



A vision for health

Supplying sustainable, accessible and affordable medicines

May 2019

Executive summary

This year, Ireland's healthcare system faces several significant challenges.

Brexit aside, two key topics will impact the future sustainability of healthcare funding for Ireland: first, the renegotiation of the current medicines National Agreement on the Pricing of Medicines with all stakeholders; and second, the long awaited National Biosimilar Policy promised over two years ago by Minister for Health Simon Harris.

Medicines for Ireland (MFI) members represent manufacturers of generic, biosimilar and value-added medicines and account for over 60% of medicines supplied to the Health Service Executive (HSE), around 42 million packs per annum for Irish patients.

As a result of generic substitution and reference pricing in 2013, over €1.6 billion in savings have been delivered to our health system. The volume of generic usage has increased from 11% in 2013 to 58% and the average price per pack of medicines has fallen from €18 to €6.

In addition, and with Brexit looming, MFI members have been extremely proactive in adopting measures to safeguard medicines supply at a significant cost to their own businesses.

Yet there is no supply and pricing agreement in place with Medicines for Ireland members. We now need a new national agreement that gives direction to the procurement, pricing and supply of medicines in Ireland especially as many of the current uncertainties impacting medicines supply will continue into the next decade, requiring more long-term sustainable solutions involving all stakeholders.

A new national pricing agreement could also help patients and our health service realise the full benefits from increased generic and biosimilars adoption.

For example, currently around €450 million continues to be spent on biologic medicines annually (through HSE Community Drug Schemes and administered in hospitals) despite the existence of more affordable biosimilars with the potential to deliver millions in savings.

The vacuum of a clear policy direction is exacerbated by State-imposed barriers that are actively restricting patient access to medicines at considerably less expensive prices. The 'biosimilar blocker' clause contained in the existing pricing agreement with originator companies is just one example. Such barriers block the creation of an open, competitive medicines market in Ireland. The knock-on impacts of this are reduced access to life-enhancing medicines for patients and increased medicine expenditure.

Reform can ensure that medicines play a meaningful part in meeting healthcare needs and keeping our population healthier.

In this document, MFI sets out the range of solutions needed to achieve this objective and urges the Department of Health to ensure that MFI are an integral stakeholder in the development of the next medicines supply and pricing agreement for the betterment of patient care and the provision of sustainable cost savings.

Owen McKeon,
Chair of Medicines for Ireland

PATIENTS

Driving access, engagement and benefits for the public



While medicines supply, pricing and policy are essential components of a well-functioning Irish healthcare system, the fact that the Irish public are the ultimate payers for (either directly, or indirectly through taxes) and the end consumer of medicine is sometimes forgotten.

Patients are often not sufficiently aware or informed about their medicine choices and the impact of those choices. Like all aspects of healthcare, demand for medicines outstrips supply. The actions of the Department of Health or prescribers can directly impact on access.

There needs to be a wider communication effort that empowers the public, patients and prescribers to make informed choices about their health and medicine therapies.

In 2013, at the time of the introduction of compulsory generic substitution there was a proactive communications approach led by healthcare stakeholders such as the HSE, pharma companies and patient groups to increase awareness of the benefits of generics to the wider health landscape. This approach to communications must remain consistent and include a greater focus on medicine adherence, opting for more affordable medicines, and encouraging patients to finish their full prescription.

In February 2019, it was reported that the HSE's budget for new medicines had been exhausted and no new therapies could be reimbursed.

At the same time, more affordable biosimilars are not being proactively promoted and so the potential to save tens of millions each year on our national medicines budget is missed.

An integrated approach by encouraging the switch to more affordable generics (a) allows more patients to be treated with the same product for the same cost; (b) creates "headroom" within the medicines budget to pay for future innovative products and the investment needed to develop them; and (c) allows the HSE to use the savings elsewhere.

Medicines for Ireland recommends:

- A greater involvement of patient group representation in the development of medicines supply, pricing and policy agreements.
- An information campaign—supported by industry and institutions—to dispel inaccurate assumptions and build patients' understanding of their medication options, the development of medicines policies and the impact of policy on supply and pricing.

POLICY

Creating a fit-for-purpose framework for Ireland



As part of the negotiations for a new national supply and pricing agreement, the Department of Health has an opportunity take a more proactive and supportive approach to medicine procurement. National policy should provide for a sustainable, competitive market driving access and affordability for the system and patients.

We welcome the decision of the Minister for Health to undertake a full review of the reimbursement system. However this must not act as a delaying mechanism to wider reforms. In particular, the High-Tech Scheme, interchangeability criteria, and procurement processes can be quickly re-examined in order to assess the efficiency and clarity of the current measures.

This review must manifest itself into reforms that encourage greater generic and biosimilar usage across the healthcare system and immediately unlock savings and efficiencies.

As one of the largest spends in the national medicines budget, Humira—a treatment for rheumatoid arthritis—costs the HSE over €100 million per annum.

In October 2018, the patent for this medicine (the molecule known as adalimumab) expired and made way for the availability of several biosimilar options at a significantly more competitive cost. However, due to the lack of an effective policy, up to **€25 million** in savings have been missed (in the 6 months from patent expiry to end March 2019).

Across Europe, several countries are proactively directing prescribers to choose more cost-effective biosimilars once available. In Ireland such a central directive does not occur, meaning prescribers often stick to what they know – the costly originator.

Medicines for Ireland recommends:

- An overhaul of the HSE's High-Tech Scheme, including:
 - A framework for interchangeability and expansion of medicines on the High-Tech List, including solid-dose medicines.
- Clarity over the High-Tech Hub process and implementing of interchangeability prior to entering the hub
- Commence an immediate and ongoing review of the criteria for non-inclusion of medicines on the Interchangeable List.
- Establishing a National Biosimilar Policy to drive uptake by encouraging competition and increased prescribing of biosimilars.
- Supporting the HSE Medicines Management Programme (MMP) by providing incentives for GPs to prescribe more cost-effective medicines.
- Encouraging further generic prescribing through:
 - The introduction of quotas mandating minimum generic and biosimilar usage
 - A competitive process allowing potential suppliers to have certainty around potential market size/share.
 - Mandate that all new patients be prescribed and dispensed more affordable generic medicines, as appropriate.

PRICING

Fair pricing to deliver cost savings and sustainable supply



Medicines pricing must be fair, sustainable and geared towards encouraging competition and securing sustainable supply.

The current supply and pricing agreement and price reduction rules were negotiated with only one of the stakeholders in the pharmaceuticals sector. This has subsequently created an imbalance and disincentivises generic and biosimilars pharmaceuticals manufacturers and suppliers from introducing new medicines to the Irish market, and hampers the ability of indigenous Irish companies to enter and compete in their own market.

The long-term impact of this lack of competition is the damage to Ireland's reputation as an open medicines market - and ultimately it is our patients who will suffer.

Existing medicine price reduction processes, which apply to branded medicines when their patent expires, are currently slow to be enforced, resulting in a significant loss of savings to the HSE and Exchequer each year.

Under existing provisions, a branded medicine supplier must apply price reductions 28 days from notification by the HSE that a generic medicine is available. It is currently taking up to 6 months, and sometimes longer, for that notification to be issued. For example, a review of six molecules where post-patent pricing processes were not implemented in a timely manner resulted in a missed saving of **€20m**.

The process needs to be amended so that price reductions are amended in real-time.

Medicines for Ireland recommends:

- Developing a national supply and pricing agreement that creates a level playing field for all, encourages competition, incentivises investment and unlocks the potential savings possible.
- A more effective procurement system that prioritises use of the most cost-effective medicines, speeds up access to new medicines and provides a clear structure for ensuring budget exists for such medicines.
- This agreement must allow for the savings made through generic and biosimilar uptake to be used for the funding of new medicines.
- A streamlined process for the implementation and enforcement of pricing rules, such as the immediate reduction of prices for off-patent/non-exclusive medicines when generic equivalents become available.
- Supports for price increases for medicines at risk of being discontinued or for suppliers that flex supply to meet market demands created by out of stocks.

CONCLUSIONS

As the supplier of 60% of medicines in Ireland, with proven European experience of policies that have delivered far higher levels of patient access to medicines and greater savings for Europe's national health services, Medicines for Ireland has a valuable contribution to make in the negotiation of the next medicines supply and pricing agreement.

Medicines for Ireland believes its recommendations provide the basis for a sustainable industry-wide medicines agreement that can bring about valuable change.

Medicines for Ireland calls on the Government, healthcare institutions and industry to cooperate towards achieving a dynamic and sustainable medicines system that works for Ireland and its patients.

The process of negotiating a new National Medicine supply and Pricing Agreement needs to start now and include all industry stakeholders. We look forward to agreeing and prioritising reforms with other stakeholders around medicines procurement, pricing and supply that will guarantee a sustainable and equitable national medicines agreement for all.



ABOUT US

Medicines for Ireland represents Ireland's leading pharmaceutical companies in the generics, biosimilars and value-added medicines space. We share one common vision: that all Irish patients have access to the medicines they need to get well and stay well.

Our membership includes producers of both prescription and non-prescription medicines, as well as manufacturers of medical devices.

As the largest supplier of medicines to the health service, we advocate for dynamic and holistic healthcare policies in Ireland and work with the Government and relevant healthcare stakeholders to inform the national debate.

Medicines for Ireland is the national member association of Medicines for Europe—the voice of the generic, biosimilar and value added industries.

Through Medicines for Europe, we aim to contribute to increasing the health and wellbeing of all Europeans through better access to high-quality medicines, and safeguarding the sustainability of Europe's healthcare systems for future generations.

WHAT OUR MEMBERS DELIVER



TEN MEMBER COMPANIES

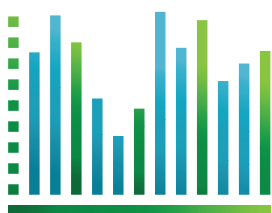
60% MEDICINES
Supplied to the HSE



1 PACK PER SECOND
Supplied to Irish Patients

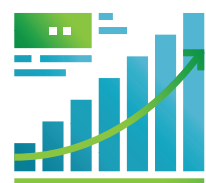


€39 MILLION
In savings delivered to the Irish system 2018



10 PLANTS NATIONWIDE

€1.6 BILLION
In savings since 2013



Medicines for Ireland Code of Conduct is available at www.medicinesforireland.ie

Medicines for Ireland's public ID number in the European Parliament's Transparency Register is: 707803931884-58

accord

