IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION

Submission to the Public Consultation on the Development of a National Cancer Strategy 2016 - 2025

An Roinn Sláinte
DEPARTMENT OF HEALTH

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INTRODUCTION

The Irish Pharmaceutical Healthcare Association (IPHA), represents the international research-based pharmaceutical companies who are responsible for developing, manufacturing and bringing innovative medicines to the Irish market. IPHA welcomes the opportunity to submit comments and suggestions to the Steering Group for consideration in the Development of the National Cancer Strategy 2016 – 2025.

The interaction between the industry and healthcare professionals is one which the industry believes brings benefits to both parties and ultimately to patient care. In this submission, the IPHA would like to outline the role of the industry in the current provision of cancer services in Ireland and the opportunities and challenges which we see now and in the coming ten years. We would also like to provide evidence of the value which the industry brings specifically in the area of medical oncology and how that could be built on through purposeful collaboration, to maximise the outcomes for Irish patients over the period 2016 – 2025.

EXECUTIVE SUMMARY

The benefit of having a clear strategy for cancer services in Ireland can be seen from the results achieved over the past ten years, it is therefore important to build on this over the next ten years and to engage all stakeholders to maximise the opportunities which the next strategy can deliver. In the area of medical oncology IPHA member companies are directly involved with Irish cancer services on a daily basis, from clinical trials right through to home delivery and nursing services. Given the level of existing activity and particularly with the degree of innovation and development in pharmaceutical treatments, the industry would like to participate purposefully and be formally included as a partner in the development of cancer services over the next ten years, at both a strategic and operational level.

There have been significant innovations in medical oncology in recent years and the development pipeline is also robust and promising. This is important in the context of rare cancers where options for patients are limited; however, such innovation can only be of benefit when it is actually used to treat patients. While it is obviously important that resources are used properly, it is also important that in evaluating innovative cancer treatments that decisions are made in an effective and timely manner, to ensure patients have the required access to the products. The industry is already working with payors/budget holders around the globe to create flexible systems to ensure both value for money and early access objectives are addressed. In order to achieve this in Ireland, early and timely access must be a strategic policy objective and should be measured accordingly via Key Performance Indicators.

The degree of treatment innovation together with demographic shifts are putting increasing pressure on cancer services in Ireland, so it is proper that there is robust evaluation of all spending and investment decisions. There is a comprehensive process for the pharmacoeconomic evaluation of all medicines, however, for a number of reasons the standard method provides challenges in the area of oncology, which can and does result in significant delays to reimbursement decisions on oncology medicines. To minimise the effect of delay on patients, IPHA would like to engage with the HSE and the NCCP to develop a system which is more appropriate for oncology and also to agree defined timelines for the reimbursement process so there is clarity for all involved.

Clinical research is of paramount importance to ensure the current degree of innovation in oncology persists. Having an active oncology research environment in Ireland is very important, primarily since patients have the opportunity to be treated early with novel products. There are a number of structural elements required to improve the attractiveness of Ireland as a location for

global clinical trials from the perspective of the pharmaceutical industry, however, there also needs to be a clear strategic vision to underpin this.

As an engaged and serious stakeholder group in medical oncology, the Irish Pharmaceutical Healthcare Association wishes to participate positively and purposefully on both a strategic and operational basis with the cancer services, through active dialogue and sharing of international best practice with both the Steering Group and the National Cancer Control Programme. IPHA is open and willing to collaborate on the development of relevant strategic objectives in the first instance and to participate in specific projects and joint working arrangements as appropriate.

FORMALISING AND RECOGNISING THE ROLE OF THE RESEARCH-BASED PHARMACEUTICAL INDUSTRY AS A KEY STAKEHOLDER IN CANCER TREATMENT

The development and use of innovative pharmaceutical therapies in cancer continues to make a significant difference in improving and extending the lives of patients. The battle against cancer is challenging and complex and requires input from all stakeholders. The pharmaceutical industry plays an important role in Ireland in advancing the scientific understanding of many cancers, in developing and making available advanced therapies to our oncology specialists and their patients, and in providing value added programmes to support patient care.

We are pleased to join other stakeholders in acknowledging the significant improvements in cancer services and outcomes over the past ten years. We recognise the central role played in this by the NCCP, as outlined in the recent Evaluation Panel Report[1]. We believe that the industry has also played a significant part through our medicines and the considerable interactions that we have with healthcare professionals across the entire cancer landscape.

Existing industry collaboration

IPHA member companies and their staff work to find solutions for healthcare professionals and their patients across the cancer spectrum, from clinical trials to the collection of data on outcomes. Examples of these activities (see Appendix for details) include:

- company sponsored trials and investigator initiated studies;
- compassionate use programmes following physician requests for patients with unmet medical needs;
- early access programmes after regulatory approval but in advance of reimbursement;
- treatment at home programme for patients in remote areas who have trouble attending the hospital for treatment;
- nurse support programme for patients;
- patient support materials;
- provision of educational support to healthcare professionals;
- projects to develop the use of predictive biomarker testing;
- support for the establishment of a National Biobank facility;
- support for the development of successful registries in Ireland.

Challenges – current & future

We share an objective of ensuring that Irish patients have timely access to the most innovative products, regardless of their means or location. Timely access to innovative medical treatments

[1] Warde, P., de Koning, H., Richardson, A., (December 2014) ***National Cancer Strategy 2006: a Strategy for Cancer Control in Ireland Evaluation Panel Report***

is of particular importance to cancer patients. Time is of the essence in all aspects, from prevention to diagnosis, cure, mitigation and palliation. It is wonderful that there have been so many ground-breaking advances in medical oncology treatment in recent years, but that has brought many challenges in terms of systems and resources required to avail of these innovations.

We are all aware of the difficulties which arise when patients cannot get access to a new and effective medicine due to administrative, budgetary or other challenges. It is imperative that the State's health authorities, healthcare professionals in cancer care and the industry work closely and productively together to ensure that these problems are minimised or eliminated.

Ensuring the appropriate use of medicines is critical to enabling the health service to deliver a high-quality, safe, efficient and effective service to patients. Benchmarking levels of oncology medicines usage with comparable countries can help inform health policy and service-delivery to ensure Ireland ranks within the best in the world when it comes to cancer care.

It is well documented globally and in Ireland that there are many challenges for healthcare systems to provide the most innovative treatments, particularly as the population ages. In Ireland, by 2025 a 50% increase in new cancer cases is expected compared to 2010[2]. A proportionate increase in the numbers of treatments is also expected, including an increase in chemotherapy of 42%-48%[3]. There will undoubtedly be further funding pressures to ensure all patients in need have access to life-saving or life-extending treatments.

Partnership – flexibility & dialogue are essential for success

The pharmaceutical industry is proactively facilitating change to enable payors/budget holders, such as the Exchequer/HSE in Ireland, to ensure that they can achieve value for money and improved outcomes for patients. We are driving initiatives such as Adaptive Licensing, Real World Evidence and Patient Access Schemes amongst others. IPHA members have access to international expertise and knowledge on how these novel initiatives are evolving and would welcome the opportunity to explore the possible options for implementation in Ireland.

IPHA requests that the National Cancer Strategy 2016 - 2025 would provide for a formal interaction with the research based pharmaceutical industry to enable collaboration on matters relevant to both parties on both current and future challenges and opportunities.

[2] National Cancer Registry, Ireland. ***Cancer projections for Ireland 2015-2040***
[3] National Cancer Registry, Ireland. ***Cancer projections for Ireland 2015-2040***

MAKING EARLY ACCESS TO INNOVATION A KEY PERFORMANCE INDICATOR FOR 2016-2025

Advances in medical care, including the use of innovative medicines and vaccines, have played a crucial part in the huge improvements seen in the health outcomes of the Irish population, with the resulting increases in life expectancy. This is nowhere more obvious than in the treatment of cancer, recent examples include:

- the 40% reduction in the recurrence of HER2+ Breast Cancer brought about by trastuzumab[4] and
- doubling of five year survival rates in Chronic Myeloid Leukaemia from 31% in the 1990s to 60% for those diagnosed from 2004 to 2010 through the introduction of imatinib[5]

The research and development of innovative medicines is complex and carries many risks. On average, only one or two of every 10,000 promising molecules will satisfy the extensive testing and regulatory requirements and make it all the way to the patient. The estimated cost of developing a new medicine is almost €1.4 billion and the process takes up to 12 years on average[6]. However, the benefits which arise from pharmaceutical innovation, as highlighted above, make the risk worthwhile. There is a complex balance to be struck in sharing the benefits of innovation between patients, payors and pharmaceutical companies who need to invest in ongoing Research & Development to sustain the capacity to innovate.

The contribution of pharmaceutical products to the improvement in outcomes in Ireland is noted by the National Cancer Registry in their report "Cancer in Ireland 1994-2012"[7]

> *"For the majority of cancers, however, improvements in treatment are probably the major contributor to survival improvements. Most notably, the use of chemotherapy, either on its own or more frequently in combination with other treatment modalities, has increased markedly across the majority of relevant cancer types."*

The importance of early access to innovation and the reality in Ireland

Cancer often presents as a rapidly progressive disease or is diagnosed at a late stage. New oncology drugs are often licenced initially only for late stage disease (with earlier stage disease

[4] http://onlinelibrary.wiley.com/doi/10.1002/cncr.25347/pdf
[5] http://www.cancer.net/cancer-types/leukemia-chronic-myeloid-cml/statistics
[6] ABPI (2012), ***Time to Flourish – Inside Innovation: the Medicine Development Process***
[7] http://www.ncri.ie/publications/statistical-reports/cancer-ireland-1994-2012-annual-report-national-cancer-registry

taking longer to show survival benefit in clinical trials). This means that early access to new oncology drugs is critical for oncology patients and supports the NCCP's overall objectives.

Recognising the impact that these medicines can have on patients and their families, the pharmaceutical industry in Ireland has demonstrated its commitment to early pre-licence access for patients through local clinical trials and Early Access Programmes.

Unfortunately the time from the regulatory approval to patient access for oncology drugs is increasing in Ireland. Lengthy reimbursement discussions and pricing negotiations are causing unnecessary delays for patients in urgent need of new treatment options. To provide a measure of the timeframe from initial regulatory approval in Ireland to reimbursement approval, IPHA conducted an internal survey of members in July 2015 to determine the time it takes to make new oncology medicines available to all Irish patients. The survey covered 16 products from 13 IPHA companies, which received regulatory approval in the period 2011 to 2013. It was found that for these oncology medicines, the average time from regulatory approval to reimbursement approval was 566 days or approximately 18 months (range 293 days to 1,021 days), where the standard process sets out a timeframe of 180 days (excluding negotiations or other discussions).

This is clearly much longer than acceptable or desirable for all involved, most importantly, the patient and their treating physicians, and also, we take it, the NCCP, the HSE and Department of Health. It is clear, therefore, that both the State health authorities and the industry need to explore novel methods to reduce these delays in getting products to the patients who need them.

Examples of solutions – adaptive pathways

The adaptive pathways approach (formerly known as 'adaptive licensing') is part of the European Medicines Agency's (EMA) efforts to improve timely access for patients to new medicines. The concept of adaptive pathways foresees either an initial approval in a well-defined patient subgroup with a high medical need and subsequent widening of the indication to a larger patient population, or an early regulatory approval (e.g. conditional approval) which is prospectively planned, and where uncertainty is reduced through the collection of post-approval data on the medicine's use in patients.

This approach is particularly relevant for medicines with the potential to treat serious conditions with an unmet medical need, such as cancer, and may reduce the time to a medicine's approval or to its reimbursement for targeted patient groups. It involves balancing the importance of timely patient access with the need for adequate, evolving information on a medicine's benefits and risks.

In March 2014, the EMA began inviting companies to participate in a pilot project on adaptive pathways, and published a framework to guide discussions on individual pilot studies. EMA changed the name of its pilot project from adaptive licensing to adaptive pathways to better reflect the idea of a life-span approach to bringing new medicines to patients with clinical drug development, licensing, reimbursement, and utilisation in clinical practice and monitoring viewed as a continuum.

In some European countries, payors/budget holders provide immediate access to innovative drugs prior to or immediately after marketing authorisation. In the UK, under the Early Access to Medicine Scheme (EAMS), the Medicines and Healthcare products Regulatory Agency (MHRA) provides a scientific opinion on the benefit/risk balance of the medicine based on the data available at the time of the EAMS submission. The opinion lasts for a year and can be renewed. Following this, in England, EAMS medicines will be commissioned by the NHS to ensure that there is equity of access to eligible patients across the country. It does not replace the normal licensing procedure.

In France, the "Autorisations Temporaires d'Utilisation" ("Temporary Authorisations for Use") or ATU procedure is an exceptional measure making available medicinal products that have not yet been granted a Marketing Authorisation (MA). The ATU is issued by the ANSM (Agencie Nationale de Securitie du medicament et des produits de sante). The aim of ATUs is to provide early access to new promising treatments where a genuine public health need exists, i.e. in the treatment of patients suffering from serious disease and having reached a situation of therapeutic impasse. ATUs are granted as an exceptional and temporary measure, when the following conditions are met:

1. for the treatment of serious or rare diseases,
2. in the absence of a suitable therapeutic alternative (with a MA) available in France, and
3. there is presumed to be a positive benefit/risk ratio.

It is therefore important that those involved in the assessment of innovative treatments prioritise timely and predictable decision making processes. We urge all concerned to be flexible in terms of making effective and logical decisions without undue bureaucracy or unnecessary layers of decision-making. The industry is certainly willing to collaborate with the NCCP and the HSE to ensure the process does not delay patient access. For example, while there is already a process for Horizon Scanning for near term budgetary planning, the industry would be happy to engage in

a medium to long term horizon scanning conversation to allow for resource and systems planning for the NCCP.

Opportunity to endorse and measure early access to innovation

In autumn 2015, IPHA and the relevant government departments and HSE will engage in substantive discussions on a successor agreement to the current framework agreement which expires on 31 October. We believe a key policy objective should be early access to innovative medicines for patients and predictable, stable pathways for new medicines approvals. This can be done in ways that are economically viable for the State and commercially sustainable for the industry. We will bring forward specific proposals for the Government on this. If we can agree a method for early and fast access, patients will benefit as clinicians will have the best treatments available for use. We believe this is achievable in the context of an overall agreement and will be highly beneficial for the operation of the next phase of the National Cancer Strategy.

IPHA requests that early access to innovative medicines be included as a priority in the new National Cancer Strategy and that the time from Marketing Authorisation approval to patient access be included as a Key Performance Indicator of cancer services.

BROADENING THE EVALUATION OF CANCER TREATMENTS AND STREAMLINING PHARMACOECONOMICS ASSESSMENTS

In order for patients to gain access to new cancer medicines, the National Cancer Control Programme (NCCP) and ultimately the HSE must agree to reimburse them. IPHA recognises the need for appropriate review to assess the value of innovative cancer medicines. In the context of finite resources, pharmacoeconomics may help the decision maker to evaluate which programme, intervention or medicine represents the best value for money.

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

Challenges with standard pharmacoeconomic evaluation in oncology

Pharmacoeconomic assessment of cancer medicines in an Irish context is not without its challenges. The Willingness to Pay (WTP) threshold is fundamental to pharmacoeconomic analyses i.e. what we are prepared to pay for improved outcomes. However, the current WTP threshold may be considered more appropriate for chronic disease rather than end of life. Pharmacoeconomic analyses from an Irish perspective are also difficult due to the absence of a standardised costs database and the lack of utility data for the Irish population. Orphan cancer medicines present a particular difficulty due to the rarity of these patient populations and the associated data limitations. Science is evolving rapidly with novel chemotherapy, biologics and immuno oncology therapies presenting particular new challenges for cancer drug evaluation.

Currently the NCCP and the HSE work together to evaluate oncology medicines for reimbursement. The standard system involves the pharmaceutical company submitting a HTA to the National Centre for Pharmacoeconomics (NCPE) to demonstrate the benefit of the product compared to the standard of care, in comparison to the cost implications of the introduction of the treatment (a cost-effectiveness analysis). This process applies to all therapy areas. For oncology medicines a separate clinical review is conducted by the NCCP Technology Review Group comprising clinical experts in the designated tumour type.

Cost effectiveness/cost utility analyses have been the primary methodologies used to inform the evaluation process, however these are not the only approaches which may be relevant.

Additional methods such as Multi-Criteria Decision Analysis (MCDA) and/or comparative clinical effectiveness rather than cost effectiveness could be considered when Cost Effectiveness (CE)/Cost Utility Analyses (CUA) are difficult or impossible due to local data gaps, orphan incidence etc. Where CUA/CE is not possible, this Clinical Review conducted by the NCCP Technology Review Group could play a more central role in informing the reimbursement decision.

These relevant analyses are then considered in order to make the reimbursement decision, however, there are many difficulties associated with the standard HTA process which make it very challenging for making decisions for end of life treatments as opposed to those for chronic disease. It is also true that the future of cancer research and innovation will bring new indications to existing medicines and the increasing use of biologics and other therapies in combination. The current HTA threshold and process does not facilitate the evaluation of combination medicines. Thus other clinical, ethical and social considerations are important in the review of new cancer medicines; in many Scandinavian/EU countries, the societal perspective is incorporated in the decision making process to reflect broader societal benefits, including cost offsets in non-medicine budgets and people living with cancer continuing to contribute to society as a result for many years.

Addressing the challenges – Real World Evidence (RWE) and other data collection

The challenge of measuring outcomes for Irish cancer patients looking forward is one faced by healthcare professionals, the Department of Health, the NCCP and the industry. Through collaboration across all stakeholders these outcomes can be measured and evaluated in a transparent, timely manner. As we enter the era of adaptive licensing, avenues to capture clinical effectiveness/real world evidence will become more important in addressing uncertainty and evaluating longer term risk/benefits with new cancer medicines.

As scientifically credible, anonymised patient-level data becomes more accessible around the globe, real-world evidence is becoming the new currency in healthcare. Healthcare decisions can now be better informed based on millions of patient experiences in the real world, supplementing randomized clinical trials that typically involve thousands of patients in a controlled setting. Using RWE, patients, clinicians and budget holders can better assess the value of treatments and services based on actual health outcomes and the total cost of care.

It is widely acknowledged that the availability and comparability of data in the broader Irish healthcare setting is a challenge, and this is also the case in oncology. With increasing demands on cancer services and funding, it is imperative that data is collected in a systematic way to

facilitate informed decision making. There is evidence from the Systemic Anti-Cancer Therapy system in the UK that this can achieve many outcomes in terms of infused medicines' delivery alone, including:

- Provide evidence and information for service planning – reducing waiting times, improve patient throughput and make visible areas for service efficiency improvement
- Provide mechanism for monitoring of wastage and financial governance
- Monitoring adherence to guidelines
- Management of State approved patient access schemes.

IPHA members are in many cases currently working on an ad hoc basis across a number of registries; the industry is willing to engage with the NCCP to develop a strategy for the collection and management of these types of data. IPHA companies often have access to resources and knowledge at a global level that could provide much assistance to the NCCP in managing oncology data.

Ensuring efficient evaluation processes facilitate good decisions and timely access

The difficulties outlined above contribute to increasing the complexity of the reimbursement decision which can in turn result in delays for patients in accessing medicines. Therefore, the industry would like to work closely with the HSE, the NCCP and all relevant parties to ensure that the systems and processes required to make timely, rational and effective decisions are in place, fit for purpose and are properly implemented. To achieve this, IPHA requests that the following items be considered:

Additional methodologies to inform the evaluation process could be considered where cost utility/effectiveness analysis is not possible. In such instances, the Clinical Review conducted by the NCCP Technology Review Group could play a more central role in informing the reimbursement decision.

Efficient pharmacoeconomic review through a clear assessment process with defined timelines for reimbursement decisions should be implemented and measured for all new cancer medicines.

DRIVING CLINICAL RESEARCH INTENSITY TO A NEW LEVEL IN IRELAND

Clinical research is vital for innovation in oncology treatment. The number of drugs in the oncology pipeline is four times the size of the next largest therapeutic class and with the global market for oncology drugs, including supportive care, reaching $100 billion in 2014[8].

Clinical trials of cancer medicines examine the use of new or existing drugs, or combinations of these, to treat cancer with the final aim of improving survival and quality of life. Without clinical trials, it would not be possible to develop new more effective treatments. IPHA members have a key role to play in bringing global clinical trials to Ireland, as well as supporting local clinical trials, conducting these either independently or in partnership with research institutions such as ICORG.

Benefits of a robust clinical trial environment in Ireland

IPHA members provide cost savings for the State through the provision of medicines for clinical trial purposes. The estimated cost of drugs provided for ICORG managed clinical trials between 2012 and 2014 is €18m[9]. This does not include the cost of drugs provided through other trials. Recent ICORG figures indicate that, in Ireland, nine major pharmaceutical companies, all IPHA members, have an estimated current investment of €32m in clinical trials with this expected to increase to €100m by 2020. ICORG managed trials alone have recruited more than 5,600 patients between 2006 and 2013 with a further 2,329 patients in 2014.

Clinical trials may provide cancer patients in Ireland with early access to innovative therapies. They also play a valuable role in growing scientific knowledge and in ensuring that Irish clinicians have sufficient access to meaningful research opportunities. Drug development clinical trials that fail to demonstrate expected treatment benefit may still yield valuable scientific information about a disease.

Pharmaceutical companies also support preclinical research, supporting such academic institutions as the Molecular Therapeutics for Cancer, Ireland (MTCI). This investment in research and development has a positive economic impact, nurturing collaboration among diverse stakeholders, from SMEs to academia, creating new jobs and making Ireland a more attractive location for clinical scientists in oncology and clinicians who are involved in research.

Importance of supporting and developing Clinical Research

However, while oncology is the most advanced therapeutic sector in Ireland with respect to clinical trial activity, Ireland itself is an under-performer globally as a preferred location for clinical

[8] IMS Institute (2015) ***Global oncology trend report***
[9] http://icorg.ie/international-clinical-trials

trials. This is mainly due to the lack of an integrated approach and the resulting difficulties (mostly administrative and bureaucratic) that make it challenging for Ireland to compete for participation in many international trials. The lack of a comprehensive infrastructure to facilitate research was commented on by the previous review panel (A Strategy for Cancer Control 2006) and what currently exists, does not appear to be co-ordinated to best effect.

Ireland should position itself as a primary site for high quality integrated oncology research from bench to bedside. IPHA recommend that one of the key areas for inclusion in the new Cancer Strategy is the need for a clear strategic vision for cancer research in Ireland. IPHA members can contribute to the development of this research agenda. We will work collaboratively with State organisations, the Department of Health, HSE and particularly the Health Research Board, in advancing this goal, as well as continuing to build our partnerships with academic and non-Governmental organisations in the area. In particular, IPHA requests that the Steering Group considers the following items:

To create a strategic multidisciplinary research agenda that provides a vision for oncology research in Ireland with adequate funding for the HRB to promote this, with input from the pharmaceutical industry.

To support the strategic vision with the appropriate infrastructure, to include:

- **Establishment of a national Research Ethics Board for multi-institutional studies, as has been done in other jurisdictions.**
- **Promote participation in clinical trials in general (particularly in oncology) as a platform for increasing Ireland's scientific knowledge. This should ultimately lead to better outcomes for cancer sufferers, but would also provide them with the possibility of early access to potential new medicines.**
- **Establish an integrated laboratory R&D network to underpin translational oncology research and support the evaluation of pharmaceutical oncology pipelines.**
- **Ensure ICORG's continued successful increase in clinical trial participation by providing funding via the HRB, ring-fenced for oncology research.**
- **Establishment of a national Biobank to underpin oncology research and support evaluation of pharmaceutical oncology pipelines. This is essential for Clinical and Academic researchers who require human tissue samples for research.**

APPENDIX – EXAMPLES OF ACTIVITIES SUPPORTED BY IPHA COMPANIES

1. BIOMARKER TESTING

Collaboration between a number of IPHA companies has helped to establish three national Centres of Excellence for predictive biomarker testing for oncology patients. This set-up was enabled through financial & administrative support from pharmaceutical companies and leveraged best in class international standards. Predictive testing stratifies patients into two groups, those that respond to a specific therapy and those that don't. This helps ensure the correct selection of patients for oncology therapies enabling better outcomes and significantly reducing the cost burden for the HSE. This can and has enabled early access to patients receiving certain therapies through supporting the validation and clinical implementation of the appropriate biomarker tests for the relevant patients.

2. COMPASSIONATE USE PROGRAMMES

The industry recognises the challenges faced by the healthcare system in the period between the completion of clinical trials and new medicines receiving their marketing authorisation and ultimately reimbursement. While the EMA adaptive licensing pathway may address this issue for a small number of medicines up to the time of marketing authorisation, companies do take a broader approach on occasion, through the roll out of compassionate use programmes for new molecules. In doing so industry takes on the responsibility for funding these patients, beyond the point of marketing authorisation up to the time of reimbursement; with the increase in length of time to reimbursement, examples exist where compassionate use programmes have run for close to two years.

3. EDUCATIONAL SUPPORT

The role of the pharmaceutical industry in providing educational support to healthcare and associated professionals cannot be underestimated, and this is especially evident in the oncology field. Some examples of initiatives provided by pharmaceutical companies over the duration of the first National Cancer Control Strategy include, but are not limited to:

- Independent funding for training (e.g. SpR Education Programme in Medical Oncology)
- Ongoing CPD/CME training across a range of tumour types
- Fellowships for overseas placements (e.g. ISMO fellowship to Memorial Sloan Kettering)
- Support for MDT meetings
- Facilitation and support of disease specific fora, such as All Ireland Cancer Conferences in Breast, Lung, Colorectal, Ovarian, Melanoma and Lymphoma, which take place annually or biennially

These initiatives have been key in the development of treatment guidelines and the elucidation of best practice models for service delivery in oncology in Ireland.

4. NATIONAL BIOBANK FACILITY

Many IPHA companies are trusted partners in supporting the current project to establish a National Biobank Facility to enable better translational research infrastructure for Irish cancer patients. This would enable Irish patients to benefit from the latest advances in molecular research by ensuring that local tissue & blood samples are managed in a quality assured biobank, and released for approved basic research and clinically directed molecular pathology investigations.

5. REAL WORLD EVIDENCE

The generation of real world evidence (RWE) is essential to ensure the appropriate use of new medicines. The pharmaceutical industry is a key stakeholder in the generation of RWE, both at local and at international level. Over the last number of years, the development of disease specific registries has played an important part in the development of local RWE. Industry has provided significant support to these registries from a financial perspective. In addition, industry is uniquely placed to share best practice and expertise from registries they have supported in other countries and regions.