Group Briefing
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IPHA and the Government finally reach agreement on the supply and pricing of medicines in Ireland

On 20 July 2016, following much debate and lengthy negotiations, the Irish Government, the Health Service Executive ("**HSE**") and the Irish Pharmaceutical Healthcare Association ("**IPHA**") signed the Framework Agreement on the Supply and Pricing of Medicines (the "**Agreement**") .

SCOPE

The new Agreement, which came into effect on 1 August 2016, governs the supply and pricing of medicinal products that are included on the HSE Reimbursement List , supplied to, or reimbursed by, the HSE, State-funded hospitals or any other publicly-funded entities and State agencies providing similar services ("**Hospital Medicines**"), or subject to an application for inclusion on the Reimbursement List, or for supply or reimbursement as a Hospital Medicine.

APPLICATION TO NON-IPHA MEMBERS

The previous Agreement stated that the agreement applied to "all suppliers" of products that fall within the scope above. However, the 2012 Agreement did not define the term "supplier" nor did it differentiate between IPHA member companies and non-IPHA member companies.

The new Agreement applies only to IPHA member companies (listed in Schedule 2 of the Agreement). The HSE and IPHA member companies may now only rely on the provisions of the new Agreement by agreement.

We would anticipate that many non-IPHA members will take account of the pricing criteria in the new Agreement when submitting an application for pricing approval or come to their own arrangements with the HSE. This would not depart radically from previous practice under the 2012 Agreement.

ENFORCEABILITY

Section 21(2) of the Health (Pricing and Supply of Medical Goods) Act 2013 (the "**2013 Act**") allows the HSE to take account of a number of different factors, only one of which is the terms of the Agreement, when considering the proposed price of a product submitted by a supplier.

The Agreement purports to reflect this position by stating that the Agreement does not create legal relations or legitimate expectations which can be enforced by or against the parties. The Agreement also states that it will not limit the HSE's powers under the 2013 Act, allowing the HSE to take into account other factors when assessing the proposed price of a medicinal product.

KEY CHANGES

Outlined below are a number of notable differences between the new more comprehensive Agreement and its predecessor.

Four year term

The Agreement is for a period of four years rather than the previous three year term.

Extension of the number of nominated EU Member States

Under the previous Agreement, prices were set at the average of the currency-adjusted ex-factory price (price to wholesaler) in nine EU Member States, namely, Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Spain and the UK. The new Agreement introduces five additional EU Member States (Greece, Italy, Luxembourg, Portugal and Sweden), bringing the proposed price of a product in line with the average ex-factory price in 14 Member States.

Annual price realignment

All medicinal products will now be subject to an annual price realignment commencing on 1 August 2016 and on 1 July for each subsequent year. The price realignment will be set as the average ex-factory price of the 14 Member States.

The price realignments will be downwards only. The HSE and the suppliers should have agreed new prices for 2016 no later than 20 July 2016.

Rebates increase

Rebates from suppliers to the HSE for products will increase from 4% to 5.25% (1 June 2016 – 31 July 2018) and 5.5% (1 August 2018 – 31 July 2020) of the ex-factory price. It is intended that further guidance in relation to the payment and collection of rebates with regard to Hospital Medicines will be developed by the HSE and IPHA.

Reduction in price of patent-expired products

The price of a medicinal product that has lost patent protection and for which a generic product is available will fall to 50% of the original ex-factory price.

Similar to the 2012 Agreement, the HSE will notify the supplier when a generic medicinal product has become available and the date from which the new price will apply, which will be no less than 28 days following notification.

Reduction in price of patent-expired biological products

For the first time, the Agreement differentiates between generic medicinal products and biosimilar products when considering price reductions for patent-expired products. Patent-expired biological products will now be subject to a 20% reduction in price once a biosimilar enters the market.

In addition to the price cut and, unlike generic medicinal products, suppliers of biological products must pay the HSE a rebate of 12.5% of the value of the reduced price.

Penalties related to continuity of supply

Under the 2012 Agreement, suppliers in breach of the provisions related to continuity of supply, such as notice periods, were required to either source and supply alternative equivalent products at the same price as the unavailable product or reimburse the HSE any difference in cost arising from the shortage.

The new Agreement no longer includes this provision. However, the Agreement mentions that suppliers must adhere to the IPHA/HSE Statement of Best Practice for Notifying the Discontinuation of a Medicine from the Irish Market ("**Best Practices**") which still includes these penalties. Suppliers should monitor any amendments to the Best Practices.

Guidance and transparency when assessing new medicinal products

Schedule 1 of the Agreement sets out detailed principles and processes for the assessment of pricing and reimbursement of new products in Ireland. The new principles and processes provide some clarity and transparency with regard to the decision making structure and timelines. The new Agreement formalises the Annual Horizon Scan, the Rapid Review Process and provides clarity in relation to the HSE Drugs Group recommendations.

One of the most notable changes in the decision making process is the introduction of the role of the Department of Health and the Government when reviewing products which cannot be funded from within existing HSE resources, such as products that exceed the budget impact or a certain cost-effectiveness threshold. At the first instance, the HSE Leadership will assess such products. If the HSE cannot reimburse the product, the HSE can inform the Department of Health who, in turn, may apply to the Government to request consideration of the funding of the product. It is hoped that more clarity as to the practical application of such a high level review for specific products will be provided once the Agreement comes into force.

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