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The Health (Pricing and Supply of Medical Goods) Act 2013

by **lk-shields**

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The Health Minister has welcomed the passing of new legislation (28 May 2013) allowing pharmacists to substitute prescribed non-generic medicines with less expensive generic alternatives. It is hoped that the legislation will substantially increase the uptake of generic drugs, secure significant savings on the State's health spend and reduce costs for patients.[1]

Summary of the Legislation

The Act substantially alters the Irish pricing structure system and supply chain by introducing (i) groups of interchangeable medicinal products, (ii) generic substitution, and (iii) reference pricing.

(i) Interchangeable Medicinal Products. The Act provides that the Irish Medicines Board (IMB), which is to be renamed as the Health Products Regulatory Authority, will be tasked with establishing groups of interchangeable medicinal products. All of the medicinal products falling within a group will be interchangeable with each other for prescription purposes.

(ii) Generic Substitution. Previous to the passing of this legislation, pharmacists were required to dispense the medicinal product as prescribed by the healthcare provider (HcP). The Act provides that pharmacists will now be required to offer patients the opportunity to substitute a prescribed non-generic, interchangeable medicinal product with the less expensive generic alternative. Where the patient declines the substitution of a medicinal product the price of which is at or below the reference price, the patient will be responsible for paying the pharmacist the difference between the reference price and the price of the product dispensed.

Importantly, there is a clinical exception to this obligation. Where the prescriber of a non-generic medicinal product is satisfied for clinical reasons that the product should not be substituted, the prescriber is obligated to write "do not substitute" on the prescription beside the name of the medicinal product. The aim here is to protect patients with specific clinical needs from being adversely impacted by substitution.

(iii) Reference Pricing. A common reimbursement price will be set by the Health Service Executive (HSE) for groups of interchangeable medicines. The Act provides the criteria which the HSE will be required to take into account when setting or reviewing such reference prices; including, the ability of suppliers of listed items to meet patient demand; the equivalent prices in other EU member states where the listed item is marketed; and the terms of any agreement between the HSE and any representative body of the supplier of medicinal products being the Irish Pharmaceutical and Healthcare Association (IPHA).

HcP, Patient and Pharmacist Concerns

While the legislation has generally been welcomed as a means of securing significant savings on the State's drug health spend, the legislation is not without its critics. Commentators point to the potential regulatory and monitoring implications arising out of the increasing level of authority the HSE will likely have in terms of determining availability of medicines; as against the decrease in clinical decision making of the HcP and potential restrictions on drugs available for prescription. Indeed the nature and extent of any impact on the supply chain and availability of certain listed drugs is only likely to be fully realised in the months and years

following this legislation.

Campaigners against the legislation maintain that certain medications are not readily interchangeable, but are carefully concentrated for each patient, and there are concerns as to the potential adverse consequences arising out of such substitution. A good example of this is with anti-epileptic drugs (AEDs), where any variation in the manufacture and composition of a tablet or capsule introduces a factor that may disturb the balance and may result in breakthrough seizures. Epilepsy Ireland had campaigned for the legislation to be amended to specifically exempt AEDs in line with other Member States (such as the UK). However, AEDs have not been specifically exempted under the Act; though it is hoped that sufficient protection will be afforded under the clinical exemption.

The Irish Pharmacy Union has also expressed concerns as to the short-lead time which will mean that pharmacists with existing stocks will be financially hit. In summary, medicinal products that pharmacists stock on their shelves on behalf of the HSE will now be paid by the HSE at the new lower rates, despite having been purchased by pharmacists at the higher prices.

Impact on Drug Manufacturers

Generic manufacturers look likely to reap the rewards of this Act. This is particularly so given that the timing coincides with a number of high-value, “blockbuster” non-generic drugs coming off patent protection; most notably, the launch of generic versions of Pfizer’s cholesterol lowering drug, Lipitor. This expiry of such patents has made for greater market competition, generally affecting demand and pricing at a global level; with non-generic manufacturers having to adapt traditional research and development models to diversify in the face of altered revenue streams. In short, the Act is likely to be a catalyst for both generic and non-generic drug manufacturers to look towards adapting traditional drug development models so as to benefit from the new pricing and supply system.

Our Services

At LK Shields Solicitors we will be closely monitoring the impact of the Act over the coming months to gauge the practical impact on our life science clients at all levels of the supply chain: manufacturers (generics and patent-holders), distributors and pharmacies. It would be prudent for all those who operate in this industry to conduct a review of their business plans and intellectual property strategies with reference to this new Act.

[1] Ireland has one of the lowest levels of generic substitution amongst EU member states. As at October 2012, the Government reported that just 5% of drugs health spend is on generic medicines. This is in stark contrast to other EU member states; in the UK the drugs health spend on generic medicines runs closer to 80%.

About the Author