THE FRAMEWORK AGREEMENT ON THE SUPPLY AND PRICING OF MEDICINES (FASPM) 2026-2029

THE IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION (IPHA)

March 3, 2026

Contents

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 or a new meaning is introduced through legislation, 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, off-patent, or non-patented Medicinal Products, excluding blood products, vaccines, and non-reimbursable non-prescription products, without prejudice to sub-clause 15.2, 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) 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. The UK is included in the basket for the May 1st, 2026, realignment only.

"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 Schemes" 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 company(ies), including Manufacturers, importers, or their agents

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

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

This Agreement shall commence on 1st January 2026 and shall continue in force until 31st December 2029, 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 – IE and EU law

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 Regulation (EU) 2022/2371.

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-clause 15.4 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

5.2.1 The Price of all on patent Medicines reimbursed before 31 December 2025 will be realigned, downwards only, in accordance with the following provisions:

5.2.2 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 May 2026*
(ii) 1st March in each of 2027, 2028, and 2029

The 1st of May 2026 realignment will include the UK in the basket of Nominated States. The UK is not included in the 2027, 2028, and 2029 realignment baskets.

5.2.3 The Prices of each Medicine added to the Reimbursement List or funded as/received pricing approval as a Hospital Medicine during the Term will be realigned, downwards only, on March 1st, 2029. Pricing realignments of these medicines will occur in accordance with the following provisions:

5.2.4 For the first pricing realignment, the Price of an on patent 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 November 1st 2028, if that day is at least 1,095 days (36 months) after its addition in Ireland as a New Medicine to the Reimbursement List, or 1,095 days after having been priced as a Hospital Medicine.

For subsequent realignments, the price will be realigned in accordance with the provisions of 5.2.2.

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

(i) For realignments on 1st of May 2026, the period shall be 1st of August 2025 to 31st of October 2025

(ii) For realignments occurring on 1st of March in each of the years 2027, 2028, and 2029, the period shall be from 1st of July to 30th of September of the relevant preceding year.

5.2.6 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.

5.2.7 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) March 31st 2026, and

(ii) (ii) 20th of December in each of the years 2026, 2027, and 2028

5.2.8 Where a Supplier considers itself to be disproportionately prejudiced by Clause 5 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. The HSE will endeavor to respond within 28 days.

5.2.9 In the interests of continuity of supply, where it becomes uneconomic for a Supplier to supply a particular Medicine under Clause 5 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.

5.3

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 2025 between the HSE and a supplier, shall not be superseded by the terms of this agreement in the administration of this Clause 5.

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 3, 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 Supplier Proposed Price

6.2.1 For 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 between the 1st of January 2026 and 31st of December 2027, the supplier shall propose a price which shall be considered by the HSE in accordance with the 2013 Act and, as applicable, the Assessment Principles.

6.2.2 Suppliers acknowledge that the HSE, in assessing and developing pricing arrangements 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 have regard to the currency-adjusted relevant prices (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.

6.2.3 All New Medicines added to the Reimbursement List and/or priced as Hospital Medicines during the Term shall be subject to price realignment and rebates in accordance with the provisions of Clause 5 and Clause 10 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 The Price of a Medicine that becomes a Patent-Expired Non-Exclusive Medicine after the 1st of January 2026 shall, in accordance with Sub-Clauses 7.3, 7.4 reduce to 40% of the Ex-Factory Price of that Medicine as of 1st of October 2025 dictated in Sub-Clause 7.4.

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.

7.2.2 The provisions of Clause 5 and Clause 10 shall not apply to Patent Expired Non-Exclusive Medicines that have been subject to the price reductions specified in 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.

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 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.

7.4 Pricing of Generic medicines

7.4.1 In respect of all Medicines from the 1st of January 2026 the price submitted by a Supplier to the HSE for a New Medicine, whether for inclusion on the Reimbursement List or for pricing as a Hospital Medicine, shall be no greater than 40% of the 1st of October 2025 price of the equivalent branded original Medicine.

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

7.4.2 Where 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 does not have an equivalent originator Medicine available in the market, the Supplier shall propose a

price which shall be considered by the HSE in accordance with the 2013 Act and in line with the Assessment Principles set out in Schedule 3.

8 Pricing Of Patent-Expired Non-Exclusive Biologic Medicines and Biosimilar 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 Pricing of Patent-Expired Non-Exclusive Biologic Medicines

8.2.1 The Price of a Biologic Medicine that becomes a Patent-Expired Non-Exclusive Biologic Medicine after 1st of January 2026 shall, in accordance with Sub-Clauses 8.2.2 and 8.3, reduce to 62.86% of the ex-factory price of that Biologic Medicine as of 1st October 2025. 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.

8.2.2 In addition to the applicable price reduction in respect of any Patent-Expired Non-exclusive Biologic Medicine pursuant to Sub-Clauses 8.2.1, 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 Sub-Clause 8.2.1, of any 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 8.2.2 shall be paid by the Supplier in the manner set out in Clause 10 as applicable.

8.2.3 The provisions of Clause 5 and Clause 10 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.

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 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.

8.4 Maximum Supplier Proposed Price for Biosimilar Medicines.

8.4.1 The price that 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 55% of the 1st of October 2025 price of the equivalent branded original medicines.

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

8.4.2 Where 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 does not have an equivalent originator medicine available in the market, the Supplier shall propose a price which shall be considered by the HSE in accordance with the 2013 Act and in line with the Assessment Principles set out in Schedule 3.

9 Pricing Procedures for Hybrid Medicines And Patent-Expired Medicines In Respect Of Which A Hybrid Medicine Is Available For Supply

9.1 Scope

This Clause 9 shall apply to Hybrid Medicines and 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. That is, excluding Generic and Biosimilar Medicines.

9.2 Pricing of Patent-Expired Medicines in Respect of which a Hybrid Medicine is Available for Supply

9.2.1 The Price of a Medicine that becomes a Patent-Expired Non-Exclusive Medicine after 1st of January 2026 shall, in accordance with Sub-Clause 9.3, reduce to 50% of the Ex-Factory Price of that Medicine as of the 1st of October 2025. 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.

9.2.2 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 9.2.1 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.

9.4 Maximum Supplier Proposed Price for Hybrids

9.4.1 The price that 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 50% of the 1st of October 2025 price of the reference originator.

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.

9.4.2 Where 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 does not have an equivalent originator medicine available in the market, the Supplier shall propose a price which shall be considered by the HSE in accordance with the 2013 Act and in line with the Assessment Principles set out in Schedule 3.

10 Rebate on sales

10.1. Operation for New Medicines 2026-2029

10.1.1 Each Supplier shall rebate to the HSE: [X]% of the value, at the Price or relevant ex-factory price for on patent new medicines added to the Reimbursement List or a New Medicine priced as a Hospital Medicine between 1st of January 2026 to 31st December 2029.

- Year 1: 1st of January 2026 – 31st of December 2026 (12 months) = 9%
- Year 2: 1st of January 2027 – 31st of December 2027 (12 months) = 7%
- Year 3: 1st of January 2028 – 31st of December 2028 (12 months) = 6%
- Year 4: 1st of January 2029 – 31st of December 2029 (12 months) = 5%

10.2 Operation of Medicines added to the reimbursement list or priced as a hospital medicine prior to January 2026

10.2.1 Each Supplier shall rebate to the HSE 9% of the value, at the Price or relevant ex-factory price, for new medicines including new presentations and indications added to the Reimbursement List or a New Medicine priced as a Hospital Medicine prior to January 2026.

10.3 The HSE and IPHA will continue to work together to support the payment and collection of rebates payable under Sub-clauses 10.1and 10.2. Suppliers must discharge rebate payments in a timely fashion.

10.4 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

10.5 Hospital medicines rebate

10.5.1 The HSE and IPHA will continue to work together to support the payment and collection of rebates payable under Sub-clauses 10.1and 10.2 in respect of the supply of Hospital Medicines.

10.6

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 2025 between the HSE and a supplier, shall not be superseded by the terms of this agreement in the administration of this Clause 10.

11 Pricing to Address the Security of Supply of Medicines

11.1 Measures to address the use of Exempt Medicinal Products (EMPs) and Pharmacy Circular 12/23

11.1.1 Purpose

The Parties acknowledge that Exempt Medicinal Products (EMPs) are supplied in accordance with applicable legislation to address specific clinical needs where authorised medicinal products are unavailable or unsuitable. The objective of this provision is to support the transition, where appropriate, from EMP supply arrangements to authorised and reimbursed medicinal products available on the Irish market

11.1.2 Identification of Relevant EMP Products

Where an EMP has been assigned an administrative reimbursement code by the HSE at an agreed reimbursement price, the HSE shall publish the relevant product information including:

a) the applicable reimbursement price;
b) the strength, formulation and presentation to which the administrative code applies; and
c) confirmation that the product is being reimbursed under EMP arrangements pursuant to Pharmacy Circular 12/23.

11.1.3 Engagement with Marketing Authorisation Holders

Where a medicinal product equivalent or therapeutically comparable to an EMP-coded product is authorised in Ireland, the HSE may encourages Supplier(s) to who have licenced products on the Irish market, to submit applications for reimbursement.

Such engagement shall recognise that EMP utilisation may arise due to temporary supply disruption, market conditions, or clinical practice considerations.

11.1.4 Pricing Framework

Where a Supplier submits an application for reimbursement for a medicinal product corresponding to an EMP-coded product, the submitted application price shall not exceed 90% of the published reimbursement price of the relevant EMP-coded product.

12 Supply to the HSE and relevant agencies

12.1

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.

12.2 Special Supply Arrangements

12.2.1 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 12.1 above.

12.2.2 Where a manufacturer chooses to supply directly to a dispenser, delivery will be at the price to wholesaler.

12.2.3 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).

13 Continuity of supply

13.1 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.

[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.

13.2 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 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.

(ii) (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.

[2] https://assets.hpra.ie/data/docs/default-source/external-guidance-document/sur-g0045-medicines-shortages-framework-v4.pdf

13.3

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).

13.4

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, or equivalent legislation[3], which at the time of writing 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."

13.5

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

13.6

Market authorisation holders and their authorised distributors shall within the limits of their respective responsibilities, use all reasonable and proportional efforts to ensure appropriate and continued supply of medicinal products to pharmacies and persons authorised to supply medicinal products so that patient needs are met in the state in accordance with the above Directive as amended and applicable HPRA regulatory requirements.

The Parties acknowledge that obligations relating to continuity of supply shall be interpreted and applied in a manner consistent with applicable EU and Irish law, including the shared responsibilities of manufacturers, marketing authorisation holders, wholesalers, healthcare system actors, and competent authorities.

Nothing in this Agreement shall be construed as creating an absolute guarantee of supply or imposing liability for shortages arising from factors outside the reasonable control of the Marketing Authorisation Holder or its distributors, including but not limited to global supply chain disruptions, manufacturing constraints, regulatory actions, or market-wide shortages.

---

[3] In the event that Directive 2001/283/EC is repealed during the lifetime of this Agreement, the equivalent article of the repealing Directive will apply for the purpose of this sub-clause. The relevant Article of the proposed Directive published by the European Commission is Article 56 at the time of writing, but this may be subject to change dependent on the form of the final text.

13.7

Where a supplier is in breach of this Clause for off patent medicines, 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 IPHA in relation to any such cases, if so, requested by a manufacturer.

13.8

To enhance the security of supply of medicines IPHA companies will examine their companies' portfolios and, where possible, bring to market their medicines that are available in other European countries but not in Ireland.

14 Short shelf-life products

14.1

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.

14.2

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.

14.3

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.

14.4

Without prejudice to Sub-Clause 14.2, 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[4] and any other quality requirements.

[4] https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/compliance-post-authorisation/good-distribution-practice

15 Administration of the Agreement

15.1 General

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

15.2 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.

15.3 Provision of Information

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

15.3.2 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 12-18 months in advance of the submission of a pricing application as part of the exercise of examining the pipeline of new medicines (known between the Parties as the "new medicines horizon scan").

15.3.3 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 to assist the HSE in publishing, each January, a list by ATC / INN from which it may initiate a best-value biological (BVB) medicine / best-value medicine (BVM) process in that calendar year. 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.

15.3.4 To assist the HSE in planning for BVB / BVM processes, Suppliers will provide, in June of each year, the HSE with information, in a standardised format, of their current pipeline of biosimilar medicines including indicative dates of availability on the Irish market, where available.

15.3.5. 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 EU Member 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 EU Member States.

15.4 Exceptional Circumstances

15.4.1 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. The HSE will endeavour to respond within 28 days.

15.4.2 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.

15.4.3 Where representations are made to the HSE under this sub-clause, the applicant would be encouraged to make their submission within the first 6 months of the application year with a view to making the decision within 180 days, for implementation in the following budget year. 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.

15.5 Price Modulation

15.1.1 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.

15.1.2 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 the Clause are not adhered to.

15.6 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.

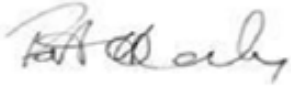
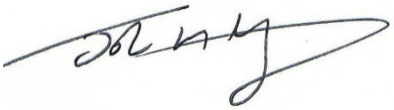
15.7 Governance of Agreement

The Parties agree to meet as outlined in Schedule 1 to review and discuss any issues arising from the operation of the Agreement.

In Witness whereof this Agreement has been entered into by the Parties on 3rd March 2026.

SIGNED BY

for and on behalf of the Parties:

The State Negotiation Team	The Health Service Executive	The Irish Pharmaceutical Healthcare Association
(DOH, D/PER, HSE)	(HSE)	(IPHA)
Signature:	*Signature:*	*Signature:*
		
Name:	**Name:**	**Name:**
Niall Redmond	Pat Healy	Shane Ryan
Assistant Secretary	National Director	President
Department of Health	Health Service Executive	IPHA

Schedule 1 Governance of Agreement

1. Implementation of this Agreement

The State negotiation team and the Irish Pharmaceutical Healthcare Association will work together to implement the measures outlined within this agreement, using project management methodology, with regular review and agreed timelines for the completion of key milestones across all clauses of the agreement.

2. Process of Ongoing Strategic Engagement

The State parties are committed to a process of ongoing, structured engagement with FASPM signatories to address the Programme for Government commitments on medicines. For example, the Department of Health will engage Irish Pharmaceutical Healthcare Association, as a strategic partner, in the development of an early access scheme for rare diseases.

The continuation of a high-level, enduring strategic relationship is designed to support the shaping and delivery of sustainable access to medicines within a more integrated, efficient, and patient-centred health system.

3. Review and Evaluation

In addition to on-going oversight and governance of the Agreement, the parties will engage in periodic review and evaluation of the commitments in the Agreement, for two principal purposes:

- To assess if the overall goals of the Agreement are being met satisfactorily from each party's perspective.
- To consider the features of the Agreement and its contribution to medicines policy, including budgetary management and overall affordability to the State, and to evaluate if mutually agreed modifications are appropriate in the then circumstances.

An oversight committee of the parties to the agreement consisting of representatives of the Agreement signatories will meet as part of the review processes. It is intended that these bi-annual meetings will take place in May and October of each year including for the mid-term review. The May meetings will act as preparatory engagements ahead of the substantive October reviews.

A review and evaluation will take place in October 2026 to consider:

- Progress towards agreed timeline for reimbursement decisions and applicant compliance with agreed processes based on data and KPIs set out in the Agreement that will be shared in advance with IPHA.

- The net effect of the change in Clause 6 relating to offer list prices, and the emergence of any substantial risk of otherwise unanticipated net expenditure, in the opinion of the state, arising from this measure in particular. This will be based on an analytical framework to be developed by the parties over the first half of 2026. It will be based on transaction information from HSE systems. The purpose of the analysis will be to assess whether or not expenditure risks have materialised or are about to materialise. This review will inform engagement and agreement to the parties in relation to the operation of Clause 6 following December 31,2027, having regard to the outcome of the assessment. Consistent with this and prior Framework Agreements, IPHA affirms that it does not enter expenditure limitation agreements.
- The October 2027 midterm review and evaluation will consider:
- Potential additional financial savings measures – these measures may include those related to 'Off Patent Unique' products, that will have been analysed between IPHA and the DoH/HSE in advance of October 2027, which, subject to formal agreement, will be considered for implementation from January 2028 onwards; This will be will be without prejudice to the details of the overall outcome of the review in 2027
- Any modifications to the Loss of Exclusivity mechanisms on Clauses 7,8 and 9 that would give the highest possible assurance of the predictability of the timing of the price reduction/rebate measures in those clauses, consistent with security of supply of medicines and related policy considerations, for implementation from 1st January 2028 onwards. Such modifications will be discussed between the parties in advance of October 2027 so that discussions then will be most efficient and effective. Other measures may include volume-based discounting and indication-based pricing.
- A review of the impacts of Clause 6 to date will inform updated terms and conditions for Clause 6 for the last two years of the Agreement will be agreed between the parties in late 2027.
- Progress towards achieving agreed targets for pricing and reimbursement decision timelines based on agreed KPIs reflective of State and applicant engagements in the process.
- Suitable timelines for future review and evaluation engagements if necessary.

Schedule 2 Processes for the Assessment and Selection of Best-Value Biological (BVB) Medicines / Best-Value Medicines (BVM)

1. The best-value biological (BVB) medicine / best-value medicine (BVM) process will predominately be used to ensure that the efficiencies presented by the availability of biosimilar medicines are fully realised to achieve best value for the state. The BVB / BVM process can also be employed in the case of generic medicines and hybrid medicinal products, where additional measures are required in order to ensure best value.

2. The HSE-Medicines Management Programme (MMP) is responsible for the identification of BVB / BVMs, and for the co-ordination and implementation of measures to support prescribing and utilisation of the recommended BVB / BVMs.

3. Each January, the HSE will publish a list by ATC / INN from which it may initiate a BVB / BVM process in that calendar year. This will include those medicines for which the HSE may undertake a review or revisit of previous BVB / BVM recommendations.

4. To assist the HSE in planning for BVB / BVM processes, Suppliers will provide, in June of each year, the HSE with information, in a standardised format, of their current pipeline of biosimilar medicines including indicative dates of availability on the Irish market, where available.

5. The availability of biosimilar medicines on the HSE Reimbursement List and/or with hospital pricing approval, is a key enabler for BVB / BVM processes to commence. Suppliers commit to submitting pricing and reimbursement applications to the HSE for biosimilar medicines at the earliest opportunity, in order to enable timely commencement of BVB / BVM processes after lapse of market / patent exclusivity.

6. There will be three stages to a BVB evaluation process:
    a. Submission phase (90 days; day 1 – 90)
    b. Evaluation phase (90 days; day 91 -180)[5]
    c. Pre-implementation phase (60 days; day 181 – 240).

[5] The evaluation phase will last up to 90 days, i.e. it may be completed in a shorter timeframe than 90 days.

7. Where the HSE has a reasonable expectation that four or more marketing authorisation (MA) holders / suppliers will be able to participate in a BVB / BVM process and there are no particular material considerations in relation to the BVB / BVM process, the HSE will, save for exceptional circumstances, commence the BVB / BVM process after the:
    a. addition of the first biosimilar medicine to the HSE Reimbursement List, and /or
    b. issuing of a hospital pricing approval letter for the first biosimilar medicine.

8. Where, based on the information available, the HSE expects that three or less MA holders / suppliers will be able to participate in a BVB / BVM process, the HSE reserves the right to commence the BVB / BVM process at the appropriate time in order to maximise participation in the initial BVB / BVM process. In these circumstances, the HSE will seek to commence the BVB / BVM process at the earliest possible opportunity after the:
    a. addition of the first biosimilar medicine to the HSE Reimbursement List, and /or
    b. issuing of a hospital pricing approval letter for the first biosimilar medicine,

   while also seeking to enable maximum participation in the initial BVB / BVM process.

9. The HSE will issue a notification to each relevant MA holder / supplier at the time of commencement of submission phase. In addition, the HSE will also inform IPHA at this time.
    - The submission phase will last 90 days.
    - Only biosimilar medicines for which a MA holder / supplier submits a dossier during the submission phase will be considered during the evaluation phase.

10. The following are required in order for a MA holder / supplier to participate in the initial BVB / BVM process for a particular medicine / INN / group of medicines:
        - Submission of a dossier to the HSE during the submission phase containing any information relevant to the criteria specified by the HSE for identifying BVB / BVMs.
        - The criteria that may be considered by the MMP in identifying BVB / BVMs are outlined in section 14 below.
        - On the final date of the submission period, the supplier must have a valid MA for their medicinal product, or have a reasonable expectation that a MA will be granted for the medicinal product before the completion of the evaluation phase (i.e. the MA holder should have received a positive opinion from the European Medicines Agency [EMA] Committee for Medicinal Products for Human Use [CHMP] for their medicinal product).
        - Where a MA holder / supplier submits a medicinal product with EMA CHMP positive opinion:
            - The MA holder / supplier is required to provide a copy of the Summary of Product Characteristics and European Public Assessment Report as part of the dossier submission. The HSE cannot progress evaluation in the absence of these documents, and the medicinal product will be excluded from the BVB / BVM process.

        - The MA holder / supplier is required to immediately notify the HSE when a MA is granted for the medicinal product and to submit a formal pricing and reimbursement application for the medicinal product.
        - By the end of the evaluation phase, the medicinal product must be the subject of a valid marketing authorisation and have received formal HSE reimbursement approval. If both of these requirements are not met, the submission from the MA holder / supplier is automatically excluded from the BVB / BVM process at this point.
- By making a submission, the MA holder / supplier is committing to ensuring that adequate stock of their medicinal product will be available by the end of the pre-implementation phase to meet any increased demand arising from the MMP recommendations.
- MA holders / suppliers that do not meet the criteria outlined above to participate in the initial BVB / BVM process for a particular medicine will be provided with an opportunity to participate in the review process outlined in Section 13 below.

11. The evaluation phase will commence after the submission phase.
    a. The evaluation phase will last up to 90 days, and will include some or all of the following elements:
        - Internal evaluation by MMP, including review of submitted dossiers
        - Issuing by MMP of request(s) for clarifications to MA holders / suppliers
        - Engagement with MA holders / suppliers in relation to submitted dossiers and clarifications, including meeting with MMP
        - Submission of clarifications by MA holders / suppliers
        - Drafting of final evaluation report by MMP
        - Engagement with MA holders / suppliers of medicinal products that the MMP is minded to recommend as BVB / BVMs, to confirm supply. The MA holder / supplier is required to confirm at this stage that they will have adequate stock available by the end of pre-implementation phase to meet any increased demand arising from the MMP recommendations.
        - Formal submission to CPU by MA holders / suppliers of medicinal products that the MMP is minded to recommend as BVB / BVMs, of final pricing proposal submitted to MMP
        - Finalisation of MMP Evaluation Report and HSE approval in line with governance lines.
    b. The duration of the evaluation process (up to 90 days) encompasses time during which the process rests with the HSE; it will not include any time where the HSE is awaiting receipt of information from MA holders / suppliers; a clock stop will operate during this time. This includes the following actions that are required by MA holders / suppliers:
        - Submission of clarifications to MMP
        - Confirmation of supply to MMP
        - Submission of finalised pricing proposal to MMP.

c. The evaluation phase will conclude when the evaluation report is published on the MMP website. The MMP will notify each MA holder / supplier who participated in the process of the outcome.

12. The pre-implementation phase will commence after the evaluation phase.
    a. The pre-implementation phase will last 60 days.
    b. This phase allows suppliers of the recommended BVB / BVMs to have sufficient lead-in time to ensure there is adequate stock available by the end of pre-implementation phase to meet any increased demand arising from the MMP recommendations.
    c. During this phase, the HSE will consider the suite of measures that are required to support clinical teams in preparing for implementation of the recommended BVB / BVMs. Certain measures may be commenced by the HSE during this phase, e.g. clinical engagement.

13. Implementation of the recommended BVB / BVM processes will commence after the pre-implementation phase, on day 240.
    a. The HSE shall commence measures at this time to support uptake of the recommended BVB / BVMs.

14. The HSE may commence a review process of a BVB / BVM recommendation no earlier than one year after the initial implementation of the initial BVB / BVM evaluation process, referred to in section 13 above.
    a. The review process will follow the same structure as the original BVB medicine evaluation process:
        - Submission phase (90 days)
        - Evaluation phase (up to 90 days)
        - Pre-implementation phase (60 days).
    b. The HSE will issue a notification to each relevant MA holder / supplier at the time of commencement of submission phase of the review process. In addition, the HSE will also inform IPHA at this time.
    c. The criteria that may be considered by the MMP in identifying BVB / BVMs during the review process are outlined in section 14 below.
    d. During the submission phase of the review process, submission of dossiers will be accepted from the following, provided they meet the requirements outlined in section 9 above:
        - MA holder / supplier of a medicinal product that was recommended as a BVB / BVM in the initial BVB / BVM evaluation process
        - MA holder / supplier of a medicinal product who was previously unsuccessful in the initial BVB / BVM evaluation process
        - MA holder / supplier of a medicinal product who was excluded from the initial BVB / BVM evaluation process
        - MA holder / supplier of a medicinal product who did not participate in the initial BVB / BVM evaluation process.

e. Recommendation as a BVB / BVM in the initial BVB / BVM evaluation process does not guarantee continued recommendation as a BVB / BVM after the review process. The MA holder / supplier of a medicinal product that was recommended as a BVB / BVM in the initial BVB / BVM evaluation process is required to submit a dossier during the submission phase of the review process, to determine if they will be recommended as a BVB / BVM in the review process. A medicinal product recommended as a BVB / BVM in the initial BVB / BVM evaluation process may not be subsequently recommended as a BVB / BVM following the review process.
f. The HSE may decide to commence further review processes when deemed necessary.

15. The following are the criteria that may be considered by the MMP in identifying BVB / BVMs:
    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 are and the 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.

Schedule 3 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[6] (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[7]. 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.

---

[6] 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.

[7] 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

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. Suppliers will aim to submit these applications and/or meaningfully engage with the HSE & NCPE, within 6 months of the granting of Marketing Authorisation. Within the timelines specified in Schedule 4

(or such longer period which may arise if further information is sought from the Company) following receipt of a complete application, 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, or both, under section 59 of the Act of 1970,
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 Executive.

In submitting an application for reimbursement, a Company will propose a price for reimbursement having regard, as applicable, to this Framework Agreement 2026. 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 2026 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 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). It is acknowledged that the processes described below will evolve to accommodate Regulation (EU) 2021/2282 on health technology assessment (HTAR) which has taken effect. Each application's status will be visible on the HSE's online tracker.

1. Applicant companies must submit a notification of intent for products for which pricing and/or reimbursement applications are expected to be made within the following 12-18 months outlining the pertinent information relevant to medicines for which a potential application is likely to be made as per the required form. To enable NCPE consideration of the most appropriate assessment approach for an application and Applicant preparation, Companies will confirm with the HSE/NCPE their intention to seek HSE pricing and reimbursement no later than 3 months prior to submission to the NCPE.

The HSE/NCPE may also approach companies to seek submission of an application for pricing and reimbursement in Ireland and seek a rationale for non-application following Marketing Authorisation.

2. Companies will be enabled to engage with 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 may invite applicants to a focussed pre-submission meeting to establish the data and approaches required for a full Health Technology Assessment (HTA) where deemed necessary.

Regardless of the assessment to be undertaken, the applicant will provide the NCPE with the required materials in a timely manner.

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 marketing authorisation has been granted and pursuant to Regulation (EU) 2021/2282.

5. When a complete application is received by the HSE CPU, the commissioning of assessments by the HSE CPU with the NCPE will happen immediately on application.

6. The NCPE will issue a Rapid Review Assessment report within four weeks of commissioning of the assessment and validating the dossier received.

7. The NCPE will make every effort to complete its assessment of a submitted application within 90 days of validation for all applications (with clock stops). This timeline is not inclusive of periods during which further information is awaited from the applicant as outlined in Schedule 4. The NCPE will aim to achieve this in line with the target decision timelines specified in Schedule 4.

The NCPE will continue to facilitate the NCPE Patient-Organisation Submission process.

8. When the HSE receives an Assessment report it will 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.

9. In instances where a final decision cannot be reached at this point, commercial engagement between the HSE and the Company may be required. These engagements are to be brief with final offers submitted to the HSE promptly.

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

11. 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.

12. The HSE will 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.

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

14. The decision of the HSE Leadership Team will be reached within the relevant timeline specified in Schedule 4 (subject to clock stops) and 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).

15. 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.

16. Where reimbursement is subject to a Managed Access Protocol (MAP), the State will target to complete the development and implementation of MAPs post SLT decision within 90 days. The timelines of such decisions are to be communicated to applicants at decision point and applicants should be engaged with by the HSE and MMP throughout the development process.

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

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

19. 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.

Schedule 4 – Programme of change for pricing and reimbursement

The State is committed to achieving a 180-day review of new medicines and new uses of existing medicines.

This will require a significant change programme which will involve an end to end, outcomes-based review to be conducted in 2026. The State will assess progress and review to identify any potential further requirements between the signing of the Agreement and 1st of October 2026.

Health Technology Assessment and NCPE processes

The NCPE will robustly apply the clock stops agreed between the Parties. To facilitate compliance and the planning of resource allocation, applicants shall now inform the NCPE of their intention to make a submission no less than 3 months prior to doing so. The NCPE will establish the most appropriate assessment for a product. This may be a Rapid Review or, in some cases, a full Health Technology Assessment In either case, the NCPE will advise the applicant of the materials required for the assessment to take place. Where deemed necessary the NCPE may invite the Applicant to a meeting prior to submission.

HSE Drugs Group

In 2026, the focus of the State will be on increasing the capacity of the HSE Drugs so that there is enhanced capacity at Drugs Group level to review significantly more applications. Some of this capacity will be used to address and finalise any applications currently pending a notice of proposal. Enhancement of the Drugs Group will take place in two phases over 2026:

Phase 1 – during H1 2026

a) Increase membership to 23 – 27 members
b) Appoint a vice-chair
c) Will facilitate 16-17 Drugs Group meeting annually (consideration of 84 applications). The aim is to ensure that six months of this additional capacity will be realised in 2026.

Phase 2 – by end of Q4 2026

a) Increase membership to 33 – 37 members
b) Appoint a second vice-chair
c) Will facilitate 31 meetings (consideration of 124 applications) beginning in 2027.

The HSE and IPHA Executive will align their understanding of the medicines at Notice of Proposal stage of those medicines and progress on them be monitored actively throughout 2026.

Minutes of Drugs Group meetings will continue to be published on the HSE website with commercial in confidence information redacted.

Stop clocks

The HSE and applicant companies will apply robust and transparent mutually agreed stop clock procedures for all new applications submitted from 1st January 2026.

During 2026, the HSE will update its online application tracker to capture these stop clocks alongside summary data on clock stops during the NCPE's assessment.

Key Performance Indicators (KPIs)

The HSE and NCPE will monitor and report several KPIs to assess progress towards achieving the stated commitments. These KPIs will be established collaboratively by the State and IPHA. KPIs will be subject to ongoing review as part of the annual review process. Their monitoring shall commence from the 1st of May 2026. Among the KPIs tracked will be:

The following KPIs are the committed targets of the State to 180 days:

a. 270 days by Q4 2027

b. 180 days by Q1 2029

ENDS THIS PAGE IS INTENTIONALLY LEFT BLANK