

Economies in Drug Usage in the Irish Healthcare Setting

Address for correspondence:

Dr. Michael Barry
National Centre for Pharmacoeconomics
St. James's Hospital
Dublin 8
Tel: 01 4162303
E-mail: mbarry@stjames.ie

Terms of Reference

The October 2008 budget ended the arrangement whereby medical cards were automatically issued, without a means test, to all those aged 70 years and over. The initial thresholds for eligibility were revised on the 21st October 2008 maintaining eligibility for the majority of those over 70 years of age. The government statement indicated that savings required by the budgetary framework will be achieved through the ending of automatic entitlement to a medical card for those with incomes in excess of the new threshold, the setting of a new capitation rate in respect of patients aged 70 years and over and through economies in drug usage. The government statement of October 21st indicated that a review group would be set up to develop recommendations for good practice which will ensure safe and effective prescribing for patients while maximising the potential for economy in the use of public funds. The report will be prepared by the 1st of December giving a timeframe of just under six weeks.

Terms of reference for the review group to consider efficient and cost-effective prescribing in the GMS and Community Drugs Schemes

- To recommend efficiencies and savings in drug costs under the GMS and Community Drugs Schemes whether through more rational and cost-effective prescribing at GP level or otherwise.
- To advise on the information and educational or training initiatives, or standards and protocols, that might be put in place to support more efficient and cost effective prescribing.
- To identify areas where over use or inappropriate use of certain drugs could be reduced or eliminated.
- To consider the capacity for increased generic prescribing by GPs.

Membership of the review group

Dr. Michael Barry (Chair),
National Centre for Pharmacoeconomics.

Dr. Ronan Boland
General Practitioner, Cork. - Irish Medical Organisation (IMO).

Prof. Colin Bradley
Department of General Practice, University College Cork

Dr. John Devlin.
Deputy Chief Medical Officer, Department of Health & Children.

Ms. Claudine Hughes.
Chief Pharmacist, National Medicines Information Centre (NMIC).

Ms. Pamela Logan
Director of Pharmacy Services, Irish Pharmacy Union (IPU).

Dr. Niall MacNamara
General Practitioner, Waterford. – Irish Medical Organisation (IMO).

Dr. Michael Mehigan,
General Practitioner, Churchtown, Dublin. – Irish Medical Organisation (IMO).

Ms. Kate Mulvenna,
HSE Pharmacist, PCCC Directorate, Health Service Executive

Mr. Brian Murphy.
Director of Commercial Affairs, Irish Pharmaceutical Healthcare Association (IPHA).

Ms. Sheila O'Connor.
Patient Focus Ireland

Dr. Mairin Ryan.
Director of Health Technology Assessment,
Health Information & Quality Authority (HIQA).

Dr. Lesley Tilson.
Chief Pharmacist, National Centre for Pharmacoeconomics (NCPE).

I am very grateful to all the members of the review group for their help in the preparation of this report.

Dr. Michael Barry

02/12/2008

Contents

Terms of reference	1
Membership of the review group	2
Contents	4
Executive Summary	5
Recommendations	6
Background	8
Drug pricing	13
Pharmacoeconomic assessment	14
Patent expired medicines	16
Drugs savings under the community drugs schemes	16
Prescribing practice	22
Quality prescribing indicators	26
Medicines use review	28
Influence of hospital prescribing on the community drugs schemes	29
Wholesaler margins and payment to pharmacies	30
Audit and inspection	31
Conclusion	32
References	33

Executive Summary

The October 2008 budget ended the arrangement whereby medical cards were automatically issued, without a means test to all those aged 70 years and over. The initial thresholds for eligibility were revised on the 21st October 2008 maintaining eligibility for the majority of those over 70 years of age. However, savings required by the budgetary framework would have to be made elsewhere i.e. the setting of a new capitation rate in respect of patients aged 70 years and over and through economies in drug usage.

This review group was set up to develop recommendations on how to achieve economies in drug usage. As patient care is paramount the recommendations avoid restricting access to essential medicines yet have the potential to make significant savings if adopted. Whilst some of the recommendations could produce immediate savings others will be achieved over time.

The support of prescribers will be essential to realise many of the savings outlined in this report. There should be feedback to general practitioners in relation to quality prescribing indicators facilitated by prescription software systems, prescription data analysis and professional prescribing advice and support. The recommendations in this document do not impact on the prescribing rights of medical practitioners.

It is evident that all aspects of the drugs supply chain need to be addressed if savings are to be optimised. Due to the very short timeframe i.e. less than six weeks, this review cannot be all encompassing however we believe that the target of €65 million in savings is achievable. Such savings will not occur automatically and investment will be required to deliver same. An implementation group involving the relevant stakeholders should be established with immediate effect.

Recommendations

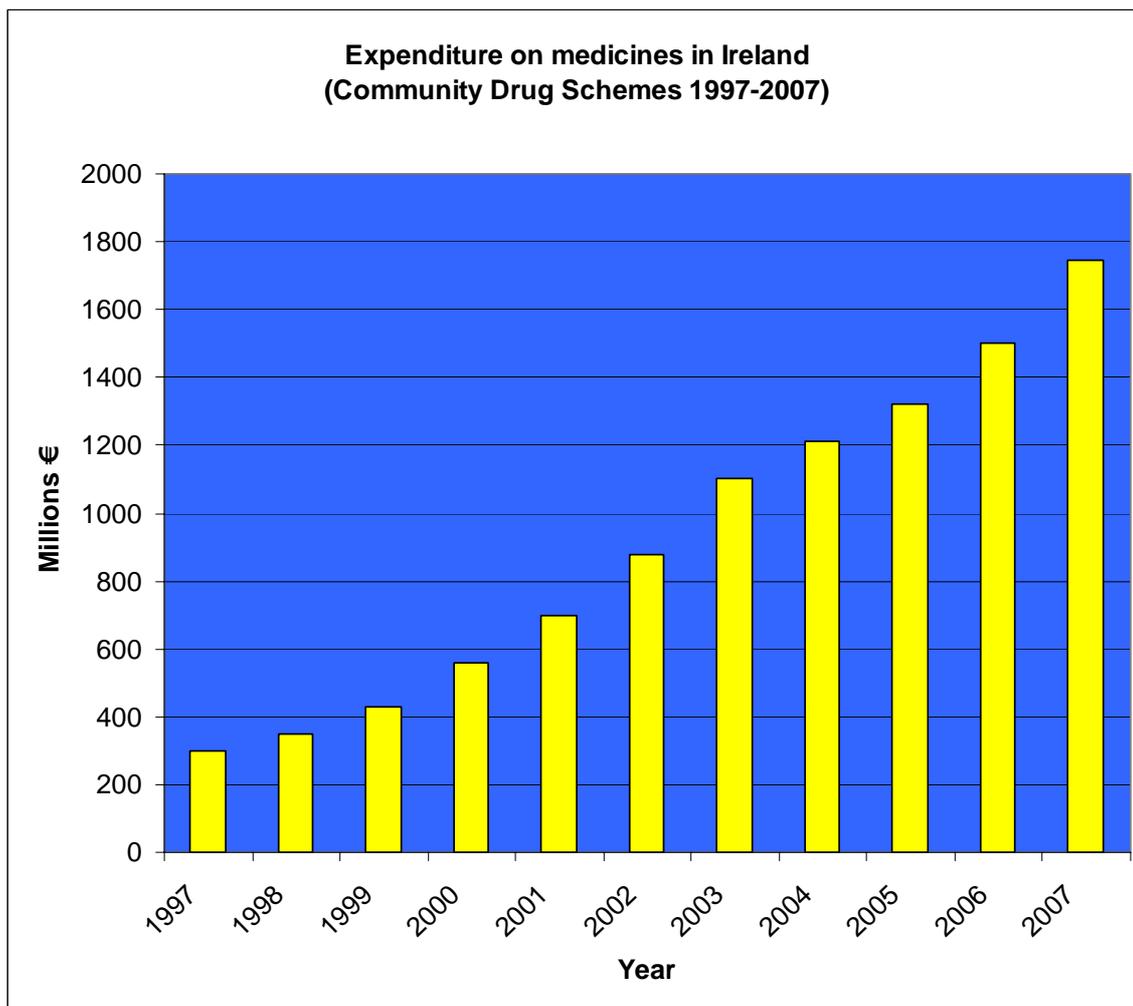
1. Significant savings may be achieved by ongoing monitoring of the current IPHA/HSE pricing agreement. The development of analytical capacity for this purpose should be a priority.
2. A cost-effectiveness analysis should be conducted for products reimbursed under the community drugs schemes where available evidence queries the value for money associated with such products. Reimbursement of these products should be reconsidered following assessment. In view of the current IPHA/HSE agreement initial savings in the region of €5 million may be achieved with another €5 million over the coming years.
3. The reimbursement status of products such as clinical nutritional products, glucosamine and other therapies under the Drugs Payment scheme should be considered, mindful of the IPHA agreement. This has the potential for savings in excess of €10 million per annum. Consideration should be given to separate reimbursement lists for the GMS and DP schemes.
4. Patients should be better informed in relation to the pricing of medicines and the information that accompanies medications so that they may play a role in optimising value for money and reducing wastage.
5. The ex-manufacturer price for generic preparations should be reviewed with consideration given to the introduction of a price considerably below the price of the relevant proprietary product. Pricing generics at 20% to 30% below current prices could result in savings ranging from €15 million to €20 million per annum.

6. Generic prescribing by general practitioners should be encouraged and facilitated by prescription software systems, prescription data analysis and professional prescribing advice and support. Even at current generic pricing savings of over €10 million per annum are achievable.
7. There should be feedback to general practitioners in relation to quality prescribing indicators. Further development and expansion of the new prescribing analysis reporting system will facilitate same. It has the potential to produce savings in excess of €15 million per annum. Incentivising general practitioners to enhance quality and cost-effective prescribing using quality prescribing indicators should be considered.
8. Medicines use reviews should be considered in an attempt to improve compliance and health outcomes as well as reducing wastage associated with prescription drugs.
9. In view of the influence of hospital prescribing on drug expenditure in the community the HSE should develop continuity across hospital and community prescribing.
10. When pursuing savings in relation to the drugs bill the HSE should continue its current consideration of wholesaler margins and payments to pharmacies with a view to achieving value for money from the community drugs schemes.
11. Audit and inspection procedures should be reviewed to ensure that they are robust and comprehensive enough to validate any State expenditure on any part of the medicines supply chain.

Background

In 2007 expenditure on medicines under the Community Drugs Schemes (approximately 85% of total drug expenditure) was €1.74 billion, a greater than five-fold increase over the decade 1997 to 2007. (figure 1)

Figure 1.



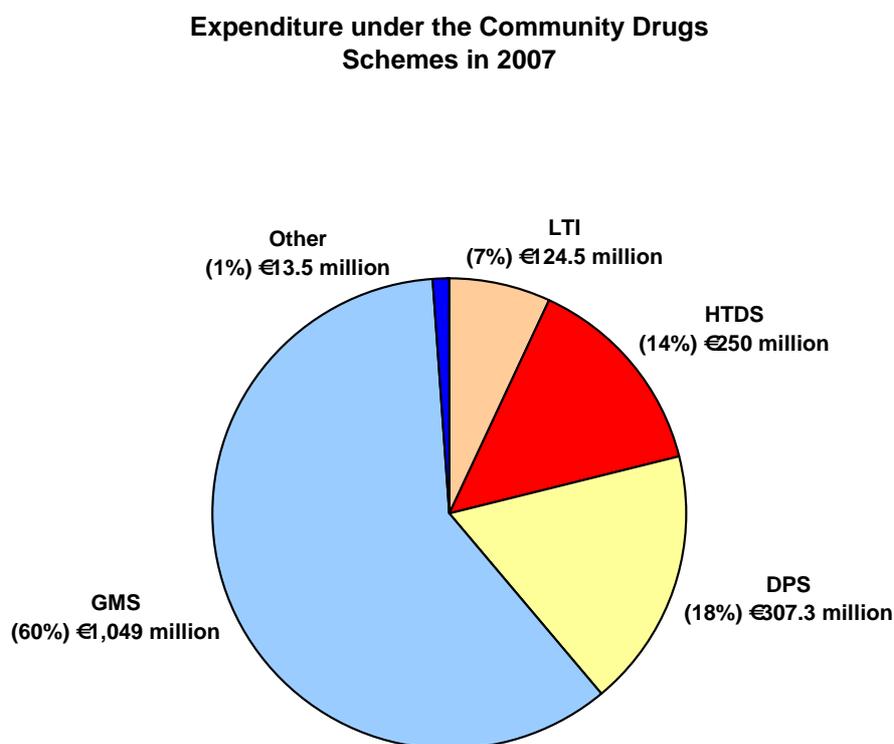
The year on year increase in pharmaceutical expenditure in Ireland is amongst the highest in Europe with medicines now accounting for approximately 13.5% of total healthcare spending. An agreement between the Health Service Executive (HSE) and the Irish Pharmaceutical Healthcare Association (IPHA) on the pricing and supply of medicines to the Irish Health Service came into effect on the 1st of September 2006 and provides the framework for the pricing and reimbursement of medicines in Ireland.^[1] It applies to all

medicines granted marketing authorisation by the Irish Medicines Board or European Commission that can be prescribed and reimbursed under the Community Drugs Schemes and all medicines supplied to the HSE, state funded hospitals and to the state agencies whose functions normally include the provision of medicines. There is a ‘common list’ of medicines which are reimbursable under the GMS and Community Drugs Schemes i.e. those products that satisfy the criteria as published by the Minister, in April 2003.

Community Drugs Schemes

Expenditure under the Community Drugs Schemes is shown in figure 2. The largest scheme is the General Medical Services (GMS) scheme where the number of eligible patients was 1,276,178 in 2007, approximately 30 % of the population.^[2]

Figure 2.



GMS = General Medical Services scheme **DPS** = Drug Payment scheme

LTI = Long Term Illness scheme **HTDS** = High Tech Drugs scheme

Those who are unable without undue hardship to arrange general practitioner (GP) medical and surgical services for themselves and their dependents are eligible to receive free GP services under the GMS scheme and are issued with medical cards which are means tested. Medical card holders are entitled to free prescription drugs, medicines and

appliances through their local participating pharmacist. From July 1st 2001 all residents over the age of 70 years were entitled to a medical card regardless of means and therefore received their medications free of charge. Following the October 2008 budget the Government ended the arrangement whereby medical cards were automatically issued without a means test to all those aged 70 years and over. The new income threshold for medical cards in respect of persons aged 70 years and over is a gross weekly income of €700 (€36,500 per annum) or less for a single person or €1400 (€73,000 per annum) for a couple.

There were 44.35 million prescription items issued under the GMS scheme in 2007 and aspirin was the most frequently prescribed medication. (Table 1).^[3]

Table 1

Top 10 most commonly prescribed products under the GMS scheme in 2007	Prescribing Frequency
Aspirin	2,305,894
Atorvastatin	1,436,264
Levothyroxine	781,578
Calcium, Combinations	697,914
Amlodipine	673,315
Bisoprolol	661,142
Salbutamol (Inhaled)	655,263
Paracetamol	650,774
Amoxycillin and Enzyme inhibitor	628,645
Ramipril	615,200

Expenditure under the GMS scheme exceeded €1 billion in 2007 and atorvastatin (Lipitor®) was the number 1 selling drug (Table 2).

Table 2.

Top 10 products of highest ingredient cost under the GMS scheme in 2007	Cost
Atorvastatin	€ 57.6 million
Clinical Nutritional Products	€ 37.9 million
Omeprazole	€ 24.6 million
Salmeterol + drugs for OAD	€ 24.6 million
Lansoprazole	€ 21.4 million
Esomeprazole	€ 20.8 million
Pravastatin	€ 20.0 million
Olanzapine	€ 19.2 million
Clopidogrel	€ 18.2 million
Diagnostic Products	€ 12.7 million

OAD: obstructive airways disease

The Long-term Illness (LTI) scheme entitles patients suffering from any one of sixteen specified chronic conditions including diabetes mellitus, multiple sclerosis, parkinson's and epilepsy to full drug reimbursement, irrespective of income, for medicines relating to their primary condition. Approximately 2.6 % of the population are registered under the LTI scheme, however, only half of those registered are active users of the scheme.^[3] The number of prescription items issued under the LTI scheme exceeded 2.3 million in 2007 with an associated expenditure of €124.5 million. Therefore approximately one third of the population are eligible to receive free medications under the GMS and LTI schemes. The remaining two thirds of the population pay towards the cost of their medication.

The Drugs Payment (DP) scheme, introduced on the 1st July 1999, applies to Irish residents who do not have a medical card. Under the DP scheme no individual or family will be required to pay more than €100 in any calendar month for approved prescribed medicines for use by that person or his/her family in that month. The number of persons registered under the DP scheme exceeded 1.5 million in 2007 and the cost of the 13.4

million prescription items issued under the scheme was €307.3 million. The European Economic Area (EEA) scheme provides visitors from other Member States with established eligibility emergency GP services while on a temporary visit. Expenditure under the scheme was €2.3 million in 2007.

The High Tech Drugs (HTD) scheme introduced in November 1996 facilitated the supply by community pharmacies of certain high cost medicines (e.g. those used in conjunction with chemotherapy and IFN- β), which have previously been supplied primarily in the hospital setting. The cost of medicines dispensed under the HTD scheme is paid directly to the wholesalers and pharmacists. In recognising the complexity of these particular medicines pharmacists are paid a patient care fee of €59.04 per month (in 2007) to cover dispensing, counselling and advice on their safe and effective use. In 2007 payment to wholesalers under the HTD was €238.5 million and payment to pharmacies to cover dispensing fees was €11.6 million. The €250.1 million expenditure under the HTD scheme in 2007 represents a nine-fold increase since 1997 and reflects the five fold increase in the number of patients registered under the scheme in the same period. The TNF antagonists etanercept and adalimumab which are used for the treatment of conditions such as rheumatoid arthritis and psoriasis account for over 25 % of total expenditure (€51.1 million) under the HTD scheme.^[3] The growing number of biologic drugs for cancer therapy and other chronic conditions represents a major challenge for any cost containment measures.

Factors contributing to the observed increase in drug expenditure under the Community Drugs schemes include the prescribing of newer more expensive medications i.e. “product mix”. In 1997 the average cost per dispensed item under the GMS scheme was €11.20 as compared with €23.27 in 2007. In addition to the “product mix” there is the “volume effect” comprising of growth in the number of prescription items issued. In 1997 twenty million prescription items were issued under the GMS scheme. This increased over two-fold to 44.35 million items in 2007. Initiatives such as the cardiovascular health strategy has resulted in increased use of cardiovascular medicines, improved health outcomes and an understandable increase in expenditure. Changes in demographics and eligibility criteria for the Community Drugs Schemes (e.g. the introduction of the Drugs Payment scheme in July 1999 and the extension of the GMS scheme to provide free medicines for all those over 70 years of age in July 2001) have also contributed to the increasing expenditure on pharmaceuticals.

Drug Pricing

Since 1993 the price of medications introduced into Ireland were linked to the currency adjusted wholesale price in the UK, or the average of the wholesale price in Denmark, France, Germany, the Netherlands and the UK (whichever was lower). As all of these countries with the exception of France were recognised “high priced” member states, the price control formula for Ireland established a “Northern European” price that was above the community norm. As a consequence, medicine prices in Ireland at that time, prior to the negotiation of the 2006 IPHA agreement had been amongst the highest in Europe. A study conducted by the National Centre for Pharmacoeconomics in 2004 demonstrated savings in excess of €16 million per annum could be anticipated if Ireland reimbursed medication at the average European price.^[4] The 2006 IPHA/HSE agreement links the price of medicines in this country to nine EU states including Austria, Belgium, Finland, Denmark, France, Germany, the Netherlands, Spain and the UK. The inclusion of countries such as Austria, Belgium, Finland and Spain, whilst not resulting in an average European price, would be expected to reduce the price of medicines in Ireland over time. The price to the wholesaler of any new medicine introduced to Ireland under the new agreement shall be realigned to the currency adjusted average price to the wholesaler in the nominated EU member states in which the medicine is available two and four years following commencement of the agreement. Many EU Member States have negotiated price freezes and cuts in recent years. The UK are proposing a 3.9% cut in the cost of drugs sold to the NHS in February 2009 and a further cut of 1.9% in January 2010.

Significant savings have been achieved as a result of the revised pricing mechanism under the new IPHA/HSE agreement and will continue with the ongoing monitoring of drug utilisation and expenditure data under the Community Drugs Schemes. The development of analytical capacity for this purpose should be a priority.

Recommendation 1

Significant savings may be achieved by ongoing monitoring of the current IPHA/HSE pricing agreement. The development of analytical capacity for this purpose should be a priority.

Pharmacoeconomic Assessment

In the new agreement the HSE reserves the right to assess new and existing technologies, such as pharmaceuticals, diagnostics and devices, which may be high cost or have a significant budget impact on the Irish healthcare system. Where a new medicine is subjected to a pharmacoeconomic assessment the reimbursement decision will be notified within 90 days of receipt of the reimbursement application.^[5] Assessments will be conducted in accordance with existing agreed Irish Health Technology Assessment (HTA) guidelines. Products subject to an assessment would become reimbursable under the scheme within 40 days of a positive reimbursement decision. Should reimbursement be refused an appeal may be made to an expert committee whose final decision may be made within a further 90 days and will be accepted as binding.

Pharmacoeconomic evaluations will usually be in the form of cost-effectiveness analysis (e.g. cost per life year gained, LYG) or cost-utility analysis (e.g. cost per quality adjusted life year, QALY). A cost effectiveness threshold in the region of €45,000/QALY has been adopted in the assessment process.^[5] However products with an incremental cost effectiveness ratio (ICER) exceeding this threshold have been reimbursed. The reimbursement decision will be influenced by factors such as the degree of uncertainty in calculating the ICER, the innovative nature of the technology, particular features of the condition and population receiving the technology and wider societal costs and benefits.

In view of the significant year on year increase in drug expenditure it is likely that more new medicines will be required to prove cost-effective prior to reimbursement. To enable such assessment the current HTA capacity would need to be increased with a greater level of investment than has been evident to date. Examples of recent pharmacoeconomic evaluations are shown in table 2.

Table 2. Example of pharmacoeconomic evaluations

Drug	Indication	Cost/QALY (€)
Spirolactone (Aldactone®)	Heart failure	400
Atorvastatin (Lipitor®)	Secondary prevention CHD	1700
Carvedilol (Eucardic®)	Heart Failure	2600
Atorvastatin (Lipitor)	Primary prevention CHD	22,375
Natalizumab (Tysabri®)	Multiple Sclerosis	30,600
Rimonabant (Acomplia®)	Antiobesity drug	30,666
Pravastatin (Lipostat)	Primary prevention CHD	42,250
Inhaled Insulin (Exubera®)	Diabetes mellitus	44,526
Omalizumab (Xolair®)	Asthma	57,196
Sunitinib (Sutent®)	GIST and mRCC	57,280

CHD: Coronary heart disease; GIST: Gastrointestinal stromal tumors; mRCC: Metastatic renal cell carcinoma; QALY: Quality-adjusted life year.

All products with the exception of omalizumab (Xolair®) were reimbursed. Sunitinib (Sutent®) for the treatment of gastrointestinal stromal tumours and metastatic renal cell carcinoma was reimbursed despite exceeding the €45,000/QALY threshold on the basis of being a new innovative product. Pharmacoeconomic assessment has demonstrated the cost effectiveness of cardiovascular medications such as antihypertensives and statins.^[6,7] Such therapies have contributed greatly to the reduction in cardiovascular mortality in Ireland. The new IPHA/HSE agreement represents a major change in the reimbursement of pharmaceuticals in Ireland as it allows decision makers to request and use evidence of the cost effectiveness of a new medicine in the reimbursement decision. The outcome in relation to HPV vaccination indicates that whilst the incremental cost effectiveness of a technology is an important consideration, budget impact may have a greater influence over reimbursement and/or implementation decisions.^[8]

Patent Expired Medicines

Although it is widely accepted that generic prescribing enhances cost effectiveness, the generic prescribing rate in Ireland is low as compared with other EU member states. In 2007 just over 19% of prescription items were dispensed generically with branded generics accounting for 16.5% and non-branded generics 2.6%. In expenditure terms generic prescribing accounted for approximately 8% of total expenditure under the GMS scheme in 2007. Over the past decade generic prescribing rates have fallen significantly as the percentage of items prescribed generically exceeded 22% by volume and 12% by expenditure in 1997. An important component of the new IPHA/HSE agreement is the 35% two-stepped price reduction for patent expired medicines. This ensures that the HSE no longer pays a price premium for many medications that are off patent.

The HSE/IPHA agreement has the potential to make a significant impact on the annual increase in drug expenditure as suggested in the fall in the cost per item under the drugs payment and long term illness schemes. Over the next few years a range of leading medicines go off patent providing further savings.

Drugs Savings under the Community Drugs Schemes

Recommendations in relation to potential savings under the Community Drugs Schemes will fall under two headings i.e. drug reimbursement and prescribing practice.

Drug reimbursement

There were over 60 million prescription items issued under the community drugs schemes in 2007. The vast majority of prescription items (greater than 99%) and expenditure (greater than 99%) are accounted for by four of the schemes i.e. the GMS (Medical Card) scheme, Drugs Payment scheme, Long Term Illness scheme and the High Tech Drugs scheme. Therefore this report will focus on these four schemes. This document highlights just some examples where potential savings could be achieved.

GMS (Medical Card) scheme

In 2007 the top 100 products of highest cost in the order of their total ingredient cost accounted for 78.63 % of total expenditure under the scheme. There are a number of areas for potential immediate savings to be obtained. These areas include:

Clinical Nutritional Products

Clinical nutritional products are indicated for disease states, allergic conditions, malnutrition, metabolic and absorption problems. Oral nutritional supplements account for approximately 60% of the €46 million expenditure on clinical nutritional products under the community drugs schemes. Commonly prescribed oral nutritional supplements include high calorie sip feed, standard sip feed, high fat sip feed and high protein sip feed. The role of oral nutritional supplements in primary care was reviewed by the National Medicines Information Centre (NMIC) in 2004.^[9] The NMIC bulletin indicates that there is a lack of good quality clinical data evaluating the use of oral nutritional supplements in the community setting. The publication points to a paucity of data demonstrating improvements in either mortality or functional outcomes following the use of these products. There were four key summary points including (1) the clinical use of oral nutritional supplements has greatly increased in recent years in Ireland especially in the elderly, but the evidence base for their usage is poor (2) short-term use of oral nutritional supplements appears to produce small weight gain in underweight patients and a shorter length of stay in underweight hospitalised patients, but the impact of long-term use is currently unknown (3) audits suggest that up to 50% of prescribed supplements may not be consumed by patients (4) in the absence of evidence based guidelines, the potential benefit of oral nutritional supplements in primary care should be critically assessed on an individual basis and closely monitored throughout use. The report emphasises that food is the best vehicle for appropriate nutritional consumption. Therefore significant expenditure on such products where the evidence base is “poor” particularly during long-term use raises concerns. An updated systematic review of the clinical and cost-effectiveness of these products should be undertaken. In the meantime consideration should be given to reimbursing these agents on a short-term basis only. In situations where a genuine clinical need is determined the product should continue to be reimbursed.

Glucosamine

Glucosamine Sulphate is a sulphate salt of the natural amino-monosaccharide glucosamine and the active ingredient of a number of licensed products. Glucosamine is important in the metabolism of glycoproteins including those in cartilage where one of its major roles is in the formation of the glycosaminoglycan chains in aggrecan and other proteoglycans. DONA® is indicated for the management of symptoms of osteoarthritis. Each sachet contains glucosamine sulphate 1884mg (equivalent to glucosamine sulphate 1500mg). Thirty sachets are priced at €27.36. Expenditure on glucosamine under the GMS scheme was €5.63 million in 2007. A review by the National Centre for Pharmacoeconomics in 2000 concluded, “that there is no good evidence that this drug is a cost effective intervention in the treatment of osteoarthritis”. The review by the National Institute for Health & Clinical Excellence in the United Kingdom was presented on the 27th February in 2008. NICE guidance indicates that “the use of glucosamine is not recommended for the treatment for osteoarthritis”. The Scottish Medicines Consortium (SMC) reported on the 9th May 2008 that “glucosamine is not recommended for use within the NHS Scotland for relief of symptoms in mild to moderate osteoarthritis of the knee”. The report highlights that no direct clinical trial evidence of the efficacy and safety of this product is available and randomised controlled trials indicate little or no benefit over placebo in improving symptoms in patients with osteoarthritis of the knee. The SMC considered that the manufacturer did not present a sufficiently robust economic analysis to gain acceptance. A Drug & Therapeutics Bulletin report (November 2008) also highlights the fact that glucosamine should not be reimbursed on the NHS until more evidence is available to support its use. Therefore glucosamine has been selected for pharmacoeconomic assessment, in accordance with the 2006 IPHA/HSE agreement which provides that whilst medicines reimbursable at the commencement of the agreement will remain so for the duration of the agreement the HSE may seek to influence the prescribing habits of doctors.

Recommendation 2

A cost-effectiveness analysis should be conducted for products reimbursed under the community drugs schemes where available evidence queries the value for money associated with such products. Reimbursement of these products should be reconsidered following assessment. In view of the current IPHA/HSE agreement initial savings in the region of €5 million may be achieved with another €5 million over the coming years.

Drugs Payment Scheme

In 2007 the top 100 products of highest cost in order of their total ingredient cost accounted for 79.81 % of total expenditure under the scheme. Areas for potential savings include:

Clinical Nutritional Products

As mentioned above there are concerns in relation to the value for money associated with the Clinical Nutritional Products particularly oral nutritional supplements. These products accounted for an ingredient cost exceeding €4.5 million under the Drugs Payment scheme in 2007. The reimbursement status of clinical nutritional products under this scheme should be reconsidered with a view to removing the products from the DPS scheme. Prior HSE sanction should be sought in situations where a genuine clinical need is identified and where issues of access arise.

Glucosamine

As outlined above there is little evidence to support the cost effectiveness of glucosamine for the treatment of osteoarthritis therefore the reimbursement status of glucosamine under the DPS should be reconsidered in the context of the provisions of the HSE/IPHA agreement. The ingredient cost for glucosamine under the DPS exceeded €2.3 million in 2007.

There are other examples such as therapies for erectile dysfunction that could be considered in the future. A review by the National Centre for Pharmacoeconomics indicated that the product sildenafil was not reimbursed in many European countries including Belgium, Czech Republic, Denmark, Norway, Lithuania, Poland and Portugal. In the United Kingdom it is not reimbursed except for erectile dysfunction associated with conditions such as diabetes mellitus, parkinson's disease and multiple sclerosis.

Recommendation 3

The reimbursement status of products such as clinical nutritional products, glucosamine and other therapies under the Drug Payment scheme should be considered, mindful of the IPHA agreement. This has the potential for savings in excess of €10 million per annum. Consideration should be given to separate reimbursement lists for the GMS and DP schemes.

Long Term Illness Scheme (LTI)

The top 100 products of highest cost in order of total ingredient cost accounted for 93.23 % of total expenditure under the LTI scheme in 2007. As with the other schemes there are areas where savings could be made. It should be emphasised that the scheme is designed to reimburse only those drugs and medicines which relate directly to the patients primary condition other than those added through ministerial direction for cardiovascular complications of diabetes. Where a patient has a medical card, medicines should be accessed through a GMS prescription to enhance cost effective provision of medicines.

Diabetic Test Strips

While recognising the critical importance of regular blood glucose monitoring for people with diabetes a review of LTI claim data indicates that there may be significant wastage in relation to the utilization of diabetic test strips.

High Tech Drugs Scheme (HTD)

Total expenditure under the High Tech Drugs Scheme was €250.1 million in 2007. A number of products reimbursed under this scheme have already undergone pharmacoeconomic assessment e.g. sunitinib and bosentan. Etanercept and adalimumab are TNF alpha antagonists indicated for the treatment of conditions such as rheumatoid arthritis and ankylosing spondylitis. Expenditure on these two products exceeded €51 million in 2007 which was over 25% of total expenditure under the HTD scheme. A cost effectiveness analysis of such products is already underway at the National Centre for Pharmacoeconomics and will provide evidence in relation to the value for money associated with these agents.

Ensuring Value for Money Going Forward

In an attempt to ensure value for money from the drugs budget and in accordance with the recent IPHA agreement it is envisaged that pharmacoeconomic assessment of new and existing pharmaceutical products will continue. In relation to existing products such assessments may be considered in high cost areas. Examples include:

Antipsychotic drugs i.e. olanzapine, risperidone and quetiapine where the ingredient cost under the GMS scheme was €19.2 million, €8.7 million and €6.1 million respectively in 2007.

Antidepressants including high cost drugs such as venlafaxine (€10.5 million), escitalopram (€7.4 million) and citalopram (€5.8 million).

The treatment of Alzheimers Disease with products such as donepezil (€11.5 million) and memantine (€2.1 million).

Enhancing patient information

Research published by the Irish Patients Association demonstrates a significant lack of knowledge amongst patients in relation to prescription medications. This research focused mainly on areas such as indications for drug therapy and associated adverse effects of medicines. The Association felt that patients should be fully informed about the medications they take. We believe that patients should be better informed in relation to the pricing of medications and the significant differences in price that may exist for the same pharmaceutical product. Patients should also be aware of the information which accompanies their medication and the need to read this carefully to ensure the greatest possible benefit. There is also a role for patients to reduce accumulation of medicines in the home thereby reducing wastage. Enhancing patient information in relation to the pricing of medicines should be pursued.

Prescription only medicines to over the counter products

The potential to change the status of medications from prescription only medications (POM) to over the counter (OTC) supply under pharmacist supervision has been used in other Member States. This may be relevant for certain high cost medicines such as cholesterol lowering statins and proton pump inhibitors. There are however wider clinical issues that would need to be considered prior to any move in this direction.

Recommendation 4

Patients should be better informed in relation to the pricing of medicines and the information which accompanies medications so that they may play a role in optimising value for money and reducing wastage.

Prescribing Practice

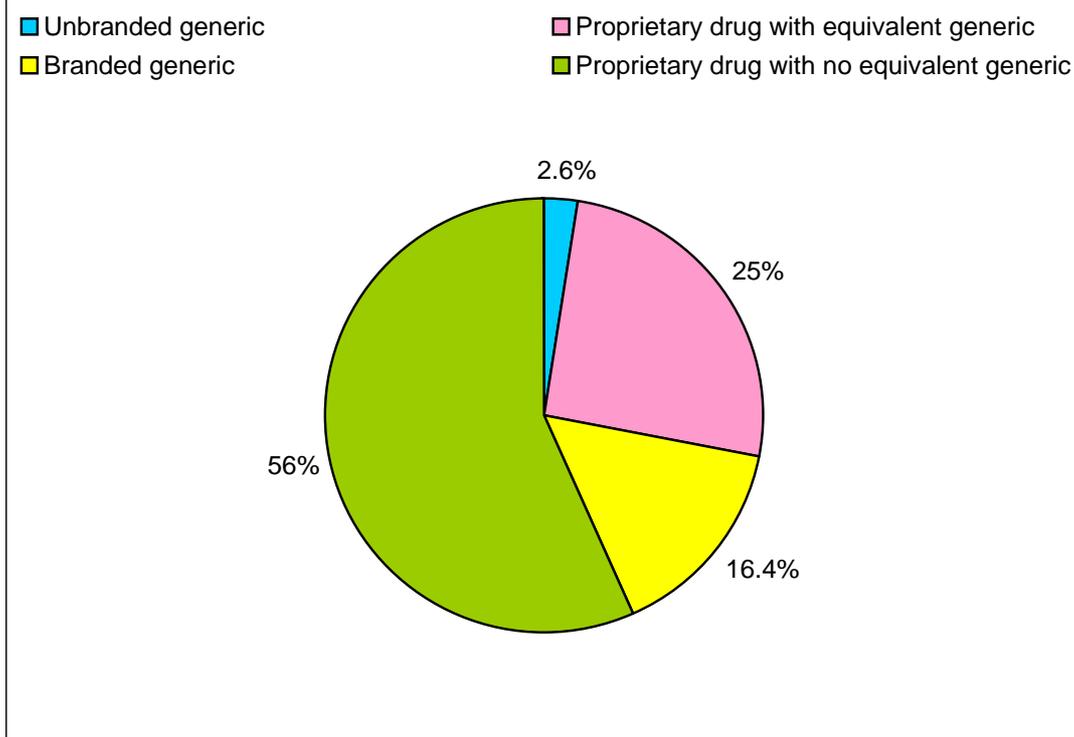
Generic prescribing:

It is generally accepted that the prescribing of generic medications optimises cost effectiveness. In many EU countries cost containment policies have included incentives and regulations to encourage prescription and/or substitution of cheaper generic drugs for more expensive original branded products. Generic prescribing rates exceed 50% in countries such as Denmark, Finland and the United Kingdom. In the UK NHS it is estimated that 83% of prescriptions were issued generically with 64% being dispensed generically in 2007.^[11] A key driver for this high rate of generic prescribing has been the acceptance by UK practitioners of writing prescriptions by generic name without specifying the brand or manufacturer i.e. open prescribing.

The potential impact of implementing generic substitution on the Community Drugs Schemes in Ireland was reviewed by Tilson et al.^[12] This study found that 21% of prescriptions items on the GMS scheme and 23% under the DP scheme were dispensed as proprietary preparations when a generic equivalent was available in 2003. At the time of the analysis (before the 2006 IPHA agreement) substitution of the cheapest generic equivalent preparations for the top thirty drugs by expenditure in each scheme would result in estimated annual savings €12.5 million on the GMS and €9.1 million on the DP scheme. Therefore the study indicated that over €20 million could be saved through enhanced generic prescribing. The study also indicated that a greater proportion of generic drugs were dispensed on the GMS scheme as opposed to the DP scheme.

Generic prescribing rates have been falling over the past ten years and in 2007 approximately 19.0% of prescriptions items were dispensed generically (unbranded generics 2.6%, branded generics 16.4%). Approximately 25% of prescription items were dispensed as a proprietary preparation when a generic equivalent was available (figure 7).

Figure 7: Percentage of prescription items dispensed generically under the GMS scheme in 2007



Proprietary drugs with no generic equivalent accounted for 56% of prescription items issued under the GMS scheme in 2007. It is in the area of proprietary drugs with equivalent generics that savings could be made and this percentage has increased from 21.3% in 2003 to 25% in 2007.

As mentioned above the IPHA/HSE 2006 agreement has significant implications for generic prescribing. Section 6 of the agreement outlines changes for patent expired medicines highlighting the objective to ensure the future supply of innovative medicines to Irish patients through the introduction of appropriate price reductions on patent expired medicines. The price reductions will apply to specific dosage forms of patent expired medicines where the identified pharmaceutical form of that medicine, approved by the Irish Medicines Board or EU Commission is available for prescription under the schemes and all medicines supplied to the HSE, state funded hospitals and to state agencies whose functions normally include the provision of medicines.

Section 6.1 indicates that six months following the commencement of the new agreement the price to the wholesaler of existing patent expired medicines and medicines due to go off patent within six months of the commencement of the new agreement will be reduced by 20%. Twenty-two months after the first price reduction the price to the wholesaler will be reduced by a further 15% of the original price to the wholesaler. For medicines whose patents expire beyond six months following the commencement of the new agreement the price to the wholesaler will be reduced by 20%. Similarly, twenty-two months thereafter the price to the wholesaler will be reduced by a further 15% of the original price to the wholesaler.

The price reductions outlined above will be implemented within sixty days of the date of the relevant HSE notification. In effect the new IPHA/HSE agreement will result in a 35% reduction in the ex-manufacturer price of off patent medicines. A consequence of the current pricing structure means there is little difference between the price of the proprietary drug and the available generic in certain therapeutic areas. Therefore the role of generic prescribing in producing significant cost savings is limited, unless the ex-manufacturer price of generic products is reduced substantially.

This is reflected in a study by Walsh et al. which investigated the cost effectiveness of statin therapy for the primary prevention of coronary heart disease in the Irish healthcare setting.^[13] Under the GMS scheme the most cost effective statin was atorvastatin at €17,900 per life year gained (LYG). In fact atorvastatin, rosuvastatin and fluvastatin were all more cost-effective than the generic statins i.e. simvastatin and pravastatin. This is in part related to the pricing of such products on the Irish market. Follow up analysis (unpublished) indicates that the price of generic simvastatin and pravastatin would need to be reduced by up to 20% and 30% respectively to be considered the most cost effective options. Therefore consideration should be given to the introduction of a fixed ex-manufacturer price for such products in the region of 20% to 30% below current prices.

The statistical analysis of claims and payments 2007 report from the HSE – Primary Care Reimbursement Service indicates that two groups of drugs i.e. the cholesterol lowering statin medications and the proton pump inhibitors account for over one fifth of total expenditure under the GMS scheme. Total expenditure in terms of ingredient cost for the top four statin medications was €136.9 million in 2007 i.e. atorvastatin €88.7 million,

pravastatin €27.4 million, rosuvastatin €14.2 million and simvastatin €6.6 million. Expenditure in terms of total ingredient cost on the proton pump inhibitors exceeded €113.5 million across the community drugs schemes in 2007 i.e. omeprazole €33.75 million, lansoprazole 28.27 million, esomeprazole €30.7 million, pantoprazole €15.0 million and rabeprazole €5.7 million.

Therefore it is appreciated that enhanced generic prescribing (with appropriate pricing) has the potential to produce significant savings. A study by McGowen et al. investigated the potential impact of generic prescribing of proton pump inhibitors under the GMS scheme.^[14] The study indicated that generic omeprazole preparations would be expected to produce cost savings in excess of €5 million per annum. Similarly, Feely & Bennett demonstrated that generic prescribing of the off patent statins pravastatin and simvastatin could save up to €6.4 million per annum, even at current generic prices.^[15]

In view of the studies mentioned above, enhanced generic prescribing would be expected to produce savings of at least €10 million per annum. In addition to the potential for savings in drug expenditure, generic prescribing is also a recognised quality prescribing indicator. Therefore the review group would encourage an increase in the generic prescribing rate not only to produce savings in drug expenditure but also to enhance quality prescribing. Open prescribing may be encouraged by prescription software systems, prescription data analysis and professional prescribing advice and support.

Recommendation 5

The ex-manufacturer price for generic preparations should be reviewed with consideration given to the introduction of a price considerably below the price of the relevant proprietary product. Pricing generics at 20% - 30% below current prices could result in savings ranging from €15 million to €20 million per annum.

Recommendation 6

Generic prescribing by general practitioners should be encouraged and facilitated by the provision of prescription software systems, prescription data analysis and professional prescribing advice and support. Even at current generic pricing, savings of over €10 million per annum are achievable.

Quality prescribing indicators

The review of the medical and economic literature during the 2007 review of the Indicative Drug Target Savings Scheme (IDTSS) revealed the potential for the improvement in prescribing in many European Countries including Ireland. A study by Teeling et al. investigated prescribing trends of statin medications under the GMS scheme from 1998 to 2002.^[16] The rate of statin prescribing was lower than expected, with statins being prescribed for just 52% of persons with ischaemic heart disease and 40% of patients with diabetes mellitus. Patients aged 45 years to 64 years were more likely to receive statins as compared with those aged 65 years and older. The authors concluded that “the type of drug and doses prescribed still do not reflect the evidence base available from pivotal studies”. In 2003 Williams et al. using the GMS database identified over 15,000 patients with ischaemic heart disease on the basis that they received a prescription for nitrate therapy over a twelve-month period.^[17] Evidence for age and gender bias in the secondary prevention of coronary heart disease was found. Female patients were less likely to receive a prescription for a beta-blocker, aspirin and ACE inhibitors. More recently Okechukwu et al. found considerable divergence between theory and practice in the application of quality indices following analysis of GMS prescribing.^[18]

Such work suggests that potential exists for an improvement in quality prescribing. A report on indicators in quality prescribing practice was completed by the National Centre for Pharmacoeconomics in August 2005. This report highlighted the fact that the use of such indicators would not only improve quality but may also reduce costs significantly. A good example is seen in maintenance therapy with proton pump inhibitors which are indicated for conditions such as peptic ulcer disease, non steroidal anti-inflammatory drug (NSAID) induced ulceration and gastro-oesophageal reflux disease (GORD). A regular maintenance low dose of most proton pump inhibitors will prevent GORD symptoms in 70% to 80% of patients and should be used in preference to the higher healing dose. This may be used as an indicator of quality prescribing. Analysis of the GMS database for the 2005 report indicated that maintenance therapy in the community drugs schemes is frequently with the higher proton pump inhibitor dose. The percentage of prescriptions dispensed at the higher dose were as follows: omeprazole 40mg (5%) and omeprazole 20mg (78%), lansoprazole 30mg (72%), pantoprazole 40mg (62%), rabeprazole 20mg (73%) and esomeprazole 40mg (43%). The percentage of prescriptions dispensed at the higher dose for the drugs payment scheme were similar. The potential

cost savings following 100% substitution at the lower maintenance dose was estimated at over €16 million for the GMS scheme and €6 million for the drugs payment scheme. In clinical practice approximately 70% to 80% of these estimated savings could be expected thereby resulting in potential savings in the region of €15million to €17million, should the anticipated step down rate be achieved. It is clear that a review of long term therapy with expensive drugs such as the proton pump inhibitors and other medications for the treatment of chronic diseases needs to occur. A system of regular review of long term drug therapy is time consuming and general practitioners need to be supported in this e.g. the provision of protected time to conduct such reviews. Such a review process would help target expensive drug therapy to those who fulfilled best evidence criteria. Efforts could be co-ordinated by the proposed professional prescribing support service in conjunction with the Irish Medical Organisation to maximise potential benefit.

There are many other areas where quality prescribing indicators may be incorporated including the prescribing of antibiotics, hypnotics and anxiolytics. It must be emphasised that quality cost-effective prescribing in the community requires constant feedback to practitioners with up to date information on drug utilization and expenditure. This would of course be facilitated by enhanced prescription software systems.

Recent developments such as the Quality Outcomes Framework (QOF) in the United Kingdom, incentivises general practitioners for high quality care. The framework sets out a range of standards based on best available research evidence. This would encourage general practitioners to develop practice protocols for common conditions such as the treatment of hypertension.

Recommendation 7

There should be feedback to general practitioners in relation to quality prescribing indicators. Further development and expansion of the new prescribing analysis reporting system will facilitate same. It has the potential to produce savings in excess of €15 million per annum. Incentivising general practitioners to enhance quality and cost-effective prescribing using quality prescribing indicators should be considered.

Medicines use review

Once a medicine is dispensed there is no structured follow-up on drug compliance or wastage within the current health system. The 2007 National Audit Office Report ‘Prescribing Costs in Primary Care’ suggests that as much as 10% of all prescribed drugs are wasted. The full cost of wastage is not just the medication cost but costs associated with non adherence.

There is no reason to believe the situation differs in Ireland. In fact, the campaign, Dispose of Unused Medicines (D.U.M.P) organised in certain areas by the HSE together with community pharmacists to dispose of unused/out of date medicines safely has resulted in large volumes of unused and in-date medicines being returned by members of the public to pharmacies. The most common reasons for returning medicines included the medications being out of date, not required or being unwanted. The majority of returned medicines could be classified as ‘general’ including antibiotics, diuretics, corticosteroids, cardiovascular and respiratory drugs.

In this context the review group suggests that consideration be given to how medicine usage review should be conducted within the health system. Information flow between patient, community pharmacist and medical practitioner should be encouraged, particularly where complicated medication regimens are involved. International evidence suggests that medicines management initiatives, lead to improved health outcomes and quantifiable savings.

Recommendation 8.

Medicines use reviews should be considered in an attempt to improve compliance and health outcomes as well as reducing wastage associated with prescription drugs.

Influence of hospital prescribing on community drugs schemes

Approximately 15% of all prescribing takes place in the hospital environment. Recent trends in Europe and the US include an increase in hospital based health technology assessment (HTA). This results in certain high cost medicines being subjected to pharmacoeconomic assessment in order to demonstrate value for money.

The influence of hospital prescribing on community prescribing was highlighted by Feely et al. who described how hospital doctors initiated 38% of GMS prescriptions, particularly repeat prescriptions and those for cardiovascular, hormonal and centrally acting agents.^[19] The median cost for hospital initiated GMS prescriptions was almost 70% greater than general practitioner initiated prescriptions. The authors concluded that hospital initiated prescriptions were responsible for a significant proportion, both in volume and cost of general practitioner prescribing.

Discounting of products at hospital level can result in significant prescribing of such products in the community. The development of prescribing guidelines, particularly in high cost areas, which could be implemented across the hospital and community setting should be considered following consultation with relevant stakeholders. Such guidelines would need to be updated periodically in line with emerging evidence. Individual hospital's product selection and prescribing procedures should be required to recognise the impact of decisions on the healthcare system as a whole.

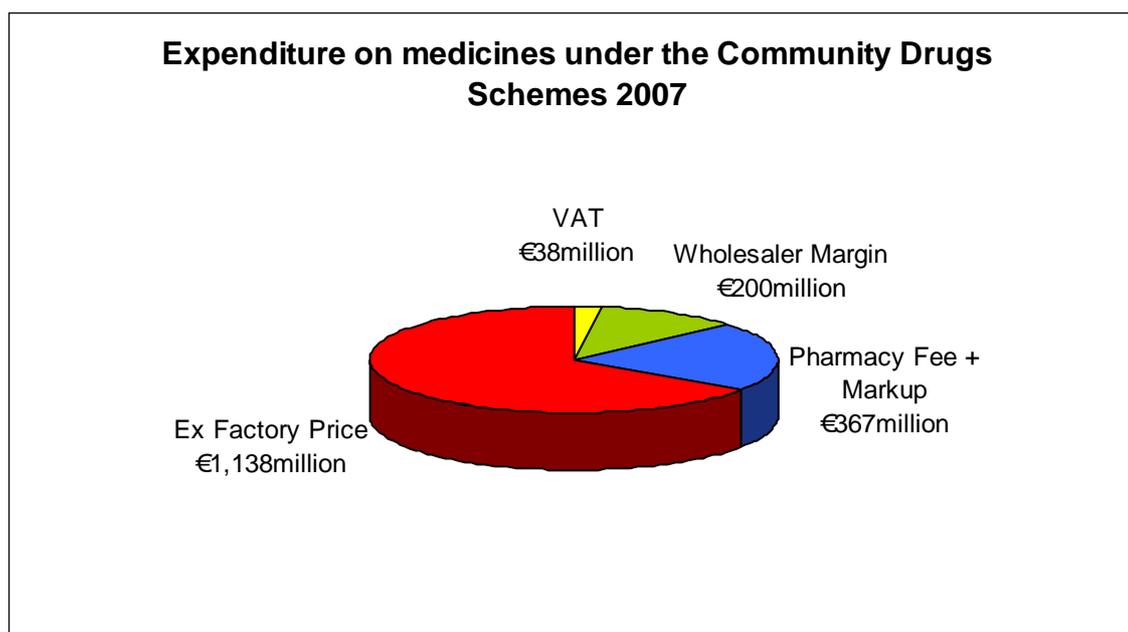
Recommendation 9

In view of the influence of hospital prescribing on drug expenditure in the community the HSE should develop continuity across hospital and community prescribing.

Wholesaler margins and payment to pharmacies

When considering savings on expenditure on medicines it is important to consider all aspects of the drugs supply chain including wholesaler margins and payment to pharmacies, figure 8.

Figure 8.



While this issue does not come within the terms of reference of the review group it is noted that payments to wholesalers exceeded €200 million in 2007. The Department of Health & Children/HSE is reviewing this margin with a view to reducing same. This would appear appropriate in the quest for savings from the drugs bill. Similarly, pharmacy fees and mark-up exceeded €367 million in 2007. The independent body on Pharmacy Contract Pricing report (June 2008) considered alternative reimbursement models that may achieve the aims of being fair and transparent whilst presenting a satisfactory business proposition for community pharmacists in addition to curtailing the escalation of public spending on pharmaceuticals.^[20]

Recommendation 10

When pursuing savings in relation to the drugs bill the HSE should continue its current consideration of wholesaler margins and payments to pharmacies with a view to achieving value for money from the community drugs schemes.

Audit and inspection

The growing scale of counterfeit medicines entering the European market shows the scale of the danger in terms of patients health and fraud on the public purse. Some 4.1 million counterfeit medicines were seized by EU customs authorities in 2007, an increase of almost five fold as compared with 2005. These seizures may only represent a fraction of the counterfeit penetration into the European market.

Recommendation 11.

Audit and inspection procedures should be reviewed to ensure that they are robust and comprehensive enough to validate any State expenditure on any part of the medicines supply chain.

Conclusion

Significant savings on medicines may be obtained by monitoring the price of pharmaceuticals in accordance with the current IPHA/HSE agreement. This requires ongoing, timely information on drug utilization and expenditure under the Community Drugs Schemes. The development of analytical capacity for this purpose is a priority.

Open generic prescribing has the greatest potential to reduce prescribing costs in the long term. It is also recognised as a quality measure within clinical practice and can improve patient safety. Prescribers would benefit from ongoing timely prescribing information to facilitate quality, cost-effective prescribing. It is clear that the support of prescribers will be essential to realise many of the savings outlined in this document.

The application of health technology assessment particularly for high cost drugs or drugs with a significant budget impact is required to ensure value for money. The reimbursement status of products which are deemed not to be cost-effective should be reviewed. While, under the current IPHA/HSE agreement, such products may remain reimbursable for a further period of time, prescribers should have the opportunity to consider cost effectiveness information.

The influence of hospital prescribing on expenditure in the community is highlighted and attempts should be taken to achieve continuity across primary and secondary care. Quality prescribing should be enabled through information and education initiatives and through national guidelines as and when they become available. Medicines use review would help to improve compliance and health outcomes as well as reducing wastage associated with prescription drugs.

References:

1. Agreement between the Irish Pharmaceutical Healthcare Association Ltd and the Health Service Executive on the supply terms, conditions and prices of medicines supplied to the health services (2006).
http://www.dohc.ie/publications/pdf/ipha_agreement_2006.pdf
2. HSE annual Report and Financial Statements 2007.
www.hse.ie/publications
3. HSE Primary Care Reimbursements Service.
Statistical analysis of claims and payments 2007.
4. Tilson L, McGowan B, Bennett K, Barry M.
The high cost of medicines in Ireland. Is it time change the pricing mechanism?
European Journal of Health Economics 2004; 49: 341-344.
5. Barry M, Tilson L.
Recent developments in pricing and reimbursement of medicines in Ireland.
Expert Review of Pharmacoeconomics Outcomes Research 2007; 7(6): 605-611.
6. Walshe V, Nash A, Barry M.
Cost effectiveness of statin therapy for the primary prevention of coronary heart disease.
Irish Medical Journal 2006; 99: 144-145.
7. Barry M, Heerey A.
Cost effectiveness of statins for the secondary prevention of coronary heart disease in Ireland.
Irish Medical Journal 2002; 95: 133-135.
8. The role of human papillomavirus vaccines in reducing the risk of cervical cancer in Ireland. A Health Technology Assessment.
Health Information and Quality Authority 2008. www.hiqa.ie
9. The role of oral nutritional supplements in primary care.
National Medicines Information Centre 2004, Bulletin 10 (2) 1-4.
10. Glucosamine for knee osteoarthritis – what’s new
Drugs & Therapeutics Bulletin 2008; 46 (11)81-84
11. Darroch C & Kay A.
Current and future trends in the use of generic medicines in the UK.
The Pharmaceutical Journal 2008;281:507-509.
12. Tilson L, Bennett K, Barry M.
The potential impact of implementing a system of generic substitution on the Community drugs schemes in Ireland.
European Journal of Health Economics 2005;50:267-273

13. Walshe V, Nash A, Barry M.
Cost effectiveness of statin therapy for the primary prevention of coronary heart Disease.
Irish Medical Journal 2006;100(3):144-145.
14. McGowan B, Bennett K, Tilson L, Barry M.
Cost effective prescribing of proton pump inhibitors (PPIs) in the GMS scheme
Irish Medical Journal 2005;98(3):78-80.
15. Feely J & Bennett K.
Epidemiology and economics of statin use.
Irish Medical Journal 2008;101(6)188-191.
16. Teeling M, Bennett K, Feely J.
The influence of guidelines on the use of statins:analysis of prescribing trends 1998 – 2002.
British Journal of Clinical Pharmacology 2004;59:227-232.
17. Williams D, Bennett K, Feely J.
Evidence for an age and gender bias in the secondary prevention of ischaemic heart disease in primary care.
British Journal of Clinical Pharmacology 2003;55:604-608.
18. Okechukwu I, Bennett K, Feely J.
General practitioners ranking of evidenced based prescribing quality indicators: a comparative study with a prescription database.
British Journal of Clinical Pharmacology 2006;62:218-224.
19. Feely J, Chan R, McManus J, O’Shea B.
The influence of hospital based prescribers on prescribing in general practice.
Pharmacoeconomics 199;16(2):175-181.
20. Independent Body on Pharmacy Contract Pricing.
Report June 2008. www.doh.ie/publications