



**Submission to the  
Oireachtas Committee  
on the  
Future of Healthcare**

**August 26<sup>th</sup> 2016**

## **Introduction: who we are and what we do**

The Irish Pharmaceutical Healthcare Association represents 46 research-based suppliers of innovative medicines for the benefit of patients in Ireland. Our member companies supply medicines that are subject to prescription by clinicians and medicines available to patients over the counter or via pharmacists without prescription.

Our members and Association contribute to health policy goals by

- Ensuring patients in Ireland continue to access innovative medicines at affordable prices in line with European best practices, via agreements with the State
- Working closely with State authorities, in particular, the Healthcare Products Regulatory Authority, to foster a robust assurance and compliance culture, respecting all statutory requirements, regulations and our industry voluntary Code of Practice governing interactions with healthcare professionals
- Supporting the development of, and access to, clinical trials in Ireland by working with stakeholders on an efficient regulatory and administrative research infrastructure, thus ensuring that patients in Ireland get early access to ground-breaking innovation
- Assuring patients on the integrity of medicines, providing leadership with all stakeholders implementing the Falsified Medicines Directive by 2019
- Contributing to policy development on *Healthy Ireland* and self-management of care
- Enabling Ireland's capacity for sophisticated value-for-money assessments in healthcare via Health Technology Assessments, through developing the human resources and processes required

## **Executive Summary**

1. Investing in health should be seen as value, at preventive, maintenance, curative and palliative levels. Medicines have played, and will continue to play, a central role in healthcare gains in recent decades, leading to the cure of disease and the alleviation of previously long-term debilitating conditions. With over 7,000 medicines in development, the exciting new wave of medical innovation will play a key role in delivering better health outcomes for patients and healthcare systems. The pharmaceutical industry is a key partner in healthcare, identifying unmet medical needs and investing long term in research and clinical trial programmes.
2. The pharmaceutical industry has pioneered many initiatives that facilitate early discharge from hospital and delivery of community and home based care that otherwise would necessitate hospital admission and care, e.g. the delivery of home care therapy. As part of a support for allocating resources to the lowest level of complexity necessary, and to support a greater role for primary care, public health literacy and the appropriate use of self-management of care for minor illnesses should be further encouraged.
3. Innovation in healthcare is essential. The ability to adopt to the innovation that will arise over the next ten years will be vital for Ireland. Irish patients deserve the same access to the new drugs that will come to the market as patients elsewhere in Europe.
4. Patients would benefit from a funding model that focuses on outcomes that improve, and often prolong patients' lives. Ireland should move towards a funding system that focuses on outcomes for patients. Activity based funding should be viewed as just the first step of this journey. The challenges of anticipating and evaluating pharmaceutical innovation, of cost, pricing and service adoption, require an array of experts from both industry and Government (regulators, clinicians, management) working on technical issues and shared data towards the over-arching goal of providing medicines that improve patient outcomes.
5. An appropriate set of policy principles guiding value-based payment should be agreed, meeting the objectives of sustainable financing, timely access to new medicines for patients and the appropriate incentivisation of innovation.
6. The technical requirements to enable payment for value/outcomes should be addressed, including the implementation of patient identifiers and the investment in IT infrastructure, registries and real-world evidence reporting systems. This will generate insight into opportunities for performance and outcomes improvement along the patient pathways that we serve.

## **Recommendations included**

1: Patients in Ireland deserve the same access to new medicines as patients elsewhere in Europe. The Oireachtas Committee should state an explicit policy goal for the health service that the uptake of medicines innovation will be a core capability and that the systems, evaluations and information necessary to evaluate innovation and use it cost-effectively shall be developed and resourced appropriately.

2: The uptake of innovation for patients' best outcomes will best be achieved by partnership between the State and industry. This means collaborative, stable working relationships between the State and industry, with Pricing and Supply Agreements and other arrangements tuned to meeting the key policy objectives.

3: To ensure value for money, treatment should take place at the lowest appropriate level of complexity. Self-management of healthcare, including the appropriate use of non-prescription medicines, contributes to the strategy of allocating resources to the lowest level of complexity possible. Investment in public health literacy and the promotion of appropriate self-management will enable a more efficient use of resources.

4: Ireland should take the necessary measures to grow the number and range of clinical trials in Ireland, as a benefit to patients and in order to increase our scientific and life sciences industry capacity and reputation.

5: More flexible, value and outcomes-based models of funding healthcare, where designed appropriately, offer a way forward to achieving the best value for investment in health and would benefit patients. Activity based funding is a valuable first step on this journey.

6: Outcomes-based payment models should be designed on the basis of clear principles and evidence so as to align the value created for payor, patients and provider, encourage innovation by clinicians and support particular therapies.

7: The Oireachtas Committee should support specific reporting measures and investment in IT infrastructure that will enable the design and implementation of effective outcome and value-based funding of healthcare.

## **Part One: Strategic issues**

The key challenges for a ten year plan for the health service in Ireland is to achieve the best possible health and well-being of the population, with value and effectiveness for the resources devoted to this goal. An important goal is to achieve confidence that investment in health – at a personal, community and State level – works for all. This is not simply to achieve technical efficiency, but a widespread understanding, underpinned by evidence, that well- targeted, sustained investment in health delivers clear net economic and social benefits for all. Investing in health should be seen as value, at preventive, maintenance, curative and palliative levels. Without a shift to a perspective of investment and value, and putting in place the capacity to assess and decide priorities on that basis, the dominant narrative around health is likely to remain about cost, inefficiency and unmet need.

### *Health gains due to medicines*

Innovative medicines have been responsible for paradigm shifts in healthcare. Since the 1980s, in developed countries, we have seen death rates from HIV fall by over 80% due to advances in medicines<sup>1</sup>. Since the 1990s deaths from cancer have fallen by 20%<sup>2</sup>. Recent pharmaceutical innovation means 95% of people living with Hepatitis C can be cured through a 12 week course of medicines<sup>3</sup>. The effective use of preventive care, vaccines and medications can slow disease progression, avoid illness and reduce costs.

Medicines play a role in helping people to live longer; a recent OECD study has shown that there was an increase in life-expectancy of 4 years in Ireland in the period from 2000-2011. A separate study on 30 OECD countries has showed that up to 73% of the improvement in life expectancy was attributable to medicines.

### *Innovation pipeline*

With over 7,000 medicines in development<sup>4</sup>, the exciting new wave of medical innovation will play a key role in delivering better health outcomes for patients and healthcare systems.

The evolution of medical science, and particularly our understanding of the genetic causes of disease, is opening up a promising new era of pharmaceutical innovation addressing many unmet needs. As they have in the past, pharmaceuticals will continue to play a major role in transforming the standard of care, moving towards more personalized and targeted drug technologies and enabling improvements in patient, health and social outcomes.

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<sup>1</sup> EFPIA, The Pharmaceutical Industry in Figures 2015

<sup>2</sup> PhRMA, Biopharmaceutical in Perspective, Spring 2015

<sup>3</sup> PhRMA, (2014), 25 Years of Progress against Hepatitis C and PhRMA (2015), 2015 profile

The pace of change, the direction science is taking and the cost may seem to pose very daunting challenges for health services globally, and for Ireland in particular, given some of our deficiencies, for example, in relation to health information technology infrastructure.

A strategic issue posed for a ten year view of Irish health services is how Ireland can and should aim to be an early adopter of healthcare innovation, particularly in medicinal therapies.

It is useful to set an explicit policy objective that Ireland will make innovative medicines available in our health services, so that patients in Ireland have the same access to new medicines as patients elsewhere in Europe.

The Government's Strategy for Research and Development, Science and Technology, *Innovation 2020*, states that innovation is critical to our social development:

*'Innovation is vital to address the sustainability of Ireland's health system, and to address health challenges, including the development of more effective treatments and strategies for disease prevention through behavioural and lifestyle change'<sup>5</sup>*

*'The highest performing healthcare systems have research embedded in service delivery and produce innovation and outcomes that are of benefit to patients, enterprise, the nation's health and the tax payer as funder.'<sup>6</sup>*

The value of innovation in healthcare is to deliver better outcomes for patients. This is the context in which our Association advocates a strategic commitment to the uptake of medicines innovation in our health services.

**Recommendation 1:** Patients in Ireland deserve the same access to new medicines as patients elsewhere in Europe. The Oireachtas Committee should state an explicit policy goal for the health service that the uptake of medicines innovation will be a core capability and that the systems, evaluations and information necessary to evaluate innovation and use it cost-effectively shall be developed and resourced appropriately.

The second issue is how to achieve this objective, embedding the uptake of pharmaceutical innovation in the health services. The pharmaceutical industry recognises that there is a key challenge about cost and affordability, which is linked to pricing and the incentivisation of, and reward for, innovation. In addition, the health services are challenged to understand and evaluate appropriately the nature of the innovation being made available and in the pipeline.

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<sup>5</sup> Innovation 2020, p.20

<sup>6</sup> Ibid., p.48

The challenges of anticipating and evaluating pharmaceutical innovation, of cost, pricing and service adoption, require an array of experts from both industry and Government (regulators, clinicians, management) working on technical issues and shared data towards the overarching goal of providing medicines that improve patient outcomes.

The issues involved are not confined to Ireland of course; key considerations about value, access to innovation for patients and paying for outcomes are relevant at European and international levels. Therefore, the IPHA believes Ireland needs to consider how to develop collaboratively the capacity to adopt new models of reimbursement for medicines which are linked more closely to the value of innovation.

The role of clinicians is central in the adoption of innovative therapies. In respect of new medicines, we believe that Clinician Review Groups, as used in some therapy areas like oncology, play an important role in assessing the value of new medicines.

While different roles and mandates must be respected, a close degree of partnership and collaborative working in a stable policy framework makes the best policy results possible. Pricing and supply agreements between IPHA and the State are one aspect of this. Over a ten year period, the content and range of such agreements and working relationships should strengthen and adapt to meet the needs of the healthcare vision adopted in the State.

**Recommendation 2:** the uptake of innovation for patients' best outcomes will best be achieved by agreement and collaborative, stable working relationships between the State and industry, with Pricing and Supply Agreements and other arrangements tuned to meeting the key policy objectives.

Medicines have an important role to play in all aspects of healthcare, from self-management of minor ailments to primary care, complex tertiary care, through to palliative care. IPHA supports the strategic direction of allocating healthcare resources to enable treatment at the lowest level of complexity possible that is, fostering a greater emphasis on self-management and primary care. The case is well-made elsewhere that this will enable a more efficient and sustainable use of resources in health services. Self-management of healthcare, both to achieve healthy living and better health status, has an important role to play. Within that, the appropriate use of medicines to deal with minor illnesses contributes to better outcomes and efficient use of resources. Enabling this will be improved levels of health literacy in the population.

In addition, IPHA also advocates – and its member companies actively support – programmes which enable patients to receive assistance in their homes in their adherence to medicines.

The value of these programmes in terms of patient welfare and avoidance of hospitalisation costs should be further recognised and promoted.

**Recommendation 3:** self-management of healthcare, including the appropriate use of non-prescription medicines, contributes to the strategy of allocating resources to the lowest level of complexity possible. Investment in public health literacy and the promotion of appropriate self-management will enable a more efficient use of resources.

Clinical trials are essential to medicines development. A higher number and range of clinical trials in Ireland will bring further benefits of innovation to patients in Ireland.

Ireland has invested significantly in life sciences education in recent decades. We are growing our workforce's capacity to provide world class clinical research. The State should promote participation in clinical trials both as a way of bringing innovation to patients and of increasing Ireland's scientific knowledge. 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.

IPHA encourages policymakers to benchmark Ireland's clinical research environment against best in class in Europe, e.g. the record of Denmark.

Clinical research in Ireland can be further supported by

- an administrative environment that facilitates clinical research within hospitals, 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;
- the establishment of a national Research Ethics Board for multi-institutional studies, as has been done in other jurisdictions
- consistent adherence to legislation, guidance and timelines by Research Ethics Committees.

**Recommendation 4:** Ireland should take the necessary measures to grow the number and range of clinical trials in Ireland, as a benefit to patients and in order to increase our scientific and life sciences industry capacity and reputation.

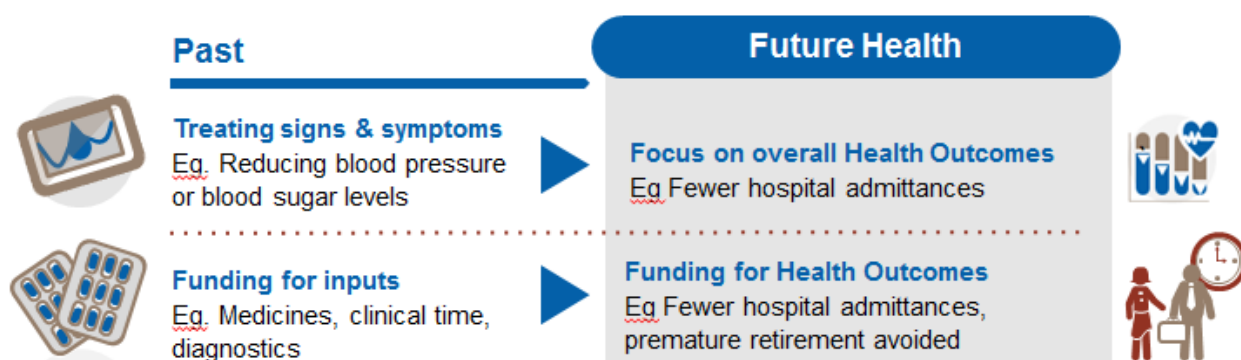


## **Part Two: Funding issues – outcomes and value**

Given the innovation pipeline and what is known about the cost of research and bringing advanced new medicines to patients, Government and industry stakeholders need to work together to identify new ways of sustainable and flexible pricing mechanisms that recognise the value of innovative medicines.

Current pricing policies may not be fit for purpose for the new wave of technology in the future. The sustainability of our health system will not be solved simply by buying things more cheaply. The emphasis should change to aligning expenditure more to value, that is, to the actual outcomes achieved for patients and to providing the right incentives to transform how we deliver care.

The health services in Ireland and patients would benefit from a model that focuses more on health outcomes. Focusing on health outcomes is attractive for patients, the Exchequer and health services as, the State would pay providers for ‘positive patient outcomes’ (e.g. emergency visits avoided), rather than paying for an input like a medicine. Payment would be made for ‘what works’, thereby improving the cost-effectiveness of the public service provision.



Health outcomes based models offer a way forward, because they set the right incentives, offering a reward for those interventions that deliver most value. Rewards would be tied to specific results or outcomes achieved (e.g. exacerbations/relapses avoided), not merely the amount of treatments (e.g. individual medicines) supplied or used.

### *Best practices*

A 2016 OECD health policy report “Pricing – Paying for outcomes”, looks at the ways that various OECD countries are paying for outcomes. It concluded,

*‘investment in payment innovations generate good bang for the buck. Fundamentally, they are helping to align payers and providers. And more broadly health systems,*

*towards what they aim for – that is, best outcomes for patients given resources invested.*<sup>7</sup>

The OECD report makes reference to the issue that paying for “positive patient outcomes” is difficult to measure and implement and health services worldwide are attempting projects that could be replicable across chronic disease areas.

There are technical barriers which need to be overcome and implementation will require the support of all healthcare stakeholders. The key technical barrier that needs to be overcome is the implementation of the individual patient identifier number as this means that patients’ health outcomes can be measured.

The funding for outcomes concept is becoming part of healthcare policy development in Ireland, as evidenced in the HSE’s Activity-Based Funding Programme Implementation Plan 2015 – 2017. It is critical of course to link activity to outcomes.

Some pharmaceutical companies are already taking accountability for the performance of their medicines in terms of health outcomes. The key to effective and sustainable implementation of these concepts is to have well-designed parameters agreed between the supplier and payor.

Concepts include reimbursement tied to the response level of patients prescribed a particular medicine or linked to certain levels of hospitalisation avoidance. Some similar arrangements are beginning to be put in place in Ireland by bilateral agreement between the supplier and the HSE. Some companies have been willing to ask for payment only for positive patient health outcomes. There are examples where the company will provide initial doses free of charge to identify responders or where the company will reimburse hospitals for any non-responders within a defined period of commencing treatment; as a result, the healthcare system only pays for patients with positive health outcomes.

The value of a medicine can include the level of support and service that is provided to the patient. Some IPHA member companies, for instance, add a nurse-led patient support program, self-management programs, smart phone patient recorded outcomes in real time and adherence programs, as a service alongside the prescription. These additional services are designed to improve patient outcomes and, although sometimes cannot be studied in combination with clinical outcomes, should be part of the value proposition for the medicine and so be considered as part of a flexible funding model. This will incentivise companies to provide programmes that improves the patient’s usage of medicine and in the case of chronic disease, enables them to become a more empowered self- manager of their condition.

In the long-term, tying incentives and payments to health outcomes is not just appropriate for medicines but for healthcare systems as a whole. Funding outcomes offers a coherent

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<sup>7</sup> [http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/better-ways-to-pay-for-health-care\\_9789264258211-en#page1](http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/better-ways-to-pay-for-health-care_9789264258211-en#page1)

support to meeting economic and affordability challenges. When used appropriately, it offers the promise of a transparent way of pricing and rewarding health interventions, and will allow patients, payors and clinicians to be assured of value.

**Recommendation 5:** more flexible, value and outcomes-based models of funding offer a way forward not just for medicines expenditure but for broader areas of the health services

Outcomes based funding models for medicines – and other interventions - need to be founded on a number of common principles agreed between stakeholders, including:

- Timely and equitable access for patients who will benefit from new therapies
- Distribution of the economic value created by continued incentives for innovation, recognising the important role of intellectual property rights
- Evidence-based and accompanied by solid real-world data collection
- Appropriate levels of transparency in the design of outcomes-based models to ensure that the interests of all parties are protected
- Outcomes measures to be well defined
- Value based, recognising that a ‘cost plus’ payment or ‘lowest price procurement based’ approach is inappropriate for valuing new technologies and creating an environment that will encourage on-going innovation
- Aligned incentives to ensure that outcomes flow through the system, and that it is not just medicines where payment for outcomes is applied
- Optionality and flexibility: in some cases these models will not be appropriate because simpler pricing schemes may be more adapted

**Recommendation 6:** outcomes-based payment models should be designed on the basis of clear principles that align the value created for payor, patients and provider, encourage innovation and are flexible for particular therapies.

For Ireland to avail of promising collaborations in health outcomes in the short-term and medium term, it is recommended that the Oireachtas Committee would give its support for several inter-related specific measures:

- Implementation of the patient identifier number as soon as possible, as this means that patients’ health outcomes can be measured. Electronic patient records will also be essential to collect Real World Evidence (RWE) of performance
- The collection and use of Patient Recorded Outcomes Measures (PROMS) and Patient Recorded Experience Measures (PREMS) so that the patient experience and observations are incorporated.
- Investment in the appropriate infrastructure and policy change to ensure that health outcomes are appropriately measured and tracked – this will not only be

an enabler for new pricing and contracting models but will also generate insight into opportunities for performance and outcomes improvement along the patient pathways that we serve. Outcomes-based pricing will require better capture of outcomes data, through registries and interoperable and harmonised electronic patient records, and the ability to analyse and link different data sets, including clinical, patient reported and administrative measures within an environment that respects data privacy. Rapid development in e-health and cognitive use of big data will support the needs for capturing outcomes data.

- Ensuring that efficiencies from the better use of medicines are translated into improved and more efficient patient care.

**Recommendation 7:** the Oireachtas Committee should support specific reporting measures and IT infrastructure that will enable the design and implementation of effective outcome and value-based funding of medicines.

### **Part Three: Other issues for consultation**

Several issues raised by the Oireachtas Committee are strictly outside IPHA's role, e.g. the design of public entitlements, the financing of healthcare, purchaser/provider roles and the role of healthcare professionals in relation to policy change in these areas.

Suffice it to say that it is our working assumption that public policy in Ireland is, and shall be, aimed at providing timely access to medicines to the population as a whole based on medical need. We believe that any barriers, financial or otherwise, to that goal should be identified and removed. This would include any potential geographic inequities in access to medicines arising from different arrangements with regard to medicines in hospitals across the State.

We believe that our recommendations relating to payment for outcomes and value can be implemented within different health financing models (i.e. the method whereby the resources for health are raised from the population). Indeed, divergent financing models exist across Europe, while each health system has an active interest in achieving improved efficiency in the allocation of resources to best patient outcomes.

IPHA member companies have considerable interaction with healthcare professionals in continuing education, clinical research and patient services projects. Our experience is that healthcare professionals are strong advocates for innovation and the best outcomes for their patients.

26<sup>th</sup> August 2016