Newsletter - Health (Pricing and Supply of Medical Goods) Act 2013 July 2013

In This Issue

Print Version »

Welcome message

Dear Pharmacist,

This special e-newsletter is intended to give you general information and guidance on the Health (Pricing and Supply of Medical Goods) Act 2013, which was commenced last month. This legislation amends the Pharmacy Act 2007 in respect of a number of provisions, and will have practice implications for pharmacists and pharmacy owners.

It is important that all pharmacists read this legislation and keep themselves up-to-date with the various changes that will be occurring over the coming months. It is expected that the first interchangeable medicines list will be published by the Irish Medicines Board (IMB) next month and that the first reference prices will be set by the HSE by November.

As the frontline healthcare professional managing patients' medicines, pharmacists will be interacting directly with patients in respect of the changes introduced by the legislation. Therefore, it is important that pharmacists have the appropriate information and supports to assist them dealing with patient queries.

Pharmacists should also be cognisant of the fact that as the experts in medicines, prescribers and other healthcare professionals may seek their advice on the management of individual patients and/or medicines. Pharmacists should also seek to collaborate with prescribers, particularly at local level, and particularly in respect of the management of vulnerable or complex patients.

Information about the legislation is available on the Department of Health website and the Irish Medicines Board website.

The HSE is also developing resources for the public on their website over the coming months.

The PSI will be happy to deal with any queries you may have at info@thepsi.ie.

Background

The Health (Pricing and Supply of Medical Goods) Act 2013 was commenced on 24th June 2013.

This legislation will provide much greater access to generic medicines in Ireland and aims to reduce medicine costs for patients and for the State. The Act introduces a system of generic substitution and reference pricing which will allow patients to opt for lower cost interchangeable (i.e. generic) medicines. It also establishes a list of prescribed items which may be supplied or reimbursed by the HSE to patients under State drugs schemes, and establishes mechanisms for setting the prices of those items.

Generic substitution will be introduced incrementally, prioritising those

medicines which will achieve the greatest savings. Further information on the Act is available on the Department of Health website.

Implications for Pharmacists

This legislation has a number of significant practice implications for pharmacists and pharmacy owners. Therefore pharmacists must ensure that they are familiar with and practice in accordance with the Act. In particular pharmacists must be cognisant of their duties, outlined in Chapters 2 and 3 of Part 2 of the Act, in relation to prescriptions for interchangeable medicinal products under branded name and under common name; and of their duties, outlined in Part 3 of the Act, in relation to the dispensing of medicinal products under common name where they are not interchangeable medicinal products.

Patient Consultation and Communication

As pharmacists will appreciate, the importance and impact of providing information and education to patients when providing a substitute medicinal product cannot be overestimated. Patient counselling and developing a correct understanding of generic medicines has been shown to increase the acceptability of generics to patients. Therefore, when a medicine is substituted, pharmacists must particularly take time to ensure that patients receive appropriate counselling and understand the correct use of their medicines.

Communication should be clear, reassuring and unrushed and should seek to remove any confusion. Pharmacists should provide patients with the opportunity to ask questions, should answer any questions asked and should check patient understanding. In certain situations it may be appropriate to discuss the substitution with or in the presence of a family member or carer. Pharmacists should ensure that they emphasise the active ingredient name/ international non-proprietary name (INN) in all consultations with patients.

When counselling patients on substituted medicines, the pharmacist should:

- Draw the attention of the patient to the label on the packaging and explain that the prescribed medicine is being replaced with an alternative brand.
- Explain that the product contains the same active ingredient (the ingredient that makes the medicine work) at the same strength and explain any differences in the appearance of the product or packaging. (Some patients may associate such changes with a change in efficacy or safety, while other patients may rely on the appearance of medicines to identify their purpose and dosage regimen).
- Reassure patients that generic products are required to meet the same quality, safety and manufacturing standards as branded medicinal products.
- Explain that the product is expected to be equally effective and cause the same beneficial and adverse effects as a branded medicine.
- Acknowledge that the inactive ingredients may be different, but explain that these rarely cause adverse effects.
- Advise the patient that if unexpected adverse effects occur, they should seek medical advice.
- Ascertain that patients understand the change being made and how to take their medicines safely

Patients should be given contact details for the pharmacy should they have any queries or issues that they need to discuss with the pharmacist after they leave the pharmacy.

Mitigating the Risk of Dispensing Errors

Substitution may introduce an additional step(s) to the dispensing process which may increase the potential for dispensing error. Pharmacists should therefore ensure that they are extra vigilant when substituting and employ a thorough double check system. Products should be clearly labelled with *"This medicine replaces … Do not use both"*, whenever the brand is changed, if appropriate. Pharmacists should avoid making multiple brand switches as this may compound any patient confusion.

Where the prescriber has indicated "do not substitute" on a prescription, this should be recorded in a manner which allows the pharmacist to identify those patients where substitution is not always appropriate.

Identification of Patients Where Additional Care is Required

Many patients will welcome substitution once they have been reassured that generic products are as effective and safe as their branded equivalents and advised of the cost benefits.

Inappropriate substitution or insufficient counselling has the potential to result in a number of problems e.g. patients taking two products, patients stopping their medication, reduced patient adherence or adverse reactions to excipients.

In particular, pharmacists should take steps to prevent patient confusion leading to 'double dosing' with two interchangeable products, eg encouraging patients/carers to review their medicine stocks at home and returning unused medicines to the pharmacy for disposal.

Some of the potential issues which could lead to substitution problems include:

- Patients with clinically significant intolerances or allergy to excipients e.g. gluten, lactose.
- Patients with cognitive or visual impairment.
- Patients with dexterity problems.
- Patients on complex medication regimes.
- Patients with literacy or language difficulties.
- Patients with conditions in which negative perceptions of substitution can impact on treatment adherence or response (e.g. some patients with mental illnesses).
- Cultural issues e.g. concerns about inferior/counterfeit product and inactive ingredients may be important in the observation of some religious/cultural practices.

Pharmacists should exercise their professional judgement in appropriately managing such issues. In many cases patient counselling can allay fears and correct misunderstandings. The information material and other resources provided by the HSE for the public may be helpful in supporting these discussions with patients. Where issues arise, pharmacists may need to collaborate with the patient's medical practitioner to find an appropriate solution.

Pharmacists should exercise their professional judgment when substituting products to ensure that substitution is safe and that efficacy will not be affected e.g. they should not substitute medicines with a narrow therapeutic index or those with differing pharmacokinetic profiles likely to impact on efficacy or safety.

Amendments to the Role and Functions of the PSI

The Health (Pricing and Supply of Medical Goods) Act 2013 introduces several amendments to the Pharmacy Act 2007.

These include amending the principal functions of the Pharmaceutical Society of Ireland to include supervision of compliance by pharmacists with Chapters 2 and 3 of Part 2, and Part 3, of the Health (Pricing and Supply of Medical Goods) Act 2013. As a result of this additional function, Authorised Officers of the PSI may assess compliance with this legislation during inspections/investigations of registered retail pharmacy businesses.

Section 18 of the Pharmacy Act is also amended by the Health (Pricing and Supply of Medical Goods) Act 2013. This amendment permits the Minister to make regulations which impose duties on a Pharmacy Owner, the Superintendent Pharmacist or the Supervising Pharmacist to supervise compliance by pharmacists with Chapters 2 and 3 and Part 2 and Part 3 of the Health (Pricing and Supply of Medical Goods) Act 2013.

Under Part 6 of the Pharmacy Act 2007 complaints may be made to the Council of the PSI in respect of registered pharmacists and registered retail pharmacy businesses.

The Health (Pricing and Supply of Medical Goods) Act 2013 amends section 35(1) of the Pharmacy Act 2007 by introducing two new grounds whereby complaints may be made in respect of registered pharmacists for;

- "a failure to comply with Chapter 2 or 3 of Part 2, or Part 3, of the Health (Pricing and Supply of Medical Goods) Act 2012".
- "a failure to comply with any duties referred to in section 18(1A) imposed on the pharmacist by regulations made under section 18".

The Health (Pricing and Supply of Medical Goods) Act 2013 also amends section 36(1) of the Pharmacy Act 2007 by introducing one new ground whereby complaints may be made in respect of retail pharmacy businesses on the ground that "the pharmacy owner has failed to comply with any duties referred to in section 18A imposed on the pharmacy owner by regulations made under section 18".

Policies and Procedures

Superintendent and supervising pharmacists should ensure that all relevant policies and procedures are reviewed and updated as the various changes come on-stream. They should also reflect on the measures that need to be put in place to reduce the risk of patient confusion or misunderstandings arising from interactions with individual patients.

Superintendent pharmacists should ensure that a complaint handling policy is in place and that all staff are familiar with the appropriate procedure for dealing with complaints or concerns of patients and the public e.g. where a patient is unhappy with a substituted product, believes that a substituted product is not working, does not understand the substitution or is reporting a suspected adverse reaction.

Information around substitution and/or pricing changes should be explained in a clear and transparent manner to patients.

All pharmacy staff should be educated about medicinal product substitution and the relevant patient care issues. Training should be appropriate for their level of patient interaction. Training should ensure that staff can appropriately advise, inform, educate and refer, where required. Staff should be trained to be alert to the potential for patient confusion. Training should ensure familiarity with all relevant policies and procedures.

FAQs for Healthcare Professionals

These FAQs have been developed by the DoH/HSE implementation

group for the legislation and are being circulated to pharmacists and prescribers

What is generic substitution?

Generic substitution allows pharmacists to substitute medicines which have been designated as interchangeable by the Irish Medicines Board (IMB). The IMB will begin by reviewing an initial 20 active substances, which equates to approximately 1,500 individual medicinal products. There are twenty of these medicines currently identified and they include statins, proton pump inhibitors, angiotensin-converting-enzyme (ACE) inhibitors and angiotensin II receptor blockers (see table below)

Anastrozole	Lansoprazole	Pantoprazole	Ramipril
Atorvastatin	Lercanidipine	Perindopril	Risperidone
Candesartan	Losartan	Pravastatin	Rosuvastatin
Clopidogrel	Olanzapine	Quetiapine	Simvastatin
Esomeprazole	Omeprazole	Rabeprazole	Valsartan

It is expected that the first List of Interchangeable Medicines, containing groups of atorvastatin products, will be published in mid-August 2013. The IMB will publish subsequent lists for other groups of medicines on an ongoing basis. From the end of the year onwards, hundreds of thousands of prescriptions will be subject to generic substitution, which will offer choice and reduced prices to patients. Further information on interchangeable medicines is available on the IMB website.

What is reference pricing?

Reference pricing sets a common reimbursement price for groups of interchangeable medicines. The HSE will set a reference price for each group of medicines published on a List of Interchangeable Medicines, and this is the price that the HSE will reimburse for all medicines in that group. Following the process set out in the legislation, the first reference prices will be available by November 2013, and will continue to be introduced incrementally over time. Further information on reference pricing is available here and a list of frequently asked questions is available here.

What will change for prescribers?

- Prescribers should prescribe generically, where appropriate, and ensure the international non-proprietary name (INN) is written on prescriptions;
- As lists of interchangeable medicines are published, prescribers should explain to the patients taking that medicine that they may be offered an alternative version of that medicine at the pharmacy; and later on, in 2013, that a reference price will apply to their medicine.
- Occasionally, due to an individual patient issue, a prescriber may decide it is not advisable for clinical reasons to switch between different versions of a medicine even if the medicine is included in a group of interchangeable medicines. When this arises a prescriber should indicate that substitution should not take place by writing, legibly and by hand, 'Do Not Substitute' on the prescription beside the name of the medicine;
- The prescriber should also ensure their Medical Council number is clearly written on the prescription.

What will change for pharmacists?

- The legislation puts an onus on pharmacists to offer all patients an interchangeable medicine which is of lower cost to the HSE or patient, as the case may be - unless "Do Not Substitute" is written on the prescription;
- The pharmacist explains to the patient that the interchangeable medicines being offered to the patient have the same active ingredients,

the same effects and the same safety profile as the previously supplied medicines but may not look the same;
- When reference pricing is introduced for a specific group, the pharmacist provides information to patients regarding the price of: the prescribed product, the product offered for substitution, and the group reference price;
- If the patient accepts the offer of substitution made by the pharmacist, the pharmacist dispenses one of the interchangeable medicines that is kept in stock;
- In addition to recording what was dispensed, the pharmacist must also record and transmit data on the product prescribed; and
- If the GP prescribes by INN, the pharmacist must offer the cheapest version of that product.

What will change for patients?

- From August onward, patients will be more likely to be offered a less expensive version of the prescribed branded interchangeable medicine written on their prescription;
- Groups of medicines will become affected by this legislation over time, starting with Atorvastatin, a cholesterol controlling drug and proceeding over weeks and months through 20 priority medicines;
- Patients are likely to notice a reduction in cost when switching to alternative lower cost medications;
- If a doctor feels, for clinical reasons, that the patient's medicine should not be substituted, they can write 'Do Not Substitute' on the prescription and the pharmacist will dispense the medicine which has been prescribed;
- Later in 2013, reference pricing will begin — meaning there will be one reference price for each group of interchangeable medicines. This is the price the HSE will cover for all medicines in a group. Patients should ask their pharmacist if the price of the product offered is at or below the reference price;
- If the patient prefers to take the more expensive branded product, and their doctor hasn't given a clinical reason not to substitute, the patient will have to pay the difference between the price of the product dispensed and the reference price for the relevant group of interchangeable medicines;
- If the GP has written 'Do Not Substitute' on the prescription, the pharmacist dispenses the product prescribed and the patient will not have to pay any extra; and
- If a pharmacy does not have a medicine available at or below the reference price the patient may request the pharmacy to order a suitable medicine or alternatively seek a lower cost medicine from another pharmacy. If the GP prescribes using the international non-proprietary name (INN) of the product, the pharmacist must offer the cheapest version of that product.

PSI House,
Fenian Street,
Dublin 2
Phone: +353 1 2184000
Fax: +353 1 2837678
Email: info@thepsi.ie

Published by PSI