medicines for ireland

Ireland's Patients First

2020–2022

Published August 2020

Executive Summary

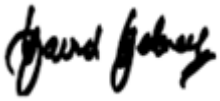
As the supplier of the majority of medicines in Ireland to both the HSE and to patients directly, Medicines for Ireland members are a critical and central stakeholder in the Irish health service.

Working with Government, patients and health professionals, Medicines for Ireland can help deliver further sustainable value for the medicines budget whilst increasing patient access to everyday medicines, from cardiac care to cancer and everything in between. Circulatory diseases and cancer remain the two leading causes of death in Ireland and it has been shown that increased access to medicines and treatment in these areas are leading to better patient outcomes in Ireland.

Since 2013, the use of generic medicines and biosimilars have provided savings of €1.6bn to the Irish state. There is further potential to save much more and the members of Medicines for Ireland will continue to work with Government on behalf of patients and their families to ensure a sustained supply for patients in Ireland.

The National Pricing and Supply of Medicines Agreement with industry was due to expire on 31 July 2020, however it has been extended for a further six months by agreement. The process of negotiating a new National Medicine Supply and Pricing Agreement needs to include all industry stakeholders. Negotiations should be inclusive, a partnership between industry, Government, health professionals and patients. As the supplier of the majority of medicines in Ireland, Medicines for Ireland (MFI) is central to an optimal outcome of these negotiations for a new National Medicines Supply and Pricing Agreement. MFI members are at the forefront of national efforts to ensure that patients continue to access medicines despite the multitude of challenges that the Covid-19 pandemic introduced to the global medicine supply chain. The measures set out in this document will result in increased patient access to cost effective everyday medicines in Ireland.

This report covers four areas, Patient Access, Biosimilars, Generics and Sustainability. The recommendations contained in this report, if implemented, have the potential to save the state **€1bn over the next five years.** These projections are on the conservative end of the spectrum and further savings are achievable if there are higher targets set for uptake in generics and biosimilar medicines.



David Delaney
Chairperson, Medicines for Ireland

"Since 2013, the use of generic medicines and biosimilars have provided savings of €1.6bn to the Irish state"

Ireland's Healthcare System

Challenges and Opportunities

The challenges facing the healthcare system in Ireland are well understood. The healthcare system is under pressure with long delays for specialist appointments and elective surgery, overcrowding and capacity constraints, all of which impact significantly on patient access and patient outcomes. Covid-19 has made these challenges even greater.

It is recognised in the Sláintecare Report of 2017 that reforms are needed to cope with existing demand and expected changes in demographics and patient care. Life expectancy in Ireland has increased nearly six years since 2000. There will be growing demands on the healthcare system, as the proportion of people in Ireland aged over 65 is expected to double by 2050. Around 50% of people aged 65 and over have at least one chronic disease or disability. Therefore, policy decisions now must reflect the challenges that are coming down the track in terms of funding for medicines and treatments.

> *"Around 50% of people aged 65 and over have at least one chronic disease or disability"*

"The total amount spent by the HSE on medicines (€2.2 billion) is the largest single item in the healthcare budget (apart from payroll costs)"

There is immense competition for public resources in Ireland, yet expenditure on health in Ireland is one fifth higher than the EU average. The total amount spent by the HSE on medicines (€2.2 billion) is the largest single item in the healthcare budget (apart from payroll costs) and yet further reforms are needed to deliver better value and greater patient access. There are many untapped areas of reform within the medicine pricing and reimbursement system in Ireland that can deliver further value for patients and the state, and Medicines for Ireland can help deliver these changes quickly. A new National Pricing and Supply of Medicines Agreement is one such opportunity for the HSE and Government to supporting access and affordability of medicines for Irish patients. Targeted measures as set out by MFI will further help increase access and usage of generic and biosimilar medicines in Ireland, helping to bring Ireland closer in line with other EU countries.

The increasingly complex healthcare requirements are also an opportunity for the HSE and the Government to be more innovative and ambitious in terms of increasing the use of generics and biosimilars in Ireland, thereby redirecting scarce resources into other areas of the healthcare system. At present Ireland has approximately 2.9 beds per 1000 of population, compared with an EU average of 5.1, resulting in longer waiting times for inpatient treatment as 95% of all hospital beds are occupied at any given time. Failure to address the high cost of medicines, with more sustainable generic or biosimilar options will ensure that funding constraints remain a millstone around the neck of an already overstretched healthcare system in Ireland.

Former Taoiseach Leo Varadkar (Dáil debates – 15 May 2019)

"I absolutely agree that we need to make better use of biosimilars and that when drugs come off patent, we should be using the generics rather than the branded items."

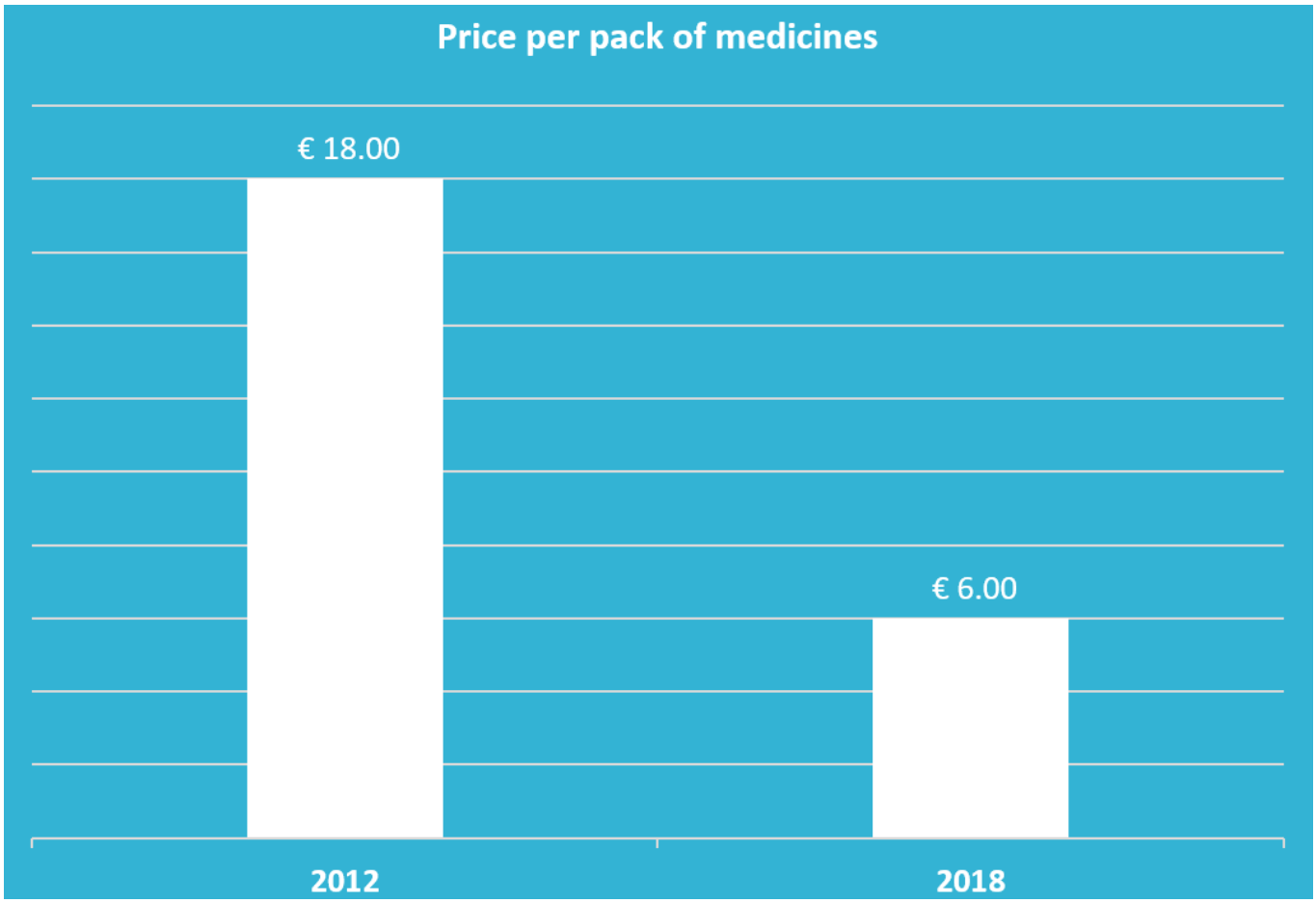
Improved patient access to medicines in Ireland

Medicines for Ireland supports the approach set out in the Sláintecare Report in relation to the management of medicines as it recognises the challenges faced by the health service to secure access to new medicines for patients in a sustainable and affordable way.

Medicines for Ireland and our members work with patient groups, advocacy groups and NGOs to promote greater sustainability within the healthcare system while ensuring ongoing improvements to patient access to medicines.

Like the ten-year vision set out in the Sláintecare Report, a strategic plan is required to ensure greater patient access to medicines and treatment is delivered though the National Pricing and Supply of Medicines Agreement. As the supplier of the majority of medicines in Ireland to both the HSE and to patients directly, Medicines for Ireland is in a position to deliver these reforms and help increase and improve patient access at the same time.

Figure 1: The average wholesale price per pack of medicines has fallen from €18 in 2012 to €6 in 2018



Example – HIV Case Study

In the area of HIV, thanks to the availability of generics in Ireland for the treatment and prevention of HIV, there is greater patient access and support for those at risk from HIV. The role out of the Government's HIV PrEP Programme is working because of the increased availability of generics in Ireland.

Our Recommendation

Sustainability of supply is crucial for patients, their families and the medical professionals supporting them. Medicines for Ireland welcomes Sláintecare and looks forward to partnering in the stakeholder process, while also helping to deliver greater patient access to medicines and treatments.

Why Biosimilars can increase patient access to cost effective everyday medicines in Ireland

Since 2013, the use of generic medicines and biosimilars have provided savings of €1.6bn to the Irish state. While the savings were most associated with reference pricing of generics, changes introduced for biosimilars such as the 'High Tech Ordering and Management System" in March 2018 and the MMP Best-Value Biologic Medicine Initiative have been a success but much more can be done, if a partnership approach is adopted.

Medicines for Ireland believes that the processes in place can be enhanced, in keeping with the principles of procurement as set out by the Department of Health, ensuring that all relevant procurement regulations should be applied so that:

- competition is promoted;
- value for money secured;
- equal access to publicly funded contracts is afforded to all taxpaying suppliers; and
- openness and transparency assured.

As measured against these four principles, there is currently a lack of transparency in relation to the operation of the Hub across several headings:

- the length of time;
- the number of suppliers; and
- the incentives in place.

The incentives in place should remain in operation for a minimum of three years, to support behaviour change and ensure sustainability of medicines supply.

It is recognised by Government, the industry and healthcare professionals that the use of Biosimilar medicines represents a significant cost-saving opportunity for the State, providing more affordable alternatives to costly, comparable biologic medicines, in areas such as osteoporosis, arthritis, colitis, diabetes and cancer. Uptake on biosimilar use in Ireland remains extremely low and therefore policy changes are required to address this.

In an area such as cancer treatment, Medicines for Ireland members are the largest suppliers of anti-cancer treatment in Ireland. Increased uptake of biosimilars has transformed patient treatments and has resulted in more patient access and more timely access.

In parallel with a new National Pricing and Supply of Medicines Agreement, an educational awareness campaign is required to promote the usage of biosimilars in Ireland, similar to that done with generics.

Paul Reid, CEO, Health Service Executive (3 October 2019)

"HSE chief Paul Reid said the hospital consultants were being urged to prescribe biosimilar drugs, which are more cost-effective than branded medicines, where possible".

https://www.independent.ie/irish-news/health/hse-wants-cheaper-medicines-prescribed-in-hospitals-38558201.html

Example – HSE case study

In the years 2016-2018, under various HSE schemes, a total of €1.283bn was spent on high cost branded biological medicines, as opposed to just 1% or €2.28m on biosimilar medicines. In December 2019, as a result of policy modernisation work, biosimilar usage had increased to 16.68%. This growth has continued into 2020. This is in comparison with other EU countries having usage of biosimilars in the range of 80 - 90%.

Savings and Reform

The current penetration rate for biosimilars medicine in Ireland is now above 20%, while the average across other EU countries is in the range of 80 - 90%, illustrating the immense opportunity for further savings in this area. With an annual spend of approximately €800 million by the HSE, moving towards the levels in other EU countries will bring about significant savings. Due to the current low level of biosimilars penetration in Ireland, **savings of €500 million over the next five years** are attainable. An increase in biosimilar usage will lead to savings for the state, more patient access – better security of supply, thereby freeing money up for the funding of frontline services.

Our Recommendation

Medicines for Ireland welcomes the significant policy modernisation work led by Prof. Michael Barry in the Medicines Management Programme. The High Tech Hub and Incentives Scheme are successful and MFI believe that they should be further improved, giving greater transparency to the procurement process, in line with the principles of procurement set down by the Department of Health. These schemes provide flexibility to the Department of Health and the HSE to make changes, disease area by disease area, helping to promote greater stability and sustainability of supply.

Why Generics can increase patient access to cost effective everyday medicines in Ireland

In 2020, the Department of Health's expenditure on health services is projected to be €17.4 billion, a figure that has risen dramatically in recent years. Ireland's spend on healthcare services remains high relative to other countries and per capita is one of the highest in the OECD. The total spend by the HSE on medicines (€2.2 billion) is the largest single item in the healthcare budget (apart from payroll costs) and yet while there has been some progress in Ireland in the use of generics, it is still falling behind countries such as the UK who have almost 90% generics use.

> *Ireland's spend on healthcare services remains high relative to other countries*

International Reference Pricing (IRP) is working well. It is a precise instrument and gives a policy tool to the Department of Health and the HSE to use a targeted approach if necessary. As a policy tool, reference pricing should be enhanced. The average wholesale price per pack of medicines has fallen from €18 in 2012 to €6 by 2018, as illustrated in section 1 (Patient Access).

> *Reforms are needed to address funding challenges to the state*

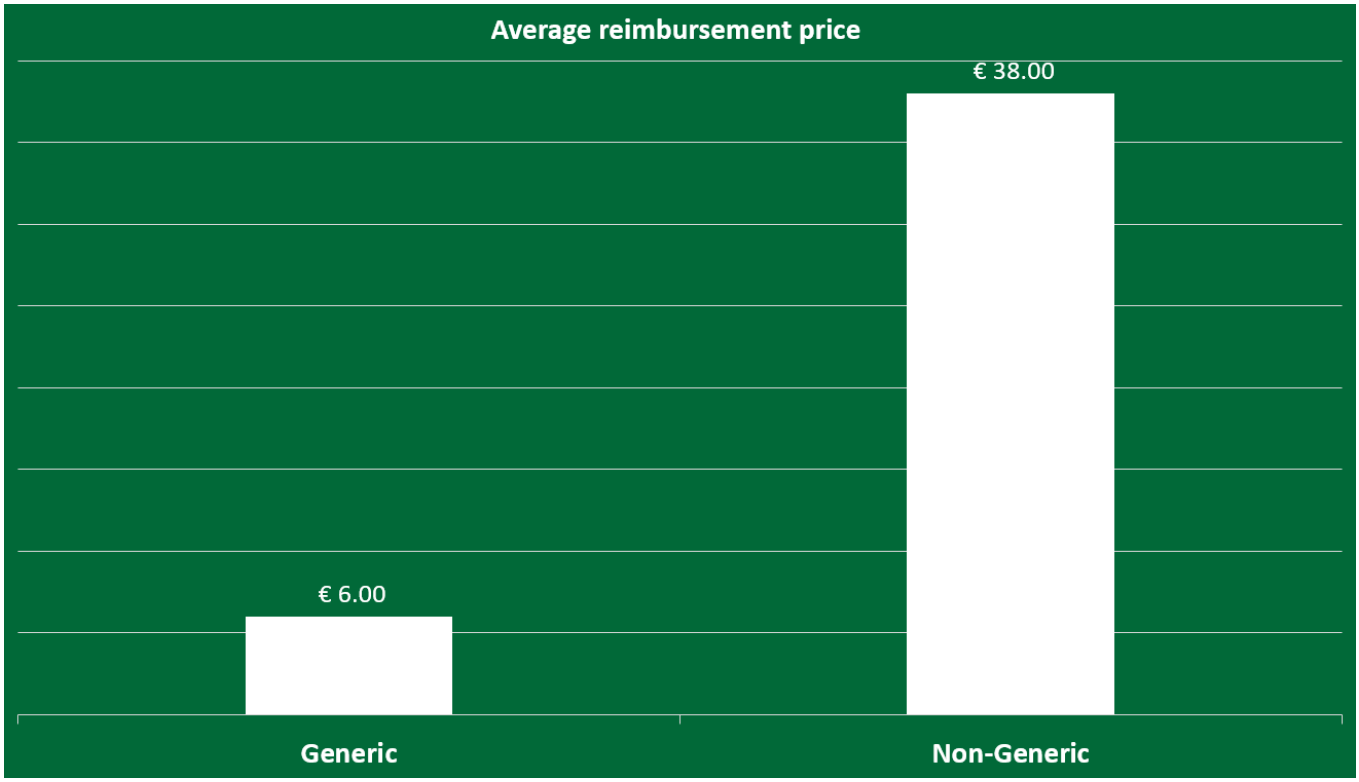
There are many untapped areas of reform within the medicine pricing and reimbursement system in Ireland that can deliver further value for patients and the state, and Medicines for Ireland can help deliver these changes speedily. Ireland is far behind the rest of Europe in terms of take up of generics medicine. The new National Medicines Supply and Pricing Agreement has the potential to help increase that figure to the 80-90% level that exists across other EU member countries. A new agreement can address the significant number of areas that have yet to be reformed and where medicines prices remain higher than necessary and where the opportunity to achieve further savings has been missed. Reforms are needed to tackle funding challenges for the state to address the impacts arising from an ageing population and a higher incidence of chronic diseases.

Where interchangeability works well, more patients benefit. Focus should be on enhancing the processes around interchangeability to ensure greater patient access and thereby helping to improve patient outcomes across the board. An overhaul of the HSEs High-Tech Scheme is required to ensure greater procurement transparency is required. High-tech solid dose medicines must be placed on the Interchangeable List (and thereby open to substitution) immediately following patent expiry.

In 2015, 42 million packs of interchangeable medicines were dispensed to Irish patients. As a consequence of this interchangeability status, generic penetration rose, such that by 2019 Medicines for Ireland members supplied 76% of these products. Importantly, since 2015, while the volume of products dispensed increased by a further 3 million to 45 million per annum, the total cost of supplying these medicines last year actually reduced by 30% (€144m).

In the last 12 months the average reimbursed price of generic medicines was €6 versus non-generic medicines which were €38, illustrating the very significant savings that remain available for the state to avail of.

Figure 2: The average reimbursed price of generic medicines versus non-generic medicines over the last 12 months



Example – Statins case study

The cumulative spend on Ireland's most used medicine, statins, which are used to lower cholesterol, has fallen from €160 million to €36 million per annum as a result of generic medicines.

Savings and Reform

The current penetration rate in Ireland is 73%, well behind the EU average. The use of generics has grown in Ireland over the last decade, however an increase in line with the EU average would lead to savings for the state, more patient access – better security of supply, thereby freeing money up for the funding of frontline services. In the area of generics medicines, last year the state spent €665 million on non-generic medicines that are off-patent. Saving of at least €100 million per annum could be achieved through measures to increase the use of generics. **Over a 5 year period, savings of €500 million are achievable** with modest changes. A more ambitious target however could be achieved to get to the comparable level of generic usage in the UK, which is higher than the EU average, thereby freeing up more funding for the delivery of frontline services within the healthcare system.

Our Recommendation

In order to increase patient access to cost effective everyday medicines in Ireland, Medicines for Ireland believes that targets need to be set to get generic usage in Ireland up to the EU level, through the use of greater interchangeability and price modulation. Coupled with sustainable regulatory costs, the generics sector can help ensure greater stability and access to medicines, while also increasing patient access to medicines and treatments.

Robert Watt, Secretary General, Department of Public Expenditure and Reform (8 May 2019)

"If the HSE overpays for drugs, there is less funding for cancer and disability services."

https://www.independent.ie/irish-news/health/financing-for-cancer-and-disability-services-hit-if-hse-overpays-for-drugs-38094342.html

Sustainability and the supply of medicines

A number of major international and transnational issues are significant factors to be considered in the context of a new National Pricing and Supply of Medicines Agreement. They all have the potential to increase the cost of medicines and therefore pose a significant risk to sustainability and the supply of medicines in Ireland. Since the start of the Covid-19 pandemic, MFI member companies have worked diligently with the Department of Health, the HSE, the HPRA and other stakeholders to protect supply chains into Ireland and to ensure the surge in demand for Covid-19 medicines was met.

Brexit, the Falsified Medicines Directive (FMD), the Pharmaceuticals in the Environment (PiE) Directive, and the risk to supply posed by the Covid-19 are risk factors for the sector. Individually and collectively, they have the potential to reverse some of the great advances of recent years that have led to increased patient access to cost effective everyday medicines in Ireland. They are set out in more detail in Appendix 1.

Our Recommendation

Medicines for Ireland will continue to work in partnership with Government on areas such as Covid-19, Brexit, the Falsified Medicines Directive (FMD) and the Pharmaceuticals in the Environment (PiE) Directive. Medicines for Ireland welcomes greater transparency, a focus on regulatory costs and increased use of the HUB as the cornerstone of a sustainable medicines market in Ireland, helping deliver great patient access to medicines and treatments in Ireland.

Darragh O'Loughlin, Secretary General, Irish Pharmacy Union (8 July 2018)

"Substituting expensive biological medicines with more cost-effective biosimilars would require a legislative change, but could save the Exchequer up to €800m over five years".

https://www.independent.ie/irish-news/health/pharmacists-we-can-save-state-millions-on-biologics-37092190.html

Appendix 1

Brexit

Medicines for Ireland has successfully engaged with Ireland's Department of Health, HPRA, IPU and other stakeholders to ensure consistency of messaging and aligned approach to Brexit. We plan to continue this engagement as the future relationship between the UK and Europe evolves. Our position on the future trade relationship between the EU and UK is based upon the following elements:

- the need for the UK to remain closely interlinked with the EU's regulatory framework for pharmaceuticals (to secure patients' safety / supply / competitiveness etc);
- completing a UK-EU Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP) as soon as possible;
- the MRA on GMP should cover waiving batch and import testing by manufacturers;
- the MRA should not give the UK a competitive advantage in growing its pharma sector;
- the MRA for NI with EU is untenable given the acquis and NI protocol. There must only be a UK-EU MRA; and
- the EU currently has GMP MRAs with many key global partners such as Switzerland and Canada.

Falsified Medicines Directive (FMD)

- The implementation of the Falsified Medicines Directive (FMD) safety feature requirements is a major milestone for patient safety in Europe
- The FMD system, operational as of 9th February 2019, aims to prevent falsified medicines from entering the legal supply chain which brings medicines to patients
- The pharmaceutical industry invested over €1 billion for the new system
- For lower cost, but very essential medicines, it is imperative to engage in dialogue with national governments on how to sustain supplies in the future
- For the generic industry, which supplies over 67% of prescription medicines in Europe, this project was a massive undertaking from a manufacturing, IT and regulatory perspective. Medicines for Europe commends our manufacturers and the associations which have set up the European and national IT hub (EMVO & NMVOs, such as INMVO in Dublin) for their incredible commitment to deliver this project on schedule.

- These costs simply cannot be absorbed for the majority of generic medicines on the EU market. Consequently, Medicines for Ireland calls on national authorities to urgently review with us the sustainability of supplying Europe's essential medicines at very low cost while having to invest in massive regulatory compliance projects like FMD

Pharmaceuticals in the Environment (PiE) Directive

The members of the IAI Pharmaceuticals in the Environment (PiE) Task Force welcome the publication of the European Commission's Strategy on PiE. The Task Force, which includes AESGP, MFI (via Medicines for Europe) and EFPIA, supports the Strategy's holistic lifecycle approach to minimising the impact of pharmaceuticals on the environment and encouraging the stakeholders to lead, including by facilitating exchange of best practices.

Minimising the impact of medicines on the environment while safeguarding access to effective treatments for patients is a critical issue across all sectors of the pharmaceutical industry. It has been the driver behind the creation of the IAI PiE Task Force, the development of the industry EcoPharmaco-Stewardship (EPS) initiative and a number of projects, such as the #Medsdisposal campaign raising awareness regarding the safe disposal of medicines and Innovative Medicines Initiative project.

We broadly support the policy areas that the European Commission puts forward in its strategic approach on pharmaceuticals in the environment, most of which are aligned with the actions that industry has identified to effectively reduce possible environmental risks. We look forward to discussing this with Irish Government stakeholders.

These actions include:

- increasing awareness and promoting the responsible use of human and veterinary pharmaceuticals;
- monitoring the environmental impact through improved Environmental Risk Assessment (eERA); and
- increasing data transparency supporting the environmental risk assessment, improving the collection of unused or expired medicines and supporting continuous research on the topic.

We are supportive of measures to foster research into the feasibility of greener products, and industry has been increasingly developing greener manufacturing methods bearing in mind that the safety and the efficacy of the medicines we produce must remain our primary objective. The publication of the strategic approach to PiE gives the pharmaceutical industry another opportunity to reaffirm its commitment to minimising the impact of medicines on the environment and we look forward to working in partnership with the European Commission and other stakeholders across the areas of work detailed in the Strategy.

Covid-19 - Coronavirus

The World Health Organisation (WHO) declared the coronavirus outbreak to be a global health emergency on 30th January 2020. In the absence of interventions, Covid-19 would have resulted in 7.0 billion infections and 40 million deaths globally this year. The coronavirus disease continues to spread across the world following a trajectory that is difficult to predict. Globally there have been several million confirmed cases of Covid-19, including hundreds of thousands of deaths, reported to the WHO.

“The coronavirus crisis will likely redefine our politics, our geopolitics and possibly globalisation itself. And in this new world Europe will need to stick together through thick and thin”, President of the European Commission Ursula von der Leyen said at the European Parliament in relation to the EU’s coordinated response to the virus and its consequences. To help mitigate the severity of the economic and social impacts of the crisis, the EU Commission have so far announced state aids amounting to €1.8 trillion.

In this context, Medicines for Ireland has worked pro-actively with Government, regulators and key policy makers to ensure round the clock continuity of supply in Ireland. Medicines for Ireland continues to work directly with the Department of Health and the Health Products Regulatory Authority (HPRA) as well as the HSE, EU Commission and all relevant EU institutions to ensure a solution focused approach is taken to secure a stable supply of medicines to the Irish market.

The global Covid-19 outbreak led to an acute shortage of essential supplies, including personal protective equipment, diagnostics, and medicines. During the crisis the EU Commission formally called on the pharmaceutical industry to increase production capacity for all medicines for which there is an increased demand as a result of Covid-19, and in particular for those for which there is a risk of supply shortages.

medicines for ireland

Members are proud to support


Hugh's
house


HIV
Ireland


Peter
McVerry
Trust


St. Francis Hospice Dublin
Dignity | Respect | Compassion


Marymount
University Hospital & Hospice


sexual violence centre cork


snowflakes
autism support


DOGS AID
ANIMAL SANCTUARY


IRISH
OSTEOPOROSIS
SOCIETY


THE Alzheimer
SOCIETY OF IRELAND


Pharmacy Benevolent
Fund


GET INSPIRED WITH ACTIVE RETIRED
Active Retirement
Ireland


AnamCara
Supporting Parents after Bereavement


Irish
Cancer
Society


Special
Olympics
Ireland


TRINITY
YOUTH SERVICES


Cystic
Fibrosis
Ireland


Féileacáin


Cork Simon
Community


MQI
Merchants Quay Ireland

medicines for ireland

Members

Clonmel Healthcare is a subsidiary Company of STADA Arzneimittel AG

Fannin Ltd is a subsidiary company of DCC Vital

Pinewood Healthcare is a subsidiary company of Wockhardt Ltd

Rowa is a subsidiary company of Rowex Pharmaceuticals

Medicines for Ireland is extremely grateful for the support of Medicines for Europe on the publication of this report

medicines for europe
better access. better health.

Delivering to the right place at the right time with quality tailored solutions.

About United Drug

In challenging times, you need suppliers and logistics teams you can really rely on. That's why United Drug promises to deliver the products you need, when you need them, at a fair price.

We're committed to keeping that simple promise, every day. We work with principals, pharmacies and hospitals to shape our services around their requirements. And we get your products to the people who need them – your patients.

Our business began with supply chain services, and we're proud to remain market leaders. Our experience in the healthcare sector and experience in handling specialist products, as well as our position within a leading international healthcare group, makes us a dependable long-term partner for your business.

We pride ourselves on our proactive approach. We know there's always room for improvement and we're constantly thinking ahead and suggesting new ways to add value and improve performance. Above all, we vow to look after your business as if it were our own.

Medicines for Ireland is extremely grateful for the support of its sponsor, United Drug, on the publication of this report

UnitedDrug

Medicines for Ireland
Company Registration Number: IE602169
Company Directors: David Delaney, Mylan (Chairperson); Deirdre Kelly, Consilient Health; Jeffrey Walsh, Pinewood Healthcare