

Manifesto for Europe

01 | Equitable access to essential medicines

Reform of the EU pharmaceutical laws to ensure equitable access to medicines for all Irish patients. This involves fostering timely competition and sustainable uptake of generic, biosimilar, and value-added medicines.

MFI will work towards driving competition and supporting initiatives that invest in affordable off-patent innovation, including promoting the development and availability of cost-effective generic and biosimilar medicines to increase access to essential treatments.

Our members will also advocate for measures to improve supply chain security and reduce the risks of medicine shortages in Ireland. This involves promoting practical transparency processes around temporary supply disruptions and implementing strategies to mitigate these risks.

OUR KEY ASKS

- Call for support for pro-competitive measures in pharmaceutical and intellectual property legislation at EU level to facilitate the earlier entry of generic, biosimilar, and value-added medicines into the Irish market, thereby increasing competition and patient availability.
- Advocate for the creation of a pricing framework for the development of value added medicines in Ireland, which can address specific healthcare needs and challenges.
- Tackle the **economic root causes of medicine shortages** in Ireland and facilitate a solidarity-based allocation of medicines across the EU to help reduce shortages.

02 | Safeguard Europe's pharmaceutical production

Advocate for investment in the off-patent medicines manufacturing industry in Ireland to make it more competitive, environmentally friendly, and digitally focused, while enhancing its strategic autonomy.

MFI will support initiatives that invest in EU and Irish manufacturing capabilities and work towards the development and manufacturing of more complex medicines in Ireland to ensure a more secure and resilient supply of medicines for Irish patients and to address future healthcare needs.

Our members will invest in initiatives to train a highly skilled workforce in Ireland to ensure Ireland remains competitive in this critical industry, enhancing the country's capabilities in pharmaceutical innovation.

OUR KEY ASKS

- Call for the adoption of a Critical Medicines Act to promote open strategic autonomy in healthcare, restore Europe's manufacturing competitiveness, and reduce dependency risks for essential medicines.
- Advocate for EU support for investments in **new**, **greener**, **and automated manufacturing technologies** in Ireland while also focusing on **upskilling** the workforce to adapt to these advancements.
- Push for agreement on a harmonised list of critical and essential medicines for EU public health, ensuring a coordinated approach to securing the supply of essential medicines across member states, including Ireland.

03 | Establish a contemporary regulatory framework

Advocate for the digitalisation, harmonisation, and automation of the medicines regulatory framework in Ireland and across the EU to streamline processes and improve efficiency.

MFI will support investments in the digitalisation of regulatory and supply chain activities, ensuring alignment with future EU IT systems to enhance regulatory oversight and efficiency. We will advocate for finding a balance between investments in sustainability and ensuring access to affordable essential medicines for Irish patients.

OUR KEY ASKS

- Call for the fast-tracking of the digital and regulatory efficiency chapters of the new EU pharmaceutical legislation to ensure timely implementation of modern regulatory practices, aligning approval regulations with the latest scientific advancements and global development standards to improve access to medicines for Irish patients.
- Push for measures that **enable regulatory flexibility** to prevent shortages, such as accelerating the introduction of Electronic Product Information Leaflets(EPIL). This goes hand in hand with advocating for the introduction of a **viable shortage prevention and mitigation policy** and investing in a single digital, interoperable, and automated shortage management platform to help address medicine shortages in Ireland and across the EU.
- > Ensure measures to address **environmental challenges** do not undermine access to affordable essential medicines in Ireland.

04 | Promote healthcare innovation

The creation of a policy for affordable innovation on off-patent medicines in Ireland, ensuring that patients have access to improved therapies with the latest technologies.

MFI will support initiatives that encourage collaboration between the healthcare community and industry in Ireland to co-create off-patent research, improve existing therapies including value added medicines, and address healthcare challenges. We will embrace digital opportunities to enhance healthcare delivery and outcomes in Ireland, ensuring that the country remains at the forefront of technological advancements in healthcare.

OUR KEY ASKS

- Advocate for the recognition and reward of off-patent innovation in EU legislation while preventing abuses such as evergreening to ensure fair competition and affordability of medicines for Irish patients.
- Ensure that the **healthcare community in Ireland has a voice** in improving essential and critical off-patent medicines, addressing issues related to adherence and access to care.
- Support investment in **digital infrastructure** to address major healthcare challenges in Ireland while ensuring coherent regulation and market policies to facilitate innovation and accessibility.

Impact of medicine shortages

Medicines shortages have received significant public and political attention in Ireland and across the EU. A recent RED C survey* captured the scale of the impact among patients and their families. The survey illustrates how the public perceives the shortages of medicines and how they impact their lives.



1 in 5 (20%) have been personally affected by shortages in medicines in the past 2 years, while 22% say that family members/friends have been impacted. In total, 38% have been either directly or indirectly impacted by medicine shortages.



Nearly half (49%) agree that shortages are a problem that has gotten worse over the past 2 years.



3 in **4** (75%) believe that fixing any issues related to this should be prioritised by the Government.



According to those directly or indirectly affected, shortages in the availability of medicines most commonly **resulted in having to revisit the pharmacy** to get their medicine (37%), **wait for the medicines to become available** (35%), or be **provided with an alternative by the pharmacist** (32%).



For those directly or indirectly impacted, **nearly 2 in 5 (37%) say that the shortages are related to pain relief medication**. Other categories of treatment affected include respiratory, gastro, and rheumatology.

About Medicines for Ireland

Founded in 2016, Medicines for Ireland (MFI) is an established industry voice within the Irish healthcare system. It represents 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, it is 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. MFI is a member of Medicines for Europe.

Our member companies















