Health (Pricing and Supply of Medical Goods) Bill 2012 Client Update

Establishment of a list of Interchangeable Medicinal Products

Under the terms of the proposed legislation, the Irish Medicines Board will establish a system of generic substitution or reference pricing. This system will allow pharmacists to substitute cheaper equivalent medicines, at the patient's request, when a more expensive product has been prescribed. Under the proposed reference pricing system, only the reference price will be reimbursed by the State for a selected group of interchangeable medicines.

An authorisation holder of a medicinal product may apply to the IMB to have a product added to a group of interchangeable medicinal products or to add a group of interchangeable medicinal products to the list. This application may be made at the time of seeking a market authorisation from the IMB. The Bill sets out the timeframe for decisions of the IMB. The IMB may also add a medicinal product to a group of interchangeable medicinal products or add a group of interchangeable medicinal products, on its own initiative, or at the request of the Minister for Health or the HSE.

The criteria that interchangeable medicinal products must satisfy to be added to the list are set out in the Bill, along with the circumstances where the IMB shall not add a medicinal product to a group of interchangeable medicinal products. The IMB may also remove products from the list of interchangeable medicinal products, in certain circumstances.

The Bill provides for the regular review of the reference price for a group of interchangeable medicines by the HSE and outlines the criteria to be taken into account when setting or reviewing a reference price. It provides that the HSE must give notice in writing to the supplier of a particular item of decisions it makes in this regard.

Duties of pharmacists

The Bill also proposes to amend the duties of pharmacists regarding prescriptions for interchangeable medicinal products under branded names.

Where a pharmacy stocks the branded product named in a prescription and substitute medicinal products of lower cost, the pharmacist must offer the patient the opportunity to substitute the lowest cost interchangeable product. If a patient, eligible under the GMS or CDS, does not opt for substitution of a lower cost product, they are liable to pay the difference between the reference price and the price of the product supplied.

When the patient presents for a prescription for an interchangeable medicinal product under any common non-proprietary name, then the pharmacist must dispense the lowest cost available medicinal product. In relation to a prescription containing the common name for a medicinal product that is not interchangeable, the pharmacist must dispense the medicinal product, which is of the lowest cost to the HSE or the patient.

A prescriber may indicate on a prescription that a branded interchangeable medicinal product should not be substituted for clinical reasons. However, the Bill permits the Minister for Health to make regulations requiring prescribers, who write prescriptions for patients who use State schemes, to set out the clinical reasons for the exemption.

Establishment and Maintenance of Reimbursement List

The Bill proposes that the HSE will establish a list of medicines and medical and surgical appliances for supply or reimbursement to patients. All products currently on the existing reimbursement lists maintained by the HSE will be automatically deemed to be on the reimbursement list established under the Bill, subject to any conditions that were attached.

The Bill sets out statutory procedures governing the supply, reimbursement and pricing of medicines and other items to patients under the GMS and CDS. It also sets out criteria that the HSE must take into account when making reimbursement decisions.

A supplier of a product may apply to the HSE for inclusion of a product on the list of reimbursable items. The HSE will be required to give notice in writing to suppliers of decisions it makes regarding the placement of a product, or otherwise, on the reimbursement list. Where a decision is based on expert opinions and recommendations, the HSE must provide copies of these opinions and recommendations to the supplier.

The Bill also sets out the criteria to be taken into account by the HSE when considering the proposed price of an item. It allows the HSE to review and alter the price of a listed item and to use a competitive process to determine prices.

The Bill allows for the HSE to attach conditions to the supply or reimbursement of listed items in the interests of patient safety, cost effectiveness, maximising appropriate use of the items concerned or appropriately applying the resources available to the HSE. It will also be able to remove items from the list in the event of inadequate supply.

Finally, the HSE may also exercise its discretion to make arrangements to supply an item to patients under its schemes even if that item is not a listed item, if it is satisfied that the patient requires it for clinical reasons and there is no listed item that is a suitable alternative.