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.

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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.

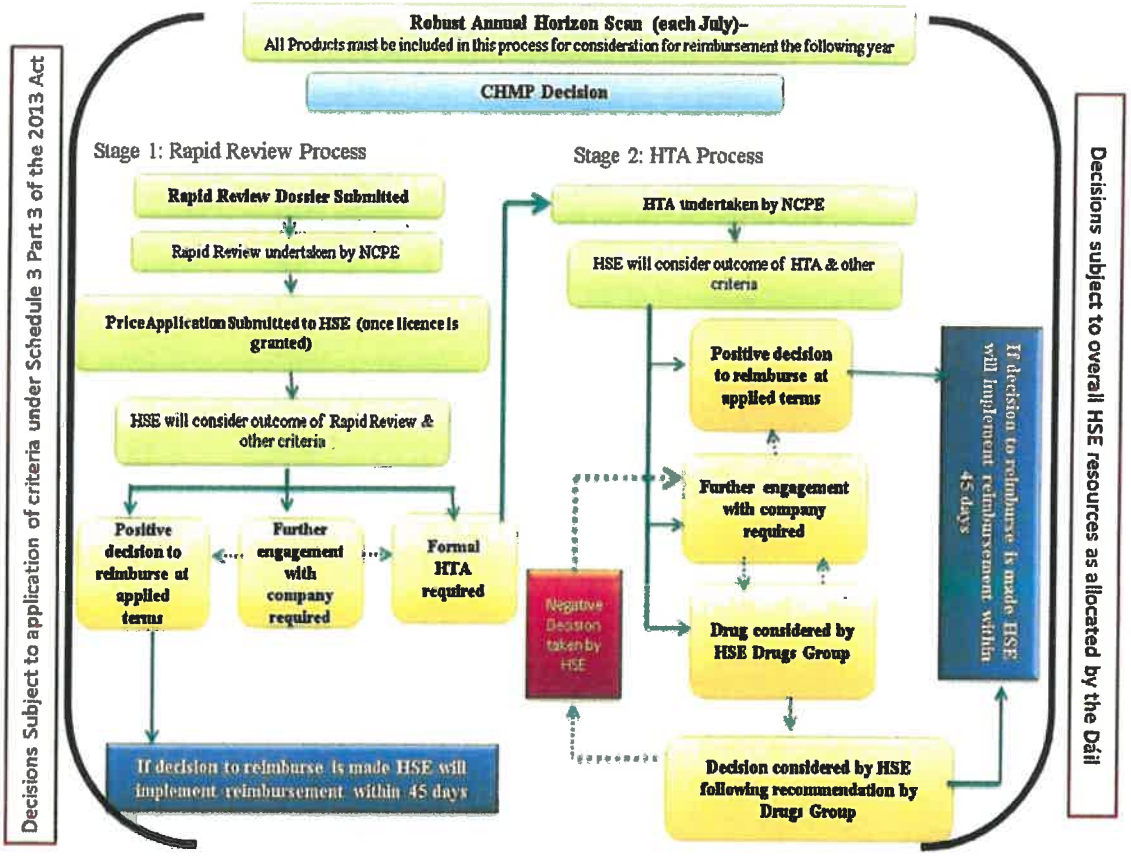
13. The HSE will publish the list of planned dates for Drugs Groups meetings at the outset of each year.

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

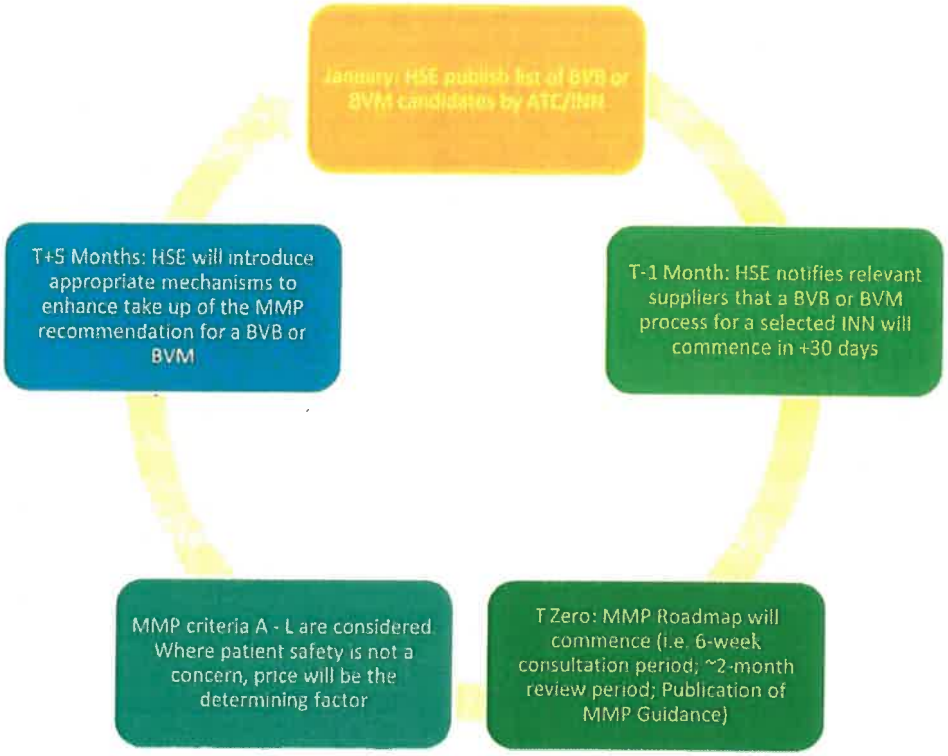
4. A number of Criteria may be considered by the MMP in identifying BVB or BVM medicine(s) including

    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