# GENERICS@5

## AFFORDABLE, ACCESSIBLE, FOR ALL

medicines for ireland

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# Contents

# Executive Summary

2018 marks the fifth anniversary of the introduction of compulsory generic substitution and reference pricing in Ireland through the Health (Pricing and Supply of Medical Goods) Act 2013 ("2013 Act"). The Act has led to a significant shift in medicine usage in Ireland—away from branded, originator medicines to more affordable but equally effective generic medicines.

While starting from a very low base of 11% generic usage by volume pre-2013, generic penetration of the Irish medicines market now stands at 58% of the market. The benefits to patients, our healthcare system and the Exchequer are clear, with an estimated €1.6 billion in medicine savings realised over the period[1], solely from generic substitution.

1
Based on Medicines for Ireland company and IMS data

*Our Government must be more proactive in fostering a competitive off-patent medicines market*

Patients have been the largest beneficiaries of this change. Generic substitution ensured continued access to medicines for patients at a time when our health service was challenged by the worst aspects of the recession. Medicines for Ireland, as the largest suppliers of medicines to the HSE, acutely understands this benefit, but we believe we must do more to safeguard patient access into the future.

However, as we look to the next five years, it is evident that Ireland continues to lag behind most EU states in our usage of generic medicines. Generic penetration of the market stands at 80-90% in many EU states, however in Ireland, we remain well behind that level and we are not closing the gap. The most recent data suggests that the growth in generic medicines has now begun to slow to below 2% per annum for 2016 and 2017.

There remains a significant number of areas of our medicine market which have not yet been reformed. In these areas, medicines prices remain higher than is necessary and the opportunity to achieve further savings has been consistently neglected. Patients are the ultimate and most impacted losers in this scenario.

To ensure that we are achieving the best value for patients and taxpayers and to fully realise the potential of generic medicines, our Government must be more proactive in fostering a competitive off-patent medicines market here.

Five years ago, Medicines for Ireland were to the fore in driving and implementing generic substitution and delivering medicine savings. We are now concerned that, with a growing economy, the reform momentum of the recession years is being abandoned. When it comes to medicine reforms, Ireland Inc. has relapsed.

Given the massive healthcare challenges we are facing in the decades ahead with an ageing population and a higher incidence of chronic diseases, we simply cannot ignore the opportunity to further reform our medicines market and deliver additional and much needed savings.

In this document, Medicines for Ireland have set out five key proposals which we urge the Department of Health and wider Government to support and quickly move to implement.

**Key Medicines for Ireland reforms include:**

- A new National Pricing Agreement with the generic, biosimilar and value-added medicines industry to achieve further savings;
- Allow for increased use of biosimilar medicines;
- Increasing competition in the medicines market, particularly the low-value, high-volume sector currently valued at €260 million;
- Allowing all new patients access to generic medicines;
- Reform of the High-Tech Medicines Scheme, whose cost has increased by €325m or 96% (from €337m to €662m) over the period 2009 to 2016.

**Medicines for Ireland's reforms will:**

- Deliver additional savings to the already financially stretched health budget;
- Provide patients with greater access to medicines at a more affordable price;
- Stimulate the increased use of more affordable generic medicines across all healthcare settings;
- Create additional budget for the HSE to spend on other critical areas of health;
- Ensure more predictable market conditions for payers and suppliers;
- Drive competition in the Irish medicines market, thereby exerting a downward pressure on pricing.

Many of the gains made over the last five years are now at risk of being undone because of a complacency around the need for further reform. With affordability now a key concern in respect of ensuring Irish patients have access to the medicines they need, when they need them most, the Department of Health, Government, and wider medical community cannot afford to continue to ignore opportunities for further savings, such as those proposed today by Medicines for Ireland.

***- Owen McKeon, Chairperson of Medicines for Ireland, July 2018***

*Gains made over the last five years are now at risk of being undone because of a complacency around the need for further reform*

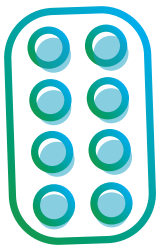
Owen McKeon - Chairperson of Medicines for Ireland, July 2018

# Facts & Figures

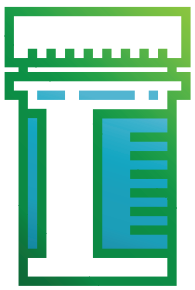
**€1.6 BILLION**

in savings from generic substitution since 2013

**PRICE €6 PER PACK**



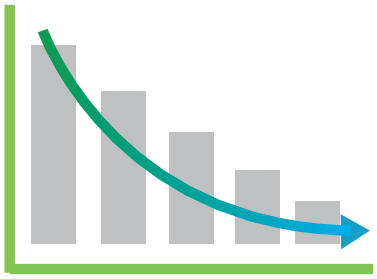
Average price per pack of medicines in 2018 has fallen by €12, from €18 in 2012



**VOLUME 11% ▲**

**VALUE 53% ▼**

While the volume of medicines has increased by 11% since 2012, the value of this medicine has fallen by 53%



**SPEND €124mil ▼**

Spend on Statins has fallen from €160m to €36m

*Refers to reference priced medicines only

# Medicines for Ireland key reform proposals

We believe that the following proposals, if implemented, can drive competition in the medicines market, deliver savings for our healthcare system and patients and protect continuity of medicine supply.

## 1: A new National Pricing Agreement with the generic, biosimilar and value-added medicines industry

The last agreement expired in 2016. The medicines market has changed hugely over that time. A new pricing agreement is now critical to drive further reforms and savings in the Irish market.

## 2: Allow for increased use of biosimilar medicines

The use of biosimilar medicines, is the norm in most EU states, yet Ireland's usage of biosimilars is only 2%. This is leading the State to miss out on millions in savings from these more affordable medicines. We need proactive measures, such as quotas or gainsharing, to increase their uptake.

**Potential saving: €25 million**

## 3: Increasing competition in the medicines market

A lack of competition in our medicines market, in areas such as the high volume but lower value medicines segment, is resulting in supply issues and a missed opportunity to unlock medicines savings.

Mechanisms to drive greater competition in this market,
such as pricing reviews, must now be implemented.

**Potential saving: €75 million**

## 4: Allowing all new patients access to generic medicines

Mandate that all new patients be prescribed and dispensed more affordable generic medicines, as appropriate.

Commence an immediate and ongoing review of the criteria for non-inclusion of medicines to the Interchangeable List, relative to best practice in other countries.

**Potential saving: €18 million**

## 5: Reform of the High-Tech Scheme

Medicines included on the High-Tech Scheme must be open to greater competition.

High-tech solid dose medicines must be placed on the Interchangeable List (and thereby open to substitution) immediately following patent expiry.

**Potential saving: €20 million.**

Table 1: Estimated savings based on Medicines for Ireland reform proposals

| | |
|---|---|
| **Allow for increased use of biosimilar medicines** | €25 million |
| **Increasing competition in the medicines market** | €75 million |
| **Allowing all new patients access to generic medicines** | €18 million |
| **Reform of the High-Tech Medicines Scheme** | €20 million |
| **Total savings** | €138 million |

# Introduction

2018 marks the fifth anniversary of the introduction of compulsory generic substitution and reference pricing in Ireland through the Health (Pricing and Supply of Medical Goods) Act 2013 ("2013 Act") for medicines deemed interchangeable by the Health Products Regulatory Authority ("HPRA"). During this period, there has also been a significant shift in attitudes towards generic medicines amongst stakeholders – prescribers, dispensers and patients. This has translated into an increased uptake in usage.

Over the five years, there has been substantial generic penetration of the Irish medicines market, from 11% usage, by volume pre-2013 Act, to 58% by end 2017. The benefits to patients, and more broadly the Exchequer and taxpayers, has also been evident with the extent of savings realised. An estimated €1.6 billion in savings have been delivered over the period 2013 to 2017 inclusive from generic substitution.[2]

**2**
Based on Medicines for Ireland company and IMS data

As the largest suppliers of medicines to the Health Service Executive ("HSE") and representatives of the Irish generic, biosimilar and value-added medicines manufacturing industry, Medicines for Ireland understand the benefits that generic medicines have provided for Irish patients in enhancing access and affordability of medicines. However, as we look ahead to the next five years, we are conscious that much more progress is needed to maintain this momentum and to meet the challenge of continued accessibility. We also need to ensure that unreformed, but equally as important, areas of our medicines market are addressed over the coming years.

*Much more progress is needed to maintain this momentum and to meet the challenge of continued accessibility.*

# Challenges ahead

As we begin to consider how the medicines market will develop in the years ahead, it is clear that policymakers must continue to proactively shape the medicines market to ensure that it continues to deliver for patients. Ongoing reform of our medicines market is the only way to ensure that the market remains dynamic and fit for purpose. Reform priorities for the period ahead include:

- Continuing to develop a competitive medicines market, with a focus on dynamic and responsive off-patent molecule pricing mechanisms (including reference pricing) led by the HSE's Corporate Pharmaceutical Unit (CPU);

- Further increasing the uptake of generic medicines amongst Irish patients and across all medicines categories, through expanding the list of interchangeable medicines. This work can be continued by the HPRA. In Ireland, generic usage stands at 58% versus 83% in the UK and 80% in Germany;
- Agreeing and implementing a single National Medicine Pricing Agreement which encompasses the branded and generics industry and drives better value for our health service, through one competitive national medicine pricing agreement;
- Continuing to increase awareness of the equivalence of generic medicines to prescribers and patients;
- Enacting a new National Biosimilar Policy to allow for the introduction of more affordable biosimilars, allowing biosimilars to be used instead of more-costly comparable biologic medicines, particularly at hospital level;
- Stimulating competition in the high-volume, lower value, off-patent medicines market by realigning the prices of these medicines to attract more suppliers into the market, thereby reducing the risk of medicine shortages.

## Addressing challenges

While 2013 marked a positive step forward in bringing Ireland in line with the norms of other EU medicine markets, we cannot afford to discard the need for further reforms. Without a more 'hands-on' approach by policymakers, the State will struggle to contain medicine cost pressures in the years ahead and our current spend of €2.2 billion per annum is expected to grow by 20% by 2020 (according to the Department of Public Expenditure).

To address this challenge, the Government and Department of Health must now sit down with all stakeholders and develop a clear pathway for medicines strategy for the next decade. Medicines for Ireland is committed to finding ways to promote cost-effective prescribing and ensure that the Irish taxpayer gets value for money when it procures our medicines.

Our membership comprises the pharmaceutical companies who were to the fore in delivering significant savings. In the years ahead, we can play a major part in driving the next wave of much needed medicine reforms to deliver continuity in the supply of cost-effective medicines to the patient, prescriber and payer.

*Promote cost-effective prescribing and ensure that the Irish taxpayer gets value for money when it procures our medicines.*

# The health of the nation

## Our health services

Across the globe, governments are facing the challenges of providing increased and ever-more complex healthcare services, as well as finding the means to fund them.

The increasing demand on services, which has resulted in escalating healthcare spending, is being fuelled by common factors: an ageing population; the growing prevalence of chronic diseases and related conditions; the development of life-changing but costly clinical innovations (including new medicines); and rising patient expectations, knowledge and awareness.

*Between 2007 and 2016, total public expenditure on health increased by 9.4%.*

## Spending on healthcare in Ireland

In 2018, the Department of Health's expenditure on health services will be €15.3 billion, representing an increase of over €600 million on 2017's allocation. This is despite the fact that the 2017 Budget was itself an €1 billion increase on the 2016 budget.

Ireland's spend on healthcare services remains high relative to other countries. When measured by health expenditure per capita, Ireland ranks as the 8th highest spend amongst 35 OECD countries, and the 11th highest in health expenditure expressed as a percentage of GDP[3]. This pattern of an increasing proportion of overall public expenditure funding spent on health services has accelerated in recent years; between 2007 and 2016, total public expenditure on health increased by 9.4%.

## Population health

There are numerous reports and research which have all broadly indicated that, as a nation, while we are living longer, many people are unhealthier than was the case with previous generations. Key challenges for the provision of health services in the years ahead include:

**3**
Health In Ireland: Key Trends 2016, Department of Health http://health.gov.ie/blog/publications/health-in-ireland-key-trends-2016/

## An ageing population:

- Census 2016 data indicates that 18.4% of the population are now 60 years or older. This figure grew by 210,000 between 2006 and 2016, now stands at 860,000, and is expected to reach 1.15 million by 2026;
- Additionally, the group of individuals aged 80 and over has increased by more than 20,000 between 2006 to 2016 to 68,000, and is expected to reach 104,000 by 2026[4];
- Life expectancy in Ireland has increased by almost two and a half years since 2005 and has been consistently higher than the EU average throughout the last decade.[5]

## Burden of Illness:

- Chronic illness is a major problem for all health systems and is more prevalent as people age. 65% of those over 65 and 80% of those over 85 have two or more chronic conditions[6];
- The incidence of chronic diseases in older people is expected to grow by 29% by 2020;
- Obesity is the most prevalent disease in Ireland;
- 37% of the adult population is overweight, while a further 23% is described as clinically obese[7];
- 52.9% of males and 53.5% of females aged 65 and over reported suffering from a chronic illness or health problem.[8]
- In the 75+ age category, 42.8% and 50.2% of males and females respectively reported some or severe limitation in usual activities due to health problems.[9]

## Health service expenditure:

Total public expenditure on health in 2018 is expected to be €15.3 billion, an increase of over €600 million on 2017 spend;

In terms of health expenditure per capita, Ireland ranks as the 4th highest spend amongst EU countries, and more than 40% above the EU average.[10]

**4**
Census 2016

**5**
Ibid.

**6**
HSE, 2017 Planning for Health, Trends and Priorities to inform Health Service Planning

**7**
Ref: RCPI. An expert report on how to clinically manage and treat obesity in Ireland, October 2015. & Healthy Ireland Survey, 2015 Summary of Findings, Chapter 9

**8**
Health in Ireland Key Trends 2016, Department of Health http://health.gov.ie/blog/publications/health-in-ireland-key-trends-2016/

**9**
Ibid.

**10**
State of Health in the EU, Ireland: Country Health Profile, 2017 (November, 2017) http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/ireland-country-health-profile-2017_9789264283435-en#.WowwWahl-Uk#page1

# Current medicine usage and expenditure

As our population ages and the number of people living longer with chronic illnesses increases, we need to find a way to make our spending on medicines sustainable for the future.

Medicines are becoming increasingly sophisticated, treating and managing a range of illnesses and conditions that were previously untreatable. But the research and development process is incredibly costly, making medicines one of the most expensive areas for the public budget - over 14% of total health expenditure.

- Total spend on medicines in 2017 by the HSE was €2.2 billion – the largest single item in the healthcare budget;
- The numbers of people on the Long-Term Illness Scheme has increased significantly in recent years and now stands at over 138,000 people[11], costing €170 million per annum;
- Over 70,000 people now avail of the High-Tech Drug Scheme costing €662 million per annum. This represents an increase in spend of €325m or 96% over the period 2009-2016.

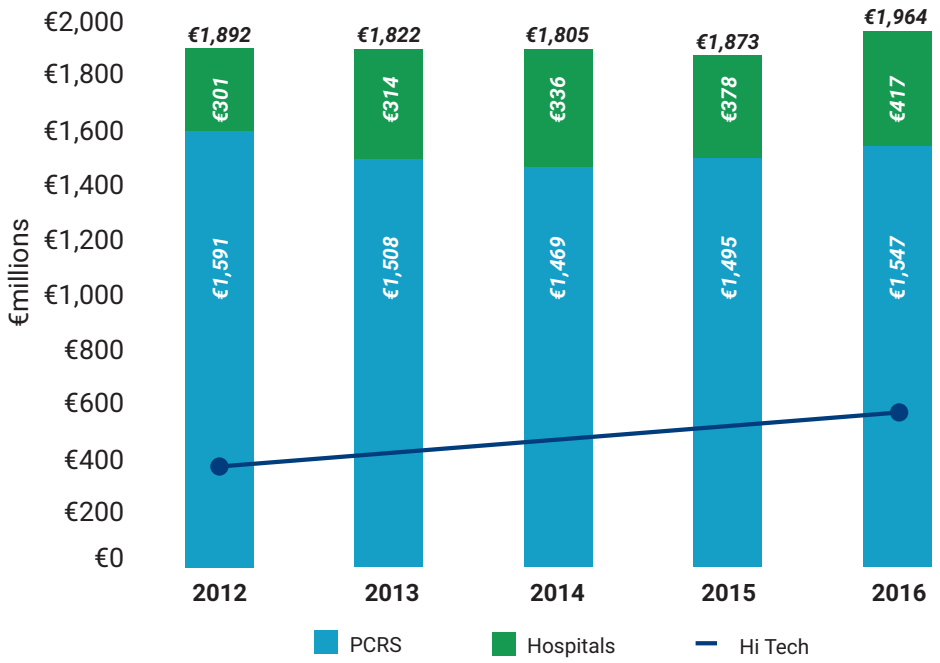
**11**
HSE, Primary Care Reimbursement Service Statistical Analysis of Claims and Payments, 2015

The most recent HSE data on medicine spend relates to 2016. What is clear from this data is that even during the recession, expenditure on medicines fluctuated between 2012 and 2016. Spend on some community schemes decreased from 2012 to 2015 because of emergency spending reduction measures including tightening eligibility and reducing supplier fees.

However, these savings were offset by the rising cost of the High-Tech Medicine Scheme. This is a scheme which supports innovative, high-cost medicines, many of which are used and / or prescribed in hospital settings.

Expenditure on the High-Tech Scheme has continually increased with spend increasing by €335m or 96% over the period 2009 to 2016. By 2017, spend on the scheme rose to €662 million and is expected to continue to increase. The continued growth in spend is driven by the introduction of new medicines and the extension in indications of existing medicines.

Figure 1: Pharmaceutical Spend Across Hospitals and Community Schemes 2012 - 2016




*This is a scheme which supports innovative, high cost medicines*

**KEY TAKEAWAYS:**

Savings realised by the HSE on community medicine schemes in recent years have been consumed by expenditure on the High-Tech Scheme, which continues to increase.

## The 2013 Act – what did it do?

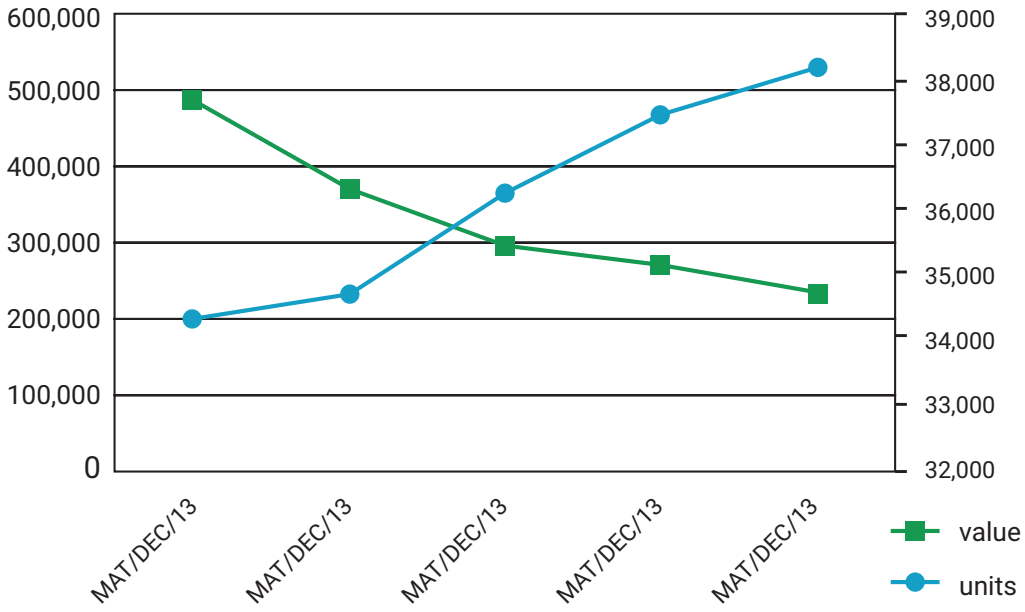
*Pharmacists could substitute a less expensive generic medicine for a more expensive, branded medicine*

The Health (Pricing and Supply of Medical Goods) Act 2013 introduced generic substitution for the first time for those medicines deemed interchangeable by the HPRA.

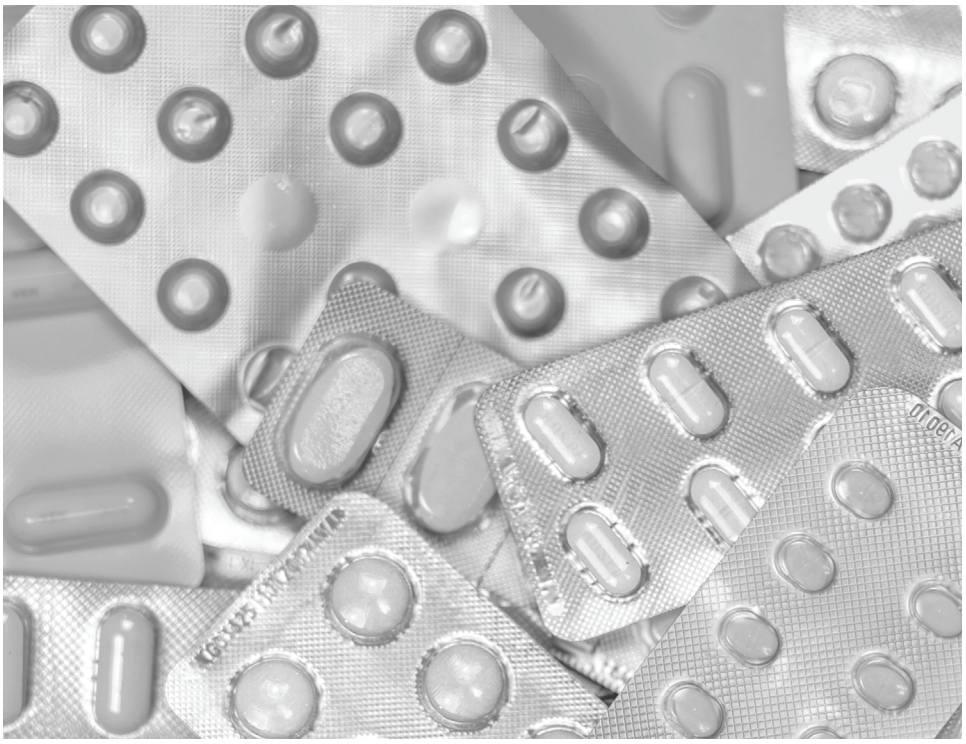
After the Act was introduced in 2013 and coupled with the implementation of reduced pricing for off-patent / generic medicines and / or reference pricing, pharmacists could substitute a more expensive, branded medicine for a less expensive generic medicine where the molecule(s) was deemed interchangeable by the HPRA.

Generic substitution / reduced pricing strategies has given pharmacy an important role as gate keeper in driving the use of cost-effective medicines and saving the state and the patient money. It has delivered tangible results.

**Figure 2: Impact of generic substitution and reference pricing – Savings delivered on reference priced molecules**




*Based on Medicines for Ireland company and IMS data.



A review of Medicines for Ireland company and IMS data highlights the extent to which generic substitution and reference pricing has delivered substantial savings. A number of key statistics stand-out:

- While the volume of reference priced medicine molecules has continued to grow over the period 2013 to 2017 (by over 4 million packs), the value / cost of these medicines has fallen significantly;
- Over €1.6 billion in savings have been realised on referenced-priced molecules over the period 2013 to 2017;
- The average cost price of a pack of referenced priced medicines has fallen from almost €18 per pack in 2012 to below €6 by end 2017.

The Department of Public Expenditure in 2017 estimated that if no change of policy had taken place in 2013, then Ireland's spend on pharmaceuticals had the potential to increase by 33% over the period 2014 to 2019.[12]

**12**
Future Sustainability of Pharmaceutical Expenditure, Department of Public Expenditure and Review, May, 2017DEPR Report, p16

## Generics medicines share of the market – Positive impact on medicine pricing

Just five years ago, the 2013 Act was introduced to help move Irish patients from costly branded medicines to equivalent, more affordable generic medicines. As the table below outlines, noteworthy progress has been made.

**Table 2: Growth in volume vs decline in value of referenced priced medicines, 2012 - 2017**

| | | | | | | | % Growth / decline | Absolute growth / decline |
|---|---|---|---|---|---|---|---|---|
| 000s | End 2012 | End 2013 | End 2014 | End 2015 | End 2016 | End 2017 | | |
| Units | 28,007 | 34,269 | 34,688 | 36,267 | 37,947 | 38,174 | 36% | 3,905 |
| Value | 491,879 | 489,829 | 369,764 | 295,410 | 266,842 | 232,498 | -53% | -257,331 |
| Av. Price per pack | €17.56 | €14.29 | €10.66 | €8.15 | €7.12 | €6.09 | -57% | -€8.20 |

**KEY TAKEAWAYS:**

Volume of reference priced generic molecules has grown by 36% over the period 2012 to 2017.

The value of referenced priced generics decreased by 53%.

While the average price per pack of this category of medicines fell by 57%, from €17.56 to €6.09 from 2012 to end 2017.

Overall, significant savings have been realised by the HSE because of generic substitution and reference pricing and are estimated to total €1.6 billion. These savings have in turn allowed the Department of Health to reinvest these monies into wider healthcare services and new medicines provision.

# Medicine categories where generic substitution has had the greatest positive impact

## Case Study One – Statins[13]

Statins are medication used to lower cholesterol levels to reduce the risk of heart disease and stroke. They are the most used medicines in Ireland, with 250,000 adults using the medication and costing the HSE, at a peak in 2009, over €160 million per annum.

Statins were the first medication to benefit from the 2013 Act and the introduction of reference pricing and generic substitution. The Act has made a huge impact, as set out below, in significantly lowering the price of these medicines.

The first chart below details the growth of statins by volume and the second chart outlines the declining cost / value of the statins market in Ireland.

**13**
See Appendix 1 for a further case study involving Proton Pump Inhibitors

*The Act has made a huge impact, as set out below, in significantly lowering the price of these medicines*

Figure 3: IMS Volume (units) Statin Market 2008-2017

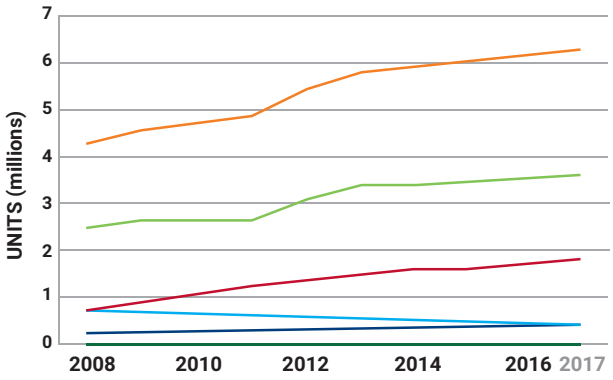
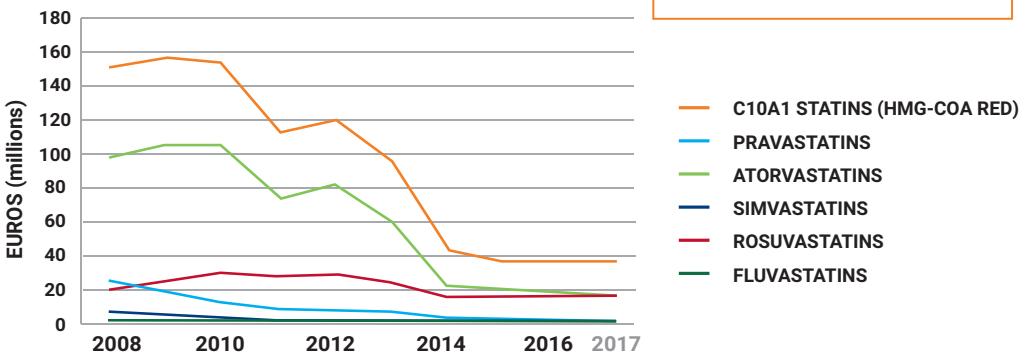



Figure 4: IMS Value (€) Statin Market 2008-2017




### KEY TAKEAWAYS:

The volume of statins used in Ireland has continued to increase from 5.8 million units in 2013 to over 6.3 million units by end 2017.

However, the value / spend on statins over the same period decreased from €95.3 million per annum in 2013 to €36 million in 2017.

# Impact of the 2013 Act on the top 15 most used medicines

A Report from the Economic and Social Research Institute (ESRI) in mid-2017[14] set out the full impact of the 2013 Act on pricing of the most used medicines reimbursed by the HSE. The range of price reductions span from an almost 90% reduction to just over a 51% price cut, as set out in more detail in the table below.

**14**
The savings from the 2016-2020 Framework Agreement on the Supply and Pricing of Medicines in Ireland: which counterfactual? Paul Gorecki, Economic and Social Research Institute, June 2017 https://mpra.ub.uni-muenchen.de/79481/

**Table 3: Original and Reference Price, Average Ingredient Cost per Prescription, Leading 15 GMS Interchangeable Medicines, 2005 & 2015, Ireland.**

| INN | Average Ingredient Cost per Prescription 2005 Original Price | Average Ingredient Cost per Prescription 2015 Reference Price | Average Ingredient Cost Reduction (%) |
|---|---|---|---|
| Atorvastatin | €37.55 | €4.61 | 87.7 |
| Esomeprazole | €41.59 | €7.86 | 81.1 |
| Olanzapine | €117.39 | €31.32 | 73.3 |
| Omeprazole | €49.03 | €7.75 | 84.2 |
| Rosuvastatin | €29.95 | €8.56 | 71.4 |
| Lansoprazole | €38.73 | €6.52 | 83.2 |
| Quetiapine | €60.58 | €18.76 | 69.0 |
| Pantoprazole | €33.84 | €6.52 | 80.7 |
| Clopidogrel | €54.45 | €7.58 | 86.1 |
| Pravastatin | €41.55 | €5.27 | 87.3 |
| perindopril | €20.03 | €5.98 | 70.1 |
| Risperidone | €63.33 | €30.97 | 51.1 |
| Ramipril | €16.32 | €3.62 | 77.8 |
| Valsartan | €24.06 | €6.08 | 74.7 |
| Losartan | €27.40 | €6.72 | 75.5 |

## What benefits have generics brought to Ireland's medicines market?

The benefits of a dynamic, competitively-priced medicines market with generics to the fore are clear. They include:

- Enhancing access and affordability of medicines for patients;
- Delivering substantial savings to the Exchequer and taxpayers from generic substitution and reference pricing – €1.6 billion since 2013;
- Funding new and costlier medicines from the savings derived from generic medicines;
- Driving competition in the medicines market to ensure that Irish medicines are competitively priced relative to comparable EU states;
- Creating greater security and sustainability in the medicines market through greater price certainty and affordability;
- Allowing our health service to manage health cost pressures through medicine savings, particularly for community schemes;
- Creating sustainability in the supply of older off-patent medicines by bringing multiple competitors into the market.

## Medicine accessibility and affordability

*Overall, the Department has estimated that it expects pharmaceutical spend by 2020 to be 11% higher than 2016 levels*

Pharmaceutical spend in Ireland is predicted to grow over the coming years because of the pressures outlined above; including an aging population living longer, often with chronic diseases, and the cost of new innovative and increasingly individualised medicines.

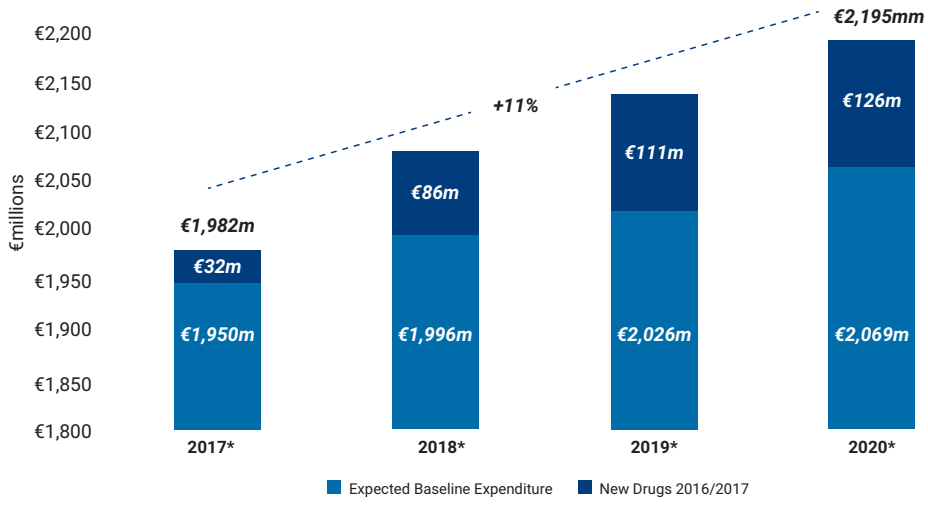
The current rapid growth in hospital expenditure and the high cost of new drugs will be particularly prominent in driving expenditure costs.

As at May 2017, the Department of Public Expenditure estimated that the average annual spend on medicines would increase by 3% per annum.

Overall, the Department has estimated that it expects pharmaceutical spend by 2020 to be 11% higher than 2016 levels or over €200 million.

This level of growth does not include the introduction of any new medications which are likely to be reimbursed by the HSE up to 2020 and only covers those already in use at that date. So, in reality this increase is likely to be even higher.

**Figure 5: Forecast of pharmaceutical spend 2017 - 2020**




### KEY TAKEAWAYS:

The Department of Public Expenditure expects medicine expenditure to 2020, even without any further growth or reimbursements to increase by 11%.

This increase does not allow for reimbursement of any new medicines.

# Future opportunities for reforms and savings

While the 2013 Act introduced a step change in improving affordability and access to medicines for our health service and patients, the changes were a stepping stone only on the road to more extensive reforms.

Government also recognises the need for further reforms. Last year, the Department of Public Expenditure acknowledged the capacity for further pricing initiatives when it noted:

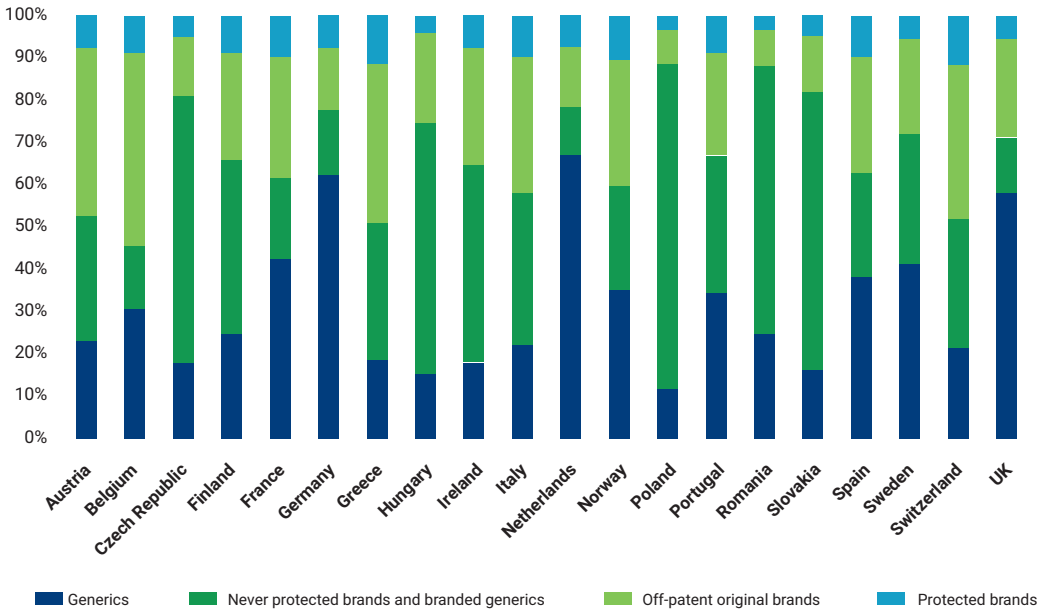
"The vast disparity in price per item across drug categories highlights a clear opportunity to reduce overall costs through facilitating greater use of cheaper equivalents."[15]

Even with the increase in generic substitution since 2013, there is still the capacity for greater generic uptake, when Ireland is compared with its European neighbours. The chart below highlights this fact further.

**15**
Ibid

*The changes were a stepping stone only on the road to more extensive reforms.*

**Figure 6: Protected and off-patent market shares (volume) by country, June 2015**




Sources: QuintilesIMS Health, MIDAS, Q2 2015, retail and hospital channel.
Notes: Non-original brands and branded generics include copy products in some countries; Generics include INN branded and company branded.

# Medicine for Ireland reform proposals

Reference pricing and generic substitution opened up the market for generic medicines and greatly increased our use of generics to treat Irish patients. But reference pricing and generic substitution alone don't capture the range of further savings we can and should continue to make.

Since its establishment, Medicines for Ireland has been advocating for further systemic reforms in a number of key areas of medicines supply and procurement, in line with two broad priorities:

- Encouraging cost-effective prescribing
- Opening the market to greater competition

We have five key reforms which we believe, if implemented, have the potential to deliver savings of up to €138 million, which can be used to fund new medicines and / or other priority areas of our health service.

Our key reform proposals are set out below.

## Reform Proposal One – A new National Pricing Agreement with the generic, biosimilar and value-added medicines industry

*Our industry needs certainty on pricing and future projections for supply in the Irish market.*

The last pricing agreement with the generic, biosimilars and value-added medicines industry was negotiated in 2012 and expired in 2016. Since that date, there has been no updated agreement - despite the fact that a new agreement was concluded with the Irish Pharmaceutical Healthcare Association (IPHA) in July 2016.

Our industry needs certainty on pricing and future projections for supply in the Irish market. A new agreement can also drive further reforms (as detailed below) in the Irish medicines market and deliver additional savings for patients and taxpayers. To this end, we urge the Minister and Department of Health to enter into negotiations with Medicines for Ireland.

**KEY TAKEAWAYS:**

A new pricing agreement with the generics industry is now critical to drive further reforms and savings in the Irish medicines market.

# Reform Proposal Two – Allow for increased use of Biosimilar medicines

Biosimilar medicines represent a significant cost-saving opportunity for the State, providing more affordable alternatives to costly, comparable biologic medicines.

Biosimilars are equivalent versions of biologics, which can be manufactured after the branded biologic goes off-patent. They are subject to the same regulatory and safety checks, and the European Medicines Agency has licenced 38 biosimilars for use in the EU.

These medicines treat a range of conditions including osteoporosis, arthritis, colitis, diabetes and cancer. They also offer scope for significant savings – potentially €25 million - as a starting point, with this figure growing as more biosimilars become available.

However, the uptake in Ireland is extremely low.

The overall percentage uptake for biosimilars versus biologics hovers at around 2% for biosimilars, compared to 98% for biologics. The table below outlines the current market share of biologics vs. biosimilars.

*Biosimilar medicines represent a significant cost saving opportunity for the State.*

Table 4: Current market share of biologics and biosimilars

| Biologic | Volume | % share of the market |
|---|---|---|
| Enbrel | 53,766 | 99% |
| Lantus | 121,943 | 99.8% |
| Neupogen | 21,613 | 86% |

| Biosimilar | Volume | % share of the market |
|---|---|---|
| Benepali | 365 | 1% |
| Abasaglar | 248 | 0.2% |
| Tevagrastim | 3,290 | 13% |
| Accofil | 205 | 1% |

*Data based on IMS figures for January 2018

As was the case with generic medicines, Ireland is slow to embrace change and cost-effectiveness tends not to be a dominant consideration at the point of prescribing. We need to change this.

Putting in place key policy measures to increase the use of biosimilars is vital if we are to attract more biosimilar medicines onto the market and improve their rate of use.

Medicines for Ireland has identified a number of incentivising measures which would help prescribers make the switch to biosimilars.

**Our proposals:**

- Introduce gainsharing, which would allow hospitals which switch to biosimilars to keep a portion of the savings made;
- Introduce quotas which would create a target for prescribing biosimilars, counteracting an aversion to change and creating a culture of cost consideration;
- Introduce a prescriber / patient public awareness campaign about biosimilars, educating on what they are and what they do;
- Promote competition in the market by removing the 30% automatic discount on branded medicines, which is acting as a barrier to new entrants.

*Promote competition in the market by removing the 30% automatic discount on branded medicines.*

**POTENTIAL SAVING: €25 MILLION**

**KEY TAKEAWAYS:**

Ireland's lack of a coherent national approach to promoting biosimilars, as a more affordable alternative to costly and widely used biologics, means patients are missing out on millions in savings.

One year on since it was promised, a National Biosimilar Policy is yet to be published.

# Reform Proposal Three – Increasing competition in the medicines market high-volume, low-value medicine market

## High volume, low value medicine market

Each year, the HSE spends up to €260 million on hundreds of low-value but often high-volume medicines i.e. medicines types each costing the State less than €2 million a year.

Cumulatively, these make up 10-15% of the total medicines budget. In addition, a large number of these medicines currently enjoy a monopoly position in that they are supplied by only one pharmaceutical supplier without any competitors in the market.

This lack of competition can have a particularly detrimental impact for continuity of supply and patient safety if the sole supplier is no longer able to supply the Irish market. Medicine shortages can also have a knock-on effect on the price paid by the HSE for such medicines, with the HSE forced to secure emergency supply of these medicines for several multiples more than the original reimbursement price.

There is currently very little incentive for generic manufacturers to enter this section of the medicines market because the existing price entry point is artificially low. Some medicines in this category haven't seen a price change in decades, making this a neglected, uncompetitive part of the medicines market. In addition, the low-price points have stifled innovation in terms of the launch of new presentations / dosage formulations that may aid patient adherence and ultimately save the government money.

We estimate that up to €75 million could be saved if this market was opened up to competition, negating the costs and patient hardships associated with medicines shortages.

*Lack of competition can have a particularly detrimental impact for continuity of supply and patient safety.*

**POTENTIAL SAVING: €75 MILLION**

**Our proposals:**

- Undertake a full entry pricing review of the high volume/low value medicine market segment, led by the HSE's Corporate Pharmaceutical Unit (CPU), to update pricing of these medicines to reflect market norms;
- Introduce a mechanism to facilitate medicine price increases, where warranted, to ensure greater competition and to safeguard continuity of supply;
- Ensure that the legal requirement for the price of branded medicines to be reduced upon patent expiry is implemented immediately in each case. Currently this does not happen automatically, leaving the State to pay unnecessary higher costs for extended periods.

**KEY TAKEAWAYS:**

The low value / high volume of the medicines market is a significant section of the market, treating tens of thousands of patients and costs the HSE €260 million per annum.

The market is stagnant with minimal competition and €75 million in savings could be realised if the HSE changed its pricing structure.

## Reform proposal four – Allowing all new patients access to generic medicines

Where patent protection has fallen, the majority of medicines are now open to generic substitution; however, this is not the case for a small but notable number of categories of medicines, classified as non-interchangeable by the HPRA.

For newly diagnosed patients commencing treatment, there is no clinical reason why these patients cannot use generic medicines. This currently does not happen, as the provisions of the 2013 Act prevent pharmacists from providing a generic substitute to these patients.

We need change to allow for new patients to be prescribed and dispensed generic medicines from the point at which they commence their treatment.

**Our proposals:**

- Commence an immediate and ongoing review of criteria for non-inclusion of medicines to the interchangeable list, vis-à-vis best practice in other comparable markets;
- Develop an indicative drug budgeting scheme, which incentivises cost-effective prescribing.

*Develop an indicative drug budgeting scheme, which incentivises cost-effective prescribing.*

**POTENTIAL SAVING: €18 MILLION**

(from respiratory products alone)

**KEY TAKEAWAYS:**

The HPRA must undertake an immediate and ongoing review of the medicines deemed non-interchangeable list to ensure that their non-interchangeability remains relevant.

Prescribers need to be incentivised through an Effective Drugs Prescribing Strategy to opt for the most cost-efficient medicine.

## Reform proposal five – Reform of the High-Tech Medicines Scheme

The High-Tech Scheme was introduced to facilitate the supply of certain medicines, e.g. those used in conjunction with chemotherapy, which had previously been supplied primarily in the hospital setting. While these medicines are prescribed in hospital, they are dispensed by a community pharmacy.

In recent years the cost of this scheme has almost doubled by over 96% in the last nine years, with expenditure now over €662 million per annum (from €337 million in 2009) spent on this scheme alone. However, medicines reimbursed as part of this scheme are particularly negatively impacted by a lack of competition, due to a very low usage of generic medicines.

*The costs of this Scheme has almost doubled by over 96% in the last nine years to €662m per annum.*

In the past three years alone, six medicines reimbursed under this Scheme, with a value of over €20 million, have lost patent exclusivity. Yet, generic uptake of these six medicines is below 20% on average. Equally, the use of generic medicines under the High-Tech Scheme remains almost 40% lower than the use of generics in other areas of medicine reimbursement and this is costing the State.

The medicines covered by the High-Tech Scheme should be updated on a more regular basis than is currently the case to ensure that off-patent medicines are open to generic competition. If more medicines from the High-Tech Scheme were open to generic competition, on a par with the overall national usage of generics (58%), then the State would save up to €20 million per annum on these medicines alone.

**Our proposals:**

- Place high-tech solid dose medicines on the interchangeable list immediately following patent expiry;
- Medicines included on the High-Tech Scheme must be open to greater competition.

**POTENTIAL SAVING: €20 MILLION**

# Conclusion

The success of generic substitution is borne out by the huge increase in generic uptake over the past five years since its introduction which, in most circumstances, became mandatory. The increase in usage from 11% to 58% speaks to this success.

However, our medicine budget has begun to creep upwards again, not least due to the increasing population and healthcare demands now placed upon it. At the same time, our uptake of generic medicines is beginning to slow. This must be a cause for concern.

With growing demands and a limited budget, and without further reforming interventions, patient medicine access will suffer. We can see this trend already emerging with the inability of the State to reimburse many new, innovative but high-cost medicines over recent years.

As we have shown throughout this document, there remains many untapped areas of reform within our medicine regime which have the capacity to deliver further savings. The reforms can be implemented in a relatively short space of time if the willingness exists amongst key stakeholders – the Minister and Department of Health, HSE, medical and pharmacy community, patient representatives – to embrace and push through these reforms.

Ireland has a history of missing out on huge savings in the health system, particularly in medicines. Our experience with generic medicines for many years prior to 2013 shows this.

Our reform proposals for the next five years are driven by a desire to create a stable and sustainable medicine supply for all Irish patients. A new structure is now required which recognises the changing market landscape, prioritises further reform of that market and plans for the future needs of patients.

We urge the Minister for Health to now move to engage with relevant stakeholders to implement these proposals.

*Our reform proposals for the next five years are driven by a desire to create a stable and sustainable medicine supply for all Irish patients.*

# About Medicines for Ireland

Medicines for Ireland is a national organisation comprising the leading pharmaceutical companies in Ireland which have united under a common vision for the reform of Ireland's national medicines policy.

Together, we are the largest suppliers of medicines to the HSE. Our members are based across Ireland and collectively employ over 2,500 people in Ireland[15].

## Medicines for Ireland - Our Members

### Accord Healthcare

Accord Healthcare was established in Ireland in 2012 and is one of the fastest growing generic pharmaceutical companies in the country. In early 2017,

Accord Ireland merged with Actavis Ireland resulting in a combined extended portfolio of retail and hospital products, along with an exciting pipeline of value-added products and biosimilar medicines for different therapeutic areas.

Accord's Irish office is headquartered at the former Actavis site, Euro House, in Little Island, Cork. It services the sales, marketing, finance, quality, regulatory and business information needs of the business. Accord Healthcare prides itself on its best-in-market nationwide distribution channels; its ability to adapt to market volatility; its consistency of supply; its ability to supply over 70% of the molecules on the generic interchangeable list; and its quality products.

Approximately 9 million packs of Accord medicine are distributed in Ireland each year. Every 4 seconds a patient somewhere in Ireland takes an Accord medicine. Accord takes this responsibility of providing Irish patients with high quality products very seriously and will continue to offer value, choice, service and support to its range of valued customers across the country into the future.

**15** Through their parent companies, including: Stada (Clonmel), DCC Healthcare (Fannin), Wockhardt (Pinewod), Rowex (Rowa)

## Consilient Health

Consilient Health is a privately owned pharmaceutical company operating in Ireland, Europe and the Middle East, and is headquartered in Dublin. We have an established heritage in the area of contraceptive care and endocrinology. Our focus is to make a positive impact in these therapeutic areas and offer meaningful benefits and educational supports, centred on the needs of the healthcare professional, patient and payer.

## Clonmel Healthcare

Established in 1970, with in excess of 40 years' experience, Clonmel Healthcare continues to supply an extensive range of medicines to the Irish population through pharmacists, and the medical professions. In addition, the company exports product to several regions within Europe. Throughout its long history, Clonmel Healthcare has been and will continue to be a significant contributor to both the national and local economy.

Clonmel Healthcare is part of the international global pharmaceutical company STADA AG which employs more than 10,000 people across 22 countries. Clonmel Healthcare's registered offices are in Clonmel, Co Tipperary. The company currently operates across two locations: administration, logistics, warehousing and regulatory affairs in Clonmel; and sales, marketing and business development in Parkwest, Dublin 12.

Clonmel Healthcare has a number of business divisions in Ireland. Its prescription medicines offer a wide range of generics, branded and hybrid products. In addition, the company has a particular interest with specialised product in the therapeutic areas of neurology, psychiatric, diabetes and osteoporosis. The company is also a leader in over-the-counter medicines through its business unit established in 2007, specialising in analgesia, mother and baby, and dermatological products.

In 2016, Clonmel Healthcare launched its biosimilar division and intends to offer a comprehensive range of product into this space over the next couple of years. Annually, Clonmel Healthcare places 10.8 million packs of medicine into the Irish market. This makes the company one of the top two suppliers in Ireland. Going forward, Clonmel Healthcare has a robust portfolio of new products for all its business divisions.

## Fannin Pharma

Caring for life, at Fannin we provide the medical devices, medicines and diagnostic products that help healthcare professionals and patients across the Island of Ireland and the UK manage illness and restore health. But what we deliver is more than simply the mechanics of treatment. We seek to be the best service provider of medical devices, medicines and services to the healthcare sector.

With the heritage of care-giving dating back to 1829, we have the track record to support our claims. We deliver confidence in our ability and with the backing of DCC, one of Ireland's largest PLCs; we have the financial strength to sustain and develop our business which is underpinned by our dedicated workforce.

Fannin has a strong history in supply of innovative and quality medicines. Originally focused on the hospital sector we have expanded our business to community pharmacy where we now have a substantial presence.

We provide products across a range of therapeutic areas including respiratory, oncology, haematology, anaesthesia, immunology, and infection control. Our portfolio includes well-established brands together with value-based generic products.

All of the products and services provided by Fannin Pharma are backed up by dedicated support teams including customer service, logistics, quality control, pharmacovigilance and medical information.

DCC Vital Pharma develops, manufactures, markets, sells and distributes a broad range of pharmaceutical products in the UK & Ireland. For our international customer base, we provide contract manufacturing services for oral beta-lactams and also licence-out options on our range of our own developed products. DCC Vital group affiliates include Fannin Limited and Athlone Laboratories in Ireland, as well as Kent Pharmaceuticals in the UK.

## Mylan

Mylan is one of the world's leading global pharmaceutical companies and employs approximately 1,600 people in Ireland. Its medicines include vaccines, medical devices, generics, biosimilars, over-the-counter, and brand name products. It provides multiple dosage forms, such as difficult-to-manufacture injectables, transdermal patches and HIV / AIDS therapies.

It has innovative research and development capabilities, a robust pipeline, and is one of the world's largest active pharmaceutical ingredient manufacturers. In addition, every one of its medications meets one global quality

standard, regardless of where it is produced. Its growing portfolio contains approximately 1,400 products that cover virtually every dosage form and therapeutic category.

The company's workforce is approximately 32,000 people strong. It serves customers in approximately 145 countries and territories. In Ireland, with its manufacturing facilities in Galway and Dublin exporting globally, its Global Respiratory R&D Centre in Dublin, and European Business Centre of Excellence in Dublin, Mylan has deep roots in Ireland and is a proven top employer.

## Pinewood Healthcare

Pinewood Healthcare, established in 1976, is a widely diversified pharmaceutical group presently marketing its products in over 30 countries worldwide. Pinewood Healthcare is part of Wockhardt International, a global pharmaceutical Company.

With a highly regarded and recognised brand name, Pinewood Healthcare has a strong and unique position in Ireland and the UK, and increasingly in other European and global markets. Pinewood Healthcare is a recognised manufacturer of liquids, creams, ointments, and powders for the pharmaceutical and medical industries in Ireland and international markets.

Pinewood Healthcare has three sales divisions offering products in the following therapeutic areas: antibiotic, cardiovascular, analgesic, dermatological, opioid, gastrointestinal, CNS, rheumatology, hormonal, urological, dietetic, allergy and respiratory. International Market Pinewood Healthcare manufactures and distributes a wide range of generic ethical and OTC products for the European and world markets. Pinewood Healthcare's dosage forms include: oral liquids and suspensions, non-beta lactam powders, creams, ointments.

Pinewood Healthcare has exported worldwide for over 30 years from the manufacturing site in Co. Tipperary and operates in a first-class internationally recognised facility that offers a professional and quality service to our customers. Pinewood Healthcare manufactures in a GMP environment in compliance with Irish and EC Regulations and has received ISO9001, ISO 13485: 2003 and CE Mark accreditation.

Irish Market Pinewood Healthcare is one of the leading generic pharmaceutical companies in Ireland and as such we are proud to offer the medical community throughout the country the choice to prescribe and dispense quality generic treatments at inexpensive prices. The company markets and distributes a wide range of generic ethical and OTC products direct to retail pharmacies and wholesalers in Ireland from its purpose-built facility in Dublin, ensuring our policy of next-day delivery (same day in Dublin area). Our Retail & Wholesale division supplies over 5.1 million packs annually to the Irish market.

Pinewood Healthcare has a well-established and dedicated Hospital Pharmacy Sales Division and is one of the leading generic suppliers of pharmaceuticals to the Irish hospitals market. The company has an extensive hospital product portfolio covering most therapeutic areas, including biosimilar medicines.

## Rowa Pharmaceuticals

Rowa Pharmaceuticals Ltd. was established in Bantry, Co. Cork in 1959 and is currently exporting to over 80 countries worldwide. Today the company employs over 100 people from their base in Bantry, Co. Cork.

Patient welfare, quality and customer focus are the core values of Rowa Pharmaceuticals Ltd. The company is supported by an experienced and highly skilled workforce.

The main manufacturing focuses in Bantry are liquids ointments and creams. Rowa Pharmaceuticals Ltd. production processes are strongly influenced by the company's German origin. Rowa Pharmaceuticals Ltd. facilities include modern laboratories that meet the highest technological standards, quality assurance procedures, manufacturing, production and packaging facilities, warehouses and storage, administration, export and product marketing.

In 1993, Rowa Pharmaceuticals Ltd. formed a joint venture partnership with Sandoz-Novartis and now today Rowex Ltd. is one of the leading generic companies in Ireland, providing the Irish market with high quality products across a wide range of therapeutic areas including strongly supported OTC brands.

## Teva Pharmaceuticals

Teva Pharmaceuticals Ireland employs over 1,000 people across Ireland, with a number of manufacturing sites and a commercial division in Dundalk.

In 2013, Teva became Ireland's largest generics company (by volume and value) and is also the largest supplier of prescription medicines to Irish patients. Teva now supplies 13% of the total volume prescriptions medicines to the market. Teva places over 13 million packs of medicines on the Irish market each year. Teva's medicine portfolio encompasses a large and growing range of generic medicines together with branded speciality medicines for the treatment of diseases in the areas of central nervous system, cancer, respiratory conditions and pain management.

Teva has an increasing range of biosimilar medicines. In addition, Teva also has a significant over-the-counter medicines range, with many household brands such as Sudocrem, Venos, Infacol, Bisodol.

# Appendix 1 - Case Study Two (Proton Pump Inhibitors)

Proton Pump Inhibitors (PPIs) are medicines used to treat stomach ulcers or gastric reflux. They are the second most used medication in Ireland after statins and, pre-2013, accounted for as much as 10% of the total medicine spend.

In 2013, PPIs were included as part of a Preferred Medicines Management Programme, aimed at ensuring better value and savings for the HSE. The objective has been realised, as the tables below outline. While the volume of PPI usage has grown, the overall spend on these medicines has fallen in recent years.

Over the period 2007 to 2013, an estimated €316 million has been saved through generic substitution and reference pricing.

Figure 7: IMS Units PPI 2008-2017

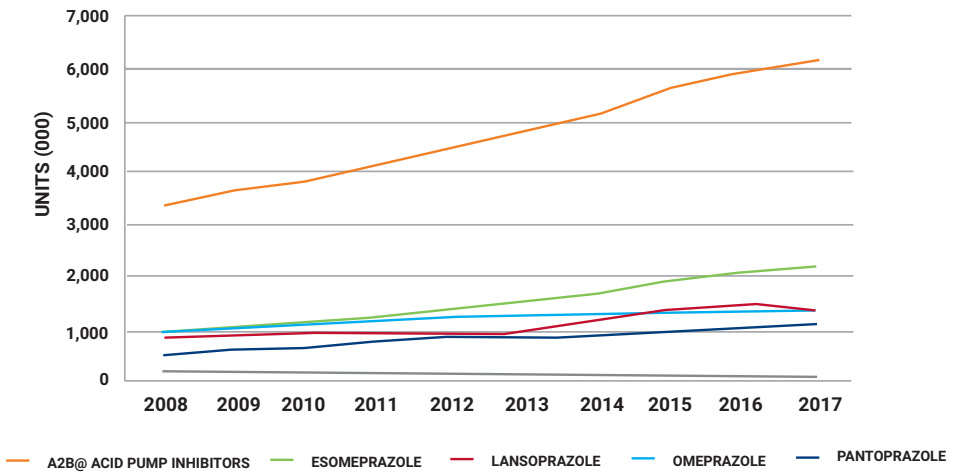
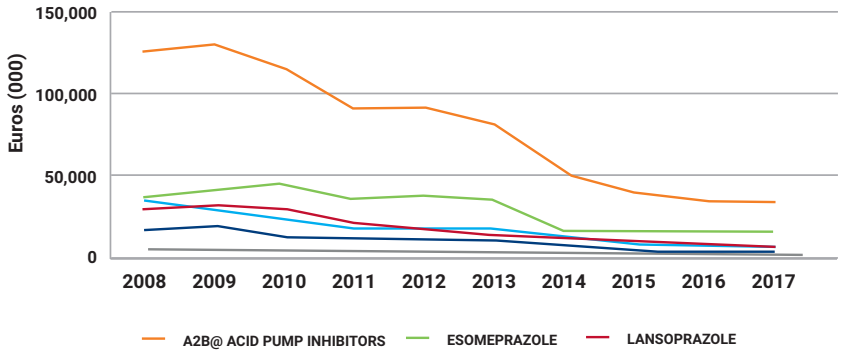



Figure 8: IMS Units €PPIs 2008-2017




Further savings are now being made in these therapy areas by the HSE Medicines management program (Preferred Drug initiative). The availability and continuous supply of cost effective generic medicines has made these savings possible.

# Appendix 2 - Future Challenges

## Falsified Medicines Directive

Medicines for Ireland fully supports the implementation in Ireland of the EU Directive on Falsified Medicines (2011/62/EU). The Directive's objective is to tackle the growing problem of false or counterfeit medicine entering the legitimate medicines supply chain. The Directive states that each eligible medicinal product must have a unique identifier and a tamper-evident seal to allow for the verification of each medicine pack at the point of dispensing.

This verification system must be fully in place by February 2019. Each EU member state must have a single national body to oversee and implement the terms of the Directive in Ireland. In Ireland, this organisation is the Irish Medicines Verification Organisation (IMVO). IMVO has been established through a collaboration between relevant stakeholders in the Irish prescription medicines supply chain.

Medicines for Ireland has been actively involved in the development of IMVO and is committed to ensuring that this system of verification is successfully implemented by the 2019 deadline.

We believe that its implementation will ensure patients are better protected against counterfeit medicines through enhanced traceability and stronger verification processes.

However, it must also be noted that the full implementation of this Directive will add a significant cost and time burden to the pharmaceutical sector, which will exert an upward pressure on medicine prices.

## Brexit

Ireland exports €4.8 billion of pharmaceuticals annually to the UK and consumes €2.9 billion of pharmaceuticals in our pharmacies, and as ingredients in our pharmaceutical manufacturing. These statistics highlight the level of interdependencies which exist between both countries in medicine usage. They also underline the importance of securing cooperation between the UK and EU on medicines regulation.

Whilst we respect the phased approach of negotiations, Medicines for Ireland wants to see progress on these issues made in the negotiations as soon as possible. We urge Brexit negotiators on both sides to agree on a transition period that adequately reflects the time needed by companies, as

well as all relevant authorities at EU and national level, to adapt to changes in view of the UK exiting the EU. The transition period should provide for continued EU-UK partnership on the regulation and supply of medicines to avoid supply disruption while moving forward towards a future cooperation agreement between the EU and the UK.

For our sector, Brexit represents a challenge in several areas, notably regulatory procedures, quality testing of medicines, supply chain, trade, and intellectual property. For example, medicines companies may need to submit applications for the transfer of marketing authorisation for many products, move batch release sites, and duplicate quality testing for products or move personnel into either jurisdiction. This will take a significant amount of time and will result in capacity issues which cannot be resolved before March 2019.

Maintaining good working relationships with the UK's regulatory authority, the MRHA, is essential for the transition period after the UK leaves the EU, so that the pharma and biotech companies here can make the necessary adjustments smoothly.

Brexit creates challenges for both the patients we supply and for the sustainability of the pharmaceutical sector here.

The challenges for patients include the following:

- Border and related time delays, due to more rigid custom controls, pose a risk to short life medicine products and increase patient waiting times where emergency supplies of medicines may be required;
- Custom controls between Ireland and the UK also add to the administrative burden of importing medicines into Ireland, thereby increasing the cost of medicines for our health service and patients;
- With a small market size and new regulatory and customs burdens, Ireland may no longer be an attractive export market for UK medicines manufacturers. This could exacerbate the existing problem of medicines shortage in Ireland. With over 140 medicines currently out of stock, this problem could grow.

For the pharmaceutical sector here, our main concerns over Brexit include:

- The business cost impact of custom inspections and controls, VAT declarations, and lengthy border delays; and
- Differing medicines regulatory regimes between Ireland and the UK, as the latter leaves the European Medicines Agency and potentially opts for distinct regulatory provisions. This will add a new compliance burden and increased manufacturing costs for pharma companies here seeking to export into the UK.
- Companies who rely on their UK affiliates for Pharmacovigilance, regulatory / licencing and Quality expertise will be obliged to duplicate some of their expertise / resource within the EU area. This will also add significant costs.

## Recommended approach

The agreement of transitional arrangements after March 2019 must be prioritised to ensure there is minimal disruption to patients receiving medicines after the UK leaves the EU.

Such a period will be essential in allowing companies to make any necessary changes to marketing authorisations, to their supply chains and to their regulatory procedures to ensure that patients don't experience a disruption to their access to medicines. As such, negotiators should include access to medicines and the implications of Brexit for patients across the EU in the second phase of negotiations and this should be agreed in both the future agreement and in transitional arrangements.

In the longer term, we seek continued cooperation between the EU27 and the UK in medicines regulation. This is necessary to ensure the continued access to medicines for European citizens. For Ireland, it is a particularly acute problem as we are highly reliant on batch-sharing and access to the UK market to maintain the supply of medicines.

# Appendix 3 - Further opportunities for growth of the phamaceutical sector

## SPC manufacturing waiver

Under current EU legislation, generic medicines producers are not allowed to manufacture for commercial purposes during the patent period as it is deemed to infringe patent rights.

In addition to this patent protection, the EU's Supplementary Protection Certificate ("SPC") Regulation allows holders of patents to authorise medicinal products to partially extend their product exclusivity by up to 5 years. The purpose of the legislation was to recompense product-developing companies for the time taken to obtain regulatory approval of their medicines and give them a longer market monopoly in the form of an SPC.

However, currently the SPC Regulation has the unintended effect of putting the European generic medicines industries at a competitive disadvantage vis-à-vis manufacturers producing in non-EU countries where no similar patent/SPC protection exists.

The latter can take advantage of export markets years earlier than European producers and enter the EU market immediately once the SPC expires in Europe. Therefore, European manufacturers are currently required to outsource production outside Europe to supply countries without SPCs or where SPCs expire earlier than in Europe, and to provide competition as soon as SPCs expire in Europe.

Medicines for Ireland recommend an SPC manufacturing waiver which would:

- Allow European pharmaceutical producers to start manufacturing generic medicines during the SPC period to export to countries where IP protection is no longer in place;
- Resolve the competitive disadvantage of European producers vis-à-vis producers in other regions with less rigid IP systems;
- Avoid forcing European producers to invest abroad to seize business opportunities in unprotected markets;
- Have no impact on originator industry IP protection;
- Provide an opportunity to maintain and create high tech jobs in Europe, including manufacturing and R&D;
- Make it easier for regulators to deal with local manufacturing;
- Be important for security of supply (e.g. there is limited anti-biotic production left in Europe).

# Tables and figures

## Tables



## Figures

medicines for ireland

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