2021

FRAMEWORK AGREEMENT ON THE SUPPLY AND PRICING OF MEDICINES

06 DECEMBER 2021

FINAL VERSION

Contents

FRAMEWORK AGREEMENT ON THE SUPPLY AND PRICING OF MEDICINES

INTRODUCTION

The Irish Pharmaceutical Healthcare Association ("**IPHA**"), for and on behalf of and with the authority of the member companies of IPHA, the Department of Health, the Department of Public Expenditure and Reform and the Health Service Executive (the "**HSE**") (hereinafter, the "**Parties**") have agreed on the terms of this Framework Agreement on the supply and pricing of medicines as set out below (the "**Agreement**"). This Agreement will come into effect on 1st October 2021 save where specified in the Agreement.

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

In entering this agreement, the State aims to ensure reduced prices and security of supply for originator medicines.

The State intends that sufficient administrative resources are in place to ensure timely processing of pricing and reimbursement applications for new products, subject to compliance with this pricing framework.

1. INTERPRETATION

1.1.

Unless otherwise defined in this Agreement or unless the context otherwise requires, words and expressions defined in the Health (Pricing and Supply of Medical Goods) Act 2013 (as may be amended from time to time) ("**the 2013 Act**") shall have the same meanings in this Agreement.

1.2.

In this Agreement the following expressions shall, unless the context otherwise requires, have the following meanings:

> **"Available for Supply"** means a Medicinal Product in respect of which a Marketing Authorisation has been issued by the HPRA or the European Commission and which is available for sale and supply in the State
>
> "**Biologic Medicine(s)**" means Medicine(s) that are biological medicinal product(s) as defined in Annex I of Directive 2001/83/EEC in respect of which a Marketing Authorisation has been issued by the HPRA or the European Commission

"**Biosimilar Medicine(s)**" means biological medicinal product(s) that contain a version of the active substance of a Biologic Medicine, and which are similar to other Biologic Medicines in terms of quality characteristics, biological activity, safety, and efficacy, and in respect of which a Marketing Authorisation has been issued by the HPRA or the European Commission

"**Exchange Rate"** means the applicable currency exchange rates published by the Central Bank of Ireland on the date(s) of relevant assessment

"**Generic Medicine(s)**" means generic medicinal product(s) as defined in Article 10(2)(b) of EC Directive 2001/83/EC in respect of which a Marketing Authorisation has been issued by the HPRA or the European Commission

"**Hospital Medicine(s)**" means Medicines which are supplied to, or reimbursed by, the HSE or Relevant Agencies otherwise than for the purposes of the Relevant Schemes

"**HPRA**" means the Health Products Regulatory Authority

"**Hybrid Medicine(s)**" means a medicinal product which although similar to a reference medicinal product has been authorised in accordance with the hybrid abridged procedure under Article 10(3) of Directive 2001/83/EC in circumstances where:

- the strict definition of a generic medicinal product as defined in Article 10(2)(b) of EC Directive 2001/83/EC is not met;
- the bioavailability studies cannot be used to demonstrate bioequivalence; or
- there are changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration compared to the reference medicinal product;

including, for the avoidance of doubt, where it has been authorised by the HPRA under the national procedure by reference to Article 10(3) of Directive 2001/83/EC in accordance with the Medicinal Products (Control of Placing on the Market) Regulations 2007 (as amended);

and for the avoidance of doubt, Hybrid Medicine does not include the original reference medicinal product relied upon in any such said hybrid abridged procedure

"Marketing Authorisation" means an authorisation to place a medicine on the market as issued by the HPRA or the European Commission to an "authorisation holder", as defined in section 2 of the 2013 Act

"**Medicine(s)"** means any patent-protected Medicinal Products and any off-patent Medicinal Products (and which have not been declared interchangeable by the HPRA pursuant to the 2013 Act), excluding blood products, vaccines, and non-reimbursable non-prescription products without prejudice to clause 13.2, and in respect of which a Marketing Authorisation has been issued

"**Medicinal Product(s)"** means "medicinal products" as defined in Directive 2001/83/EC (as amended) as:

a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

b) (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological, or metabolic action, or to making a medical diagnosis

"**New Medicine(s)**" means any Medicine(s) with a Marketing Authorisation introduced in the State after the commencement of this Agreement, during the Term, in respect of which a Supplier submits an application to the HSE pursuant to section 18 of the 2013 Act requesting their addition to the Reimbursement List or in respect of which a Supplier makes an application to the HSE to have it/them priced as a Hospital Medicine

"Nominated State(s)" means Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the UK.

"Original Ex-Factory Price" in respect of any Medicine means the ex-factory price at which it was first approved for reimbursement or supply by the HSE, its predecessor(s) or a Relevant Agency

"**Price**" means the ex-factory price (otherwise known as the price-to-wholesaler) of a Medicine as determined in accordance with this Agreement, exclusive of Value Added Tax (VAT)

"**Relevant Agency(ies)**" means State-funded hospitals (including any hospital groups) providing hospital services, including hospitals providing services on behalf of the HSE pursuant to section 38 of the Health Act, 2004 and any other publicly-funded entities and State agencies in each case whose functions include the provision of Medicinal Products and any reference in this Agreement to a "supply to the HSE and Relevant Agencies" shall mean a supply of Medicines to the HSE and/or any of the Relevant Agencies otherwise than for the purposes of the Relevant Schemes

"**Relevant Scheme(s)"** shall have the meaning attributed to that expression in the 2013 Act

"Reimbursement List" means the reimbursement list established under Part 4 of the 2013 Act

"**State**" means Ireland

"**Supplier(s)**" means the IPHA member companies from time to time as set out in SCHEDULE 3 hereto.

"Term" means, subject as provided in Clause 3, the period referred to in Clause 3

1.3.

Except to the extent that the context requires otherwise, any reference in this Agreement to:-

1.3.1. any statute shall include any order made or regulation issued thereunder, any statutory modification or re-enactment thereof from time to time in force, and, unless otherwise stated, any reference to a statute shall be a reference to a statute of Ireland

1.3.2. the singular shall include the plural and vice versa.

1.4.

The headings to the clauses and sub-clauses of this Agreement are inserted for convenience of reference only and shall not form part of or affect the construction or interpretation of any provision of this Agreement.

1.5.

In this Agreement references to Clauses and Schedules are references to Clauses hereof and Schedules hereto, references to sub-clauses or paragraphs are, unless otherwise stated, references to sub-clauses of the clause or paragraphs of the Schedule in which the reference is contained.

2. SCOPE OF AGREEMENT

2.1.

This Agreement applies solely to such Medicines of Suppliers included on the Reimbursement List and/or supplied to, or reimbursed by, the HSE and/or any of the Relevant Agencies and, for the avoidance of doubt, includes New Medicines approved during the Term.

2.2.

This Agreement has been entered into by IPHA for and on behalf of and with the authority of the Suppliers.

2.3.

The Parties enter this Agreement in good faith with the intention of implementing the within terms. However, it is hereby declared that in entering into this Agreement the Parties do not intend to create legal relations and/or legitimate expectations (or similar) and this Agreement shall not constitute a binding agreement and/or the creation of any legitimate expectation(s) (or similar) enforceable by or against any of the Parties hereto (including, for the avoidance of doubt, any Supplier).

3. TERM OF AGREEMENT

This Agreement shall commence on 1st October 2021 and shall continue in force until 30th September 2025, after which date all obligations under this Agreement shall cease unless continued by mutual agreement of the parties, given to each other in advance.

The Parties agree that negotiations on any successor or replacement Agreement should begin at least 6 months before the expiry of the Term.

4. STATUTORY OBLIGATIONS AND EU COOPERATION

4.1.

The Parties acknowledge that the terms of this Agreement will not supersede any of the Parties' legal obligations including, without limitation, those arising under any statute or regulation or by the operation of law.

4.2.

It is acknowledged by the Parties to this Agreement that the Suppliers and the HSE have respective statutory obligations, responsibilities, and powers, as the case may be, in respect of the pricing and reimbursement of Medicines pursuant to, among other legal provisions, the 2013 Act and nothing herein shall be deemed or construed as in any way fettering or limiting the exercise by the Suppliers and/or HSE of their respective rights thereunder.

4.3.

For the avoidance of doubt and notwithstanding any other provision of the Agreement, the Parties agree that this Agreement constitutes an agreement within the meaning and for the purposes of section 21 (2) (g) of the 2013 Act.

4.4.

This Agreement is entered into without prejudice to the Parties obligations and commitments under EU law including, without limitation, procurement obligations.

4.5.

This Agreement will not prevent the State entering into arrangements with other EU Member States, including without limitation, to jointly procure medical countermeasures under EU Decision 1082/2013/EU.

4.6.

Nothing in this Agreement shall prevent the State cooperating with other EU Member States and the European Commission.

5. GENERAL PRICING

5.1. No Price Increase

5.1.1. Save for such price increases as may be agreed by the HSE with a Supplier pursuant to Sub-Clauses 14.3 and/or 14.4, the Price of each Medicine will not be increased during the Term.

5.1.2. For the avoidance of doubt, any Medicinal Product which at any point during the Term no longer falls within the definition of Medicine shall, notwithstanding same, continue to be subject to Sub-Clause 5.1

5.2. Price Realignments

The Price of all Medicines will be realigned, downwards only, in accordance with the following provisions:

5.2.1. The Price of a Medicine shall be calculated and set at the average of the relevant price (being the ex-factory price or equivalent thereof) in the Nominated States in Euro on the following dates:

(i) 1st March 2022

(ii) 1st March in each of 2023, 2024, and 2025

5.2.2. Currency adjustments will be calculated, where required, by taking the average Exchange Rate over the period, as follows:

(i) For realignments on 1st of March 2022, the period shall be 1st of August 2021 to 31st of October 2021

(ii) For realignments occurring on 1st of March in each of the years 2023, 2024, and 2025, the period shall be from 1st of August to 31st of October of the relevant preceding year

5.2.3. The relevant price (being the ex-factory price or equivalent thereof) in any Nominated State shall be that as of 1st of November in the relevant year.

5.2.4. The Price shall be agreed by the HSE and Suppliers on the basis of the foregoing provisions of Sub-Clauses 5.2.1, 5.2.2, and 5.2.3 no later than:

(i) 20th of December 2021, and

(ii) 20th of December in each of the years 2022, 2023, and 2024

6. PROPOSED PRICING OF NEW MEDICINES

6.1. Scope

This Clause 6 applies to the proposed price submitted by a Supplier in any application to the HSE for the addition of a New Medicine, including new presentations and indications to the Reimbursement List or to have a New Medicine priced as a Hospital Medicine.

For the avoidance of doubt, an application for the addition of a New Medicine to the Reimbursement List shall be made in accordance with the relevant provisions of the 2013 Act and with the provisions set out in Schedule 1, the Principles and Processes for the Assessment of New Medicines in Ireland (hereafter "the Assessment Principles"), which form an integral part of this Agreement. An application to have a New Medicine priced as a Hospital Medicine shall be made in accordance with the Assessment Principles.

6.2. Maximum Supplier Proposed Price

6.2.1. The price which a Supplier shall submit to the HSE in respect of a New Medicine for which an application is made for its addition to the Reimbursement List or to have it priced as a Hospital Medicine shall be no greater than the average of the currency-adjusted relevant price (being the ex-factory price or equivalent thereof and using the applicable Exchange Rate) applicable in such of the Nominated States in which the Medicine is available on the date of application.

6.2.2. If a New Medicine in respect of which application is made for its addition to the Reimbursement List or to be priced as a Hospital Medicine is available in none of the Nominated States, the Supplier shall propose a price which shall be considered by the HSE in accordance with the 2013 Act and, as applicable, the HSE Assessment Principles.

6.2.3. All New Medicines added to the Reimbursement List and/or priced as Hospital Medicines during the Term shall be subject to an annual price realignment in accordance with the provisions of Sub-Clause 5.2 of this Agreement.

7. PRICING OF PATENT-EXPIRED NON-EXCLUSIVE MEDICINES

7.1. Scope

This Clause 7 shall apply to patent-expired Medicines (other than Biologic or Hybrid Medicines) in respect of which a Generic Medicine is available for Supply

7.2. Price Reductions

7.2.1. On 1st of January 2022, the Price of each existing Patent-Expired Non-Exclusive Medicine shall be reduced to 40% of the Original Ex-Factory Price. The HSE shall notify the Supplier of this reduced price not less than 28 days before the 1st of January 2022.

7.2.2. The Price of a Medicine that becomes a Patent-Expired Non-Exclusive Medicine after 1st of January 2022 shall, in accordance with Sub-Clause 7.3, reduce to 40% of the Ex-Factory Price of that Medicine as of 1st October 2021.

These are the maximum prices –a supplier may supply at lower prices provided this is notified to the HSE so that it maintains an up-to-date reimbursement list.

7.2.3. The provisions of Sub-Clause 5.2 and Clause 10 shall not apply to Patent Expired Non-Exclusive Medicines that have been subject to the price reductions specified in this Sub-Clause 7.2

7.3. Price Reduction Notification

7.3.1. The HSE shall notify the Supplier of a Patent-Expired Non-Exclusive Medicine when a Generic Medicine has become available for Supply resulting in a Patent-Expired Medicine being subject to a price reduction in accordance with Sub-Clause 7.2.2.

7.3.2. The notification referred to in Sub-Clause 7.3.1 shall specify the reduced price applicable in accordance with Sub-Clause 7.2.2 and shall specify the date from which such reduced price shall take effect. Said date being not less than 28 days from the date on which such notification was given pursuant to Sub-Clause 7.3.1, and the price reduction shall take effect only from the date so specified.

8. PRICING OF PATENT-EXPIRED NON-EXCLUSIVE BIOLOGIC MEDICINES

8.1. Scope

The provisions of this Clause 8 shall apply to patent-expired Biologic Medicines for which a Biosimilar Medicine is available for Supply

8.2. Price Reductions

8.2.1. On 1st of January 2022, the Price of each existing Patent-Expired Non-Exclusive Biologic Medicine shall be reduced to 62.86% of the 31st of July 2016 Ex-Factory Price. The HSE shall notify the Supplier of this reduced price not less than 28 days before the 1st of January 2022.

This measure shall not apply to those medicines that have been subject to a best-value-biologic initiative before 1st October 2021 for so long as any direction to prescribers from the HSE not to prescribe those medicines or to supply only biosimilar alternatives to them remains in place, or for so long as any financial incentive to prescribe such alternative biosimilar medicines remains in place.

8.2.2. The Price of a Biologic Medicine that becomes a Patent-Expired Non-Exclusive Biologic Medicine after 1st January 2022 shall, in accordance with Sub-Clause 8.3, reduce to 62.86% of the ex-factory price of that Biologic Medicine as of 1st October 2021.

These are the maximum prices –a supplier may supply at lower prices provided this is notified to the HSE so that it maintains an up-to-date reimbursement list.

8.2.3. In addition to the applicable price reduction in respect of any Patent-Expired Non-Exclusive Biologic Medicine pursuant to Sub-Clauses 8.2.1 or 8.2.2, the Supplier shall pay to the HSE or the Relevant Agency a rebate of a sum equal to 12.5% of the value, at the price reduced in accordance with this Sub-Clause 8.2, of such Patent-Expired Non-Exclusive Biologic Medicine reimbursed by the HSE in the Relevant Schemes and of any such Patent-Expired Non-Exclusive Biologic Medicine supplied to the HSE or a Relevant Agency. Any rebate payable under this Sub-Clause 8.2.3 shall be paid by the Supplier in the manner set out in Sub-Clauses 10.1 and 10.3 as applicable.

8.2.4. The provisions of Sub-Clause 5.2 and Clause 10.2 shall not apply to Patent Expired Non-Exclusive Biologic Medicines which have been subject to the price reductions specified in this Sub-Clause 8.2.

8.3. Price Reduction Notification

8.3.1. The HSE shall notify the Supplier of a Patent-Expired Non-Exclusive Biologic Medicine when a Biosimilar Medicine becomes available for Supply resulting in a Patent-Expired Non-Exclusive Biologic Medicine being subject to a price reduction in accordance with Sub-Clause 8.2.2.

8.3.2. The notification referred to in Sub-Clause 8.3.1 shall specify the reduced price applicable in accordance with Sub-Clause 8.2.2 and shall specify the date from which the price reduction shall take effect. Said date being not less than 28 days from the date on which such notification was given pursuant to Sub-Clause 8.3.1, and the price reduction shall take effect only from the date so specified.

9. PRICING OF PATENT-EXPIRED MEDICINES IN RESPECT OF WHICH A HYBRID MEDICINE IS AVAILABLE FOR SUPPLY

9.1. Scope

This Clause 9 shall apply to patent-expired Medicines (other than medicines in scope of Clause 7 or Clause 8) in respect of which a Hybrid Medicine is available for Supply

9.2. Price Reductions

9.2.1. On 1st of January 2022, the Price of each existing Patent-Expired Non-Exclusive Medicine in respect of which a Hybrid Medicine is available for Supply shall be reduced to 50% of the original ex-factory price. The HSE shall notify the Supplier of this reduced price not less than 28 days before the 1st of January 2022.

9.2.2. The Price of a Medicine that becomes a Patent-Expired Non-Exclusive Medicine after 1st of January 2022 shall, in accordance with Sub-Clause 9.3, reduce to 50% of the Ex-Factory Price of that Medicine as of 1st October 2021.

These are the maximum prices –a supplier may supply at lower prices provided this is notified to the HSE so that it maintains an up-to-date reimbursement list.

9.2.3. The provisions of Sub-Clause 5.2 and Clause 10 shall not apply to Patent Expired Non-Exclusive Medicines that have been subject to the price reductions specified in this Sub-Clause 9.2

9.3. Price Reduction Notification

9.3.1. The HSE shall notify the Supplier of a Patent-Expired Non-Exclusive Medicine when a Hybrid Medicine has become available for Supply resulting in a Patent-Expired Medicine being subject to a price reduction in accordance with Sub-Clause 9.2.2.

9.3.2. The notification referred to in Sub-Clause 9.3.1 shall specify the reduced price applicable in accordance with Sub-Clause 9.2.2 and shall specify the date from which such reduced price shall take effect. Said date being not less than 28 days from the date on which such notification was given pursuant to Sub-Clause 9.3.1, and the price reduction shall take effect only from the date so specified.

10. REBATE ON SALES

10.1. Operation

10.1.1. Each Supplier shall rebate to the HSE: [X]% of the value, at the Price or relevant ex-factory price, of all Medicines reimbursed by the HSE in the Relevant Schemes and of all Medicines supplied by the Supplier to the HSE or Relevant Agencies from 1st of October 2021 to 30th of September 2025

10.1.2. The rebate payable pursuant to Sub-Clause 10.1 shall be promptly paid by the Supplier

10.1.3. The HSE will advise each Supplier of the quantity and value of each of its Medicines (excluding Patent-Expired Non-Exclusive Medicines, Patent Expired Non-Exclusive Biologic Medicines, and patent-expired Medicines in respect of which a Hybrid Medicine is available for Supply) reimbursed by it under the Relevant Schemes each month and of the amount of the rebate payable. Any rebate payable shall be paid by each Supplier in accordance with such terms as may be agreed between it and the HSE

For the avoidance of doubt, the terms of any commercial-in-confidence patient access scheme contract, or other similar bilateral contractual agreement that is in place up to and including 31st December 2021 between the HSE and a supplier shall not be superseded by the terms of this agreement in the administration of this Sub-clause 10.1.

10.2. Rebate percentages

The following rebate percentages will apply, as denoted by "X%" in clause 10.1.1:

- Year 1a: 1st of October 2021 – 31st of December 2021 (3 months) = 5.5%
- Year 1b: 1st of January 2022 – 31st of December 2022 (12 months) = 7.75%
- Year 2: 1st of January 2023 – 30th of September 2023 (9 months) = 8.25%
- Year 3: 1st of October 2023 – 30th of September 2024 (12 months) = 8.50%
- Year 4: 1st of October 2024 – 30th of September 2025 (12 months) = 9.00%

10.3. Hospital medicines rebate

The HSE and IPHA will continue to work together to support the payment and collection of rebates payable under Sub-clause 10.1 in respect of the supply of Hospital Medicines.

11. SUPPLY TO HSE AND RELEVANT AGENCIES

11.1.

The supply of Medicines delivered to the HSE, and Relevant Agencies, shall be at the Price[1] where:

(i) an order with a minimum value of €634.57 (excluding VAT) is given to the nominated distributor of an individual Supplier, or
(ii) where the order is placed directly with the Supplier.

11.2. Special Supply Arrangements

11.2.1. The HSE (and relevant agencies) reserves the right at all times to procure by tender or to enter into special arrangements for supply to the HSE and Relevant Agencies with individual Suppliers, manufacturers, or agents, designed to secure more favourable terms than those referred to in Sub-Clause 11.1 above.

12. CONTINUITY OF SUPPLY

12.1. Scope

Continuity of supply is recognised by all Parties to this Agreement as crucially important to the effective operation of arrangements for the supply of Medicines to patients in the State. Equally, it is recognised that from time-to-time interruptions to supply may arise, which are outside the control of the Supplier.

12.2. Shortages, Discontinuations, and Transfers of Marketing Authorisation

(a) Foreseeable or Prolonged Stock Shortages

For the avoidance of doubt, a medicines shortage is when the supply of a medicinal product is inadequate to meet the needs of patients, as defined in the HPRA Medicines Shortages Framework[2].

(i) Suppliers who experience foreseeable or prolonged stock shortages, or the possibility of such shortages, must notify the HSE and the HPRA 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, Suppliers who intend to discontinue supplying particular Medicines to the Irish market must provide the following 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.

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1 "**Price**" as defined in this Agreement means the ex-factory price (otherwise known as the price-to-wholesaler) of a Medicine as determined in accordance with this Agreement, exclusive of Value Added Tax.
2 https://www.hpra.ie/docs/default-source/default-document-library/medicine-shortages-framework.pdf?sfvrsn=0

(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 Supplier

All transfers of Marketing Authorisations of medicines within the scope of this agreement must be notified to the HSE.

Where the transfer of a Marketing Authorisation is likely to materially change the arrangements for the supply of a Medicine, the original Marketing Authorisation holder must provide at least 3 months' notice to the HSE of the transfer of the Marketing Authorisation.

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

12.3.

In all cases relating to withdrawal of a Medicine, Suppliers must complete and return the HSE Product Withdrawal Form (as may be amended from time to time).

12.4.

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."*

12.5.

All the notification forms can be found on www.hse.ie

13. SHORT SHELF-LIFE PRODUCTS

13.1.

Suppliers shall use best endeavours to ensure that all Medicines supplied to the HSE, and Relevant Agencies, shall have a minimum shelf life of 12 months.

13.2.

Medicines with a remaining shelf life of less than 12 months may only be supplied subject to the agreement that unused date-expired quantities can be refunded promptly.

13.3.

The HSE or Relevant 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.

13.4.

Without prejudice to Sub-Clause 13.2, the HSE and IPHA shall endeavour to develop arrangements to minimise waste that may arise in the High-Tech Arrangements. Such arrangements may involve consultation with other relevant supply chain stakeholders and in any event shall be subject to the Guidelines on Good Distribution Practice[3] and any other quality requirements.

14. ADMINISTRATION OF THE AGREEMENT

14.1. General

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

The State intends that sufficient administrative resources are in place to ensure timely processing of pricing and reimbursement applications for new products, subject to compliance with this pricing framework.

14.2. Vaccines and Blood Products

This Agreement will not prevent arrangements being made with any Supplier for the supply of vaccines, blood products, or similar products to the HSE and/or Relevant Agencies.

14.3. Price Modulation

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

14.3.2. 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.

14.4. Exceptional Circumstances

14.4.1. Where a Supplier considers itself to be disproportionately prejudiced by the terms of this Agreement, direct representations may be made to the HSE by that Supplier for variation of any term of this Agreement including its price terms.

3 https://www.ema.europa.eu/en/human-regulatory/post-authorisation/compliance/good-distribution-practice

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

14.4.3. Where representations are made to the HSE under this Clause, the HSE shall have the final decision on whether to vary the terms of this Agreement in any case but will consult with the Supplier before reaching its decision. In considering a request under this Clause, the HSE shall have regard in reaching its decision to any price modulation requested or applied under Sub-Clause 14.3.

14.5. Provision of Information

14.5.1. IPHA shall immediately notify the HSE in writing of all changes to its member companies during the Term.

14.5.2. Where practicable all New Medicines intended to be submitted for addition onto the Reimbursement List in accordance with the 2013 Act or for which a pricing application as a Hospital Medicine is to be made shall be notified to the HSE by the Supplier in the preceding year as part of the exercise of examining the pipeline of new medicines (known between the Parties as the "new medicines horizon scan").

14.5.3. Where practicable all Medicines whose patent / data exclusivity may be expected to lapse shall be notified to the HSE by the Supplier in the preceding year as part of the exercise of assisting the HSE in informing suppliers of planned BVB or BVM processes. In the event that a supplier fails to so notify, it can have no reasonable expectation of the HSE being in a position to provide information.

14.5.4. For the purposes of Clauses 5 and 6 of the Agreement, the Suppliers shall supply the HSE, in commercial confidence, with the currency-adjusted relevant price (being the ex-factory price or equivalent thereof and using the applicable Exchange Rate) applicable in the Nominated States in which the Medicine is available. The provision to the HSE of such information is provided on the understanding that, when calculating the Price, the HSE may have regard to such further information as the HSE deems appropriate including, without limitation, information sourced from EURIPID or received directly from the Nominated States.

14.6. Acknowledgement

The Parties acknowledge that the mechanisms for the pricing of Medicines set out in this Agreement are mutually agreed between them and that decisions arising thereunder do not constitute decisions under or pursuant to section 21 of the 2013 Act.

14.7. Oversight of Agreement

14.7.1. The Parties agree to meet annually on dates to be agreed between the Parties to review and discuss any issues arising from the operation of the Agreement.

14.7.2. The governance and operation of this Agreement will be formally reviewed by the Parties during 2024 (no earlier than February 2024 and no later than July 2024).

In Witness whereof this Agreement has been entered into by the Parties on the _____day of October 2021.

SIGNED BY
for and on behalf of the Parties:

The State Negotiation Team (DoH, D/PER, HSE)	**The Heath Service Executive (HSE)**	**The Irish Pharmaceutical Healthcare Association (IPHA)**
Signature:	*Signature*:	*Signature*:
_____	_____	_____
Name: Fergal Goodman	**Name:** Paul Reid	**Name:** Paul V. Reid
Title: Assistant Secretary, DoH	**Title:** CEO, HSE	**Title:** President, IPHA

2021

FASPM 2021 -2025: Supporting Materials

03 DECEMBER 2021

SCHEDULE 1

Principles And Processes for The Assessment of New Medicines in Ireland

Secure, Affordable, and Timely Access for Irish Patients to New Medicines: Principles and Processes for the Assessment of New Medicines in Ireland

Introduction

Medicines play a key role in improving the health of patients in Ireland. Securing timely access to medicines for patients at an affordable price, in particular innovative medicines offering enhanced health outcomes, is a key priority for Ireland. Securing the cost effective and economic provision of medicines to the health services in Ireland is vital to free up resources for continued investment in new and innovative medicines for patients; this Agreement is a key element in delivering that objective. This will ensure that Ireland remains at the forefront of its European peers in terms of early access to these new medicines in an affordable manner and within available resources.

Purpose

The purpose of this Schedule is to outline the central principles and guidelines that will underpin the assessment of new medicines in Ireland which seek to be added to the Reimbursement List maintained by the HSE or priced for supply or reimbursement as a hospital medicine to State funded hospitals[4] (both processes referred to hereafter as applications for reimbursement).

The Health (Pricing and Supply of Medical Goods) Act 2013 ("**the 2013 Act**") requires the HSE to maintain a publicly-accessible list on the internet of all medicines (and other medical products) which may be reimbursed by the HSE pursuant to the various Community Drugs Schemes[5]. The processes and procedures which apply when an application is received to add a new medicine to the Reimbursement List are governed by the 2013 Act. Applications may also be made to the HSE to have a medicine priced as a hospital medicine for the purposes of supply to or reimbursement by the HSE, State-funded hospitals and related agencies.

The principles set out herein, while following the 2013 Act, are also informed by the Health Act 2004.

4 Such supply or reimbursement may also be to the HSE or publicly funded entities and State Agencies whose functions include the provision of medicines. Reference to State-funded hospitals in this document should be taken to refer to all such possible entities. The processes set out herein are without prejudice to any recourse the HSE and hospitals may or do have to procure medicines through tender processes or public procurement procedures.

5 Such schemes include the Drugs Payment Scheme and the General Medical Services (Medical Card) Scheme.

The document sets out the following:

- The principles underpinning the assessment process for new medicines;
- A step-by-step guide as to how the assessment process is intended to operate; and
- A diagram illustrating the decision process

For the avoidance of doubt, this document does not relate to the process by which a new medicine is approved for general supply and marketing in the State (it is limited only to the direct reimbursement by the State of such medicines). It is a pre-requisite that any new medicine applying to be reimbursed by the HSE must first hold a marketing authorisation granted by the Health Products Regulatory Authority ("the HPRA") or the European Commission.

The HSE reserves the right to amend or update the content hereof as it deems appropriate. The HSE will afford IPHA the opportunity to make representations and the HSE will consider such representations prior to implementing the amendment or update.

A copy of the 2013 Act can be found at:

- http://www.irishstatutebook.ie/eli/2013/act/14/enacted/en/pdf.

The Reimbursement List is publicly accessible and can be found at:

- http://www.hse.ie/eng/staff/PCRS/items/

Principles Underpinning the Assessment Process for New Medicines

In line with statutory obligations, the HSE operates within the resources provided by Dáil Éireann each year. The HSE has statutory responsibility for decisions on pricing and reimbursement of drugs in accordance with the 2013 Act. As part of this statutory assessment process the HSE must consider the affordability of each individual decision against overall resources as allocated. To facilitate the on-going management of resources, medicines intended to be submitted for reimbursement should be included as part of the new medicines horizon scan furnished to the HSE by the supplier or manufacturer (hereafter, the "Company" or "Companies") in the preceding year.

In line with the 2013 Act, if a Company would like a medicine to be reimbursed by the HSE pursuant to the Community Drug Schemes or as a hospital medicine, the Company must first submit an application to the HSE to have the new medicine added to the Reimbursement List or to be priced as a hospital medicine. Within 180 days of receiving the application (or such longer period which may arise if further information is sought from the Company), the HSE will decide to either:

- add the medicine to the Reimbursement List/agree to reimburse it as a hospital medicine, or

- will refuse to reimburse the medicine.

In reaching its decision, the HSE examines all the evidence which may be relevant in its view for the decision (including the information /dossier submitted by the Company) and will take into account such expert opinions and recommendations which may have been

sought by the HSE at its sole discretion (for example, from the National Centre for Pharmacoeconomics). In considering an application, the HSE will also have regard to Part 1 and Part 3 of Schedule 3 of the 2013 Act. Part 3 requires the HSE to have regard to the following criteria:

1. the health needs of the public,
2. the cost-effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,
3. the availability and suitability of items for supply or reimbursement
4. the proposed costs, benefits and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits, and risks,
5. the potential or actual budget impact of the item or listed item,
6. the clinical need for the item or listed item,
7. the appropriate level of clinical supervision required in relation to the item to ensure patient safety,
8. the efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies), and
9. the resources available to the HSE.

In submitting an application for reimbursement, a Company will propose a price for reimbursement having regard, as applicable, to this Framework Agreement 2021. In determining the price at which the medicine will be reimbursed or supplied, the HSE will have regard to Clause 6 of this Framework Agreement 2021 as well as the provisions of section 21(2) of the 2013 Act.

The final decision on reimbursement is made by the HSE, and, in respect of medicines to be added to the reimbursement list, will be determined in line with the 2013 Act.

The above principles are intended to underpin the HSE assessment process for new medicines and should be considered as applying to the rest of this document.

Notes on the Assessment Process for New Medicines

The following sets out HSE guidance on how the HSE and related bodies will endeavour to engage with Companies submitting applications for reimbursement. It does not purport to be an exhaustive description of the entire processes applicable (which are at all times subject to the 2013 Act, where appropriate, and HSE discretion)

1. Companies will normally be required to submit a new medicine horizon scan by the end of July each year which should indicate all new medicines in respect of which the Company intends to apply for reimbursement in the forthcoming years. Those medicines included in the horizon scan may be submitted for Rapid Review Assessment and as appropriate Health Technology Assessment ("HTA") in the following year.

2. Companies will be enabled to submit a rapid review dossier to the National Centre for Pharmacoeconomics (the "NCPE") / HSE on receiving European Medicines Agency Expert Advisory Group (CHMP) recommendation provided that they have certainty around the list price they intend to apply for. (This is generally two to three months before a market authorisation is granted).

3. The NCPE will endeavour to issue a Rapid Review Assessment report within four weeks of receipt.

4. An application to be added to the Reimbursement List or to be priced as a hospital medicine, together with any relevant fees and a Rapid Review Assessment dossier and HTA dossier (as appropriate), can be submitted as soon as the market authorisation has been granted.

5. When the HSE receives a Rapid Review Assessment report or HTA report it will endeavour to consider that report within 14 days in conjunction with the criteria set out in the 2013 Act. A final decision can thereafter be reached for certain medicines and will be duly notified to the Company.

6. Following engagements with a Company, a medicine may be required to be submitted for consideration by the HSE Drugs Group (the "Drugs Group").

7. The HSE will advise Companies if their application for reimbursement has been submitted for consideration by the Drugs Group and will be notified of the date of the meeting at which the application will be reviewed.

8. The HSE will endeavour to advise the Company in writing of the recommendation of the Drugs Group within 14 days of the making of that recommendation. This recommendation will be commercially confidential between the HSE and the relevant Company to enable appropriate due process to be completed.

9. Recommendations from the Drugs Group will be considered at the next HSE Leadership Team meeting and the HSE will endeavour to make a decision on the application within 45 days of the Drugs Group recommendation.

10. The output of the consideration by the HSE Leadership Team may result in:

    a. a decision to reimburse at the applied terms,
    b. a decision not to reimburse at the applied terms, or,
    c. a requirement to meet with the applicant Company to address any issues arising or to seek clarifications (see assessment process chart below).

11. Where the HSE approves an application to reimburse a medicine, reimbursement will be implemented within 45 days. On such approval, and where the application for reimbursement was made pursuant to the 2013 Act, the medicine will be added to the Reimbursement List and will specify the price at which the medicine will be eligible for reimbursement.

12. In a situation where the HSE cannot fund the medicine from within existing resources, it may inform the Department of Health of its decision in this respect. The Department of Health may, as it deems appropriate, bring a memorandum to Government in relation to the funding implications and requesting consideration of same.

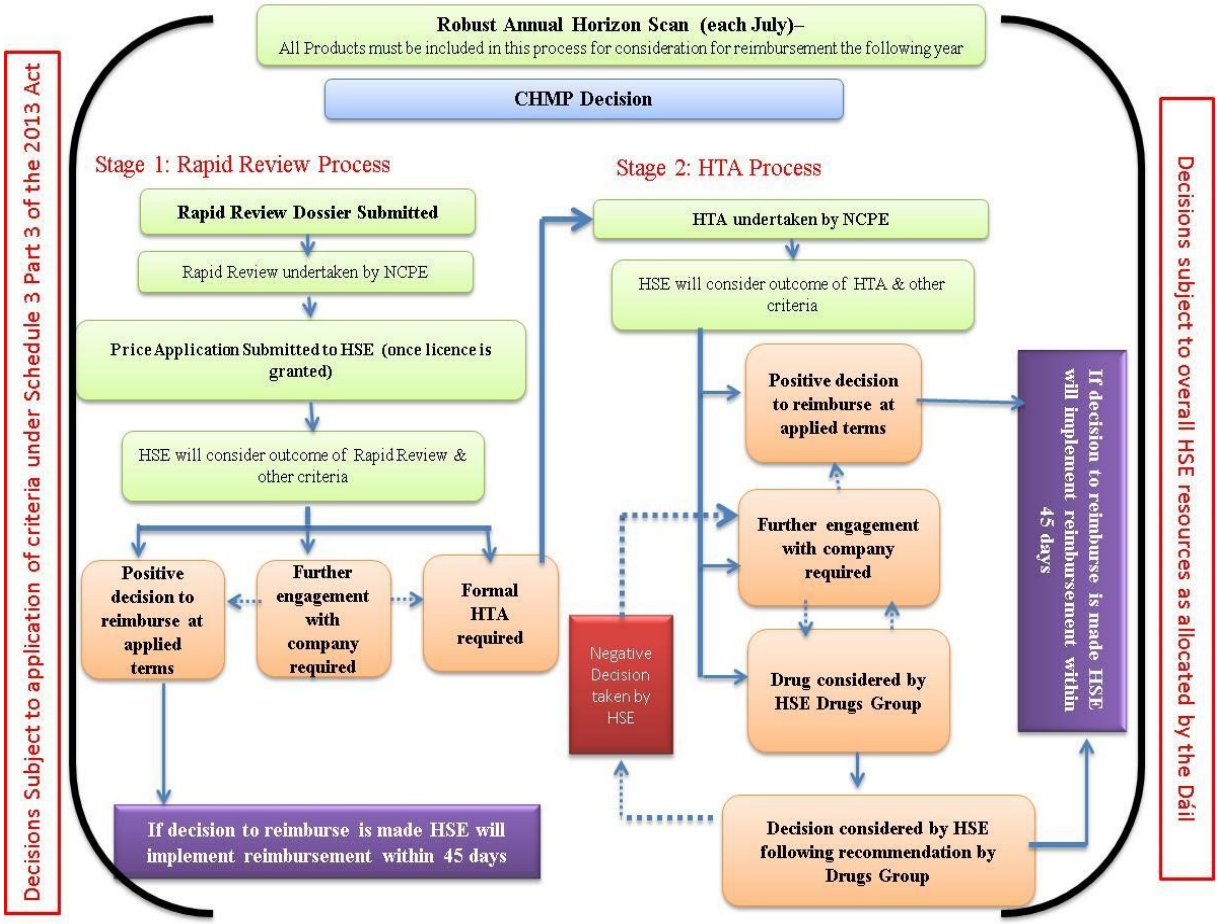
13. The HSE will publish the list of planned dates for Drugs Groups meetings at the outset of each year.

14. The HSE will publish a Drugs Group meeting note in relation to its deliberations on each medicine considered by the Drugs Group.

15. At all stages of the decision-making process, the HSE will subject each medicine to an assessment of affordability in accordance with the 2013 Act and as set out in the principles for the assessment process above.

Diagram of the Assessment Process

The diagram below seeks to map out the processes that the HSE will endeavour to follow in making decisions on the reimbursement of new medicines.



SCHEDULE 2

Processes for

The Assessment and Selection of Best Value Biologic Medicines

1. Each January the HSE will publish a list by ATC/ INN from which it may initiate a BVB or BVM process in that calendar year. The MMP have previously indicated that colony –stimulating factors, erythropoietins, and fertility medicines are therapeutic areas under consideration.

2. The HSE will give a month's notice to each supplier of initiating a BVB or BVM process for a particular INN

3. The BVB or BVM process will follow that already set out in the MMP Roadmap for the prescribing of best value medicines in the Irish healthcare setting

    a. Six weeks formal consultation phase
    b. Review period (typically two months but may require longer)
    c. Publication of Prescribing and Cost Guidance to relevant stakeholders

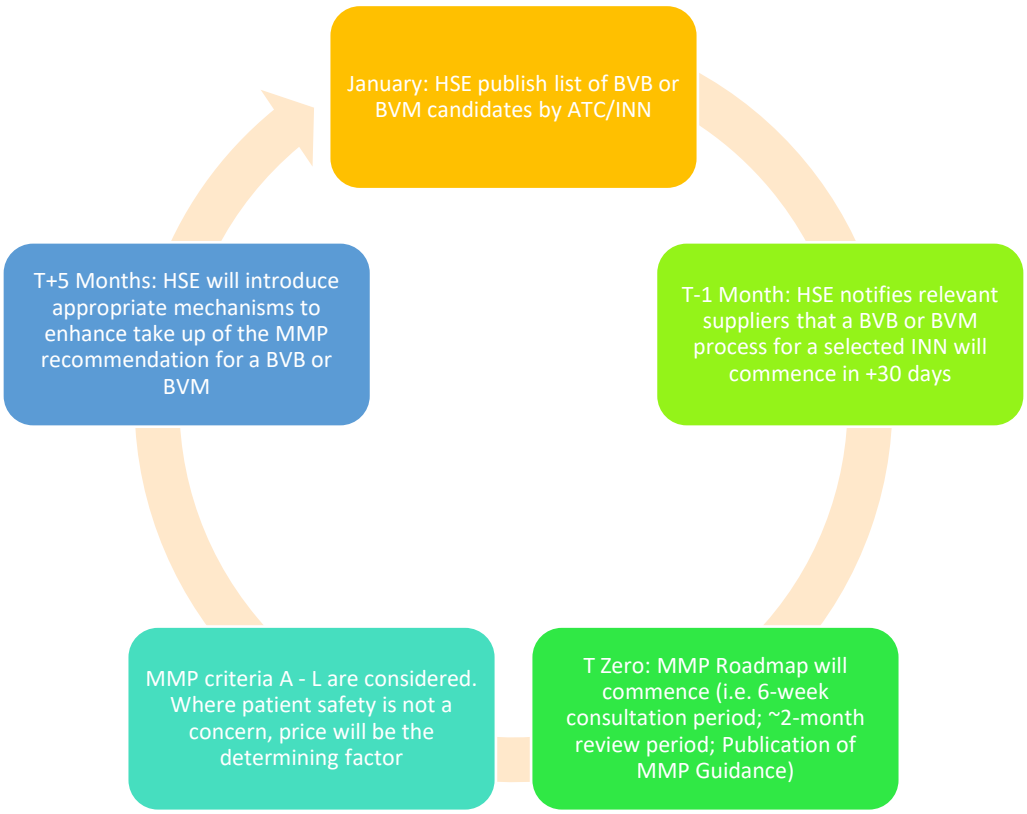
4. A number of Criteria may be considered by the MMP in identifying BVB or BVM medicine(s) including

    a. Acquisition cost
    b. Therapeutic Indications
    c. Formulation Considerations
    d. Product Range including pack sizes and strengths available
    e. Product stability including storage requirements
    f. Administration devices
    g. Patient factors
    h. Expenditure in the therapeutic area and potential for cost efficiencies
    i. Clinical Guidelines
    j. Security of Supply to the Irish Market
    k. Utilisation and clinical experience with the biological medicine
    l. Any other relevant factors with respect to the particular INN

5. Where the MMP is satisfied that all other factors are similar and comparable such that patient safety is not a concern, price will be the determining factor

6. The HSE will publish the MMP recommendation for a BVB or BVM and introduce as appropriate mechanisms to enhance take up of the MMP recommendation for a BVB or BVM.

Figure 1: Illustrative process flow



T = time point, e.g., T minus 1 is one month before a key point; T Zero is a key point; T+5 Months is 5 months after T Zero

SCHEDULE 3

List of IPHA Members

1. A Menarini Pharmaceuticals Ireland Ltd
2. AbbVie Ltd
3. Alliance Pharmaceuticals Ireland
4. Almirall Ltd.
5. Alimera Sciences Europe Ltd.
6. Amgen Ireland Limited
7. Astellas Pharma Ltd
8. Bayer Limited
9. Biogen Idec (Ireland) Ltd
10. Boehringer Ingelheim Ireland Limited
11. Bristol-Myers Squibb Pharmaceuticals
12. Celgene Limited
13. Chugai Pharma UK
14. Daiichi Sankyo Ireland Limited
15. Eisai Limited
16. Eli Lilly & Company (Ireland) Ltd
17. Gilead Sciences Ireland UC
18. GlaxoSmithKline
19. Grunenthal Pharma Ltd
20. Ipsen Pharmaceuticals limited
21. Janssen
22. Jazz Pharmaceuticals
23. LEO Pharma
24. Lundbeck (Ireland) Ltd
25. Merck
26. MSD
27. Mundipharma Pharmaceuticals Company
28. Novartis Ireland Ltd
29. Novo Nordisk Limited
30. Organon Pharma (UK) Ltd.
31. Otsuka Pharmaceuticals (UK) Ltd.
32. Pfizer Healthcare Ireland
33. Roche Products (Ireland) Ltd
34. Sanofi Ltd
35. Servier Laboratories (Ireland) Limited
36. Shionogi BV
37. Takeda Products Ireland Ltd
38. Tillotts Pharma Ltd
39. UCB Pharma Limited