

Price Strategy Bulletin

Steep Price Cuts on Off-patent Brands and More Reference Countries Feature in New Irish Pricing Agreement

Introduction

Ireland might be one of the most likely places in Europe for rain to fall, but it does offer one of the most welcoming environments for the pharmaceutical industry. Tax breaks and other incentives have resulted in 120 mostly foreign companies, including 14 of the top-15 multinationals, setting up operations in the country and directly employing 24,000 people. More than €4.3 billion has been invested locally by the sector in the last six years and with 2005 exports exceeding €14.75 billion, Ireland has become the largest net pharmaceutical exporter in the world.

For global pharmaceutical companies the Irish market might be a very small one, but the government has long been keen to extend its benign approach to the industry to cover the pricing environment for reimbursable medicines under the General Medical Services (GMS) Scheme.

Largely unchanging multi-year agreements quietly concluded with the Irish Pharmaceutical Healthcare Association (IPHA) were the norm. Freedom of access to the GMS for all eligible new products was assured, delisting was outlawed, and doctors enjoyed complete prescribing freedom. While Ireland's enthusiasm to attract even more inward investment by pharma remains undimmed, there are signs in the latest IPHA/government pricing agreement of a slightly tougher cost containment policy emerging.

One reason might be that drug expenditure by the state, currently totaling €1.8 billion, is increasing by 14.6% per year (approximately double the European average). IPHA points out that the market value figure is gross and includes all distribution mark-ups and prescribing incentives to doctors. It attributes high market growth to:

- starting from a very low base;
- a population growth of 2% pa;
- an ageing population and
- government investments in targeting cardiovascular disease and cancer.

Another likely contributing factor is that the latest round of negotiations by IPHA were conducted not

just with the Department of Health and Children, as usual, but for the first time with a new, stand-alone unitary purchasing and reimbursement body covering both hospitals and community schemes, the Health Service Executive (HSE).

The agreement (signed on July 6th to come into effect from September 1st and to last four years) applies to all medicines prescribable and reimbursable under the GMS Scheme, the Community Drug Schemes, and medicines supplied to state-funded hospitals and the HSE. Twelve months' notice to renegotiate terms may be given by either party after three years.

Replacing the 1997 agreement (which was extended in May 2001), it represents the eighth successive accord between the state and the pharmaceutical industry in Ireland since the GMS was introduced in 1972.

The HSE anticipates the new deal with IPHA will deliver €300 million savings over the term of the agreement, and reduce annual drug cost inflation to 6%. Talks are due to begin shortly with representatives of pharmaceutical wholesalers, domestic manufacturers and community pharmacists that are expected to yield further savings, HSE notes.

Main Points of New Agreement

- The manufacturer selling price (MSP) of any newly introduced prescription medicine shall not exceed the currency-adjusted average MSP in an expanded list of nine nominated EU states (Austria, Belgium, Finland and Spain have now been added to the original five reference countries of Denmark, France, Germany, the Netherlands and the UK. The direct link with prices in the UK – the principal country of origin – has also been broken).
- Manufacturers will be required to re-align prices for new medicines approved under the agreement to the currency-adjusted average price in the nine nominated EU reference states two years and four years following the commencement of the agreement (under previous agreements there were no set times for price re-alignment).

- A single price per product will apply across hospital and community supply (officially the same, in practice they previously differed)
- New medicines, including new presentations and applications, will become reimbursable within 60 days of application (unless a prior pharmacoeconomic assessment – see below – is required). Existing reimbursable medicines will not be delisted.
- The MSP of all marketed medicines covered by the agreement will continue to be frozen, though price modulation will be permitted on an exceptional basis (the price freeze has now been in place since 1993).
- Reimbursement of a drug with a high cost or having a significant budgetary impact may be refused or have conditions placed on it following a pharmacoeconomic assessment (in previous agreements the payer also 'reserved the right' to assess cost-effectiveness/cost-benefit, though no examples of this affecting market access or reimbursement are known)
- Manufacturers will be required to pay a rebate of 3.53% of the value at MSP of their products dispensed under the GMS Scheme (GMS rebates, at up to 5%, have featured since the very first agreement).
- Patient choice will be facilitated through consultation with the prescriber. The HSE will attempt to increase patient awareness of the range of available prescription options (new). No substitution by the pharmacist will be allowed (unchanged).
- A 35% price reduction in two steps – 20% initially and a further 15% after 22 months - will apply to specific substitutable forms of patent-expired original brands (new). Products affected by the price cut will not be subject to the GMS rebate.
- Distribution arrangements to state hospitals have to be discussed in advance with HSE. Where a manufacturer chooses to supply direct, delivery will be at the price to the wholesaler. HSE reserves the right to appoint one of more wholesalers on a regional or national basis (new).

The full text of the agreement is available at <http://www.hse.ie/en/Publications/HSEPublications/IPHAAgreement/>.

Implications for Strategy Development

Ireland is a good example of an industrial policy inclined towards the pharmaceutical sector that brings rewards to all. The country strives to portray itself as an attractive location for pharma companies and P&R cannot be separated out from the attractiveness equation.

The agreement itself is often held as a model for other countries to copy. As debate rages elsewhere on the size of patients' contribution to healthcare costs many think that Ireland also has the balance right with its means-tested GMS Scheme and safety net provisions for the rest of the population.

The widening of the country reference basket in the new agreement should be noted too. Geographic price referencing is now a fast-changing phenomenon with knock-on effects worldwide. Companies must keep abreast of such changes.

PriceSpective is an international firm of pricing strategy experts, focused on providing strategic guidance in pricing and reimbursement to the pharmaceutical and biotechnology industries. PriceSpective has specific expertise on a wide range of policy matters and detailed knowledge of P&R rules in all major markets worldwide.

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