Irish Pharmaceutical Healthcare Association

Policy and Budgetary Perspective

2015 | 2016

ipha
IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION

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We represent 47 international research-based pharmaceutical companies that develop and supply innovative new medicines for the benefit of people in Ireland.

Foreword

A message from **Dr. Leisha Daly,** President of the Irish Pharmaceutical Healthcare Association:

"Over the past number of years, the pharmaceutical industry has played a key role in Ireland's recovery.

In economic terms, the industry has supported 50,000 jobs directly and indirectly, generated substantial sums in tax revenue for the exchequer and delivered €1.2bn in savings through our consecutive multi-annual framework supply agreements with the Irish Government.

It is important however that we also consider the wider impact that the pharmaceutical industry has had on society. Last year alone, over 29 new medicines were delivered to Irish patients by our pharmaceutical companies. These medicines achieved greater outcomes, a much improved quality of life and increased life expectancy for many Irish patients.

Ensuring timely access and a security of supply to innovative medicines that tackle diseases such as Parkinson's, diabetes, cancer, hepatitis C, asthma, schizophrenia and other conditions is a priority for the Irish Pharmaceutical Healthcare Association (IPHA).

This policy and budgetary perspective outlines a number of key measures that the Government can take to ensure that the expenditure invested in the health sector realises the best possible outcomes for patients in Ireland.

By implementing these measures the Government can continue to reap the positive economic benefits that are attached to the pharmaceutical industry whilst ensuring society can share in the positive health benefits that are a direct result of providing access to new medicines effectively and efficiently."

Leisha Daly

Dr. Leisha Daly,
President of IPHA

1 Summary and policy objectives

Summary

1 **Who we are:**
The Irish Pharmaceutical Healthcare Association (IPHA) represents 47 international research-based pharmaceutical companies that develop and supply innovative new medicines for the benefit of the Irish people. Since the mid-1980s IPHA and successive Irish governments have provided the environment for the secure supply of innovative medicines to Irish patients through consecutive multi-annual framework supply agreements.

2 **Our contribution to stabilising the public finances:**
The pharmaceutical industry has played its part in the stabilisation of the public finances. The Minister for Health has confirmed that price reductions of the order of 30% per item of medicine has been achieved since 2009. The average price of an item of medicine distributed in Ireland via the HSE's community drug schemes has dropped every year since 2009. Since 2006, savings of €1.2bn from the medicines bill have been delivered by pharmaceutical companies which are members of IPHA.

3 **Our contribution to the Irish economy:**
Ireland is the EU's largest net exporter of medicines. Nine of the world's top 10 pharmaceutical companies have significant presences in Ireland.

Policy objectives

1 **Healthcare expenditure should grow as a proportion of GDP:**
Countries like Ireland with advanced economies typically see health spending track or exceed economic growth. Having fallen as a proportion of GDP and GNP while the Irish economy was in recession, public spending on health should now grow as a proportion of GDP as the country moves forward.

2 **Patients should have early access to new medicines:**
Early access to innovative new medicines should be at the heart of Irish healthcare policy. This would greatly benefit Irish patients. We urge that there would be cross-party consensus on this goal. A policy of early access can be achieved next year, in agreement with IPHA. It should be a policy objective of the Irish government that Ireland would be a leading country within the European Union for early access for patients to innovative new medicines. Patients' access to new therapies can be delayed because of resource issues that impact the process used by the HSE for evaluating proposed new therapies. Health technology assessment processes should be properly resourced to ensure efficient decision making about proposed new medicines. This should be a performance measure of the HSE.

3 **Scrutinise healthcare expenditure to identify value and waste:**
It should be Government policy to embed cost-effectiveness appraisal across all domains of healthcare expenditure, as a pathway to identifying value and potential for improving health outcomes and the welfare of society.

4 **Patients' awareness of the benefits of adherence to prescriptions should increase:**
Up to 50% of patients do not adhere to prescriptions. This negatively impacts patient well-being, the efficacy of treatments, and causes avoidable use of healthcare resources, including hospitals. The Irish Pharmaceutical Healthcare Association is interested in partnering with the Department of Health on initiatives to assist patients in adhering to their prescribed therapies.

5 **Improve Ireland's clinical research environment:**
Ireland's opportunity to become a global leader in clinical research is not being exploited because of the country's currently disjointed clinical research system. Ireland should benchmark its clinical research environment against leading countries, such as Denmark.

6 **Patients should be treated at the appropriate care level:**
The concept of self-care should be actively encouraged by legislators, regulators and healthcare professionals. Patients should be encouraged to keep healthy and to access treatment at the appropriate care level rather than, as too often happens, seeking treatment at a higher level than required.

Introduction

The Irish Pharmaceutical Healthcare Association (IPHA) represents 47 international research-based pharmaceutical companies that develop and supply innovative new medicines for the benefit of the Irish people. Since the mid-1980s IPHA and successive Irish governments have provided the environment for the secure supply of innovative medicines to Irish patients through consecutive multi-annual framework supply agreements.

IPHA welcomes the continuing recovery of the Irish economy and the Government's confirmation that the cycle of retrenchment across Irish public health services has ended.

With the conclusion of consecutive years of cutbacks, 2015 marks the beginning of a new era for Ireland. IPHA proposes that this new era should be marked by a renewed focus on value, loyalty to the economic principles that are increasing sustainable employment, and on intelligent deployment of public resources.

In 2014, pharmaceutical companies which are members of IPHA delivered at least 29 new medicines for the benefit of Irish patients

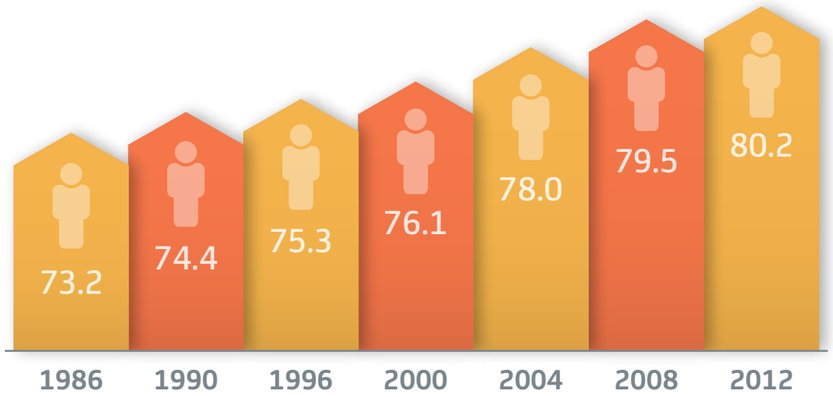
Since the mid-1980s IPHA and the Irish government have provided the environment for the secure supply of innovative medicines to Irish patients through consecutive multi-annual framework supply agreements.

2 The value of good health

The European Commission notes that 'keeping people healthy and active for longer has a positive impact on productivity and competitiveness'[1]. It is estimated that a 1% increase in life expectancy results in an average 6% increase in total Gross Domestic Product.[2]

Innovative medicines have been a significant driver of improved life expectancy in Ireland. Life expectancy increased from 77.1 years in 2002 to 80.2 years in 2012. Since 1940, these new discoveries have been a major contributing factor in increasing the life expectancy of the average Irish person by 33% (CSO).

Figure 1: Life expectancy in Ireland 1986-2012



Irish mortality rates improved significantly between 1990 and 2011:

- Cancer reduced by 21%
- Ischemic heart disease (heart attack) reduced by 59%
- Cerebrovascular disease (stroke) reduced by 54%.[3]

[1] EU Commission Communication, 29 June 2011, COM (2011) 500 Final
[2] R Swift, Health Economics, Vol 20, Issue 3, March 2011
[3] Eurostat, Healthy Years and Life Expectancy at Birth, 2015

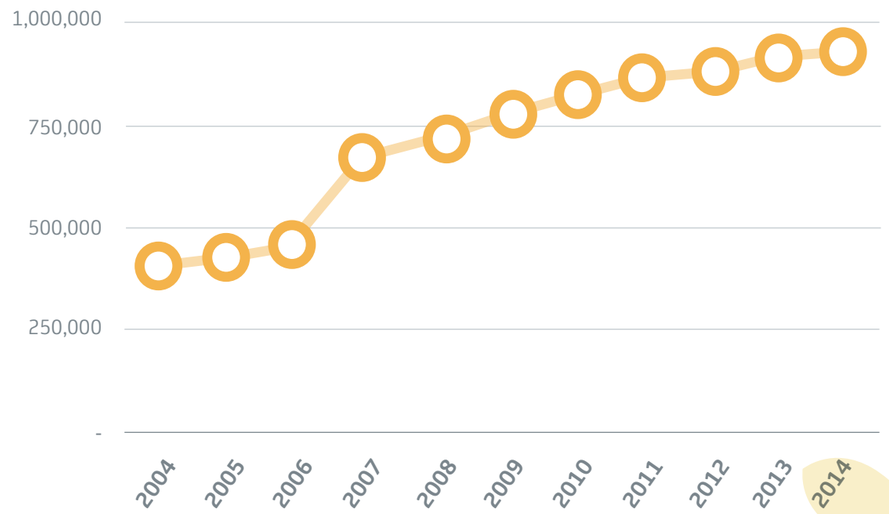
Innovative medicines help people to live longer, healthier, more productive lives. The pharmaceutical industry's greatest contribution is in the value of helping people to enjoy better quality of life, to get back to work and to contribute to communities.

Innovative new medicines[4] which are prescribed in hospitals in Ireland are supplied to patients by the HSE through community pharmacies via the Primary Care Reimbursement Service's High Tech scheme[5]. Such medicines include anti-rejection drugs for transplant patients or medicines used in conjunction with chemotherapy or growth hormones. Funding for the High Tech scheme has been cut consistently since 2008.

IPHA welcomes the new departure in Irish national health policy, expressed in *Healthy Ireland: A Framework for Health and Wellbeing 2013-2025,* whereby health is recognised as a driver of growth across all sectors and not just a value in itself. Healthy Ireland promulgates a 'whole of Government approach to health in all policies'. IPHA encourages political leaders to develop healthcare budgetary policy for 2016 and subsequent years from this starting point.

Innovative medicines help patients to recover more rapidly, and this has significant downstream benefits for patients, their carers and for the healthcare system. Irish policymakers are frequently confronted by resource issues in hospitals and other healthcare settings; innovative medicines that help patients to recover more quickly enable hospitals to provide care to more patients every year. The number of day cases treated in Ireland has increased by 239% since 2003. Effective therapies have been shown to be associated with significantly shorter hospital stays in important therapy areas, including cardiac health.[6]

Figure 2: Number of day cases treated in Irish hospitals 2003-2013 (Source: Health in Ireland, Key Trends 2014, Department of Health)



[4] PCRS reports (2008 – 2013), Financial & Statistical Analyses, Table 52 HTD: The Top 100 Products by Ingredient Cost
[5] HSE Primary Care Reimbursement Service
[6] Every NR, Spertus J, Fihn SD, Hlatky M, Martin JS, Weaver WD. Length of hospital stay after acute myocardial infarction in the Myocardial Infarction Triage and Intervention (MITI) Project registry. J Am Coll Cardiol. 1996;28:287–293.

The National Competitiveness Council has noted that the Irish economy loses 14 million working days each calendar year due to absence and ill health[7]. The current Irish health technology assessment threshold and process do not facilitate the evaluation of combination medicines. Thus other clinical, ethical and social considerations are important in the review of new cancer medicines. In many EU and Scandanavian countries, the societal perspective is incorporated in the decision making process to reflect broader societal benefits, including cost offsets in non-medicine budgets and people living with cancer continuing to contribute to society as a result for many years. IPHA advocates widening the perspective that underpins national health technology assessment guidelines, so that potential gains in the total welfare of society are understood.

A significant source of waste in Irish healthcare is in not securing achievable improvements to people's health state and quality of life when it would be affordable and economic for the state. Examples of this include not addressing unmet needs and not making available effective new medicines. IPHA favours intelligent investment in healthcare outcomes that deliver growth and reduce waste.

- The Irish Pharmaceutical Healthcare Association supports the *'whole of Government approach to health in all policies' that is enunciated in Healthy Ireland: A Framework for Health and Wellbeing 2013-2025,* whereby health is recognised as a driver of growth across all sectors and not just a value in itself.
- Innovative medicines help people to live longer, healthier, more productive lives. The pharmaceutical industry's greatest contribution is in the value of helping people to enjoy better quality of life, to get back to work and to contribute to communities.
- IPHA advocates widening the perspective that underpins national health technology assessment guidelines, so that potential gains in the total welfare of society are recognised. Evaluations that don't contemplate non-HSE costs and benefits do not state true economic or social value.

[7] National Competitiveness Council, Ireland's Competitiveness Challenge, Dec 2014).

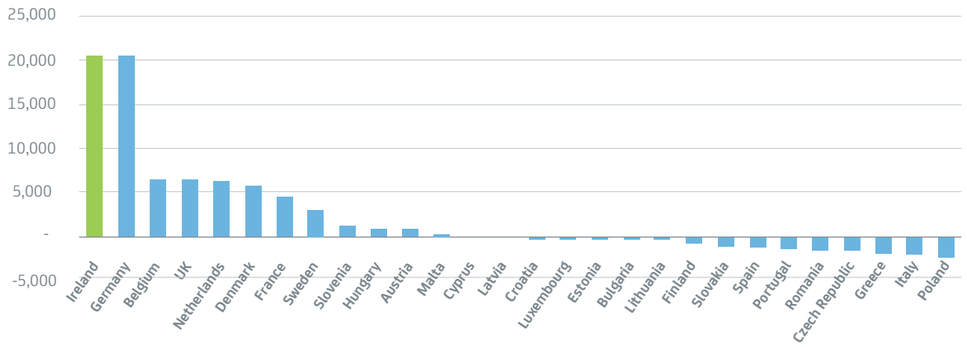
3 Recovery – a new era

Ireland's economy grew by 4.8% of GDP in 2014[8], and Budget 2015 was the first expansionary budget introduced by an Irish Government in seven years. The Government's April 2015 Spring Statement predicts GDP growth of 4% in 2015, thereby exceeding the Budget 2015 prediction of 3.9% growth and also exceeding previous ESRI[9] predictions. Unemployment has fallen to 9.8%[10]; the IMF predicts that it will fall to 8.8% in 2016 and by 0.5% annually for the subsequent five years.[11]

Government expects nominal GDP in 2016 to exceed the pre-crisis peak of 2007[12], and since April last year, Government forecasts have increased predicted GDP in 2018 by €27.7bn[13]. The IMF projects that GDP per capita will increase from €40,223 per capita in 2014 to €44,366 per capita in 2016.[14]

The pharmaceutical industry is playing a central role in this recovery story: Ireland had the EU's largest yearly increase in industrial production in 2014, and the highest sectoral rises in the EU were Ireland's pharmaceutical and high-tech sectors[15]. Our industry contributes over €38bn per year to Irish exports, and last year the industry employed 26,373 people[16] in high-skilled jobs in Ireland. 56% of all employees in the pharmaceutical industry are third-level graduates.[17]

Figure 3: EU 28 pharmaceutical trade balances (€m, 2013)



[8] ESRI, Quarterly Economic Commentary, Spring 2015
[9] ESRI, Quarterly Economic Commentary, Spring 2015
[10] CSO, Live Register, March 2015
[11] IMF; ESRI; Spring Economic Statement
[12] NTMA Presentation for Institutional Investors, January 2015, page 10
[13] Budget 2015, Economic and Fiscal Outlook; Department of Finance, Stability Programme Update (Table A1, page 45), April 2015.
[14] IMF, Ireland: Staff report, June 2015, page 3
[15] Eurostat, Euroindicator (7/2015), 14th January 2015, page 2
[16] IDA Ireland, Biopharmaceuticals in Ireland, 2015
[17] IDA Ireland, Biopharmaceuticals in Ireland, 2015

A further estimated 25,000 people are employed in support services to the pharmaceutical industry. IPHA represents American, Belgian, British, Danish, French, German, Irish, Italian, Japanese, and Swiss companies. Nine of the world's top 10 pharmaceutical companies have significant presence in Ireland, and our industry is responsible for 20% of all research and development investment in Ireland. 25% of all PhD researchers in Ireland are employed in the pharmaceutical industry.[18]

Our industry is a leader of workforce gender equality. Research conducted by PwC in 2015 finds that 64% of commercial employees within IPHA companies are female.

- Ireland is the EU's largest net exporter of medicines. Nine of the world's top 10 pharmaceutical companies have significant presence in Ireland.
- The pharmaceutical industry has played its part in the stabilisation of the public finances. The average price of an item of medicine distributed in Ireland via the HSE's community drug schemes has dropped every year since 2009.
- The Irish Pharmaceutical Healthcare Association (IPHA) supports Ireland's 12.5% corporation tax rate, and encourages political leaders to be vigilant about the efficiency of Ireland's corporate tax code.

IPHA firmly supports the 12.5% corporation tax rate, and encourages all policymakers to remain firm about Ireland's corporate tax and general competitiveness into the future. It should be a priority for Irish policymakers to reduce energy costs for manufacturing industries, and to facilitate industrial growth by upgrading broadband infrastructure throughout the country[19]. Ireland remains an expensive location for energy compared to most of our EU peers, and this is a particular issue for energy intensive sectors like pharma. In 2014 industrial electricity prices for larger energy users in Ireland were 7.8% higher than the euro area average, and in 2014 industrial energy prices in Ireland were 8.2% higher than prices were in 2009[20].

In 2012 the Minister for Jobs, Enterprise and Innovation and the Minister for Communications, Energy and Natural Resources acknowledged the need to reduce energy costs for manufacturers in Ireland when they launched the Government's Total Energy Management for Production Operations (TEMPO) project[21]. IPHA acknowledges Ireland's competitiveness in simplifying corporate taxation compliance, and encourages policymakers to be ambitious in promoting Ireland as a location where it is straightforward and efficient for international companies to do business.

[18] IDA Ireland, Biopharmaceuticals in Ireland, 2015

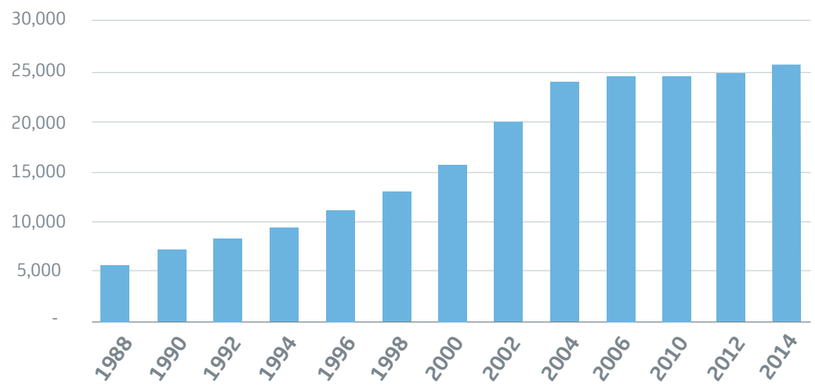
[19] 'Ireland ranks poorly in terms of fibre connections and significantly lags leading countries in terms of upgrading the local broadband access network to fibre' (National Competitiveness Council, Ireland's Competitiveness Scorecard 2014, page 85)

[20] National Competitiveness Council, Cost of Doing Business in Ireland 2015 (April 2015), page 21

[21] International Energy Research Centre, TEMPO Project (June 2012 – May 2015).

Recovery – a new era

Figure 4: Number of employees in Ireland's pharmaceutical industry



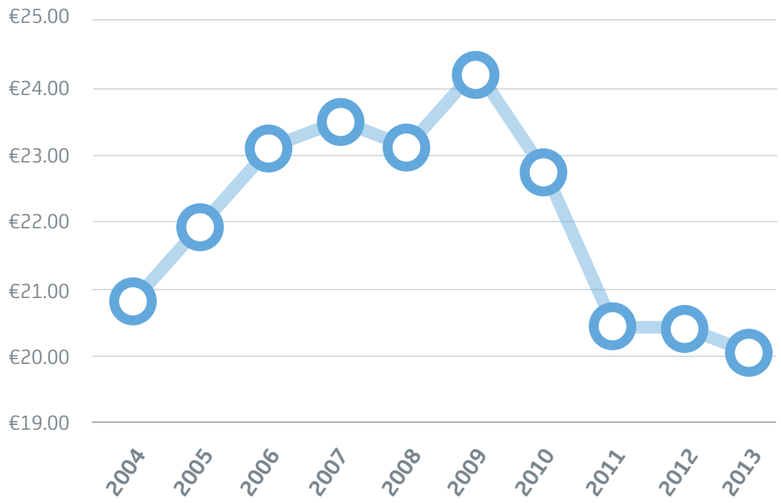
The pharmaceutical industry contributed significantly to the national effort to stabilise Ireland's public finances. IPHA companies have provided medicines to the Irish people via successive "framework agreements" with the Irish government. The 2006-2012 Framework Supply Agreement delivered €800m in savings for the exchequer, and the Minister for Health has confirmed that the gross savings arising from 2012-2015 Framework Supply Agreement is delivering over €400m in further savings for Irish taxpayers.[22]

- The average price per item of medicine in the HSE community drug schemes has fallen every year since 2009, and is now running at 2001/2002 levels. The Minister for Health has confirmed that price reductions of the order of 30% per item have been achieved between 2009 and 2013.[23]

[22] Leo Varadkar TD, Minister for Health, Dáil Éireann, 25th February 2015 (PQ 7978/15)

[23] Leo Varadkar TD, Minister for Health, Dáil Éireann, 25th February 2015 (PQ 7978/15)

Figure 5: Average price per item of medicine (all schemes)[24]



Policymakers need to be mindful of the need for security of supply of medicines for Irish patients. Today, because of the substantial price reductions, the supply of some medicines which Irish patients use is at risk from parallel exports of those medicines to other countries where better prices are on offer.

The stabilisation of Ireland's economy and the country's journey towards recovery open up a new era in Ireland, which IPHA believes should be underpinned by a renewed commitment to innovation in public policymaking.

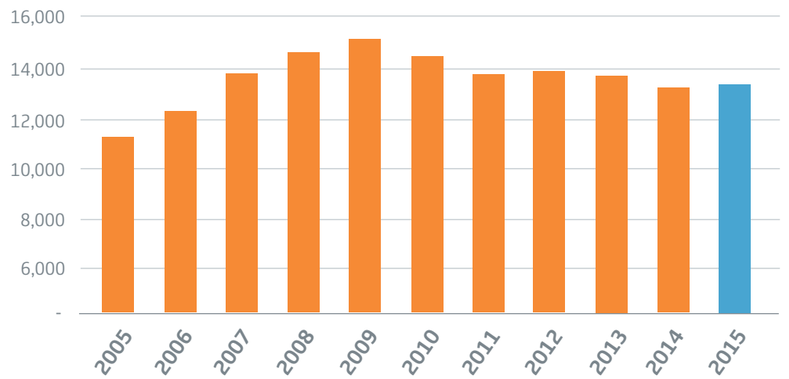
[24] Sourced from PCRS, Financial & Statistical Analyses (2003-2012) & HSE performance reports

4 Healthcare expenditure

Government health spending should grow in the period to 2020. In the financial crisis, the policy was to cut as much as possible: current public expenditure on health was cut by 14% in the years 2009-2014[25]. Through the fiscal adjustment, health current spending fell from almost 28% of Gross Current Expenditure to almost 25%[26]. The Minister for Health has confirmed that the era of nominal cuts in expenditure is over.[27]

The European Commission and Government project that Irish public spending on health and long-term care will rise from 6.7% of GDP (2013) to 7% of GDP in 2020[28]. This expansion is not, however, yet provided for in the Government's own spending plans i.e. the health ceilings 2015-2017 that were introduced in October 2014. Instead, there is an implied continued fall in the proportion of national income being devoted to public health spending, even as national wealth increases[29]. This is not tenable economically or socially.

Figure 6: Irish public expenditure on health 2005-2015 (€m)



[25] HSE gross expenditure dropped by 14% between 2009 and 2014 (DPER).

[26] Department of Public Expenditure and Reform – Databank

[27] Minister for Health, 21 February 2015

[28] Department of Finance, Stability Programme Update, (Table 21: Long-term spending projections, page 42), April 2015

[29] In 2015 Health Gross Spending is to be 7% of GDP, 8.3% of GNP. By 2018, based on the current expenditure ceilings set out in the Comprehensive Expenditure Review 2015-18 and reasonable assumptions on capital investment, it is likely to be 6.2% and 7.5% respectively.

Policy on health spending ought to reflect the economic and social realities and aspirations of the country. Countries like Ireland with advanced economies typically see health spending track or exceed economic growth; however public expenditure on health services as a share of GDP is lower in Ireland than average expenditure across OECD countries[30]. The United Kingdom, Spain, France, Czech Republic, Germany, Austria, The Netherlands, Finland, Portugal, Greece and Sweden each invests a higher proportion of GDP per capita on public health services than Ireland[31]. Having fallen as a proportion of GDP and GNP[32] while the Irish economy was in recession, public spending on health should now increase as a proportion of Irish GDP as the country moves forward[33]. When properly balanced across all areas of public expenditure, we believe that such a policy is consistent with EU public expenditure rules.

As continued efficiencies are pursued in models of care and costs, the scope for matching increasing demand with new funding is greater because of the upswing in the economy and employment. A lower need for social welfare spending can be expected, as unemployment continues to fall. The share of Government current expenditure should tilt to health relative to other areas as a reflection of public need and the changed economic circumstances.

If the proportion of public current expenditure on healthcare were to return to its pre-recession share, or to remain even at the relatively low rate of 7% of GDP, there would be scope for intelligent additional investment in healthcare.

[30] OECD, *Focus on health spending,* OECD Health Statistics (July 2015)
[31] OECD, *Focus on health spending,* OECD Health Statistics (July 2015)
[32] Department of Health, *Health in Ireland Key Trends 2014,* page 59.
[33] Overall Government expenditure growth is to be lower than nominal GDP growth in order to reduce the debt/GDP ratio

5 Intelligent investment in health

Budget 2015 marked the end of the era of budgetary austerity, and the Government and other agencies are projecting consecutive years of sustained growth towards 2020. IPHA proposes a renewed emphasis on innovation and value, with a focus on intelligent and cost-effective use of public resources.

The Department of Public Expenditure and Reform's Public Spending Code (July 2012)[34] sets out best practice in the appraisal, implementation and evaluation of projects and programmes, and sets out Cost-Benefit Analysis as the mandatory appraisal technique for all public projects costing more than €20m. IPHA supports assessments of costs, benefits and value: we already operate a sophisticated assessment of costs and benefits.

Pharmacoeconomics is the scientific discipline that compares the value of one intervention (medicine or treatment strategy) to another. A pharmacoeconomic study compares the cost (expressed in monetary terms) and effects (expressed in terms of monetary value, efficacy or enhanced quality of life) of a medicine. Pharmacoeconomic studies serve to guide optimal healthcare resource allocation in a standardised and scientifically grounded manner. These may otherwise be known as Health Technology Assessments (HTA).

Since 2006, consecutive framework supply agreements between IPHA and the Department of Health/HSE have established that health technology assessment (independent research about the clinical- and cost-effectiveness of health technologies) is the basis for decision-making about proposed new medicines in Ireland. The standard system involves the pharmaceutical company submitting a HTA to the National Centre for Pharmacoeconomics (NCPE) to demonstrate the benefit of the medicine compared to the standard of care, in comparison to the cost implications of the introduction of the treatment (a cost-effectiveness analysis). This process applies to all therapy areas. IPHA believes this process ensures that there is a focus on innovation and value in decision making about the reimbursement of medicines in Ireland.

[34] Department of Public Expenditure and Reform, Public Spending Code (2012)

The Path to Universal Healthcare: White Paper on Universal Health, which the government published in April 2014, sets out the Government's plans for the development of a universal healthcare system over a five-year period. The White Paper envisages that health technology assessment should be used to select the basket of health services to be provided in Ireland via universal health care.

IPHA believes that it should be Government policy to embed this focus on cost-effectiveness and extend the concept of intelligent investment across all domains of healthcare expenditure, as a way of identifying value and potential for improved health outcomes for Irish People.

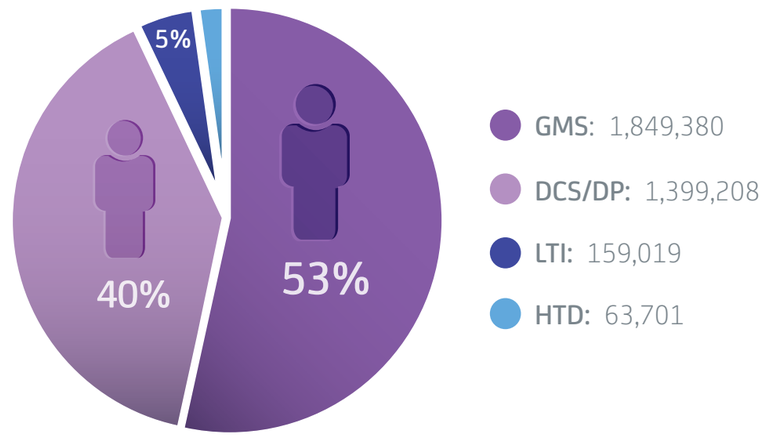
- It should be Government policy to embed cost effectiveness appraisal in healthcare policymaking. Budget 2016 and subsequent budgets should embed cost-effectiveness appraisal across all domains of healthcare expenditure, as a pathway to identifying value and potential for improved health outcomes for Irish people.

The State pays for approximately 80%[35] of all medicines in Ireland, principally via the HSE's four community drug schemes:

- General Medical Services Scheme (GMS)
- Drug Payment Scheme (DPS)
- Long-term Illness Scheme (LTI)
- High Tech Drugs (HTD)

More people in Ireland are eligible for these HSE community drug schemes than ever before, and this is likely to continue to increase. In 2013 3.47m people in Ireland were eligible for the community drug schemes, up from 2.67m eligible people in 2003. The number of items of medicines prescribed in Ireland via these schemes increased by 70.2% between 2003 and 2013 (43.24m items in 2003; 73.58m items in 2013).

Figure 7: Number of people eligible for the HSE Community Drug Schemes (2013)

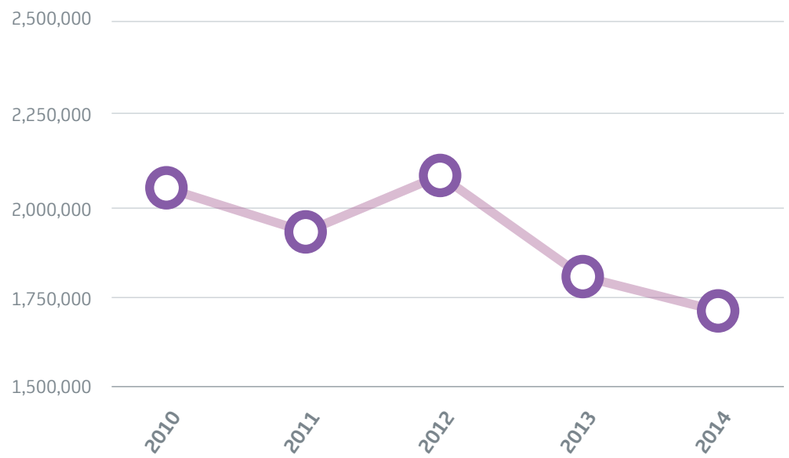


[35] Irish Pharmacy Union, Presentation to the Joint Oireachtas Committee on Health and Children, 5th March 2015

This increase in the volume of prescriptions explains the expansion of the State's medicines expenditure. The average price of an item of medicine was €19.19 in 2003; the average in 2013 was €19.91 – meaning an increase of just 3.7% over 11 years. Irish consumer prices increased by 14% in the same period.[36]

In 2014 public expenditure on pharmaceuticals represented 13% of total public expenditure on health. This was a drop from 14.65% in 2012.[37]

Figure 8: Public expenditure on medicines via the HSE community drug schemes has dropped from €2.07bn in 2012 to €1.69bn in 2014



Globally and in Ireland the requirement for patient access to new medicines is likely to grow, rather than diminish. Many diseases are now better managed and even cured. New, more complex medicines are on the horizon. The requirement for patient access to new medicines will grow. A health ecosystem that supports clinical research, early adoption of innovative new medicines, real-time clinical evaluations, and a stable business environment will benefit everyone.

IPHA advocates for additional funding for health, not to pay more for existing medicines but to meet real, growing need and to fund new therapies and medicines, while the costs of older ones fall. Falls in prices for older medicines contribute to affordability, although there is not a correlation between scope for funding new therapies and reducing prices for established medicines.

[36] Central Statistics Office, Harmonised Consumer Price Index

[37] HSE Management Data Reports 2010-2014

Intelligent investment in health

Ireland can be a leader in providing innovative medicines for patients. Pricing should reflect Irish conditions and policy goals: economic for the State and for companies; aligned with the economic status and income levels in Ireland; and meeting healthcare needs specific to the Irish population.

- Government health spending should grow in the period to 2020.
- Countries like Ireland with advanced economies typically see health spending track or exceed economic growth. Having fallen as a proportion of GDP and GNP while the Irish economy was in recession, public spending on health should now approximately track GDP/GNP growth as the country moves forward.

- The number of items of medicines prescribed in Ireland via these schemes increased by **70.2%** between 2003 and 2013. The average price of an item of medicine was **€19.19** in 2003; the average in 2013 was **€19.91**.
- The IPHA-Department of Health/HSE Framework Supply Agreement 2012 2015 will deliver savings of **€400m** for taxpayers on Ireland's medicines bill.

6 Patients in Ireland should be able to access new medicines quickly

Patients should be able to access affordable and effective new therapies as quickly as possible.

IPHA welcomed the announcement in November 2014 by the Minister for Health of the HSE's programme for early access to powerful new drugs for Hepatitis C patients. The early access programme is designed for patients who are deemed to have an urgent need for treatment.

Patients in Ireland would benefit from application of this early access model across all therapy areas. Early access to innovative new medicines should be at the heart of healthcare policies for the government and for all political parties. We urge that there would be cross-party consensus on this policy goal. Ireland should prioritise access for patients who can benefit most, while ensuring that the financing model is sustainable and affordable. This should be a performance measure of the HSE.

IPHA strongly believes that this can be achieved through a new Framework Supply Agreement, and that it can be implemented by Government in 2016. We therefore urge that the policy goal of early access to medicines should be addressed in Budget 2016.

- Early access to innovative new medicines should be at the heart of Irish healthcare policy. We urge that there would be cross-party consensus on this goal.
- A policy of early access can be achieved in 2016. The Irish Pharmaceutical Healthcare Association therefore urges that it be addressed in Budget 2016.
- It should be a policy objective of the Irish government that Ireland has the earliest access to innovative new medicines in the European Union.

The Health Information and Quality Authority, HIQA, has statutory responsibility under the Health Act (2007) for evaluating the clinical- and cost-effectiveness of health technologies and provides advice arising out of its evaluation to the Minister for Health and the HSE. HIQA delegates this function in respect of pharmaceuticals to the National Centre for Pharmacoeconomics (NCPE). The NCPE assesses evidence for comparative effectiveness and cost-effectiveness, through assessment of evidence submitted by manufacturers and independent systematic review. This process is informed by the European Commission's *Transparency Directive* (2012)[38], which lays down a general procedural framework and strict time limits to ensure the transparency of measures regulating the pricing and reimbursement of medicines.

IPHA values the NCPE as a trusted partner in the process which delivers new innovative therapies to people in Ireland. In 2014 the NCPE approved at least 29 new medicines that are manufactured by IPHA companies – up to 700,000 patients can benefit. These are for:

- Parkinson's disease
- Diabetes
- Cancer
- Hepatitis C
- Asthma
- Schizophrenia and other conditions

[38] On 1st March 2012 the European Commission adopted the *Directive relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems.*

The NCPE's evaluative process involves at least one and sometimes two forms of appraisal – an NCPE rapid review assessment and, pending the outcome of the rapid review assessment, a full pharmacoeconomic assessment[39]. Successive framework supply agreements between IPHA and the Department of Health/HSE have set out the NCPE's stated timelines for the various stages of the process.

The volume of proposed new medicines is increasing, because of the pace of innovation and the demand for new therapies across so many challenging disease areas. IPHA observes that the journey through the process has been steadily lengthening in recent months. Table 1, below, illustrates the extent of the delays that are being observed at rapid review assessment stage; the NCPE has stated this process should typically take 2-4 weeks. The NCPE should be adequately resourced to conduct its evaluations within reasonable timeframes.

Table 1. Overview of NCPE Rapid Review Assessment timelines 2012-2015

Year	No. of Reviews	Average no. working days	Weeks
2012	8	16	3.2
2013	44	19	3.8
2014	46	24	4.8
2015 January-June	19	28	5.6

- The National Centre for Pharmacoeconomics should be adequately resourced to conduct the evaluations of proposed new medicines which it carries out for the HSE.

[39] National Centre for Pharmacoeconomics, *Submission process flowchart* (last accessed 29 July 2015)

Patients in Ireland should be able to access new medicines quickly

7 Opportunity for Ireland to be clinical research global leader

Clinical trials of medicines examine the use of new or existing drugs for treating diseases with the final aim of improving survival and quality of life. Clinical trials are central to the development of new, more effective treatments. Clinical trials can provide patients with early access to innovative therapies, grow scientific knowledge about diseases, and provide local clinicians with access to meaningful research opportunities.

A new medicine can contain 25,000 atoms, and on average only one to two of every 10,000 substances which are synthesised in laboratories will successfully pass all stages of development that are required to become a medicine that is approved for prescribing to patients. It takes an average of 12 to 15 years to develop an effective new medicine. The estimated cost of bringing a new medicine to market is €1.4 billion. The economic impact of such investment in research and development is manifold: it drives collaboration among diverse stakeholders, from SMEs to academia; it creates new jobs; and it makes the host country an attractive location for clinical scientists and clinicians who are involved in research.

Ireland is an under-performer globally as a preferred location for clinical trials. This is mainly due to the lack of an integrated administrative approach. It should be a policy goal for Ireland to compete as a primary site for high quality integrated clinical research.

Ireland has invested significantly in life sciences education in recent decades. We are growing our workforce's capacity to provide world class clinical research. Pharmaceutical companies can bring global clinical trials to Ireland, and can support local clinical trials. Pharmaceutical companies conduct clinical trials either independently or in partnership with research institutions. Pharmaceutical companies that are members of IPHA conduct Phase II, III and IV clinical trials in Ireland, to evaluate the safety and the effectiveness of the medicine. The data from these clinical trials is then reviewed by the Health Products Regulatory Authority (HPRA). IPHA values our strong partnership with the HPRA.

Clinical research in Ireland can be supported by:

1. An administrative environment that facilitates clinical research within hospital – including appointment of a designated research hospital signatory for clinical trials; an agreed process for reviewing sign-off requests; dedicated research time for staff; and ring fenced research funding.

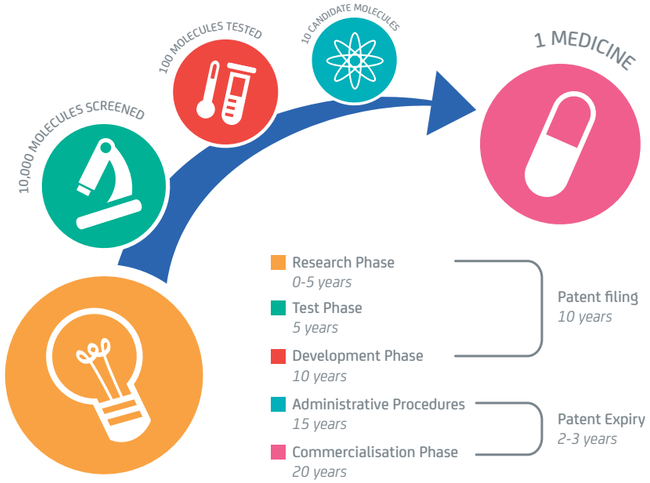
2. Establishment of a national Research Ethics Board for multi-institutional studies, as has been done in other jurisdictions.

3. Consistent adherence to legislation, guidance and timelines by Research Ethics Committees.

4. Promote participation in clinical trials in general as a platform for increasing Ireland's scientific knowledge. This should ultimately lead to better outcomes for patients, and would also provide them with the possibility of early access to potential new medicines.

IPHA encourages policymakers to benchmark Ireland's clinical research environment against that of Denmark. Applying for a clinical trial authorisation in Denmark is simple and fast. There is a clear government strategy for attracting clinical trials to hospitals which facilitates identification and contact with leading clinical centres of excellence. This strategy includes standard clinical trial agreements between Danish regions and industry, and a one stop shop for hospital staff and industry for technology transfer assistance, legal advice and grant support.[40]

Figure 9: From concept to product: steps in the genesis of a medicine



- It should be a policy goal for Ireland to compete as a primary site for high quality integrated clinical research.
- IPHA notes that enhancement of Ireland's clinical research environment is an objective of the National Rare Disease Plan for Ireland 2014-2018. Ireland should benchmark its clinical research environment against that of Denmark.

[40] Developing GeneLibrary Ireland, *Health Research Board (2005)*, page 6

8 Patients need to be supported to adhere to prescriptions

IPHA believes that the Department of Health should implement a national campaign to increase patients' adherence to prescriptions. The World Health Organisation reports that approximately 50% of patients do not adhere to prescriptions when long-term medication is prescribed. It is estimated that 20% - 30% of patients do not adhere to prescriptions that are set to cure or relieve symptoms, and that 30% - 40% of patients do not adhere to prescriptions that are designed to prevent health problems[41].

Non-adherence to medications can have a negative impact on the efficacy of treatments, patient well-being and the use of healthcare resources including avoidable re-hospitalisation of patients. Patient non-adherence also causes significant costs for healthcare systems: medication non-adherence contributes to the premature deaths of 200,000 people in the European Union annually[42], and medication non-adherence is estimated to be costing EU governments €125bn per annum.

The Irish Platform for Patients' Organisations, Science and Industry (IPPOSI) has identified patient non-adherence as an important concern which must be tackled[43]. IPHA encourages policymakers to heighten awareness about the benefits of adherence through a dedicated Department of Health initiative. Such an initiative should harness the guidance and expertise of patient organisations, which provide excellent representation in Ireland for patients and their carers.

[41] World Health Organization, *Adherence to long-term therapies: Evidence for action (2003)*
[42] European Council Policy makers Debate. An EU response to medication non-adherence. Brussels, 2010
[43] Irish Platform for Patients' Organisations, Science and Industry. *A Focus on Patient Compliance and Adherence in 2013.*

- Up to 50% of patients do not adhere to prescriptions. This negatively impacts patient well-being, the efficacy of treatments, and causes avoidable use of healthcare resources, including hospitals.
- The Irish Pharmaceutical Healthcare Association is interested in partnering with the Department of Health on initiatives to assist patients in adhering to their prescribed therapies.

IPHA and the Irish Platform for Patients' Organisations (IPPOSI) hosted an Innovation & Partnership Conference in Dublin in June 2015. The conference discussed how best to articulate the patient voice in healthcare. More than 50 patients organisations were represented at the conference.

9 Our ageing population and the prevalence of certain diseases in Ireland require vigilance

Policy decisions relating to the volume, funding and composition of Irish health services should take account of the incidence and prevalence of diseases in Ireland and the future needs of the population.

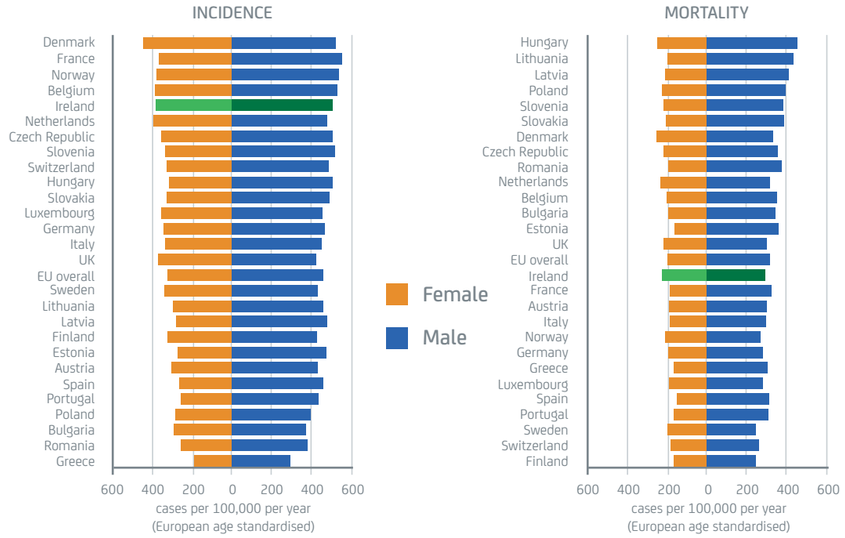
Some have observed that Ireland's relatively youthful population should result in relatively low public healthcare expenditure compared with other EU Member States[44], but Ireland has median to high prevalence for significant disease areas when compared with other EU Member States. Ireland's population is also ageing more quickly than other populations in the EU. In 2011 there were 532,000 people in Ireland aged 65+; in 2046 there will be 1.4 million people in Ireland aged 65+[45]. Demographic changes will increase demand for health and social care services.

Cancer incidence in Ireland is amongst the highest in Europe, with Irish females ranked fifth and Irish males ranked eighth out of 27 European countries that were analysed for cancer incidence by the *European Cancer Observatory*[46]. In 2012 incidence rates for cancer were 15% (female) and 10% (male) higher than the overall EU averages respectively.

The European Cancer Registry's 2012 report ranks Ireland seventh (females) and ninth (males) highest in the European Union for colorectal cancer incidence rates[47]. Female rates were 14% higher than the EU average and male rates were 10% higher. Irish females ranked amongst the highest in Europe for both incidence and mortality in respect of lung cancer, with incidence rates 55% higher than the EU average. Female breast cancer incidence in Ireland was 12.5% higher than the EU average in 2012 and ranked 6th highest of 27 countries overall. Of 27 European counties Ireland had the fourth highest incidence of prostate cancer, with rates over 50% higher than the EU average.[48]

[44] European Commission, Council recommendation on Ireland's Stability Programme (2014), page 4
[45] Central Statistics Office: Population and Labour Force Projections 2016-2046
[46] European Cancer Observatory (ECO) . [Online] [Cited: 19th April 2013.] http://eco.iarc.fr/.
[47] Annual report of the National Cancer Registry 2012
[48] European Cancer Observatory (ECO) . [Online] [Cited: 19th April 2013.] http://eco.iarc.fr/.

Figure 10: Cancer data is shown for 25 of the current EU28 countries with Norway and Switzerland also included.



Despite our youthful population – Ireland is one of the most youthful countries in the European Union, with 40% of our population currently aged under 30[49] – the prevalence of diabetes in Ireland is broadly consistent with those of EU Member States whose economies and healthcare systems are comparable with Ireland's. Ireland (5.54%) ranks with Belgium (5.18%), Finland (5.79%), France (5.62%), Germany (5.52%), Netherlands (5.89%) and the UK (5.59%). Prevalence of diabetes is notably higher in Austria (7.3%) and Spain (7.15%), and notably lower in Sweden (4.23%).[50]

Rheumatoid arthritis is 50% more prevalent in Ireland and other countries in northern Europe than it is in southern Europe[51]. Asthma, chronic obstructive pulmonary disease (COPD) and cystic fibrosis are other diseases which are more prevalent in Ireland than in other European countries.

The Department of Health addresses disease prevalence in its annual *Health in Ireland – Key Trends* (2014). The Department of Health, in observing that the gradient for chronic conditions rises very steeply with age, notes that Ireland's population is ageing more rapidly than other EU countries (see Figure 12). In June 2015 the International Monetary Fund warned that demographic pressures in Ireland will prompt sizable adjustment challenges that will require a rise in public investment[52]. The Minister for Health has written that 'satisfying unmet needs would cost between €700 million and €1 billion, on top of the natural increase needed yearly to cope with a rising, ageing population'[53].

[49] Eurostat, *What it means to be young in the European Union today*, April 2015
[50] International Diabetes Federation, *Diabetes comparative prevalence* (%) WHO Standard, 2012
[51] Alamanos Y, et al. Incidence and prevalence of rheumatoid arthritis, based on the 1987 American College of Rheumatology criteria: a systematic review. Seminars in Arthritis and Rheumatism. 2006;36:182-188.
[52] *Ireland: Staff report for the third post-program monitoring discussions*, June 2015, page 2
[53] Irish Times, 1 July 2015

Figure 11: CSO: Population and Labour Force Projections 2016-2046

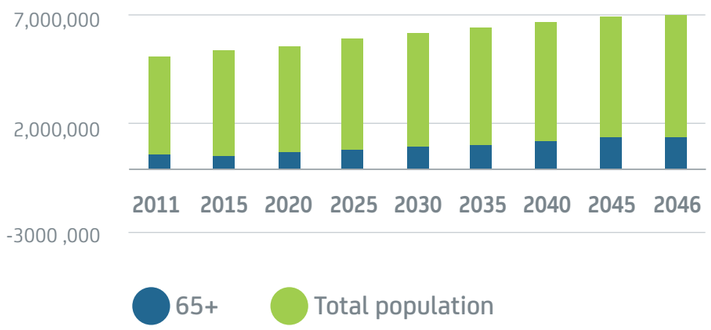
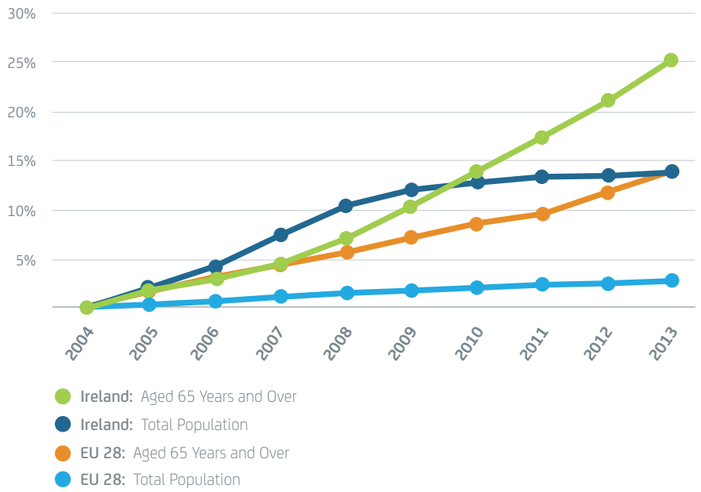


Figure 12: Cumulative % increase in population, all ages and 65+, Ireland and EU28, 2004 – 2013 ('Health in Ireland – Key Trends Department of Health, 2014)



New innovative medicines, advancements in health care and healthier lifestyle choices are contributing to reduced Irish mortality rates in cancer (reduced by 21% between 1991 and 2011), ischemic heart disease (59%), and stroke (54%). Life expectancy in Ireland increased from 77.1 years in 2002 to 80.2 years in 2012.

- Ireland has median to high prevalence for significant disease areas when compared with other EU Member States.
- The health of Ireland's population is improving, but analysis of disease incidence and prevalence points to significant challenges that are facing Irish society and Ireland's health and social care services. Irish health policy decisions should take account of these important trends.

Our ageing population and the prevalence of certain diseases in Ireland require vigilance

10 Reduce waiting lists and protect resources by treating patients at appropriate levels

Patients should be encouraged to keep healthy and to access treatment at the appropriate care level rather than, as too often happens, seeking treatment at a higher level than required. When patients engage with the healthcare system at a higher level than required, an inevitable outcome is avoidable increases to waiting lists in impacted care settings. It is estimated, for example, that 18% of a GP's workload is spent dealing with minor ailments in the United Kingdom[54]. Another recent UK study showed that 19.1% of those attending accident and emergency departments were for self-treatable conditions[55].

The Self-Care Framework for Ireland 2015 was agreed by organisations including the Irish Pharmacy Union, Trinity College Dublin, University College Cork and IPHA. The Self-Care Framework for Ireland 2015 recommends that:

- Legislators should ensure that self-care is at the heart of the healthcare system, consistent with the Government's Healthy Ireland framework.
- The regulatory environment must be balanced, proportionate and focused on meeting the needs and expectations of patients and other stakeholders.
- The role of the pharmacist should be expanded.
- Patients should have access to good quality, trustworthy information so that they can seek care at the appropriate level and, thus, enhance their independence within the health system.
- The range of medicines made available to patients should be expanded through switching.

The concept of self-care should be actively encouraged by legislators, regulators and healthcare professionals. This is consistent with Healthy Ireland, which shows that to create positive change in population health and wellbeing, a whole-of-government approach and the involvement of local communities are required.

IPHA encourages policymakers to implement the recommendations of the Self-Care Framework for Ireland.

[54] Pharmaceutical Society of Ireland, *Pharmacy Ireland 2020*
[55] Proprietary Association of Great Britain *Annual Review 2015*

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