



Medicines for Ireland 2024

Pre-Budget Submission

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Introduction from Chairperson

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EXECUTIVE SUMMARY



In the realm of healthcare, ensuring reliable access to essential medications stands as a cornerstone of effective medical treatment and patient care. Guaranteeing unfettered access to treatments while safeguarding against potential shortages requires strategic coordination, planning and effective communication across the healthcare ecosystem.

In that context, Medicines for Ireland’s main focus is to help Government ensure market conditions in Ireland remain sustainable in order to retain and secure access to reliable and affordable treatment for Irish patients. As a small market, Ireland is more likely to be negatively impacted by inflationary pressure and as costs continue to rise, market conditions will become increasingly unviable for companies supplying generic medicines to Irish hospitals and pharmacies.

There is immense competition for public resources in Ireland. 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 MFI can help deliver these changes quickly. 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.

Based on most recent data available, the volume of generic medicines used in Ireland has increased by 70% since 2012, accounting for 57 per cent of all prescribed medicines compared with just 33 per cent 10 years ago. However, Ireland remains far short of the European average for generic usage, which is 70 per cent.

It is worth noting that MFI welcomes the significant policy modernisation work led by the Medicines Management Programme, particularly the Primary Care Reimbursement Service and the High Tech Hub. Moving forward, MFI would like to see greater policy improvements in line with market developments. Giving increased transparency to the procurement process, in line with the principles of procurement set down by the Department of Health.

A new transformative framework agreement can address the significant number of areas that have yet to be reformed. It is essential that the state maximises generic penetration in the market to realise maximum savings.

Moving forward, MFI have set out 3 key recommendations in this submission, which we believe would help tackle the current risk of medicine shortages.

“MFI would like to see greater policy improvements in line with market developments.”



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Develop a flexible Pricing Mechanism to safeguard against risk of medicine shortages.

MFI are of the view that a pricing mechanism needs to be put in place in order to allow for price increases in line with rising inflationary costs. This change will be key to mitigating the risk of medicines shortages by ensuring more viable market conditions for suppliers of generic, biosimilar and hybrid medicines.



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Establishment of a national medicines reserve

MFI believe serious consideration should be given to the creation of a national medicines reserve in Ireland, given the ongoing risk of shortages.

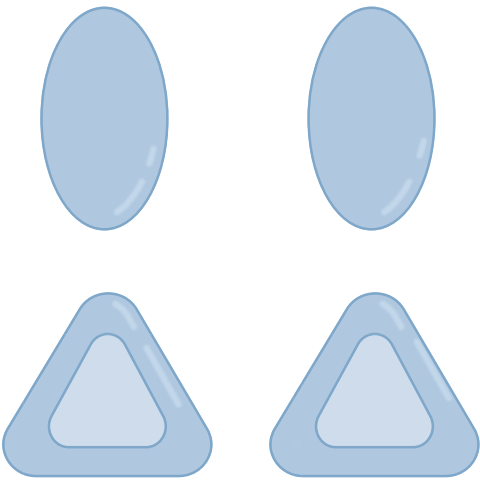


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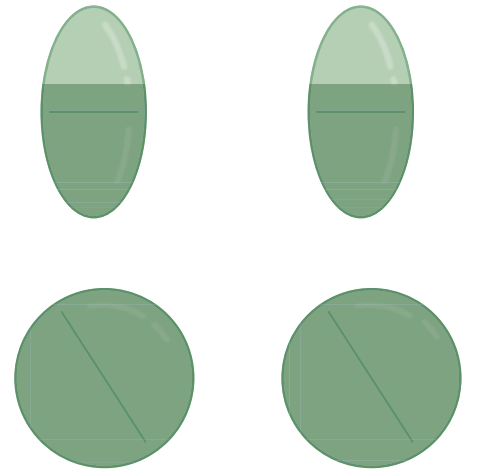
Effective preparatory measures to facilitate implementation of the EU Pharmaceutical Package

The introduction of the EU pharmaceutical package in Ireland is a significant undertaking that demands meticulous preparatory work. Ultimately, this groundwork will position Ireland to navigate the transition smoothly, minimise disruptions, and harness the full potential of the EU pharmaceutical package for the benefit of patients, healthcare professionals, and the pharmaceutical industry.

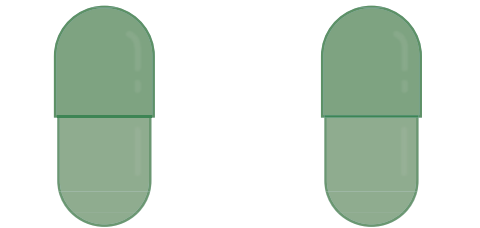
60%
of all medicines used in the State come from MFI member companies.



90%
of member companies think potential medicine shortages will have a negative impact on patient health in Ireland.



90%
of MFI member companies are currently engaging with the HPRA on shortages.



100%
of MFI member companies think potential medicine shortages will affect access to essential treatments for patients with lifetime or long-term illnesses.

100%
MFI member companies expect to see increases in the cost of manufacturing and procurement in the next 12 months.

INTRODUCTION FROM THE CHAIRPERSON



We are at the halfway stage of the current framework agreement on the supply and pricing of medicines. As an industry recognised, solution focused organisation, we look forward to transformative engagement with the HSE and the Government on the next agreement in order to satisfy the needs of patients, Government and industry.

As the supplier of the majority of medicines in Ireland to both the HSE and to patients directly, MFI members are a critical and central stakeholder in the Irish health service. Policy decisions now must reflect the challenges that are coming down the track in terms of funding for medicines and treatments.

Global market fluctuation and unprecedented supply chain disruptions could have major implications for the supply of medicines to Ireland, it is therefore important the next framework agreement does all it can to mitigate against supply risks.

“**Global market fluctuation and unprecedented supply chain disruptions could have major implications for the supply of medicines to Ireland...**”

Additionally, in some cases, our reimbursement prices for certain medicines are too low compared to other EU countries and price adjustments in Ireland are historically downward only. This adds to unsustainable market conditions for suppliers.

The problem of shortages has received significant public and political attention in Ireland and across the EU. There is no basis to assume this matter is temporary or will resolve autonomously. Consequently, it is evident that proactive measures are required. These actions should involve stakeholders across the generic medicine value chain as well as policymakers on both national and European scales.

Our primary objective at MFI continues to be centred on assisting Government to maintaining sustainable market conditions, thus safeguarding continued access to cost-effective treatments for patients in Ireland.

ABOUT MEDICINES FOR IRELAND

Medicines for Ireland (MFI) is a pharmaceutical industry body committed to affecting real change and reforms that guarantee patients across Ireland have access to the medicines they need at affordable prices.

Since its foundation in 2016, MFI has been promoting the benefits of the increased use of non-patented, generic, and biosimilar medicines in Ireland. In 2022, our membership supplied over 60 million packs of prescription medicines to Irish patients this year. This equates, to an average

of 2 packs of medicines every second and 60% of all medicines used in the State come from MFI member companies.

As an organisation, our core objective is to improve the way Ireland procures and supplies medicines to help expand patient access to affordable, lifesaving and life-enhancing treatment.

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

- Safeguard the supply of medicines to Ireland by helping to ensure supply chains remain secure and reliable.
- Innovate our approach to acquiring, supplying, and distributing medicines nationwide with the dual objective of pushing down costs and delivering greater equality of access for patients.
- Inform key stakeholders of the specific and wider benefits associated with the increased usage of off-patent medicines.

“60%
of all medicines used in the State come from MFI member companies.”



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



KEY PRIORITIES FOR MFI



Develop a flexible Pricing Mechanism to safeguard against risk of medicine shortages

According to figures provided by the Oireachtas Parliamentary Budget Office, health spending has exceeded its allocated budget for 7 of the last 8 years, with increased costs of drugs and medicines a key driver of this increase¹.

In 2015, health spending amounted to €13.34 billion, while the initial allocation for 2023 was just over 24 billion. This represents an increase in the health allocation of 80 per cent over the period, and now makes up about a quarter of total Government expenditure.

“The ramifications of shortages include reduced treatment quality for patients, an intensified workload for healthcare professionals

The ramifications of shortages include reduced treatment quality for patients, an intensified workload for healthcare professionals tasked with identifying and administering substitute treatments and added strain on healthcare systems. All of which can be mitigated through the availability of generic medicines.

It is our belief that if we work collaboratively with Government, patients and health professionals, MFI can help deliver further sustainable value for the medicines budget whilst increasing patient access to everyday medicines.

Over the past 10 years increased generic medicine usage in Ireland has yielded hundreds of millions in savings for the State, due to inflationary pressures and trade disruptions we are currently experiencing increasing shortages in low-cost medicines, generally older off patent medicines. Additional investment would contribute to the security of supply for these medicines.

MFI is very happy to be part of the ongoing process in negotiating a new National Medicine Supply and Pricing Agreement. Our aim is to assist stakeholders’ debate and formulate best policy options in the new Agreement, for sustainable patient access, continued savings via generics, and to support pharmaceutical exports.

1. https://data.oireachtas.ie/ie/oireachtas/parliamentaryBudgetOffice/2023/2023-08-15/health-spending-in-ireland-2015-2023_en.pdf

Establishment of a national medicines reserve

A national medicines reserve would hold profound advantages for Ireland, enhancing the country’s healthcare preparedness and resilience. It would serve as a safeguard against disruptions in pharmaceutical supply chains, ensuring availability of essential medication during emergencies and times of crisis.

Under the National Oil Reserves Agency and Provision of Central Treasury Services Act 2020, Ireland has a 90-day supply of oil in the case of a national emergency, MFI have repeatedly called for a similar reserve facility for medicines which would be critical to Irish healthcare moving forward.

Such a reserve would offer a reliable solution to address unforeseen events that could potentially disrupt the flow of medications. Natural disasters, health crises, global supply chain interruptions and geopolitical uncertainties can all lead to shortages of vital medications. By maintaining a

reserve, Ireland can mitigate against any interruption to the availability of medications, ultimately protecting public health.

A national medicines reserve will also nurture public confidence in Ireland’s healthcare system. Knowing that a reserve of essential medications is readily available

during these uncertain times would reassure the public that their medical needs will be met and there will be no disruption to their care.

Many countries, including the UK and the US, have a national medicines reserve specifically to help during a public health emergency. While Medicines For Europe have called for reserve policies to “avoid distorting supplies of medicines to certain (smaller) EU Countries”², Ireland continues to face this risk without a national reserve. MFI believe serious consideration should be given to the creation of a national medicines reserve in Ireland, given the ongoing risk of shortages.

“By maintaining a reserve, Ireland can mitigate against any interruption to the availability of medications, ultimately protecting public health”

2. <https://www.medicinesforeurope.com/news/hera-must-address-outstanding-weaknesses-in-eu-pharma-framework-to-be-successful/>





Effective preparatory measures to facilitate implementation of the EU Pharmaceutical Package

Ensuring a seamless transition to the introduction of the EU pharmaceutical package in Ireland necessitates comprehensive preparatory work. This package embodies a significant shift in the pharmaceutical landscape, encompassing diverse aspects such as regulations, supply chains, and patient access. Hence, meticulous planning becomes paramount to mitigate potential disruptions and maximise the benefits of this transformative initiative.

“meticulous planning becomes paramount to mitigate potential disruptions and maximise the benefits of this transformative initiative.”

The complexity of the EU pharmaceutical package demands a thorough understanding of its implications. Ireland’s healthcare ecosystem, including regulatory bodies, medicines manufacturers, healthcare professionals, and patients, must grasp the package’s intricacies to adapt smoothly. A robust preparatory phase allows for the identification and mitigation of potential bottlenecks. While MFI supports the majority of the current proposal, we have some concerns about the impact some elements will have on the availability of

medicines in the Irish context such as the introduction Transferable Exclusivity Vouchers. By proactively addressing challenges in areas such as supply chain logistics and regulatory compliance, Ireland can play a proactive role in preventing unexpected hurdles that might otherwise impede the rollout. This preparation grants stakeholders the time to find alternative solutions, establish contingency plans, and minimise any adverse effects on patient care or market stability. Furthermore, effective communication is a cornerstone of successful transitions. Structured engagement with all relevant parties, from medicine manufacturers to healthcare providers and patients, about the upcoming changes is essential. Transparent and timely communication helps manage expectations, reduces uncertainties, and facilitates a smoother adjustment period. It allows all stakeholders to align their strategies, adapt their operations, and collaborate on a unified front to navigate the complexities of the new pharmaceutical landscape.

BIOGRAPHIES



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Padraic O’Brien

Chairperson of Medicines for Ireland
Director of Medicines for Ireland
Managing Director, Accord Healthcare Ireland

Padraic is Managing Director at Accord Healthcare Ireland. He is a graduate of DIT and Trinity College Dublin. He has held a number of senior management positions within Accord, most recently as Commercial Director where he has overseen the implementation of the Accord Sales Strategy.



Paul Neill

Vice Chairperson
Vice-Chairperson of Medicines for Ireland
Director of Medicines for Ireland

Paul is the Director of Generic Medicines for Teva Pharmaceuticals Ireland, the largest supplier of prescription medicines to the State. Paul brings with him a wealth of practical experience gained from almost twenty years in various commercial roles in the Pharmaceutical Market – ten of these in leadership roles in Teva.





www.medicinesforireland.ie