



Pre-Budget Submission 2023

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Executive Summary

Generic medicines now account for almost 60% of the Irish prescription market. Over the past 10 years the volume of generic medicines across Ireland has risen significantly, in 2012, generic supply was at 33% and has now risen to 57% in 2022.

The greater use of generic medicines in Ireland helps patients access high quality treatments at considerably lower costs, it also produces significant savings for the State.

However, skyrocketing inflation, supply chain disturbances and soaring energy costs have created unforeseen challenges for the generic medicines sector across Europe including Ireland, resulting in thousands of generic medicines disappearing from the market.

Unfortunately, this is not the first time that our national medicines supply has been at risk. Over the past few years, issues arising from the Covid -19 pandemic and post Brexit changes have posed a threat to our medicines supply. Following on from this, we feel that additional safeguarding measures need to be put in place to ensure the security of our medicines supply as a matter of urgency.

Based on industry insights, we believe supply security can be dramatically enhanced by the implementation of targeted pricing adjustments. In some cases, our reimbursement prices for certain medicines are too low compared to other countries across the EU and price adjustments in Ireland are historically downward only. This coupled with rising inflationary costs, means it is becoming increasingly unviable for generic medicine companies to supply Irish hospitals and pharmacies.

MFI members are willing to work directly with Government to help tackle this serious issue and prevent potential medicines shortages, ensuring reliable and affordable access to medicines for Irish patients.

With respect to this, MFI have set out three key recommendations in this submission, which we believe would help tackle the current risk of medicine shortages:

Enhancement of national pricing and procurement policies to help mitigate the risk of medicine shortages.

Establishment of a National Medicines Reserve.

Extension of the 0% VAT rate that currently applies to certain oral medicines to non-oral medicines.

Introduction from Chairperson

Every time a generic medicine is dispensed, it represents a cost saving to the State and an opportunity for additional funding to be channelled to other areas of the healthcare system.

Our membership will aim to supply over 60 million packs of prescription medicines to Irish patients this year. This equates to an average of 2 packs of medicines every second.

Despite these progressions, Ireland's generic medicines usage still falls below the European average of 70%, and recent supply chain bottlenecks and additional inflationary costs are causing major disruptions to supply.

In turn, these price hikes will lead to critical shortages right across our healthcare system with serious health implications for Irish patients.

Given the positive impact increased generic usage has had on the Irish healthcare system, MFI feel that urgent steps must be taken to safeguard our generic medicine supply chains to prevent shortages.

As an organisation we aim to deliver industry insights and extend our expertise to help improve the development of medicinal pricing and procurement policies in Ireland.

We believe it is time for us to revisit our work with Government and the HSE on the Framework Agreement on Supply and Pricing and develop improvements to mitigate against supply risks.

In some cases, reimbursement prices are too low making the Irish market increasingly unviable for companies supplying generic medicines. Many of these prices have been in place for many years and have become outdated.

Our main focus is to help Government ensure market conditions in Ireland remain sustainable in order to retain and secure access to affordable treatment for Irish patients.



Padraic O'Brien
**Chairperson for
Medicines for Ireland**

About Medicines for Ireland

Medicines for Ireland 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, Medicines for Ireland has been promoting the benefits of the increased use of non-patented and generic medicines in Ireland. Our members supply the majority of medicine in Ireland to the HSE and patients directly. In 2021 MFI members made a significant contribution to the Framework Agreements on Pricing and Supply of Medicines 2021-2025 agreed with the Department of Health, the Department of Public Expenditure and Reform, and the HSE.

The agreements, announced by Minister for Health, Stephen Donnelly late last year are estimated to reduce the State spend on medicines by about €700 million.

Medicines for Ireland Members Survey 2022

In August 2022, representatives from each of our member companies were invited to take part in a short survey regarding the current challenges facing companies producing and supplying off patent medicines in Ireland and the risk of possible medicine shortages due to supply chain disruption and inflation. The majority of findings from this survey are presented within this pre-budget submission



Clonmel Healthcare is a subsidiary Company of STADA Arzneimittel AG

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Fannin Ltd is a subsidiary company of DCC Vital

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Pinewood Healthcare is a subsidiary company of Wockhardt Ltd

WOCKHARDT

Rowa is a subsidiary company of Rowex Pharmaceuticals

ROWEX

Generic Medicine Usage in Ireland

In 2012, generic supply was at 33% and has now risen to 57% in 2022



Over the past 10 years the **volume of generic medicines** across Ireland has risen by **72%**



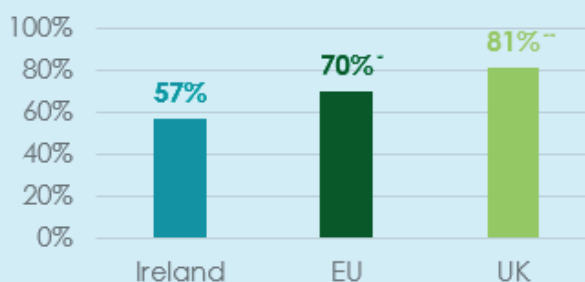
Generic Medicines account for **57%** of the volume of the total Prescription Market



MFI members supply 75% of generic medicines in Ireland

How do we compare?

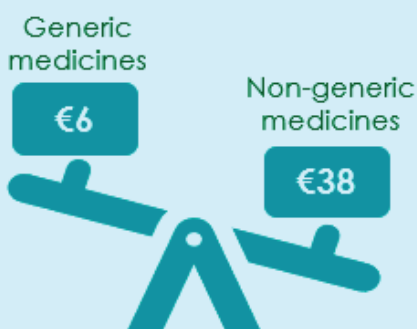
Despite the considerable progression over the past 10 years, we still fall behind the UK and the rest of Europe who have much higher levels of generic medicines use



How Generic Medicines can reduce State spending?

Massive price differentials (**average €32 per medicine**) between generic and non-generic medicines produce significant savings for the state when it comes to reimbursement costs

Average reimbursement cost



How can Generic Medicines help patients and our healthcare system?



Increased use of generic medicines means more patients can access essential treatments at lower costs



Generic medicines can yield huge savings for our healthcare system by reducing the State spend on medicines by millions



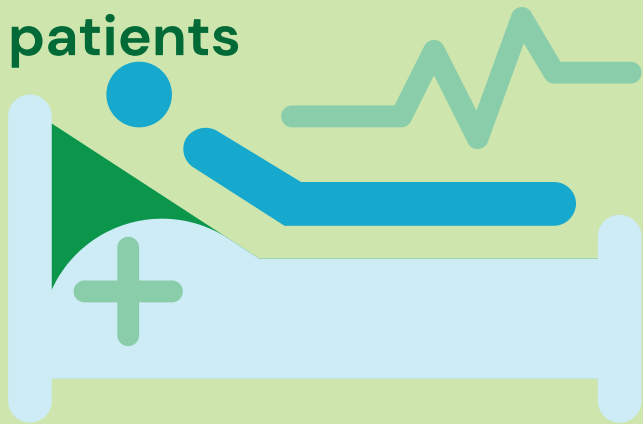
Money saved from increased use of generic medicines means extra funding for other healthcare services

Based on data compiled by IQVIA, Ireland in 2022 for Medicines for Ireland and figures published in Generic Medicines in Ireland Report published by Medicines for Ireland in June 2021

* Figure from Medicines for Europe ** Figure from NHS

Key Priorities for Medicines for Ireland

Ensuring reliable and secure supply of medicines for Irish patients



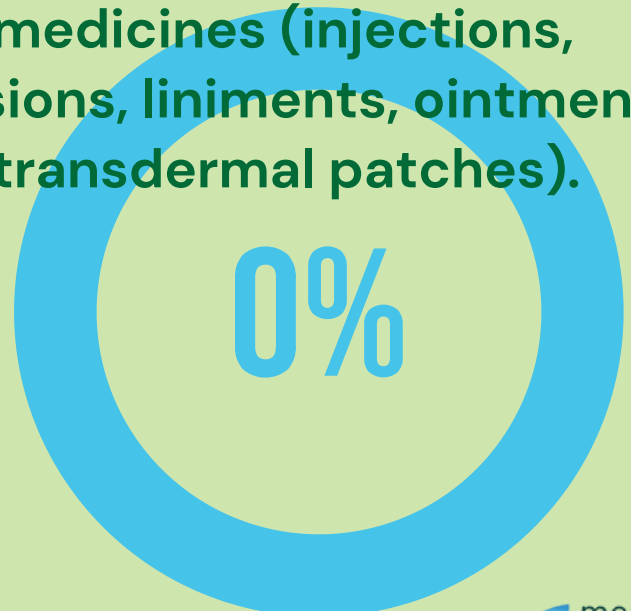
To inform the development and implementation of safeguarding drug pricing policies



The establishment of a national medicines reserve.



Extension of the 0% VAT rate that currently applies to certain oral medicines to non-oral medicines (injections, infusions, liniments, ointments and transdermal patches).



Challenges facing the generic medicines sector

A recent European Commission report published in December 2021 entitled Future-proofing pharmaceutical legislation —study on medicine shortages concluded that *“Medicine shortages present a growing problem for many EU/EEA countries. Consequences of shortages include a decreased quality of treatment received by patients and an increased burden on healthcare professionals, who need to identify and provide alternative treatments, and on health systems.”*

The study also confirms *“that medicine shortages occur frequently across the region, most often involving older, off-patent and generic medicines.”*

This report also identified national pricing and procurement practices as a contributing factor, this is a significant issue in Ireland. Our current reimbursement prices for many older, off patient drugs are often substantially below other European countries, putting us at a significant disadvantage and creating impractical market conditions for suppliers.

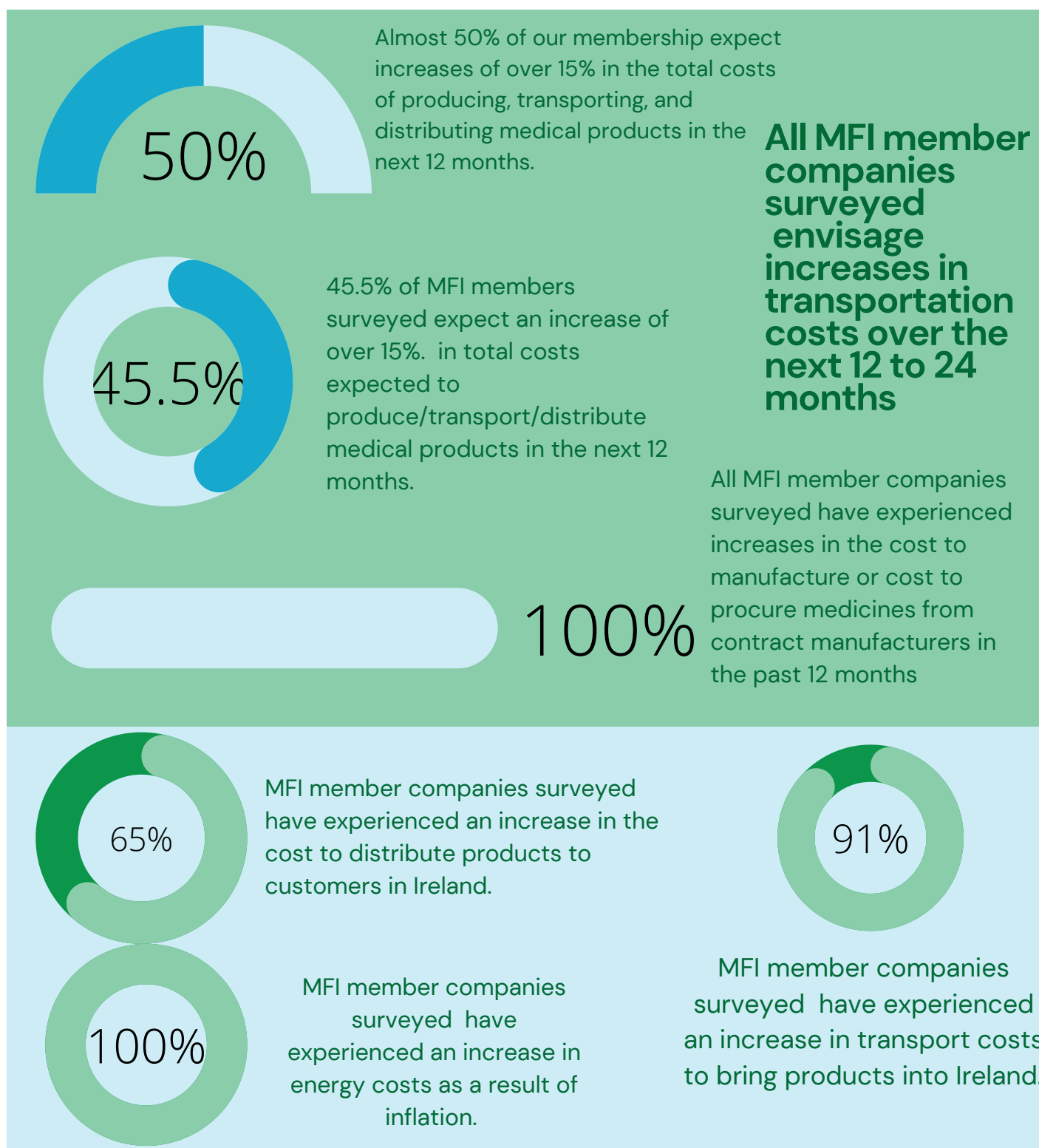
Almost 91% of MFI members surveyed experienced increased costs associated with import and/or manufacturing of pharmaceutical and medical products for the Irish market in 2022.

All MFI member companies envisage increases in transportation costs over the next 12 to 24 months



Over the past few months this growing problem has been further exacerbated by the issues arising from the crisis in Ukraine. The generic medicines industry has been hard hit by rising energy and transportation costs as well as difficulties related to global supply chain instabilities. These recent challenges have impacted how we manufacture and supply medicines to patients in Ireland.

The culmination of rising inflation and uncompetitive reimbursement rates will mean that many medicines suppliers will be forced to step away from the Irish market, leading to significant medicines shortages.



How do these challenges impact the supply of medicines in Ireland?

As a small market Ireland is more likely to be badly impacted by inflationary pressure and as costs continue to rise, market conditions will become increasingly unviable for companies supplying generic medicines.

In this context, current medicines pricing policies including inflexible reimbursement prices add to unsustainable market conditions for suppliers, leading to more and more moving away from the Irish market.

This will ultimately lead to reduced access for patients to vital medicines and treatments.

In light of the recent manufacturing and supply chain challenges with respect to rising energy and transport costs, all MFI members surveyed agree that a mechanism within the Framework Agreements on Pricing and Supply of Medicines 2021-2025 should exist to protect supply if product viability is threatened.

They have also indicated that relevant Government Departments and State bodies including the Department of Health, HSE, HPRA should work towards actively safeguarding the supply of medicines to Ireland and put additional measures in place to prevent medicine shortages.



According to the HPRA there are currently **169 medicines in short supply across Ireland**



According to Medicines for Europe several smaller countries across the EU are experiencing shortages:

Romania have seen 2000 medicines disappear from the market

In Belgium one in five medicines available last year, are now no longer available.

How will medicine shortages impact patients?

Medicine shortages and supply disruptions to hospitals and pharmacies can have a major impact on patient health.

Shortages tend to impact the supply of older, off patent medicines which have been used in patient treatments for many years.

Uncertainty around supply can mean that patients with long term or major illnesses may need to change their treatments and go through the difficult process of adapting to new medicines.

Shortages may also mean that some over the counter generic medicines may not be as widely available, reducing consumer choice in the midst of a cost-of-living crisis.

91% of our members surveyed think potential medicine shortages will result in changes to treatment programmes for patients with long term or lifelong illnesses

78% think potential medicine shortages will mean a reduction in access to over-the-counter generic medicines for Irish patients

Medicine Shortages in Ireland



Smaller markets like Ireland are more likely to be harder hit by inflationary pressures



Rising costs make it unsustainable for companies to continue supplying generic medicines to the Irish market



Causing shortages of essential generic medicines in Irish hospitals and pharmacies



Outdated and historically downward adjusting pricing policies for generic medicines



Medicines affected are general older, off patent medicines which have been used for many years in patient treatments



Reduced access to medicines due to shortages can cause major health implications for patients

How medicine shortages impact the overall healthcare system?

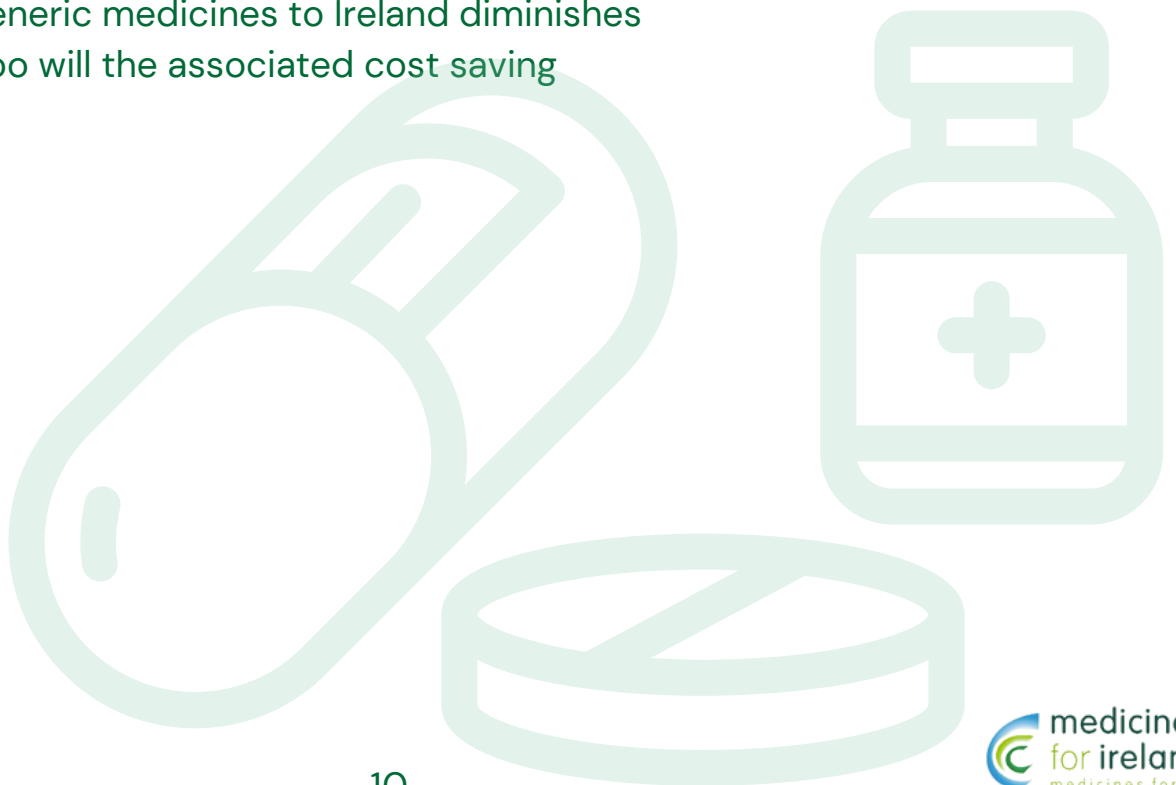
The growth of generic medicines over the past 10 years has had a hugely positive effect on the Irish healthcare system.

The increased usage of generic medicines generally equates to increased savings for the State, as well as lower treatment costs and broader treatment options for patients.

Money saved through the use of generic medicines can provide additional funding for other much needed healthcare services, such as additional medical staff and specialised equipment.

If the supply of generic medicines to Ireland diminishes significantly, so too will the associated cost saving benefits.

All MFI members surveyed believe that the State should put additional measures in place to prevent medicine shortages in Ireland.



How can we prevent medicine shortages?

Medicines for Ireland Recommendations:

Enhancement of national pricing and procurement policies to help mitigate risk of medicine shortages

Global supply chain issues and energy shortages affecting the European market are contributing to the risk of medicine shortages in Ireland, unfortunately as a nation we have little power to resolve these issues.

Notwithstanding the current circumstances, targeted enhancement of pricing and procurement policies at national level can play a huge role in safeguarding the supply of medicines to Irish patients.

As mentioned previously, the increased use of generic medicines can translate into significant cost savings for the State.

At the moment these savings primarily seen as freeing up funding for new drugs. While this is vital, it is equally necessary, that some of these savings are re-invested to ensure that low cost generics that have supported patient treatments for years, are priced and reimbursed at sustainable levels.

90% of our membership have indicated that if a mechanism to allow for flexibility in the reimbursement price was introduced for a period of time it would assist with securing vital medicines for Irish patients.

91% of MFI members surveyed believe a mechanism should exist within the Framework Agreements on Pricing and Supply of Medicines 2021-2025 that permits variability to reimbursement prices in line with rising supply and distribution costs.

In addition to this, pricing adjustments are historically downward only, with rising production and transport costs, this model becoming unsustainable and requires remodelling.

As the largest supplier of medicines to the HSE and patients directly, Medicines for Ireland are willing to work with Government directly to revise our current pricing and procurement policies in order to protect patient access to high quality affordable treatment.

Establishment of a National Medicines Reserve.

The global Covid pandemic has illustrated the importance of preparedness when it comes to the supply of medicines, medical equipment, and PPE.

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 believe that a similar reserve facility for medicines would be critical to Irish healthcare at this time.

Many countries including the UK and the US have a national medicines reserve specifically to help during a public health emergency. We do not have one in this country and MFI believe serious consideration should be given to the creation of a national medicines reserve in Ireland, given the current risk of shortages.

91% of our members think that a national medicines reserve should be established in Ireland.

Extension of the 0% VAT rate that currently applies to certain oral medicines to non-oral medicines (injections, infusions, liniments, ointments and transdermal patches).

Medicines for Ireland welcome the recommendation set out in the Budget 2023 Tax Strategy Group papers to “expand the zero VAT rate that currently applies to certain oral medicines to cover non-oral medicines, including injections, infusions, liniments, ointments and transdermal patches.”

According to the TSG paper on VAT “the Department of Health has suggested that all non-oral medications on the HSE's formal reimbursement list benefit from a zero VAT rate.”

The Department of Health notes that this would be in line with the Programme for Government which contains a commitment “to reduce the cost of medicines, including via generic prescription, where appropriate, and to set a fair price for drug reimbursement”.



MFI Leadership



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 native of Monaghan and a graduate of DIT and Trinity College Dublin and 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 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.

MFI Committees



Melissa Fisher

Chair of the Generics Committee

General Manager, Viatrix

Melissa joined the pharma landscape in Ireland 14 years ago, where she held numerous roles across Finance and Commercial. Prior to this she owned a retail business, while also providing supply chain consultancy services to multi nationals in Ireland. Melissa is a graduate of The University of Johannesburg and Technical University Dublin.



Sarah O'Neill

Chair of the Regulatory Committee

Sarah is Group Technical Director for DCC Vital and has over 25 years of experience in the healthcare industry in a variety of roles including sales, marketing and technical functions. Sarah is responsible for Quality, Regulatory and EHS for medicines, medical devices and associated services across the DCC Vital group of companies including Fannin Limited.



Paul Williams

Chair of the Communications Committee

Senior Director of Corporate Affairs, Teva

Paul Williams has worked in the generics industry for nearly 20 years at Teva. He is a public affairs specialist and had senior roles in the UK and the Netherlands, before becoming Teva's Corporate Affairs head for Ireland and the UK in 2019. He has been Chair of the Communications Committee since its inception.





Michael Comerford

Chair of Biosimilars Committee



Michael is Commercial Director at Celltrion Healthcare and chair of the Biosimilars committee. He has over 25 years managing products and leading teams across various therapeutic disciplines and has been working with biosimilars since 2014. He established Celltrion Healthcare in Ireland and is responsible for the strategic management of their expanding biosimilar portfolio.



Anna Daly

Chair of Finance Committee



Anna works as an Accounts Assistant at Rowa/Rowex Pharmaceuticals Ltd. She recently received her Diploma in Management Accounting and is working towards achieving the Chartered Institute of Management Accounting (CIMA) qualification. She is also a BComm (Hons) graduate of UCC



Clodagh Kevans

Chair of Value Added Medicines Committee



Director of Specialty Medicines, Teva Pharmaceuticals Ireland
A graduate of Trinity College Dublin and UCD Smurfit Business School Clodagh leads the Specialty business for Teva Pharmaceuticals in Ireland, the largest supplier of prescription medicines to the State. Clodagh has a depth of experience built up from over twenty years in the Pharmaceutical Industry. She has been a member of the Leadership Team for Teva Pharmaceuticals Ireland for the past 10 years.



David Delaney

Chair of EU Affairs Committee



Head of Policy & Market Access in Europe NW, Viatrix

David is head of Policy and Market Access Europe NW at Viatrix and Co-Founder and Board member of Medicines for Ireland. He leads advocacy at the European Parliament and Trade Committees for MFI and as a Board member of Medicines for Europe. David helps manage the MFI relationship with Ireland's Department of Health, other Government Departments, regulators and media on key industry related matters.



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