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Ireland

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Abstract

In Ireland, State expenditure on medicines is approximately €2.7 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 currently is 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. Population grew by an estimated 3.8% from the last census in 2016 to 2019, with the most significant growth in those over age 65.

In recent years, the State has reformed the Irish pricing and reimbursement system and introduced a number of measures to reduce healthcare expenditure. Suppliers are also entering into novel contractual arrangements to add value and demonstrate the costeffectiveness of their products. Despite these reforms, suppliers 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 40% of residents taking out private insurance. While Ireland spends around one-fifth more on health *per capita* than 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 Children, and administered through the Health Services Executive (HSE). The HSE operates a positive reimbursement list (the 'List of Reimbursable Items') and HSE expenditure on medicines is approximately €2.7 billion *per annum*.

Over the past decade, the population of Ireland has increased by nearly 7% to approximately 4.98 million. The demographic ageing of the population means that demand for medicines, especially medicines for chronic diseases, is increasing. As a result, pharmaceutical 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 recent years. New legislation introduced a number of measures to reduce healthcare expenditure, primarily a system of generic substitution and reference pricing. The State also entered into a four-year framework agreement with industry in 2016 for the supply and pricing of medicines to help contain pharmaceutical costs. This framework agreement has been extended to 31 July 2021, and at the time of writing (July 2021), further negotiations are underway. Despite the savings provided by these measures, there has been relatively little growth in the HSE budget for new medicines. Consequently, suppliers face significant challenges in securing reimbursement of new medicinal products, in particular hi-tech medicines and those for rare orphan diseases. 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. However, even those products that are deemed to be costeffective are facing reimbursement delays due to the lack of overall affordability for the Irish healthcare system. It remains to be seen what effect the COVID-19 pandemic will have on healthcare expenditure for innovative medicines. 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 which 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, but certain nonprescription 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 nonprescription 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 Scheme (GMS) (commonly known as the 'medical card' scheme)*: a patient receives their medicines after paying a €1.50 per item prescription charge (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 €114 per month for 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 Scheme (LTI)*: 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 Scheme*: a patient receives expensive medicines required for long-term care either pays the first €114 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 or the medicine is for a specific condition covered by the LTI. 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).

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 (2013 Act) requires the HSE to maintain a positive 'List of Reimbursable Items' (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 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 guidelines published by the Health Information 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;
- 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 came into effect on 1 August 2016 and is operative, after two extensions, until 31 July 2021 (2016 Agreement). IPHA and the State entered into negotiations on a new framework agreement on 25 June 2021.

The 2013 Act, together with the 2016 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 Health Technology Assessment (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 CostEffectiveness 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 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 part of the Drugs Group review, the HSE's Corporate Pharmacy 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 Medicinal Products/Technology Review Committee for recommendations.

- 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;
  - not to add the product to the Reimbursement List; 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 or not 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 2016 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 thinks 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 2016 Agreement, and is underpinned by the 2013 Act. The 2016 Agreement should only strictly apply to IPHA members that are listed in Schedule 2 of the 2016 Agreement. In practice, however, most suppliers follow the terms of the 2016 Agreement when seeking reimbursement.

The 2016 Agreement sets the ex-factory price at the currency-adjusted average exfactory price (price to wholesaler) in the UK and 13 EU Member States (namely, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, 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 a rebate of 5.5% (1 August 2018–31 July 2020) of the ex-factory price. IPHA has said its member companies would continue to pay the HSE a rebate of 5.5% on medicines for supply to community and hospital services.

The 2016 Agreement also provides for a 50% price reduction in the original ex-factory price of a medicinal product (excluding biologics) that has lost patent protection once a competing

generic is available on the Irish market. For patent-expired biologics, the 2016 Agreement requires a 30% reduction in its ex-factory price 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 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 that 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 2016 Agreement and agreements between the HSE and IPHA. It is important to also note the penultimate criterion which specifically states that the 'resources available to the HSE' must be taken into account. Lack of resources has been a factor which has been cited in decisions to not reimburse a number of drugs in recent times.

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 2016 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 a HTA and the supplier submits a lower price in the HTA application, 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 thereby is deemed to be not cost-effective, 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.

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 and biosimilar competition also affects the price of innovator products on the Irish market. Under the 2016 Agreement, the entry onto the market of a generic or biosimilar following the expiry of the innovator's patent, results in a significant mandatory cut in the price of the innovative product.

Policy issues that affect pricing and reimbursement

In Ireland, State expenditure on medicines was approximately €2.2 billion in 2020. It 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 increased over 70% from 2011–2017).

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). Over the past decade, Ireland also has achieved significant improvement in life expectancy. 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. 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 that 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, there has been little growth in the public expenditure budget for medicinal products in recent years due to the difficult economic climate. In 2019, the additional budget for innovative medicines was €10 million (0.4% of the annual medicines

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 seems untenable, not least because lack of access to novel innovative medicines merely on budgetary grounds will meet considerable patient opposition. Such patient opposition has led to the HSE funding 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. Recently, government allocated an additional €50 million to new medicines in the 2021 State budget.

The State needs to adopt a pricing and reimbursement policy that strikes a balance between affordable access to medicines and fostering innovation. However, it remains to be seen what impact the COVID-19 pandemic will have on healthcare expenditure.

Emerging trends

COVID-19: The pricing and reimbursement of medicinal products in Ireland has undergone significant changes in recent years. The 2013 Act and the 2016 Agreement introduced a number of measures to reduce healthcare expenditure; however, the pricing of drugs and market access remains controversial. The 2016 Agreement has been extended to 31 July 2021 and the new agreement currently under negotiation between the Government and industry is likely to focus on access for new innovative products on the one hand, and on cost and efficacy on the other hand. The pressure on the HSE's resources and expenditure is only likely to be increased by the COVID-19 pandemic.

Biosimilars: Despite the mandatory price cuts in innovative biologics following the entry 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. In 2020, two additional TNF-α inhibitor biosimilars were designated 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. The HSE has indicated it intends to expand the BVB scheme to other therapeutic areas, such as colony-stimulating factors and erythropoietins.

Hi-tech drug reimbursement: The Drugs Group of the HSE continue to recommend additional drugs for reimbursement under the Hi-Tech Scheme. Between July 2020 – March 2021, the Drugs Group recommended the following drugs:

- Tagrisso for 1L EGFR mutation positive non-small cell lung cancer;
- Lynparza for 1L maintenance in BRCAm positive advanced ovarian cancer;
- Prevymis for prophylaxis of CMV infection;
- Rinvoq for rheumatoid arthritis;

- Zejula for ovarian cancer;
- Dupixent for atopic dermatitis in adults;
- Dupixent for atopic dermatitis in adolescent;
- Lenvatinib for hepatocellular carcinoma; and
- Fremanezumab for migraine prophylaxis.

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. Funding arrangements for new drugs in 2021 may assist with this. Nonetheless, for the time being, there are considerable delays in market access for innovative medicinal products in Ireland compared to the 14 reference countries.

Another recent survey of 34 countries (24 EU, and 10 non-EU) ranked Ireland 34th 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 477 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 54 of the 152 drugs surveyed were approved in Ireland.

These delays are leading to increasing frustration and lobbying from the Irish innovative industry and from patient groups. IPHA reported in February 2021 that €30m was released for the reimbursement of 'backlogged' medicines at same time as the industry agreed an extension to the 2016 Framework Agreement.

Orphan products: The reimbursement process has 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 a 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 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. With an ageing population in Ireland and the increase in new innovative hi-tech drugs, the cost pressures for reimbursement mean the HSE is increasingly focused on real world evidence and patient outcomes to demonstrate clinical and cost-effectiveness. Suppliers are also entering into novel contractual arrangements; 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 products. The Irish Government also is seeking greater coordination on access to medicines and has joined two cross-border initiatives, the BeNeLuxa Initiative and the Valleta Declaration, that seek to collaborate on HTAs and price negotiations of new medicines across various EU Member States.

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 2016 Agreement is key. The 2016 Agreement provides a good foundation for pharmaceutical companies to follow to ensure that they meet the requirements, but evidence of good clinical efficacy remains one of the critical success factors. Negotiations were underway at the time of writing (July 2021) on a replacement agreement to the 2016 Agreement, though there was no indication that the established criteria would change.

It remains to be seen what effect COVID-19 will have on healthcare expenditure, but any new pricing and supply framework agreement negotiated between the Irish Government and industry is still likely to focus on access for new innovative products and, in turn, cost and efficacy.

* * *

Endnote

1. EFPIA Patients W.A.I.T. Indicator 2020. Available at: https://www.efpia.eu/media/602652/efpia-patient-wait-indicator-final-250521.pdf.

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