LITERATURE REVIEW

Best Article

Taming the escalating costs of Ireland's community drugs schemes

Duncan Fortescue-Webb (*Third Year Medicine, TCD*)

CLINICAL POINTS

- The Community Drugs Schemes provide prescription drugs to patients through community pharmacies, and cost €1.9 billion in 2008.
- Minister Harney has recently implemented legislation to reduce the cost of the Community Drugs Schemes by reducing payments to drugs manufacturers, wholesalers and pharmacists; and requiring patient co-payments for all prescriptions dispensed.
- Future legislative reform is likely to include introduction of reference pricing, pharmacist-led substitution, renegotiation of prices with manufacturers, and disinvestment of ineffective drugs.
- Prescriber initiatives to reduce drugs expenditure can significantly ease the healthcare budget and forestall cutbacks to services.
- Generic prescribing continues to have an important role in improving patient safety and reducing drugs costs.
- Prescriber comparison of the prices of competing drugs and brands for the same indication can improve cost-effective prescribing.
- One third of prescriptions for the over 70s contain potentially inappropriate items. The most frequent include: PPIs at full therapeutic strength for over 8 weeks, NSAIDs for over 3 months, long-acting benzodiazepines for over 1 month, and duplicate drugs.
- Use of antibiotics to treat illnesses that are not likely to be bacterial is ineffective, causes adverse effects in one fifth of patients, and leads to antimicrobial resistance.

ABSTRACT

A reduced public budget has increased pressure to improve the efficiency of healthcare provision in Ireland. Legislative changes to reduce margins throughout the drugs supply chain and increase patient co-payments have recently been implemented. The background and implications of these changes are considered for manufacturers, wholesalers, pharmacists, patients and the public purse. Together, the changes are predicted to reduce the cost of providing drugs in the community in 2010 by nearly €270 million (11% of the projected €2.4 billion they would otherwise cost). However, underlying growth trends in drugs expenditure, particularly in the burgeoning high-tech drugs market, mean that although recent changes should contain the cost of drugs in 2010 at a level similar to 2009, annual growth of 12% is likely to resume thereafter unless additional reform is implemented. Slated future legislative changes that could be worth a further €200 million or more annually include: reference pricing, pharmacist-led substitution, renegotiation of manufacturer prices, and disinvestment of non-cost-effective drugs from public schemes. Finally, ways to improve prescriber habits are considered that could save an additional €100 million annually. These include periodic and critical reviews of patient prescriptions, more judicious use of antibiotics, generic prescribing, prescriber awareness of drug prices, and provision of prescribing software.

INTRODUCTION

Health accounted for 27% of Ireland's total public current expenditure in 2008 and, therefore, is of central importance in any strategy to ease the public budget[1]. The Health Service Executive (HSE) provides most public healthcare and had a budget of over €14 billion in 2008[2]. €1.9 billion of this was spent on prescription drugs supplied through pharmacies via the Community Drugs Schemes[3]. The cost of these schemes has been growing lately by about 12% each year[3,4] (Figure 1), and quintupled during the last decade because of changing demographics, the introduction of expensive new therapies, and a bloated supply chain. The rate of increase is among the highest in Europe[5] and the burden on public finances has come under increasing criticism. Mary Harney, Minister for Health and Children, recently implemented cost-containment measures to reduce payments to manufacturers, wholesalers and pharmacists, and to increase patient co-payments. This paper will examine the background and effects of these changes, the potential for further cost-control legislation, and the role of prescribers in the development of an efficient drugs supply system.

OVERVIEW OF DRUG DEVELOPMENT AND SUPPLY IN IRELAND

Drug research and manufacturing produces over half of Ireland's exports, employs about 24,500 people directly, and contributes over €1 billion in corporation tax[6]: it naturally also enjoys considerable political clout. To bring a new drug to market can take a research-based manufacturer upward of a decade and cost as much as €1 billion[7]. Once

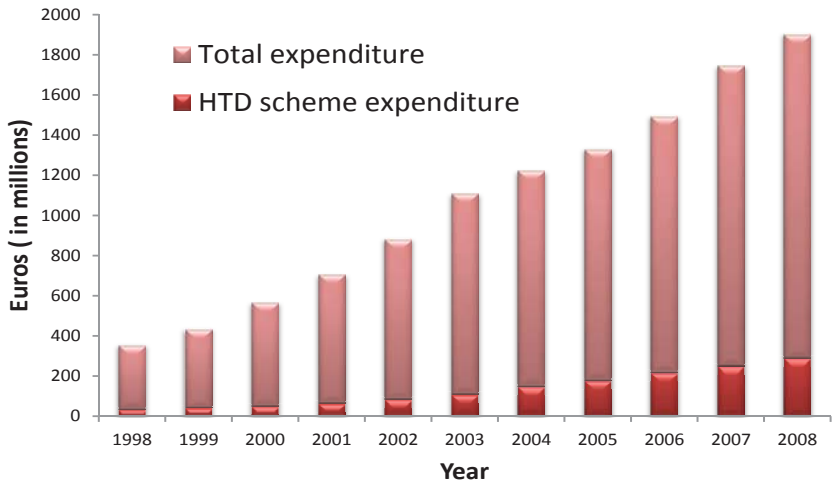
chemical entities with promising biological activity are identified they must be assessed for safety, toxicity, pharmacokinetics, metabolism and efficacy via a series of in vitro, animal and human clinical trials. The vast majority of potential drugs fail. A twenty year patent is commonly granted to the originator company once a promising chemical entity has been identified. This patent typically lasts 8-12 years beyond the time required to bring the drug to market[7] and gives the company exclusive rights to manufacture and supply the drug. When the patent expires, generic competitors may enter the market.

Every drug has an International Nonproprietary Name (INN) granted by the World Health Organisation (WHO). The INN reflects the therapeutic mechanism of the drug and is used to refer unambiguously to a specific chemical entity (e.g. omeprazole). In addition, the originator company chooses one or more brand names under which to market the drug (e.g. Losec). When the patent expires other manufacturers may also market the same drug under generic brands (e.g. BySec, Lopraz, Losamel, Ulcid) or the INN. These generic manufacturers incur relatively low development and regulatory costs, and typically sell the drugs at a lower price than the originator company.

Once a drug has been approved for sale in Ireland, the HSE negotiates an ex-factory price with the manufacturer based on the average price in nine European countries[8]. The manufacturer sells the drug to wholesalers, who add a mark-up and sell it on to pharmacists and hospitals. Pharmacists then dispense the drug, adding any applicable mark-up and fees. A prescription that specifies a brand of drug cannot be dispensed as another brand, but a generic prescription (where only the INN is used) can be dispensed as any available brand. About 85% of all community prescription drugs are paid for by the HSE through the Community Drugs Schemes[9]; the remainder is paid for by patients.

There are four major Community Drugs Schemes in Ireland providing prescription drugs through pharmacies. The largest Community Drugs Scheme is the means-tested General Medical Scheme (GMS) which provides drugs to medical card holders for 50c an item. The Long-Term Illness scheme (LTI) provides drugs to treat any of fifteen chronic conditions (e.g. cystic fibrosis, epilepsy, diabetes) for 50c an item. Together, the GMS and LTI cover approximately one third of the population and account for two thirds of expenditure[3] (Figure 2). The Drugs Payments Scheme (DPS) is available to all residents and limits the drugs cost to a €120 co-payment per family per month. Finally, the High Tech Drugs scheme (HTD) provides certain high-price drugs such as chemotherapy adjuncts and biologic agents that would otherwise be provided primarily in hospitals, with patient co-payment dependant on eligibility under the GMS, LTI or DPS schemes. The HTD is the most rapidly expanding scheme, with costs increasing between 2004 and 2008 by 18% a year (Figure 1) (HTD historic cost data from M Barry; personal communication, 16 February 2010)[10,11,12].

Minister Harney has sought ways to control drugs costs while still encouraging future drug innovation and ensuring continuity of supply to patients. To achieve this she has recently undertaken extensive renegotiation of the agreements that govern costs throughout the drugs supply chain.



▲ **Figure 1.** Expenditure under the Community Drugs Schemes, 1998-2008

Recent legislative changes affecting the Community Drugs Schemes

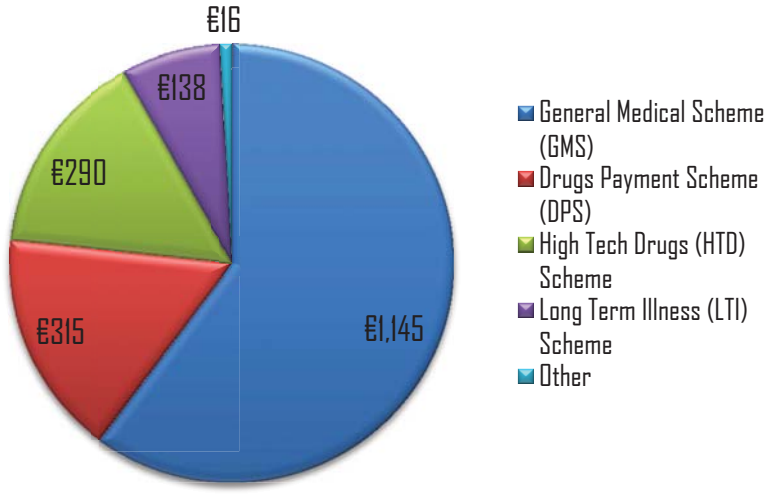
In order to conserve scarce resources for home support and acute hospital activities, Minister Harney implemented several measures in 2009 and 2010 to reduce public costs throughout the drugs supply chain. The groups targeted to achieve this reduction include manufacturers, wholesalers, pharmacists and patients.

Since 2006, under the IPHA/HSE Agreement, when a drug's patent expires and a generic competitor enters the market, the price is reduced immediately by 20% and then by another 15% of the original price 22 months later[13]. The Irish Pharmaceutical Healthcare Association (IPHA) of research-based manufacturers have now agreed to reduce prices of nearly 300 off-patent drugs by a further 40% from February 2010[14], leaving these drugs at least 61% below their previous on-

patent price. Prior to February 2010, original branded drugs typically cost 10% more than their generic competitors[15]. Now, however, Ireland is in a unique situation with many well known proprietary brands of drugs from IPHA manufacturers costing about 30% less than equivalents from competing generic manufacturers.

In addition, IPHA manufacturers are required from February 2010 to pay the HSE a rebate of 4% of the ex-factory price for all other drugs sold under any of the Community Drugs Schemes. Previously a 3.53% rebate applied under only the GMS. Together, the 40% price reduction and the increased rebate are expected to save €94 million per year[14].

Legislative changes to wholesale and pharmacist mark-ups and fees were implemented in July 2009 to contribute to cost reduction. The wholesale mark-up has been reduced from 17.66% to 10%, which brings the price paid for delivery of drugs to pharmacies back towards the European average of 8%[16]. Previously about half of the wholesale mark-up was being passed from wholesalers to pharmacists as discounts[17]. The pharmacist mark-up applicable under the DPS and LTI schemes has also been reduced from 50% to 20%. Furthermore, the previous standard dispensing fee structures under the GMS, LTI and DPS (to cover miscellaneous costs such as spoilage and repackaging) have been replaced with a more generous single sliding scale: €5 for the first 1667 items dispensed by a pharmacy per month, €4.50 for the next 833, and €3.50 for any remaining items[18]. The standard patient care fee of €60.52 per month paid to pharmacists under the HTD scheme is unaffected. These changes in payments to wholesalers and pharmacists should save €141 million per year.



▲ **Figure 2. Expenditure by Community Drugs Scheme (in millions of Euros), 2008**

Finally, the maximum patient co-payment under the DPS has been increased by 20% to €120 per family per month from January 2010. Patient co-payments of 50c per item (capped at €10 per family per month) have also been introduced under the GMS and LTI schemes from April 2010. These co-payments should save €52 million per year[1].

Without intervention, the 12% per year growth trend of the Community Drugs Schemes would have brought their cost to about €2.4 billion in 2010. Altogether, the above measures recently introduced by Minister Harney are predicted to reduce the 2010 Community Drugs Schemes cost by €270 million (about 11%), minimising any cost increase over 2009.

EFFECTS OF RECENT LEGISLATIVE CHANGES

Minister Harney's recent legislative changes will promote efficient healthcare and bring long term cost benefits. However, the disruption as the drugs market adjusts to these changes is likely to bring many indirect consequences which will erode the cost savings.

Minister Harney's recent changes will reduce revenues of IPHA drug manufacturers through the implementation of the 40% price reduction on 300 off-patent drugs and the 4% rebate for all other drugs. However, these manufacturers have secured two significant concessions by agreeing to reduce prices six months before their existing contracts were due to expire in September 2010. Firstly, renegotiation of prices for on-patent drugs (which account for about 75% of drug expenditure[19]) has been deferred 18 months until February 2012, protecting the largest part of the manufacturers' revenues from any further reduction. Secondly, the 40% price reduction will not automatically apply to drugs whose patents expire after January 2010[20]. Several blockbuster drugs will come off patent in 2011 including: atorvastatin (Lipitor) which cost €94 million in 2008, clopidogrel (Plavix) which cost €24 million, and olanzapine (Zyprexa) which cost €23 million[3]. Revenues from these drugs will therefore remain relatively high even once the patents expire and generic competitors can enter the market. These two concessions mean IPHA manufacturers will be able to maintain revenues from their most lucrative drugs for longer, offsetting the price reductions for their off-patent drugs and the increased rebate, and thereby diminishing the true savings to the Community Drugs Schemes.

However, non-IPHA generic manufacturers declined to match the IPHA 40% price reduction and 4% rebate. Their prices are now less competitive compared to IPHA manufacturers', and they risk losing significant market share. Many generic manufacturers may find that it is no longer profitable to operate within the Irish market and may cease operations in Ireland entirely, with adverse implications for employment and long-term competition. Additionally, the 2006 IPHA/HSE Agreement triggers a phased 35% price reduction when a drug comes off-patent only if a generic competitor enters the market. If fewer generic manufacturers operate in Ireland it is likely there will be a longer delay between patent expiration and generic entry, allowing IPHA manufacturers to maintain market dominance and high prices for their drugs that come off-patent.

The recent changes are also expected to bring wholesaler and pharmacist dispensing revenues down by about 30%[17], encouraging competition and efficiency. Between 2004 and 2010, the number of pharmacies in Ireland increased by 28% to 1705[21,22]. This boom is unsustainable in the face of such severe revenue cuts and the general economic downturn. Already many pharmacies are running at a loss, several have closed, and the Independent Pharmacy Ownership Scheme (which had minority holdings in nearly 150 pharmacies) has gone into liquidation[23]. There is a risk that patient access to services will be hindered if pharmacies in rural or deprived areas close. A further problem is that the Community Drugs Schemes provide a perverse incentive to pharmacists and wholesalers to fill generic prescriptions with the most expensive available drug in order to maximise their mark-up. With many pharmacies and wholesalers in financial difficulty it is likely some will resort to preferentially supplying more expensive brands, inflating the costs of the Community Drugs Schemes. Parallel imports, where pharmacists and wholesalers source drugs more cheaply from wholesalers abroad, allow greater profit margins and are likely to increase, bringing the hazard that counterfeit drugs may more easily enter the supply chain.

Changes to patient co-payments are intended both to raise revenue and to discourage unnecessary drug use by influencing prescriber and patient habits. However, the system of patient co-payments has two major flaws. Firstly, increased patient co-payments will cause some price-sensitive patients to reduce their consumption of drugs that have significant clinical merit for chronic conditions such as cardiovascular disease[24]. Reduced consumption will hinder disease management programmes, increase acute hospital admissions, and add to HSE running costs. Secondly, although the co-payments may ease the Community Drugs Schemes budget, they merely shift the costs onto patients. Therefore the overall proportion of the nation's wealth that is spent on drugs is not reduced, and so no net resources are freed for use elsewhere. Future reform should aim to reduce total drug expenditure across both public and private sectors.

Altogether, Minister Harney's recent reforms are intended to reduce the projected €2.4 billion cost of the Community Drugs Schemes in 2010 by €270 million. Assuming that market adjustments do not erode these savings significantly, this will be sufficient to restrain overall drug expenditure near 2009 levels during 2010. However, unless long-term strategies are developed to improve both price competition within the drugs market and prescribing habits, underlying growth trends of 12% per year will then resume. An emerging issue is the HTD scheme, which cost €290 million and accounted for 15% of the Community Drugs Schemes expenditure in 2008. Recent reforms fail to address the cost of the scheme beyond imposing a 4% rebate on the ex-factory price of these drugs, worth €14 million in 2010[3,18]. The cost of the HTD scheme has been increasing by 18% per year between 2004 and 2008, far more than the 11% increase of the other schemes (Figure 1). If this growth rate continues unchecked, the HTD scheme expenditure will approach €900 million in 2015.

Long-term control of the costs of the Community Drugs Schemes without compromising patient care requires ongoing reform from both legislators and prescribers. Several strategies to further reduce drug expenditure are available. Future legislative reform offers the chance to address some of the current shortcomings in current drugs market legislation as well as to implement entirely new initiatives. Educational efforts to improve the cost-effectiveness of prescribing while improving patient care could begin immediately but are likely to be relatively slow to show results.

FUTURE LEGISLATIVE CHANGES TO THE COMMUNITY DRUGS SCHEMES

Four major changes expected for the Community Drugs Schemes are reference pricing, pharmacist-led drug substitution, renegotiation of drug prices with manufacturers, and disinvestment of selected drugs.

Introduction of a reference pricing system has been proposed for 2011[11]. Under this system, a maximum reimbursement price would be agreed for groups of interchangeable drugs with the same active ingredient. For example, whether omeprazole is dispensed as the original brand, Losec, or as one of many available generic versions, the HSE will only reimburse at the stated reference price based on the cheapest alternative. If the patient insists on a more expensive branded product without medical justification, he must pay the price difference from his own pocket[25]. Reference pricing is an effective way to legislate for reduced drug expenditure without compromising prescriber autonomy or patient care[26], and is already in place in eighteen European countries.

Also proposed for 2011[11], obligatory pharmacist-led substitution would complement reference pricing by requiring that the cheapest available version of a drug be dispensed regardless of any brand specified on the prescription, unless the prescriber insists otherwise. There are situations when continuity of the same brand may be important and substitution is inappropriate. If the drug has a narrow therapeutic index between efficacy and toxicity, then small potential differences in bioavailability mean that continuity of a single brand for a patient may be important (e.g. ciclosporin, lithium). Also potentially unsuitable for substitution are medicines with modified release preparations, multiple ingredients, different administrative devices (e.g. between brands of inhalers or pre-filled syringes), different preparations with different indications, and products of biological origin[27].

Irish drug prices are about 20% above the European average[28], indicating that substantial savings are achievable through renegotiation of prices with manufacturers. Renegotiation with non-IPHA generic manufacturers will take effect in September 2010 when the current contract expires. Renegotiation for on-patent drugs has been deferred 18 months until February 2012. Drugs which are on-patent or lack generic competitors make up about 75% of the cost of the Community Drugs Schemes[19], meaning that even a modest 5% price reduction would save in the region of €100 million per year from 2012.

To reduce drugs costs further, certain drugs that have not been shown to be cost-effective should be disinvested from the Community Drugs Schemes. In 2008, €52 million was spent on clinical nutritional products[3] that have not been shown to bring long-term benefit in the community setting, and half of which are not consumed[29]. Over €5 million was spent on glucosamine for osteoarthritis without good evidence of benefit[3]. Disinvested products could remain available over the counter at the patient's expense.

A guiding principle for future legislation should be to simplify the supply and reimbursement of drugs. This would improve market transparency and competition, reduce perverse incentives, and lower administrative costs.

Prescriber initiatives to reduce drugs costs

Changes in prescriber habits could effect far-reaching improvements in healthcare efficiency without compromising patient care or requiring further legislation. Rational prescribing aims to use drugs most effectively while minimising risks and unnecessary costs, and is essential to efficient healthcare. Examples of rational prescribing habits include periodic and critical review of the drugs taken by every patient, judicious antibiotic use, generic prescribing, and cost-aware prescribing. To help improve rational prescribing habits, specialist prescribing software could be provided to GP surgeries and hospitals to automatically assess the quality of prescriptions.

Periodic and critical review of the drugs prescribed to every patient could reduce unnecessary expense, adverse drug effects, drug interactions and wastage. Over a third of prescriptions for those over age 70 have been shown to be potentially inappropriate, costing €46 million in 2007: 9% of the total drug expenditure for that age group. The main contributors to this include: proton pump inhibitors (PPIs) prescribed at full therapeutic dose for more than eight weeks, non-steroidal anti-inflammatory drugs (NSAIDs) prescribed for more than three months, long-acting benzodiazepines prescribed for more than one month, and duplicate drugs on the same prescription claim[30].

Ireland has been among the least successful of European countries at reducing unnecessary antibiotic use[31]. Prescribers often feel pressured to provide antibiotics even for viral infections such as colds and flu where they offer no benefit[32]. Unnecessary antibiotic use wastes about €41 million a year and leads to adverse drug effects for one fifth of patients[33].

It also threatens the health of the wider community by encouraging antimicrobial resistance, which leads to the increased morbidity, increased fatality and prolonged epidemics seen with multidrug-resistant Staphylococcus aureus (MRSA), Streptococcus pneumoniae and Haemophilus influenzae[34]. Redoubled education campaigns such as the European Antibiotic Awareness Day are required to change patient expectations and prescriber habits.

Generic prescribing, where drugs are specified by their INN, is usually seen as a key strategy to improve patient safety by avoiding potential prescriber, pharmacist and patient confusion over the diverse brand names that exist for the same drug. Fewer mistakes translate into fewer adverse drug reactions, better patient outcomes and reduced healthcare costs. Generic prescribing also has potential to reduce drugs costs (without waiting for reference pricing or pharmacist-led substitution to be legislated) by allowing the cheapest equivalent alternative brand of a drug to be dispensed. This in turn encourages price competition between manufacturers. In England nearly two-thirds of prescription items are dispensed generically[35], contrasting with less than one fifth here[4]. The low rate seen in the Irish system is driven by the marketing of branded drugs to prescribers, public perception that generic drugs are inferior, and prohibition of pharmacist-led generic substitution for branded prescriptions. The IPHA 40% price reduction for 300 off-patent drugs has temporarily created an anomalous situation in Ireland where many well-known branded drugs cost considerably less than their generic equivalents from non-IPHA manufacturers. This anomaly

will not persist if reference pricing and pharmacist-led substitution are introduced in 2011, or if non-IPHA generic manufacturers agree to reduce their prices from September 2010. Meanwhile, prescribers can maintain patient safety and ensure their patients receive the cheapest version of a drug by checking prices in an up-to-date Monthly Index of Medical Specialties (MIMS) and specifying both the least expensive brand and the INN on the prescription e.g. "BySec (omeprazole) 20 mg". However, if the pharmacist is out of stock of a particular brand of a drug, then specifying that brand on a patient's prescription may lead to a delay in dispensing while supplies are delivered.

Additionally, prescribers should be aware that competing drugs for a given indication may have very similar efficacy and safety, yet very different prices. For example, there may not be any medical reason to prefer a particular PPI over another for a patient with dyspepsia. Yet, despite evidence that esomeprazole (Nexium) and omeprazole are equally effective for most patients[36], the ex-factory price of Nexium is double that of the cheapest omeprazole because it is still on-patent. Nexium cost €37 million in 2008[3]. As Thomas Scully said while Administrator of the Centers for Medicare and Medicaid Services in the US: "You should be embarrassed if you prescribe Nexium," because it increases costs with no medical benefits[37].

Drug prices can also vary considerably between hospital and community settings. Hospital prescribers initiate over a third of GMS prescriptions, at a median cost 70% greater than those initiated by general practitioners[4]. In part, this reflects the differing morbidities of patients seen in hospital and by GPs. Also, however, hospitals are often offered discounts on certain drugs, which lead to these drugs' continued prescription in the community after discharge despite their community cost being significantly higher than competing drugs for the same indication. Hospital prescribing guidelines should be amended to reflect costs both to the hospital and to the Community Drugs Schemes[4].

These suggested changes to prescriber habits will require an ongoing investment in the education of prescribers and patients about best practices. Provision of prescribing software to general practitioners and in hospitals would facilitate analysis and feedback in relation to quality prescribing indicators such as dose, duration, potential drug-drug and drug-disease interactions, and generic prescribing rates[4]. If such software is able to save prescribers time, improve the quality of their prescribing, and prevent drug errors that harm patients and lead to lawsuits: it is likely to be received enthusiastically.

> **"You should be embarrassed if you prescribe Nexium, because you're screwing your patients and you're screwing the taxpayers."**

Prescribers control patient access to prescription drugs and therefore have a responsibility to ensure that they prescribe effectively based on best evidence and up-to-date cost data. Efforts to improve rational prescribing such as periodic patient drug reviews, more judicious antibiotic use, generic prescribing, and cost aware prescribing all offer improved patient care and more efficient drug use. This in turn will reduce the costs of healthcare.

THE OVERALL FINANCIAL EFFECT OF RECENT AND PROPOSED CHANGES

The cost savings from these recent and proposed changes are not trivially additive; ways to erode the savings will be found by those whose incomes are affected, investment will be required for reform, there will be knock-on effects throughout the supply chain, and secondary effects such as reduced antibiotic-resistant infections will alter healthcare requirements. However, simple summation does indicate something of the magnitude of savings available. Minister Harney's recent changes could save €270 million in 2010. Future introduction of reference pricing, pharmacist-led substitution, renegotiation of on-patent and generic drug prices, and disinvestment of ineffective drugs could save over €200 million more. Prescriber initiatives such as periodic prescription reviews, more judicious prescribing of antibiotics, generic prescribing, cost-aware prescribing and amended hospital prescribing guidelines offer another €100 million per year.

Minister Harney's recent reforms should be sufficient to restrain overall drug expenditure at 2009 levels during 2010 but, unless long-term strategies are developed to improve both prescribing habits and price competition within the drugs market, underlying growth trends will then reassert and growth of 12% per year will resume.

The magnitude of available savings still available for the Community Drugs Schemes indicates the significant direct benefit of renewed efforts to reduce drugs costs. The secondary benefits from resource reallocation, reduced drug-resistant infection and improved health that these policies could bring are difficult to quantify, but are perhaps even more valuable.

CONCLUSION

Public budget cuts provide an impetus to legislators and prescribers to overhaul the provision of healthcare. Efforts to improve the efficiency of the drugs supply in Ireland can both save public money and improve patient care. Recent changes to the Community Drugs Schemes are a generally promising first step, but the need remains for further legislation and improved prescriber habits. Future policy debate is likely to be dominated by how to encourage price competition within the drugs market and how to address the rapidly growing costs of novel biologic products. Ireland can afford to maintain one of the best healthcare systems in the world; what we can no longer afford is to run the system inefficiently.

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