. Ensure regimen has been through local approval processes e.g. clinical governance and financial approval and/ or is included on a list of locally approved regimens.
3. On the first cycle check the regimen is the intended treatment as documented in a treatment plan, in the clinical notes or in the electronic record.
4. Check regimen is appropriate for patient's diagnosis, medical history, performance status and chemotherapy history (using the treatment plan, clinical notes or electronic record).
5. Check there are no known drug interactions (including with food) or conflicts with patient allergies and other medication(s).
6. Check that the timing of administration is appropriate i.e. interval since last treatment.
7. Check patient demographics (age, height and weight) have been correctly recorded on prescription.
8. Check body surface area (BSA) is correctly calculated, taking into account recent weight. Note there should be local agreement for frequency of monitoring and checking patient's weight.
9. Check all dose calculations and dose units are correct and have been calculated correctly according to the protocol and any other relevant local guidance, e.g. dose rounding / banding.
10. Check cumulative dose and maximum individual dose as appropriate.
11. Check reason for and consistency of any dose adjustments, e.g. reduction(s) or escalations and ensure reason is documented.
12. Check method of administration is appropriate.
13. Check laboratory values, FBC, U&E's and LFT's are within accepted limits if appropriate.
14. Check doses are appropriate with respect to renal and hepatic function and any experienced toxicities.
15. Check other essential tests have been undertaken if appropriate.
16. Check supportive care is prescribed and it is appropriate for the patient and regimen.
17. Sign and date prescription as a record of verification.

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

Appendix 5

Figure 1: Overall prescribing frequency/cost of OAM covered under High-Tech Reimbursement Scheme 2006-2008 (data from Primary Care Reimbursement Service)¹¹

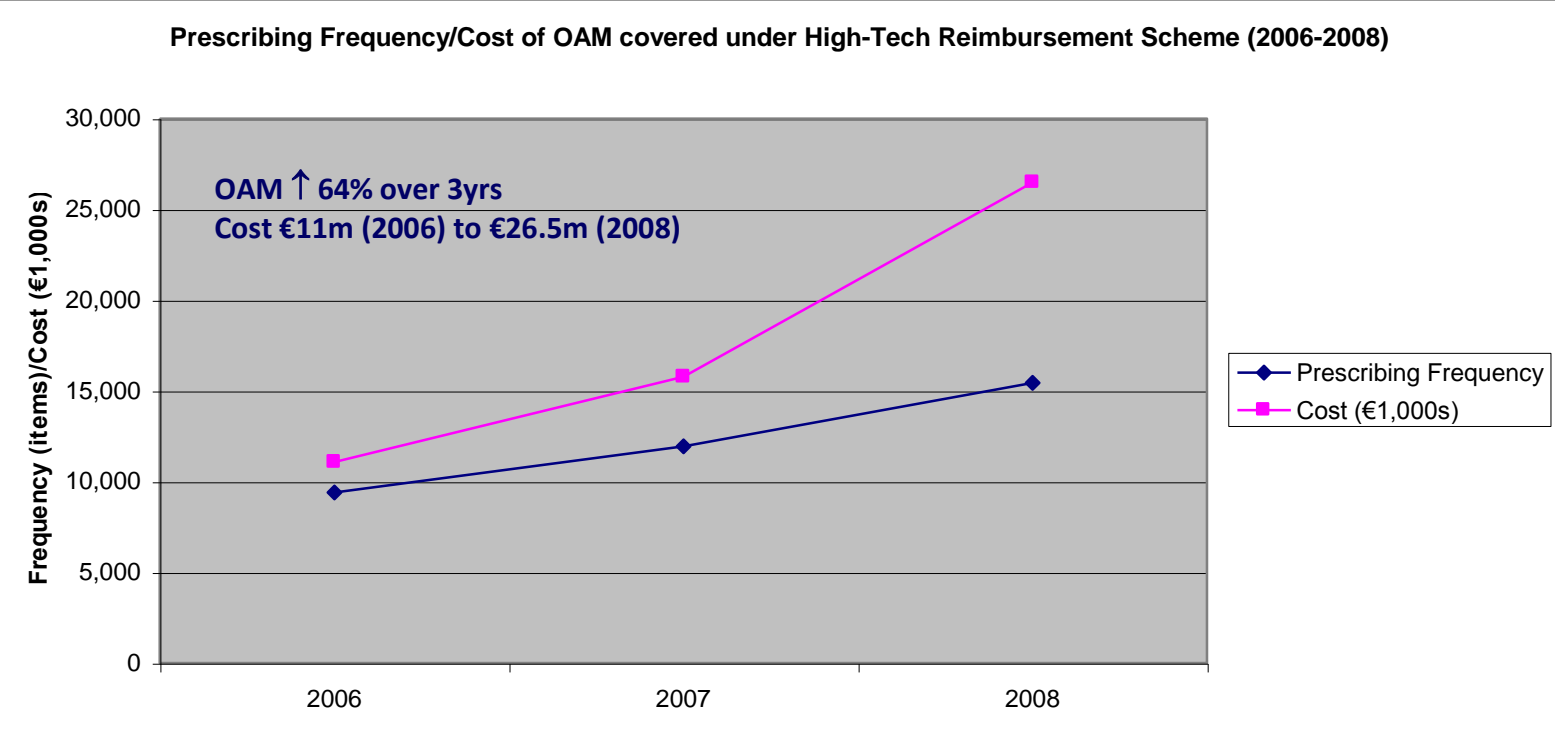
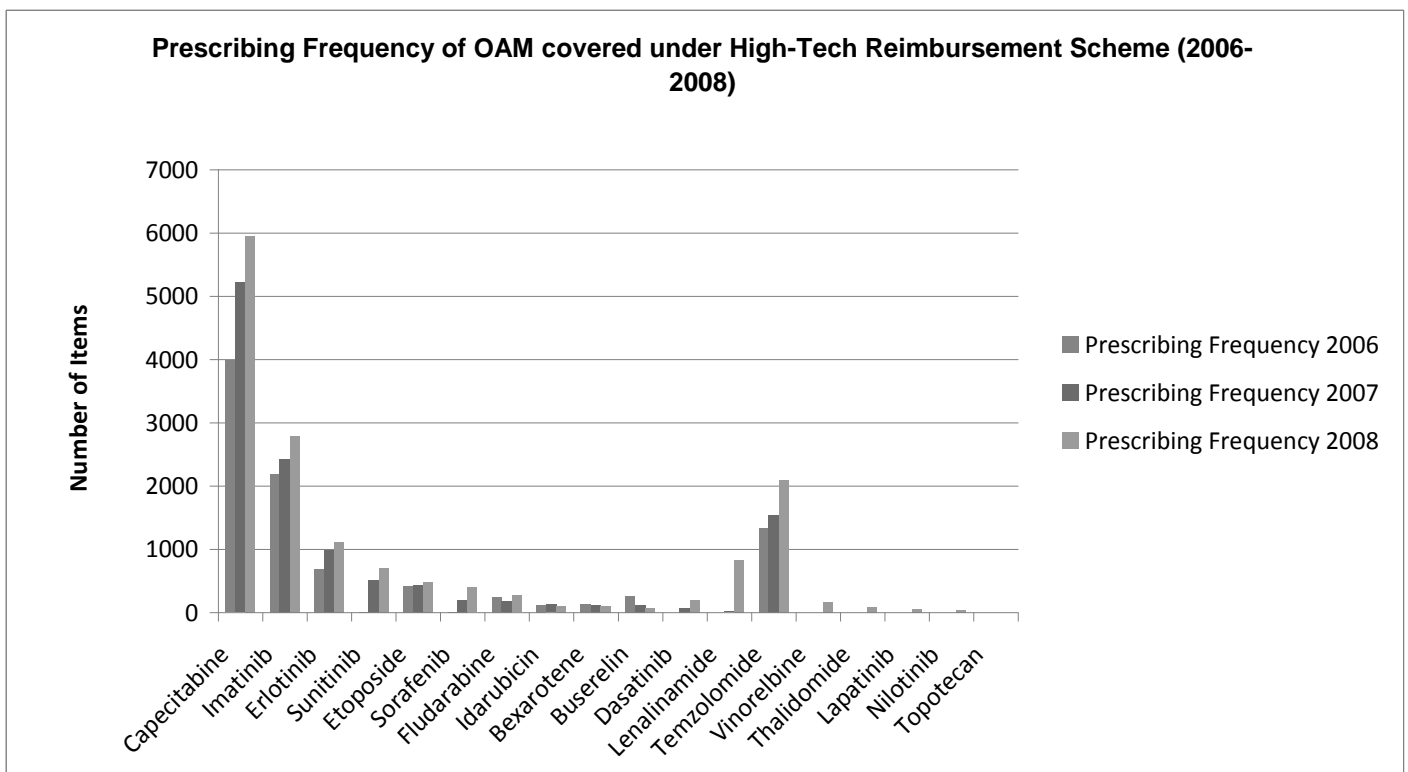


Figure 2: Prescribing frequency/cost of individual OAM covered under High-Tech Reimbursement Scheme 2006-2008 (data from Primary Care Reimbursement Service)¹¹



Summary of High Tech Scheme Information

The PCRS reimburses the pharmaceutical companies directly for the cost of the High Tech medications. Community Pharmacies are entitled to receive a dispensing fee (referred to as a patient care fee) from the PCRS. The High Tech Patient Care Fee per patient per month is **€60.52**.

A Community Pharmacy may charge the PCRS for a patient care fee for up to three months after last dispensing. A Patient Care Fee is payable in respect of **each patient** registered with a Pharmacist for whom a claim is submitted.

Patient Entitlement Categories

Patients entitled to services under the High Tech Scheme will be categorised under one of the following categories:

- Medical card holders are entitled to all High Tech items from the agreed list free of charge.
- Persons covered under the Health (Amendment) Act, 1996 are entitled to all items from the agreed list free of charge
- LTI persons are entitled to an item(s) from the agreed High Tech list free of charge only if the item has been authorised for their particular Long Term Condition.
- DPS card holders will continue to pay €120 towards the total cost of all their medication (High Tech and regular medicines).

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