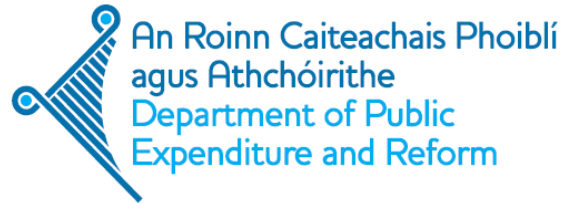




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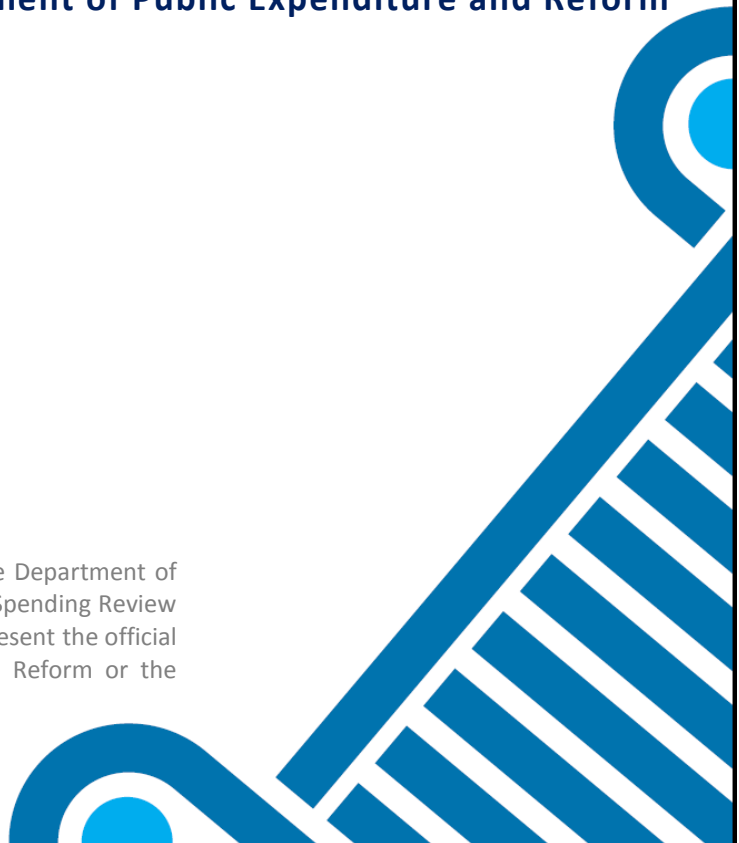
Spending Review 2017

Future Sustainability of Pharmaceutical Expenditure

May, 2017

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This paper has been prepared by IGEES staff in the Department of Public Expenditure & Reform in the context of the Spending Review 2017. The views presented in this paper do not represent the official views of the Minister for Public Expenditure and Reform or the Department of Health.



Summary

Total public expenditure on pharmaceuticals (ingredient cost) totalled €2 billion in 2016. This is split across Acute Hospitals, Primary Care Reimbursement Service (PCRS) and Local Schemes.

The key drivers of pharmaceutical expenditure are High-tech drugs and new hospital drugs.

- Expenditure on High-tech drugs increased by €250m or 76% over the period 2009-2016. High-tech drugs are generally only prescribed or initiated in hospital, they include items such as anti-rejection drugs for transplant patients or medicines used in conjunction with chemotherapy.
- In 2015, pharmaceutical expenditure in hospitals totalled €363m. Expenditure is on an upward trajectory, increasing annually by 8% in the past two years.

In 2014, Ireland ranked among the highest in terms of pharmaceutical spend per capita. This high spend was supported by both higher-than-average prices as well as a high medicine consumption per capita. Some positive developments have been made in the pharmaceutical policy area in 2016, such as a new industry agreement, these will improve Ireland's international position. An updated international benchmarking exercise is expected to be published by the Department of Health in 2017.

The State entered a framework agreement with industry for the supply and pricing of medicines in 2016.

The savings from this agreement will provide headroom to fund a limited level of growth in the existing stock of medicines over the coming years while the ability to introduce new drugs remains a significant challenge.

Funding new innovative medicines is a significant challenge in the future. Given the continued advancements in technology, the scale of new drugs coming on stream has increased considerably. This pressure is further exacerbated through the high price attached to these new treatments.

Reform Agenda: *Other levers available to better manage pharmaceutical expenditure.*

1. Internal Reference Pricing

2. Biosimilar Policy

3. Prescribing Protocols

4. Arrangement of Community Schemes

Introduction

Pharmaceuticals are a major component of health care expenditure. The significance of the sector means that the level of resources allocated to the reimbursement of pharmaceuticals impacts overall growth trends. According to the OECD, the rapid increase in pharmaceutical expenditure historically has been a major contributor to overall growth in health expenditure. Consequently, highlighting the need for better management of pharmaceuticals across growing economies.

The objectives of this paper are to:

- Provide a brief overview of the composition of pharmaceutical spend in Ireland
- Set out the key trends in the pharmaceutical area covering both historic trends and trends in an international context
- Summarise the future trends in the pharmaceutical sector in terms of expenditure pressures
- Set out components of the reform agenda to manage growth in spend on pharmaceuticals in the future

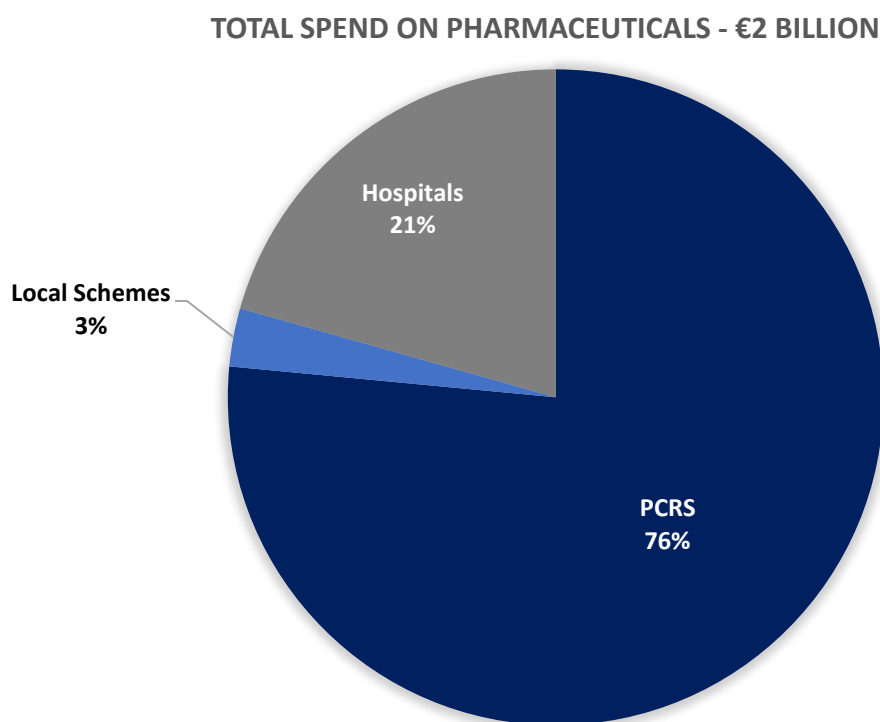
1. Overview of Pharmaceutical Spend

This paper focuses on the reimbursement price (ingredient cost) of medicines and does not include payments made to pharmacies. Pharmacy payments include dispensing fees and patient care fees paid to pharmacies under community schemes.

Expenditure in this instance covers the price the State pays manufacturers for medicines. This price is the reimbursement price (ingredient cost) of a drug and consists of two component, the ex-factory price and the wholesale mark-up.

- The **ex-factory price of a medicine** is set under national pricing frameworks and underpinned in primary legislation titled the Health (Pricing and Supply of Medical Goods) Act 2013.
- The **wholesale mark-up** is set out in statutory instruments. The current statutory wholesale mark-up is 8% for room temperature medicines and 12% for medicines which require refrigeration.

In 2016, Ireland's total drug spend was €2bn with spend split across community and hospital setting. The three key areas of drug spend include Primary Care Reimbursement Service (PCRS), Local Schemes and Acute Hospitals. The following diagram outlines the breakdown of Ireland's total spend according to cost of drugs dispensed across each sector and class of drug.



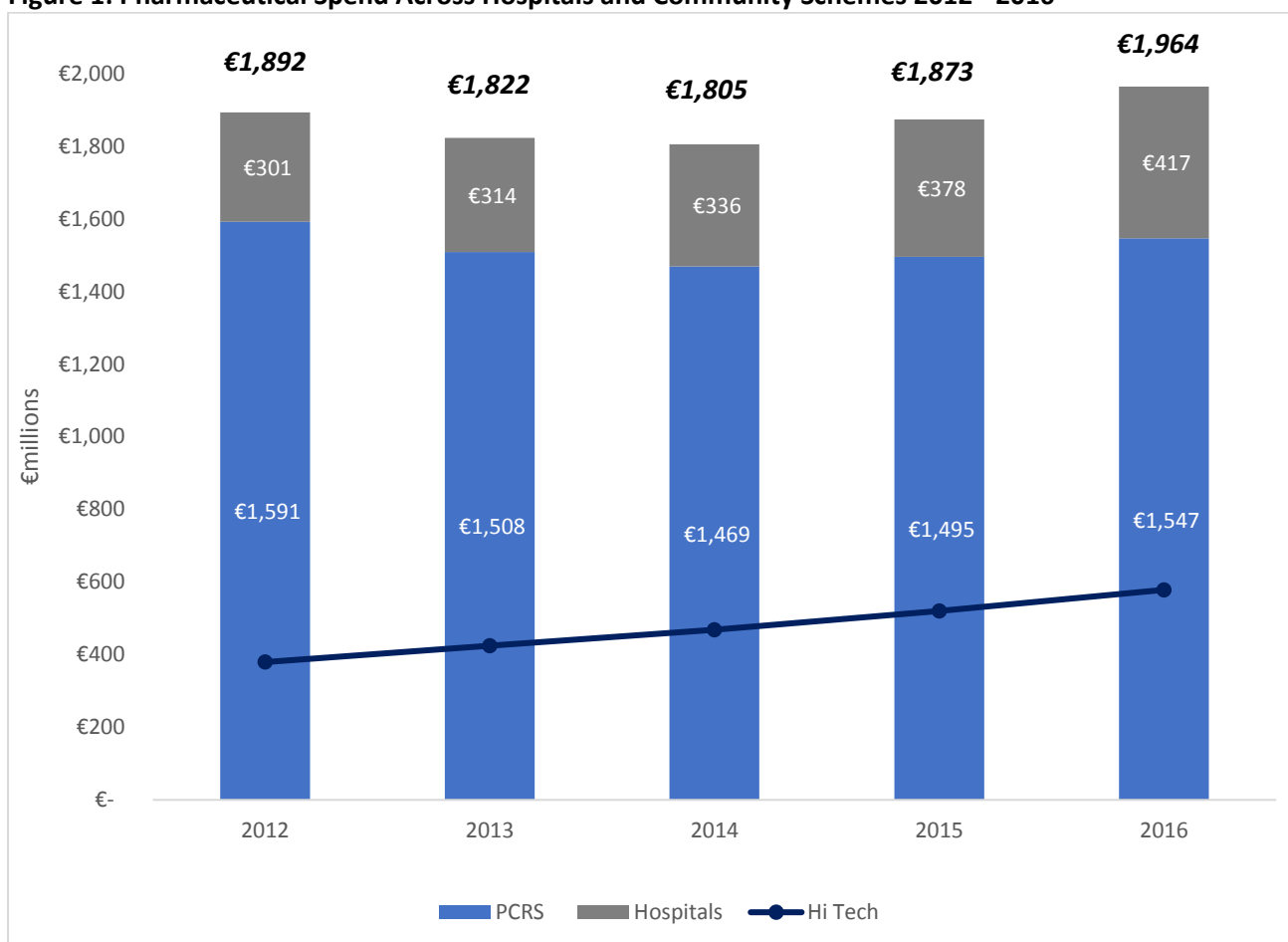
Source: HSE Correspondence

2. Trend Analysis

Expenditure

Pharmaceutical expenditure has fluctuated over the period 2012 to 2016. Spend on some community schemes¹ decreased from 2012 to 2015 as a consequence of the introduction of a number of measures tightening eligibility and reducing supplier fees. These decreases have been offset by increases in High-tech medicines. Expenditure on the High-tech scheme has continually increased over the period with High-tech spend increasing by €270m or 76% over the period 2011-2016. The continued growth in High-tech is driven by the introduction of new medicines and the extension in indications of existing medicines. Most drugs in the High-tech space are innovative drugs and spend on these drugs has been increasing rapidly, primarily due to increasing volume and associated high prices.

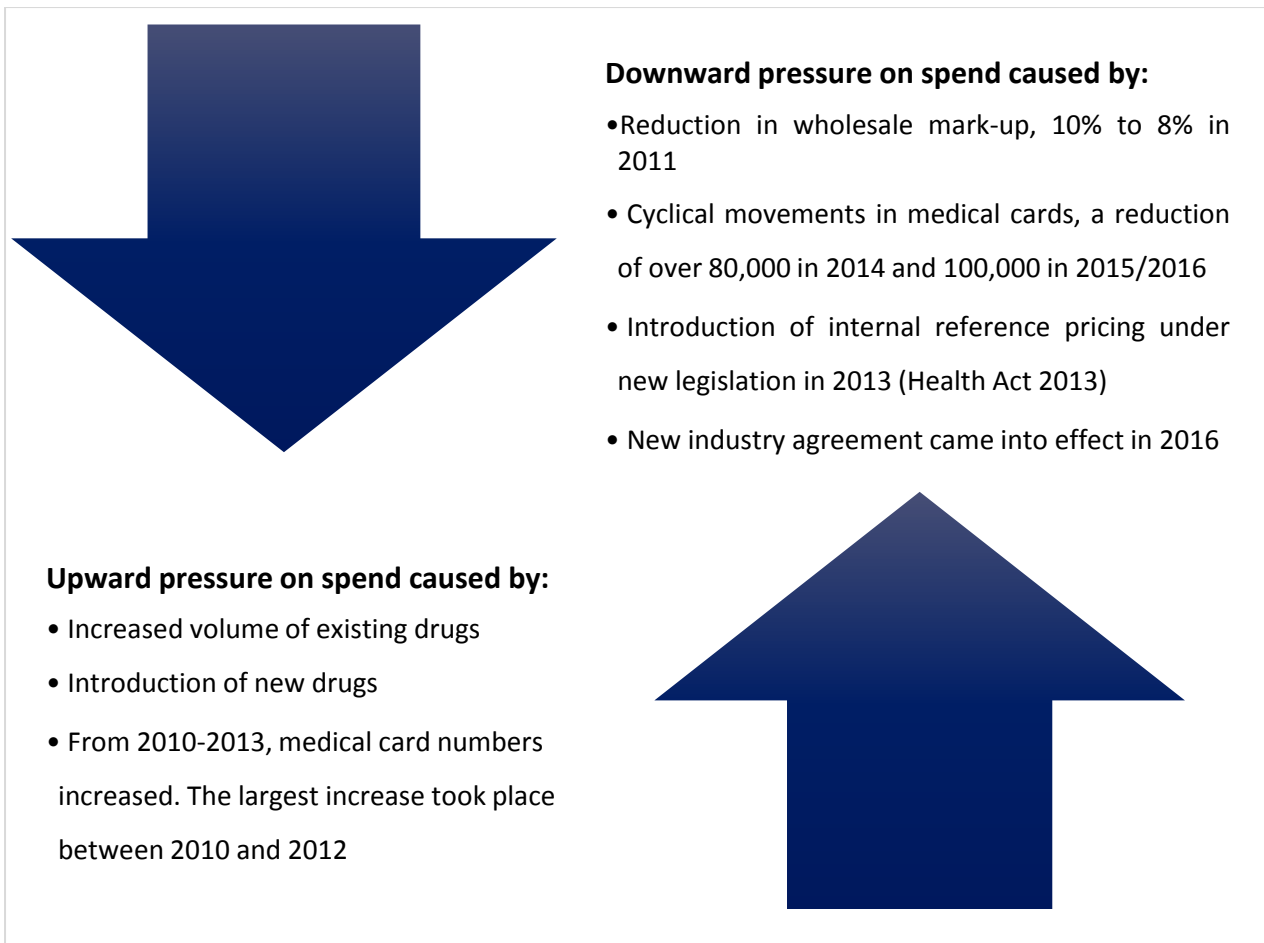
Figure 1: Pharmaceutical Spend Across Hospitals and Community Schemes 2012 - 2016



Source: PCRS Statistical Reports and HSE Hospital Data

See below for upward and downward pressures supporting the trends in spend shown in Figure 1:

¹ General Medical Services (GMS), Drug Payment Schemes (DPS), Long Term Illness (LTI)



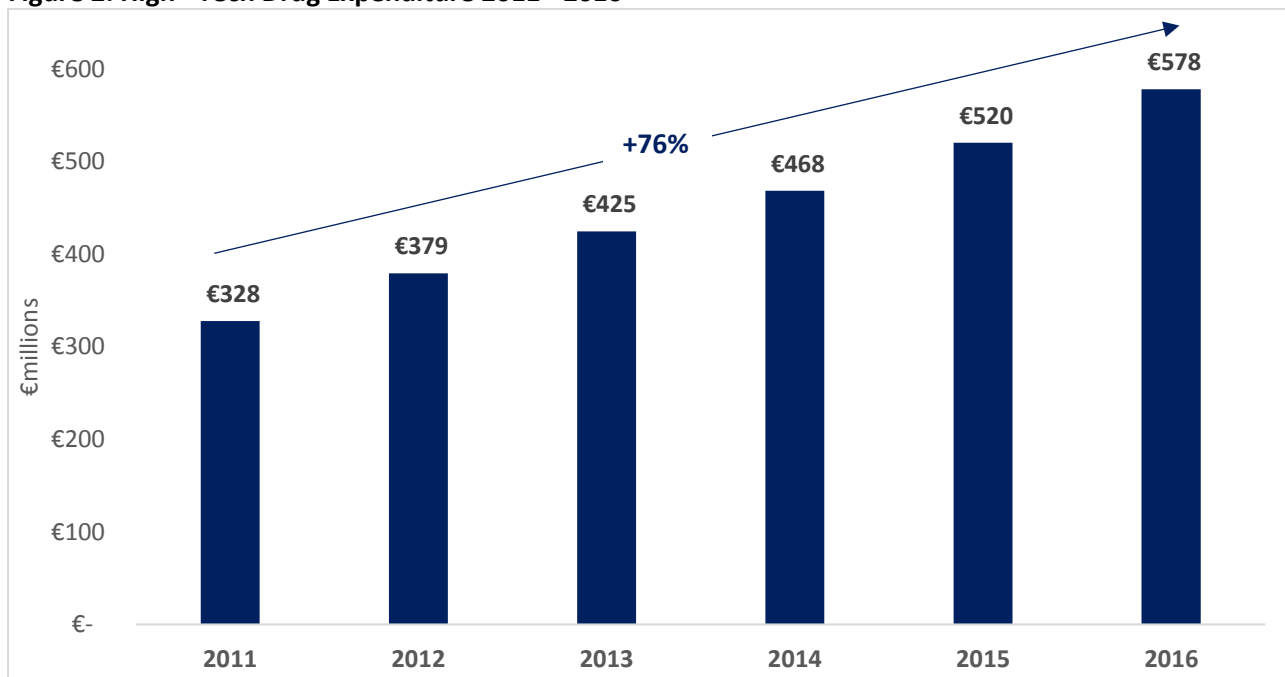
Key Drivers of Pharmaceutical Expenditure include:

[1] High-Tech Drugs

Expenditure on the High-Tech Scheme in 2016 totalled €578m, this figure excludes patient care fees paid to pharmacies. The scheme accounted for 30% of the state’s total drugs bill in 2016. The scheme is dominated by on-patent drugs which tend to be highly expensive innovative drugs.

Generally, High-tech drugs are only prescribed or initiated in hospitals these include items such as anti-rejection drugs for transplant patients or medicines used in conjunction with chemotherapy. The primary rationale for the scheme was to supply certain drugs in a community setting which had previously only been available in hospitals. High-tech medicines are purchased directly from wholesalers/suppliers by the HSE and supplied through community pharmacies for which pharmacists are paid a patient care fee. These drugs are provided under both the General Medical Services (GMS) scheme to medical cardholders and various other community schemes. The exact entitlements provided to patients under the High-Tech Scheme are set out at **Appendix 1**. See **Figure 2** below for spend on High-tech drugs from 2011 – 2016.

Figure 2: High - Tech Drug Expenditure 2011 - 2016



Source: PCRS Data. *Spend relates to ingredient cost of High-tech drugs and excludes patient care fees paid to pharmacies.

Over the period 2011 – 2016, expenditure on High-tech drugs increased by €250m or 76%. This level of growth is considerable given that High-tech drugs added an additional €50m on average to the overall health expenditure each year from 2011 – 2016. There are two key drivers of spend on High-tech drugs, these include growth in the stock of existing medicines in the system and the cost of new medicines. Understanding the multi-annual cost implication of introducing a new drug to the reimbursement list is crucial to identifying underlying growth in pharmaceutical expenditure. Once a drug is introduced in the health system the budget impact grows considerably from the year one cost, this is primarily due to a volume effect as utilisation increases. See **Table 1** below for a breakdown of the annual cost of introducing a new drug into the system. While the year 1 cost of the drugs in Table 1 is minimal at €1m, this year 1 cost is only 4% of the cumulative 5 year budget impact of the drug of €19m.

Table 1: Multi-annual budget impact of introducing new drug X² in 2016

	€m	% of 5-year cost
2016	1	4%
2017	3	13%
2018	4	22%
2019	6	30%
2020	6	31%
5-Year Impact: - €19m	19	100%

Source: PCRS Data

² Drug name withheld for the purpose of confidentiality.

There are large variations in growth in spend on existing drugs versus growth in spend on new drugs on the High-tech scheme. From 2014 to 2016, spend on High-tech drugs is expected to grow by €110m and of this increase, 65% related to spend on new drugs introduced from 2012-2016 while the remaining 35% related to the pre-2012 stock of medicines.

Table 2: Drivers of High-tech Spend 2014 – 2016

	2014	2015	2016	Growth	
	€m	€m	€m	€m	%
Hi-Tech Spend	468	520	578	110	24%
<i>Of which;</i>					
New drugs introduced 2012-2016	74	111	146	72	65%
Existing Stock pre-2012 drugs	394	410	432	38	35%

Source: HSE Correspondence

[2] New Hospital Drugs

In 2012, drug expenditure in hospitals totalled €301m and since this time this expenditure in hospitals has been on an upward trajectory with spend increasing by an annual average of 9% over the period 2012 to 2016. On a no policy change basis, this growth is expected to continue in 2017 and beyond as a number of new oncology drugs were introduced in 2016.

The number of hospital drugs coming on stream is set to increase significantly in the coming years, primarily in the area of oncology. Cancer is the therapeutic area with the highest expected spending growth driven by new drug approvals and the increasing incidence of cancer worldwide (IMS Institute for Healthcare Informatics, 2014). This considerable growth in oncology drug spend has also been experienced in Ireland.

Table 3: Growth in New Oncology Drugs introduced since 2012

	2012	2013	2014	2015	2016	Growth 2012 - 2016	
	€m	€m	€m	€m	€m	€m	%
New Oncology Drugs	€4	€5	€8	€14	€27	€23	583%
Annual Growth (€m)		€1	€3	€6	€14		
Annual Growth (%)		22%	66%	68%	101%		

Source: HSE Correspondence

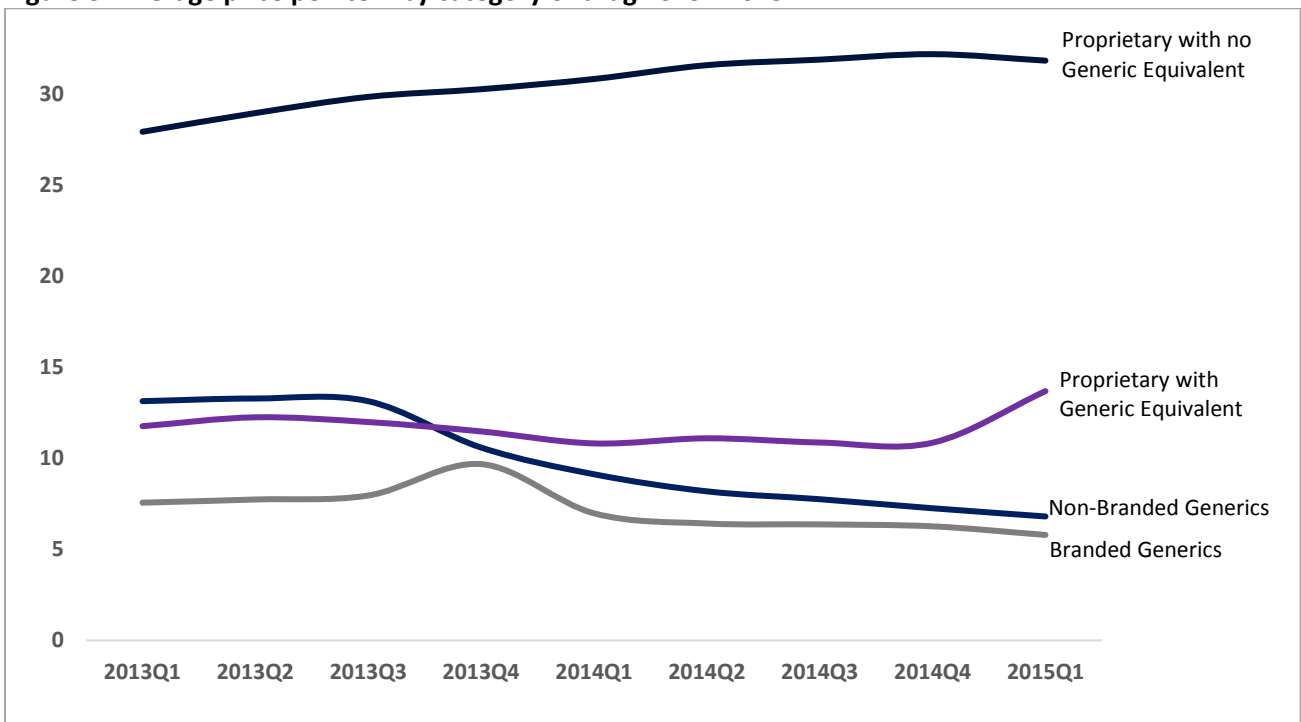
Price and Volume

The price paid for pharmaceuticals is dependent on the medicines classification, this is primarily based on the drugs patent status and/or the number of manufacturers. Broadly, pharmaceuticals fall into two categories; on-patent and off –patent. However within these categories additional classifications exist, these classifications are set out as follows:

<i>On – Patent</i>	1. Proprietary with no generic equivalent	<ul style="list-style-type: none"> Drugs in this category all hold a monopoly, either due to patent protection or due to no other identical product being available
<i>Off-Patent</i>	2. Proprietary with generic equivalent	<ul style="list-style-type: none"> Proprietor products which no longer have patent protection and generic versions have already launched
	3. Generics	<ul style="list-style-type: none"> Generic pharmaceuticals enter the market once the proprietor product no longer has patent protection. Generic pharmaceuticals can be either branded or non-branded.

The average price per item changes significantly across drug categories. **Figure 3** shows historical price differentials across key drug categories in Ireland.

Figure 3: Average price per item by category of drug 2013 - 2015

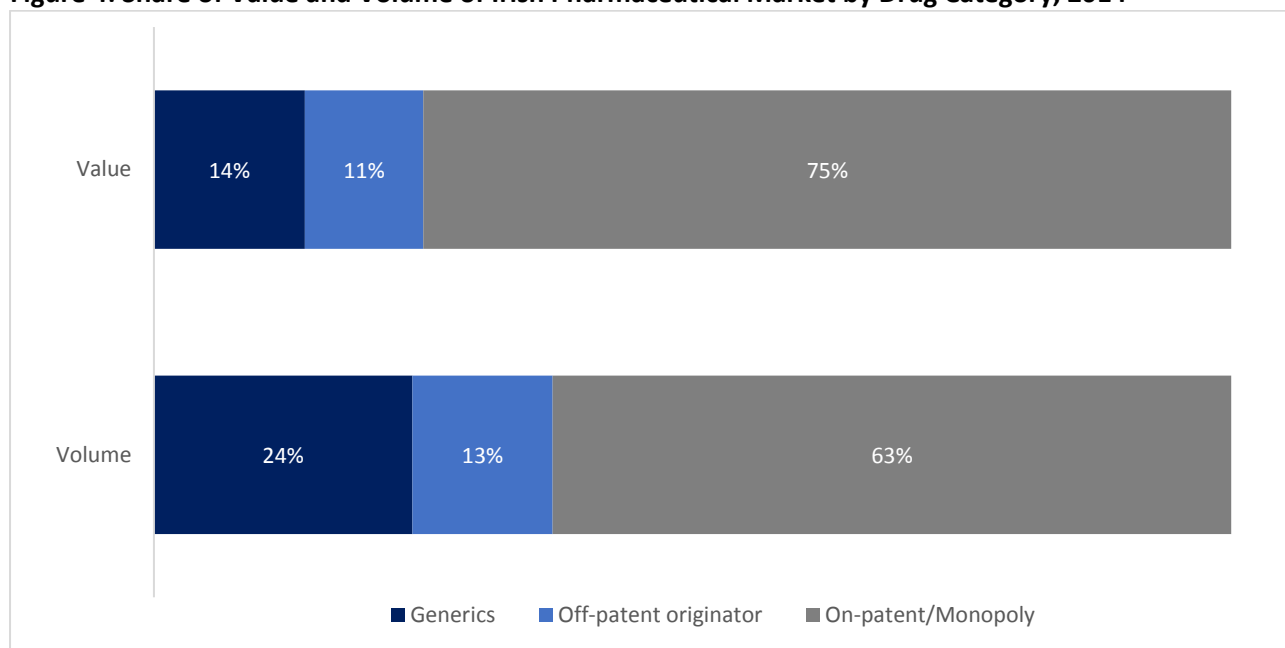


Source: PCRS Administrative Data

On-patent products are more expensive than their off-patent counterparts with proprietary medicines typically remaining more expensive. Since the end of 2013, the price per item for proprietary medicines with generic equivalents has been only slightly higher than generic products, while the price of proprietary medicines with no generic equivalent remained substantially higher. The average price per item of a proprietary medicine with no generic equivalent stood at €32 per item in 2015 compared to just €7 for a branded generic.

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. The penetration of generic products in the Irish market is considerably low at 24% in comparison to 63% for on-patent products. **Figure 4** below demonstrates the share of both value and volume held by each drug category in the Irish market.

Figure 4: Share of Value and Volume of Irish Pharmaceutical Market by Drug Category, 2014



Source: PCRS Administrative Data

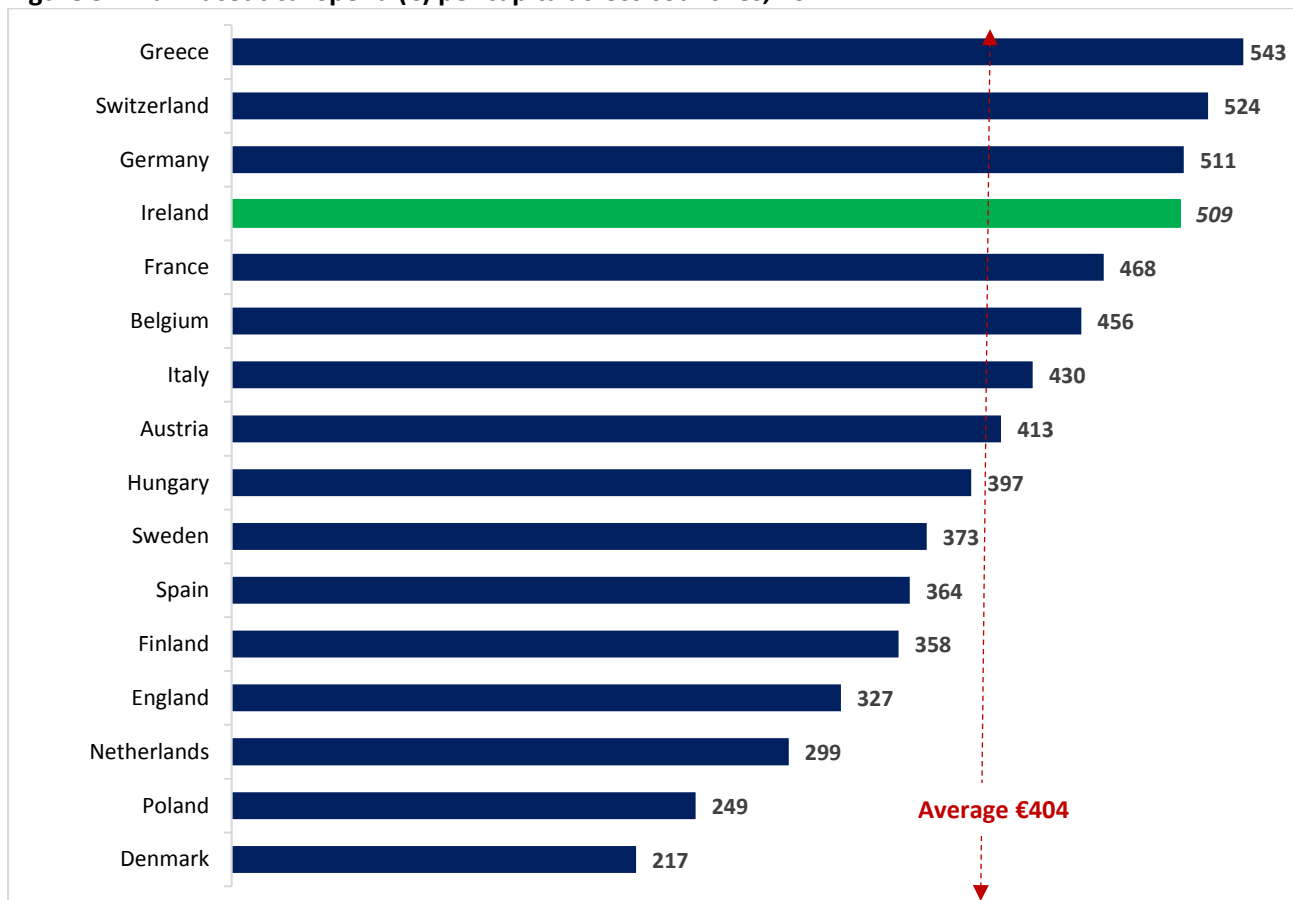
3. Irelands International Position

I. Per Capita Pharmaceutical Consumption

Trends in pharmaceutical spending result from changes across three key elements, these include, prices of existing drugs; volume of drugs consumed; and the therapeutic mix of medicines used. These individual components are driven by a range of factors associated with demographics and epidemiologic trends, dynamics of each pharmaceutical market (entry of new medicines and patent expiries), changes in medical practice and pharmaceutical policies. These factors are not mutually exclusive and therefore can interact differently across countries and therapeutic areas.

Figure 5 sets out pharmaceutical spend per capita across a selection of countries including all countries in Ireland's reference basket. Ireland is ranked among the highest in terms of pharmaceutical spend per capita. This high spend is supported by both higher-than-average prices across all drug segments as well as a high medicine consumption per capita. Ireland's pharmaceutical spend per capita ranks highest in the reference basket except for Germany. The average spend per capita across selected countries is €404 however Ireland's is much higher at €509.

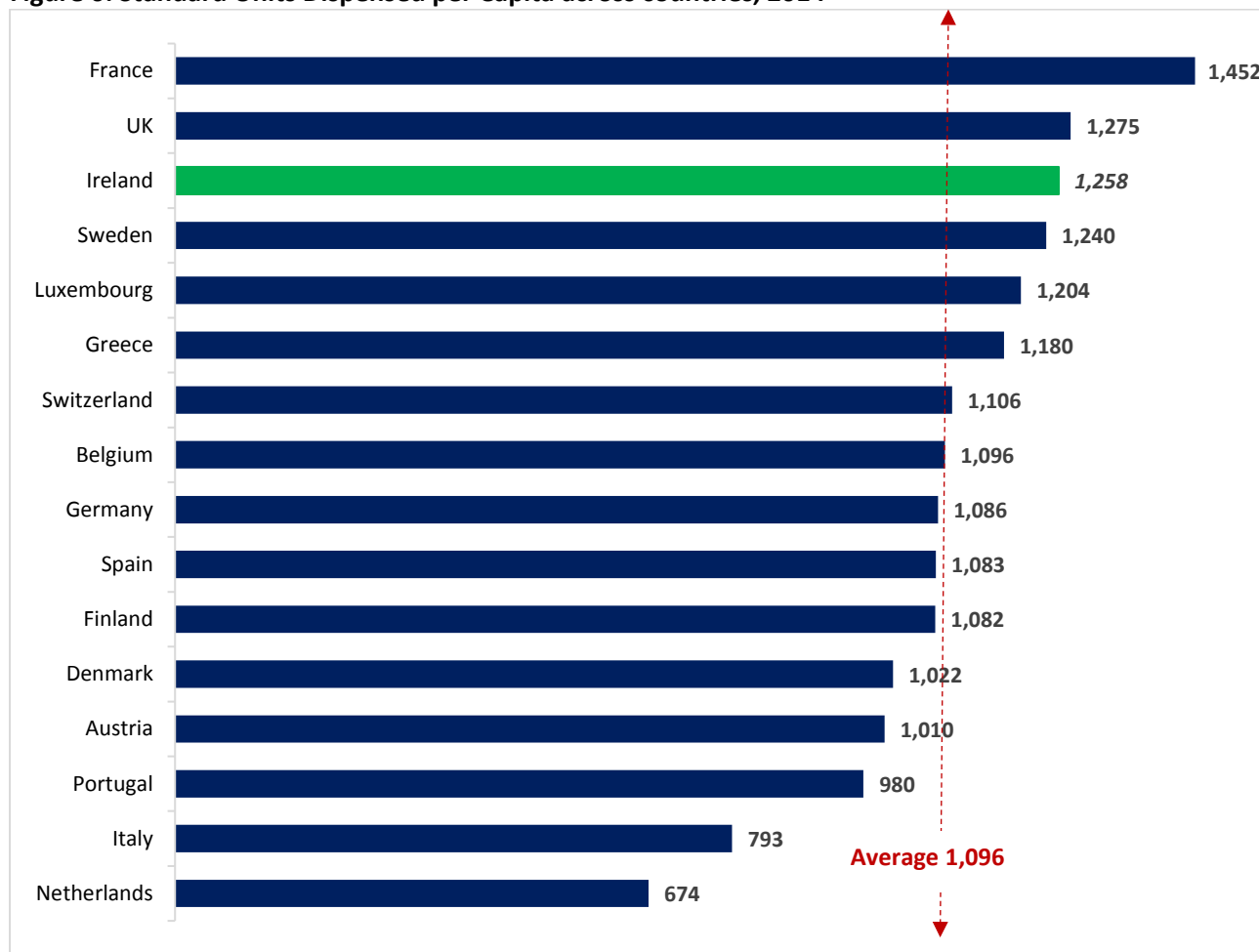
Figure 5: Pharmaceutical Spend (€) per capita across countries, 2014



Source: OECD Database

Accompanied with pharmaceutical spend per capita, another metric used to assess consumption is standard units dispensed per capita generating a view of volume across countries. **Figure 6** shows the number of standard units dispensed per capita across countries for which data is available.

Figure 6: Standard Units Dispensed per Capita across countries, 2014



Source: OECD Database

In 2014, Ireland dispensed a high volume of pharmaceuticals and ranked one of the highest countries in terms of units dispensed per capita. The UK and France are the only two countries to place ahead of Ireland. Despite ranking above Ireland on this metric, France is below Ireland in terms of spend per capita, suggesting that in 2014 France paid a lower price for pharmaceuticals than Ireland. The average units dispensed per capita across the chosen set of countries is 1,096 units, Ireland's volume is much higher at 1,258 units per capita.

The subsequent section outlines Ireland's international position in terms of price and volume across broad drug categories; on-patent medicines and generic medicines.

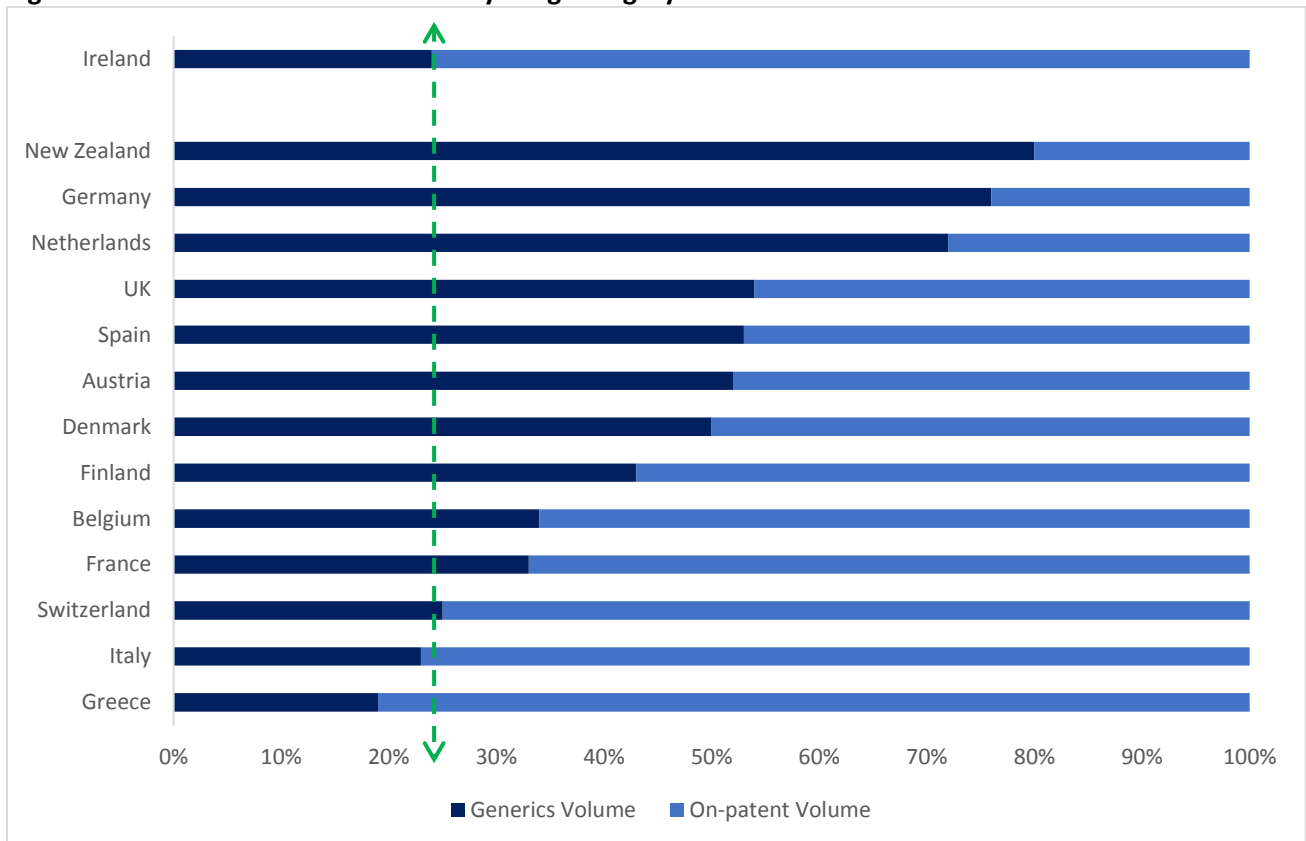
II. Value and Volume of Medicines

Predominately drugs with exclusive supply or on-patent drugs represent the largest proportion of spend across markets. However, the cost of these medicines varies and the list of these drugs also varies year to year as some drugs lose patent and other drugs are introduced. As these drugs are more expensive than drugs with non-exclusive supply, countries attempt to keep penetration low. Therefore, lower volume levels of on-patent medicines largely provide a better position in terms of overall spend.

Generic prices are substantially lower than originator products therefore high usage of generic products across markets corresponds to significant savings. Ireland had one of the lowest levels of generic penetration across its basket countries in 2014. **Figure 7** illustrates the share of volume split by generics and on-patent drugs in Ireland compared to other countries, including countries in Ireland’s reference basket.

As shown in **Figure 7** below, Ireland has the lowest level of generic penetration across basket counties with only two other countries, Italy and Greece, reporting slightly lower generic volume than Ireland. This in turn provides that Ireland has a very high penetration of more expensive on-patent medicines compared to most other comparator countries. The volume/value mismatch in Ireland indicates the scope of opportunity in the generic market in terms of pricing and usage of generic products. The scope for reform in this area is discussed in further detail in Section 5.

Figure 7: Breakdown of Total Volume by Drug Category across Basket Countries and Others in 2014



Source: IMS Institute for Healthcare Informatics

The international evidence set out above describes Ireland's position in 2014. However, since this time a number of positive developments have been made to improve the price Ireland pays for pharmaceuticals, primarily through the signing of a new agreement with pharmaceutical industry in mid-2016. An updated international benchmarking exercise is expected to be conducted by end 2017.

4. Future Pressures in Pharmaceutical Sector

Drivers of pharmaceutical spend can be split into three key components: changes in prices, changes in quantity and changes in the therapeutic mix. These components, in turn, are influenced by a range of factors which can be classified as: demand for health care, dynamics of the pharmaceutical market, and pharmaceutical policies. The interaction between the changing dynamics of the aforementioned factors influences the level of pharmaceutical spend (Callaghan and Connors, 2017). Given that each of these factors varies across markets, different levels of growth are seen in various countries. This sections describes expected future pressure in pharmaceutical spend in Ireland.

Key components of future expenditure pressures include:

➤ High Priced Innovative Drugs

Both the pipeline and baseline of innovative drugs is a key driver of the rapid growth in forecast spend. Drugs in the innovative segment are set to grow at annual rate of 35%. The high price of these drugs is a considerable barrier to access. Given the budgetary constraints within which countries operate, the high price sought for these drugs is one of the key challenges in providing access to medicines in the future. This challenge is further exemplified by the scale of new drugs in the pipeline, due to continued advancements in technology. It is imperative that pharmaceutical expenditure is managed effectively in order to provide some scope for the introduction of new medicines in the future.

➤ Hospital Drug Spend

The number of hospital drugs coming on stream is set to increase significantly in the coming years, primarily in the oncology area. Cancer is the therapeutic area with the highest expected spending growth, driven by new drug approvals and the increasing incidence of cancer worldwide (IMS Institute for Healthcare Informatics, 2014).

Future Spend on Pharmaceuticals in the Irish Market

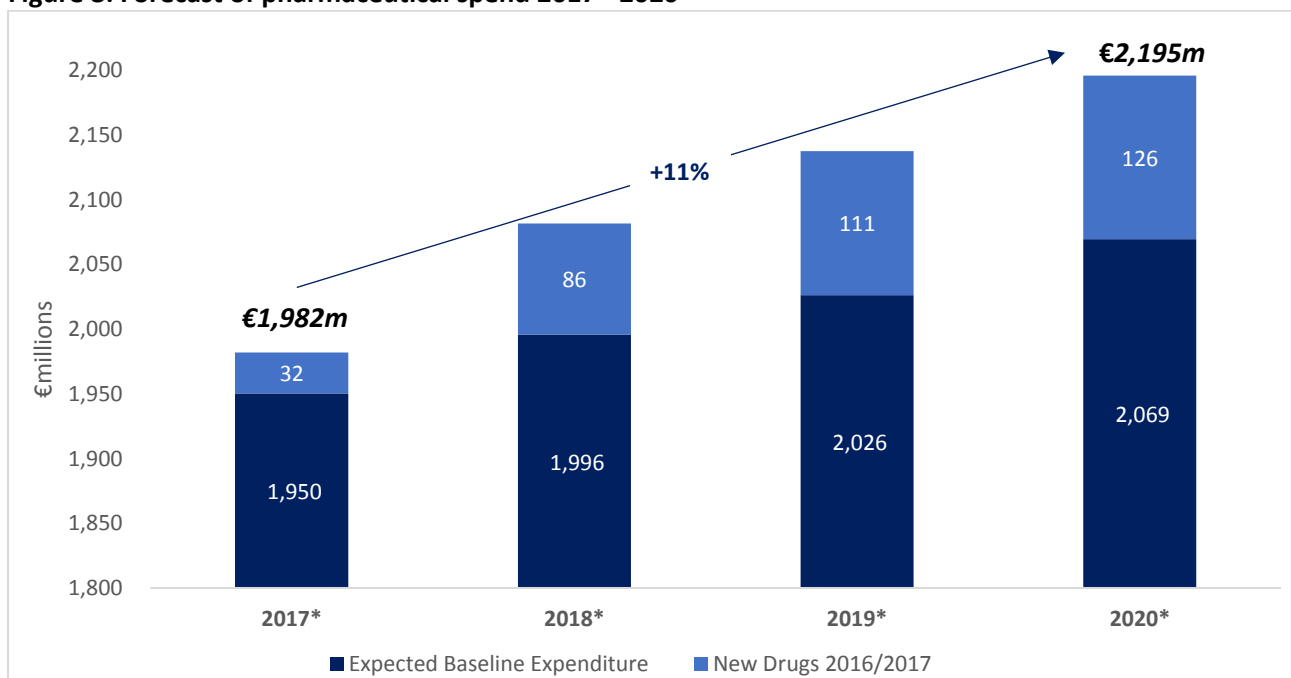
Pharmaceutical spend in Ireland is expected to continue to increase over the coming years due to the pressures outlined above, the rapid growth in hospital expenditure and the pipeline of new high cost drugs. The average annual increase in drug spend is estimated at 3% out to 2020, this does not include the introduction of new drugs beyond those already introduced in the system as at May 2017.³ The forecast only includes drugs already introduced in the health system and currently being used to treat patients.

“In 2020, Irelands total pharmaceutical spend is estimated to be 11% higher than 2016 levels”

Pharmaceutical expenditure is forecast to remain relatively flat from 2016 to 2017 at around €1.9bn. This is due to a number of positive developments in the pharmaceutical area, such as reductions in medical card numbers and implementation of the new IPHA agreement. From 2016 to 2020, overall pharmaceutical expenditure is expected to increase by €212m or 11%. This increase in expenditure is largely driven by new drugs introduced in 2016/2017, the baseline expenditure⁴

Figure 8 illustrates the extent of growth in pharmaceutical spend expected in Ireland from 2016 to 2020 without the introduction of any new drugs beyond those introduced in 2016 and June 2017 (YTD). This forecast expenditure is broken down by baseline expenditure and spend on new drugs introduced in 2016 and 2017 (June YTD), this includes Orkambi.

Figure 8: Forecast of pharmaceutical spend 2017 - 2020



Source: PCRS Data, Authors Calculations

³ The only exception being Orkambi as this funding level has been agreed by Government.

⁴ Baseline expenditure includes spend on all medicines introduced in 2015 and pre-2015.

Irish Pharmaceutical Healthcare Association (IPHA) Agreement 2016⁵

The State entered a Framework Agreement with IPHA for the supply and pricing of a large segment of medicines (mainly patented or monopoly drugs) in 2016. This is a key component in containing pharmaceutical costs and delivering value for money. The agreement includes the coordination of a range of policy levers, see the table below for the list of policy levers included in the 2016 agreement.

<i>Levers</i>	<i>IPHA Agreement 2016</i>
<i>External Reference Pricing: Basket Composition</i>	Basket extended from 9 to 14 countries ⁶
<i>External Reference Pricing: Methodology</i>	Average
<i>External Reference Pricing: Frequency</i>	Annually
<i>Rebate</i>	5.25% rising to 5.5%
<i>Small Molecule Price reduction on loss of exclusivity⁷</i>	50%
<i>Hospital Rebate (Additional on the current 15%)</i>	5.25% rising to 5.5%
<i>Biologic Price Reduction</i>	30%

Source: IPHA Agreement <http://health.gov.ie/wp-content/uploads/2016/07/Framework-Agreement-on-the-Supply-and-Pricing-of-Medicines-signed-copy.pdf>

Under a no-policy change scenario, Ireland’s spend on pharmaceuticals had the potential to increase by 33% over the period 2014 to 2019 (Callaghan and Connors, 2017). This projected growth in baseline pharmaceutical spend was due to rapid growth in the volume of existing drugs and the associated high cost. The new IPHA Agreement has assisted in containing some growth in spend on existing drugs in the system through price reductions as a result of implementing the various policy levers outlined above. See **Figure 9** below for the impact of the IPHA agreement on spend on existing drugs.

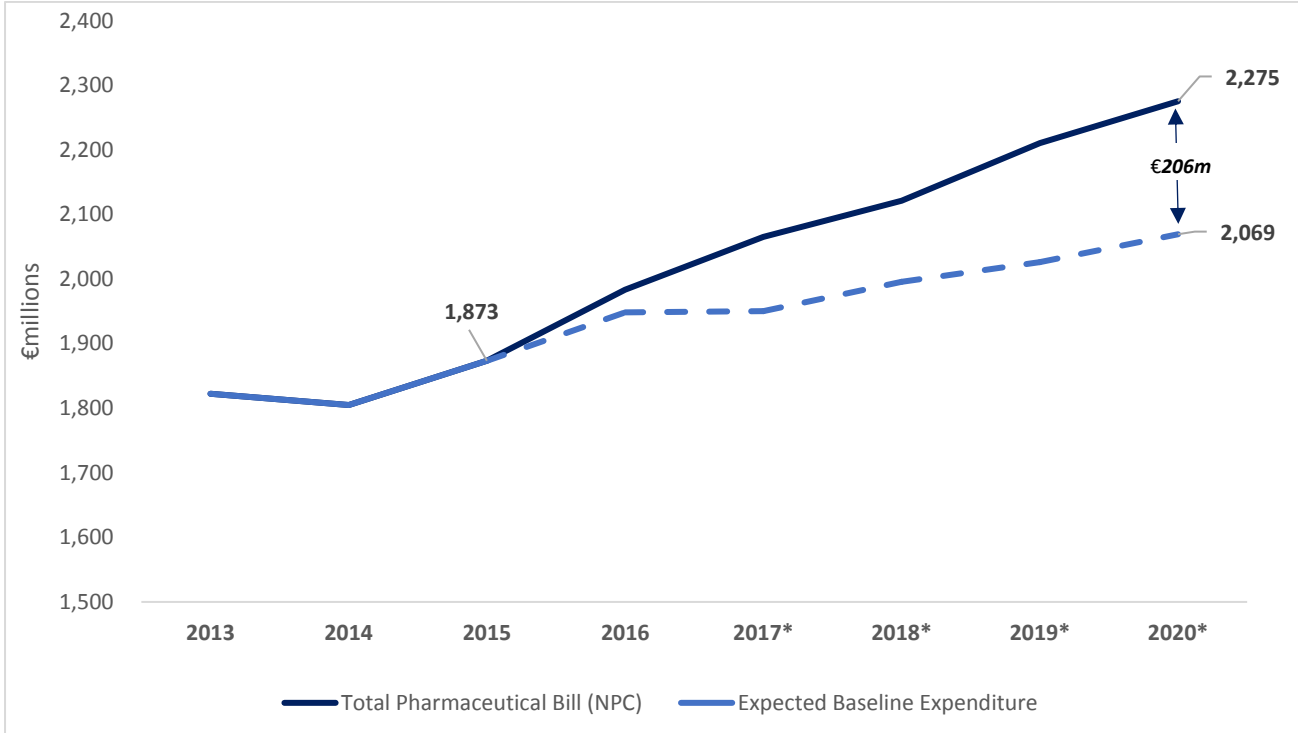
Figure 9 illustrates the extent of growth in pharmaceutical spend expected in Ireland on a no-policy change (NPC) basis (in the absence of any pricing and supply agreement with Industry) versus the actual estimate of expenditure following the implementation of the IPHA Agreement.

⁵<http://health.gov.ie/wp-content/uploads/2016/07/Framework-Agreement-on-the-Supply-and-Pricing-of-Medicines-signed-copy.pdf>

⁶ Initial basket countries (9) include, Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Spain, and the UK. This was extended in 2016 to include, **Sweden, Portugal, Luxembourg, Greece and Italy.**

⁷ Loss of exclusivity refers occurs when a drug’s patent expires and a competing product enters the market.

Figure 9: Baseline expenditure, NPC forecast V's actual spend expected



Source: PCRS Data, Authors Calculation

From 2016 to 2017, the levers under the new IPHA Agreement have reduced the expected baseline position of pharmaceutical expenditure. The savings from the agreement are front loaded and therefore the greatest impact is experienced in 2017. This can be seen in **Figure 9** as the expected baseline expenditure is forecast to remain relatively flat from 2016 to 2017, the headroom provided by the agreement covers all of the growth in spend on existing medicines. In subsequent years, the expected baseline expenditure begins to increase as the quantum of savings delivered in later years is lower. The headroom provided by the agreement only covers a limited level of growth in existing stock from 2017 to 2020. Baseline expenditure is expected to increase by an annual average of around 2%. In contrast, on a NPC basis the baseline expenditure in 2020 was forecast to be €206m or 10% greater than the level of spend now expected following the agreement.

5. Potential Reforms to Provide Sustainability

While the signing of the 2016 IPHA agreement provides significant progress in terms of price reductions, it is only one element in an extensive work plan to contain pharmaceutical costs and improve efficiency. A number of other cost containment levers are available and have the potential to provide savings of a significant and sustained nature. These policy levers are used to control drug expenditure across the EU and have the potential to influence future behaviour and expenditure in the pharmaceutical space. This list of potential policy levers is outlined and discussed in further detail in a forthcoming IGEES Staff Paper. Many of the policy levers outlined require consideration now in order to be fully implemented and incur benefits in the medium term. See below for some levers with significant scope in Ireland and the potential options for reform:

1. Internal Reference Pricing (IRP) – Patent Expired Products

The introduction of the Health (Pricing and Supply of Medical Goods) Act 2013 legislates for the implementation of internal reference pricing. Reference pricing involves the setting of a common reimbursement price, or reference price, for a group of interchangeable⁸ medicines. Under the 2013 Health Act, the Health Products Regulatory Authority (HPRA) has the role of establishing, publishing and maintaining a list of interchangeable medicines. It means that one reference price is set for each group or list of interchangeable medicines and this is the price that the HSE will reimburse to pharmacies for all medicines in the group, regardless of the individual medicine price. In November 2013, the HSE began operating IRP and the first medicine to be reference priced was Atorvastatin. Since this time more medicines have been added to the system on a regular basis and in 2017 around 50 products were internally reference priced by the HSE⁹. The implementation of IRP has resulted in substantial savings for the Exchequer, this is illustrated in the reduction in overall drug spend in 2013 shown in **Figure 1**. The set of techniques used in applying IRP have the potential to provide savings, these include the speed of initial reference pricing following patent expiration, frequency of reviewing reference prices and the price setting methodology.

In Ireland, the pharmaceutical compounds with the largest spend are being prioritised. However, there is further scope for savings in this space through shortening re-reference periods and the time span for initial reference pricing. **Table 4** below shows a list of the top 10 drugs subject to IRP and the date they were last reference priced. There is inconsistency in the re-reference period across drugs, some were last reference priced over a year ago while others were re-priced at the beginning of 2017. The standard for most Member States is to review reference prices every 6 months (Callaghan and Connors, 2017).

Table 4: List of top 10 drugs subject to internal reference pricing

	Drug	2016 Projected Spend €m	Last Reference Priced
1	Atorvastatin	9.6	01-Jan-17
2	Esomeprazole	9.2	01-Jan-17
3	Rosuvastatin	9.6	Unknown
4	Olanzapine	6.8	01-Mar-16
5	Quetiapine	6	01-Dec-16
6	Lanzaprazole	5.2	01-Jan-17
7	Omeprazole	4.4	01-Jan-17
8	Memantine	4.8	01-Apr-16
9	Escitalopram	4.4	01-Dec-16
10	Ramipril	3.6	01-Dec-16
	Total	63.6	

Source: HSE Correspondence, HSE Website <https://www.hse.ie/eng/health/hl/Generics/ref/>

⁸ Under The Health Act 2013 legislation, interchangeable medicines are defined as those medicines that (1) contain the same active ingredient in the same strength, (2) are in the same pharmaceutical form, and (3) have the same route of administration.

⁹ See full list of products reference priced <https://www.hse.ie/eng/health/hl/Generics/ref/>

Potential Reform:

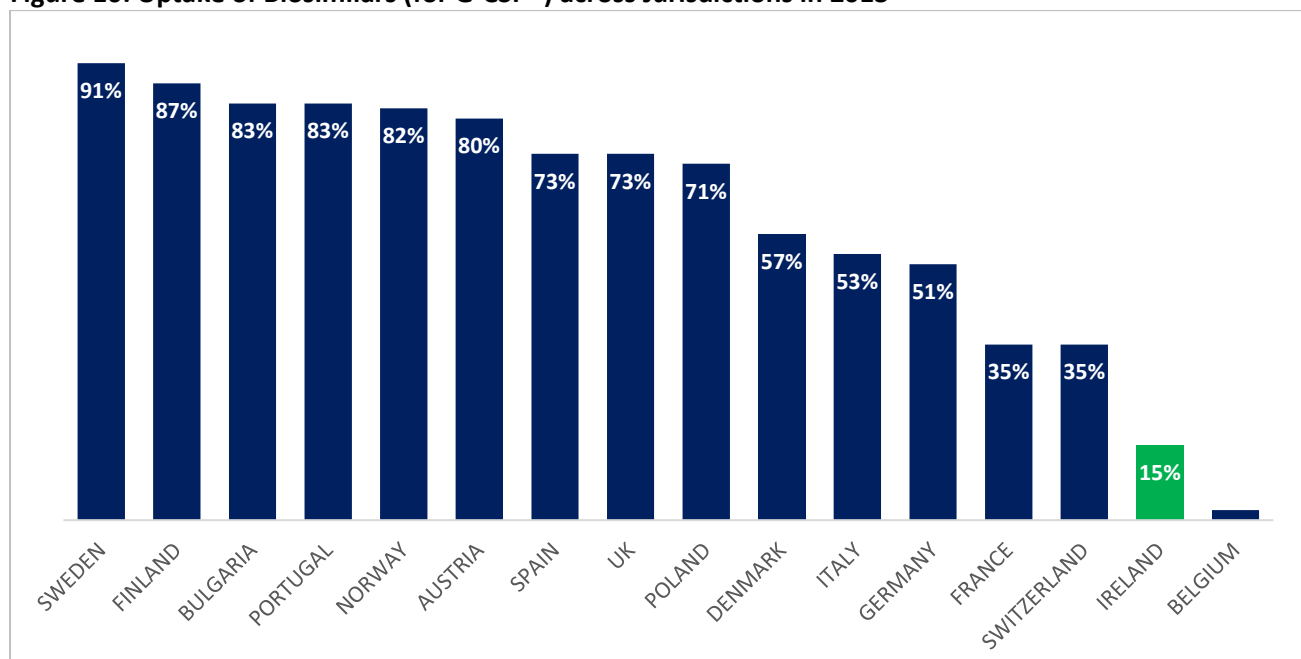
- To enhance the level of savings delivered through IRP a clear policy must be constructed around the **methodology, re-reference period and time span for initial referencing.**
- This policy should identify the maximum reimbursement rate as the price of the cheapest medicine in the group and that these prices will be reviewed every 6 months.

2. Biosimilar Policy

Biosimilars are replicates of biologic drug, typically, biologic drugs are more expensive than chemical medicines. Similar to generic drugs, biosimilars can only be sold after the patent of the original biologic drug has expired and therefore offer a cheaper alternative to the parent product. However in contrast to generics, biosimilars are not exact chemical duplicates of the original as they are produced from organic material. This is the primary reason for the slow movement towards the use of biosimilars. Biosimilars provide the opportunity to increase patient access as they deliver additional savings and allow resources to be directed toward new innovative medicines.

Biosimilars have been approved in the EU since 2006 and a total of 19 biosimilars have been authorised for use. The EU is the most advanced adopter of biosimilars and in 2011 the EU accounted for 80% of global spend on biosimilar drugs. In terms of Ireland's position, Ireland has one of the lowest biosimilar penetration levels across Europe. See **Figure 10** below for biosimilar uptake across jurisdictions in 2013.

Figure 10: Uptake of Biosimilars (for G-CSF¹⁰) across Jurisdictions in 2013



Source: IMS Institute for Healthcare Informatics 2014

¹⁰ Granulocyte colony-stimulating factor (G-CSF) is a glycoprotein that is used with certain cancer patients to accelerate recovery from neutropenia after chemotherapy, allowing higher-intensity treatment regimens.

As part of the new terms of the IPHA Agreement, a 30% price reduction clause was included for biologic drugs. This price reduction for biologic products will take effect once a biosimilar product has entered the Irish market. This price reduction should not inhibit the entry of biosimilars into the market given that biosimilars are generally priced below this level. Biosimilars are cheaper than reference medicines as the cost of bringing a biosimilar medicine to the market is less than biologics due to reduced R&D costs.

Potential Reform:

- In order to increase biosimilar uptake and take advantage of this cheaper alternative, a robust biosimilar policy must be implemented.
- This policy requires a suite of levers to effectively leverage the benefits of biosimilars. Successful optimisation of biosimilars requires a balancing act between these levers to obtain the most cost-effective and patient focused outcome. The range of levers available for biosimilar optimisation broadly fall under four key headings; **Pricing, Prescribing, Dispensing, and Education**.
- Further research is required to determine the mix of policies to be implemented and how they may work together to deliver improved prescribing and cost savings.

3. Prescribing Policy/Protocol

Irish pharmaceutical spend per capita is higher than most countries in Ireland's external reference price basket. The high level of spend is supported by higher than average prices and a high medicine consumption per capita. The rate of generic prescribing in Ireland is low and considerably out of line with prescribing levels in other countries (See **Section 2** above).

Existing Prescribing Policy: *Medicines Management Programme*

The Preferred Drugs initiative identifies a single 'preferred drug' within a therapeutic drug class, and offers prescribers useful guidance on selecting, prescribing and monitoring this drug for a particular condition. Prescribers are encouraged to make the preferred drug their drug of first choice when prescribing a drug from that therapeutic class.

Table 5: Most Commonly Prescribed Drugs across Therapeutic Classes 2014

Therapeutic Class	Preferred Drug	Most commonly prescribed (2014)
<i>Proton Pump Inhibitor</i>	Lansoprazole	Esomeprazole – 31% Lansoprazole - 23%
<i>Statin</i>	Simvastatin	Atorvastatin – 57% Rouvastatin – 26% Simvastatin – 6%
<i>ACE inhibitors</i>	Ramipril	Ramipril – 53% Perindopril – 28% Lisinopril – 12%
<i>ARB - Angiotensin Receptor Blockers</i>	Candesartan	Valsartan - 27% Losartan - 22% Telmisartan - 18% Olmesartan - 16% Candesartan - 10%

Source: Medicines Management Programme (MMP) 2014

Potential Reform:

- Clear clinical guidance should be provided to GPs and other prescribers to promote best practice in terms of prescribing behaviour.
- A **new prescribing policy** may include prioritising access to certain medicines based on clinical need or the use of **physician incentives**. Incentives to control prescribing behaviour may be financial or non-financial, such as the use of budget targets or physician quotas

4. Arrangement of Community Schemes

The arrangement of some community schemes is another area with considerable scope to further improve the management of pharmaceutical spend.

Long Term Illness Scheme

The Long-Term Illness (LTI) Scheme provides drugs for no charge to people suffering from certain conditions, these include medicines, medical appliances and surgical appliances for the treatment of that condition. The list of illnesses covered by the scheme is set out at **Appendix [4]**. The scheme is administered by the Health Service Executive (HSE), under [Section 59 of the Health Act 1970¹¹](#). In contrast to the General Medical Services (GMS) Scheme, the LTI scheme does not depend on your income or other circumstances.

A person may be eligible for both a medical or GP visit card and an LTI book. This LTI book lists the drugs and medicines for the treatment of your condition, which will be provided free of charge through your pharmacist.

¹¹ http://www.citizensinformation.ie/en/health/health_related_benefits_and_entitlements/long_term_illness_scheme.html

Drugs and medicines administered under the LTI scheme are not subject to the prescription charge. Other drugs and medicines not related to the specified condition must be paid for outside the scheme.

Expenditure on LTI has increased significantly since 2013 and this increase in spend is expected to continue in 2017. Based on the 2017 forecast, LTI spend is estimated to be €108m or 93% greater than 2011 expenditure.

Table 6: LTI Expenditure 2011 - 2017 (f)

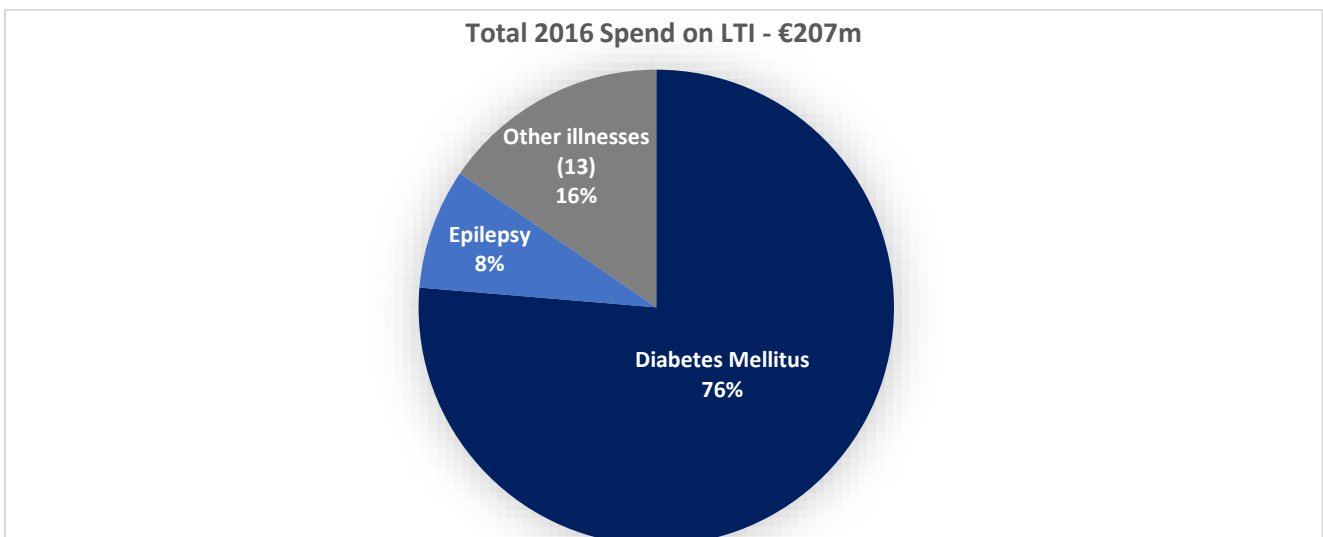
	2011	2012	2013	2014	2015	2016	2017 (f)	Growth 2011 - 2017	
LTI (€m)	116	117	106	130	182	204	224	108	93%
Annual Change (€m)		1	-11	24	52	22	20		
Annual Change (%)		1%	-9%	23%	40%	12%	10%		

Key Expenditure Drivers

At year-end 2016, expenditure on LTI was €22m or 12% higher than spend over the same period in 2015. This was primarily driven by growth in volume due to an increase in the number of claimants and the number of items per claimant. The average number of claimants increased by 14% from 2015 to 2016, reaching the highest levels ever at 129,000 in December 2016. See **Appendix [6]** for number of LTI claimants per month. This increased demand for the scheme can be attributable to the following factors:

- Movement of persons from using GMS scheme to LTI scheme due to avoidance of prescription charges or loss of medical card
- Increased prevalence of illnesses covered by the LTI scheme

The central component of spend on LTI is for items for the illness “Diabetes Mellitus”. This illness Diabetes Mellitus alone accounts for €158m or 76% of the total spend of €207m in 2016.



Diabetes Mellitus is not only the largest component of spend but it is also responsible for a significant proportion of the growth year on year. From 2015 to 2016, Diabetes Mellitus accounted for 75% of the €22m increase in overall spend on the scheme.

While demand on LTI has continued to increase over the last number of years, the increase in spend in 2016 reduced slightly this is primarily due to the IPHA agreement which came into effect from August 1. This policy development has assisted in managing some of the pressure however given that volume continues to increase, further reform should be undertaken to contain expenditure on LTI.

Potential Reform:

- Given that Diabetes Mellitus is the predominant driver of expenditure on LTI and other illnesses account for a small quantum of spend and growth in spend, it may be more cost effective and efficient to deal with diabetes separately.
- A separate scheme for diabetes may provide opportunities to utilise better tendering of diabetes medicines and medicinal products, or, the ability to implement managed agreements similar to the Hep C programme.

Conclusion

Pharmaceuticals are an important element of health services. In 2016, total expenditure on pharmaceuticals amounted to €2bn or 15% of overall health spend. Future pressures in the pharmaceutical space are considerable particularly in the context of overall health expenditure and other pressures across health systems. In 2016, a new pricing agreement with the Irish Pharmaceutical Healthcare Association (IPHA) was signed which will deliver savings over the next four years. While the signing of this agreement provides a significant improvement in price, the savings only deliver headroom to fund a limited level of growth in the existing stock of medicines from 2018 onwards. The ability to introduce new drugs will remain a considerable challenge for Government going forward as the scale of the new drugs pipeline increases and the context for new drugs policy changes. We now operate in an era of “Super Drugs”, these are innovative drugs which have potentially great benefits but come with large price tags.

Given the extensive range of other expenditure pressures facing the health sector such as pay and an aging demographic, the need to manage the pharmaceutical bill effectively is critical to the management of overall health spend. The reform agenda outlined in Section 5 highlights the list of potential levers available to further contain pharmaceutical costs. There is a need to ensure the health service has a coherent policy to provide sustainability of the overall pharmaceutical bill to secure affordable access to existing medicines and generate the ability to introduce new medicines in the future.

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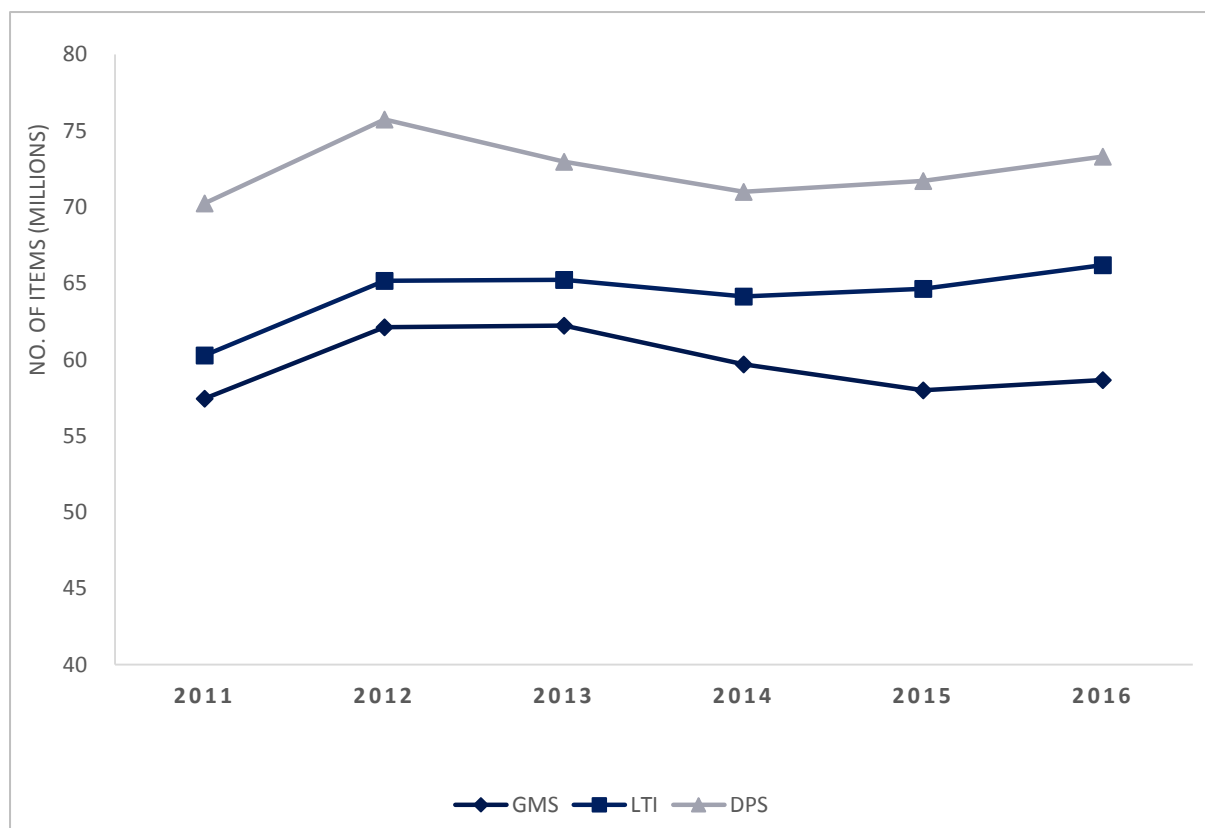
Appendix

[1] Entitlements

Category of entitlement	Entitlement under High-Tech Scheme
Medical cardholders	All items from the agreed list free of charge – no prescription charge applies
Persons covered under the Health (Amendment) Act, 1996	All items from the agreed list free of charge
LTI claimant	All items authorised for their particular Long Term Condition free of charge
DPS claimant	Flat fee of €144 towards total cost of all medication (both hi-tech and regular medicines)

Source: http://www.hse.ie/eng/Staff/PCRS/Contractor_Handbooks/PCRS_Handbook_for_Pharmacists.pdf

[2] Number of Items Dispensed across GMS, LTI and DPS from 2011 - 2016



Source: PCRS Data

[3] Policy levers implemented across countries

Table 6.

Overview of key incentive policies in the 10 selected EU countries for biosimilars (Con't) (as of November 2015).

Type of Policy	Belgium	France	Germany	Greece	Hungary	Italy	Poland	Spain	Sweden	United Kingdom
Physicians										
Pharmaceutical prescription budgets	x	x	✓	✓	No data	✓	x	x	✓	✓
Prescription quotas	✓	x	✓	No data	✓	✓	x	x	✓	x
Monitoring of prescriptions patterns	✓	x	✓	✓	No data	✓	x	✓ ^b	✓	✓
Financial incentives or penalties	✓	x	✓	✓	x	✓	x	x	✓	✓
Prescription conditions/guidelines	✓	✓	✓	✓	✓	✓	x	x	✓	✓
Switching	✓ ^b	✓ ^c	✓ ^d	No data	✓	✓	✓	✓ ^b	✓ ^e	✓
INN prescribing	x	x	x	x	x	x	✓ Physician's discretion	x	x	x
Education & Information	✓ Not specifically targeting physicians	✓ Not specifically targeting physicians	✓	No data	✓ Not specifically targeting physicians	✓ Not specifically targeting physicians	No data	✓ Not specifically targeting physicians	✓ Not specifically targeting physicians	✓
Number of policies considered for the regression analysis ^f	4	1	7	4	3	6	2	0	6	6

Policy potentially impacting biosimilar uptake
 Policy not expected to impact biosimilar uptake
 Policy not applicable to biosimilars

^a Unspecific policy for biosimilars; unrelated to pharmaceutical prescription budget or quotas (Prior dispensing authorisation system is applied through prior inspection patient visas (visados) to guarantee the appropriate use of medicines)

^b Not recommended; if done, should be initiated under supervision of the physician

^c Not recommended; switching between original and biosimilar drug should be performed as little as possible for the same patient (French Drug Agency, ANSM)

^d Usually not recommended except for specific groups of biosimilars (same producer)

^e Generally not recommended except for products included in the substitution list (products with same producer) but possible under the responsibility of physicians

^f Existence of incentives expected to enhance biosimilar uptake

Source: Rémuzat et al 2017

[4] Illnesses covered under the Long Term Illness Scheme

Illnesses covered under Long Term Illness Scheme	
Mental handicap	Cystic fibrosis
Mental illness (for people under 16 only)	Multiple sclerosis
Diabetes insipidus	Spina bifida
Diabetes mellitus	Muscular dystrophies
Haemophilia	Hydrocephalus
Cerebral palsy	Parkinsonism
Phenylketonuria	Acute leukaemia
Epilepsy	Conditions arising from use of Thalidomide