
INTRODUCTION

The Association and the Department of Health and the Health Service Executive (the HSE) have agreed on the terms set out below and this Agreement will come into effect on the 1st November 2012.

1. DURATION

The duration of the Agreement shall be three years from the 1st November 2012.

2. COVERAGE

This Agreement shall apply to all generic medicines granted a marketing authorisation by the Irish Medicines Board or European Commission, that can be prescribed and reimbursed in and supplied to the GMS Scheme and the Community Drugs Schemes, including the Drug Payment Scheme, the Long Term Illness Scheme, the High Tech Arrangement (the Schemes) and all generic medicines supplied to the HSE, State-funded hospitals and to State Agencies whose functions normally include the provision of medicines.

The terms of this Agreement shall apply to all suppliers of these products.

3. PATIENT CHOICE

Objective

It is intended that patients and prescribers have access to a range of generic medicines reimbursed under the Schemes, used according to best practice while also delivering better value for money for both the individual patient and the Schemes.

4. REIMBURSEMENT

Objective

The primary objective of the State in entering this agreement is to ensure reduced prices for generic medicines and to ensure security of supply of generic medicines.
The State will ensure timely decisions in relation to pricing and reimbursement applications for new generic products subject to compliance with the pricing framework.

4.1 Existing Medicines

Generic Medicines normally reimbursable in the schemes at the date of commencement of this Agreement will, subject to section 18(4) and 18 (5) of the Health (Pricing and Supply of Medical Goods) Act, 2013 (when commenced), and provided that they conform with this Agreement and the reimbursement criteria published by the Minister, pursuant to EC Directive 89/105/EC, remain reimbursable in the schemes for the duration of the Agreement.

4.2 New Generic Medicines

New generic medicines, including new presentations and applications and branded or other generics, granted a marketing authorisation by the Irish Medicines Board or European Commission will become reimbursable in the schemes, within 60 days of the date of the reimbursement application, subject to the provisions of clauses 4.3, 5.2 and 5.5.

4.3 Pharmacoeconomic Assessment prior to Reimbursement.

The HSE reserves the right to assess new and existing technologies (pharmaceuticals, diagnostics and devices) or to determine the cost effectiveness of products.

Assessments will be conducted in accordance with the agreed Irish Healthcare Technology Assessment Guidelines as set out by the Health Information and Quality Authority from time to time.

5. PRICING

5.1 Price Freeze

The price to wholesaler of each generic medicine covered by this Agreement will not be increased for the term of the Agreement (save as might be required under Clauses 5.3 and 10.4).

5.2 Price (to wholesale) of New Generic Medicines

All new generic medicines will be priced initially at not more than 50% of the pre-patent expiry price of the equivalent branded original medicines.

If included in the published Lists of Interchangeable Medicinal Products, new generic medicines will be priced at not more than 40% of the pre-patent prices of the equivalent branded original medicines.
These are the maximum acceptable prices – manufacturer may supply at lower prices provided this is notified to the HSE so that it maintains an up to date reimbursement list.

The State encourages generic suppliers to progressively reduce prices in line with those available in other EU countries (subject to sustainability of supply).

5.3 Price Modulation

Product price modulation will only be permitted under this Agreement, on an exceptional basis and on condition that any such product price modulation will be demonstrably cost neutral for the State in each year of the Agreement.

The HSE may require audited documentation of any price modulation and shall have the sole discretion to accept, reject or seek variation in any modulation application and to seek an appropriate refund if the terms of this clause are not adhered to.

5.4 VAT

Prices referred to in this Agreement are VAT exclusive prices.

5.5 Price Adjustment

With effect from November 1st 2012, the prices of all generic medicines will be reduced to not more than 50% of the pre-patent expiry prices of the equivalent branded original medicines, subject to no associated price increases.

Following commencement of the Health (Pricing and Supply of Medical Goods) Act, 2013, the prices of all generic medicines included in published Lists of Interchangeable Medicinal Products by the Irish Medicines Board, will be immediately reduced to not more than 40% of the pre-patent expiry prices of the equivalent branded original medicines.

The prices of all generic medicines not included in the published List of Interchangeable Medicinal Products will be immediately reduced to not more than 47.5% of the pre-patent expiry prices of the equivalent branded original medicines, when the prices of the branded medicines are reduced to 50% of their original price to wholesaler.

There will be no increase in the prices of generic medicinal products resulting as a consequence of the terms of this Agreement without the prior approval of the HSE.

Subject to the terms of the Health (Pricing and Supply of Medical Goods) Act 2013, there will be no reduction in the prices of generic medicines outside the terms of this Agreement without the approval of individual companies.
Subject to the provisions of the Health (Pricing and Supply of Medical Goods) Act, 2013, the HSE will consult with APMI in relation to the setting of reference prices. In the interests of transparency, the HSE may require that APMI members provide it with written confirmation and justification of any position put forward in such consultations.

6. **HSE/STATE-FUNDED HOSPITALS/STATE AGENCY SUPPLY**

**Objective**

To ensure that the health service has efficient and timely access to, and security of supply of a range of generic medicines at competitive prices

**Scope**

Supplies to the HSE, State-funded hospitals and State Agencies.

6.1 **Supply Arrangements from nominated distributors**

Supplies will be invoiced as per existing hospital arrangements i.e. at the Price to Wholesaler on orders over €634.87 where orders are placed:

(a) directly with the manufacturer or importer of the products concerned

or

(b) with the nominated agent/distributor for the products concerned.

No discounts (except those achieved under section 6.3 and 6.4) are due in the case of orders under €634.87 or orders placed with a distributor for products for which he/she is not the agent or importer. In all cases, the €634.87 refers to products of a single manufacturer. These terms are offered on the basis of normal monthly settlement of accounts.

Manufacturers may choose to nominate a specific channel of supply for some or all of their products and will consult with the HSE in relation to any such arrangements.

Nothing in clause 6.1 will prevent the HSE from appointing a nominated wholesaler(s) to supply the HSE, State-funded hospitals or State Agencies on a regional or national basis as appropriate.
6.2 Supply Arrangements from Manufacturers

Where a manufacturer chooses to supply direct, delivery will be at the price to wholesaler.

6.3 Price to the HSE, State-funded Hospitals and State Agencies

Supply arrangements existing at the commencement of this Agreement between individual hospitals and manufacturers (or their agents) shall remain in place until such time as the HSE or the individual hospital (or hospital group) agrees a change with the relevant manufacturer (or their agents).

6.4 Special Supply Arrangements

The HSE (or an individual hospital or hospital group on its behalf) reserves the right to negotiate special arrangements for supply to the HSE, State-funded hospitals and State Agencies, with individual manufacturers or agents, to secure more favourable terms than those referred to in Clause 6.1 above.

6.5 Settlement of Accounts

All payments for supply shall be subject to the requirements of the prompt payments legislation.

6.6 General

These terms shall apply to all suppliers, State-funded hospitals and State Agencies.

HSE procurement strategies are informed and conducted in compliance with applicable legislation and best practice (e.g., EU procurement legislation and competition law).

The HSE undertakes that all medicines ordered and supplied under this clause will be solely for consumption by the HSE, State-funded hospitals or State Agencies. The HSE will take all necessary steps to achieve this.

7. REBATE ON SALES

There will be no rebate on reimbursed sales of generic medicines.

8. CONTINUITY OF SUPPLY

Objective

Continuity of supply is recognised by the parties to this Agreement as crucially important to the effective operation of arrangements for the supply of medicines to Irish patients.
Equally, it is recognised that from time to time, interruptions to supply may arise which are outside the control of the manufacturer, importer or agent.

8.1 (a) **Foreseeable or Prolonged Stock Shortages**

(i) Manufacturers, importers or their agents who experience foreseeable or prolonged stock shortages, or the possibility of such shortages, must notify the HSE as soon as they become aware of the problem.

(ii) The supplier shall endeavour to source, within the notice period, an alternative supply.

(b) **Discontinuation of Medicines**

In the interest of an uninterrupted supply of medicines to patients, manufacturers, importers or their agents who intend to withdraw medicines from the market must provide notice to the HSE of their intention to do so.

(i) A notice period of at least 12 months must be given for the discontinuation of medicines for which there is no reimbursable therapeutic alternative for approved indications.

(ii) A notice period of at least 3 months must be given for the discontinuation of medicines for which there is a reimbursable therapeutic alternative for approved indications.

(c) **Transfer of a Marketing Authorisation to another Manufacturer**

Where the transfer of a marketing authorisation is likely to materially change the arrangements for the supply of a medicine, the original MA holder must provide at least three months notice to the HSE of the transfer of the authorisation.

The original MA holder must make the new MA holder aware of the terms (including the pricing terms) of this Agreement.

8.2 The provisions of this clause shall operate in the context of the obligations placed on marketing authorisation holders and distributors by Article 81 of Directive 2001/83/EC as amended by Directive 2004/27/EC which states that:

“...The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of the patients in the Member States in question are covered.”
8.3 All the notification forms can be found on www.hse.ie

8.4 Where a supplier is in breach of this Clause, it shall be 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 HSE will consult APMI in relation to any such cases if so requested by a manufacturer.

9. SHORT SHELF LIFE PRODUCTS

Suppliers shall use best endeavours to ensure that all medicines supplied to the HSE, State-funded hospitals or State Agencies shall have a minimum shelf life of 12 months. Products with a remaining shelf life of less than 12 months can be supplied only where unused date-expired quantities can be refunded.

The HSE/Hospital/State Agency in receipt of such short-dated stock will take all reasonable steps to make use of the stock in a timely fashion, so as to minimise waste and handling in the system.

10. ADMINISTRATION OF THE AGREEMENT

10.1 General

The governance and operation of this Agreement will be formally reviewed by the DOH/HSE and APMI during 2014 (no earlier than June 2014)). In the interim, any matter relating to the interpretation of these terms, including the price terms or the operation of this Agreement, shall be resolved in discussions between APMI and the DoH/HSE.

The terms of this Agreement will not supersede the HSE’s public procurement obligations, including those applicable under the EU Procurement Directives.

10.2 Vaccines

This Agreement will not prevent arrangements being made for the supply of vaccines or similar products for the Healthcare Services.

10.3 Application Fees

With effect from November 1st 2012, the fee for reimbursement applications applicable to generic medicines will be set at €500.
10.4 Exceptional Circumstances

Where a supplier is oppressed by the terms of this Agreement, direct representations may be made to the HSE for variation of any term of this Agreement including its price terms.

In the interests of continuity of supply, where it becomes uneconomic for a supplier to supply a particular dosage form under the terms of this Agreement, direct representations may be made to the HSE for variation of any term of the Agreement, in relation to that product, including its price terms.

The HSE shall have the final decision in whether to vary the terms of this Agreement in any case but will consult with APMI before reaching its decision.