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Ireland

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Abstract

In Ireland, State expenditure on medicines is approximately €2.5 billion *per annum*. For most medicines, other than medicines restricted to hospital or medical specialist use, the only route to State reimbursement is to appear on a positive reimbursement list. Except for cancer drugs, there is a uniform application procedure to have a product added to this reimbursement list. There is currently no distinct approval pathway for rare disease medicines or hi-tech products.

Ireland has an ageing population and, therefore, demand for medicines, and especially medicines for chronic diseases, is increasing. Ireland's population grew by an estimated 3.8% from 2016 to 2019, with the most significant growth in those over age 65.

Over the past decade, the State has reformed the Irish pricing and reimbursement system and introduced a number of measures to reduce healthcare expenditure. In recent years, the State has increased funding for new medicines as a measure to address the long delays in the reimbursement of innovative products. Suppliers are also entering into novel contractual arrangements to add value and demonstrate the cost-effectiveness of their products. Despite these reforms, suppliers still face significant challenges in securing reimbursement of new medicinal products in Ireland, especially hi-tech medicines and medicines for rare 'orphan' diseases.

Market introduction/overview

Ireland has a two-tier healthcare system, comprising the public healthcare system and the private healthcare system. The public healthcare system is funded by the State through taxation and social security contributions. Any person ordinarily resident in Ireland is entitled to receive healthcare through the public healthcare system. The private healthcare system is funded by private insurance and private funds. Private healthcare remains a popular option in Ireland, with around 50% of residents taking out private insurance. While health spending in Ireland *per capita* in 2019 was close to the EU average, public expenditure is below the EU average. Private health insurance spending explains this difference.

In Ireland, healthcare policy and expenditure are determined by the Department of Health, and administered through the Health Service Executive (HSE). The HSE operates a positive reimbursement list (Reimbursement List) and HSE expenditure on medicines in 2021 was approximately €2.5 billion.

Over the past decade, the population of Ireland has increased by over 8% to approximately 5.02 million. The demographic ageing of the population means that demand for medicines, especially medicines for chronic diseases, is increasing. As a result, pharmaceutical

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expenditure is expected to grow, with key drivers for increased spending being hi-tech drugs and new hospital drugs.

The pricing and reimbursement landscape in Ireland has undergone significant change in the past decade. In 2013, new legislation introduced a number of measures to reduce healthcare expenditure, primarily a system of generic substitution and reference pricing. The State also recently entered into a new four-year framework agreement with industry for the supply and pricing of medicines to help contain pharmaceutical costs. The new framework agreement builds on the previous 2016 agreement with industry. Despite the savings provided by these measures, there has been relatively little growth in the HSE budget for new medicines compared to the overall budget for health. In 2021 and 2022, however, the Government did allocate specific funding in the State budget of €50 million and €30 million, respectively, for innovative new medicines. This has assisted suppliers to secure reimbursement for new medicines in certain therapeutic areas; however, there are still significant challenges for new orphan medicines, where no improvement to date has been observed in reimbursement timelines. This is compounded by the fact that there currently is no separate approval process for these products, which are typically deemed cost-ineffective when assessed on standard pharmacoeconomic criteria. The high cost of new innovative drugs and delays in reimbursement are among the key challenges for market access in Ireland.

Pharmaceutical pricing and reimbursement

Regulatory classification

There are two main supply categories of medicinal products in Ireland: (i) prescription-only; and (ii) non-prescription products.

Prescription-only medicines are those that require medical supervision and are available only with a doctor's or dentist's prescription, and dispensed through pharmacies. Prescription-only medicines tend to be dispensed to patients by community pharmacists and are reimbursed by the State.

Non-prescription medicines consist of two classes: (i) pharmacy-only products that are available under the supervision of a pharmacist; and (ii) general sale products that can, with reasonable safety, be sold without the supervision of a pharmacist. In general, non-prescription medicines are not reimbursed by the State; however, certain non-prescription items are reimbursable where a doctor prescribes them.

The Medicinal Products (Control of Placing on the Market) Regulations 2007 (SI 540/2007), as amended, set out the criteria for determining the legal supply status of medicinal products. Generally, new medicines may only be supplied on prescription. After several years of use of the medicine, sufficient information may be available to justify a change in its legal supply status to non-prescription supply by a pharmacist. It may also be possible for medicines previously supplied only by a pharmacist to be supplied on general sale, if appropriate.

Who is/are the payors?

In Ireland, the State pays for nearly 80% of all medicines through reimbursement of community pharmacists. The cost to the State of medicines dispensed in the community depends on the different reimbursement schemes an eligible patient may use. The HSE Primary Care Reimbursement Service (PCRS) operates four principal reimbursement schemes:

- *General Medical Services (GMS) Scheme (commonly known as the 'medical card' scheme)*: a patient receives their approved medicines after paying a €1.50 per item prescription charge

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(up to a maximum charge of €15.00 per family per month) or for a patient aged over 70, the prescription charge is €1.00 per item (up to a maximum charge of €10.00 per person or family per month). The pharmacist receives a dispensing fee. The GMS scheme applies to those who do not have sufficient means to pay for their medicine.

- *Drug Payment Scheme (DPS)*: a patient pays a maximum of €80.00 per month for approved medicines supplied to them and their family. If an interchangeable medicine is supplied, the reference price is used to calculate the monthly cost. The pharmacist receives a dispensing fee. The DPS is not means-tested, and therefore does not depend on a patient's income or other circumstances. Anyone who is ordinarily resident in Ireland can apply.
- *Long-Term Illness (LTI) Scheme*: provides medicines to patients with specific long-term medical conditions, such as diabetes, epilepsy, multiple sclerosis and cystic fibrosis, free of charge. The LTI scheme is not means-tested, and like the DPS, the pharmacist receives a dispensing fee.
- *Hi-Tech Drug Scheme*: a patient receiving expensive medicines required for long-term care either pays the first €80 a month of the cost in accordance with the rules of the DPS, or receives the medicines free of charge, if they hold a medical card under the GMS scheme or the medicine is for a specific condition covered by the LTI scheme. Under the hi-tech scheme, pharmacists receive a patient care fee of €62.03 per patient in the month when an item is dispensed, and €31.02 in the months where no item is dispensed. The non-dispensed patient care fee may only be paid for a maximum of three consecutive months in respect of a particular patient between each dispensing.

Payments to pharmacists are regulated by the Public Services Pay and Pensions Act 2017 (Payments to Community Pharmacy Contractors) Regulations 2019 (SI 639/2019), as amended.

What is the process for securing reimbursement for a new pharmaceutical product?

The HSE is the relevant decision-making body for State reimbursement of medicines in Ireland. For this purpose, the Health (Pricing and Supply of Medical Goods) Act 2013, as amended (2013 Act) requires the HSE to maintain a positive Reimbursement List.

For most medicines, other than medicines restricted to hospital or medical specialist use, the only route to State reimbursement is to appear on the Reimbursement List. Except for cancer drugs, there is a uniform application procedure to have a product listed on the Reimbursement List. Unlike other EU Member States, there is currently no distinct approval pathway for rare disease medicines or hi-tech products.

For a medicinal product to appear on the Reimbursement List, the supplier must make a reimbursement application to the HSE. The HSE is required to make a decision on whether to add the item to the Reimbursement List within 180 days from the date on which it receives the application. In the event that additional information is required from the applicant, the HSE may extend this timeframe for as long as required to determine the application.

The 2013 Act provides that in reaching its decision, the HSE must take into account: (i) Health Technology Assessment (HTA) guidelines published by the Health Information and Quality Authority (HIQA), where the HSE considers these to be relevant; and (ii) the criteria under Schedule 3 of the 2013 Act.

In particular, Part 3 of Schedule 3 requires the HSE to have regard to:

- the health needs of the public;
- the cost-effectiveness of meeting health needs by supplying the item concerned, rather than providing other health services;

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- the availability and suitability of items for supply or reimbursement;
- 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;
- the potential or actual budget impact of the item or listed item;
- the clinical need for the item or listed item;
- the appropriate level of clinical supervision required in relation to the item to ensure patient safety;
- 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
- the resources available to the HSE.

The 2013 Act also provides that the HSE may take into account any pricing and supply framework agreement with the Irish Pharmaceutical Healthcare Association (IPHA). The current framework agreement (2021 Agreement) came into effect on 1 October 2021 and is operative until 30 September 2025.

The 2013 Act, together with the 2021 Agreement, set out the following procedure for assessing reimbursement applications for new medicinal products:

- Upon receipt of a reimbursement application, the HSE commissions the National Centre for Pharmacoeconomics (NCPE) to conduct a cost-effectiveness or pharmacoeconomic analysis of the medicine. Initially, the NCPE (which is a team of clinicians, pharmacists, pharmacologists and statisticians) assesses all medicines in accordance with its 'Rapid Review' procedure. The Rapid Review process takes approximately four weeks and is based on an abbreviated company submission intended to provide a summary of relevant information in relation to the cost-effectiveness of the product.
- For high-cost products and those with significant budget impact, the HSE requests the NCPE to conduct a more in-depth pharmacoeconomic assessment, or HTA. Similarly, the HSE may request a pharmacoeconomic assessment for a product where concerns arise in relation to value for money. The aim of an HTA is to understand the cost-effectiveness of a product in more detail, particularly by comparison to alternative therapies available.
- Generally, the NCPE has preliminary scoping discussions with the applicant before the company prepares a pharmacoeconomic dossier for submission. When assessing an applicant's submission, the NCPE considers the clinical effectiveness and health-related quality-of-life benefits and all relevant costs, including potential savings from reduced healthcare resource use (*e.g.*, hospitalisation), which the new product may provide. The main assessment criterion is the Incremental Cost-Effectiveness Ratio (ICER) of the drug per Quality Adjusted Life Year (QALY).
- Following assessment, the NCPE sends an appraisal report outlining its conclusions and recommendations to the HSE. In the case of cancer drugs, the report is also sent to the National Cancer Control Programme (NCCP) for consideration under the NCCP Therapeutic Review Process. A summary of each report is published on the NCPE website.
- The HSE may, without further assessment, approve the product for reimbursement. Usually, this is the case for drugs that the NCPE considers to be cost-effective, *i.e.*, those that in the NCPE's assessment have an ICER of €45,000 or lower per QALY.
- For products falling outside this criterion, the HSE requests a recommendation from the HSE Drugs Group, which performs an in-depth assessment of the product. As

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part of the Drugs Group review, the HSE's Corporate Pharmaceutical Unit (CPU) may interact and lead any commercial negotiations with the applicant. In the case of orphan products, the Drugs Group may refer the assessment to the Rare Diseases Technology Review Committee (RDTRC) for recommendations. The RDTRC does not consider the cost effectiveness of a product, but rather clinical issues like unmet need. The RDTRC's recommendations are intended to complement, therefore, rather than replace any part of the existing reimbursement process.

- The Drugs Group then provides its recommendation to the HSE senior leadership, which is the delegated decision-making body within the HSE that makes the final decision as to whether to add an item to the Reimbursement List. The HSE senior leadership may take one of three decisions:
  - to add the product to the Reimbursement List at the agreed terms;
  - not to add the product to the Reimbursement List at the agreed terms; or
  - to meet with the applicant to address any issues arising or seek clarifications.

The 2013 Act requires the HSE to provide the applicant with a formal notice of its proposed decision on whether to reimburse. The notice must include a statement setting out the reasons on which the HSE's proposed decision is based and also inform the applicant of its right to make representations in writing to the HSE with respect to the proposal. The HSE must consider any representations made by the applicant, if applicable, prior to adopting a final decision on pricing and reimbursement, which it must notify to the applicant.

According to the 2021 Agreement, where the HSE recommends a drug for reimbursement, but is unable to fund the product from existing resources, it may inform the Department of Health. The Department of Health has discretion to submit a memorandum to the Government to request funding for such product.

Under the 2013 Act, an applicant may appeal the final decision of the HSE to the High Court within 30 days from the date of receiving notice of the relevant decision. The High Court will examine the decision and how it was reached by the HSE to determine if the decision was unconstitutional or illegal. If there are sufficient grounds, the Court may: (i) annul the decision and replace it with a decision that the HSE could have made and that the Court considers appropriate; (ii) refer the matter back to the HSE for further consideration; or (iii) give the HSE such directions as the Court considers appropriate.

In practice, where a drug is not approved following assessment, an applicant will often first engage with the HSE in pricing negotiations to reach an acceptable price or enter into patient access schemes. As there is no explicit process for post-assessment negotiation, this stage lacks structure and set timelines, and often leads to delays in reimbursement.

How is the reimbursement amount set? What methodology is used?

In Ireland, the reimbursement price of drugs included on the Reimbursement List consists of two components: (i) the ex-factory price; and (ii) the wholesale mark-up.

The ex-factory price of a medicine is set under national pricing frameworks, currently the 2021 Agreement, and is underpinned by the 2013 Act. The 2021 Agreement should only strictly apply to IPHA members that are listed in Schedule 3 of the 2021 Agreement. In practice however, most suppliers follow the terms of the 2021 Agreement when seeking reimbursement.

The 2021 Agreement, like its predecessor, sets the ex-factory price at the currency-adjusted average ex-factory price (price to wholesaler) in the UK and 13 EU Member States (namely, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg,

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Portugal, the Netherlands, Spain and Sweden). Medicinal products are subject to an annual price realignment to the average ex-factory price of these 14 reference countries and only downwards price realignments are permitted. Suppliers must pay the HSE rebates in staged increases rising from 5.5% in 2021 to 9% in October 2024 of the ex-factory price.

The 2021 Agreement also provides for a 40% price reduction in the original ex-factory price of a medicinal product (excluding a biologic or hybrid medicine) that has lost patent protection once a competing generic is available on the Irish market. For patent-expired biologics, the 2021 Agreement requires a 62.86% reduction in its ex-factory price as of 31 July 2016 (or if the product loses patent protection after 1 January 2022, a 62.86% reduction in its ex-factory price as of 1 January 2021) once a competing biosimilar enters the market. In addition, suppliers of the biologic must pay the HSE a rebate of 12.5% of the value of the reduced price.

The 2021 Agreement also introduces a new price reduction of 50% of the ex-factory price of a patent expired non-exclusive medicine once a competing hybrid medicine becomes available on the Irish market. A hybrid medicine is a product that, although similar to an innovative reference product, was authorised via the abridged procedure under Article 10(3) of Directive 2001/83/EC, as amended. A hybrid medicine therefore does not satisfy the strict definition of a generic. The new price reduction is mutually exclusive to the price reduction that applies once a generic enters the market and is designed to close a loophole in the 2016 Agreement. The latter did not address hybrid medicines, only generic drug entry onto the Irish market.

The wholesale mark-up for community reimbursement schemes is set out in statutory instruments. The current statutory wholesale mark-up is 8% for room-temperature medicines and 12% for medicines which require refrigeration.

The 2013 Act also introduced a system of reference pricing for generic and brand-named medicines that are deemed interchangeable. The 2013 Act permits pharmacists to substitute lower-cost or generic medicines when a more expensive product is prescribed, provided all the medicinal products fall within the same group of interchangeable products. The Irish Health Products Regulatory Agency (HPRA) decides (on a case-by-case basis) which products are interchangeable and publishes the national list of interchangeable product groups. The 2013 Act specifically excludes biological medicines from being considered interchangeable.

The HSE then establishes a single reimbursement price for each interchangeable group, known as the reference price. A supplier can set the price of a product above the reference price, but the HSE will only reimburse at the reference price.

Under the 2013 Act, the HSE is required to take into account the following criteria when setting the reference price:

- ability of suppliers of the relevant items to meet patient demand;
- value for money provided by the relevant items;
- equivalent relevant prices (if practicably available) of the relevant items in all other EU Member States where one or more than one of the relevant items is marketed;
- relevant prices of therapeutically similar items;
- resources available to the HSE; and
- the terms of any agreement in place (whether entered into before, on or after the commencement of the 2013 Act) between the HSE and any representative body of the suppliers of drugs, medicines or medical or surgical appliances where the agreement relates, whether directly or indirectly, to the price of one or more of those items.

The final criterion above requires the HSE to take into account the terms of the 2021 Agreement and agreements between the HSE and IPHA. It is important to also note the

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penultimate criterion, which specifically states that the 'resources available to the HSE' must be taken into account. Lack of resources has been a factor that has been cited in decisions to not reimburse a number of drugs in the past.

How are drug prices set? What is the relationship between pricing and reimbursement?

A supplier does not need to agree a price for a medicinal product before it is placed on the Irish market if reimbursement will not be sought. However, where the product is to be included in the Reimbursement List, the price of the new medicine is subject to the criteria in the 2013 Act and the 2021 Agreement. That is, the product must be priced at the currency-adjusted average ex-factory price in the 14 reference countries. If the product is not available in all 14 countries on the date the supplier submits its initial reimbursement application to the HSE, the price of the product is calculated as the currency-adjusted average ex-factory price in those reference countries in which the medicine is available. Where the medicinal product is not available in any of the reference countries, the supplier must propose a price. In addition, if the product is subject to an HTA and the supplier submits a lower price in the HTAapplication, the lower price will apply.

Where the proposed price of a medicine means that the product has an ICER exceeding €45,000 per QALY, and is thereby deemed cost-ineffective, the HSE can meet with the supplier to negotiate and try to agree a price. Often, pharmaceutical companies agree a straight rebate or discount, or offer a rebate or discount as part of a patient access scheme or another pricing mechanism, such as a risk-based sharing agreement, to add value and reduce the cost of the product. However, the details of these negotiations are highly confidential and where an agreement is reached between the HSE and the supplier, the outcome is rarely made public. The 2021 Agreement explicitly provides that terms of any commercial in confidence patient access scheme contract, or other bilateral contractual agreement, in place between the HSE and a supplier on or before 31 December 2021 are not superseded by the sales rebate provision in the 2021 Agreement.

For medicinal products deemed interchangeable, suppliers are free to set the price of the product below or above the reference price. In the case of the latter, the HSE will only reimburse at the reference price. The patient must pay the additional cost above the reference price, unless a clinical exemption applies.

Issues that affect pricing

The price of medicinal products in Ireland is driven by a range of factors associated with demographic trends, competition, mandatory substitution, the resources available to the HSE and pharmaceutical policies. These factors are not mutually exclusive.

With an ageing population, the demand for medicines, especially for chronic diseases, is increasing. The 2013 Act introduced a number of measures to reduce the concomitant rise in healthcare expenditure, primarily generic substitution and reference pricing. In practice, this system results in suppliers of interchangeable medicines setting the price of their products at or below the relevant reference price.

Generic, hybrid and biosimilar competition also affects the price of innovator products on the Irish market. Under the 2021 Agreement, the entry onto the market of a generic, hybrid medicine or biosimilar following the expiry of the innovator's patent, results in a significant mandatory cut in the price of the innovative reference product.

Policy issues that affect pricing and reimbursement

In Ireland, State expenditure on medicines was approximately €2.5 billion in 2021. It

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is approximately 14% of the total health budget and represents over 7% of GDP. The long-term expenditure on medicinal products is expected to increase due to factors such as demographic trends and the development of hi-tech drug treatments (which have increased at an average of 11% year-on-year since 2012). The State spent €794 million in 2020 on hi-tech drugs.

Similar to other developed countries, Ireland is experiencing demographic change. In 2019, the percentage of the population who were over 65 was over 14% (up from 12% in 2013). The population of over-65s is expected to double in the next 20 years. Over the past decade, Ireland also has achieved significant improvement in life expectancy. Life expectancy in Ireland is higher than in most other EU countries, having reached 82.8 years in 2019. As Irish patients live longer, they are likely to do so with an increasing burden of chronic disease.

In the context of such an ageing population, demand for medicines, especially for chronic diseases, will increase. Indeed, nearly three in 10 people suffer from a chronic condition in Ireland. As a result, there is likely to be additional pressure on future State funding and supply of medicinal products. This funding challenge is exacerbated by the fact that new innovative medicines are often hi-tech products, which have a high cost attached to them. This is due to the significant research and development costs involved with bringing these innovative medicines to market.

Despite an ageing population, until recently there has been little growth in the public expenditure budget for medicinal products. From 2016 to 2020, the net cost of pharmaceutical services compared to the State's overall health budget remained between 13% and 14%. In 2019, the additional budget for innovative medicines was €10 million (0.4% of the annual pharmaceuticals budget), which the HSE had nearly exhausted after eight weeks. In 2020, no specific funding was allocated for new medicinal products and new indications of existing products. Instead, the HSE was obliged to consider funding each newly-recommended medicine in the context of its limited available resources. For political and policy reasons, this position was untenable, not least because lack of access to novel innovative medicines merely on budgetary grounds meets considerable opposition from industry and patients alike. In the past, such patient opposition led the HSE to fund specific medicines in a number of cases. For example, in 2017 the Government made available additional funding for the cystic fibrosis drugs Orkambi® (INN: lumacaftor/ivacaftor) and Kalydeco® (INN: ivacaftor) following an intense public lobbying campaign.

More recently, the Government funded access to Keytruda® (INN: pembrolizumab) for women affected by the national CervicalCheck controversy, but subsequently expanded access to all clinically suitable women with cervical cancer due to public pressure. Further, in June 2019 the HSE leadership team approved the orphan drug Spinraza® (INN: nusinersen) following a lengthy patient advocacy campaign, despite a negative recommendation by the HSE Drugs Group.

However, the State now seems to recognise the need to adopt a pricing and reimbursement policy that strikes a balance between affordable access to medicines and fostering innovation. In 2021 and 2022, the Government allocated specific funding of €50 million and €30 million, respectively, for innovative new medicines in the State budget. The additional funding has helped reduce the reimbursement timelines for medicines in certain therapeutic areas.

Emerging trends

Biosimilars: Despite the mandatory price cuts in innovative biologics following the entry

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of a biosimilar onto the Irish market, the uptake of biosimilars in Ireland remains low. In 2019, the HSE's Medicines Management Program reviewed the use of TNF-α inhibitors and recommended the use of certain biosimilar versions of Humira® (INN: adalimumab) and Enbrel® (INN: etanercept) as the best-value biological (BVB) medicines. From 1 February 2020, the HSE's policy is that all adult patients commencing treatment with adalimumab or etanercept should be prescribed a BVB medicine and physicians should also consider switching existing patients to a BVB medicine. Currently, the HSE recommends five biosimilar BVB medicines for adalimumab and two biosimilar BVB medicines for etanercept. The HSE intends to expand the BVB scheme to other therapeutic areas, such as colony-stimulating factors and erythropoietin. For example, the HSE has indicated that it may initiate in 2022 a BVB process for biologics such as filgrastim, follitropin alfa, pegfilgrastim and teriparatide.

Reimbursement Delays: Over recent years, there has been a growing trend in reimbursement delays. For example, for 13 new innovative medicines recently reviewed by the HSE, the average waiting time for a reimbursement decision was 1,000 days from the product being granted a marketing authorisation. Generally, delays occur when price negotiations are required between the HSE and pharmaceutical companies, but can also occur after a new medicinal product has received a positive HSE decision that it will be added to the Reimbursement List for affordability reasons. The additional specific funding for new drugs in 2021 and 2022 has assisted with this. The number of medicines reimbursed in 2020 compared to 2021 has increased, with over 20 in 2020 compared to over 50 in 2021. The State also has committed to increasing the number of HSE Drugs Group reimbursement decision-making slots. These are expected to total between 50 and 60 annually, which would represent an increase of between 35% and 62% over 2020. Nonetheless, for the time being, there are still delays in market access for innovative medicinal products in Ireland compared to the 14 reference countries.

Ireland ranks 19th out of 29 European countries for speed of access to new medicines. Another recent survey of 39 countries (27 EU, and 12 non-EU) ranked Ireland 24th for time to availability of medicines. 'Availability' was defined as 'inclusion of a centrally-approved medicine on the public reimbursement list in a country'. Ireland showed an average delay of 541 days from central EU marketing authorisation to local reimbursement; a rate that is four times slower than Germany's.[1] That pace is significantly slower than the standard of 180 days from request to decision that the HSE is obliged to adhere to. The survey also found that only 67 of the 160 drugs surveyed were reimbursed in Ireland.

These delays are leading to ongoing frustration and lobbying from the Irish innovative industry and from patient groups, in particular concerning medicines for rare orphan diseases.

Orphan Products: The reimbursement process is continuing to come under scrutiny in relation to orphan products. In 2017, the marketing authorisation holder for the orphan product Translarna® (INN: atularen) launched the first legal proceedings in the Irish Courts appealing an HSE reimbursement decision. Ultimately, the proceedings were discontinued, and the product subsequently received reimbursement. Also, in 2018, the Oireachtas Joint Committee on Health issued a report on the evaluation of orphan drugs that highlighted the inadequacy of the current reimbursement system and the use of the QALY assessment criterion for orphan products. The Committee recommended considerable change to the evaluation process of orphan drugs and for the Department of Health to commence a review of the 2013 Act to identify potential legislative barriers to the reimbursement of orphan

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drugs and corresponding legislative amendments. Proposed legislation, the Health (Pricing and Supply of Medical Goods) (Amendment) Bill 2018, sought to establish a unique process for assessing orphan drugs for reimbursement in Ireland but the Bill lapsed when the Government was dissolved in January 2020 for a general election. In October 2021, new legislation was proposed, the Health (Pricing and Supply of Medical Goods) (Amendment) Bill 2021. The Bill is currently in the legislative process and seeks to amend the 2013 Act to establish unique criteria for the HSE to consider when assessing orphan drugs in the reimbursement process. Further, the Bill proposes that no ICER or other similar threshold will be considered relevant to the assessment of orphan drugs. Moreover, the HSE will be required to consider the level of certainty provided via risk-sharing commercial agreements with suppliers of orphan products.

Successful market access

Cost and efficacy are the main issues of concern for the HSE. In order to successfully gain market access in Ireland, adherence to the criteria set out in the 2013 Act and the 2021 Agreement is key. The 2021 Agreement provides a good foundation for pharmaceutical companies to follow to ensure that they meet the requirements; however, evidence of good clinical efficacy remains one of the critical success factors. The HSE is increasingly focused on real-world evidence and patient outcomes to demonstrate clinical- and cost-effectiveness. The flexibility of suppliers to enter into novel contractual arrangements is important; in particular, nurse-led support services and medication adherence programmes for chronic diseases to add value, and risk-sharing or performance-based agreements to manage uncertainty as to clinical value and cost-effectiveness of hi-tech and orphan products.

* * *

Endnote

1. EFPIA Patients W.A.I.T. Indicator 2021. Available at: https://efpia.eu/media/636821/efpia-patients-wait-indicator-final.pdf.

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Ms. Gallagher has over 20 years of experience working with companies to bring their products to market. She is regarded as one of Europe's leading crisis management experts and has extensive experience advising FMCG companies on product recall and reputation management across the EU.

Ms. Gallagher's expertise covers drugs and devices with a particular emphasis on biologics and GxP, food and beverages, AGRI, and consumer products. Her practice covers a very wide spectrum, from product licensing to composition, labelling, and marketing. Her clients include large public companies as well as multinationals operating in the life sciences and FMCG sectors across Ireland and the EU.

Ms. Gallagher also represents businesses facing regulatory enforcement action, and she acts as a strategic and public affairs adviser in her specialist areas.

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