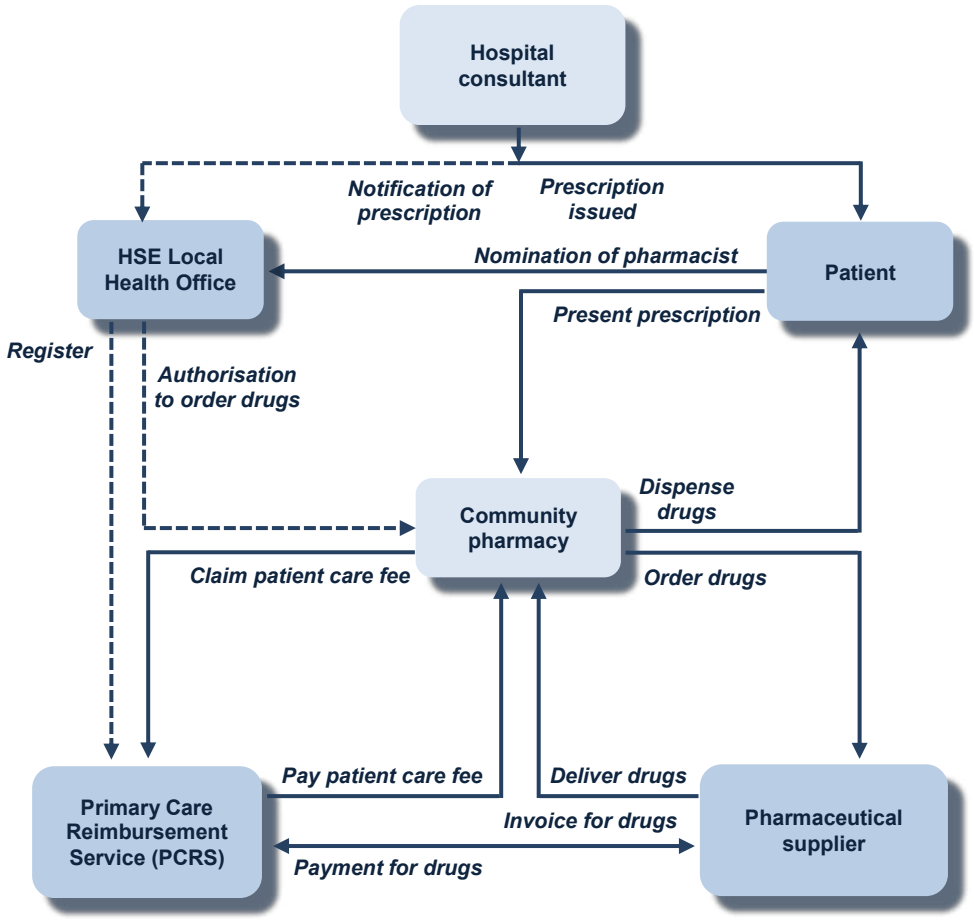
21 Control Over the Supply of High Tech Drugs and Medicines

21.1 The Health Service Executive (HSE) has special arrangements in place for the supply and dispensing of 'high tech' drugs to patients through community pharmacies.[1] Examples of the types of medicines available under those arrangements are anti-rejection drugs for transplant patients and chemotherapy drugs. While the arrangements in place do not constitute a formal payments scheme, they have been termed the high tech drugs scheme in HSE documentation. That term is used in this report, for convenience.

21.2 The high tech drugs scheme is administered by the HSE through the Primary Care Re-imbursement Service (PCRS) and the HSE's local health offices. Payments under the scheme comprise payments to pharmaceutical suppliers[2] and to community pharmacies.[3] The HSE pays pharmaceutical suppliers directly for the drugs and medicines and the community pharmacies receive a monthly patient care fee for overseeing the treatment. An overview of the scheme is presented in Figure 21.1.

Figure 21.1 Overview of High Tech Drugs Scheme



Source: Office of the Comptroller and Auditor General

1 The Health (Pricing and Supply of Medical Goods) Act 2013 sets out the statutory procedures governing the supply, re-imbursement and pricing of high tech drugs and medicines.

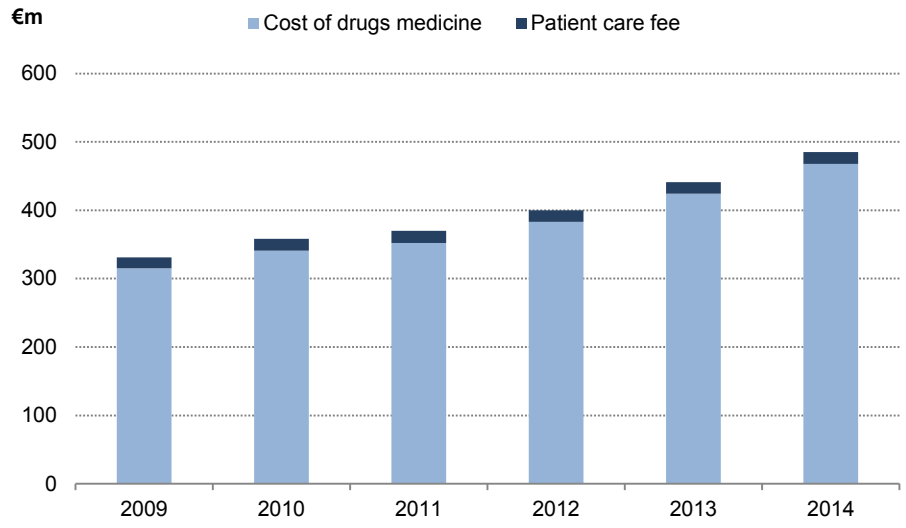
2 Authorised under SI No. 538 of 2007 Medicinal Products (Control of Wholesale Distribution) Regulations 2007.

3 Community pharmacy contractor agreement (excludes pharmacies operating in a hospital, nursing home or similar institution).

Expenditure on High Tech Drugs

21.3 Expenditure on the scheme was €485 million in 2014, representing an almost 50% increase when compared with 2009 (see Figure 21.2). While the patient care fee has remained relatively stable at around €17 million a year, expenditure on drugs and medicines has increased from €315 million in 2009 to €468 million in 2014.

Figure 21.2 High Tech Drug Scheme expenditure, 2009 to 2014



Source: Health Service Executive performance reports

21.4 The scheme is operated by community pharmacies who order the drugs and medicines directly from pharmaceutical suppliers and dispense to the patient. The value of stock on hand at pharmacies at the end of each year has increased in line with the increases in expenditure on the scheme. As at 31 December 2014, the value of stock held in community pharmacies was just under €45 million.

Focus of this Examination

21.5 The HSE incurs significant expenditure in relation to the provision of high tech drugs and medicines. In addition, the value of stocks held by pharmacies at any point in time is significant. This report sets out the results of an examination of the operation of the high tech drugs scheme carried out as part of the audit of the financial statements of the HSE for the 2014 year of account.

21.6 The examination focused on reviewing the controls in place over

- the ordering and dispensing of high tech drugs and medicines through community pharmacies
- the payments made to the community pharmacies and pharmaceutical suppliers
- the stock held by community pharmacies on behalf of the HSE.

21.7 This report does not examine the process by which high tech drugs and medicines are approved or the prices agreed for re-imbursement under the scheme.

Supply of High Tech Drugs and Medicines

21.8 A patient who, on discharge from a hospital, is prescribed one or more high tech drugs or medicines must nominate a community pharmacy where they propose to obtain the drugs or medicines. The local health office then advises the nominated community pharmacy of authorisation to supply those high tech drugs and medicines.

21.9 The nominated pharmacy orders the required high tech drugs and medicines directly from a pharmaceutical supplier. The HSE does not set a limit on what a pharmacy may order – the pharmacy is expected to anticipate the requirements of their patients and have available the necessary drugs and medicines for dispensing as required.

21.10 All of the drugs and medicines ordered by the pharmacy may not be used where, for instance

- a patient may not need the drug or medicine held by the pharmacy due to a change in their prescription during treatment, or due to the death of the patient, or
- a patient decides to present to a pharmacy, other than their nominated pharmacy, with a prescription form for high tech drugs or medicines and the patient is facilitated by that pharmacy.

21.11 Unless the pharmacy has another patient requiring the original drug or medicine ordered, these circumstances can give rise to excess stocks of high tech drugs and medicines being held by a community pharmacy, and (possible) destruction of such excess stocks.

Transfers between Community Pharmacies

21.12 Pharmacies are restricted under the Retail Pharmacy Businesses Regulations[1] in the transfer of medicinal products to another community pharmacy. The regulations permit inter-pharmacy exchange of medical products only where necessary to meet the immediate prescription needs of an individual patient. The regulations also provide that a detailed documented audit trail of any such exchanges should be maintained.

Returns to Pharmaceutical Suppliers

21.13 The HSE noted that legally, it is unable to intervene to transfer stock between pharmacies without a wholesaler license in its own right. The only opportunity therefore available to the HSE is for a pharmacy with excess stocks to return the drugs and medicines to the supplier for redistribution to another pharmacy through the supplier network.

21.14 The return of medicinal products is governed under EU regulations. The regulations have been codified by the Health Products Regulatory Authority[2] in a guide to suppliers in relation to the distribution of medicinal products.[3] The guide describes the action to be taken when medicinal products are returned for commercial reasons, for example, where the supplier has delivered the incorrect product or the pharmacy has ordered the product in error.

1 SI No. 488 of 2008

2 The Health Products Regulatory Authority (formerly the Irish Medicines Board) is the State entity responsible for regulating medicines, medical devices and health products in Ireland.

3 Guide to good distribution practice of medicinal products for human use, 10 April 2014. Based on European Commission guidelines of 5 November 2013 (2013/C 343/01).

21.15 The guide notes that products should normally be returned to the supplier within a ten day time frame of the pharmacy having received the drugs and medicines. It notes that there may be some exceptional circumstances whereby medicinal products may be returned outside the time frame, for example, where a small number of packs of medicinal products had been ordered to meet the anticipated needs of a patient to ensure continuity of treatment, but the patient's medication is suddenly changed or no longer required.

21.16 Where such deviations from the ten day time frame occur, a risk assessment must be performed by the supplier and justification for the stock return must be fully documented.

- The responsible person (an employee of the supplier) must approve each exception individually for return to saleable stock.
- The supplier must ensure that the correct storage conditions have been maintained during the period the product was outside their control.
- Special care must be exercised with the return of products requiring storage at low temperatures. In these cases, the supplier must have documented evidence available for review confirming that the product was maintained within the cold chain for the entire time during which it was outside of its control.
- A register or log of returns should be in place which should include all product details and reason for return.

21.17 In June 2013, the HSE sought to embed a returns system with the pharmaceutical suppliers in respect of non-refrigerated high tech stock no longer required. This excluded opened/partial packs, expired stock or stock within four months of expiry.

21.18 The HSE has stated that some suppliers co-operated with the returns system, resulting in returns of just over €1.4 million. However, a number of suppliers would not co-operate with the initiative and the HSE stated that it is proposing to address this issue in future agreements negotiated with the Irish Pharmaceutical Healthcare Association.

Payments to Community Pharmacies

21.19 Patients receiving care and treatment under the high tech drugs scheme will normally have complex medical needs. The scheme operates as a patient-specific care and treatment programme. Accordingly, the nominated pharmacy is paid a monthly patient care fee[1] in respect of registered patients, as follows.

- A patient care fee of €62.03 per month is payable to the community pharmacy nominated by a patient under the scheme where drugs and medicines prescribed under the scheme were dispensed in the relevant month.
- A reduced fee of €31.02 per month (up to a maximum of three consecutive months) is payable in relation to periods where drugs and medicines prescribed under the scheme are not dispensed. This recognises that while the patient may not be in receipt of drugs, there is a need for ongoing care and monitoring by the pharmacist.

21.20 A high tech prescription claim form (with details of the type and quantity of high tech drugs and medicines dispensed) is completed each time drugs are dispensed to a patient registered under the scheme. This form is also signed by the patient (or a person acting on their behalf) confirming receipt of the medication.

1 SI No. 279 of 2013

21.21 Each month, the pharmacy sends the high tech prescription claim forms to the HSE for re-imbursement of the patient care fee.

Payments to Pharmaceutical Suppliers

21.22 Pharmaceutical suppliers submit their invoices to the HSE for payment on a monthly basis. The invoices contain details of the pharmacy the drug was delivered to, the drug code, quantity delivered and the price of the drug.

21.23 The standard controls in relation to the payment of invoices are that the purchaser ensures that it is paying the price agreed at the time of purchase and that it is paying for goods actually received. Such controls are set out in the HSE's National Financial Regulations, as follows.

- Purchasing – the creation of a purchase order is an important control since it provides a permanent record of what was ordered and the price agreed at the time the order was placed.
- Receipting – a key control within the receiving process is to ensure that the quantity and quality of goods specified have been satisfactorily delivered to meet the customer requirements.
- Payment – payment of invoices should only occur after proper sign-off of the satisfactory receipt of goods, services or works.

Agreement of Invoice Price and Purchase Order Price

21.24 The HSE noted that there have been two price reductions for drugs reimbursable under the high tech drugs scheme, on 1 March 2011 and on 20 June 2011. The suppliers have not reflected these agreed price reductions in their billing systems. As a result, the HSE amends the amounts invoiced by reference to the reduced prices recorded on the HSE's own systems.

21.25 Pharmaceutical suppliers submit details of their invoices to the HSE electronically. These files are uploaded to the HSE systems where the drug code and quantity details are linked to the price recorded on the system, thus calculating the amount due for payment.

21.26 As part of this examination, the five highest payments made by the HSE to the pharmaceutical suppliers in July 2014 were reviewed. While suppliers had submitted invoices totalling €31.6 million, the HSE reimbursed suppliers in line with the price reductions agreed and suppliers were reimbursed to the value of €29.7 million – a 6% reduction on the invoiced amount.

Control over Receipt of Drugs and Medicines

21.27 The drugs and medicines are sent from the supplier directly to the pharmacy. Where a pharmacy is claiming the higher patient care fee in relation to patients where drugs and medicines have been dispensed in the month, the pharmacy attaches a copy of the delivery docket (received from the supplier when the goods were delivered) and highlights the relevant entry. The HSE consider that this provides evidence that the pharmacy took delivery of this drug from a supplier.

21.28 However, one delivery docket may be used as evidence of delivery in relation to multiple claims. The fact that the delivery docket is copied and used multiple times reduces the effectiveness of this control. It is not clear how the pharmacist would establish which delivery docket related to the drugs and medicines dispensed in an individual claim.

21.29 In addition, the pharmacy has only to supply evidence that drugs and medicines were dispensed once in the month in order to claim the dispensing patient care fee. There is no requirement or incentive for the pharmacy to provide details of further drugs dispensed to that patient in the month. As a result, the details of drugs and medicines dispensed included on the patient claim may be incomplete.

Verification and Compliance Checks

21.30 On a monthly basis, the HSE carries out a number of post-payment desk-based verification and compliance checks in order to monitor the accuracy of claims by pharmacies, dentists and general practitioners.

21.31 One of the verification checks includes examination of claims submitted by ten pharmacists each month. The verification exercise includes two checks.

- The patient care fee claimed is examined. Where the higher patient fee is claimed, the HSE seeks evidence that relevant drugs were dispensed. The pharmacy forwards a copy of the form signed by the patient confirming receipt of the medication.
- Details on delivery dockets attached to the patient claim fee are matched against supplier invoices.

21.32 The HSE maintain a control sheet in relation to the desk-based reviews conducted. This records the number of dispensing dockets (signed by the patient) and the number of copy delivery dockets attached to the claims examined. In the case of each pharmacy, it notes the number of discrepancies identified and records whether the discrepancies have been resolved.

21.33 In relation to inspections conducted during 2014, the control sheet recorded that discrepancies were identified in relation to 62 of the 119 pharmacies examined. A total of 219 discrepancies were identified. At September 2015, 12 discrepancies in relation to three pharmacies had not been resolved. In each case, the control sheet noted that additional information requested from the pharmacy had not been provided.

21.34 The control sheet used does not record the value of the sample examined or the nature or value of the discrepancies identified. As a result, the HSE does not have information in relation to the incidence and value of errors arising in relation to claims from pharmacists. However, the HSE has stated that the discrepancies identified (now mostly resolved) did not involve under/over payment to pharmacies.

21.35 While the HSE compares details of the delivery dockets (appended to pharmacist patient claim fees) with those on supplier invoices, it does not conduct a full check on a sample of supplier invoices to ensure that all amounts invoiced relate to stock that was delivered to pharmacies.

Stock Controls

21.36 A key feature of a good stock control system is one where stock is physically checked and counted periodically and at each year end in order to confirm the existence of the stock, the valuation of the stock and to assess the condition of the stock held.

Annual Stock Count

21.37 The HSE do not carry out an annual stock take of high tech drugs and medicines in the community pharmacies. Instead, each pharmacy is issued with a stock return form for completion at the end of each year. The stock form asks the pharmacy to identify the quantity of each type of high tech drug and medicine stock on hand, broken down into the following categories

- normal stock being held for dispensing to patients
- out of date stock
- stock with no active patients.

21.38 The year end stock figure is derived from the returns made. Where a return is not made by a pharmacy, the HSE estimate the value of stock on hand. In respect of the year end 2014, 96% of pharmacies submitted a stock return. The total value of stock on hand at 31 December 2014 was estimated at €44.8 million, of which €2.7 million was reported to be out of date. Although the HSE receive information on the stock with no active patients from the pharmacies in their year end stock returns, they do not quantify the total value of such stock on hand at year end.

Periodic Stock Counts

21.39 Each year, the HSE carries out around 100 routine on-site inspections of pharmacies. The inspection focuses on how the pharmacy operates in terms of staffing and dispensing and includes an examination of the controls in place for refrigerated drugs and medicines, and for controlled drugs.[1]

21.40 Stock counts of high tech drugs and medicines do not form part of the pharmacy inspection programme. The HSE does not carry out periodic stock counts of the high tech drugs and medicines.

Conclusions and Recommendations

21.41 In 2014, the HSE incurred expenditure of €485 million on the high tech drugs scheme, comprising payments of

- €468 million to 18 pharmaceutical suppliers for the supply of drugs and medicines to pharmacies, and
- €17 million to pharmacies in respect of monthly patient care fees.

21.42 The HSE's system for making payments to the pharmacies and to the pharmaceutical suppliers is not a fully integrated electronic system. The absence of an integrated electronic processing system presents a number of risks to value for money.

1 Regulation of Retail Pharmacy Businesses Regulations 2008 (SI No. 488 of 2008)

21.43 It is important that the HSE has controls in place to ensure that drugs invoiced and paid for have, in fact, been delivered to pharmacies. Controls in this regard are inadequate. While the majority of expenditure on the scheme is incurred in relation to payments to suppliers, the checks conducted by the HSE are focused on checking the pharmacy's claim rather than the supplier invoices.

21.44 The HSE match copies of delivery dockets submitted by pharmacies with supplier invoices. This checks that the quantity of drugs and medicines received by a pharmacy are correctly invoiced. It would not detect instances where – through error or otherwise – a supplier invoices in respect of drugs and medicines not actually delivered.

Recommendation 21.1

Pending the introduction of a fully electronic purchasing and stock control system in relation to high tech drugs and medicines, the HSE should expand the post-payment checks conducted to include validation of a sample of supplier invoices. The results of this validation should be analysed to identify weaknesses in control procedures, the cause of errors and any suppliers with a high error rate on invoices submitted for payment.

Accounting Officer's response

Agreed. However, there are significant practical difficulties with its implementation. While it is accepted a full reconciliation of invoices should be completed, an electronic approach to this is necessary. Furthermore, stakeholder agreement on the delivery of such an electronic reconciliation/product tracking system would require that this is included as part of any new formal agreement with suppliers.

21.45 Effective stock control is important in ensuring that patient care needs are met at the lowest available cost. Excess expenditure in the scheme occurs where stock acquired by the pharmacy is not used. This may arise where the patient's prescription changes or the patient decides to use an alternative pharmacy and the pharmacy does not have another patient requiring the drug. In relation to ordering stock, it is important that the optimum balance is struck between ensuring that drugs are available to satisfy patient care needs in a timely way while minimising wastage due to excess stock. In general, pharmacies cannot return unused stock to suppliers or transfer stock to other pharmacies.

21.46 At the end of each year, the HSE requires each pharmacy to supply details of the stock of high tech drugs on hand, to identify stock which does not have an active patient, and stock which has gone out of date. Of the €45 million on hand at 31 December 2014, returns from individual pharmacies indicated that stock valued at €2.7 million had gone out of date. However, this is a measure of the wastage at a point in time, and probably understates the actual level of wastage of high tech drugs occurring in a year.

21.47 The HSE does not require pharmacies to complete declarations of stock disposal or destruction in relation to out of date stock. Furthermore, the HSE does not have information in relation to the level, cause and cost of wastage due to excess stocks.

21.48 The HSE does not compare the information received from the suppliers in relation to the quantity of drugs and medicines delivered to pharmacies with information received from pharmacies in relation to the quantity of drugs actually dispensed in order to calculate the level of wastage occurring. Monitoring this trend by individual pharmacy and by type of drug would allow the HSE to take action in relation to those areas where abnormal levels of wastage may be occurring.

Recommendation 21.2

The HSE should develop a fully integrated electronic processing system which would provide assurance that all stock paid for had, in fact, been delivered to pharmacies. In addition, a reconciliation of the quantity of drugs delivered, dispensed and stock on hand would allow it to monitor stock levels and thereby minimise losses due to excess stock holding.

Accounting Officer's response

Agreed. A project (Pharmacy Interface Project) is currently underway to deliver a number of enhancements. The scope of the project includes the electronic collection of additional data from pharmacies.

21.49 Excess stocks may arise in instances where a patient opts to use a different pharmacy from the one nominated on registration for the scheme. A pharmacy protocol issued by the HSE in December 2013 allows a patient to nominate a different pharmacy if the patient lives in the locality and wishes to obtain the high tech drugs from that pharmacy in future on a regular basis. While this allows the patient freedom of choice, in general it creates a risk of excess stocks in the pharmacy nominated at registration. The HSE does not have information in relation to the incidence of losses due to patients opting to use a different pharmacy.

Recommendation 21.3

The HSE should review its protocol in relation to patients changing pharmacies including use of the existing medicines transfer protocol so that, where possible, patients receive drugs ordered for them by the pharmacy nominated at registration.

Accounting Officer's response

Agreed. The HSE does not see circumstances whereby any protocol would be acceptable at a policy level which would prevent the free movement and choice of patients. There may be some scope to modify approval documentation to encourage the patient to delay movement until existing stock would be used.

21.50 In September 2011, the HSE requested pharmacies to co-operate in maximising a 'just in time' facility in order to reduce stock held to that compatible with immediate patient need. This was reiterated in June 2013 where pharmacies were again asked to maintain a minimum stock of high tech product.

21.51 The examination noted that the current stock level, where the equivalent of just over a month's supply of stock is held in pharmacies, seems high by reference to the frequency of delivery of drugs from suppliers and lead time for orders. However, the HSE has also noted that there have been some complaints from patients and patient advocates that patients had to wait over a weekend for essential stock to be delivered to the pharmacy from the suppliers.

Recommendation 21.4

The HSE should develop more detailed guidelines for pharmacies operating the high tech drugs scheme, setting out the optimum stock holding targets by category of drug, taking account of the cost of the drug and the number of patients requiring the drug.

Accounting Officer's response

Not agreed. It would not be feasible to implement this recommendation. Pharmacies have been asked to maximise a 'just in time' facility. However, the priority is ensuring that patients get the medicines they need when they need them.

21.52 In addition, the HSE does not at any stage conduct an independent check of stock levels in individual pharmacies. It requires pharmacies to provide details of stock on hand on an annual basis.

Recommendation 21.5

The HSE should include a review of high tech drugs as part of its normal pharmacy inspection programme. This could include a review of the overall stock levels, checks of a sample of high tech drugs and a review of the levels of high tech drugs disposed of as a result of being out of date.

Accounting Officer's response

Agreed. The HSE is working towards assigning additional staff to inspection work. This would allow for a greater number of inspections to be conducted and would also allow for the conduct of a stock count as part of the inspection.

The inclusion of a full count of stocks held in respect of the high tech drug scheme as part of the pharmacy inspection would have a significant resource impact and would deflect from other practice and patient care priorities.