HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013 – FAQS

A. Status, main elements and purpose of Act

What is the status of the Act?
The Health (Pricing and Supply of Medical Goods) Act 2013 was commenced on the 24th of June 2013.

What is the purpose of the Act?
The main objectives of this Act are to promote competition between suppliers of interchangeable medicines and to ensure value for money in the supply of medicines and other prescribed items to patients under Section 59 of the Health Act 1970.

What are the main elements of the Act?
The Act provides for the introduction of a system of generic substitution and reference pricing which enables 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 Health Service Executive (HSE) to patients under the General Medical Services (GMS) and community drug schemes, and establishes mechanisms for setting the prices of those items where they are so supplied.

A copy of the Act is available at:
http://www.dohc.ie/legislation/statutory_instruments/pdf/si20130014.pdf

B. Generic substitution

What is generic substitution?
Generic substitution, under this Act, allows pharmacists to substitute medicines which have been designated as interchangeable by the Irish Medicines Board (IMB).

What is a generic medicine?
A generic medicine is a medicine that is similar to an original, brand named medicine. It has the same active substances as the original medicine and is made to the same standard to make sure it is safe and effective.

Why do generic medicines look different?
Generic versions of a medicine may have different colours, flavours or combinations of non-active substances compared to the original product. A generic medicine may also be a different shape or size and come in a different box, package or bottle. None of these differences, however, affect the way the medicine works.

Are generic medicines safe and effective?
A generic medicine must meet exactly the same standards of quality and safety and have the same effect as the original medicine.

Does every medicine have generic versions?
Not every brand-name medicine has a generic version. When new medicines are first made they are protected by patents for a number of years. The patent, which protects the company that made the medicine first, doesn't allow anyone else to make and sell the medicine. When

the patent expires, other medicine companies can start selling generic versions of the medicine.

What is an interchangeable medicine?
Interchangeable medicines are those that have the same qualitative and quantitative composition in each of their active substances, are in the same pharmaceutical form, and have the same route of administration.

Who decides if a medicine is interchangeable?
The Irish Medicines Board (IMB) will have responsibility for deciding if a medicine is interchangeable or not, subject to the qualifying criteria set out in the legislation.

Can every medicine be substituted?
No. The IMB will only add a medicine to the List of Interchangeable Medicines if it meets all the qualifying criteria and can be safely substituted for each of the medicines which fall within a group of interchangeable medicines.

Occasionally circumstances may arise where due to an individual patient issue or characteristic that it may not be advisable to switch between different brands of a medicine even if the medicine is included in a group of interchangeable medicines. When this arises a prescriber will be able to indicate on a prescription that substitution should not take place. A pharmacist will then dispense the medicine indicated on the prescription.

Can I opt for my usual brand of medicine and not the generic?
You can choose your usual brand of medicine if you prefer (see section C for price implications).

Is there a list of interchangeable medicines?
The Irish Medicines Board will establish a list of interchangeable medicines which will be published and kept updated on its website.

When will the first interchangeable list be published?
Once the legislation was commenced the IMB started the process of deciding what products on the reimbursement list are suitable for inclusion in interchangeable groups on the List of Interchangeable Products.

The Department of Health has asked the IMB to prioritise review of the classes of medicines that currently result in the greatest costs. There are twenty of these classes (which equates to approximately 1,500 individual 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

The first List of Interchangeable Medicines, containing groups of Atorvastatin products, was published on the 7th of August 2013 and is available on the IMB's website at the following link:

http://www.imb.ie/EN/Human-Medicines/Generic-and-Interchangeable-Medicines-List.aspx

The IMB will publish subsequent lists for other groups of medicines on an ongoing basis.

See additional information on the IMB's website at:
http://www.imb.ie/EN/Human-Medicines/Generic-and-Interchangeable-Medicines.aspx

Further information on generic medicines is also available on the HSE's website at:
www.hse.ie/generics

C. Reference pricing

What is reference pricing?
Reference pricing sets a common reimbursement price for groups of interchangeable medicines.

Will I have to pay more for my usual brand of medicine?
Eligible patients will not be required to pay any additional costs for medicines priced at or below the reference price. If a patient chooses a particular brand that is more expensive than the reference price they will have to pay the difference.

What happens if I need to receive a particular brand of medicine for medical reasons?
Your prescriber will be able to state on the prescription that that particular brand is to be provided. If that particular brand costs more than the reference price you will not have to pay the difference.

Do other countries use reference pricing and generic substitution?
Yes. Many European Member States have systems of reference pricing and generic substitution. Similar systems are also in operation in Canada, Australia and the United States.

Who decides the reference price?
The HSE has responsibility for setting the reference price. It will do this in accordance with criteria set out in the legislation, in particular, securing value for money for the taxpayer. It will also have to have regard to the need to ensure that prices are not set so low as to render their sale uneconomic as this could impact on their availability on the Irish market.

When will the first reference price be implemented?
Under the legislation, the HSE may set a reference price for each group of interchangeable medicines. Once the IMB publishes the first group of interchangeable medicines, the HSE will set a reference price for that group in accordance with the provisions of the legislation. The first reference price (for atorvastatin products) was introduced on the 1st of November 2013. Reference prices are being introduced on a phased basis.

Further information on reference pricing is available on the HSE's website at:
www.hse.ie/referenceprice

D. Reimbursement List

What is the reimbursement list?
The Bill provides for the establishment and maintenance, by the HSE, of a reimbursement list. This is a list of all the medicines or other items (e.g. dressings) that are reimbursed by the HSE under the General Medical Services Scheme and the other community drug schemes (e.g. the Drug Payment Scheme).

Will the Bill affect the current supply of items?
No. All items currently reimbursed by the HSE will automatically transfer to the new reimbursement list but the HSE has the right to review an item on the list at any stage.

Can changes be made to the reimbursement list?
The Bill provides for the list to be reviewed by the HSE within 3 years (or 5 years if the Minister permits it). However, the HSE may also review a listed item at any time in accordance with the legislation.

What is meant by the conditional supply of listed items?
The Bill allows the HSE to attach conditions to the supply or reimbursement of items on the reimbursement list, in the interests of various factors, such as, patient safety and cost-effectiveness.

Can new drugs be added to the reimbursement list?
Yes. The supplier of an item may apply to the HSE to have it included on the list.

Can an item be supplied if it is not on the reimbursement list?
Yes. Subject to certain conditions, the HSE has the discretion to supply an item that is not on the list if it meets particular criteria.