ipha
IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION

MANIFESTO FOR BETTER HEALTH

PATIENT CARE, POWERED BY INNOVATION

IPHA is the representative organisation for the international research-based pharmaceutical industry in Ireland. Our members discover and develop innovative medicines for treating or curing medical conditions and diseases, improving patients' quality of life and their life expectancy.

October 2018

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LINKING ACCESS AND INNOVATION

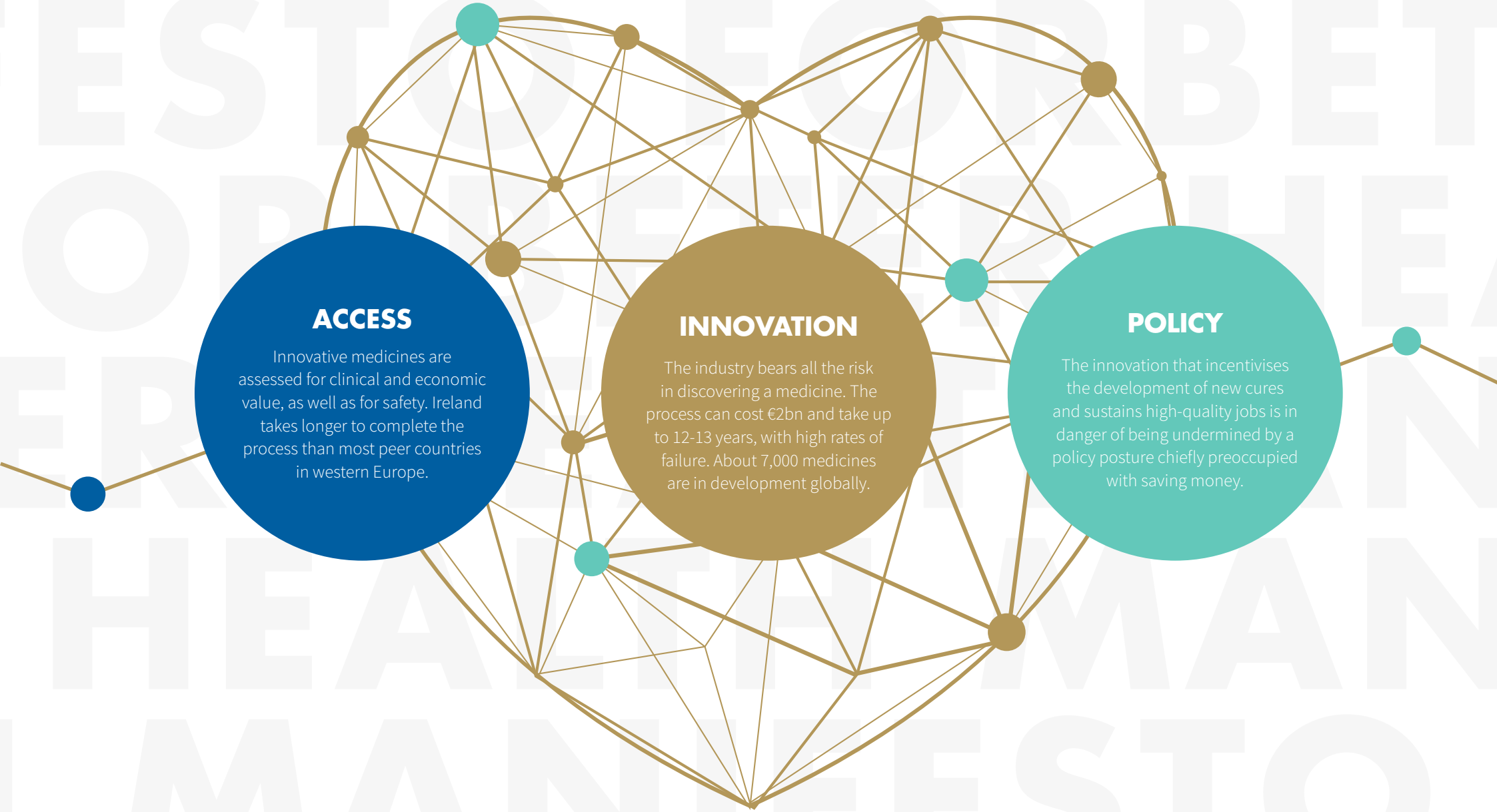
Ireland, to realise the full measure of our potential, needs a healthy population. With an economy growing faster than most others in Europe, social outcomes, which include healthcare ones, are assuming critical status, along with economic targets, in a country in flux. Life expectancy in Ireland is rising faster than the European Union average[i]. By 2040, an extra million people will live in Ireland. An additional two-thirds of a million people will be working[ii]. By 2030, one in six people will be over 65 and there will be twice as many people aged 85 and over[iii].

These trends are bringing increasing demand on social infrastructure. To keep up, Ireland will need to innovate and adapt, opting for new models of social infrastructure that embed well-being and opportunity at the heart of the community. As Ireland reaches for the promise of innovation, new jobs are emerging that require a mix of skills. How fast we adopt innovation across the economy will determine our success in achieving the future we imagine for ourselves. As the population grows, changes and ages, the role of innovation in meeting medical need becomes more vital. Our industry, made up of pharmaceutical innovators, has a major stake in Ireland's future. Both here, and across the world, our scientists are discovering tomorrow's cures, bearing the huge costs, risk and time invested in pharmaceutical innovation. Our medicines are helping people live longer, healthier lives. They are creating high-value jobs in a fast-growing economy.

This is our side of the bargain. For it to work for Ireland, the Government must give patients access to the innovative medicines we make. As things stand, it is not doing that fast enough. In other words, innovation and access are disconnected. This is now an urgent challenge.

Ireland is falling well short of healthcare expectations for a western European country. Waiting lists and waiting times grab the headlines. The basis for Sláintecare, the Government's 10-year plan for health, is to deliver a European standard, single-tier healthcare system. Meanwhile, we are denying patients access to some innovative medicines, routinely available in western European public health services, by not treating the repair of an inefficient approvals process, and an unpredictable funding arrangement, as policy and political priorities. Both the short and long-term consequences of this scenario are clear: the impact on mortality rates and, conversely, survival rates relative to European standards, as well as quality of life, will be negative. Allied with that, decisions about future investments in manufacturing sites and research centres, usually taken in boardrooms overseas, are weighed against several criteria. Among these is increasingly the capacity of countries to provide timely access to new medicines for patients. In Ireland, this process is held up by inadequate processes and funding. It must be fixed – and fast.

Our industry wants to partner with Government to speed patients' access to innovative medicines. Alongside our huge investment in discovery and the agreement of fair prices that are no more than the average of 14 other western European countries, the industry advocates for an environment in which innovation is valued and medicines are approved quickly for patients. This, in turn, will help Ireland raise standards of healthcare. It will strengthen our capacity to attract investments in research and manufacturing. That means existing jobs can be sustained and more can be generated.


ACCESS
Innovative medicines are assessed for clinical and economic value, as well as for safety. Ireland takes longer to complete the process than most peer countries in western Europe.
INNOVATION
The industry bears all the risk in discovering a medicine. The process can cost €2bn and take up to 12-13 years, with high rates of failure. About 7,000 medicines are in development globally.
POLICY
The innovation that incentivises the development of new cures and sustains high-quality jobs is in danger of being undermined by a policy posture chiefly preoccupied with saving money.

In this Manifesto, we have mapped Ireland's pharmaceutical landscape under three Vision Pillars: 'Access For All', 'Innovation Excellence' and 'Republic of Partnerships'. We are conscious that any solutions for the challenges we outline must be set within a budgetary control framework. The key policy goals are:

BOOST FUNDING

Create a predictable, multi-annual budgetary framework, with sustained, reasonable annual increases in funding for innovative medicines. This needs to be explored with payers based on 'horizon scanning' for new medicines on the way, as well as projected demand for existing treatments.

SPEED ACCESS

Place Ireland in the top quartile of European countries for access to innovative medicines. This would rank Ireland in the top seven of the EU-28 and in the top half of the 'basket of 14' used for pricing in our deal with the Government.

FUEL INNOVATION

The Government, with the support of the Taoiseach, should publicly recognise the value of the pharmaceutical industry to Ireland, with concrete actions that can be pursued jointly by a formal partnership between policymakers and industry leaders. This happens in other European countries and regions[iv].

All of this can happen if we work together for it. Through partnerships that place the patient at the centre, we can lift Ireland's standards of care to be among the best in Europe. We hope this Manifesto can help prompt the start of meaningful industry-Government dialogue to explore options for improving healthcare through pharmaceutical innovation.


VISION ONE

ACCESS FOR ALL

BRING INNOVATIVE MEDICINES TO ALL PATIENTS FASTER

Ireland performs very poorly against peer countries in western Europe on speed of access to innovative medicines.

In our most recent analysis, published in August 2018, nine innovative medicines were available, on average, in 12 of 14 western European countries – but they were not yet routinely available and reimbursed for Irish patients. The medicines were for cancer, cardiovascular disease and musculoskeletal treatment. They had been in the approvals process for more than two years[v]. Four medicines were for lung cancer – the leading cause of cancer death between 2012 and 2014[vi]. Each year, 2,500 Irish people are diagnosed with lung cancer. Lung cancer is among the top five most commonly diagnosed cancers in Ireland[vii]. Ironically, some of the medicines on the list that are available in the 12 countries but not here were made in Ireland.

Access to new, innovative treatments should be a goal shared by industry and Government. But Irish patients continue to be among the last in western Europe to get access to innovative medicines, despite prices here being calculated at the average of the price in 14 EU countries – Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK.

The Government wants to engage with our industry to 'explore ways in which new medicines might be more easily introduced in Ireland,[viii]. We are eager to engage, too, on solutions that work for both sides. There is an onus on both sides to act – but the Government must make good on its pledge to open dialogue with industry to tackle this issue as a matter of urgency.

As an industry, we do not claim to have all the answers. However, we are calling for a new era of partnership between industry and Government that speeds access to innovative medicines for patients, and recognises the centrality of innovation in building a better healthcare system for Ireland.

To deliver access for all, Ireland needs to spend more on medicines. This year, Ireland's budget increase for new medicines was around €14 million. The overall medicines and drugs bill is some €2 billion[ix]. The rise is a very small proportion of the overall budget and it falls well short of enough to meet demand.

Budgeting for medicines must go beyond the short-term, annual allocation. This has led to stop-start funding for new medicines, even within single years. In that context, we are not presenting an annual shopping list to Government at Budget time.

Rather, we advocate for a more strategic, multi-annual funding framework that takes into account a range of factors including the new medicines about to become available, projected demand for existing treatments, the increasing complexity of conditions, the rising prevalence of rare diseases, an ageing population, and other financial pressures on the healthcare system.

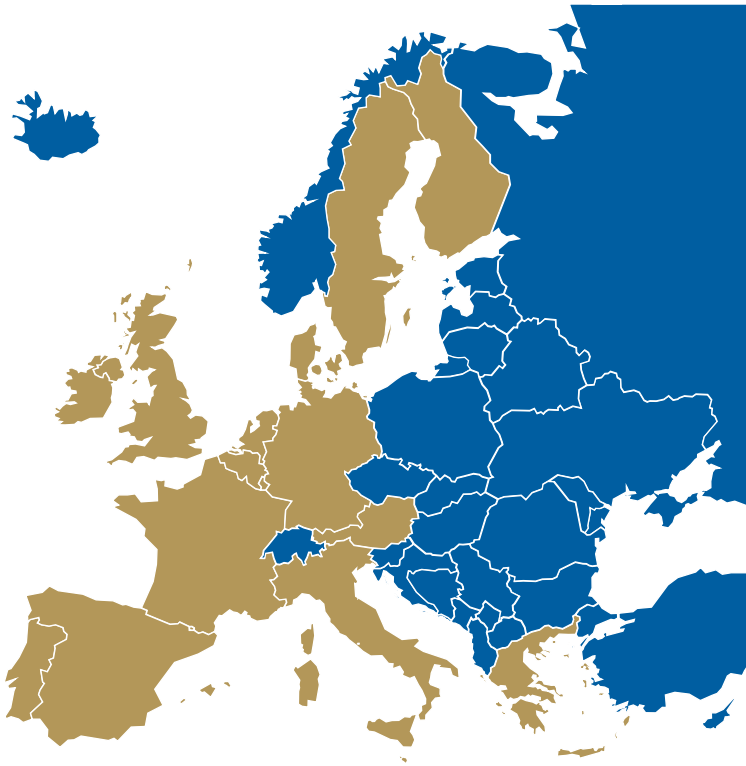
We believe a thorough consideration of these drivers can lead to the creation of a predictable, multi-annual budgetary framework, with sustained, reasonable annual increases in funding for innovative medicines. This would fit within EU fiscal rules for Ireland and prudent, controlled public health spending. In the short term, we believe the savings delivered by the industry, amounting to €785 million over the four years of the deal with the Government, should be reinvested into making new medicines available to patients faster.

There is no 'one-size-fits-all' approach to reimbursing medicines[x]. But we can learn from the experience of other countries in Europe where, unlike Ireland, many of them formally consult patients in the decision-making process for approving medicines. The ways in which other countries make medicines available to patients – often termed 'managed entry strategies' or 'market access pathways' – are broken down into financially based schemes and outcomes-based schemes.

Financially based schemes include price-volume deals, discounts and rebates, free stock, and budget and utilisation caps. Outcomes-based schemes cover pricing by performance which allow prices to reflect the benefit demonstrated in clinical practice. Outcomes guarantees, on the other hand, mean manufacturers refund part or all of the cost of treatment if patients fail to meet specific outcomes targets. Early access schemes are often used for certain diseases and conditions prevalent in the population or for rare diseases requiring highly personalised treatments.

The solution that gives patients in Ireland access to new medicines as fast as the top quartile in Europe will emerge from a detailed exploration of the most appropriate of these pathways or variations of them. The key is that the Government sets the outcome as a firm policy goal, and a challenge that demands a collective response, so that patient care in Ireland keeps up with best international standards. We should recall that the Government's National Cancer Strategy aims to place Ireland in the top quartile of European countries for cancer survival in the next decade.

PRICES FOR MEDICINES IN IRELAND ARE CALCULATED AT THE AVERAGE OF THE PRICE IN 14 EU COUNTRIES



The persistent logjam in approving cancer medicines will make it hard for Ireland to hit that target, especially when we know that survival gains for cancer are increasingly attributable to new treatments.

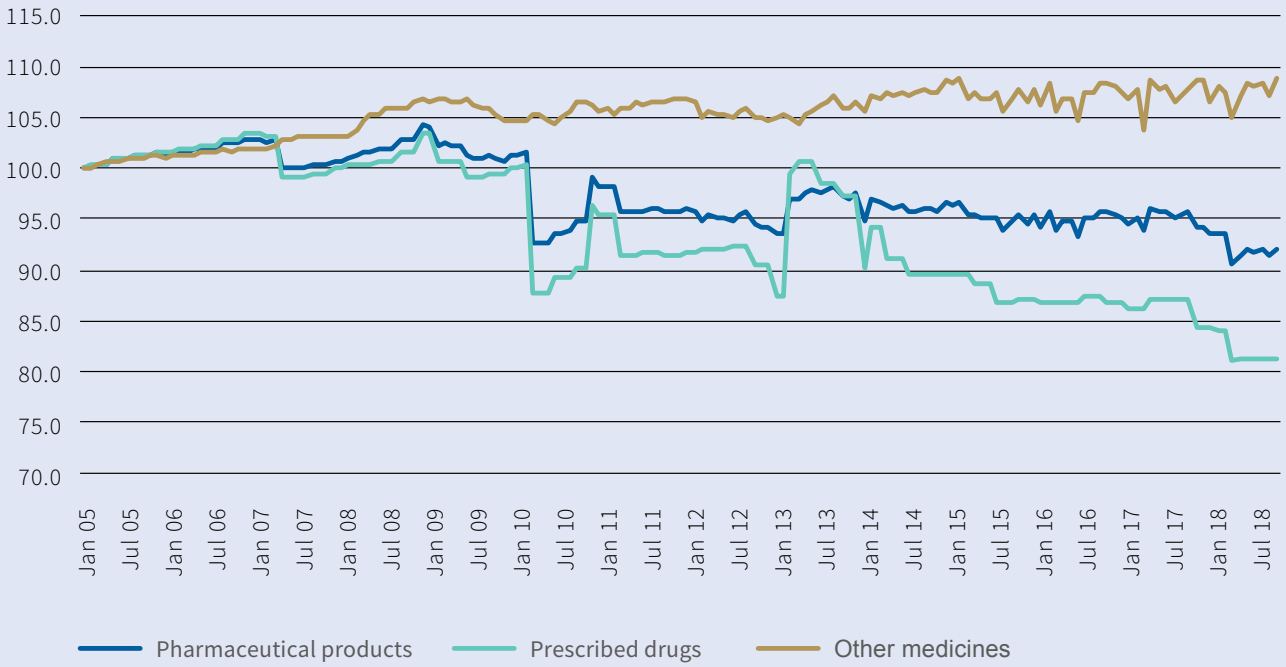
While reimbursement decisions are taken locally, we see no impediment to sharing more clinical evidence, as well as data on procurement, negotiations and capacity-building, between countries in Europe if the result is new insights that can improve access for Irish patients. So, while cross-border initiatives like BeNeLuxA are often presented as breakthroughs on pricing and supply, it is important that Ireland is not diverted from fixing problems here at home by the promise of solutions involving other nations. Assessing and benchmarking EU health systems by using patient-relevant outcomes, with the support of digital solutions and a European harmonised distributed health data network, are among the considerations for policymakers as we seek to strengthen our capacity to meet healthcare needs. Crucially, we must anticipate the new medicines on the horizon and ensure that our systems are set up to deliver them, or, better, manufacture and deliver them, effectively to patients.

EXAMPLES OF MARKET ACCESS PATHWAYS

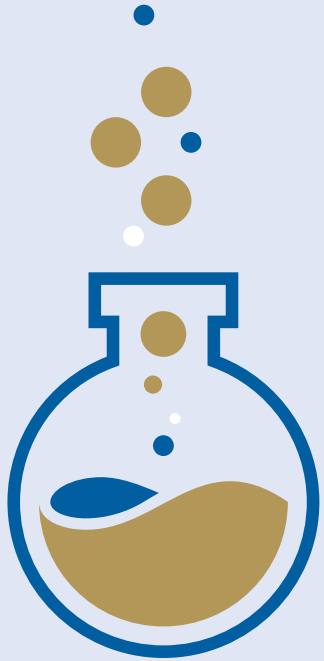
	TYPE OF ARRANGEMENT	KEY CHARACTERISTICS
FINANCIALLY BASED SCHEMES	**Price-volume agreements**	A drug's price is inversely linked to prescription volume.
	Discounts/rebates	Manufacturer offers a concession on a drug's list price in return for (favourable) reimbursement.
	Free stock	Manufacturer provides some stock without charge.
	Budget caps	Total expenditure on a drug is limited. Manufacturer covers excess costs.
	Utilisation caps	Manufacturer covers treatment costs beyond a specified level of use.
	Fixed cost per patient	Price per patient is the same, regardless of drug consumption.
OUTCOMES-BASED SCHEMES	**Coverage with evidence development**	Price reimbursement terms are subject to review based on postmarking trails and real-life data.
	Outcome guarantees	Manufacturer refunds part or all of the cost of treatment if patients do not meet specified outcomes targets.
	Patient eligibility controls	Access to a drug is restricted to patients who satisfy strict eligibility conditions, possibly controlled by enrolment in patient registries.
	Conditional treatment continuation	Continuation of treatment is contingent on patients meeting specified outcomes and milestones.
	Process of care	Reimbursement is linked to defined treatment protocols (e.g. therapeutic plans, disease management programmes).

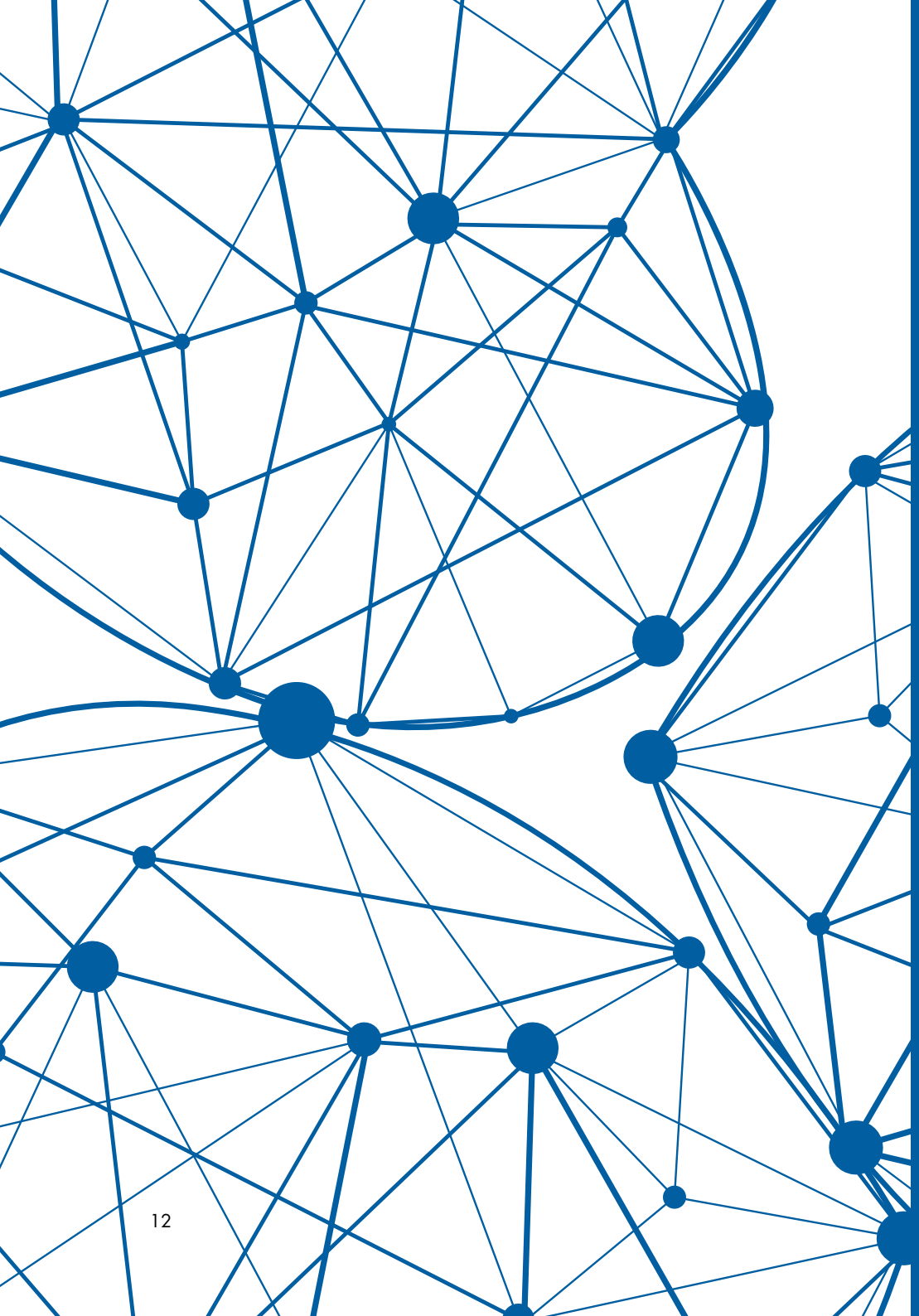
Much of the debate on pharmaceuticals is premised on price. That misses the value argument which is more about the human health and economic dividend of innovation. Even if we focus on what is paid for medicines, our prices are limited to the average of 14 European countries under the industry's deal with the Government. In the first seven months of 2018, the average consumer price of pharmacy products declined by 3.9% while the price of prescribed medicines declined by 6.5%[xi]. An analysis of the medicines reimbursed by the HSE in primary care shows that over 4,000 products, or 61%, are under €20 per pack. Just 698 products, or 11%, are priced over €100 per pack[xii].

CONSUMER PRICE OF PHARMACEUTICAL PRODUCTS



Source: CSO





WHAT IRELAND CAN DO

1 Create a predictable, multi-annual budgetary framework, with sustained, reasonable annual increases in funding for innovative medicines. This needs to be explored with the State authorities based on 'horizon scanning' for new medicines, a range of market entry methods appropriate for each medicine, data and evidence gathering, and projected demand for existing treatments.

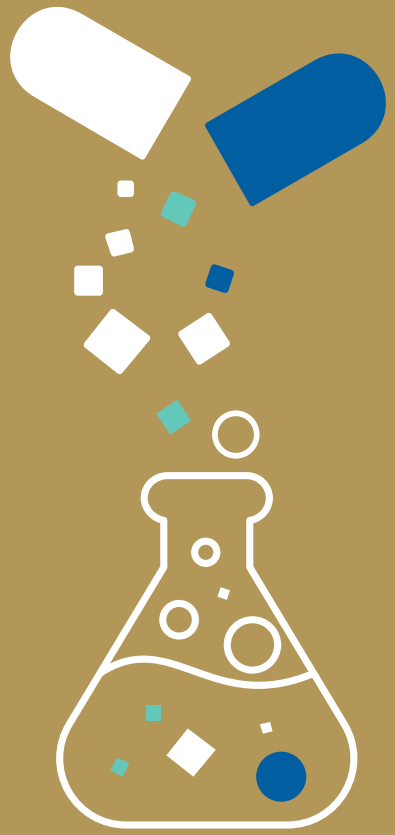
2 Place Ireland in the top quartile of European countries for access to innovative medicines. This would rank Ireland in the top seven of the EU-28 and in the top half of the 'basket of 14' used for pricing in our deal with the Government.

3 Make the reimbursement system responsive and transparent by formally involving patients in the medicines evaluation process, and publishing reimbursement decisions and their justifications.

VISION TWO

INNOVATION EXCELLENCE

BUILD IRELAND'S CAPACITY TO DISCOVER AND MAKE TOMORROW'S CURES



An exciting global wave of medical innovation is breaking around the world – and Ireland should be ready to catch it. But we have much ground to make up. Ireland's investment in pharmaceutical research and development is very low by European standards. In 2016, Europe invested nearly €35 billion in research and development. Ireland's contribution was just €305 million. The UK invested €5.7 billion. Germany, the largest spender, invested €6.2 billion[xiii].

For Horizon 2020, Europe's public research fund, Ireland set a funding target of €1.25 billion. As things stand, we have secured some €513 million in funding since 2014[xiv]. Under the Innovative Medicines Initiative, another fund to help European research projects to scale, Ireland had five projects funded, against the UK and Germany which had 58 each. Under the successor fund, known as IMI2, Ireland has six projects in play[xv]. Clearly, we should aim to take a much greater share of funding for high-potential public-private partnership projects.

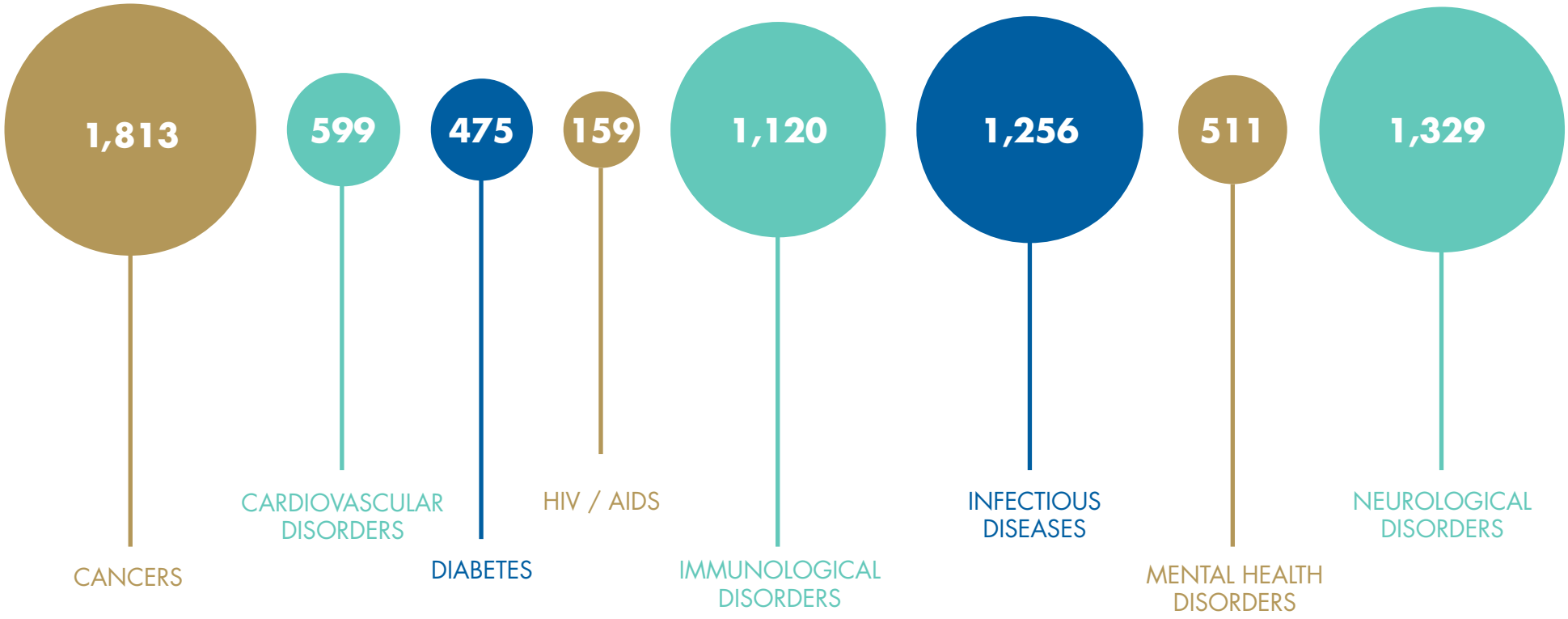
While the Government aims to make Ireland a 'global innovation leader'[xvi], it is not planning strategically for the global wave of pharmaceutical innovation. The challenge for Ireland is to build our capacity to attract more discovery and manufacturing activities for innovative medicines, especially as conditions require increasingly complex treatments, the population ages and rare diseases become more common. Ireland should aim to be a player of European consequence in unlocking tomorrow's cures. To do that, we should focus on emerging areas of discovery, as well as rare and complex conditions that require tailored treatments. In other words, we need to plan. Although SFI-backed research partnerships with our industry are creating huge value for society and the economy, there is no centrally coordinated, Government-backed strategy to exploit new opportunities in advanced therapeutics. It is critical that Ireland seizes the potential of scientific leadership. As a first step, it should appoint a Chief Innovation Officer in the Department of Health whose responsibilities would include planning for the emerging wave of pharmaceutical innovation.

For the past century, drug development consisted of tiny-molecule treatments focused on very large patient groups. This has worked for many patients but not for all. Now, we understand much more about human genetics – what makes each of us unique. With that knowledge comes the potential to make personalised medicines. Just as algorithms have made our internet experience more individual, biotechnology is revolutionising how patients are medicated.

Scientific advancements mean that we know more about illness than ever before. This knowledge is being translated into new ways of treating common conditions such as Alzheimer's disease, Type 1 diabetes, Multiple Sclerosis and many cancers, as well as rarer conditions like haemophilia. Science will be key to overcoming the increasing threat of anti-microbial resistance. These are some areas in which Ireland, with its huge pharmaceutical manufacturing clusters and local access to universities, can make progress.

CONTINUING TO DRIVE INNOVATION

With over 7,000 medicines in development, an exciting new wave of medical innovation will play a key role in addressing the challenges faced by patients and healthcare systems.



Source: EFPIA

PROMISING MEDICINES IN DEVELOPMENT HAVE THE POTENTIAL TO TRANSFORM CARE, HELPING PATIENTS LIVE LONGER AND WITH A BETTER QUALITY OF LIFE.

New medicines rely for their discovery and development on pharmaceutical incentives and rewards, including patents, supplementary protection certificates (SPCs), regulatory data protection, paediatric extensions and orphan market exclusivity. The incentives are the scaffolding that reinforce the innovation environment for pharmaceutical research and manufacturing. Through limited protection from copy and competition, the incentives give companies researching and developing new medicines some certainty about investing in the long, complex, risky and costly process of delivering new medicines to patients.

One of these incentives, the SPC, is at risk of being undermined by a European Commission proposal to introduce a manufacturing waiver for export. The Commission has submitted a proposal to Parliament and Council to amend the SPC regulation. The change would allow generics companies to manufacture in the EU during the period of exclusivity rights granted by SPCs for the purpose of exporting to non-EU countries. The proposal is solely designed to benefit the generics industry. As a principle, we see any proposal to curtail intellectual property rights through an extra exemption as the wrong path forward for Ireland and the EU. It sends a negative signal about support for a robust incentives framework that promote innovation in Europe. Though the Commission's proposal is drafted as a narrow recalibration of the SPC regime with limited impact in EU markets, we are concerned that the ongoing legislative process might lead to the amendment of the SPC regulation and added erosion of intellectual property rights.

It is important that the Government presses for the application of certain safeguards in the legislation. The manufacturing waiver should be limited to export to countries where there is no intellectual property protection or where it has expired. It should not allow for any large stockpiling during the exclusivity period. Right-holders should be notified sufficiently in advance by generics companies intending to use the manufacturing waiver so that we can ascertain that the conditions for the exemption are met. Any modification to the SCP regime should only apply to future SPCs, not applied retroactively to existing rights. That would equate to confiscation of property rights and potentially trigger retaliation from EU trade partners such as Canada which agreed to implement an SPC-like regime.

Europe faces increasing competition from emerging economies. Rapid growth in the market and research environments in countries such as Brazil and China are contributing to the move of economic and research activities to non-European markets. The geographical balance of the pharmaceutical market, and ultimately the research and development base, is likely to shift gradually towards emerging economies. Ireland, and Europe, must guard against the emerging competition.

Promising medicines in development have the potential to transform care, helping patients live longer and with a better quality of life. In some cases, medicines could prevent further illness, reduce the need for other treatments or even offer a cure. Ireland, with the right support from Government, has the opportunity to take part in global leadership in the discovery and development of these new cures. Through funds like IMI2 and Horizon 2020, as well as Horizon Europe which aims to place some €7.7 billion on the table for health research, Ireland should have a role in tackling some of the biggest health challenges that face the world. Our industry, with a global footprint and strong local innovation, should be bold enough to reach for these big-ticket, 'moon-shot' targets.

IRELAND SHOULD HAVE A ROLE IN TACKLING SOME OF THE BIGGEST HEALTH CHALLENGES THAT FACE THE WORLD.

INNOVATION PIPELINE

Some new therapy areas in development are below.

GENE THERAPY
Helping to replace defective or missing genes in cells, through the introduction of DNA, for the treatment of genetic diseases such as haemophilia and inherited retinal disease.

CELL THERAPY
Inserting living cells to help replace or repair damaged tissue and restore organ functionality in diseases such as Type 1 diabetes.

ANTIBACTERIAL TREATMENTS
Providing new ways to help the immune system fight bacterial infections.

CANCER TREATMENTS
Increasing quality and quantity of life by combining targeted cancer treatments to boost their effectiveness.

ALZHEIMER'S TREATMENTS
Helping to delay the onset and progression of the disease.

NASH TREATMENTS
Helping to tackle non-alcoholic fatty liver disease.

MICROBIOME THERAPIES
Lowering the recurrence of C. difficile infections.

Data capture is always an important consideration for healthcare policymakers. The move, envisioned by eHealth under Sláintecare, will migrate paper records to electronic capture. This will help plan a more effective healthcare system, with targeted interventions. It should improve visibility of patient outcomes, including those delivered by innovative medicines, with positive knock-on implications for creating a responsive, functioning reimbursement system. But with Sláintecare set out over 10 years, we cannot afford to wait. The work on data capture should start now. The structuring and use of big data is among the most promising projects for the future of medical progress. It has the potential to revolutionise healthcare. Ireland has a huge volume of historical healthcare data held by hospitals and healthcare professionals. This data, properly mined and applied, can lead to the development of a predictive and preventative approach to medicine. Healthcare policymakers must treat the development of a databank as a priority, with industry challenged to provide the tools and technology to yield a personalised model of patient care.

WHAT IRELAND CAN DO

1 Set targets for the conduct of research and development and clinical trials so that we become a European hub for the discovery of new medicines, not just for their manufacture.

2 Appoint a Chief Innovation Officer in the Department of Health so that we improve our readiness to adapt to the emerging wave of pharmaceutical innovation, including how we capture and mine data for personalised healthcare, and pursue the development of new cures like gene therapy and cell therapy.

3 Defend our intellectual property system by promoting strong IP protection, incentives and reward mechanisms for research and development, especially as Europe faces the rollback of the incentive to innovate through the SPC waiver.

VISION THREE

REPUBLIC OF PARTNERSHIPS

WORK TOGETHER TO ADVANCE PATIENTS' INTERESTS

When Leo Varadkar TD was elected Taoiseach by the Dáil in June 2017, he pledged to make Ireland a 'Republic of Opportunity'. Given our industry's positive impact on lives, livelihoods and lifestyles in Ireland, we believe we have a significant stake in advancing that goal. For us, the public good means helping to create a healthier population leading longer, more productive lives. It means continuing to invest in discovery because Ireland, and the world, need cures. Our job is to invent solutions that create the future of human health.

For Irish voters, healthcare remains important. In a recent survey, 62% of respondents said healthcare was the top priority for Government spending. It was followed by education (12%) and job creation (11%)[xvii]. The Government could do more to recognise and encourage the central role the research-based pharmaceutical industry has in effecting better healthcare outcomes. Recent key policy documents, including Project Ireland 2040 and Sláintecare, make disappointingly little reference to bio-innovation. At the same time, the dialogue on reimbursement, promised by the Government at the IPHA annual conference in November 2017, has not materialised.

Among the key goals of Sláintecare is to 'move our system from long waiting times to a timely service, especially for those who need it most'[xviii]. While this goal is principally applied to hospital waiting lists, once patients receive specialist care they should not have to wait longer than patients in European peer countries for timely access to new medicines. It is critical that patients are able to access internationally competitive standards of care, including innovative medicines.

For the economy, a strong pharmaceutical industry is vital. Ireland hosts 75 pharmaceutical companies, including all the top 10 in the world. Over the past 10 years, the pharmaceutical industry has invested close to €10 billion in manufacturing and research sites around the country. Between 2003 and 2018, the number of biotechnology manufacturing sites jumped from two to 20. In 1988, just 5,200 worked in the pharmaceutical industry[xix]. Today, foreign-owned pharmaceutical companies directly employ 30,000 people[xx], with about as many more working in spin-off jobs. Ireland needs a 'relentless focus on innovation' if we are to stay competitive[xxi].

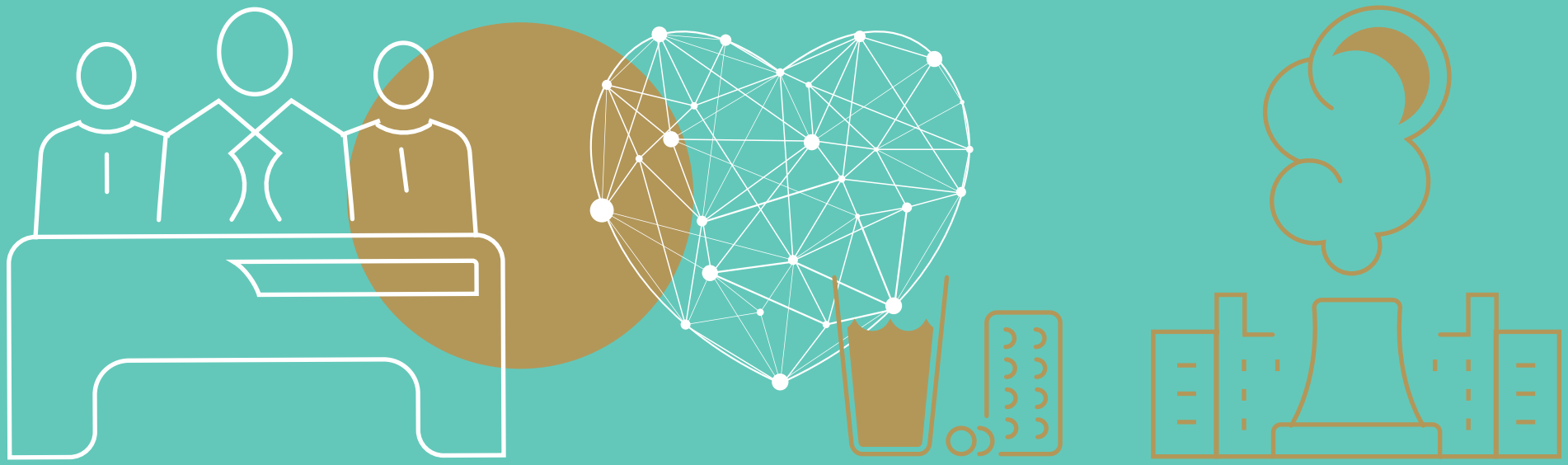
We must continue to pursue excellence in manufacturing and research, and adapt public policy to the promise of innovation in new medicines. If we do that, our industry will remain a reliable source of high-quality, well-paid jobs into the future.

Equally, to improve healthcare, our industry and the Government must work together in common purpose. As the population ages and medical conditions grow more complex, the healthcare sector will come under increasing pressure to deliver the same, or better, services. The task will be to invest smartly. Through innovation, we can develop therapies that, in the long run, will save the system money by reducing hospital stays. In the short term, these new medicines, if they are made available efficiently to patients, will enhance their lives. In some cases, they will even save them.

In France, the Prime Minister recently called for faster access to innovative therapies for patients. He urged deeper links between public research and the private sector, and the establishment of more stable and effective dialogue between the administration, manufacturers and the healthcare community. The Prime Minister tasked the Strategic Committee for Healthcare Sector Industries, reporting directly to him, to achieve these policy goals. Our industry would like a relationship with the Government that jointly sets and delivers policy goals, with buy-in from the highest level of political leadership.

Globally and in Ireland, the research-based pharmaceutical industry is at cutting edge of science. It is critical that we strive to ensure the role of innovation in creating public good is more widely understood. From discovery to pricing to impact, the human health dividend of innovative medicines is not always visible in conversations about our industry. It is important that the industry acts swiftly to challenge ill-informed criticism which sometimes seeks to undermine the importance of innovation or spuriously disassociate effective medicines from better healthcare outcomes. The reputation of our industry should not be the captive of any ideology or vested interest but rather be judged squarely against the public good, with a verifiable and transparent commercial interest.

Our industry works closely with patient advocacy groups, universities and research partnerships on delivering grassroots social impact and advancing the discovery and adoption of new medicines.



PARTNERSHIPS CASE STUDIES

AbbVie

AbbVie is part of a landmark population genomics alliance. The alliance, which includes life-sciences start-up Genomics Medicine Ireland (GMI) and global contract genomics organisation WuXi NextCODE, is a 15-year collaboration focused on developing new treatments for major chronic diseases in oncology, neuroscience and immunology. Genomics is transforming how we understand some of the world's most devastating diseases and enabling the discovery of new therapeutic approaches. The alliance will result in the sequencing of 45,000 genomes from volunteer participants across Ireland to seek new insights into the biological processes that underlie complex disease. AbbVie will use the research database developed by GMI to identify new molecular approaches for therapeutic drug discovery and development, as well as to develop companion diagnostics.

Bayer

Bayer is partnering with the Royal College of Surgeons in Ireland on a research project aimed at improving treatments for people with severe haemophilia. The collaboration is exploring new treatments that can be tailored to the severity of each haemophilia patient's condition to safely and effectively promote blood clotting. Haemophilia is an inherited bleeding disorder where one of the blood's clotting proteins is absent or present in a reduced amount. This results in prolonged bleeding that is difficult to stop unless the condition is recognised and treated. Haemophilia predominantly affects men, with about one in 4,000 men in Ireland affected. The research study is funded by a Special Project Award of €200,000 from Bayer. The award was made under the Bayer Haemophilia Awards Programme, a prestigious international award programme that supports basic and clinical research in haemophilia. The programme seeks to support the development of the next generation of care and treatment options for people with haemophilia worldwide.

Pfizer

Pfizer in partnership with Science Foundation Ireland, runs the Biotherapeutics Innovation Award programme. The collaboration gives qualified academic researchers the chance to deliver discoveries in immunology, oncology, cardiovascular and rare diseases. The programme has awarded funding to researchers across higher education whose work aims to help expedite the translation of scientific discoveries into breakthrough therapies for patients. Researchers have the opportunity to work with Pfizer's BioMedicine Design, at Grangecastle in Dublin, as well as Pfizer's R&D innovation engine, the Centres for Therapeutic Innovation. The teams' research focuses on the application of cutting-edge technologies for next-generation protein therapies.

BioPharma Ambition

IPHA, in partnership with BioPharmaChem Ireland and with the support of InterTrade Ireland, has hosted Biopharma Ambition – an all-island event that champions the island of Ireland as a hub for manufacturing and research excellence. Held in 2016 and 2018 in Dublin, we have plans to stage more events, with the support of Government, as part of efforts to share Ireland's bio-innovation story with the world.

European Research Funds

Across Europe, the research-based pharmaceutical industry is co-investing with governments in joint research projects aimed at discovering new treatments and cures for major diseases and conditions. Horizon 2020 continues to function as a key funding mechanism for the support of pharmaceutical research in Ireland and Europe. Now, as Horizon Europe prepares to invest some €7.7 billion in health research between 2021 and 2027, our industry should be ready to exploit new opportunities to fund breakthrough research. Only through 'radical collaboration', as Carlos Moedas, European Commissioner for Research, Science and Innovation characterised it at the 10th anniversary of the Innovative Medicines Initiative in Brussels, can we improve health outcomes for Europe's citizens. Ireland has a major stake in that endeavour. The structure and ambition of Horizon Europe is based on relevance and on impact for patients and society. This will require dramatically stepping up collaboration models between all stakeholders in the public and private sectors across health and technology. By building on the Innovative Medicines Initiative – IMI1 and IMI2 public-private partnerships – we can accelerate medical innovation and translate science into better patient outcomes.

Self-Care

IPHA and the Irish Pharmacy Union work together to encourage the adoption of self-care. We have partnered to empower patients in managing their own care, helping them to become more health-literate and avoid certain conditions and diseases. Patients are no longer passive recipients of healthcare and advice. They care about their personal health, with access to more information and choice than before. Public awareness campaigns are changing certain behaviours like smoking, fitness and nutrition. This should have positive implications for the avoidance of some lifestyle-related conditions like diabetes, obesity, and cardiovascular and chronic respiratory diseases. As pressure grows on the healthcare system and the population ages, self-care is a way to control costs and improve well-being. Pharmacists have the skills and training to ensure that patients have an open source of professional expertise on self-care.

WHAT IRELAND CAN DO

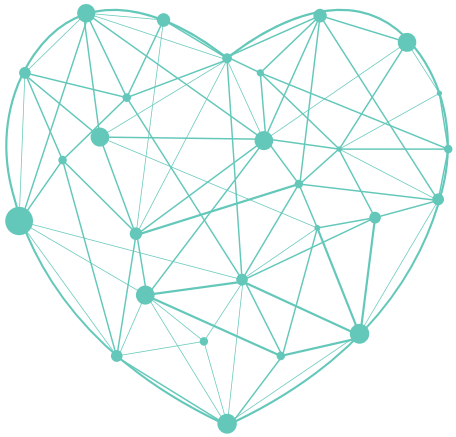
1 The Government, with the support of the Taoiseach, should publicly recognise the value of the pharmaceutical industry to Ireland, with concrete actions that can be pursued jointly by a formal partnership between policymakers and industry leaders around medicines approvals and innovation.

2 Strengthen links between the multinational and indigenous sectors, as well as with funding and research agencies, so that opportunities for collaborations are maximised and Ireland can seed a generation of start-up and scaling companies, especially in biotechnology.

3 Place self-care and health literacy at the heart of the Government's 'Healthy Ireland' strategy so that citizens are empowered to manage their own care, with support from community pharmacists whose mandate can be expanded.

CONFRONTING THE CHALLENGES, TOGETHER

It should be clear that both industry and Government share a goal for patient access to essential innovative medicines. Translating this into reality for patients and doctors is the challenge. While the industry discovers and develops the medicines, the delivery mechanism is broken. It makes no sense that other western European countries, including our nearest neighbour the UK, can afford to make innovative medicines available to their patients but Ireland cannot. This is even more stark when Ireland is at the average of these 14 countries on price. If we are to build a better, healthier Ireland, we must value innovation and fix the process for getting medicines to patients. We have a number of key challenges to overcome.



CHALLENGE	SUPPORTING FACT	CONSEQUENCES	SOLUTION
Ireland is among the slowest in western Europe for patients' access to innovative medicines.	According to IPHA data published in August 2018, nine medicines were available to patients in 12 of 14 'basket' countries but not in Ireland. They had been in the approvals process for over two years.	Irish patients could be exposed to lower life expectancy or higher mortality rates and reduced quality of life. Healthcare costs will rise in the long term with longer hospital stays.	A predictable, multi-annual funding framework, allied with a reformed medicines approvals process.
Some medicines made in Ireland are available to patients in other countries before they can be accessed here.	Several medicines are made in state-of-the-art manufacturing plants across the country but they are exported to other countries where patients there can access them faster than our own.	Characterisation of Ireland as an outlier in Europe on access, with damage caused to reputation and our capacity to draw future investments.	Reinvest some savings delivered by the industry through the pricing and supply deal back into making medicines made in Ireland available to patients here.
Ireland is not a player of European consequence in pharmaceutical research and development.	Ireland is close to the bottom of the table on research and development spending in western Europe, investing around €300 million annually.	Ireland's share of global investments in research and discovery of innovative medicines will continue to decline. Globally, 7,000 medicines are in development at any one time.	Set targets for the conduct of research and development and clinical trials so that we become a European hub for the discovery of new medicines, not just their manufacture.
The Government is not planning strategically for the global wave of pharmaceutical innovation.	Although SFI-backed research partnerships are delivering results, there is no centrally coordinated, Government-backed plan to exploit new opportunities in advanced therapeutics.	Irish scientists will miss out on opportunities to develop new therapies for complex and rare conditions, as well as exploiting opportunities in biotechnology, AI, and gene and cell therapy.	Appoint a Chief Innovation Officer in the Department of Health so that we improve our readiness to adapt to the emerging wave of pharmaceutical innovation.
IP incentives, the scaffolding of innovation, are at risk of being diluted by legislative proposals which would allow generics companies to manufacture in the EU during the period of exclusivity rights granted by SPCs for the purpose of exporting to non-EU countries.	The European Commission's proposal is to introduce a manufacturing waiver for the purpose of exporting to non-EU countries.	It sends a negative signal about support for a robust incentives framework that promotes bio-innovation in Europe.	The Government presses for the application of certain safeguards in the legislation, including that the manufacturing waiver be limited to export to countries where there is no IP protection or where it has expired, and that it should not allow for any large stockpiling during the exclusivity period.
Perception that prices for innovative medicines are high in Ireland compared to other European countries.	We limit our prices to an average of the prices in 14 EU countries. Since July 2016, there have been three rounds of price cuts for thousands of medicines. Three-fifths of products are under €20 per pack, and 11% are priced over €100 per pack.	Reform of the reimbursement process is slowed by perceptions that prices are too high, with risks for the overall reputation of the industry.	Develop partnerships, including with Government, that tells the story of the positive human impact of pharmaceutical innovation and challenges ill-informed or ideologically driven criticism.

MANIFESTO FOR BETTER HEALTH

PATIENT CARE, POWERED BY INNOVATION

The pharmaceutical industry creates impact. The medicines we make, jobs we provide and standards of living we enhance help improve Ireland's society and economy. We want an operating environment in which innovation is valued and medicines are approved quickly for patients. The 'Manifesto for Better Health' is a declaration of the industry's strategic priorities across three pillars: 'Access for All', 'Innovation Excellence' and 'Republic of Partnerships'.

WHAT IRELAND CAN DO

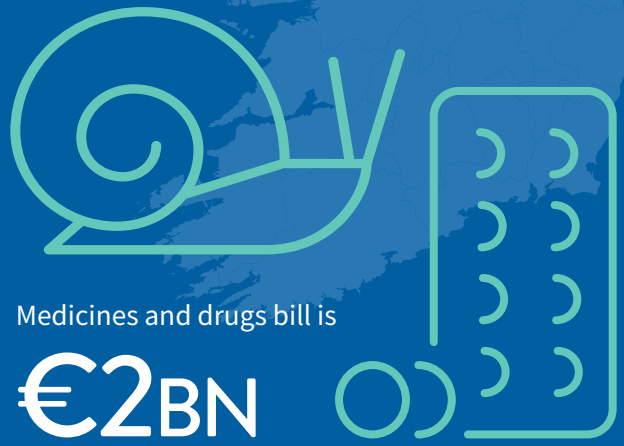
1. Create a predictable, multi-annual budgetary framework, with sustained, reasonable annual increases in funding for innovative medicines.
2. Place Ireland in the top quartile of the EU-28 countries for access to innovative medicines.
3. Improve the reimbursement system by involving patients in the medicines evaluation process, and publishing reimbursement decisions and justifications.

ACCESS FOR ALL

Bring innovative medicines to all patients faster

Ireland is among the slowest in western Europe on access to medicines.

NEW ERA OF PARTNERSHIP NEEDED BETWEEN INDUSTRY AND GOVERNMENT.



Medicines and drugs bill is

€2BN

Budget increase for new medicines for 2018 is just €14m. It's not enough.

Industry will deliver

€785M

in savings over the four-year Government deal on supply and pricing.

INNOVATION EXCELLENCE

Build Ireland's capacity to discover and make tomorrow's cures

The Government aims to make Ireland a 'global innovation leader'. Our companies partner with researchers on breakthrough science for new cures.

Globally, more than

7,000

medicines are in development at any one time. Ireland needs to take a much greater share of discovery activity.

Horizon Europe aims to provide **€7.7BN** for health research. Ireland should be ambitious about capturing a significant share.

WHAT IRELAND CAN DO

1. Set targets for the conduct of research and development and clinical trials so that we become a European hub for the discovery of new medicines, not just for their manufacture.
2. Appoint a Chief Innovation Officer in the Department of Health so that we improve our readiness to adapt to the emerging wave of pharmaceutical innovation.
3. Defend our intellectual property system by promoting strong IP protection, incentives and reward mechanisms for research and development, especially as Europe faces the rollback of the incentive to innovate through the SPC waiver.

RESEARCH AND DEVELOPMENT

€35BN
Europe invests

€305M
Ireland invests

€5.7BN
The UK invests

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Germany invests

Our industry, with a global footprint and strong local innovation, should be bold enough to be part of wider efforts to reach for big-ticket, 'moon-shot' targets on fighting disease.

As part of eHealth under Sláintecare, data, properly mined and applied, can lead to the development of a predictive, preventative and personalised approach to medicine.

REPUBLIC OF PARTNERSHIPS

Work together to advance patients' interests

62% of people say healthcare is the top priority for Government spending, followed by 12% for education and 11% for job creation.

Over the past 10 years, we have invested

€10BN

in manufacturing and research sites. In 1988, just 5,200 worked in our. Today, that number is

30,000

Through innovation, we can develop therapies that, in the long run, will save the system money by reducing hospital stays. In the short term, these new medicines, if they are made available efficiently to patients, will enhance their lives. In some cases, they will even save them.

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3. Place self-care and health literacy at the heart of the Government's 'Healthy Ireland' strategy so that citizens are empowered to manage their own care, with support from community pharmacists whose mandate can be expanded.

Our job is to invent solutions that create the future of human health. To do that, we need the support of the Government. Together, we can make Ireland better.

Ireland hosts all the **WORLD'S TOP 10** pharmaceutical companies.

i State of Health in the EU, European Commission

ii Project Ireland 2040, Government of Ireland

iii ESRI

iv In France, the Prime Minister has tasked the Strategic Committee for Healthcare Sector Industries, reporting directly to him, to speed access to innovative therapies for patients. In the UK, Health Innovation Manchester is an NHS-backed system composed of industry, health, social care and academic leaders aimed at bringing innovative solutions to local people.

v IPHA [August 2018]

vi National Cancer Registry

vii Irish Cancer Society

viii Dáil Éireann debate, Medicinal Products Availability, June, 2018

ix HSE

x WHO, Medicines Reimbursement Policies in Europe

xi CSO

xii IPHA

xiii EFPIA

xiv Enterprise Ireland

xv EFPIA

xvi EY-DKM, The Pharmaceutical Industry in Ireland, Innovation and the IP Framework

xvii Pfizer Health Index 2018 – Health of the Ages

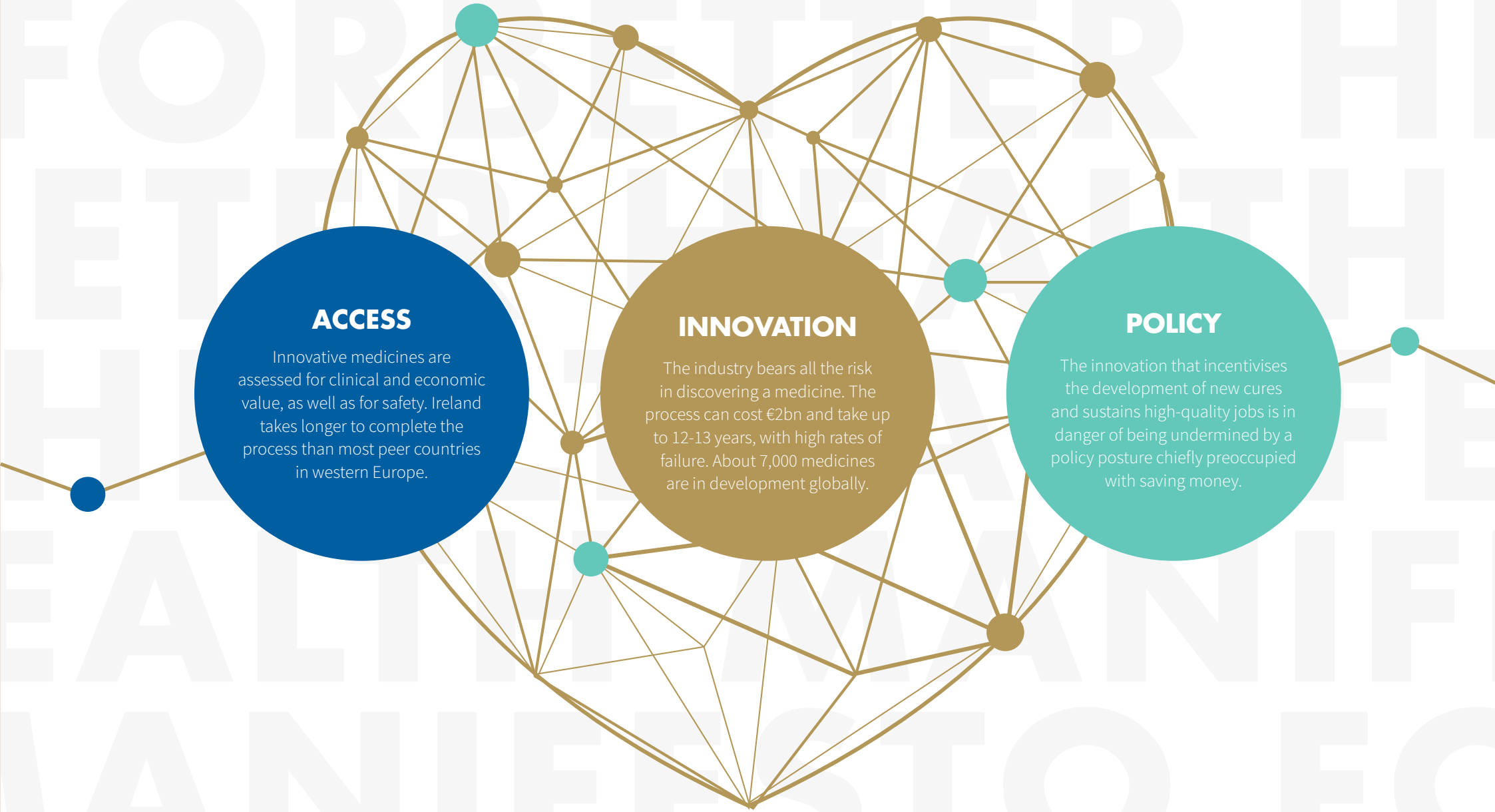
xviii Sláintecare Implementation Strategy

xix BioPharmaChemIreland

xx IDA Ireland

xxi National Competitiveness Council

Our industry, made up of pharmaceutical innovators, has a major stake in Ireland's future. Both here and across the world, our scientists are discovering tomorrow's cures, bearing the huge costs, risk and time invested in pharmaceutical innovation. Our medicines are helping people live longer, healthier lives. They are creating high-value jobs in a fast-growing economy. This is our side of the bargain. For it to work for Ireland, the Government must give patients access to the innovative medicines we make. As things stand, it is not doing that fast enough. Innovation and access are disconnected. This is now an urgent challenge that requires solutions driven by industry-Government partnership.


ACCESS
Innovative medicines are assessed for clinical and economic value, as well as for safety. Ireland takes longer to complete the process than most peer countries in western Europe.
INNOVATION
The industry bears all the risk in discovering a medicine. The process can cost €2bn and take up to 12-13 years, with high rates of failure. About 7,000 medicines are in development globally.
POLICY
The innovation that incentivises the development of new cures and sustains high-quality jobs is in danger of being undermined by a policy posture chiefly preoccupied with saving money.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HEALTHCARE ASSOCIATION

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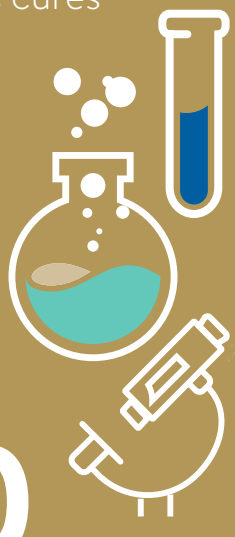

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