The Health (Pricing and Supply of Medical Goods) Act 2013 introduced changes to the way medicines are dispensed and reimbursed in Ireland.

Generic substitution is now permitted for medicines designated as interchangeable.

Where established, only the reference price of a medicine will be reimbursed at the time of dispensing.

The aim of the Medicines Management Programme is to enhance evidence-based and cost-effective prescribing and to optimise patient safety.

INTRODUCTION

Ireland’s population has shown a steady rise over the last 50 years: the most recent Census figures show a rise from 3.9 million in 2002 to 4.5 million in 2011. In addition, the population continues to age with an estimated 586,600 persons >65 years of age living in Ireland in 2014. It is well established that older people use health services more frequently, however these demographic changes are occurring at a time of rationing of health budgets: healthcare budgets were reduced by 22% (€3.3 billion) between 2008 and 2013 in Ireland.

During the 2000s, Ireland experienced one of the highest annual growth rates in pharmaceutical expenditure of any OECD country: Ireland’s pharmaceutical expenditure per capita was 20th highest of 27 OECD countries in 2000, rising to 9th highest of 31 in 2005 and 3rd highest of 25 countries in 2010. As part of its “Future Health” strategy for reform of the health service (2012-15), the Department of Health (DOH) identified savings on pharmaceutical expenditure as one method of tackling the overall costs of the health service.

The Health (Pricing and Supply of Medical Goods) Act 2013 introduced changes to the way medicines may be dispensed and the way that pharmaceutical prices are set in Ireland. In addition, the HSE’s multi-disciplinary Medicines Management Programme (MMP) was established in 2013 to enhance evidence-based and cost-effective prescribing and to optimise patient safety. This bulletin will outline the main provisions of these new initiatives and address some frequently asked questions on their potential impact (from a patient and healthcare professional perspective) on prescribing and dispensing of medicines in Ireland.

THE HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013

This legislation, which came into effect in June 2013, introduced a system of generic substitution and reference pricing. The key aim is to ensure value for money in the supply of medicines, by promoting price competition among suppliers, while ensuring continuing medication safety. The provisions relate to supply and reimbursement of medicines under the community drug schemes in Ireland. The main provisions of this legislation are described in the following sections:

Reimbursement of Authorised Medicines: The 1970 Health Act (and subsequent amendments to this act) outlined procedures for provision of specific “reimbursable” medicines to eligible patients, via the various community drug schemes (including the general medical service (GMS), drug payment scheme (DPS) and long term illness (LTI) scheme). The Health (Pricing and Supply of Medical Goods) Act 2013 (hereafter referred to as the 2013 Act) further defined the establishment and maintenance of a reimbursement list by the HSE, which should be made publically accessible. This list should contain all medicines, medical devices or other medical products (such as nutritional aids) that may be reimbursed by the community drug schemes. All medicines that were deemed reimbursable under the previous legislation were automatically transferred to the current reimbursement list. However, the 2013 Act specifies that these “transferred” medicines should be reviewed within 3 years of its implementation and the list amended (including removal of items) as appropriate. Entry to this list requires evidence of clinical and cost-effectiveness. Conditions of use may apply to certain medicines on the list; restrictions include (1) who may prescribe the medicine (2) duration of therapy (3) indication for use or (4) recommended patient group. Supply outside these conditions may not be reimbursed.

The HSE is responsible for agreeing the price of medicines on the reimbursement list with pharmaceutical companies; the HSE Corporate Pharmaceutical Unit (HSE-CPU) is the interface between the HSE and the companies in these negotiations. In addition, where the list contains several items which have been designated as “interchangeable”, a reference price for all such items may be determined by the HSE. [discussed in more detail below]. The list of reimbursable items under the community drug schemes, is available at: www.pcrs.ie.

Reimbursement of New Medicines: Under EU legislation a new medicine must be granted a marketing authorisation (licence), either from the Health Products Regulatory Authority (HPRA) or the EU Commission, before it can be made available for sale or supply in any member state. As in many other member states, in Ireland a price for the new medicine is agreed between the pharmaceutical company and the relevant body.
The National Centre for Pharmacoeconomics (NCPE) undertakes the pharmacoeconomic assessment of medicines on behalf of the HSE, to evaluate the cost-effectiveness of a medicine and thereby advise whether or not a medicine should be recommended for reimbursement. As part of the evaluation process, the medicine initially undergoes a rapid review process; high cost medicines, those with significant budget impact or where there is uncertainty regarding cost-effectiveness of the medicine, will be subjected to formal pharmacoeconomic assessment. Under the 2013 Act, a formal assessment may also be requested where there is uncertainty in relation to cost-effectiveness of existing products.

The pharmacoeconomic procedure undertaken by NCPE is summarised in Figure 1.

**Figure 1: Pharmacoeconomic evaluation process undertaken by NCPE**

<table>
<thead>
<tr>
<th>HSE-CPU NOTIFIES THE PHARMACEUTICAL COMPANY OF REQUIREMENT FOR RAPID REVIEW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company submits documentation to NCPE</td>
</tr>
<tr>
<td>↓</td>
</tr>
<tr>
<td>NCPE undertakes Rapid Review once submission received (4 weeks)</td>
</tr>
<tr>
<td>↓</td>
</tr>
<tr>
<td>Medicine recommended for reimbursement OR</td>
</tr>
<tr>
<td>Medicine recommended for full pharmacoeconomic review</td>
</tr>
<tr>
<td>↓</td>
</tr>
<tr>
<td>Company formally notified / Pre-submission consultation between company and NCPE</td>
</tr>
<tr>
<td>↓</td>
</tr>
<tr>
<td>Formal company submission to NCPE of evidence on cost-effectiveness and budget impact of medicine</td>
</tr>
<tr>
<td>↓</td>
</tr>
<tr>
<td>NCPE evaluation / interaction with company</td>
</tr>
<tr>
<td>↓</td>
</tr>
<tr>
<td>NCPE appraisal and recommendation sent to HSE-CPU</td>
</tr>
</tbody>
</table>

*The clock is stopped when NCPE seeks clarification from the company.

HSE-CPU= HSE Corporate Pharmaceutical Unit; NCPE=National Centre for Pharmacoeconomics

The NCPE assessment process follows the Health Information and Quality Authority (HIQA) Health Technology Assessment guidelines. The rapid review process takes approximately 2 to 4 weeks and the formal pharmacoeconomic assessment is completed in less than 3 months (90 days), excluding clock stops (Figure 1). The resultant NCPE report is sent to the HSE-CPU; for oncology medications, a copy of the report is also sent to the National Cancer Control Programme. Information on comparative effectiveness and cost-effectiveness is provided in the report, based on the company’s proposed (submitted) price, in order to inform the reimbursement decision makers in the HSE. The medicine may be (1) recommended for reimbursement, (2) not recommended for reimbursement or (3) not recommended for reimbursement at the submitted price. In the latter case, following price negotiation between the HSE and the company, the medicine may be made available at a lower price.

The 2013 Act places decision making in relation to pricing and reimbursement as a legal and statutory responsibility of the HSE. The HSE has a governance structure, including a National Committee, which considers applications for pricing and reimbursement of new medicines in line with criteria outlined in the Schedule of the Act.

A summary report for each HTA assessment is published on the NCPE website (www.ncpe.ie).

**WHAT ARE INTERCHANGEABLE MEDICINES?**

The 2013 Act directs that the HPRA establish, publish and maintain a list of interchangeable medicinal products fulfilling the criteria laid out in section 5 of the Act (Table 1). A previous National Medicines Information Centre (NMIC) bulletin discussed generic medicines and the potential for cost containment with generic prescribing in Ireland. A **generic medicine** may be defined as having the same qualitative and quantitative composition in active substance(s) as a medicine that has already been authorised (known as the reference / proprietary / branded medicine). Similar criteria are used to determine if a product can be considered an “**interchangeable medicine**”, as shown in Table 1.

**Table 1: Requirements for entry onto the list of Interchangeable Medicines**

<table>
<thead>
<tr>
<th>Requirements for interchangeability</th>
<th>Criteria excluding / Contraindications for interchangeability</th>
</tr>
</thead>
<tbody>
<tr>
<td>The medicine:</td>
<td>The medicine: has a clinically relevant difference in bioavailability compared to listed interchangeable medicines or contains &gt;2 active ingredients or is a biological entity (including biosimilars) or cannot be safely substituted for other listed interchangeable medicines or the device (if any) for administration significantly differs from other listed interchangeable medicines</td>
</tr>
<tr>
<td>must contain the same active ingredient in the same strength <strong>and</strong> must be in the same pharmaceutical form <strong>and</strong> must have the same route of administration as the other listed interchangeable medicines</td>
<td></td>
</tr>
</tbody>
</table>

HSE = Health Service Executive; NCPE = National Centre for Pharmacoeconomics
Once the evaluation process and a consultation phase with the relevant pharmaceutical companies are completed, the HPRA publishes the list of interchangeable medicines on its website. The interchangeability lists are reviewed and updated regularly (to amend existing listed substances and to add newly created interchangeable medicine groups). The HPRA has a useful guide to interchangeability on its website (www.hpra.ie).

The importance of the interchangeability process lies in the fact that the 2013 Act permits the dispensing pharmacist to substitute a less expensive medicine from within the list (so-called generic substitution) [discussed in further detail under the Practical Consequences section below].

At the request of the DOH, the HPRA prioritised the review of the interchangeability of active substances judged to achieve the greatest saving to the State and patients during 2013 and 2014, including statins and proton pump inhibitors. The full list of active ingredients that have been evaluated by the HPRA, together with the individual medicinal products containing that active ingredient included on the interchangeable list is published on the HPRA website at: http://www.hpra.ie/homepage/medicines/medicines-information/generics-lists.

WHAT IS MEANT BY REFERENCE PRICING?

The 2013 Act confers on the HSE the right to set a price (referred to as the “reference price”) for a relevant group of interchangeable medicines, which will be applicable only to those medicines included on the interchangeable medicines group list. The 2013 Act lays out certain criteria by which the HSE shall set the reference price (see Table 2).

Table 2: Factors to be taken into account in determining a reference price*5,22,23

- Value for money
- Ability of relevant supplier(s) to meet patient demand
- Equivalent relevant prices (if practically available) in other member states with ≥ one of listed medicines on the market
- Relevant prices of therapeutically similar listed medicines
- The terms of existing pricing agreements relevant to the listed medicines (e.g. with IPHA / APMI)
- The resources available to the HSE

*The 2013 Act also permits use of a competitive process to set the reference price for a particular group of interchangeable medicines.

IPHA=Irish Pharmaceutical Healthcare Association; APMI=Association of Pharmaceutical Manufacturers of Ireland.

Once a reference price has been set for a group of interchangeable medicines, community pharmacists are notified by the HSE, at least 4 weeks before it comes into effect. The reference price for each interchangeable list of medicines should be reviewed at least yearly and amended as appropriate. The full list of active substances that have been assigned a reference price under the 2013 Act is available on http://www.hse.ie/referenceprice/.

WHAT ARE THE PRACTICAL CONSEQUENCES OF THE 2013 ACT FOR HEALTHCARE PROFESSIONALS AND PATIENTS?

Reference Pricing: If a reference price exists for an interchangeable group, then only the reference price will be reimbursed, whenever a prescription for a medicine within that group is dispensed. This means that if the branded medicine, written on the prescription costs more than the reference price and the patient is unwilling to agree to generic substitution as outlined above, he/she will be liable to pay the additional cost (i.e. difference between the reference price and the cost of the branded medicine), if covered by any of the community drug schemes. However, if the prescriber is satisfied that a branded interchangeable medicine should not be substituted for clinical reasons, then the prescriber may write by hand “Do not substitute” on the prescription beside this medicine. In such circumstances, the medicine will then be dispensed as written (i.e. no generic substitution) at no additional cost to the patient.

Interchangeable Medicines: The 2013 Act states that once a list of interchangeable medicines for a specific active substance has been published by the HPRA, a reference price may be determined by the HSE. However, in order to satisfy the requirements of consultation and notification for reference pricing, outlined in the 2013 Act, there will be a delay of at least two months between publication of the interchangeability list for an active substance and determination of its reference price. When a prescription for an interchangeable medicine (for which there is no reference price) is presented to a dispensing pharmacist, the 2013 Act outlines the following: (1) if the prescription uses the generic name, then the pharmacist shall dispense the least expensive version of the active substance in stock (2) if the name written on the prescription is not the least expensive version (e.g. is a more expensive brand or branded generic), the pharmacist shall offer the patient the opportunity to agree to the least expensive version of the active substance available in stock being dispensed. If the patient agrees, the pharmacist shall “effect the substitution”; if the patient doesn’t agree the pharmacist shall dispense the medicine according to the brand name written on the prescription. There are no cost penalties to the patient if no reference price exists.
The Medicines Management Programme (MMP) was established in 2013 to promote safe, effective and cost-effective prescribing of medicines by enhancing evidence-based prescribing and optimising patient safety. The MMP team is supported by experts from several national bodies, including the NMIC and NCPE, and works in collaboration with the HSE-PCRS. It is currently involved in the following prescribing initiatives, full details of which are available on the MMP website: [www.hse.ie/yourmedicines](http://www.hse.ie/yourmedicines).

**Preferred Drugs Initiative** identifies a single ‘preferred drug’ within a therapeutic drug class, and offers prescribers guidance on selecting, prescribing and monitoring this drug for a particular condition. The preferred drug is selected following a review of the available evidence, including data on clinical effectiveness, safety profile, dosing schedules, the potential for drug-drug interactions, cost, national prescribing trends, and national / international clinical guidelines. Table 3 outlines the preferred drug of each therapeutic class that has been reviewed to date.

### Table 3: Preferred drug according to therapeutic class*27,28

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>MMP Preferred Drug**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiotensin-Converting Enzyme (ACE) inhibitors</td>
<td>Ramipril</td>
</tr>
<tr>
<td>Angiotensin-II Receptor Blockers (ARB)</td>
<td>Candesartan</td>
</tr>
<tr>
<td>Proton Pump Inhibitors (PPI)</td>
<td>Lansoprazole</td>
</tr>
<tr>
<td>Serotonin Noradrenaline Reuptake Inhibitors (SNRI)</td>
<td>Venlafaxine</td>
</tr>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRI)</td>
<td>Citalopram</td>
</tr>
<tr>
<td>Statins</td>
<td>Simvastatin</td>
</tr>
<tr>
<td>Urinary Antispasmodics (urgency, frequency and overactive bladder)</td>
<td>Tolterodine ER (extended release)</td>
</tr>
</tbody>
</table>

*list correct as of 20 January 2015; **a full report for each preferred drug is available at MMP website: [www.hse.ie/yourmedicines](http://www.hse.ie/yourmedicines)

Prescribers are encouraged to make the preferred drug their drug of first choice when prescribing a drug from that therapeutic class.

**Prescribing Tips and Tools:** A summary prescriber guide for each of the preferred drugs (Table 3) as well as for the new oral anticoagulants (NOACs) is available on the MMP website to optimise safe and effective use of these medicines.

**Prescribing and Cost Guidance:** This initiative provides evidence-based information regarding the prescribing, monitoring and reimbursement of treatments in a specific therapeutic area. The goal is to increase awareness among prescribers and other relevant healthcare professionals of the costs of these treatments, and to encourage the prescription of less expensive, equally effective therapies for patients where possible. To date the MMP has published prescribing and cost guidance on Asthma and Chronic Obstructive Pulmonary Disease (COPD). The recommendations on preferred drugs and the prescribing guidance will be reviewed regularly by the MMP and updated in line with current available evidence.

### USEFUL RESOURCES

- [www.ncpe.ie/pharmacoeconomic-evaluations/](http://www.ncpe.ie/pharmacoeconomic-evaluations/): Summary reports on all pharmacoeconomic evaluations undertaken by the National Centre for Pharmacoeconomics
- [www.hpra.ie/homepage/site-tools/register](http://www.hpra.ie/homepage/site-tools/register): Registration site for the Health Products Regulatory Authority (register to receive regular pharmaceutical updates, including Interchangeability Listings)
- [http://www.hse.ie/referenceprice/](http://www.hse.ie/referenceprice/): Site contains a quick guide (and Q & A document) to reference pricing and lists all substances with their reference price
- [www.hse.ie/yourmedicines](http://www.hse.ie/yourmedicines): The Medicines Management Programme website (containing full details of ongoing MMP initiatives)
References for: UPDATE ON PRESCRIBING AND DISPENSING OF MEDICINES IN IRELAND
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