Looking forward

Building the framework for a sustainable generic, biosimilar and value added medicines industry in Ireland

Vision Strategy 2024 - 2029

medicines for ireland
medicines for all

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Chairperson's Foreword

In Ireland, the healthcare system is facing formidable challenges. Access to essential medicines stands as a key cornerstone of public health, ensuring people can attain the treatments they need to lead long, healthy, and fulfilling lives.

Long and growing waiting lists, waiting lists for specialist appointments, overcrowded facilities, and capacity constraints are impeding patient access and risking patient outcomes. These well-documented and widely acknowledged challenges underscore the urgent need for comprehensive reforms to ensure the sustainability and efficacy of Ireland's healthcare system for patients and the State.

Our five-year vison strategy aims to foster a collaborative approach among key healthcare players, to drive value for the State and patients, and implement targeted interventions to overcome existing challenges when it comes to the supply of generic, biosimilar and value added medicines and other health care therapies. Building further recognition of the interconnected nature of healthcare delivery, policy frameworks, and economic considerations will be a core component to achieving this ambition.

The significance of a resilient and sustainable generics, biosimilars and value added medicines industry cannot be understated, particularly given the mounting challenges posed by escalating medicine budgets, demographic shifts towards an ageing population, and the escalating costs linked with managing chronic diseases and long-term care.

According to the Organisation for Economic Co-operation and Development (OECD), Ireland is facing substantial pressures on health expenditure projected up to 2060. As a strategic measure to mitigate the growing healthcare spend, the OECD has recommended increased use of generic medicines, a call our members are well positioned to support and deliver.

In 2024, the Department of Health project that almost €3 billion will be spent on medicines, representing nearly €1 in every €8 spent by the State on healthcare. This includes a €10 million reduction that is expected to be accumulated through a rapid switch to generics and biosimilars. Garnering €10 million in savings will necessitate reforms to optimise value and enhance patient access.

Opportunities for reforming the medicines pricing and reimbursement system promises substantial benefits for patients and the State alike.

A new National Pricing and Supply of Medicines Framework Agreement presents a pivotal opportunity for the Health Service Executive (HSE) and Government to access more affordable generic, biosimilar, and value-added medicines and thereby treat a growing number of Irish patients.

The volume of generic medicines used in Ireland has increased significantly since 2011. Generic medicines now account for 58 per cent of all prescribed medicines compared with just 32 per cent in 2011. However, Ireland remains far short of the European average for generic usage, which is 70 per cent.

Greater penetration of generic, biosimilar and value added medicines offers a pathway to redirect scarce resources within the healthcare system, thereby alleviating strains on capacity and reducing waiting times for critical treatment. With Ireland's current bed-to-population ratio lagging the EU average, the imperative to address the high cost of medicines through sustainable alternatives cannot be overstated.

As we look ahead to the next five years, our Vision Strategy reflects a comprehensive and forward-thinking approach grounded in our core values while embracing emerging opportunities and addressing evolving challenges. Through collaborative efforts, strategic partnerships, and proactive engagement, we aim to advance our mission further and strengthen our position as a trusted leader in the generic and biosimilar sector.

This document is a roadmap outlining the key objectives, initiatives, and strategies that will guide our collective efforts over the next five-year period. Priority areas for the association include improving patient access and affordability, advocating for policy changes to support sustainable supply chains, and implementing practices to enhance environmental protections.

By leveraging our collective expertise, fostering innovation, and staying agile in response to external developments, we are poised to unlock new avenues for growth, enhance patient access to high-quality medicines, and drive sustainable value for our members, stakeholders, and the State. We will align our actions with our mission and values, confident that we can navigate the complexities of the healthcare landscape and continue to make a meaningful difference in patients' lives.

Paul Neill
Medicines for Ireland
Chairperson

CHAPTER ONE

About Medicines for Ireland

Founded in 2016, Medicines for Ireland (MFI) is the established industry voice within the Irish healthcare system, representing the pivotal role and interests of manufacturers and suppliers of generic, biosimilar, and value added medicines.

With MFI members supplying the majority of medicine in Ireland to the HSE and patients directly, we are committed to effecting real change and reforms that guarantee patients have access to the medicines they need at affordable prices.

MFI members form a key part of an efficient supply chain which ensures patients can access the medicines they need in a timely manner. To support the ongoing work of our member companies, we actively engage with Government, the HSE, and the Health Products Regulatory Authority (HPRA) to ensure product safety, quality, and sustainability of supply.

Our industry continues to drive patient access to life-changing and life-saving medicines by bringing competition to the medicines marketplace at molecule level when patents or any data or market exclusivity expire. Expanded competition has proven to reduce market prices, bolster security of medicines supply and motivate originators to drive innovation around new medicines. Medicines for Ireland is also a member of Medicines for Europe.

Key successes for MFI to date include:

Securing a seat at the national policy decision-making table as a recognised and informed voice on transformative patient access to medicines.

Establishing structured channels of engagement on regulation through our Regulatory Affairs Committee and within the European policy environment through our EU Affairs Committee.

Maintaining a consistent flow of medicines into Ireland during the COVID-19 pandemic and managing effective communication on the same to patients, policy makers, and the wider healthcare system.

The introduction of generic and biosimilar medications by our members triggering significant price cuts across a range of molecules and biologics resulting in savings for patients and the State.

Campaigning to revise the Northern Ireland Protocol through the signing of the Windsor Framework, as the former threatened the supply of medicines to Northern Ireland.

Active involvement in the formation and management of the Irish Medicines Verification Office to comply with the EU Falsified Medicines Directive.

Our members:

CLONMEL HEALTHCARE
Consilient Health
Fannin Caring for life
FRESENIUS KABI caring for life
accord
PINEWOOD HEALTHCARE First for Generics
teva
VIATRIS
HEALTHCARE CELLTRION
SANDOZ trading as ROWEX

Our mission and vision

Our vision is that all Irish patients can afford and access the medicines they need to get well, stay well, and live well. As an organisation, our core objective is to improve how Ireland procures and supplies medicines to expand patient access to affordable, lifesaving and life-enhancing treatment.

Medicines for Ireland's overarching mission is to:

Enhance access to high-quality medicines for patients across Ireland at an affordable price.

Safeguard the supply of medicines to Ireland by ensuring supply chains remain secure and reliable.

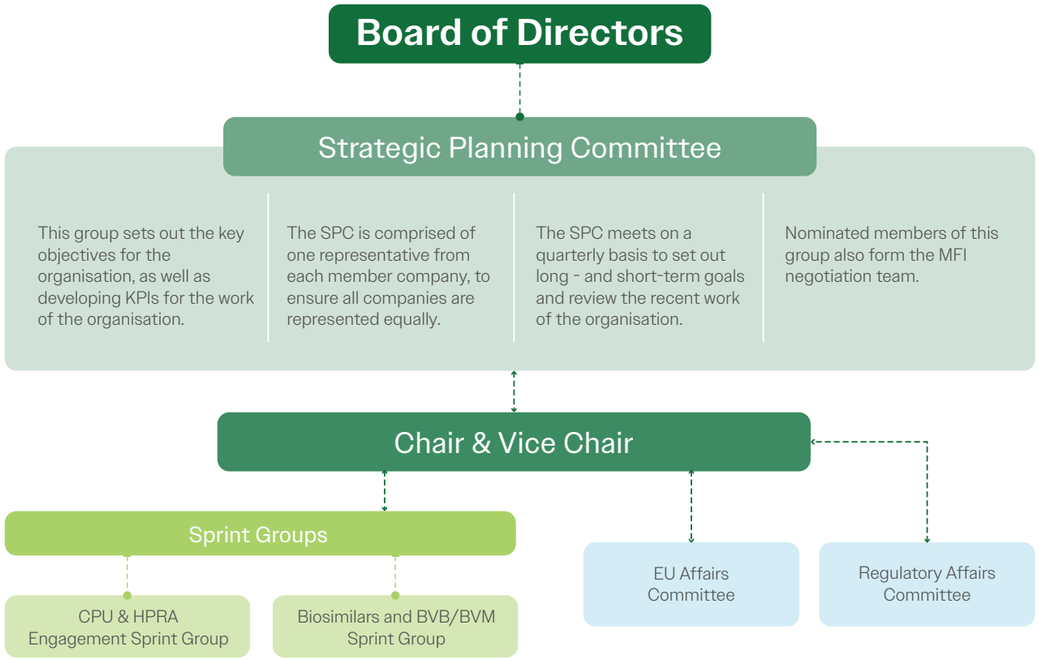
Innovate our approach to developing, supplying, and distributing medicines with the dual objective of delivering better value and greater equality of access nationwide.

Inform key stakeholders of the specific and wider benefits associated with the increased usage of off-patent medicines.

Our ambition is to achieve this mission while upholding the following values:

- Patient-centred care
- Professionalism & expertise
- Ethical standards & integrity
- Value & sustainability

Medicines for Ireland structure



Generic, biosimilar, and value added medicines explained

Generic medicines are comparable substitutes to well-known brand name medicines. They have the same active ingredients as the original medicine and are produced to the same standard to ensure they are as effective as an original. A generic medicine must work the same way in your body and produce the same treatment result as the brand name medicine.

When a pharma company develops a new original medicine, it will take out a patent on that medicine, preventing other manufacturers from producing or selling the same medicine for a set number of years.

When the patent comes to end, other pharma companies can then make a similar version of the original medicine. This is known as a generic and usually costs less than the original branded product, because less investment is required in research, development, and marketing compared to producing an original medicine.

Generic medicines must demonstrate through clinical studies that they are bioequivalent to the original product, ensuring equivalent medical benefits for patients. Where deemed interchangeable by the Health Products Regulatory Authority (HPRA), a pharmacist can substitute a branded medicine with a generic equivalent.

Biosimilar medicines are biological medicines that are highly similar and clinically comparable to an existing biological medicine and are marketed after the expiry of the patent on the originator or reference biologic. The original biological medicine already has marketing authorisation and has been approved for use in patients.

Biological medicines including biosimilar medicines are highly complex, protein-based medicines, made or derived from living organisms typically using recombinant DNA technology.

Typically, biologics including biosimilars, are used to treat long term and complex diseases including cancers, growth disorders and numerous autoimmune diseases. Due to their complexity, biological medicines are considerably more expensive to develop and manufacture than conventional medicines, however the use of biosimilar medicines offers the opportunity for increased access for the patient by creating competition, in turn reducing cost.

In September 2022, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) issued a joint statement confirming that biosimilar medicines approved in the European Union (EU) are interchangeable with their reference medicine or with an equivalent biosimilar. The decision to replace a biologic with a biosimilar is made by the patients physician.

Value Added Medicines (VAMs)[1] including bio-hybrids represent a small but growing segment of medicines, focusing on the evolution of commonly used, well established existing molecules to provide additional benefits to patients, healthcare professionals, and healthcare systems.

In many cases, the goal is to address healthcare or patient needs that are not fully met by the original formulations or uses of these medicines. VAMs can contribute as evolutions of commonly used molecules in the following ways:

Improved efficacy: By altering the formulation, combination, or delivery system of an existing medicine, VAMs can enhance its efficacy. This might involve developing a new formulation that allows for better absorption or developing a medicine in an easier to administer delivery system that reduces resource needs or potential for reconstitution errors.

Increased home administration options: Novel delivery systems for older molecules may in some cases, facilitate treatment in the outpatient or home settings, significantly reducing associated costs and delaying progression to more expensive in-hospital treatments.

Reduced side effects: Modifications to the original molecule or its delivery system can minimise side effects, making the medicine easier to take for patients. For instance, a new delivery mechanism or carrier of a molecule could help the patient target or retain the medicine more precisely to where it's needed in the body or make it easier to apply thus reducing wastage.

Enhanced convenience and adherence: VAMs often focus on making medicines more convenient to use which can improve patient adherence to treatment regimens. This might include creating extended-release versions that require less frequent dosing or developing a combination product that reduces the number of pills a patient needs to take.

Digital health solutions: Incorporating digital technology, such as smart pill dispensers, wearable health monitors, and mobile health apps, into treatment regimens can significantly improve patient adherence and monitoring. These technologies can provide patients and healthcare providers with real-time feedback on treatment effectiveness and patient health status, enabling more personalised and responsive care.

New indications: Through clinical research, previously known molecules can be repurposed for new therapeutic indications. This aspect of VAMs can lead to new treatment options for diseases that previously had limited or no effective therapies or where existing treatments are expensive.

New patient populations: VAMs can fill gaps in healthcare by providing solutions where none existed before or by improving upon the limitations of current treatments. This includes developing formulations that can be used by specific patient groups, such as children or the elderly, who may have different needs than the general population.

VAMs are typically developed in response to market needs and will prolong the use of many well-established molecules in the treatment of a variety of conditions. This may delay the switching of patients to medications that are recommended further down the treatment continuum, potentially enhancing efficacy, and reducing cost.

VAMs can also include drug repurposing, which involves utilising existing molecules that are already approved for one condition to treat other conditions and is becoming increasingly significant in pharmaceutical development and healthcare strategies. Repurposing already approved molecules allows the pharmaceutical industry to explore new therapeutic possibilities and accelerate the availability of treatments for various diseases. This method not only optimises resources but also leverages existing knowledge about drug safety and efficacy, ultimately benefiting patients by providing faster access to effective treatments across a range of medical conditions.

The development of value added medicine is a growing field and can greatly enhance patient care. It is incumbent on health care systems to foster and recognise the value of these medications and fund patient access so that pharmaceutical companies continue to evolve older well-established molecules in medication presentations that meet current needs.

1. A bio-hybrid is a follow-on product to a biological reference product, but in contrast to a biosimilar it may differ in strength, pharmaceutical form, route of administration or immediate packaging

Executive summary

Medicines for Ireland (MFI) has set out an ambitious vision for the generics, biosimilars and value added medicines industry for the next five years. This Vision Strategy provides an overview of the industry, highlighting the growing impact of generic medicines in Ireland and their role in delivering value to patients and the State.

MFI addresses the current challenges in the generic market, such as the escalating medicine budget, demographic shifts, and inflationary pressures on the generics industry. One of the most pressing issues identified by MFI is the complexity of the system in which the industry operates and the impact that has on the shortages of essential medicines. These factors are negatively impacting patient health outcomes and leading to additional burden on certain elements of the supply chain such as pharmacists who are tasked with finding alternative medicines for patients.

As a small island nation on the edge of Europe, MFI highlights the challenges posed by the highly regulated pharmaceutical market in Europe. Policies such as mandatory price discounts and external reference pricing threaten competition and sustainability in the generic medicines market, which has a direct impact on patients' access to medicines.

At the heart of the strategy are three core pillars.

The first focuses on enhancing patient access and affordability. This pillar aims to deliver a resilient framework agreement on the supply and pricing of medicines, establish a sustainable pathway for biosimilar medicines, advance the role of value-added medicines, and influence policy that promotes fair competition and value. MFI is committed to working in collaboration with patient representatives, conducting and publishing research into the impact of shortages and the issues causing them, advocating for dynamic policies that foster competition, conducting and publishing research on options available to enhance the sustainability of the BVB process, and implementing E-PIL across the generics industry to assist with alleviating EU-wide shortages through seamless allocation of medicines across the EU.

The second pillar is securing a sustainable supply chain. This pillar focuses on establishing robustness in the supply chain ecosystem and championing favourable EU pharmaceutical policy. To address the industry's challenges, MFI is dedicated to leading the development of research and engaging with the Department of Health, the Health Service Executive, the Health Protection and Regulatory Agency, and other key stakeholders to enhance supply chain transparency and maintain greater certainty of product supply.

The final pillar focuses on embedding industry sustainability through fostering a balanced approach to environmental practices. Environmental concerns must not overshadow public health benefits, particularly when viewing and debating legislation at a European level. Decisions must be made in light of evidence demonstrating the impact of environmental measures on the availability of medicines for patients. We will continue to advocate for the acceleration of electronic patient information leaflets and streamlining digital communications, which are areas where significant action can be taken to improve environmental sustainability within the industry.

Our Vision Strategy will serve as the roadmap for MFI as it navigates the complex and evolving landscape of the generics industry in Ireland and beyond. It underscores the association's commitment to its mission and values, as well as its dedication to enhancing patient access and affordability, securing a sustainable supply chain, and embedding industry sustainability.

CHAPTER TWO

Industry overview

The growing impact of generic medicines

Generic medicines are crucial in making essential medicines more affordable and creating innovation. When a branded medicine loses patent protection, multiple manufacturers typically introduce generic versions, creating competition that drives prices down significantly as they render the originator non-exclusive, which triggers initial and significant price reductions.

Generics not only affect the market by contributing to its supply, saving costs in budgets, and impacting the macroeconomic sector through employment and investments, but they also benefit patients by improving health outcomes and medication adherence. Moreover, the emergence of generic competition incentivises innovation.

A cornerstone of the robust generics industry in Ireland is its ability to introduce competition into the supply of prescription medicines, rendering them more affordable for the HSE increasing their accessibility to patients.

The Health (Pricing and Supply of Medical Goods) Act 2013, pricing policies for generic medicines have resulted in 45% of the top 100 most expensive General Medical Services (GMS) medicines being subject to generic reference pricing and/or price reductions upon generic entry[2].

Generic medicine usage in Ireland

Generic companies play an essential role in the supply of prescription medicines in Ireland, with eight of the top 10 companies in the total prescription market based on volume of units supplying generic medicines. Six of these are MFI members.

In terms of the volume of prescription medicines, generic medicines are now more commonly used than non-generic or branded medicines in Ireland. In 2023, 68 million units of generic medicines were used compared to 43 million units of non-generic medicines [3].

Based on the most recent data available, the volume of generic medicines used has increased dramatically in recent years, accounting for 58% of all prescribed medicines in 2023 compared with just 32% in 2011[4].

However, there is still further scope to capitalise on the cost savings generics offer patients and the State by expanding market penetration. When reviewing the OECD health statistics for 2021, it is evident that Ireland, while not at the lowest end of the scale, has the opportunity to increase its generic penetration rates across the total pharmaceutical market to align with other European countries. The latest cross-country comparison is for 2021, and in that year, the UK (87%), Germany (83%), and The Netherlands (79%) had the highest rates of generic usage, while the lowest include Switzerland (21%) and Luxembourg (12%)[5].

Influencing factors causing Ireland to lag our European counterparts when it comes to generic medicine penetration include the current reduced price entry point, downward-only pricing structures, and lengthy timelines for price uplifts for unviable products. These factors have an overall impact on the attractiveness of the Irish market for manufacturers and lead to less competition and availability of medicines within the market.

Delivering cost saving benefits to patients

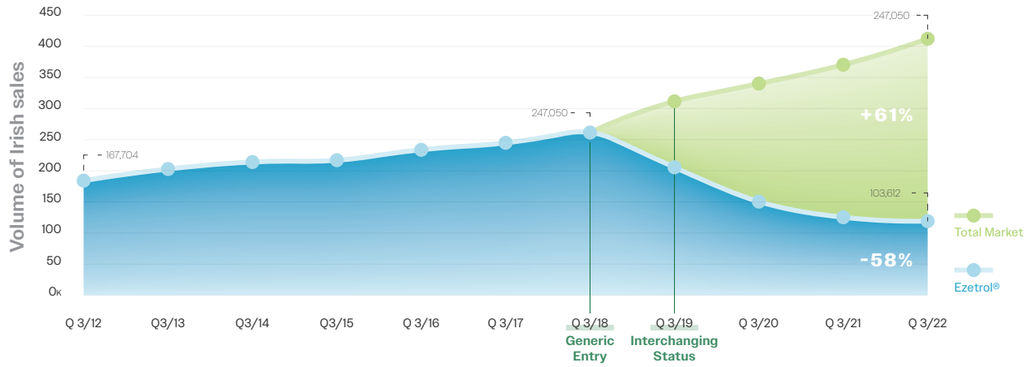
Below are examples of where generic and biosimilar medicines have delivered significant cost savings and market access benefits to Irish patients and the State. Ezetimibe (Ezetrol®), Teriparitide (Forsteo®) and Cinacalcet (Mimpara®).

(Ezetrol®) for hypercholesterolaemia, the total market for ezetimibe increased by 61% from 2018 to 2022, as generic ezetimibe became available, while sales volume for Ezetrol® fell by 58%[6].

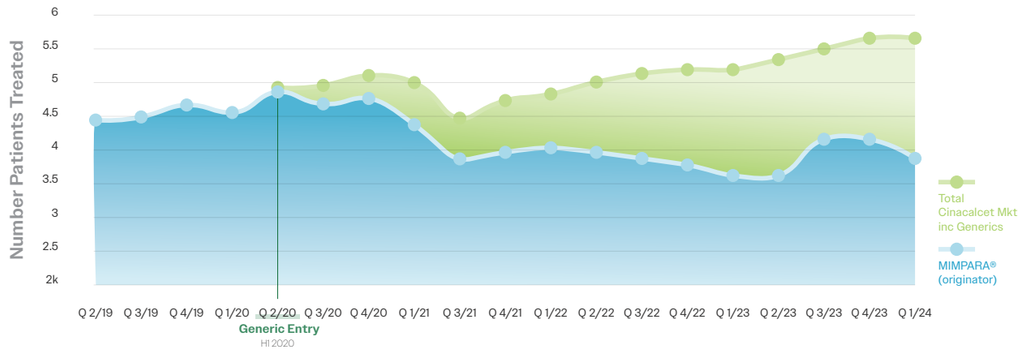
As demonstrated in the second graph below, since Q3 2020, when a generic Cinacalcet became available, the total market has grown significantly with more patients being treated using the generic than Mimpara®.

Finally, while the total Teriparatide market grew somewhat after the biosimilar was introduced in H1 2020, it has expanded considerably since the best value biologic (BVB) process was introduced for this molecule in Q2 2023. This demonstrates a increased patient access once a BVB is initiated[7].

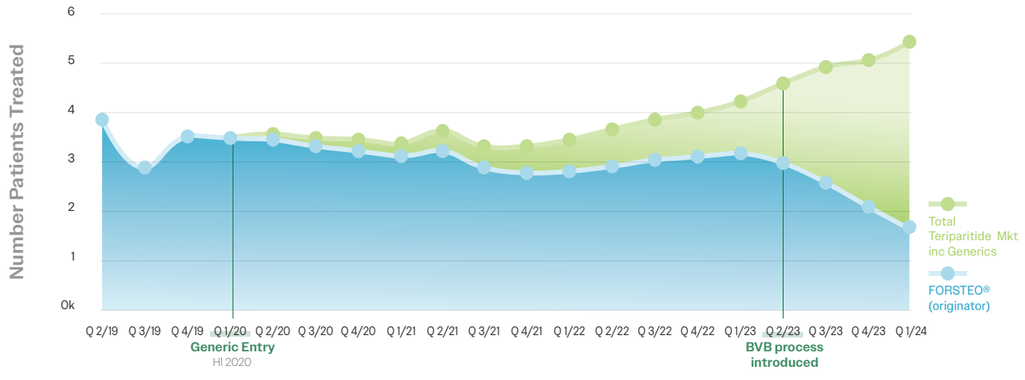
Increased access to generic Ezetimibe



Cinacalcet Mkt by Volume



Teriparatide Mkt Volume



2. Health Service Executive (HSE) The Top 100 Most Commonly prescribed products (2023)
3. IQVIA Sell In Data Mat 12/23
4. IQVIA Sell In Data Mat 12/23
5. OECD Health Statistics 2021
6. IQVIA Ireland. Poss Loss of Exclusivity 2022.
7. IRPL Data 2024

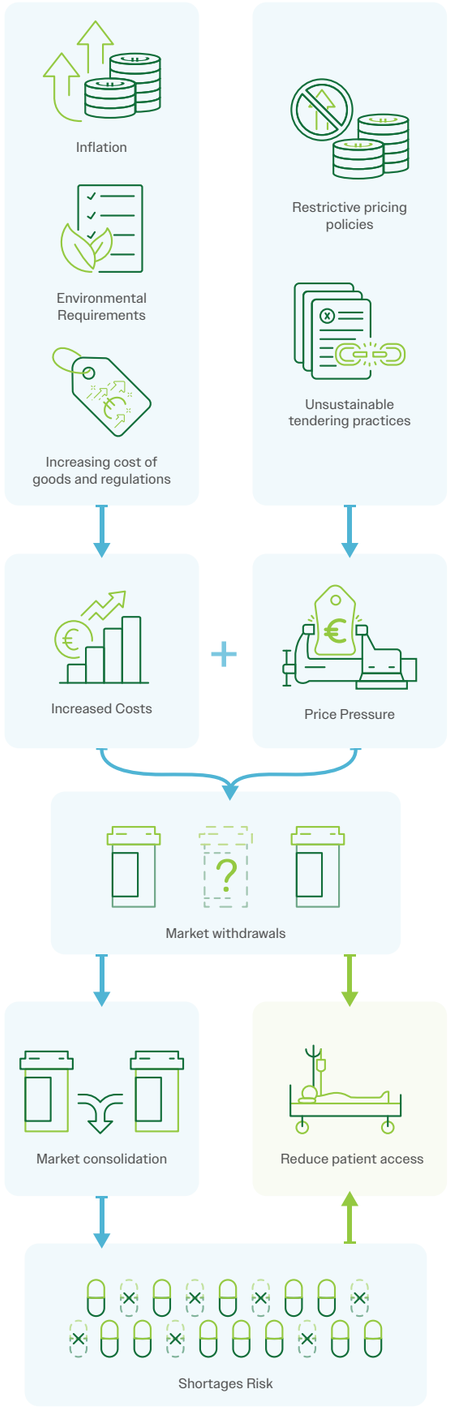
Current generic market challenges

The importance of a robust generics industry cannot be overstated, especially considering the escalating medicine budget, the demographic shift towards an older population, and the rising costs associated with chronic disease management and long-term care. The OECD has identified Ireland as facing significant health expenditure pressures up to 2060 and recommends increased utilisation of generic medicines as a strategy to manage healthcare spending[8]. According to the Parliamentary Budget Office (PBO), the primary expenditure area for Primary Care Reimbursement Service (PCRS) in 2023 is pharmaceuticals, medicines, and appliances, which make up nearly half of the PCRS budget and have seen a 43% rise compared to 2015. In 2023, almost 80% of the budget allocation for care programmes is assigned to the PCRS. The PBO indicates that factors contributing to these expenses, especially for high tech medicines, can be attributed to the higher prices of new medicines and an increase in the number of patients[9].

Recent global events, such as the COVID-19 pandemic and inflationary pressures, have underscored the challenges confronting the generics industry both in Ireland and internationally. One of the most pressing issues is the documented shortage of essential medicines. This situation impacts patient health outcomes and imposes economic burdens on pharmacies and wholesalers tasked with finding alternative sources.

These shortages, signal challenges with the current operational model, especially against a backdrop of rising costs and a reducing pricing model. A comprehensive understanding of the global and local generics medicines environment and its associated challenges is yet to be achieved by all relevant stakeholders in Ireland. This underscores the need for further investigation and strategic planning. Under this Vision Strategy, MFI wishes to develop a greater understanding of these challenges among its key stakeholders through closer engagement with policymakers, regulators, and partners in the supply chain to demonstrate the complexity of the eco-system in which generic manufacturers are operating.

The pharmaceutical market in Europe is highly regulated with governments usually relying on a combination of different policy measures to control the prices of pharmaceuticals. For generic medicines, these policies include mandatory price discounts below the reference product, external reference pricing, maximum capped prices or prices negotiated with authorities. Despite the recommendations from EURIPID 1, (the system that provides countries with data on medicines prices) not to apply this policy to off-patent multisource medicines, 60% of the countries surveyed by Medicines for Europe indicated that external reference pricing (ERP) policies applied to generic medicines. While the main objective of ERP is to keep medicines affordable and accessible for all patients, applying this policy to generic medicines threatens competition and sustainability in the market. Generic medicines already operate in a highly competitive environment, and applying ERP leads to a double price cut for generic medicines, where the price is linked to the originator's medicine. Firstly, ERP applies a price cut to the reference product price, which automatically lowers the linked generic medicine price. ERP is then applied a second time to the already reduced generic medicine price. In some cases, the prices of generic medicines go below what is commercially sustainable for generic pharmaceutical manufacturers, which leads to the withdrawal of medicines. This has been confirmed in the European Commission study on medicine shortages, where it states that 90% of withdrawals are linked to this commercial unattractiveness[10]. This can be deleterious to the generic medicines industry and also for the quality of healthcare, as these artificially low prices might endanger the security and continuity of supply, hampering the access and affordability objectives of healthcare systems in Europe.



Biosimilar use in Ireland

In 2014 the first biosimilar of a complex biologic, IV infliximab, was approved by the EMA and introduced in Ireland. Within ten years more than 80% of infliximab used in Ireland is biosimilar. Since 2016, the HSE Medicines Management Programme (MMP) facilitated the safe and effective integration of subcutaneous biosimilars into clinical practice in Ireland, aiming to ensure prudent prescribing practices while promoting cost efficiency. A biosimilar medicine contains a version of an active substance of a biologic medicine, which is referred to as the "reference medicine" or "originator medicine".

In Ireland, biosimilar medicines are approved by either the European Commission following an evaluation by the EMA or the HPRA. The decision on whether the State should cover new treatments is made by the HSE, based on an assessment by the National Centre for Pharmacoeconomics (NCPE).

The initial launch of a biosimilar brings with it significant savings to the State. Biosimilar medicines are mandated to enter the market at 55% of the innovator biologic medicine. Once a biosimilar is approved for use in the market, it triggers a mandatory discount on the innovator brand. MMP prioritises therapeutic areas / biologics via the best value biologic (BVB) process to facilitate the promotion of biosimilar medicines, ensuring their safe, effective, and cost-effective utilisation. Multiple strategies are then put in place to encourage clinicians to prescribe these identified best-value treatments, contributing to substantial cost savings for the healthcare service.

MFI recognises the significant benefits realised through introducing the BVB process for patients, the State, and the industry, including:

- Competition between originator biological medicines and biosimilar alternatives which offers increased treatment options for patients and clinicians,
- Potential cost savings,
- Expanded access of that biologic / biosimilar for patients and improved value for money for biological treatments.

8. Lorenzoni, L., et al. (2023), "Assessing the future fiscal sustainability of health spending in Ireland", OECD Health Working Papers, No. 161, OECD Publishing, Paris.
9. Health Spending in Ireland 2015 - 2023, Parliamentary Budget Office.
10. European Commission study on Public Procurement of Medicines, 2022

MFI wishes to support the process to see it succeed, but there are challenges caused by the lack of certainty on the application timelines by the HSE, as well as the wider gain share model.

In 2019, concurrent with initiating the BVB programme, the HSE launched a gain share initiative. This initiative aimed to financially motivate public hospitals and clinics to adopt biosimilar treatment switching programmes. Any incentives disbursed under the initiative were allocated to the prescribing department of the respective hospital to be utilised to enhance patient services. While accepted that it was effective, the gainshare initiative is no longer operating.

There is evidence of increased use of biosimilar products that have been approved through the BVB process, however, there is also growing concern across the industry about the level of market penetration and, therefore, the model's sustainability into the future.

MFI members have concerns in cases where the BVB process outcome includes the originator medicine, which has the significant advantage of a long-term pre-existing market monopoly. An assessment at timely intervals after the BVB would be welcomed to ascertain if this acts as a deterrent to biosimilar uptake, with consideration of potential mitigations. MFI would welcome collaboration with MMP / BVB to work on this.

Future potential of value added medicines

Value added medicines (VAMs) are medicines based on known molecules that address healthcare needs and deliver improvements for patients, healthcare professionals and payers. VAMs are usually developed by applying learnings from the in-market user experience with well-established molecules to evolve those molecules so that they better meet the changing needs of the health care system and patients. Typical examples include changing the delivery system of a molecule so that it increases patient adherence or reduces administration error or through repurposing the use of therapies already approved for other diseases to treat new conditions.

VAMs, including drug repurposing, have the potential to improve numerous patient and health care benefits, extending the potential length of time that a well-established molecule can be used to effectively manage a patients specific illness or condition, before second line and potentially less effective / more expensive therapies are required. Despite their potential benefits, the widespread adoption of value added medicines in Ireland faces certain challenges especially around market access.

The current reimbursement model and associated frameworks form the basis of the reimbursement pathways for generic, biosimilar, and innovative medications. Harnessing the benefits of VAMs will require coordinated efforts from relevant stakeholders but especially a recognition by payers that innovation in this sector will require different pathways / funding to facilitate appropriate reimbursement.

MFI is collaborating with policymakers, healthcare professionals, industry stakeholders, and patient advocates to ensure that VAMs can fulfil their promise of improving healthcare outcomes and sustainability in Ireland.

The outlook ahead

In conclusion, the generic, biosimilar, and value added industry in Ireland operates in a complex landscape and is faced with challenges such as the downward-only pricing model, competition for stock in a low-volume market and insufficient evidence of sustainable processes to garner confidence in the BVB process. The absence of substantial independent research in the generics market leads to a general lack of understanding of the impact and value of generic medicines to the State.

These factors pose significant hurdles to the growth and sustainability of the industry; however, amidst these challenges lie opportunities for progress and improvement. Through enhancing patient access and affordability, securing a sustainable supply chain, and embedding industry sustainability, MFI can support the State in improving patient outcomes and position Ireland as a leader in the generic industry across Europe.

CHAPTER THREE

Our core strategic pillars

Pillar 1: Enhancing patient access and affordability

One of the core objectives of MFI is to ensure that all Irish patients can afford and access the medicines they need. In this pillar, we outline our vision and recommendations for several reforms and initiatives that aim to improve the way Ireland procures and supplies medicines, especially non-patent medicines such as generic, biosimilar, and value added medicines. These medicines offer significant benefits for patients, healthcare providers, and the public purse, as they can lower costs, increase competition, and foster innovation.

Deliver a resilient framework agreement on the supply and pricing of medicines

Pricing policies wield a significant influence over the structure of the generic market. These policies can diminish competition, leading to market consolidation and potentially limiting access to essential medicines. This, in turn, can exacerbate health disparities. Measures like enforced price reductions and downward-only pricing policies, when applied to the off-patent market, have driven prices to unsustainable levels, impacting the attractiveness of the local market to pharmaceutical companies.

The existing pricing policies, which focus on continual reductions in medicine prices, have led to market concentration, increasing shortages of essential medications, and widening health disparities. As currently employed, external reference pricing proves inadequate in ensuring competitive pricing within the off-patent market. Moreover, the downward-only pricing policies can significantly undermine the economic viability and sustainability of the pharmaceutical supply chain.

In Ireland, promoting generic substitution and international non-proprietary name (INN) prescribing is primarily achieved through mandatory generic substitution at pharmacies, along with implementing guidelines and educational campaigns. The Health (Pricing and Supply of Medical Goods) Act 2013 puts the obligation on pharmacists to dispense the lowest cost medicine to medical card patients.

In contrast, several other European countries employ various measures to encourage generic prescribing, including financial incentives/restrictions and physician training in INN prescribing which have proven to be most effective in increasing generic usage. Furthermore, countries like the UK and Sweden incentivise pharmacists to encourage generic substitution by providing them with a margin on top of the price of the generic medicine.

MFI's ambition is to strongly advocate for and deliver a new framework approach that introduces resilient and forward-thinking strategies that counteract escalating inflation and effectively address the evolving challenges within the market landscape. A robust, responsive, and agile framework that works for patients, the State and MFI members should be influenced by models that aim to enhance competitiveness in the off-patent market. These include tiered pricing, de-linkage from the originator's price, and automatic indexation.

Tiered pricing will allow marketing authorisation holders (MAH) to adjust prices in response to changing reference price system rules, ensuring flexibility to decrease prices with new market entrants or increase them if competition is limited and supply could be compromised.

De-linkage from the originator price model will prevent the originator from influencing generic competitors' prices to economically unfeasible levels.

Automatic indexation models will offset higher costs resulting from inflation or increased regulatory burden by automatically adjusting prices based on a predetermined index value[11].

11. New pricing models for generic medicines to ensure long-term healthy competitiveness in Europe. Medicines for Europe. 2022.

Establish a sustainable pathway for biosimilar medicines

There are several opportunities to address the barriers and challenges facing biosimilar medicines, such as low uptake, lack of incentives, and regulatory uncertainty. Therefore, MFI proposes the following actions to establish a sustainable pathway for biosimilar medicines in Ireland.

There is a requirement for a fair and transparent pricing mechanism for biosimilar medicines that reflects their value and quality and ensures a suitable position for new biosimilars to launch. Longer-term viability for biosimilar suppliers and more competition in the market can be achieved if consideration is given to the conditions that should be put in place to incentivise the use of multiple biologic medicines in a BVB process. Care needs to be taken by the HSE to ensure that it does not inadvertently create conditions that favour monopoly supply of the originator product, thereby signalling that conditions favourable to biosimilar launches do not exist in Ireland.

MFI and our member companies operating in the biosimilar space will continue to build the required recognition of the BVB model's success by amplifying the increased uptake of biosimilar medicines in Ireland and urging the HSE to give due consideration to expanding this model to other therapeutic areas and by putting in place measures that encourage prescribers to utilise biosimilar medicines. We will also pursue the HSE to provide more detailed clarification around the definition and criteria of a successful BVB result and set out a more transparent and consistent evaluation process based on the 12 criteria outlined in the BVB guidance document.

Finally, we will challenge the HPRA and the HSE to implement faster and more efficient reviews of biosimilar medicines. Our members believe this should be simply implemented as the medicines are already approved by the EMA based on rigorous scientific and clinical assessments. This would significantly reduce the time to market and increase the availability of biosimilar medicines for Irish patients.

We want to achieve a future BVB model that fully delivers on the potential value biosimilars can provide to the State and high-quality care to patients. However, sustained action is required to address those sustainability challenges. MFI and our members are ready and willing to engage proactively to address these challenges.

Advance the role of value added medicines

We believe there is a great need and opportunity to establish a new and streamlined regulatory and reimbursement pathway for value added medicines in Ireland, aligning us with other leading European nations to ensure that our patients and healthcare system remain at the forefront.

There needs to be a shift in perspective when considering VAMs – from one solely focused on cost to an approach centred on providing greater benefits to the patient and health care systems through innovation with existing molecules. Currently there is a well-defined and robust health technology assessment and management process that recognises and reimburses molecule innovation. This should be mirrored by a VAMs reimbursement process that appropriately incentivises innovation with existing medications through pragmatic reimbursement while acknowledging the potential long-term benefits that value added medicines can offer to the State.

MFI believe that the following measures are required to facilitate a positive environment for VAMs benefitting all stakeholders:

- Defining VAMs within future pricing frameworks ensuring that the category of VAMs is captured on all reimbursement application documentation.
- Creating a specific reimbursement pathway for VAMs based on predetermined weighted criteria such as unmet need, disease burden, supply chain robustness, clinician feedback. The current requirements for a standard HTA are a significant barrier to bringing VAMs to market and an alternative process is required to encourage future launches of VAMs.
- Giving a much stronger voice to clinician and patient advocates in the decision-making process, especially those clinicians with experience in the specific therapy area.
- Decoupling pricing from non VAMs with the same active ingredient.
- Establishing the principle of paying a premium for innovation in this area.

Influence policy that promotes fair competition and value

As the generic and pharmaceutical regulation landscape continues to evolve, MFI will continue to proactively and constructively engage with regulatory and reimbursement authorities to advocate for policies that promote fair competition and value for the State, streamline approval processes, and ensure patient safety.

Key areas of focus for the association's regulatory strategy include harmonisation of generic drug approval standards across different jurisdictions, reducing regulatory barriers that impede day one market entry for generic medicines, and advocating for policies that facilitate the development and approval of generics and biosimilars.

Furthermore, MFI will prioritise efforts to address challenges related to intellectual property rights and market exclusivity periods, which can significantly impact the market entry and competitiveness of generic drugs.

We will continue to act as a collaborative partner with stakeholders across the healthcare ecosystem, including government agencies, healthcare providers, patient advocacy groups, and industry partners. Maintaining robust working relationships with our partners will be essential in shaping regulatory and reimbursement policies that support the broader goals of improving access to affordable medications and promoting healthcare sustainability.

MFI will continue to advocate for the introduction of the Electronic Patient Information Leaflet (E-PIL), a crucial measure that could assist with alleviating the issue of EU-wide shortages by facilitating a more seamless allocation of medicines across the EU. By leveraging E-PIL, we can ensure that the generics industry continues to contribute to a healthcare system that mitigates shortages. The implementation of E-PIL enhances accessibility to medicines and streamlines the distribution process.

In addition to advocacy and policy development, MFI will continue to facilitate the smooth two-way flow of information between the HPRA and our members, including education on compliance requirements, updates on regulatory developments, raising concerns about the implications of proposals, and advanced notification around supply chain challenges.

Our overarching commitments & deliverables:

Working in collaboration with patient representatives, conduct and publish research into the impact of shortages and the issues causing them.

Advocate for dynamic policies that foster competition by encouraging balanced price control measures, combined with demand-side policies that incentives the use of generic medicines, benefiting patients' access to affordable, high-quality and essential medicines.

Conduct and publish research on options available to enhance the sustainability of the BVB process.

Publish a position paper on enhancing regulatory pathways for value added medicines.

Implement E-PIL across the generics industry to assist with alleviating EU-wide shortages through seamless allocation of medicines across the EU.

Conduct regular member snapshot surveys to develop a real-time data dashboard that can be utilised in discussions with relevant stakeholders, including the Department of Health, the HPRA, CPU, and the HSE.

Pillar 2: Securing a sustainable supply chain

Establish robustness in the supply chain eco-system

The eco-system in which the pharmaceutical supply chain operates could be further enhanced, creating an enabling environment that addresses issues with the current model, and provides greater access to medicines for patients in Ireland.

The medicines supply chain is global and complex, encompassing numerous stakeholders. These include (but are not limited to) active pharmaceutical ingredient (API) manufacturers, excipient ingredient manufacturers, marketing authorisation holders (MAH's), finished goods manufacturers, packaging material suppliers, logistics and transportation providers, 3rd party warehousing and distribution centres, pharmaceutical wholesalers, pharmacy buying groups, community, and hospital pharmacies.

The Framework Agreement sets the price of generic medicines and that price is not reflective of the acquisition or distribution costs of medicines. There has been significant price erosion for most generic medicines in Ireland since the introduction of the Health (Pricing and Supply of Medical Goods) Act 2013, which has led to low-profit margins.

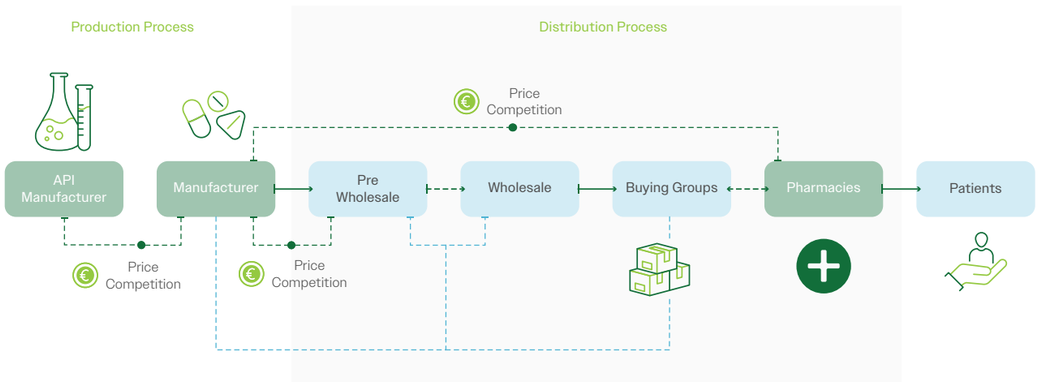
Given that pharmaceutical manufacturers are operating in a global market where large volumes of stock are supplied, Ireland is faced with the difficult challenge of being a small market. Brexit has also had a significant impact on the Irish generic medicines market, leading to disruptions in supply chains and increased regulatory burdens. This, coupled with the additional challenges posed by an inflexible downward-only pricing structure, poses difficulties for the Irish market.

The low prices and small volumes that Ireland offers in comparison to larger markets across the EU can have negative consequences for the availability and continuity of medicines for Irish patients, as well as the sustainability and competitiveness of the Irish pharmaceutical industry. As part of a new framework agreement, we will encourage the HSE to adopt a more flexible and responsive approach to the pricing and procurement of medicines. To achieve this, MFI will foster constructive dialogue and collaboration between the HSE and manufacturers to ensure that Ireland remains an attractive and viable market for them.

Enabling appropriate levels of supply chain transparency will be critical in facilitating proactive measures against shortages. With over 10 billion packs of medicine prescribed annually in the EU, leveraging existing regulatory and supply chain data, like the European Medicines Verification System (EMVS) established under the Falsified Medicines Directive, is essential. MFI will continue to advocate for the appropriate level of resourcing required to deliver effective processes to avoid shortages. To achieve this, we should avoid imposing additional reporting obligations on manufacturers already covered by the EMVS and instead utilise the information already available.

A core element of our activities is addressing barriers facing the generics industry related to environmental impact and resource burden. As such, we are evaluating alternative approaches for HCP communications, including direct healthcare professional communications (DHPCs), caution in use notifications (CIU), and additional risk minimisation measures (ARMMs), and will seek to continue engaging with relevant stakeholders in Ireland and across the EU institutions to improve the current processes.

Example of a medicine supply chain



Abbreviations: API= active pharmaceutical product.

Champion favourable EU pharmaceutical policy

The European Commission's recent proposal to amend the Pharmaceutical Directive and Regulation marks a promising initial stride toward reforming EU pharmaceutical policy to enhance access, availability, and sustainability. Expanding on this proposal, the legislation should incorporate changes that ensure consistent outcomes and provide legal clarity to harness the benefits of off-patent medicines fully.
This can be achieved in a number of ways, including:

- Providing legal certainty for generic and biosimilar medicines by modulating incentives based on public health objectives, leading to earlier competition.
- Removing barriers to entry for off-patent medicines by clarifying the Bolar provision and facilitating administrative processes.
- Rejecting transferable exclusivity vouchers (TEV) for novel antimicrobials, as they increase costs, reduce predictability, and delay access to critical therapies.
- Instead, the EU should explore solidarity-based market models to reward innovation and ensure a secure supply of reserve antibiotics.

The proposal should incorporate a European strategy aimed at preventing medicine shortages and addressing vulnerabilities in the global production chain by enhancing the efficiency and digitalisation of the medicines regulatory network.

MFI fully supports a risk-based strategy for shortage prevention plans (SPP), which would entail establishing a unified list of critical or essential medicines lacking alternatives. This approach would direct the attention of manufacturers and medicine agencies towards preventing and alleviating shortages, averting the generation of countless cumbersome reports and submissions that lack the necessary resources for review and processing.

Medicines for Europe (MFE) has published an economic analysis of the proposed extension of regulatory data protection periods in the new EU pharmaceutical legislation. The extensions could significantly increase healthcare costs by prolonging monopolies for blockbuster drugs, potentially costing between 20 and 100 billion euros[12]. This could impact access to medicines in Ireland, equivalent to the annual salary of hundreds of thousands of healthcare professionals. MFI echoes the MFE position, urging reconsideration to avoid burdening the healthcare system.

The pharmaceutical legislation provides an opportunity to enhance the security of supply in the tender design by including pro-competitive most economically advantageous tender (MEAT) criteria. Proactively embedding the European Commission's ambition to issue EU guidance on procurement and provide concrete proposals on how to better design tenders, such as securing supplier diversity, increasing demand predictability, preventing disproportionate penalties for suppliers, adjusting pricing in justified cases, and introducing MEAT criteria would lead to a significantly improved process.

As the pharmaceutical legislation revision proceeds, it must be complementary and not in conflict with the Medicines Security Act and an EU medicines manufacturing strategy. All of these will play a vital role in securing essential medicine supplies and address issues in the generic medicine market.

Our overarching commitments & deliverables:

- **Host a series of events and publish thought leadership content that focuses on the generics and biosimilars supply chain with a view to educating key partners on the complexities and the industries suggested areas for improvement.**
- **Facilitate partnerships with external experts such as technology providers and research institutions to drive innovation within the industry's supply chain.**
- **Engage with relevant stakeholders to identify how the existing data within the system can be leveraged to enhance supply chain transparency and maintain greater certainty of product supply.**
- **Publish a position paper detailing how EU policy can enhance access, availability, and sustainability of generic and biosimilar medicines in line with Medicines for Europe and the Irish Medicines Verification Organisation (IMVO).**

12. Impact of extending the duration of regulatory data protection in the new EU pharmaceutical legislation. Medicines for Europe, 2024.

Pillar 3: Embedding industry sustainability

Foster a balanced approach to environmental practices

Decisions that are taken, both in Ireland and at a European level, to address environmental issues must also be seen through the lens of the impact they can have on the availability of medicines. Exercises that aim to improve or reduce the environmental impact of manufacturing, particularly in pharmaceuticals, can have ramifications for the supply of medicines to patients. This is particularly the case for the generics and biosimilars market, which already operates on a low-cost model and is facing increasing supply chain costs. MFI will actively engage with the decision-making process on this to ensure the impact it will have on the availability of medicines for patients is fully considered in balance.

The HSE's *Climate Action Strategy 2023 - 2050* is a comprehensive and ambitious strategy that aims to achieve net-zero emissions by 2050 and provide healthcare that is environmentally and socially sustainable. MFI supports the HSE's goals and is committed to embedding industry sustainability in its operations. However, it must be acknowledged the environmental, social, and economic aspects of environmental protection must be balanced with the safety and quality of medicines and services that MFI members provide.

Ensure environmental concerns do not overshadow public health benefits

The significance of pharmaceuticals in safeguarding public health should not be underestimated in policy discussions concerning Pharmaceuticals in the Environment (PiE). Achieving a reduction in environmental pharmaceuticals necessitates a collaborative approach involving both public and private sectors, as well as the consumers they serve. MFI will continue to advocate that any actions taken by the Irish Government or the EU institutions should strive to strike a balance between the economic implications and the benefits to public health. MFI members, along with our colleagues in MFE, support the 2019 European Union Strategic Approach to Pharmaceuticals in the Environment and remains committed to implementing the industry developed Eco-Pharmaco-Stewardship (EPS) framework.

MFI members are proactively participating in research initiatives aimed at addressing the knowledge gaps associated with legacy active pharmaceutical ingredients (APIs), thereby facilitating evidence-based policy decisions on PiE. MFI, through its membership of MFE, are contributing to the iPiE project, a collaboration initiative with the European Commission, is designed to develop models for prioritising legacy products for more comprehensive environmental assessments.

Efforts are also being made to manage effluent from pharmaceutical sites effectively. Given the global uniformity of manufacturing processes, potential environmental losses from manufacturing facilities should be controllable. The industry is in the process of developing initiatives to minimise API discharges from manufacturing operations and encourages companies to share best practices in this regard.

The Eco-Pharmaco-Stewardship (EPS) is anchored by a refined Environmental Risk Assessment (ERA) process that extends beyond the initial marketing authorisation. Currently, MFI members conduct an ERA as part of a new marketing authorisation or when there is an anticipated increase in environmental exposure, such as with the approval of a new indication or the inclusion of a new patient population. The ERA is essential to evaluate the potential environmental risks of medicines and ensure appropriate measures are taken where specific risks are identified.

MFI will advocate for a scientifically driven, risk-based, and efficient environmental risk assessment framework which we believe is required to effectively manage pharmaceutical impact on the environment while ensuring uninterrupted access to essential medicines for patients. While we acknowledge there is an environmental impact of our industry, we strongly advise against altering the risk / benefit principle for pharmaceuticals and emphasise the need for careful consideration to maintain the balance between environmental protection and patient care.

Better utilisation of digital communication

The requirement for individual manufacturers to produce and distribute direct healthcare professional communications (DHCPs), additional risk minimisation measures (ARMM's) and caution in use (CIU) notifications in hard copy comes with a significant financial and environmental cost. We recognise that these communications contain vitally important information for prescribers and patients using our medicines. However, we acknowledge that we are working towards solutions and engaging with the HPRA and HCP bodies to agree on new ways of utilising digital communications and existing HSE infrastructure to reduce our environmental impact

Accelerate adoption of electronic patient information leaflets

MFI will support accelerating the pan-European adoption of electronic patient information leaflets which will empower our members to swiftly adapt to market fluctuations and efficiently distribute products across EU countries. This is crucial for addressing medicine shortages, which predominantly affect individual member states. The COVID-19 pandemic has underscored the importance of solidarity-based medicine allocation across the EU, a lesson repeatedly emphasised by the European Parliament.

Our overarching commitments & deliverables:

Identify potential hazards associated with APIs in development and explore the options to steer the design process in a greener direction; make relevant environmental data on APIs more visible and accessible to all stakeholders.

Publish evidence of the impact of environmental measures on the availability of medicines for patients.

Develop a sustainability charter outlining MFI's environmental commitments.

Work with relevant stakeholders to examine methods to increase the use of digital communications and reduce the environmental impact of printed materials.

Advocate for the accelerated adoption of electronic patient information leaflets and put in place internal mechanisms to support its role out.

CHAPTER FOUR

Measurement and evaluation of impact

The Medicines for Ireland 2024 – 2029 Vision Strategy will act as the basis for the development of annual activity and work plans for the association, which in turn will inform our performance objectives and key deliverables.

Progress against these is measured using a suite of key performance indicators (KPIs) that link the associations strategic pillar priorities to everyday activities. The KPIs are managed by MFI's Chair and Vice-Chair in partnership with the Secretariat and the association's strategic committees and sprint groups. The delivery of MFI priority areas set out in the Vision Strategy will be monitored and supported by MFI's Strategic Planning Committee.

Strategic priority impact assessment

Policy impact	
Goals	Measures
Grow policy advocacy	Track the number of supported initiatives implemented or positively influenced.
Deliver policy adoption	Monitor the number of policy recommendations endorsed by decision-makers or incorporated into regulations and legislation.
Demonstrate policy impact	Conduct regular assessments to evaluate the tangible impact of enacted policies on the targeted issues and assess alignment with MFI objectives.

Stakeholder engagement	
Goals	Measures
Educate stakeholders through increased outreach	Evaluate the frequency and reach of engagement activities with key stakeholders, including policymakers, industry representatives, advocacy, and patient groups.
Foster partnership effectiveness	Review the effectiveness of strategic partnerships by assessing collaboration outcomes, mutual benefits, and shared objectives achieved through joint initiatives.
Build stakeholder perception	Utilise quantitative and qualitative methods to analyse stakeholder perceptions, attitudes and sentiments towards MFI and its initiatives.

Media reach and perception	
Goals	Measures
Increase media penetration and engagement	Track the total number of media impressions generated through press releases, media coverage, interviews, and social media channels. Evaluate audience engagement with media content, including clicks, shares, likes, and comments to gauge the level of interest and interaction generated by communications efforts.
Develop positive media and digital media sentiment	Gauge media coverage to assess frequency, tone and content of coverage relating to MFI activities and initiatives. Conduct sentiment analysis of media coverage and social media mentions to evaluate the overall perception of MFI among key stakeholders.

Review and adaptation

Progress in implementing MFI's Vision Strategy will be reviewed bi-annually in May and again in October by the Chair, Vice-Chair and Strategic Planning Committee when developing MFI's annual work plans. In reviewing the Vision's effectiveness, we will seek feedback from members and stakeholders, and adapt approaches based on evolving policy landscapes and industry dynamics.

We will maintain a flexible and agile approach to the Vision Strategy implementation, allowing us to adapt quickly to changing circumstances and seize opportunities as they arise. By systematically reviewing and adapting our strategy, we will ensure that our organisation remains proactive, agile, and responsive in achieving our mission of enhancing patient access to affordable medications.

The full impact of this Vision strategy will be reviewed in October 2029.

Conclusion summary

As we navigate the formidable challenges facing Ireland's healthcare system, Medicines for Ireland remains steadfast in its commitment to ensuring access to essential medicines. Our five-year Vision Strategy is a testament to this commitment, outlining a collaborative approach aimed at driving value for the State and patients and implementing targeted interventions to enhance patient access and affordability, secure a sustainable supply chain, and embed industry sustainability.

Recognising the interconnected nature of healthcare delivery, policy frameworks, and economic considerations, we are dedicated to fostering a resilient and sustainable generics, biosimilars, and value-added medicines industry. This is particularly crucial given the escalating medicine budgets, demographic shifts towards an ageing population, and the rising costs linked with managing chronic diseases and long-term care.

In line with the OECD's recommendations, we are well-positioned to support and deliver an increased use of generic medicines. This is a strategic measure to mitigate the growing healthcare spending, which is projected to face substantial pressures until 2060.

With the Department of Health projecting that almost €3 billion will be spent on medicines in 2024, our strategy aims to optimise value and enhance patient access, thereby contributing to significant benefits for the State. The new National Pricing and Supply of Medicines Framework Agreement presents a pivotal opportunity for the HSE and Government to access more affordable generic, biosimilar, and value-added medicines.

While the volume of generic medicines used in Ireland has increased significantly since 2011, there is still room for growth. Greater penetration of generic, biosimilar, and value-added medicines offers a pathway to redirect scarce resources within the healthcare system, alleviate strains on capacity, and reduce waiting times for critical treatment.

As we move forward, we will continue to engage closely with the Department of Health, HSE, HPRA, and other supply chain partners to develop a greater understanding of the challenges facing the generics industry among our key stakeholders and demonstrate the complexity of the ecosystem in which our members operate.

Our Vision Strategy reflects a comprehensive and forward-thinking approach grounded in our core values. Through collaborative efforts, strategic partnerships, and proactive engagement, we aim to advance our mission further and strengthen our position as a trusted leader in the generic and biosimilar sector.

Acknowledgements

MFI would like to acknowledge the significant contributions made by various parties, including our member companies, Medicines for Europe, Salutem Insights, and Instinctif Partners, to the drafting of this Vision Strategy.

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