



HSE Strategy for the Procurement of Medicines in Acute & non-Acute Hospitals

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Introduction

The World Health Organisation defines pharmaceutical procurement as a complex process, which involves many steps, agencies, ministries and manufacturers (1). Irrespective of the model employed, to manage the procurement and distribution system, efficient procedures should be in place; to select the most cost-effective essential medicines to treat commonly encountered diseases, to quantify requirement needs, to pre-select potential suppliers; to manage procurement and delivery, to ensure good product quality and to monitor the performance of suppliers and the procurement system. Failure in any of these areas leads to lack of access to appropriate drugs and to waste.

The Organisation for Economic Co-operation and Development (OECD) cite minimising waste and optimising the value derived from expenditure on pharmaceuticals as critical to efficient and sustainable health systems (2). This includes the combination of supply and demand side policy levers that include ensuring value for money in selection and coverage, procurement and pricing of medicines; exploiting the potential of savings from generics and biosimilars; encouraging rational prescribing and use; and improving adherence to treatment. Ultimately, progress in reducing wasteful spending may be seen as not only a barometer of quality improvement, but also an ethical and financial imperative in the pursuit of more resilient and equitable health care systems.

An objective of the 2020 Pharmaceutical Strategy for Europe is to ensure that patients have access to affordable medicines and that health systems remain financially sustainable (3). The Strategy is patient-centred and aims to ensure the quality and safety of medicines, while boosting the sector's global competitiveness and ensuring supply chain continuity.

In 2014, the EU Procurement Directive 2014/24/EU was introduced which is applicable to medicines purchased by public funds (4). The Health Service Executive (HSE) is required to comply with the legislation therein where the health service directly purchases the medicines i.e. medicines used in acute and non-acute hospitals (5).

The National Pharmaceutical Procurement Support Team (NPPST) was established in 2019, with clinical leadership provided by a Chief II Pharmacist, Acute Hospital Drug Management Programme (AHDMP) and procurement expertise by Assistant Head of Sourcing and Contracting, HSE Procurement. The purpose of the NPPST is to;

- Provide advice and support to hospital pharmacists and procurement personnel on the procurement and contractual knowledge required to achieve legally compliant procurement of medicines
- Operationalise the HSE Strategy for the procurement of medicines in acute and non-acute hospitals
- Manage the day-to-day operations of the Dynamic Purchasing System (DPS). The DPS is the preferred procurement process for medicines, to facilitate compliance where there are multiple suppliers.
- Update and maintain the Sole Source List (SSL) of medicines through twice a year engagement with the marketplace. This process is used to confirm medicines with a single supplier through the publication of the SSL. A Pharmacy department may then

purchase these medicines and demonstrates compliance with the National / EU Procurement Legislation.

- Development of standardised tender documents for use by acute and non-acute hospitals. This reduces duplication of work and minimises inter-tender variation, which facilitates ready completion of the tender documents by suppliers. This standardisation aims to reduce the number of administrative processes that add no value and might dis-encourage a smaller supplier from participating in a tender.
- Regular engagement with pharmaceutical suppliers to understand emerging market trend and to provide support and feedback as requested.

The NPPST are supported by the National Pharmaceutical Procurement Expert Advisory Group (NPPEAG), with membership comprised of pharmacist representatives from acute and non-acute hospitals providing subject matter expertise.

The HSE Strategy for the procurement of medicines in acute and non-acute hospitals is to ensure legislatively compliant, safe and cost effective procurement of medicines. The procurement of medicines is clinically led by pharmacy, in collaboration with colleagues in finance, procurement and relevant clinical areas.

Vision

The vision for the purchase and supply of medicines within the acute & non-acute hospitals is clinically led, enabling a healthy market where products of good quality are available at affordable and transparent prices on a sustainable and timely basis.

HSE Procurement holds key values in managing all procurement related transactions. (6) In addition, those engaging in procurement decisions for medicines are expected to espouse the following;

- Preserve the highest standard of integrity, fairness, efficacy and confidentiality in all dealings with suppliers or potential suppliers
- Meet the requirements of customers and deliver medicines safely to a patient when they need them
- Optimise value while enabling effective outcomes for patients
- Commitment to good business conduct and compliance with the relevant procurement procedures set out in legislation (EU procurement Directives), HSE's National Financial Regulations and Medicinal Products supply legislation (7)
- Demonstrate probity



Current Landscape

Procurement of medicines is an operations activity within the HSE. Ultimately, the Health Region Chief Executive Officer (CEO) or designate (e.g. Hospital Chief Pharmacist / Pharmacy Executive Manager) in each hospital is responsible for the procurement of medicines at the level of their individual hospital and for ensuring that this activity complies with Medicinal Products supply legislation and National/EU Procurement legislation. The majority of medicines are procured directly by acute & non-acute Hospitals and are funded through individual hospital budgets. Certain other medicines are compliantly procured at a national level e.g. vaccines. Acute & non-acute hospitals drug expenditure accounts for approximately 20% of the overall HSE spend on medicines.

Manufacturers and wholesalers regard each pharmacy department as the 'customer' rather than the HSE as a whole. The historical practice of operating as independent purchasing units limited the value achieved when purchasing medicines, as limited supplier discounts were secured. The more recent trend towards aggregating volumes through regional tenders is noted and commended. Introduction of the Hospital Medicines Management System (HMMS) improves transparency in medicine pricing. Through common "expense code categories" with the Integrated Financial Management System (IFMS) a full view of medicines purchase and supply will be achieved.

Competition-inducing policy measures should be tailored to the respective care settings (community vs hospital-procured) and take into account issues of long-term supply certainty. The overall attainment value for the HSE is improved when hospitals undertake competitive procurement processes for medicines. The evidence suggests that direct regulation of generic prices, for example, by imposing fixed discounts relative to originator products (or using reference prices) is less effective in reducing prices than (where the health system is the direct purchaser of the medicines) the use of competitive mechanisms such as tendering or negotiation (2).

The experience since the introduction of the NPPST is that hospital pharmacy departments collaborating in a procurement processes through the DPS with aggregating their medicine requirements achieves greater supplier participation and increased cost efficiencies. Since 2019, an increasing number of hospitals have partaken in local or regional competitive procurement processes for their medicine requirements.

The framework for pricing of medicines was established under the Framework Agreements on the Supply and Pricing of Medicines (8; 9). The Framework Agreements set the maximum price to be paid and additional reductions in price can be offered to hospitals. The experience to date is that the pricing negotiations undertaken by the HSE Corporate Pharmaceutical Unit (CPU) achieves best value for SSL medicines and the suppliers do not exhibit a willingness to provide additional discounts at hospital level. The absence of supply competition for medicines listed under the SSL, means that tendering is not an effective approach for achieving value in the pricing of these medicines. Instead central price negotiation at the point of entry into the Irish public health system by the CPU provides the leverage required to secure value for the purchase of these medicines.

There are free of charge (FOC) medicines schemes offered by pharmaceutical companies that are managed by individual hospitals. In this context, a FOC medicine scheme is defined as an arrangement where a licensed or exempt medicinal product (EMP) is provided FOC by the pharmaceutical company to an individual patient or an identified cohort of patients, often for a finite period of time in advance of national pricing /reimbursement approval by the HSE. The Irish Pharmaceutical Healthcare Association (IPHA) policy around supply of FOC medicines, where unmet clinical need is the rationale provided, requires the pharmaceutical company to offer the medicine only following a request from the patients treating physician (10). It is evident that the supply of medicines in this matter falls outside of purchase agreements but may impact on future purchase arrangements and decisions in relation to reimbursement of medicines. It is expected that hospitals will have carefully considered the implications of these arrangements. In advance of agreeing a FOC medicine schemes, confirmation in writing should be sought that the individual pharmaceutical providers intending to apply for reimbursement under the national procedures and which details the proposed arrangements for continued supply of the medicine to patients following drug approval or non-approval by the HSE.

The HSE Senior Leadership Team (SLT) retains the sole authority to make financial commitments on behalf of the HSE in relation to the pricing and reimbursement of new medicines or new uses of existing medicines. The HSE SLT decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

Scope

The organisational scope of this Strategy is acute and non-acute hospitals.

The scope of this Strategy includes:

- Update and maintain this Strategy document outlining the requirement for the compliant procurement of medicines to enable cost effective purchase of medicines by the HSE in acute & non-acute hospitals, including both voluntary and statutory hospitals. The NPPEAG with membership from pharmacist representatives from acute and non-acute hospitals provides subject matter expertise, informing the work and decision making of the NPPST.
- Continue to operationalise the appropriate infrastructure to support a national procurement model (e.g. DPS).
- For the purpose of this procurement strategy, all medicines purchased by acute & non-acute hospitals include but not limited to:
 - Dublin and North East Health Region
 - Dublin and Midlands Health Region
 - Dublin and South East Health Region
 - Mid-West Health Region
 - South West Health Region
 - West and North West Health Region
 - Section 38 and 39 Agencies

Outside the Scope

- Revision of the current model of pharmacy-led procurement of medicines.
- Medicines supplied under the High Tech Arrangement within the community setting or reimbursed under this scheme are outside the scope of this strategy. The purchase of drugs prescribed under the High Tech Arrangement is under the remit of the Primary Care Reimbursement Service (PCRS). The exception is where a high technology drug is purchased and paid for by the hospital for use during an inpatient hospital stay. These will be included in the PMC/DPS¹ system as hospital pharmacy departments will be required to procure in these situations.

Key Stakeholders and Governance

This Strategy document aims to address compliance with EU procurement legislation, safe and cost effective procurement of medicines and implemented in acute & non-acute hospital pharmacy departments. Further details on the governance structure and the main stakeholders in this strategy is summarised in appendix 1 and 2 respectively.

Strategy Objectives

1. To ensure the continued clinical pharmacy leadership and expert input by hospital pharmacists in the procurement of medicines supported by colleagues in finance, procurement and relevant clinical areas.
2. To operationalise an appropriate model for the procurement of hospital medicines including;
 - a. Nationally coordinated electronic DPS system for hospital medicines to enable cost effective purchase of medicines.
 - b. For medicines that can only be provided from a single source, publication of a Preliminary Market Consultant (PMC) for the supply of SSL for authorised medicines, twice a year.
 - c. To ensure any procurement model considers the legislative requirements as laid out in EU Procurement Directive 2014/24/EU, national requirements as described in the National Financial Regulations and national commercial partnership agreements such as the IPHA and Medicines for Ireland (MFI) Agreements on the supply and pricing of medicines.
3. To promote patient safety through introduction of a procurement strategy by;
 - a. Purchasing medication safely through reputable suppliers.
 - b. Ensuring appropriate review of labelling and packaging requirements and suitability of delivery device when applicable and when there is potential to influence patient safety.

¹ PMC: Preliminary Market Consultation
DPS: Dynamic Purchasing System

4. Operationalise a robust mechanism for the HSE to use to obtain competitive prices for medicines while ensuring that Ireland retains a competitive, sustainable marketplace for pharmaceutical companies. Strategies employed to ensure this balance is maintained include:
 - a. Aggregating demand within and across hospitals where appropriate to enhance the purchasing power of the HSE and formalising these supply arrangements in the form of a contract allowing hospitals to participate in tendering at a local, regional or national level. Regional tenders may align to clinical networks or to Health Region geographical areas reflecting local clinical care arrangements e.g. Hub and Spoke cancer networks.
 - b. Include contractual obligation for suppliers of medicines to promote continuity of supply and effectively manage the supply chain.
 - c. Horizon scanning to ensure that contracts are not awarded just before a significant change in the market price, for example, a few months prior to patent expiry.
 - d. Foresee shortages by obligating minimum stockholding of medicines in Ireland by suppliers.
 - e. To work closely with the Health Protection and Regulatory Authority (HPRA) Medicines Shortages Unit to maximise the communication and to work towards pragmatic solutions to medication supply challenges.
 - f. Consideration for homecare services where applicable to support adherence.
5. To positively influence, purchasing and supply of medicines by acute & non-acute hospitals in accordance with legislation by assisting pharmacists operating within acute & non-acute hospitals with the necessary training and infrastructure to procure within the confines of the EU legislation. Appropriate infrastructure includes robust electronic mechanisms of recording of medicine purchase and supply via the Hospital Medicines Management System (HMMS).
6. To ensure the successful compliance with the procurement legislation through training and communication with relevant stakeholders.

Regulation for public tenders in relation to procurement of medicines in hospitals

The direct purchase of medicines by hospitals is a public contract subject to the EU Procurement Directive (4). Therefore, assuming that the cumulative value of the medicines purchased by a hospital (or a group of hospitals acting collaboratively) exceeds the threshold for the application of the Procurement Directive, (currently €221,000 exclusive of VAT), the hospital must fully comply with the Procurement Directive when procuring these medicines.

The National Financial Regulation (B1 Procurement) requires that a formal tendering procedure should be used when procuring goods with a value between €50,000 and the threshold for the EU Procurement Directive of €221,000, see table 1 (5). The cumulative value of the medicines purchased for a hospital/hospital group/nationally (depending on agreed strategy) which exceed the threshold of €50,000 should be procured either via compliant negotiation² process or via the tendering process. The calculation of the estimated value of a procurement process is based on the total amount payable for the requirement(s) over the contract period³, net of VAT, as estimated by the hospital/hospital group/nationally.

It is recognised that it may not be possible for all medicines to be procured under tender. Reasons for this include:

- Medicine(s) included on the SSL
- No bid received
- Bid received but the medicine fails on quality
- Supplier withdraws their bid or does not accept an award
- Supplier terminates contract because of production or other issues
- The tender is not awarded as there is no economic advantage e.g. a supplier may offer 2% discount through direct supply in response to a tender but there is a 10% discount available through a wholesaler
- There is a confidential patient access scheme (PAS) agreed with the HSECPU
- A derogation applies under the Directive

² Negotiated process may be used where it has been previously established that only a single possible supplier of the medicines exists.

³ It will be open to each hospital to determine the most appropriate contract period to meet their needs.

Table 1: National Financial Regulation (B1 Procurement) (5)

Value of contract (exclusive of VAT)	Tendering process type
Less than €5,000	<ul style="list-style-type: none"> Can be awarded on the basis of one written quote but it is preferred if you get three quotes by email.
€5,000 – €50,000	<ul style="list-style-type: none"> Can be awarded on the basis of responses to written specifications (such as sent by email) to at least three suppliers or service providers or Can be awarded on the basis of responses to at least three quotations obtained using the electronic request for quotes facility on eTenders (currently called quick quotes). The quick quotes facility on eTenders allows contracting authorities to search for appropriate suppliers using CPV (Common Procurement Vocabulary) codes which match their particular procurement needs and may facilitate this process or Can be awarded on the basis of a formal tendering process by advertising on eTenders.
€50,000 and up to the value of the EU thresholds	<ul style="list-style-type: none"> Must be advertised as part of a formal tendering process on eTenders in line with DPER Circular 05/2023 Evaluation should be done by HSE Procurement with the budget holder in the local area.

Requirement for advertising in the Official Journal of the European Union (OJEU)

To comply with the EU procurement directive, the purchase of medicines for hospitals must be advertised in the OJEU in accordance with normal EU procurement procedures. The NPPST support this advertisement on behalf of hospitals. The responses from the marketplace will indicate whether one of the limited number of exemptions, which facilitate direct negotiation, can be availed of or whether a subsequent competitive process (i.e. DPS mini-competition) will be required. In either event, a formal contract award notice must be published in the OJEU in order to ensure compliance.

Preliminary Market Consultation (PMC) - Sole Suppliers

EU Procurement legislation permits a contracting authority to negotiate directly with a “sole supplier” to procure a “sole supplier” product outside the DPS using the exemption available for the negotiated procedure under Article 32 of the Directive. “Sole supplier” medicines will be identified by HSE. However, it is still necessary to interact with the market place to identify bona fide “sole suppliers”. “Preliminary Market Consultation (PMC)” outlines how the NPPST will engage with the market place twice a year to confirm sole suppliers of medicines, thereby enabling a hospital pharmacy department to conduct compliant negotiations directly with that supplier.

Dynamic Purchasing System (DPS) – Multiple Suppliers

The DPS acts as a procurement tool, to establish and maintain a national qualified list of suppliers of medicines eligible for participation in subsequent mini-competitions. Hospitals utilise this tool to conduct mini-competitions for medicines for where it has not been established that there is only one possible supplier. The DPS facilitates the demonstration by suppliers of compliance with regulatory and medicines quality standards as part of their application to the DPS. The DPS allows suppliers to apply and to be added to the DPS at any stage throughout the lifetime of the DPS.

According to EU Directive 2014/24, contracts should be awarded based on the most economically advantageous tender (MEAT) criteria, which allows use of both price, and non-price criteria (e.g. criteria on security of supply). The procurement of medicines with a loss of exclusivity through tender processes by acute and non-acute hospitals, supported by the NPPST, utilising the recommended procurement tool, the DPS is based on MEAT criteria.

In 2022, the European Commission published the '*Study on Best Practice in the Public Procurement of Medicines*', contract award is based on MEAT criteria and included the following information reflecting practice in Ireland; '*Security of supply is used as an award criterion together with other criteria in some countries (Belgium, Bulgaria, Denmark, France, Iceland, Ireland, Latvia, Netherlands, Norway, Spain, Sweden).*' (11)

Mini-competitions under the DPS can be conducted at a local, regional and national level to allow for aggregated demand and to maximise the purchasing power of the HSE. Additional benefits of this approach includes allowing hospitals to engage in compliant procurement processes to select suppliers and prices for the hospital's medication requirements with the assistance of pro-forma tender documents, SOP's and standard contract agreements to ensure transparent, compliant purchasing of medicines. Competitions under the DPS will have a shorter timescale to award of contract as the administrative burden under open tender procedures will be reduced for both the suppliers and the hospital.

The Health Region REO or designate (e.g. Hospital Chief Pharmacist / Pharmacy Executive Manager) are responsible for implementation of the contracts after award when purchasing medicines for relevant hospitals.

Management of Supply Chain

The HPRA framework on medicinal product shortages was developed to address the issue of medicine shortages in Ireland. The HPRA outlines its role in medicine shortages as co-ordination of a response to medicines shortage across stakeholders to mitigate the impact as much as possible. It has a number of regulatory tools and strategies to assist stakeholders to prevent or minimise the impact of medicine shortages (11).

Possible strategies to mitigate medicine product shortages would be to include an obligation for minimum stockholding of medicines in Ireland by suppliers in the contract agreement.

Purchasing for Safety

Patient safety underpins this Strategy, which

- Seeks continued availability and access to safe medication for patients while
- Optimising the price for the health service and
- Supporting procurement through reputable supply chains

The DPS system provides a procurement tool for hospitals to continue to ensure safe purchasing of high quality medication through reputable suppliers that is clinically led by the hospital pharmacy departments. It also continues to ensure patient safety through labelling and packaging requirements are met. The necessity for hospitals to purchase exempt medicinal products (EMP) is not expected to decrease. Exempt medicinal products will continue to be procured by the hospital pharmacy departments facilitated through the NPPST to ensure compliance with legislative requirements.

Enabling Infrastructure

Infrastructure within a robust procurement system to support the successful implementation of the EU procurement legislation and patient safety is necessary; infrastructure includes electronic mechanisms for recording medicines purchase and supply via a standardised medicines management system such as HMMS that interfaces to e-prescribing and financial systems. This will assist with compliance to financial regulations and support development of data reporting at a hospital, regional and national level.

The introduction of the standardised HMMS Drug file will provide a consistent approach to the identification and coding of medicines, which will support medicines management, prescribing and procurement.

Training and Communication

Training and communication are crucial to ensure the ongoing successful implementation of the recommendations for the compliant procurement of medicines. Support materials (e.g. sample tender document) are provided by the NPPST to underpin procurement by hospital pharmacists compliant with the Medicinal Products supply legislation, National Financial Regulations and EU Procurement Directives.

Regular engagement with stakeholders including hospital pharmacists and procurement personnel working in acute & non-acute hospitals and pharmaceutical suppliers is an ongoing requirement.



Conclusion

It is the responsibility of the NPPST to implement and operationalise robust mechanisms to assist the HSE to obtain competitive prices for medicines, whilst ensuring that Ireland retains a competitive, sustainable market place for the suppliers of medicines. The utilisation of structured procurement processes coupled with greater aggregation of demand for medicines will maximise purchasing power of hospitals increasing the likelihood of enhanced supplier discounts. In addition, the supply arrangements will be formalised in the form of a signed contract agreement with the supplier. The strategic approach of the procurement of medicines is clinically led by pharmacy staff and continues to provide and deliver commercially effective, legislatively compliant processes by acute & non-acute hospitals.

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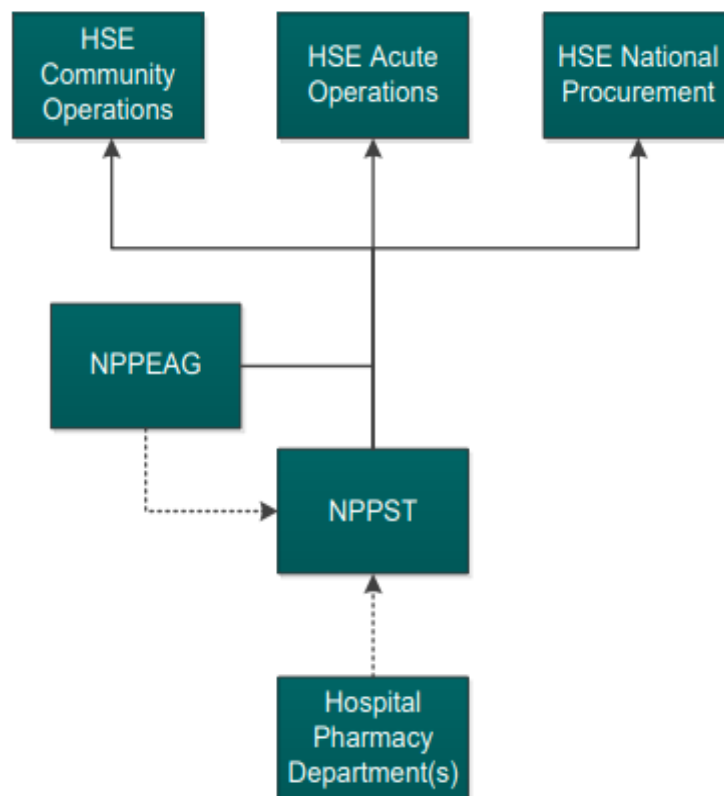
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Appendix 1: Governance Structure





Appendix 2: Key Stakeholders

Health Service Executive (HSE)

Hospitals included in this strategy framework include all acute & non-acute hospitals include but not limited to:

- Dublin and North East Health Region Dublin and Midlands Health Region
- Dublin and South East Health Region
- Mid-West Health Region
- South West Health Region
- West and North West Health Region
- Section 38 and 39 Agencies

The stakeholders within the hospitals include hospital Chief pharmacists / Pharmacy Executive Manager, Chief Executive Officers and Hospital Managers, Chief Finance Officers, and Procurement Officers.

Acute Hospital Drug Management Programme (AHDMP)

The AHDMP was established in 2016. The role of the AHDMP is to support Medicine Management initiatives within the acute hospital setting, ensure the full benefits of the Pharma Industry agreements for acute hospital services are realised effectively in the best interest of patients and services. AHDMP improve transparency around pricing, volume and cost of drugs and medicine using data analytics and engagement with pharmacy and procurement leads.

Corporate Pharmaceutical Unit (CPU)

All new medicines are introduced to the public health service through the national pricing and reimbursement application process. On behalf of the HSE, the HSE Corporate Pharmaceutical Unit (CPU) leads the assessment process for all new medicines and national price negotiations. National agreements are reached on the final negotiated ex-factory price for medicines supplied to the public health service.

Department of Health

The Department of Health's main role is to support the Minister and Ministers of State in the development and implementation of policy for the health services delivered by the HSE.

Medicines Management Programme (MMP)

The HSE multi-disciplinary Medicines Management Programme works with the National Medicines Information Centre and the National Centre for Pharmacoeconomics in collaboration with the HSE-PCRS to provide sustained national leadership relating to issues



such as the quality of medicines management process, access to medicines and overall expenditure on medicines.

HSE National Drugs Management Programme (NDMP)

In 2016, the HSE NDMP was established with the view to ensuring equitable access to medicines for patients, along with, achieving value for the taxpayer through cost-effective and compliant purchase of medicines by the HSE. The NDMP is not active since 2019.

HSE Procurement

HSE Procurement is the business division of the Health Service Executive (HSE) and provides high quality business services and solutions across the Irish public health sector.

National Cancer Control Programme (NCCP)

The NCCP was established in 2007 to ensure that all elements of national cancer policy are delivered to the maximum possible extent. The NCCP was set up to reorganise the way cancer care is delivered so that our cancer survival rates would compare more favourably with the best in Europe and the rest of the world. They produce guidance on the management of systemic anti-cancer treatment (SACT) and provide reimbursement of anti-cancer medicines via a central reimbursement scheme (ODMS) which is administered by the PCRS. In addition, the NCCP provide some direct payments for medicines to the hospitals which is administered by the NCCP.

National Pharmaceutical Expert Advisory Group (NPPEAG)

The membership of the NPPEAG are senior frontline pharmacy leaders in acute and non-acute hospitals. They provide expert advice and subject matter expertise, with oversight of updates of new suppliers to the National DPS and updates to the SSL referred to by the NPPST.

National Pharmaceutical Procurement Support Team (NPPST)

The NPPST are HSE Pharmacy and HSE Procurement representatives operationalise this Strategy and available to advise and support hospital pharmacists and procurement personnel on the procurement of medicines. The primary goal of the NPPST is to continue to support Pharmacy lead model of procurement of medicines.

Primary Care Reimbursement Scheme (PCRS)

The HSE PCRS provides a range of information and transaction services online to allow reimbursement of medications and medical devices under different schemes. Medicines reimbursed through the PCRS include the High Tech Medicines delivered in the community



setting, National Hepatitis C Treatment Programme and Oncology Drug Management System for systemic anti-cancer treatment (SACT) in a hospital setting.

Regulatory Bodies

Regulatory bodies including Health Products Regulatory Authority (HPRA) aim to protect and enhance public health by regulating medicines, medical devices and other health products. HPRA implemented the medicinal product shortages framework to minimise the vulnerability of supply in the market due to drug shortages (11).

The Health Information and Quality Authority (HIQA) also provide medication oversight and advice with their 'Guide to the HIQA's Medication Safety Monitoring Programme' in acute & non-acute Hospitals and regular inspections. (12)

Wholesalers and Suppliers

Hospitals use a large number of wholesalers and suppliers to purchase medicines for their individual hospitals including compounding manufacturers who supply reconstituted medication and exempt medicinal product wholesalers.