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Information for Hospital Cancer Services Staff

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1 NCCP Systemic Therapy Programme

The NCCP Systemic Therapy Programme was established in late 2012, with the aim of organising and developing medical oncology and haemato-oncology services. This national programme is responsible for developing quality and safety of systemic anti-cancer therapy (SACT) services, through the development of national protocols and guidelines, audits, the support of expensive oncology drugs, implementation of quality and enabling systems and the development of national plans for the future of systemic therapy services including the implementation of the National Cancer Information System (NCIS).

The SACT Model of Care was published in 2022 and is available here. The NCCP SACT Model of Care builds on the previous work of the NCCP Systemic Therapy Programme including the NCCP Oncology Medication Safety Review Report (2014) and the NCCP Oral Anti-Cancer Medicine Model of Care (2018). Patient-centred care was key to the development of this Model of Care with the overall vision that patients with cancer will receive a high quality, timely service that is accessible and appropriate to their needs. The NCCP SACT Model of Care considered and incorporated international best practice and made recommendations to enhance SACT services in Ireland with underlying principles that align to Sláintecare.

The NCCP Systemic Therapy Programme works alongside a number of different work programmes, including the NCCP Cancer Drug Management Programme, the NCCP Molecular/Genomics Programme and the National Cancer Information System (NCIS) Programme. Key areas of work for the Systemic Therapy Programme are outlined below.
Contact email for Systemic Therapy Programme: oncologydrygs@cancercontrol.ie

1.1 Implementation of National Cancer Strategy 2017-2026

There are a number of work streams currently underway to progress the Strategy recommendations:

1. Implementation of the SACT Model of Care. The SACT Model of Care was published in 2022 as to fulfil recommendation 12[1] of the National Cancer Strategy. The STP are now working towards the implementation of the twenty-five key recommendations. These recommendations were set out to optimise SACT services to ensure the provision of a safe and quality driven service for all service users. These key recommendations focus on areas including patient experience, organisation of services, governance, quality and safety and defined SACT pathways. The NCCP SACT Model of Care will provide a roadmap for the continued development of SACT services across Ireland and will form a template for the highest quality SACT to be delivered to the Irish population over the coming years.

[1] Rec 12 of the National Cancer Strategy: The NCCP will further develop the model of care for cancer to achieve integration between primary care and hospital settings at all stages of the cancer continuum, from diagnosis to post treatment care.

2. Working towards fulfilling recommendation 9[2] and 11[3] through the NCCP Haemato-oncology Clinical Leads Group.
3. Recommendation 24: Development of guidance on appropriate Multidisciplinary Team (MDT) meetings/tumour conferences, centralisation and treatment arrangements to meet the diverse needs of patients with haematological cancers. Progress to date includes:
    a. Patient pathways: ALL and AML agreed and available here; lymphoma and myeloma pathway in development.
    b. Haemato-oncology tumour conference Standard Operating Procedure Guidance: Available here.
    c. NCCP Service Specification for Haemato-oncology Services: Available here.
    d. Data collection to support these work streams
4. Medical Oncology/Haemato-oncology Key Performance Indicator review[4]

1.2 NCCP Guidance Documents and Resources

A number of guidance documents and resources relating to SACT services have been developed and are available on the NCCP website, here.

1.3 Capacity Planning

Capacity in Medical Oncology and Haematology ambulatory day units has been of concern to the NCCP for a number of years. The NCCP continues to work on a strategy to increase capacity for all SACT services nationally including day unit, in-patient and hospital pharmacy cancer services in conjunction with the HSE, the Department of Health (DoH), the Hospital Groups/Health Regions and the hospitals. The NCCP estimates that each hospital providing SACT services will require an estimated 70% increase in day unit treatment space capacity to meet the future demands of the SACT service by 2026.

1.3.1 HSE Estates/NCCP Advisory Group—Hospital Pharmacy Aseptic Compounding Units

This group was established in 2023. The purpose of this group is to review the current status of Hospital Pharmacy Aseptic Compounding Units (ACUs) which have been identified as priorities in terms of SACT infrastructure development by the NCCP. Consideration will also be given to those sites which may require establishment of a new ACU where none previously existed. Continued engagement and oversight with ongoing ACU projects is a key priority for this group. This group will also support business case development at local level.

[2] Rec 9 of the National Cancer Strategy: The HSE will ensure that cancer referrals from a GP into a hospital will be made electronically. Each Hospital Group will facilitate the phasing in of e-referral. This will be completed by the end of 2022.
[3] Rec 11 of the National Cancer Strategy: The NCCP, working with the other directorates in the HSE, will develop criteria by end 2018 for the referral of patients with suspected cancer, who fall outside of existing Rapid Access Clinics, for diagnostic tests. The NCCP will ensure, through these criteria, that GPs will have direct access to cancer diagnostics within agreed timelines.
[4] Rec 36 of the National Cancer Strategy: The NCCP will develop, publish and monitor a programme of national quality healthcare indicators for cancer care, involving both process and outcome measures, in line with international standards.

1.4 NCCP Clinical Leads Groups

The Systemic Therapy Programme support the following Clinical Leads Groups:

- NCCP National Clinical Leads Group for Haemato-oncology
- NCCP National Clinical Leads Group for Medical Oncology
- NCCP National Haematopathology Clinical Leads Group
- NCCP National Neuroendocrine Tumour Clinical Leads Group
- NCCP Hospital Pharmacist Leads Group

The leads groups meet on a quarterly basis. The membership of these groups are via nominations from Hospital Management. The development of Terms of References for these groups are facilitated by the NCCP, and agreed by the relevant group. Secretariat is provided by the NCCP.

The functions of these groups include:

- Contributing to the development and continuous improvement of SACT services nationally and locally, in line with the National Cancer Strategy and the SACT Model of Care
- Inform decision making and standardisation of service delivery across the 26 SACT hospitals and ensure appropriate communication with colleagues in each hospital/NCCP Cancer Control Network
- Play an active part in setting standards, developing guidance, encouraging audit and benchmarking exercises across and between centres so that clinical practice is developed and updated to the highest standard
- Ensure development and adherence to national standards, as relevant, and to key performance indicators
- Support the implementation of NCCP clinical guidelines relevant to medical oncology/haemato-oncology pharmacy services

1.4.1 NCCP SACT Clinical Advisory Groups

The NCCP has established SACT Clinical Advisory Groups (CAG) in medical oncology and haemato-oncology, as listed in **Table 1**. Note however this list is not exhaustive. These groups operate under a general Terms of Reference, which can be amended to suit the specific CAG.

Table 1 NCCP SACT Clinical Advisory Groups (CAGs) (Valid as of March 2024)

List of NCCP SACT Clinical Advisory Groups
Gastrointestinal
Genitourinary
Breast
Lung
Gynae
Melanoma
Lymphoid
Myeloid
Acute Lymphoblastic Leukaemia (ALL)
Plasma Cell Disorders
Myeloproliferative Neoplasms (MPN)

The work of these SACT CAGs is driven by the priorities as set by the group and the NCCP.

- Where there are clinical questions that involve evidence review, the Systemic Therapy Programme seeks 3-4 members to participate in a meeting. The NCCP prepares a summary of the evidence needed for discussion. The NCCP invites members to join a recommendation meeting (all are facilitated by teleconference).
- The group may be asked for nominations to review:
    - NCCP national treatment regimens. The initial draft is prepared by the NCCP.
    - Clinical guidelines for drugs with a relevant indication going through the reimbursement process. These are used to inform the discussion at the NCCP Technology Review Committee meetings (See 2.2.1 below). The initial draft is prepared by the NCCP.

If a consultant would like to join an NCCP SACT CAG, please contact oncologydrugs@cancercontrol.ie.

1.5 Cancer Drugs Funding

1.5.1 Oncology Drug Management Scheme (ODMS)

The NCCP introduced the Oncology Drug Management System (ODMS) in July of 2012 to oversee and manage the funding of specified hospital-administered systemic anti-cancer drug treatments to public hospitals. The Primary Care Reimbursement Service (PCRS) facilitate the operation of this system. The system also addresses the growth in costs associated with new drugs and new indications of hospital administered systemic anti-cancer drug treatment and allows for the introduction of a "money follows the patient" funding model.

The ODMS facilitates:

- National oversight of the spend on high-cost cancer drugs, allowing for coordinated planning and, potentially, national approaches to provision of cancer drugs.
- Detailed information about drug utilisation as well as cancer incidence and prevalence.
- A mechanism for assuring adherence to national drug protocols, which is a key quality and patient safety objective for the NCCP.
- A coordinated system for HSE and NCCP, hospitals and PCRS in relation to high-cost cancer drugs.

1.5.2 Cancer Drugs Growth Funding

The NCCP aims to support hospitals to address the rate of growth in expenditure on high cost cancer drugs which are not centrally funded via the ODMS – known as 'growth funding'. The allocation of the NCCP growth budget is entirely at the discretion of the NCCP and is based on hospitals' expenditure, depending on actual activity. The original list of high cost cancer drugs was based on 2012 expenditure when the then list of drugs accounted for approximately 80% of each hospital's spend. The list of drugs has been expanded to include other products that result in significant costs for the SACT service in hospitals. This list is subject to change and is kept under review by the NCCP. Funding is not available for supportive care costs; hospitals are required to meet these costs from their own funding streams.

1.6 Service planning

The National Service Plan (NSP) is issued on an annual basis. The STP are involved in the identification of priority locations for additional posts required for the provision of cancer services. This involves evaluating data on existing posts and activity levels in order to determine the allocation of new posts. The STP consider a number of data sources to aid this decision making, such as Hospital Inpatient Enquiry (HIPE) data, Planning and Business Information Unit data, staffing numbers and Key Performance Indicator (KPI) data, among others.

1.6.1 Hospital Pharmacy Cancer Services Workforce Planning

In 2020, the NCCP in conjunction with the SACT Resilience Group (now retired) published a workforce planning framework for hospital pharmacy cancer services. This framework can be found here.

This framework allows a standardised approach for hospital pharmacy departments to assess their needs and to support business cases where required. This informs long-term service planning for all hospital pharmacy cancer related resource requirements.

The Hospital Pharmacy Cancer Services Workforce Planning Framework supports the implementation of the recommendation in the National Cancer Strategy 2017-2026 on the need to develop a comprehensive workforce plan for cancer services and is in line with the SACT Model of Care.

To support the NCCP in preparing an annual service plan submission, all hospitals are requested to complete an associated workforce planning excel tool on an annual basis. This identifies current staffing levels along with current deficits.

1.7 National Annual Meetings

The NCCP holds national meetings with a range of disciplines involved in providing SACT services to patients. These meetings provide an opportunity for front-line staff to contribute to the national planning of services and allow communication across different service providers and disciplines.
These meetings are held both online and in person. This hybrid option allows attendees the opportunity to meet and network face to face, or to dial in virtually.
Annual meetings are held for a number of different groups such as:

- Haemato-oncologists
- Haematopathologists
- Medical oncologists
- Hospital Pharmacists

Key contacts – Systemic Therapy Programme		
Name	**Role**	**Contact Details**
Tracy Folliard	Programme Manager	Tracy.folliard@cancercontrol.ie
Fiona Murphy	Project Manager	Fiona.murphy27@cancercontrol.ie
Patricia Heckmann	Assistant National Director	Patricia.heckmann@cancercontrol.ie

2 NCCP Cancer Drug Management Programme

The Cancer Drug Management Programme was established by the NCCP to develop and improve the care provided to patients receiving treatment with cancer drugs.

2.1 SACT Regimens

The HSE National Cancer Control Programme develops national Systemic Anti-Cancer Therapy (SACT) Regimens to support safe, evidence-based and cost-effective cancer treatment for all Irish cancer patients. These regimens are developed under the guidance of Medical Consultants involved in the treatment of patients with cancer with input from nursing staff, pharmacists and other healthcare professionals. These regimens underpin the National Cancer Information System (NCIS) and include specific indications for specific drugs. They do not direct care in the same manner as clinical practice guidelines.

The regimen development process is separate to the standard HSE reimbursement assessment process. The reimbursement status is included on the regimens for user convenience but this is not the primary intended purpose of the regimens. Details on the cancer drugs approved for reimbursement are available here. Providers of SACT services may submit regimens for consideration by completing the NCCP National SACT Regimen Request form, which is available to download as a word document from this webpage. This form and other comments or feedback can be emailed to oncologydrugs@cancercontrol.ie.

2.2 Drug Reimbursement Process

Since the implementation of the Irish Pharmaceutical Healthcare Agreement (IPHA) 2012 agreement between the Department of Health, HSE and the pharmaceutical industry, the Health (Pricing and Supply of Medical Goods) Act 2013 and the subsequent 2016 and 2021 IPHA agreement, there has been a standard assessment process in place for the consideration of HSE reimbursement of new drugs, and new indications for existing drugs. This assessment process ensures that there is transparency in the pricing and reimbursement application process and is intended to arrive at decisions on the funding of drugs that are clinically appropriate, fair, consistent and sustainable. All cancer drugs which have been approved for reimbursement since 2012 have gone through this process.

This process involves the company firstly submitting a horizon scan document for drugs for which pricing and/or reimbursement applications are expected to be made within the following 18 months. This ensures that projected budget impacts can be included for service planning and secure funding if the product is approved for reimbursement. Once a drug is licensed, the company then submit a pricing and reimbursement application to the HSE Corporate Pharmaceutical Unit (CPU).
At this point the HSE CPU may ask the National Centre for Pharmacoeconomics (NCPE) to rapidly review the pricing and reimbursement application to determine if there is a requirement for a health technology assessment (HTA) with regard to cost effectiveness and budget impact. A HTA will be commissioned if required.

The HSE drugs group consider the HTA assessment carried out by the NCPE and NCCP Technology Review Committee (TRC) recommendations in addition to other factors when deciding on recommendations regarding reimbursement approval to the HSE Executive Management team.
The HSE Executive Management Team are the final decision makers with regard to approval for reimbursement.

The NCCP website has a list of the cancer drugs approved for reimbursement, available here.
Queries with regard to the work of the CDMP can be sent to: Oncologydrugs@cancercontrol.ie

2.2.1 NCCP Technology Review Committee

- The NCCP TRC was established in March 2011 and is responsible for reviewing proposals received from industry or expert groups in Ireland for funding of new cancer drugs, or expanded indications for existing cancer drugs. The recommendations are based on the degree of clinical effectiveness, the acute and chronic toxicity and the cost effectiveness of the proposed technology. Recommendations from the NCCP TRC are brought to the HSE Drugs Group for prioritisation in a national context. The HSE Executive Management Team makes the final decision on funding for all new drugs/technologies.
- The NCCP Technology Review Committee (TRC) is an NCCP managed group.
- Members of the TRC include representatives from the following:
  - Irish Society of Medical Oncologists (ISMO)
  - Irish Haematologists Society (IHS)
  - National Centre for Pharmacoeconomics (NCPE)
  - Health Information Quality Authority (HIQA)
  - HSE Corporate Pharmacy Unit (CPU)
  - National Cancer Control Programme (NCCP).
- The NCCP TRC meetings are usually scheduled as a virtual meeting and documentation is circulated 2 weeks in advance of the meeting. Meeting frequency depends on the progress of the reimbursement assessment process but the maximum would be one a month.
- Information on the NCCP TRC is available on the website here.

If you have interest in finding out more about the work of the Cancer Drug Management Programme, please contact Oncologydrugs@cancercontrol.ie

Key contacts – Cancer Drug Management Programme		
Name	**Role**	**Contact Details**
Aishling McLoughlin	Chief I Pharmacist	Aishling.McLoughlin@cancercontrol.ie
Elizabeth Breen	Chief II Pharmacist	Elizabeth.breen@cancercontrol.ie
Margaret Triggs	Chief II Pharmacist	Margaret.triggs@cancercontrol.ie
Patricia Heckmann	Assistant National Director	Patricia.heckmann@cancercontrol.ie

3 Molecular Diagnostics Advisory Group

The National Cancer Strategy 2017 - 2026 acknowledged that an accurate pathological diagnosis was at the core of multidisciplinary management of any patient diagnosed with cancer but that there was largely a lack of direction in regard to molecular cancer diagnostics in Ireland. The strategy recognised that a mechanism was required to determine how well current testing is being performed, where testing should be performed, how effective the service is for patients and clinicians, when tests should be replaced and when new tests should be considered.
In 2017 the NCCP established the NCCP Molecular Diagnostics Advisory group, comprising of representatives from pathology, haemato-oncology, medical oncology and laboratory science, to ensure that the required molecular tests predictive for drug use are available in parallel to the HSE's reimbursement assessment process. This group was limited in scope to cancer molecular diagnostic tests predictive for drug use. The scope of this group has been extended to include molecular biomarkers for diagnosis, prognosis, disease monitoring, in addition to treatment options and treatment stratification. This work aligns with the HSE National Genetics and Genomics Strategy.
The group has developed a Framework for Decision Making for Tests in the Irish Molecular Pathology Service, available here, which outlines the decision making process to agree to appropriate tests ensuring molecular diagnostics for cancer is carried out in a coordinated and standardised way. This includes the development of a Test proposal form, available here. The Test Proposal Form should be completed by the referring clinical user in partnership with one or more local Molecular Pathology Laboratories where applicable. The form should be submitted to the NCCP Molecular Diagnostics Advisory Group for consideration by emailing completed forms to oncologydrugs@cancercontrol.ie.

A Framework for Precision Cancer Molecular Service in Ireland has been developed by the group and approved by the NCCP Executive Management Team. The recommended framework is broadly based on the model implemented by Norway which allows hospitals to self-designate their level and would allow step-wise progression for some hospitals in parallel with the development of capacity for comprehensive multi gene panel testing in designated Level 3 laboratories. This framework recommended the development of a Genomic Test Directory for Cancer and the group is now commencing work in this area.

There is a standard process in place for the HSE reimbursement of new drugs, and new indications for existing drugs. As one component within the standard HSE assessment pathway for reimbursement, the National Centre for Pharmacoeconomics (NCPE) is commissioned by the HSE to carry out a Health Technology Assessment (HTA). This considers the anticipated budget impact of each reimbursement application as well as many associated direct costs e.g. companion drugs, administration costs but there may also be a number of indirect costs to be considered e.g. the cost of testing a broad population for a particular molecular target to identify those who would benefit from the treatment in question. While the HTA may flag the associated molecular testing costs, approval for reimbursement does not include additional budget to cover the costs associated with the introduction of the companion molecular test.

To date the NCCP has engaged with prescribers and pathologists through specifically convened sub-groups of the NCCP Molecular Diagnostic Advisory group to ensure that the required molecular predictive tests are available in parallel to the HSE's reimbursement assessment process. The approach of the NCCP has been:

- to agree the testing pathway with Consultant Pathologists and Consultant Medical Oncologists /Consultant Haematologists (depending on the drug indication)
    - Hospitals may decide to make the test available locally, to utilise the services of another Irish hospital or to find a service abroad
    - Hospitals are advised of the need to include the cost/staffing resources of companion molecular diagnostic testing for future years in service planning
- to support laboratories in the validation of and set-up of new companion molecular diagnostic lab developed tests (LDT's) where LDTs are being developed
- to support the introduction of new testing costs, on a once off funding basis, between service planning cycles within the constraints of the NCCP budget.

This approach has been used to agree the testing pathways for

- PD-L1 testing across a number of different tumour types e.g. head & neck, lung, gastro-oesophageal to support prescribing of immunotherapy agents
- NTRK testing to support prescribing of larotrectinib
- Prescribing of parp inhibitors for HSE reimbursed indications in breast, ovarian and prostate cancer.

If you have interest in finding out more about NCCP Molecular / genomics, please contact Oncologydrugs@cancercontrol.ie.
Webpage is available here.

Key contacts – Molecular / Genomics		
Name	**Role**	**Contact Details**
Clare Meaney	Chief II Pharmacist	Clare.meaney@cancercontrol.ie
Patricia Heckmann	Assistant National Director	Patricia.heckmann@cancercontrol.ie

4 NCCP National Cancer Information System (NCIS) Programme

The National Cancer Information System (NCIS) is one of NCCP's key projects and a recommendation of the National Cancer Strategy 2017-2026. The goal of the NCIS project is to deliver a clinical information system to support the care of cancer patients (including the provision of SACT, Systemic Anti-Cancer Therapy, and recording of Tumour Conference (MDM) outcomes) across Ireland. The system is underpinned by a national regimen library based on the NCCP SACT regimens and a national drug file for SACT medications.

The NCIS project is sponsored by the Director of the NCCP, the HSE Chief Information Officer and the HSE Director of Acute Hospitals. Overall project oversight is provided by the NCIS Steering Group, which is chaired by the Director of the NCCP. Operational and clinical oversight, as well as project assurance, is provided by the multi-disciplinary NCIS Implementation Group. The Implementation Group ensures the interests of primary stakeholders, including end-users, are served during the configuration and implementation of NCIS. There is also an NCIS User Group where the end users share and discuss their use of the system. Interested users from sites that have commenced NCIS

implementation are invited to join the NCIS User Group. If you would like to know more about the NCIS Implementation Group or the NCIS User Group, please contact ncis@cancercontrol.ie.

The NCIS National Office, based in the NCCP, provides significant support to sites during the installation of NCIS, guiding local teams on the application of the system to local workflows. The multi-disciplinary team oversee the day-to-day business operations of the system, maintain ongoing communication with end users of NCIS through the NCIS User Group and manage all system changes, including regimen and drug file updates.

The NCIS implementation project includes all 26 hospitals delivering systemic cancer treatment nationally. The first site, St Luke's Hospital, Dublin, went live in May 2019, installation in 16 hospitals was completed by the end of 2023. The NCIS National office in coordination with local hospital implementation teams are working to plan and install the system in the remaining hospital sites.
If you have interest in finding out more about NCIS, please contact ncis@cancercontrol.ie

Key contacts – NCIS		
Name	**Role**	**Contact Details**
Nicola Newcombe	NCIS Programme Manager	Nicola.newcombe@cancercontrol.ie
Grant Carroll	Chief I Pharmacist	Grant.carroll@cancercontrol.ie
Patricia Heckmann	Assistant National Director	Patricia.heckmann@cancercontrol.ie

5 Abbreviations

ACU	Aseptic Compounding Unit
CAG	Clinical Advisory Group
CPU	Corporate Pharmaceutical Unit
DoH	Department of Health
HIPE	Hospital Inpatient Enquiry
HIQA	Health Information Quality Authority
HTA	Health Technology Assessment
IPHA	Irish Pharmaceutical Healthcare Agreement
IHS	Irish Haematologists Society
ISMO	Irish Society of Medical Oncologists
KPI	Key Performance Indicator
LDTs	Lab Developed Tests
MDT	Multidisciplinary Team
NCCP	National Cancer Control Programme
NCIS	National Cancer Information System
NCPE	National Centre for Pharmacoeconomics
NSP	National Service Plan
ODMS	Oncology Drugs Management Scheme
SACT	Systemic anti-cancer therapy
STP	Systemic Therapy Programme
TRC	Technology Review Committee