

PRESCRIPTION FOR INNOVATION



Improving health and economic well-being in Northern Ireland

INTRODUCTION

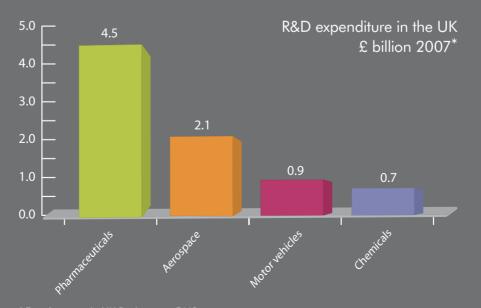
The Association of the British Pharmaceutical Industry (ABPI) represents more than 80 pharmaceutical companies in the UK that are engaged in the research, development, manufacturing and supply of prescription medicines. ABPI member companies manufacture and supply more than 80 per cent of the medicines that are prescribed through the NHS, and export medicines to countries all over the world.

ABPI Northern Ireland (ABPI NI) was established in 2007 in recognition of the evolving distinctiveness of the health agenda in Northern Ireland and to enable the work of a collaboration of ABPI members with a declared interest in Northern Ireland. ABPI NI currently has an active membership of over 20 ABPI member companies. This includes the majority of major global pharmaceutical companies and smaller companies with a strong presence in Northern Ireland.

Since then, ABPI NI has encouraged a greater understanding of the pharmaceutical industry in Northern Ireland by engaging in dialogue with decision makers, health policy formers and healthcare providers. ABPI NI has already been recognised as a key stakeholder by the Department of Health, Social Services and Public Safety and is working with the Department and other stakeholders to improve patient care. Modern, breakthrough medicines make a huge impact to health and well-being and everyone uses medicines at some point during their lives. Our aim is to develop medicines that change lives for the better and which are licensed and monitored in terms of quality, safety and efficacy. Some modern medicines like vaccines can prevent illness in the first place; others such as some cancer medicines can extend and save lives; while many improve the quality of lives, stop disease progression or play a key role in tackling chronic conditions such as diabetes, respiratory disease and arthritis.

The pharmaceutical industry is the longest standing independent sector partner of the NHS, and we have worked together since 1948. We share a common commitment to improve the lives of the people of Northern Ireland and work alongside healthcare professionals and patients under the strict governance arrangements of the ABPI Code of Practice. This ensures that medicines promotion and joint working with the NHS is conducted in an open, responsible and ethical way.

ABPI NI is committed to continue working with our partners to support a common understanding and a shared value for new and innovative medicines.





A PRESCRIPTION FOR INNOVATION

This document describes a number of actions to:

- Deliver better patient health
- Enhance cost-effectiveness in the HSC
- Drive the industry's contribution to the Northern Ireland economy

The UK has led the field globally in life sciences for many years. Scientists here discovered penicillin, unravelled the secrets of DNA, developed betablockers and helped map the human genome. Today, one in five of all major medicines used around the world were discovered in the UK. We should be proud of our record of scientific achievement and innovation and strive to maintain the UK's pre-eminent position as a location for the discovery, development and manufacture of new medicines.

Medical discoveries brought to the patient by the life sciences industry have transformed millions of lives. The prospects of patients with coronary heart disease, epilepsy and diabetes have been transformed, as these conditions are now eminently treatable. For example, recent analysis shows Northern Ireland to be particularly successful in the treatment of stroke - Northern Ireland has low prevalence figures and good outcomes for stroke which has been suggested as being due to its investment in medicines, clinical leadership and access to stroke units. As well as the clear benefits of improved lives and patient outcomes, such progress has saved money for the taxpayer by preventing or reducing complications and hospitalisations in conditions ranging from asthma and stomach ulcers to diabetes and cancer. Medicines allow many patients to remain in work, successfully managing long-term conditions and contributing to the health and wealth of the Province.

In Northern Ireland, industry, academia and government have made significant commitments to the fast-developing life sciences sector over the past five years, attracting government support totalling \$60 million. The life sciences sector directly employs around 4,000 people in high value jobs whilst each year almost 4,000 life science graduates qualify from Northern Ireland universities.

Each year the pharmaceutical industry invests £4.5bn in research and development in the UK, representing a quarter of all private sector R&D investment. Globally, the market opportunity is close to \$1 trillion and Northern Ireland must continue to strive to earn its share of this market.

Political and clinical leadership is critical to ensuring that the pharmaceutical industry continues to deliver better health outcomes; value to the HSC; and a return to the taxpayer in terms of continued industry investment. This document sets out our industry's vision of how this is to be achieved in Northern Ireland.





Partnership case study

The Happy Hearts project in Nottingham has targeted deprived areas to identify people at most risk of developing coronary vascular disease (CVD). It then offered appropriate intervention, support and education to help them manage and reduce that risk. The project had two objectives: to reduce mortality and to reduce health inequalities in what is the UK's 13th most deprived local authority. The project was co-funded by the pharmaceutical industry (the companies involved were Sanofi-Aventis, Novartis, Schering-Plough, MSD, Merck Serono and Solvay) and NHS Nottingham City, with a joint steering committee allowing each party to bring its particular skills and expertise to the table. In just over 12 months, over 2,000 patients were identified and seen by the project and around half were referred for further investigations either for CVD, hypertension or diabetes.

"Our workforce needs to be better qualified and more flexible. In the years to come it will be an ability to change that will be the hallmark of a successful economy. Our companies must become more innovative and invest much more in research and development and we must encourage a culture of enterprise and business growth."

First Minister Peter Robinson - October 2009



BEATING DISEASE: BETTER ACCESS TO INNOVATIVE MEDICINES

Ensuring the right patients receive the right medicine at the right time

By giving HSC patients better access to innovative medicines, we can lead the world in extending patient survival and quality of life. We want to see a HSC that welcomes cost-effective, innovative technology and adopts it promptly where it benefits the patient. Uptake of new, innovative medicines is often much higher in other European countries, but it is only fair and right that patients in Northern Ireland have access to the best available medicines.

Access to medicines is neither fair nor consistent and Northern Ireland does not have a system which monitors the implementation of national guidance on medicines. Inconsistent implementation causes inequities in terms of access to treatment.

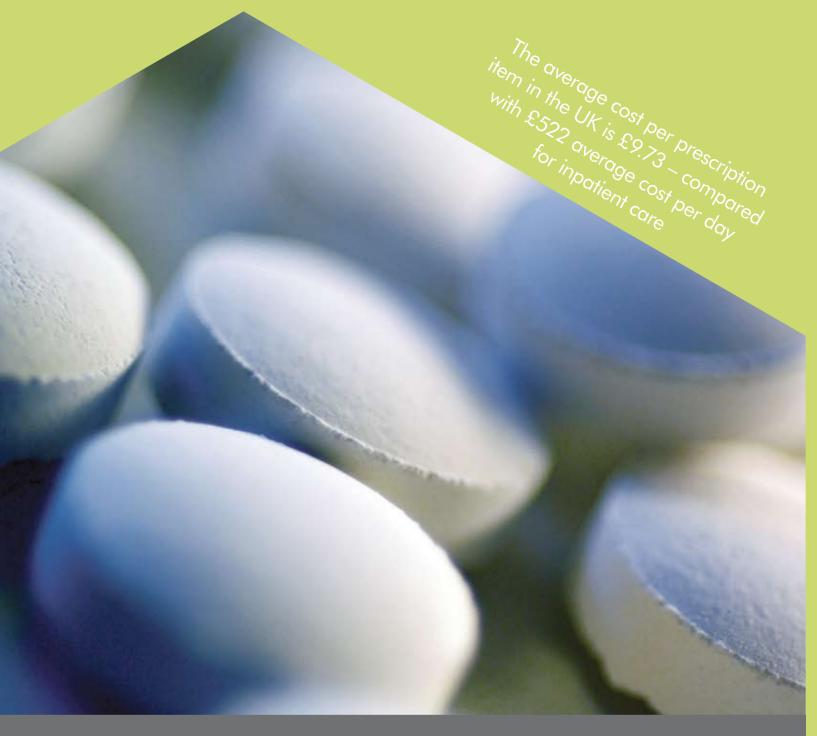
The notion that there is not enough money to pay for new medicines has repeatedly proven to be erroneous, with medicines, year on year, making up a smaller and smaller part of the overall HSC budget. The combined savings from Government negotiations' with pharmaceutical companies and branded medicine 'patent expiry' has been estimated to benefit Northern Ireland by over £200 million over the next 5 years.

The pharmaceutical industry commits to:

- Working with governments, political parties, health professionals, academia and the NHS to give patients faster and better access to new medicines.
- Contributing to better financial and service planning for new medicines in the HSC, by means of improved 'horizon scanning'.
- Continuing to contribute expertise and resources to local NHS projects targeted at improving patient outcomes and reducing health inequalities. Such projects are conducted in line with appropriate governance arrangements such as the ABPI Code of Practice.

We call on political parties, clinical leaders and policy makers to:

- Provide the Health and Social Care Board, in partnership with Local Commissioning Groups, with real power to deliver improved uptake of innovative medicines and technologies in Northern Ireland, and to be held accountable for progress.
- Retain savings from reduced costs in branded medicines to ensure funding for new, innovative medicines.
- Encourage the HSC to work with industry, regional accountable bodies and the National Institute for Health and Clinical Excellence (NICE) to allow patients earlier access to innovative medicines.
- Ensure that Northern Ireland Assembly health policy is fully implemented, and that LCG and Trust implementation and budgetary processes are more transparent.
- Establish and fully fund the monitoring of NICE Guidance to ensure guidance on new medicines is implemented more quickly and consistently.
- Encourage the Department of Health, Social Services and Public Safety to develop an open and transparent framework for partnership working between us and the HSC.



Understanding Value

In Northern Ireland an integrated medicines management project has been undertaken to achieve patient benefits including reduced length of stay in hospital, reduced readmission rate, a more accurate medication history and improved discharge process.

Pharmaceutical Clinical Effectiveness (PCE) refers to the process of using existing evidence to evaluate clinical effectiveness and then cost effectiveness in terms of the impact of such pharmaceutical technologies on both patients and the healthcare system.

ABPI NI has been identified as a key stakeholder by the Department of Health, Social Services and Public Safety (DHSSPS) Regional Pharmaceutical Clinical Effectiveness Group and is working with the Department and other stakeholders to improve patient care whilst ensuring that all such processes are transparent, robust and undertaken with appropriate rigour.

"The contribution made by our business community to developing a culture of innovation in Northern Ireland is therefore very important. Every business, regardless of size or sector, can and should be looking at how to work better and smarter."

"The strongest businesses in any market have innovation and R&D at the centre of their operations. This is especially true during the current economic downturn. A commitment to developing new products and processes, or improving existing ones, can open up lucrative opportunities that may not otherwise have been available and provide a springboard for future growth, when the recovery comes."



GETTING FULL VALUE FROM OUR MEDICINES

Ensuring the full clinical and economic benefits of medicines to patients and public services are realised

Appropriate use of medicines provides excellent value for money to the HSC, saves lives and often deals with a condition earlier and more effectively. Saving money by not providing optimal treatment is a false economy for the health service and the broader economy as a whole and conflicts with the principles of A Healthier Future, the 20 year vision for Health and Wellbeing in Northern Ireland.

As well as the clear benefits of improved lives, such progress has saved money for the taxpayer by preventing or reducing complications and hospitalisations. Many patients have been shown to be able to remain in work, successfully manage their long-term conditions and contribute to the economic well-being of the country. Such wider benefits of medicines need to be fully considered if patients and taxpayers are to reap the full value of medicines. Higher than average spending on cancer medicines in Northern Ireland has been linked to us having the highest five year survival rates for breast, colorectal and lung cancer across the UK. However, concerns have been raised regarding recent patient access to newly licensed, innovative medicines.

We are hopeful that the new health structures in Northern Ireland will help introduce an integrated and holistic approach to the HSC budget, allowing the benefits and costs of medicines to be balanced across primary, secondary, tertiary and social care costs. We believe the new structure will allow the development of a common understanding of the value of medicines which takes into account: the incremental nature of innovation; unmet medical need; the nature of the disease or condition; savings made to health and social care budgets and; the indirect economic benefits of effective medicines.

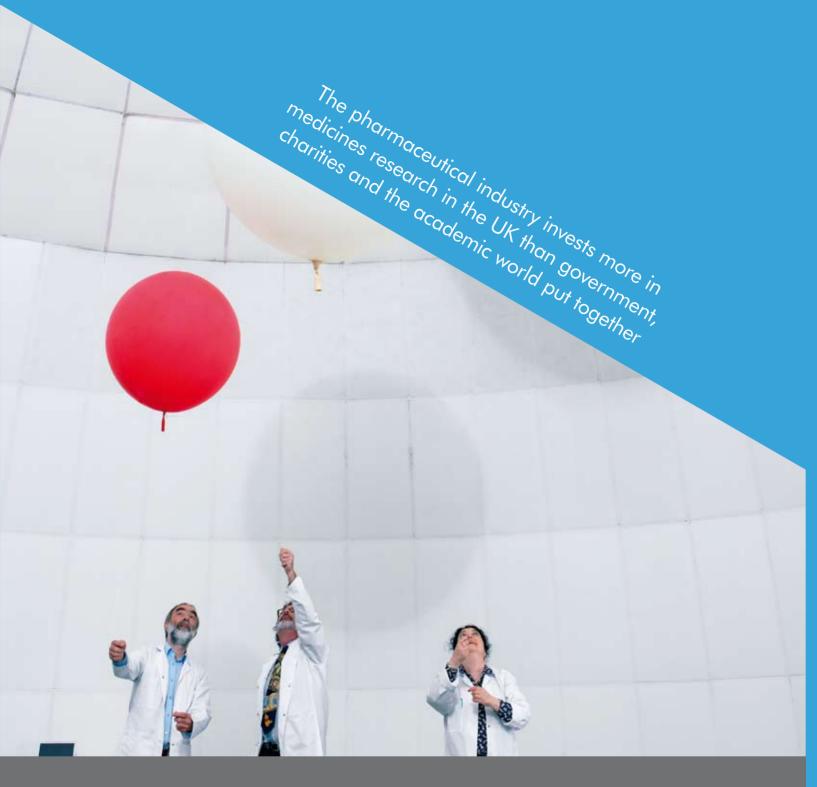
NICE is an internationally respected appraisal body and has increased its remit to all aspects of medicine availability. We believe the remit of medicines assessment bodies in Northern Ireland should be closely co-ordinated with NICE to avoid duplication, unnecessary confusion, inequities for patients and time delays in implementation. We have worked with the Pharmaceutical Clinical Effectiveness Group (PCE) and support its aim of supporting quality prescribing and improved patient safety. We believe that our continued involvement will bring further benefit of greater consistency, transparency and wider stakeholder consultation and agreement.

The pharmaceutical industry commits to:

- Work with the government, public, patients and healthcare professionals to strive for a common understanding of the value of medicines, ensuring it is fully taken into account in decisions by government, the HSC and NICE.
- Contribute expertise on the management of acute and chronic conditions, to help improve patient care and health outcomes, as well as supporting efficient use of NHS resources.
- Work with partners to tackle medicines waste in order to provide money to invest on new medicines, if such savings were retained in the medicines budget.
- Continue to strive to ensure that our medicines provide value for money and to work in partnership with NICE and PCE to try to help make assessment processes work as effectively as possible.

We call on political parties, clinical leaders and policy makers to:

- Work with us, and with NICE and PCE, to achieve a common understanding of the 'value' of medicines which aligns with the views of the public, patients and healthcare professionals.
- Implement this shared, holistic definition of value across HSC and use it as a basis to develop a strategy to make optimum use of modern medicines.
- Ensure consistent and timely implementation of NICE guidance.
- Remove any barriers, obstacles or delays in the funding and availability of new innovative medicines.



Recognising Excellence

ABPI NI is proud to be a regular sponsor of the Northern Ireland Healthcare Awards. Supporting the GP of the Year Award in 2008. ABPI NI decided to develop our sponsorship and will present the Consultant of the Year Award in 2009.

The Consultant of the Year Award was developed to recognise consultants from all clinical backgrounds who are at the forefront of their profession, whether developing best practice models or implementing improvements in patient care. Reasons for award may include:

- A proactive approach to continuing education resulting in the rise of practice standards
- A commitment to research and development
- A display of exemplary patient relationship skills
- Progressive interfacing with colleagues
- A dedicated effort in keeping GP colleagues up to date with best practice in their specialised area

"I have no doubt that knowledge-based industries are the key to the future of this country." Sir Allen McClay, Almac and McClay Foundation - September 2009



BOOSTING INNOVATION AND ITS ECONOMIC CONTRIBUTION

Transform the productivity of biomedical research and innovation

Medical innovation is important to the health and wealth of Northern Ireland. Innovation is key to creating effective new medicines to tackle the burden of disease. Northern Ireland, in line with the rest of the UK, needs a better environment which fosters and rewards innovation if it is to continue to be a world-leader in life sciences and fully benefit from the industry's investments. For example, industry sponsored clinical trials provide patients with access to the very latest medicines, scientists with research opportunities and the HSC with additional revenue. Innovation can help governments deliver on their policy objectives - 40 per cent of all medicines introduced in the last 10 years were in the top priority areas of cancer, heart disease, mental health and diseases of the elderly.

The life science industry is a critical part of the knowledge economy and key to the UK's global economic competitiveness. The pharmaceutical industry is working with the NHS to combat a sharp fall in the number of trials located in the UK. However, evidence suggests further efforts by governments and the NHS are needed.

The pharmaceutical industry commits to:

- Continue to work in partnership with stakeholders in order to make Northern Ireland a more attractive place for the Industry to invest.
- Continue to work with governments to promote innovation and improved horizon scanning for modern medicines.

We call on political parties, clinical leaders and policy makers to:

- Encourage an 'open innovation' approach that removes barriers to partnerships between companies and public sector researchers, allowing the country's foremost talent to collaborate, co-create and flourish.
- Encourage the recognition of the importance of innovation to HSC by incorporation of an R&D performance measure in its Annual Operating Framework.
- Ensure the Northern Ireland Assembly match the UK Government's level of investment in medical research and development, supporting innovation and improved horizon scanning for the HSC.
- Support the Northern Ireland Office of R&D to eliminate excessive regulation by urgently implementing a single central approval process for clinical trials.
- Honour the commitments of the Northern Ireland Assembly to the PPRS to support innovation and improved horizon scanning for HSC.
- Establish a high level Life Sciences Northern Ireland Board to consider the implication of the "issues" raised within the 'Office of Life Science Blueprint' and prioritise its recommendations in order to maximise Northern Irelands contribution and competitive advantage.



Partnership Case Study

GlaxoSmithKline (GSK) has established an Academic Drug Performance Unit (DPU) to identify promising academic groups that can help take some of GSK's research and innovation forward. This fresh approach will allow GSK compounds that don't fit into the traditional R&D structure to be passed on to suitable academic partners to explore their future potential. In giving academics a project leadership role, GSK is trying to improve upon the traditional way in which industry accesses academic expertise. The Academic DPU aims to combine GSK's expertise in, for example, toxicology, pharmaceutical development and regulatory know-how, with the very best of UK academic expertise. By stripping a drug down to its bare essentials they can ask fundamental questions about it, allowing scientists and clinicians to find potential uses that pharmaceutical companies might sometimes overlook. The DPU has announced two deals so far: one with Cambridge University in metabolic disease and neuroscience and another with Cancer Research UK's world-class scientists.

"Growing the economy is our top priority. This is vital if we are to provide the wealth and resources required to build the peaceful, prosperous, fair and healthy society we all want to see. We need to meet the challenges of global competition and take advantage of new opportunities to make our economy more competitive, deliver increased prosperity and tackle disadvantage and poverty."

Northern Ireland Executive Programme for Government 2008-2011



CONCLUSION: A PRESCRIPTION FOR INNOVATON

In this document we have described a vision in which patients have better and earlier access to innovative medicines and technologies. In our vision, medicines are used optimally in Northern Ireland to maximise the benefits of innovation to the patient, the HSC and the taxpayer. They contribute to cost-effectiveness in the HSC, a healthy workforce and support a knowledge based economy.

This vision allows the countries of the UK to continue to be world-leading in biomedical innovation, competing successfully in the global knowledge economy and sustaining some of the highest value jobs and R&D facilities in the country.

The opportunities are vast but global competition is intensifying.

We have called for actions that will:

- Deliver better patient health
- Enhance cost-effectiveness in the HSC
- Drive the industry's contribution to the Northern Ireland economy

The pharmaceutical industry commits to playing its full part in making this vision a reality by working with all governments, the NHS and other stakeholders through existing partnerships and new models of collaboration. We are committed to continued open dialogue with all of our stakeholders.

The HSC is the largest customer in Northern Ireland of medicines and technologies produced by life sciences companies. If our industry is to fulfil its potential, driving economic growth and prosperity, it is vital that the HSC values and uses cost-effective innovations, and provides an excellent environment for clinical trials and investigations.

Political leadership is critical in this, so that the industry continues to deliver better health outcomes; value to the NHS; a return to the taxpayer in terms of continued industry investment and revenue to the Exchequer.

We call on politicians, leaders throughout the HSC and our partners in healthcare and research, to work with us to deliver improved patient outcomes and sustain a thriving life sciences industry.



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