ipha
IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION

# NEW MEDICINES FOR PATIENTS AS FAST AS IN EUROPE:

## NEED FOR SUSTAINED FUNDING GROWTH

Briefing for policymakers

# SUMMARY

**Innovative medicines are a valuable investment in health, providing great benefits for patients and society over many years.**

- Ground breaking medicines have made a big impact on patients lives.

**Recent medicine spend in Ireland has seen little to no growth, while many more patients are treated.**

- Ireland's spend per person on medicines is very close to the average of reference countries in Europe.
- The IPHA/State Agreement continues to provide significant savings and headroom for innovation.

**Patients in Ireland are not receiving new medicines that are available in many other EU countries.**

- Ireland is ranked 16th out of 26 countries in Europe in the availability of new medicines to patients.
- Only one-fifth of new cancer drugs launched internationally in 2014-15 are available in Ireland; Ireland performs worst on this measure.
- Prices and spending on medicines in Ireland are at the average of the reference countries but availability of new medicines is lowest.

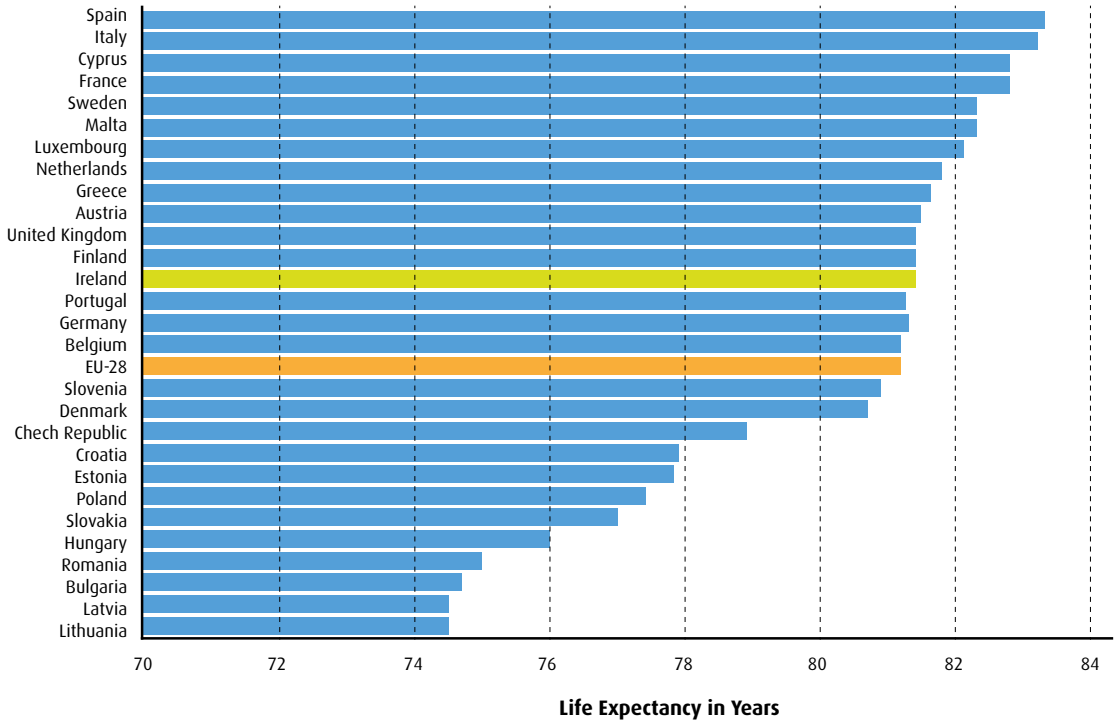
**The Government must provide sustained growth, year on year, in funding for medicines, so that innovative medicines are available to patients as fast as elsewhere in Europe.**

- With sufficient funding, collaboration with industry will provide solutions.
- Need to be consistent with investment in Ireland as an innovation island.

# Innovative medicines are a valuable investment in health, providing great benefits for patients and society over many years.

Many new technologies have changed the world in recent years. Among them are groundbreaking innovative medicines which cure diseases, prolong life and improve quality of life. The result is clearly visible through the increase in life expectancy experienced in many developed countries. Over the past decade, Ireland has achieved significant improvement in life expectancy. It has increased by almost two and a half years since 2005 and has been consistently higher than the EU average throughout the last decade, as shown in figure 1 below[1].

**FIGURE 1: LIFE EXPECTANCY AT BIRTH FOR EU-28 COUNTRIES, 2014**




In a study of 30 OECD countries over the period 2000-2009, an improvement in population weighted mean life expectancy at birth of 1.74 years was seen. Innovative medicines are estimated to have contributed to 73% of this improvement, once other factors are taken into account (e.g. income, education, immunization, reduction in risk factors, health system access)[2].

1 | Health in Ireland - Key Trends 2016: http://health.gov.ie/wp-content/uploads/2016/12/Health-in-Ireland-Key-Trends-2016.pdf

2 | Lichtenberg, F: Pharmaceutical innovation and longevity growth in 30 developing OECD and high-income countries, 2000 - 2009 (2012)

## Ground breaking medicines have made a big impact

Specific examples of medicines which have provided ground-breaking improvements in health are statins, anti-retrovirals in HIV and the direct acting antivirals used in the treatment of Hepatitis C.

- Statins caused a revolution in the treatment of high cholesterol, a serious risk factor for circulatory diseases. Their introduction in the mid-1990s has had a significant impact on mortality rates from circulatory system diseases in Ireland which fell by 28% between 2006 and 2015[3].

- HIV/AIDS was first discovered in 1984: while the first treatments were approved in 1987, it was the introduction of combination anti-retrovirals in 1996 that transformed HIV from a terminal disease to a chronic illness; today a 20 year old HIV patient can expect to live to over 70.

- The treatment of Hepatitis C has been transformed by pharmaceutical medicine: the new medicines have a cure rate of over 95%, fewer side effects than previously available therapies, and can completely cure the disease within three months[4].

The development of new medicines such as these needs prolonged, meticulous high levels of research. New medicines are rigorously tested for quality, safety and efficacy through highly regulated and expensive clinical trials before they are authorised to be provided to patients on the direction of their clinicians. While new products may have twenty years patent protection, half or more of the protected years may be spent in trials and the authorisation and reimbursement processes. Investing in innovation is key to bringing solutions to patients.

## Medicines spending has seen low or no growth, while many more patients are treated

Spending on medicines should be set in the context of benefits and value. It is too often treated as a cost without consideration of the associated benefits for patients, society and the economy. It is also important to reflect accurately facts and recent trends in spending levels.

Ireland now spends less than the EU average on medicines as a proportion of its current health budget - 13% as against the EU-27 average of 16%[5].

The State spends almost €2 billion annually on providing medicines to patients in primary care through the HSE's Primary Care Reimbursement Service (PCRS)[6]. However just over 60% of this actually relates to the cost of the medicines themselves. The additional costs include:

- the cost of distribution (pharmacy and wholesaling fees) at over €500m,
- VAT in the region of €100m and
- non-drug items (clinical foods, ostomy, dressings etc.) costing about €150m.

Thus the actual cost of the medicines themselves is in the region of €1,250m with the research based companies represented by IPHA accounting for about 75% of this total, €950m. Ireland now also spends approximately €420m on medicines in public hospitals.

3 | Health in Ireland, ibid.

4 | http://www.who.int/mediacentre/news/releases/2016/hepatitis-c-medicines/en/

5 | OCED Health Statistics - Frequently Requeted Data 2017

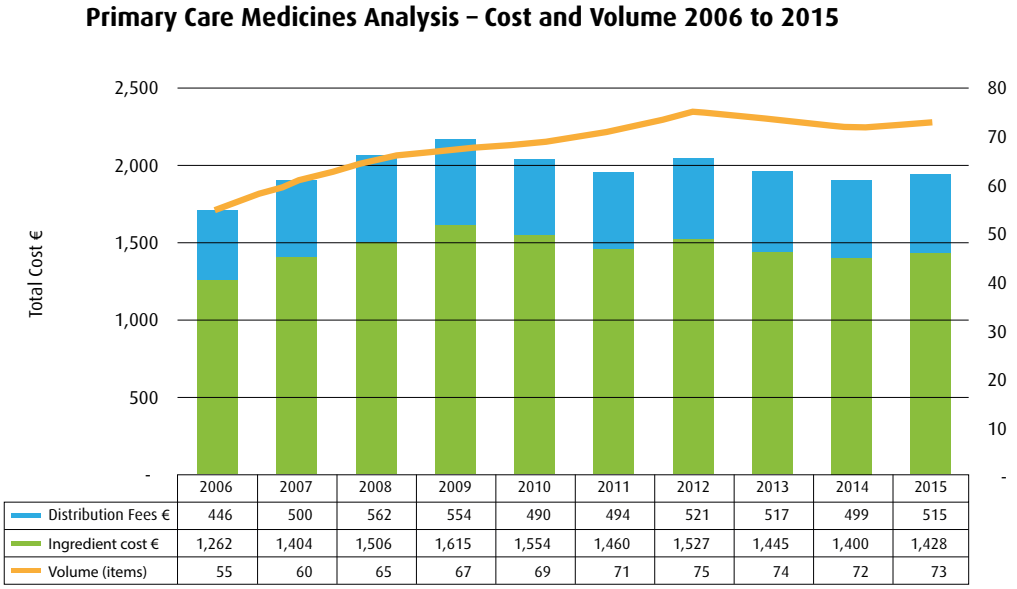
6 | PCRS Annual Report - Statistical Analysis of Claims and Payments 2015

There has been significant commentary on the growth of the PCRS over time. While PCRS expenditure grew year on year up to 2009, it has reduced slightly and remained quite flat since then (see Figure 2). This has been delivered largely through the measures in agreements between IPHA and the State.

A ten year view of the PCRS spend on medicines from 2006 to 2015 shows growth of 13.2% - a low 1.39% compounded annual growth rate. During the same period the volume of medicines provided increased by 32% from 55 million items to over 72 million items. This means that more Irish patients were being treated and indeed being better treated than previously [7]. There have been significant gains in life expectancy over this period.

Over the period 2012–15[8], spending remained flat while the volume of medicines dispensed increased by approximately 9 per cent[9].

**FIGURE 2: PCRS SPEND ON MEDICINES (INCLUDING NON-DRUG ITEMS) 2006 TO 2015**




| | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|---|---|---|---|---|---|
| Distribution Fees € | 446 | 500 | 562 | 554 | 490 | 494 | 521 | 517 | 499 | 515 |
| Ingredient cost € | 1,262 | 1,404 | 1,506 | 1,615 | 1,554 | 1,460 | 1,527 | 1,445 | 1,400 | 1,428 |
| Volume (items) | 55 | 60 | 65 | 67 | 69 | 71 | 75 | 74 | 72 | 73 |

## Ireland's spend per person on medicines is very close to the average of our reference countries in Europe

In 2016 Ireland's spend per capita on medicines was €364 - 7th out of the 13 countries, the median, and only €8 above the average spend per capita of €356.

This data is shown in Figure 3, a new comparison of per capita spend on medicines, prepared by Quintiles IMS Health. It compares spending per capita, as measured by sales, on primary care and hospital medicines for the EU-15 (Ireland plus the 14 reference countries[10] for pricing in the current Agreement between IPHA and the State). Ireland's spend per capita on medicines is very close to those of Austria, Denmark, Finland and Belgium.

7 | PCRS Annual Reports - Statistical Analysis of Claims and Payments 2006 to 2015

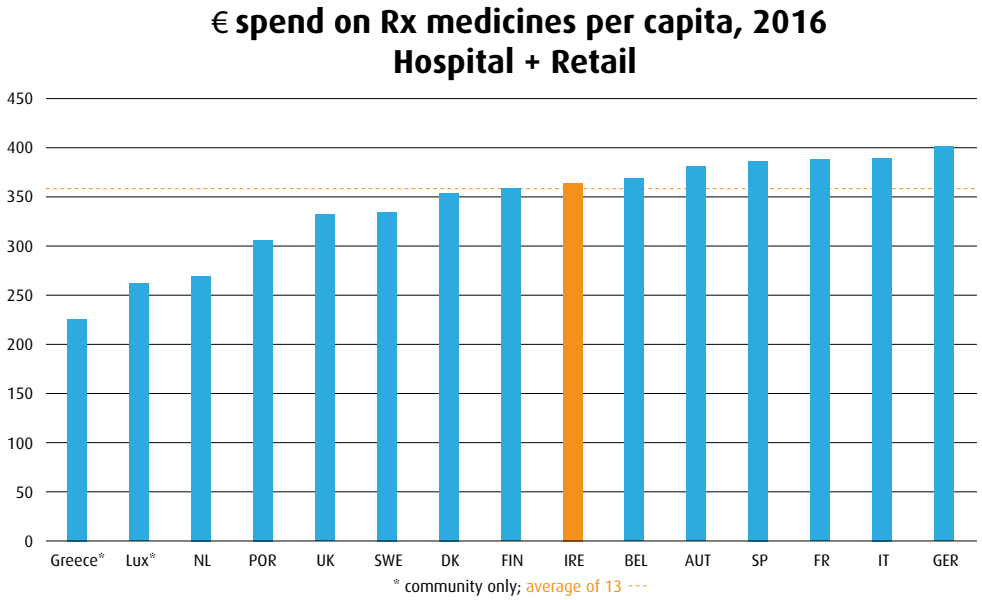
8 | http://igees.gov.ie/wp-content/uploads/2015/02/Future-Sustainability-of-Pharmaceutical-Expenditure.pdf

9 | IMS retail unit sales 2012 - 2015, prescription bound

10 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK

The significance is that prices are now set at the average of the 14 countries, and spending per capita is very near the average. Unfortunately, access to new medicines for patients in Ireland is not at the average, rather, it trails at the end of the group.

**FIGURE 3: PER CAPITA PHARMACEUTICAL SPEND (HOSPITAL AND RETAIL) IN THE EU 15 2016**




SOURCE: QuintilesIMS Midas; total audited market, Rx only, Retail and Hospital sales. Population numbers from Eurostat

Figure 3 provides a more accurate measure than a ranking produced by the OECD of pharmaceutical spend per capita, which has shown Ireland in the top quartile of countries at US$684ppp[11]. The OECD itself cautions against direct comparison of its values, for example, in relation to specialty medicines which are in Ireland's total but not in those of Denmark, Italy or Spain, as the OECD table records ambulatory costs and excludes the cost of medicines distributed through hospitals[12].

## The IPHA/State Agreement continues to provide significant savings on medicines

In July 2016, IPHA entered into a further Agreement on the supply and pricing of medicines with the State (HSE/DoH/DPER). The dual purpose of the 2016 Agreement is to provide significant savings to the State to facilitate the reimbursement and timely access to new medicines for Irish patients.

On the commencement of the Agreement, the Minister for Health stated that he was *"delighted this deal delivers better value for the State and will provide better access for patients to new and existing drugs."* IPHA member companies have fulfilled their obligations under the Agreement and continue to provide this headroom for innovation with savings on track to achieve an estimated €785m over the four year term of the Agreement.

11 | OECD Health Statistics 2017 - Frequently Requested Data

12 | OECD Health Statistics 2016 - Definitions, Sources and Methods - Pharmaceutical sales

These savings are achieved through the various cash and non-cash mechanisms as follows:

| Source of Savings (Clause of Agreement) | Savings €m |
|---|---|
| Annual price realignment of patent protected and exclusive off-patented medicines to the average price across 14 European countries[13] (Clause 5) | 317.1 |
| Price reduction of patent-expired, non-exclusive medicines (excluding biologic medicines) (Clause 7) | 112.1 |
| Price reduction of patent-expired, non-exclusive biologic medicines (Clause 8) | 104.1 |
| Rebate on sales (Clause 9) | 251.35 |
| **Total Savings** | **784.66** |

It cannot be assumed that most of these savings would have been achieved in the absence of the 2016 Agreement or that these savings are somehow not real. They represent both costs avoided and cash payments (rebates) to the HSE.

The choice in summer 2016 was between the stability of a new Agreement or no Agreement with unilateral measures to be undertaken by the HSE. There could have been no reliance by the State on the continuation of provisions of the 2012 Agreement by IPHA member companies in the absence of a new agreement; for example, there would be no ability for the HSE to secure cash rebates from suppliers without the agreement.

## Despite the savings, patients in Ireland are still not receiving access to new medicines that are available to patients in many other EU countries.

## Ireland is ranked 16th out of 26 countries in Europe in the availability of new medicines to patients.

## Only one-fifth of new cancer drugs launched internationally in 2014-15 are available in Ireland; Ireland performs worst on this measure.

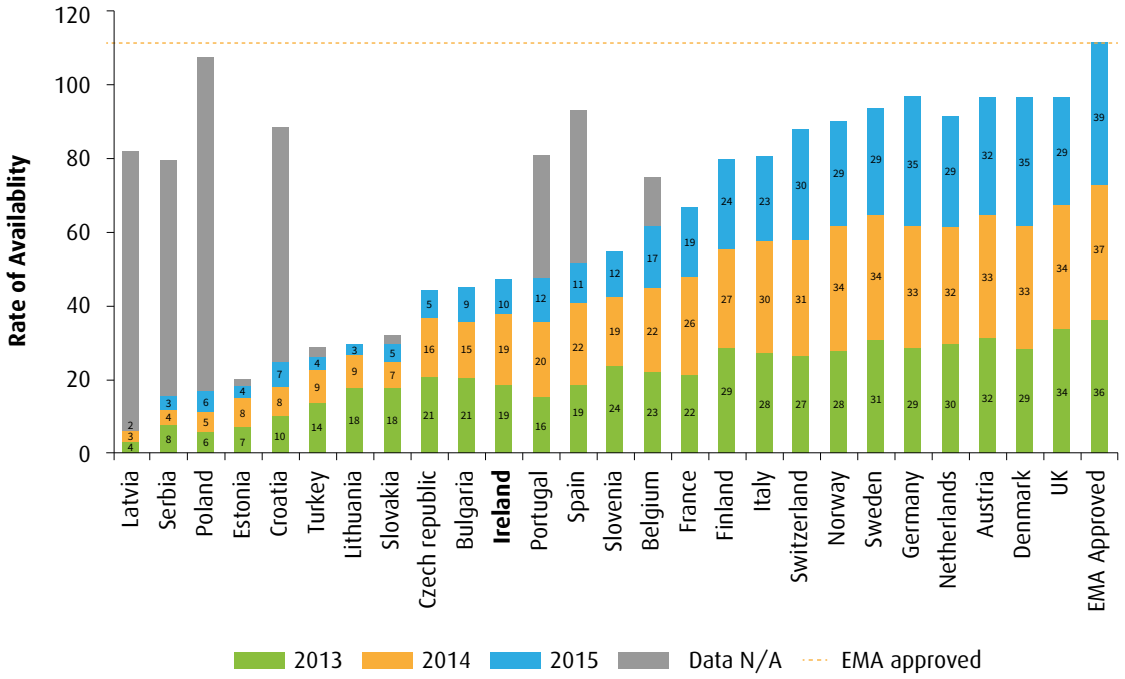
## Prices and spending in Ireland are at the average, but availability of new medicines is at the lowest.

13 | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK.

On the introduction of the 2016 Agreement, the Minister for Health stated that *"The Government wants to ensure that Irish patients continue to have access to new and innovative medicines and that Ireland remains at the forefront of its European peers in terms of early access to medicines."* In addition, the Government launched a new Cancer Strategy in July 2017 which states that Ireland aims to be in the top quartile in Europe in terms of outcomes for cancer. However, these objectives are not achievable in the absence of growth in funding.

International evidence has shown that Ireland is falling behind its European counterparts in terms of access to new medicines. The results of the 2016 EFPIA Patient W.A.I.T Indicator[14] ranked Ireland 16th of 26 countries in Europe in terms of the number of authorised medicines being made available to patients (Figure 4).

**FIGURE 4 : EFPIA PATIENT WAIT INDICATOR 2016**

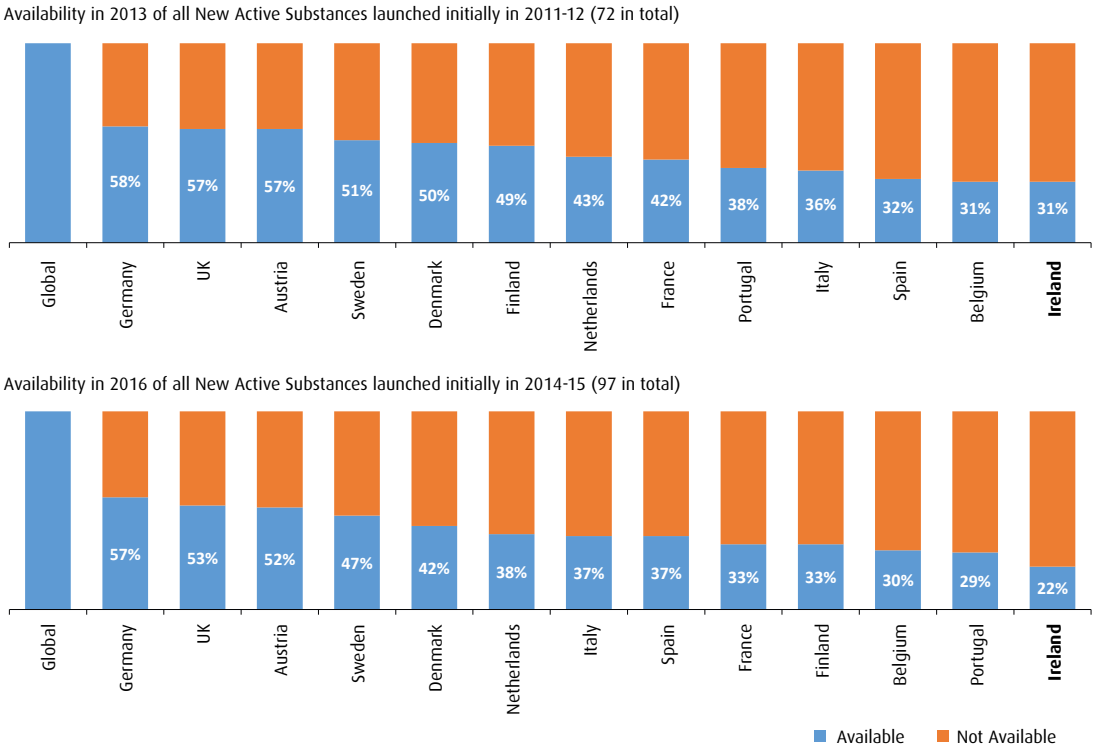



New analysis conducted by QuintilesIMS[15] has also shown Ireland to rank last among key European counterparts in terms of the availability of newly launched medicines. In 2013, just 31% of all newly launched medicines in the previous two years were available in Ireland. In 2016, this had fallen to 22%. Ireland's ranking is last among western Europe - the EU-14 reference countries used for pricing (excluding Greece and Luxembourg for technical reasons).

14 | European Federation of Pharmaceutical Industries and Associations.

15 | QuintilesIMS, MIDAS Mar 2017; the measure is recorded sales; GR and LU retail only; % represent the number of New Active Substances launched.

**FIGURE 5: RATE OF AVAILABILITY OF NEW MEDICINES LAUNCHED IN IRELAND AND COMPARABLE EU COUNTRIES**




**Source:** QuintilesIMS, MIDAS Mar 2017; % represent the number of NAS launched; GR and LU removed because retail only.

While Ireland was once an early adopter of medicines, the evidence suggests that this is no longer the case. Through IPHA agreements, prices and spending levels are now at the average of comparable EU countries – but access to new medicines is lowest.

The continuing trend in reimbursement delays is in direct opposition to the Government's stated goal for Ireland to be at the forefront of access to medicines. A clear policy must be adopted if the current situation is to be improved.

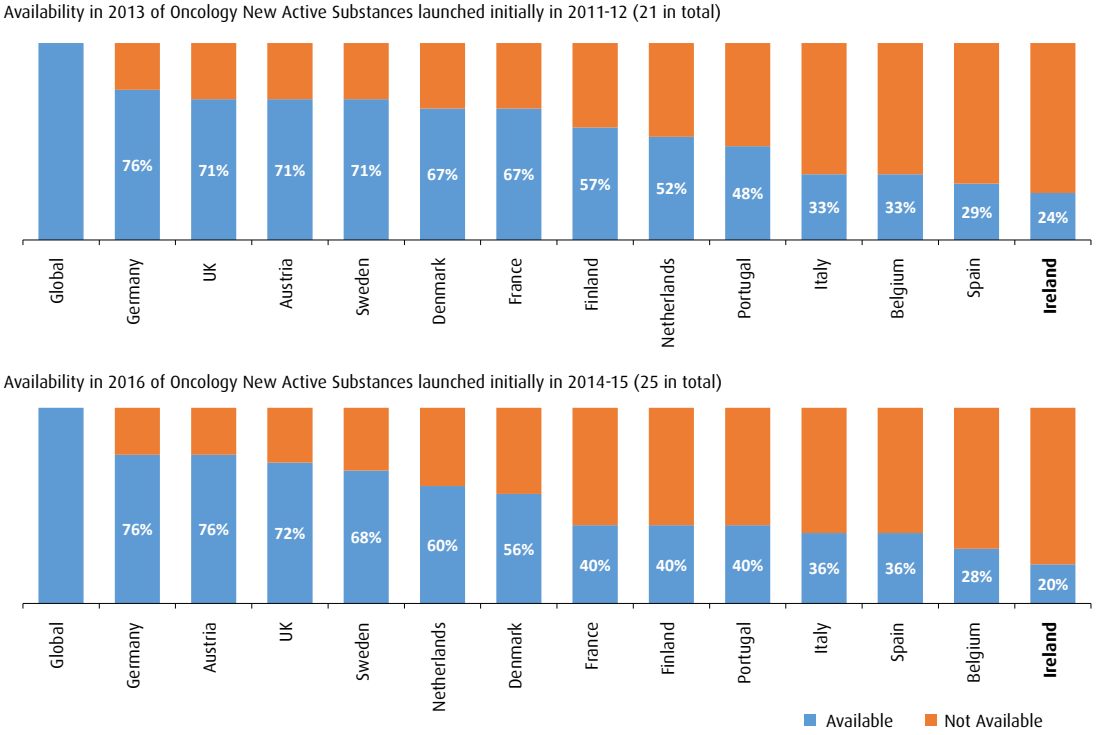
The situation for cancer medicines is even worse (Figure 6).

In 2016, only 20% of new cancer medicines launched internationally in 2014-15 were available to patients in Ireland. Double that number were available in Portugal.

Countries such as the Netherlands, Sweden, Austria and Germany brought more than three times as many new cancer medicines to patients as Ireland.

The QuintilesIMS analysis also illustrates that Ireland's bottom-ranking performance on this measure had deteriorated between 2013 and 2016.

**FIGURE 6: RATE OF AVAILABILITY OF NEW CANCER MEDICINES IN IRELAND AND COMPARABLE EU COUNTRIES**




**Source:** QuintilesIMS, MIDAS Mar 2017; *GR and LU retail only; % represent the number of NAS launched.

Patients in Ireland deserve to know that they will have access to new medicines at least as fast as patients in comparable European countries.

A policy aspiration won't be enough to deliver this. It will need sustained funding growth, a process aimed at achieving results and performance management.

IPHA calls on the Government to benchmark speed of access to new medicines against the 14 reference countries by which the price of medicines in Ireland is set.

## The Government must provide sustained growth, year on year, in funding for medicines, so that innovative medicines are available to patients as fast as elsewhere in Europe

The funding of health systems in Europe is challenging for many reasons including (i) older and ageing populations (ii) the rapid pace of technological innovation and (iii) unmet needs and demand.

Ireland is no different. However, as already mentioned, the members of IPHA have entered into an Agreement with the State to reduce the price of medicines and provide rebates in order to provide savings which can then be re-invested in new innovative medicines.

However, the Government must play its part also by adding Exchequer funding. It is not the industry's responsibility to fund new medicines. There has to be a sustained commitment to grow the Exchequer funding at a reasonable rate.

Any idea that the State can or should have virtually no growth in the medicines budget will simply deny patients access to new medicines. This is the experience in 2017, when the HSE's PCRS budget was provided with virtually zero growth. The absence of additional Exchequer funding, over and above IPHA savings, has caused inevitable delays in patients having access to medicines that are routinely available in most of western Europe.

It is not plausible to have zero growth in medicines spending, given the needs of patients and the central role of innovation in improving health outcomes. It is normal for States to provide for growth in expenditure on medicines. Our EU-14 counterparts, like us, carry out Health Technology Assessments, control spending and manage budgets – but, unlike Ireland, most provide for a reasonable level of growth in State expenditure on medicines. And most deliver much faster access to medicines for patients.

## With sufficient funding, collaboration on new models and ideas will provide solutions

IPHA members are playing their part in enabling new medicines to be funded. In addition, IPHA is open to examine new models and processes to deliver a shared aim of bringing new medicines to patients faster.

IPHA asks the Minister for Health to collaborate with industry on building a model for supporting fast patient access in Ireland to innovative new medicines, to put Ireland top of the table for supporting fast access to important new medicines, as deemed by relevant clinicians. We are open to examining the particular assessment processes and funding issues for medicines for rare diseases. We can explore appropriate risk sharing mechanisms for particular circumstances. There are many more actions that can be taken with the key goal of providing access to new medicines faster.

## Need to be consistent with investment in Ireland, an innovation island

More broadly, Ireland sells itself as an innovation island, and attracts foreign direct investment on this basis. Innovation in medicines means research, discovery, manufacturing and adoption in healthcare for patients. Ireland cannot leave the last part out.

Current delays in reimbursement are at odds with massive investment by leading pharmaceutical companies in Ireland, the support our industry provides for research and the manufacturing of many of these new medicines in Ireland.

This is reflected by the fact that approximately 50,000 people are employed in the industry here, both directly and indirectly. We are the 7th largest exporter of pharmaceutical and medical products in the world, totalling €39 billion. €8 billion of investment in research and development is committed by the Government over the next decade, a policy that actively seeks industry partnership funding[16].

This must be matched by a workable policy to make innovative medicines available to patients in Ireland's health services.

16 | http://www.idaireland.com/doing-business-here/industry-sectors/bio-pharmaceuticals/

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