HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

1. Please provide a bird's-eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

Ireland (the 'state') has both a public and a private healthcare system. The Health Acts 1947 to 2020, as amended, set out the statutory basis for the structure of the national healthcare system. The public health care system is funded by the state through taxation. Private health care is funded by private insurance and private funds. The Department of Health determines health care policy and expenditure. This is implemented by the national health provider, the Health Service Executive (the HSE).

The Irish Government's spending on healthcare in 2022, the last year for which data is available, accounted for 77 per cent of the overall expenditure on healthcare in Ireland that year, with the remaining spending being split almost equally between voluntary health contributions (predominantly private health insurance) and household out-of-pocket payments.

Public healthcare services are delivered by the HSE.

Nearly 47 per cent of Irish residents have private health insurance. The private health insurance market in Ireland is regulated by the Health Insurance Authority (the HIA), while individual insurers are regulated by the Central Bank of Ireland.

In Ireland, the state pays for around 80 per cent of all medicinal products. The ultimate cost to the state of medicinal products dispensed in the community depends on which community medicinal product scheme the patient uses to access the medicinal products.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

The Health (Pricing and Supply of Medical Goods) Act 2013 (the '2013 Act') and the framework agreement between the Irish Pharmaceutical Healthcare Association (IPHA), the Department of Health and the HSE (the 'IPHA Agreement') are the primary documents governing the pricing of medicinal products in Ireland, produced by originators. There is a similar agreement in place for the generics industry.

Ireland maintains a positive reimbursement list. If a product is not included, the supplier can apply to have it added for reimbursement eligibility. Pricing and reimbursement applications for medicinal products can only be submitted after marketing authorisations are granted.

The HSE is responsible for drug reimbursement. Under the 2013 Act, in reaching its reimbursement decision the HSE must consider a number of factors including but not limited to (1) the cost-effectiveness of meeting health needs by supplying the product concerned instead of an alternative product, (2) the health needs of the public and (3) the resources available to the HSE.

Application and process

Upon receiving a reimbursement application, the National Centre for Pharmacoeconomics (NCPE) will evaluate certain of the criteria set out in Schedule 3, Part 3 of the 2013 Act with the balance being assessed by the HSE. The price proposed by the supplier is set based on the IPHA Agreement using the average, currency-adjusted, ex-factory price of 14 nominated countries, on the date of the application. The NCPE conducts its assessment using its Rapid Review procedure, which typically takes about four weeks. All medicines undergo Rapid Review. For high-cost products or those with significant budget impacts, a more detailed pharmacoeconomic analysis (Health Technology Assessment) will be carried out by the NCPE (which takes approximately 18 weeks with the extension of that time possible when further information is sought from the applicant).

If a medicinal product is deemed not cost-effective, the HSE seeks a recommendation from its Drug Group. During the Drug Group review, the HSE's Corporate Pharmaceutical Unit may engage in commercial discussions with the applicant.

The HSE, generally speaking, will insist that the terms of the IPHA Agreement are followed by most suppliers and therefore the supply of almost all products follows the terms of the IPHA Agreement.

Per the IPHA Agreement, medicinal products undergo an annual price adjustment to match the average ex-factory price of 14 nominated countries, with only downward adjustments allowed. Suppliers must pay the HSE rebates of the ex-factory price, which increase in stages from 5.5 per cent in 2021 to 9 per cent in October 2024. The current statutory wholesale mark-up is 8 per cent for room temperature medicinal products and 12 per cent for those requiring refrigeration.

The 2013 Act mandates that the HSE must provide the applicant with formal notice of its proposed reimbursement decision. Applicants can appeal the HSE's decision to the Irish High Court.

Reference pricing

For certain groups of products under the 2013 Act, the HSE has established a common reimbursement price, known as the 'reference price', for relevant groups of interchangeable medicinal products. If a supplier charges more than the reference price, the patient must pay the difference, as the HSE will only reimburse up to the reference price. The Health Products Regulatory Authority (the HPRA), the competent authority in charge of regulating medicinal products and medical devices in Ireland, draws up the list of groups of interchangeable medicinal products. A decision on an application as to whether a product should be added to the list of interchangeable products should be made no later than 180 days from when the application is received (with the extension of that time possible if further information is sought from the applicant).

3. **What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?**

The HPRA is the competent authority in charge of regulating medicinal products and medical devices in Ireland. The Department of Health sets healthcare policy and manages expenditure, which it implements through the HSE, and is therefore responsible for pricing and reimbursement of medical goods in Ireland, as outlined above.

4. **Has there been a change with healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?**

Government spending on healthcare increased during the Covid-19 pandemic in Ireland, as it did around the world. However, since the pandemic, we are not aware of any change in respect of financing and reimbursement as a direct consequence.

5. **Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?**

Anyone who is ordinarily resident in Ireland (ie, anyone who has been living in Ireland for at least a year or intends to do so) is entitled to access public healthcare services. European Union, European Economic Area and Swiss residents can also access public healthcare services in Ireland free of charge if they have a European Health Insurance Card.

Medical practitioners are free to practice in Ireland once they hold the requisite professional indemnity insurance, are registered with the Irish Medical Council (IMC), and are otherwise entitled to work in Ireland.

Suppliers of medical goods with valid marketing authorisation can gain access to the Irish market by applying for admission onto the positive reimbursement list. This process is discussed in Q2.

HEALTH INSURANCE FINANCING AND COVERAGE

6. **How are health insurance carriers financed? How are premiums determined?**

Private health insurance in Ireland is voluntary and is funded by the premiums paid by customers.

The Irish health insurance market operates on a community rating system instead of a risk rating system. In community rating, premiums are not influenced by an individual's age, gender, or health status. Instead, each insurance plan has a fixed price, and the premium is determined by the level of coverage selected.

However, there are some exceptions: premiums may be lower for individuals aged 18–25, members of group schemes, and pensioners who belong to restricted membership insurers.

7. **How is coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in person medical appointments and telemedicine appointments?**

Per Q1 above, the HIA is the independent regulator for the private health insurance market in Ireland. Additionally, health insurers are regulated by the Central Bank of Ireland for conduct of business rules.

In Ireland, private health insurers must offer open enrolment, lifetime cover and a minimum level of benefits.

Coverage for in-person medical appointments and telemedicine appointments will vary depending on the terms of the specific insurance policy.

HOSPITAL SECTOR

8. **How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?**

There are three categories of hospitals in Ireland:

- HSE hospitals, owned and funded by the HSE.
- Voluntary public hospitals, owned by private bodies but receiving state funding.
- Private hospitals, owned by private bodies and receiving no state funding.

HSE hospitals and voluntary public hospitals are funded through the HSE's budget, allocated by the government on an annual basis.

Private hospitals operate on a pay-as-you-go model, where patients pay per treatment either out of pocket or through their private health insurance. Reimbursement for inpatient and outpatient treatment in private hospitals will vary depending on each individual patient's health insurance policy.

9. **How are the prices of such services determined? How is economic efficiency controlled?**

As of April 2023, there are no hospital charges for public inpatient care or day service care from a patient perspective. If a patient is referred by their general practitioner to a public hospital for diagnostic assessments such as X-rays or laboratory tests, there is no charge if you attend as a public patient.

Where a patient is accessing private healthcare, prices and economic efficiency are controlled by market dynamics.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. **How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?**
This can depend on the type of service being provided. As stated in Q9, if a patient is referred to a public hospital for diagnostic assessments such as X-rays or laboratory tests, there is no charge if you attend as a public patient. For services provided by a patient's general practitioner, generally this works as a pay-as-you-go model. Where a patient has a medical card or a GP visit card, all or some of the services they obtain are paid for by the HSE through the Primary Care Reimbursement Service (the PCRS). Where payment is required, patients pay out of pocket at the point of service. Where a patient has private health insurance, they may be reimbursed for a portion of these costs, depending on their policy.
11. **How are the prices of such services determined? How is economic efficiency controlled?**
In 2023 the Department of Health, the HSE and the Irish Medical Organisation renewed their framework agreement, which sets out the terms under which the general practitioners are reimbursed for the services they provide under the PCRS. Otherwise, the prices of services provided by physicians, therapists, and laboratories outside of hospitals are determined by the market.
PHARMACEUTICALS AND MEDICAL DEVICES
12. **How are pharmaceuticals and medical devices financed and reimbursed?**
Please see Q2.
13. **How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?**
The prices of pharmaceuticals and medical devices are determined pursuant to the 2013 Act, and in some cases, the IPHA Agreement, as detailed in Q2. Economic efficiency is controlled by the HSE, which is empowered to consider the value for money of the products and resources available when making a 'relevant decision' under the 2013 Act.
LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT
14. **Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.**
BUPA Ireland v Health Insurance Authority (No.1) [2006] 4 IR 201 concerned proposed changes to private health insurance and the introduction of a 'Risk Equalisation Scheme', which aimed to balance the financial risk among health insurers to ensure that no single insurer was disproportionately burdened by high-cost patients. Under the scheme the HIA recommended that Bupa make risk-equalisation payments of approximately €35m a year to its leading competitor, VHI, though the Minister for Health decided not to pursue the risk-equalisation measure recommended by the HIA. However, the Court ultimately held that the risk equalisation scheme was a legitimate measure to ensure the provision of services of general economic interest and that the scheme was necessary and proportionate to achieve its objectives. The risk equalisation scheme still operates in Ireland.
RECENT DEVELOPMENTS AND TRENDS

15. **What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes, or trends for healthcare financing and reimbursement and briefly indicate how these may foreseeably affect the medical sector in the near future.**

Orphan medicines

A draft piece of legislation, the Health (Pricing and Supply of Medical Goods) (Amendment) Bill 2021 (the 'Bill'), proposing certain amendments to the 2013 Act was initiated in 2021. The Bill was not enacted before the Irish government elections in late 2024 and so it remains to be seen if this Bill will come back into play once a new government is formed. If enacted, the Bill would:

- define 'orphan medicinal products' for the purposes of the 2013 Act;
- remove threshold incremental cost-effectiveness ratios or similar assessments from reimbursement decisions for orphan drugs; and
- define exhaustive qualitative criteria which must be considered in reimbursement decisions for orphan drugs.

IPHA Agreement

The agreement currently in place between IPHA, the Department of Health and the HSE is due to expire. Preparation for negotiations on a new agreement is in its early stages.

Mazars Review

In February 2023, the Minister for Health from Ireland's previous government published a report prepared by Mazars following their review of the HSE's governance arrangements in the drug reimbursement process. The review highlighted several areas for improvement including:

- transparency;
- communications with, and the availability of, information to patients; and
- the tracking of medicines through the process.

A working group was established between the Department of Health and the HSE to consider and progress the recommendations contained in the report. Following Ireland's general election in November 2024, the recently published programme for government contains a standalone commitment to implementation of the review, by the new administration which took office in January 2025.

More generally, the EU Pharmaceutical Package, published in 2023 and which is making its way through the legislative process, is currently under review by stakeholders and progress will be keenly monitored.