



Generic Medicines in Ireland

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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 medicines access to 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 twice for a further six months each time by agreement. The process of negotiating a new National Medicine Supply and Pricing Agreement needs to include all industry stakeholders.

Negotiations should be inclusive. 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. 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.

Good Jobus

David Delaney

Chairperson, Medicines for Ireland



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."

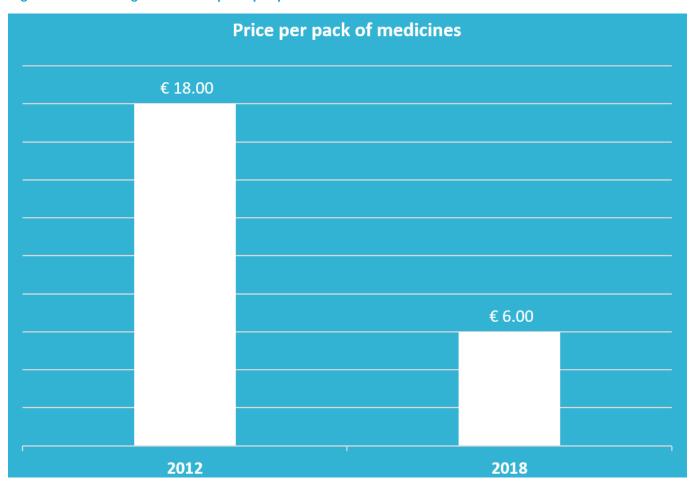
Improved patient access to medicines in Ireland

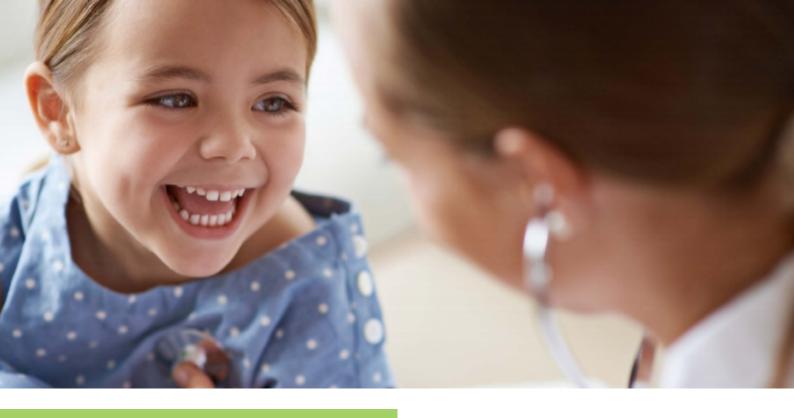
Medicines for Ireland supports the approach set out in the Sláintecare Report in relation to the management of medicines as it recognises the challenges faced by the health service to secure access to new medicines for patients in a sustainable and affordable way.

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

In 2021, the HSE's budget as set out in the National Service Plan is projected to be €20.6 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 (€2.4 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.

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).

Ireland's
spend on
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Reforms are
needed to
address
funding
challenges
to the state

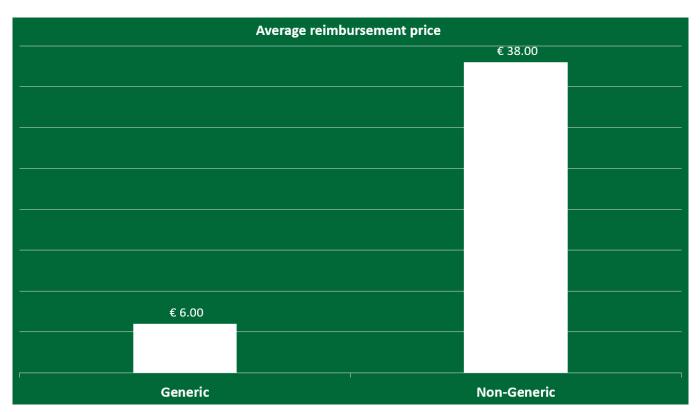
There are many untapped areas of reform within the medicine pricing and reimbursement system in Ireland that can deliver further value for patients and the state, and Medicines for Ireland can help deliver these changes speedily. Ireland is far behind the rest of Europe in terms of take up of generics 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, speaking as 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."

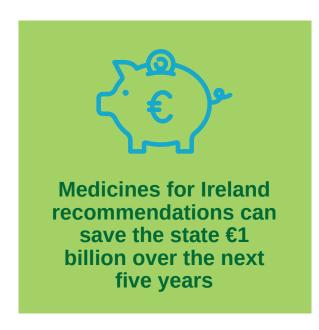
https://www.independent.ie/irish-news/health/financing-for-cancer-and-disability-services-hit-if-hse-overpays-for-drugs-38094342.html

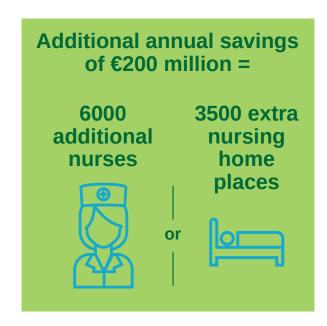
Potential cost reductions in Ireland

Since 2013, the use of generic medicines and biosimilars have provided savings of **€1.6 billion** 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 recommendations contained in the Medicines for Ireland report "Ireland's Patients First 2020-2022", if implemented, have the potential to save the state €1 billion 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.

To put this in context, the HSE currently spends €2.4 billion on medicines per annum nationally. Increased expenditure from the Covid-19 pandemic has placed even greater pressure on the resources of the HSE, therefore measures to help reduce the cost of medicines and increase access to medicines for patients, need to be prioritised.





Potential cost reductions to constituencies

	Savings since 2013		Savings per family since 2013				Potential annual savings		Additional Nurses	Nursing home places
0.00										
Constituency										
Carlow-Kilkenny	€	52,209,020	€	1,273	€	32,630,638	€	6,526,128	196	114
Cavan-Monaghan	€	47,318,228	€	1,294	€	29,573,892	€	5,914,778	177	104
Clare	€	39,723,106	€	1,285	€	24,826,941	€	4,965,388	149	87
Cork East	€	40,596,355	€	1,263	€	25,372,722	€	5,074,544	152	89
Cork North-Central	€	41,845,046	€	1,391	€	26,153,154	€	5,230,631	157	92
Cork North-West	€	29,781,381	€	1,270	€	18,613,363	€	3,722,673	112	65
Cork South-Central	€	40,751,480	€	1,299	€	25,469,675	€	5,093,935	153	89
Cork South-West	€	28,518,313	€	1,305	€	17,823,946	€	3,564,789	107	62
Donegal	€	50,367,911	€	1,294	€	31,479,944	€	6,295,989	189	110
Dublin Bay North	€	49,439,165	€	1,253	€	30,899,478	€	6,179,896	185	108
Dublin Bay South	€	40,511,771	€	1,744	€	25,319,857	€	5,063,971	152	89
Dublin Central	€	38,034,113	€	1,731	€	23,771,321	€	4,754,264	143	83
Dublin Fingal	€	54,470,038	€	1,269	€	34,043,774	€	6,808,755	204	119
Dublin Mid-West	€	39,445,285	€	1,280	€	24,653,303	€	4,930,661	148	86
Dublin North-West	€	26,207,816	€	1,334	€	16,379,885	€	3,275,977	98	57
Dublin Rathdown	€	31,584,044	€	1,332	€	19,740,027	€	3,948,005	118	69
Dublin South-Central	€	45,341,049	€	1,397	€	28,338,156	€	5,667,631	170	99
Dublin South-West	€	50,449,819	€	1,239	€	31,531,137	€	6,306,227	189	110
Dublin West	€	41,669,193	€	1,318	€	26,043,246	€	5,208,649	156	91
Dún Laoghaire	€	41,304,114	€	1,283	€	25,815,071	€	5,163,014	155	90
Galway East	€	29,937,843	€	1,289	€	18,711,152	€	3,742,230	112	65
Galway West	€	48,126,952	€	1,422	€	30,079,345	€	6,015,869	180	105
Kerry	€	49,381,661	€	1,311	€	30,863,538	€	6,172,708	185	108
Kildare North	€	39,967,496	€	1,290	€	24,979,685	€	4,995,937	150	87
Kildare South	€	38,383,479	€	1,256	€	23,989,674	€	4,797,935	144	84
Laois-Offaly	€	50,417,056	€	1,270	€	31,510,660	€	6,302,132	189	110
Limerick City	€	37,919,106	€	1,366	€	23,699,441	€	4,739,888	142	83
Limerick County	€	28,702,524	€	1,250	€	17,939,078	€	3,587,816	108	63
Longford–Westmeath	€	40,511,103	€	1,282	€	25,319,439	€	5,063,888	152	89
Louth	€	50,457,175	€	1,277	€	31,535,734	€	6,307,147	189	110
Mayo	€	42,102,809	€	1,299	€	26,314,255	€	5,262,851	158	92
Meath East	€	29,142,492	€	1,258	€	18,214,057	€	3,642,811	109	64
Meath West	€	30,199,617	€	1,270	€	18,874,761	€	3,774,952	113	66
Roscommon-Galway	€	28,706,871	€	1,280	€	17,941,794	€	3,588,359	108	63
Sligo-Leitrim	€	38,085,933	€	1,305		23,803,708	€	4,760,742	143	83
Tipperary	€	51,879,379	€	1,260	€	32,424,612	€	6,484,922	195	113
Waterford	€	38,840,163	€	1,272		24,275,102	€	4,855,020	146	85
Wexford	€	50,055,320	€	1,239	€	31,284,575	€	6,256,915	188	109
Wicklow	€	47,615,774	€	1,237		29,759,859	€	5,951,972	179	104
Total		,600,000,000	€	1,315		1,000,000,000		200,000,000	6000	3500



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



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Medicines for Ireland

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