Access to Innovation

Outcome Report

Roundtable Meeting
Held on the 6th June, 2012
at the European Parliament Information Centre
THE REPORT AND ITS AIMS

The Irish Platform for Patients’ Organisations, Science and Industry (IPPOSI) facilitated a roundtable meeting between members and guests on the 6th June, 2012 entitled - ‘Access to Innovation’. This report outlines the current issues concerning access to innovation raised at the meeting and the recommendations reached by the participants. The aim is to further inform key stakeholders on the facts concerning access to new and innovative treatments with the patient perspective firmly to the fore.

BACKGROUND

In May 2012, the Board of IPPOSI became aware of the issues concerning access to new treatments (drugs and technologies). The feedback indicated that products which had passed the Health Technology Assessment process in the National Centre for Pharmacoeconomics (NCPE) and therefore found to be cost effective had not been approved for reimbursement by the Health Service Executive (HSE).

The Board then took the step, through the CEO, to collect the views of patient organisations on the issue. It was found that patients were experiencing difficulties in accessing these new treatments. However, Patient Organisations also reported difficulties with treatments already in the system and inequitable-access issues for certain disease-specific patient groups.
EXECUTIVE SUMMARY

IPPOSI is a patient-led organisation and as such, patients lead the discussion and set the scene at all members’ meetings. In this context, the opening reports were made at the IPPOSI Roundtable on the 6th of June by patient representatives who explained the difficulties their members face in accessing new treatments.

Key patient contributions were made by Ava Battles, MS Ireland, Anna Moran, Fighting Blindness and Kathleen O’Meara, the Irish Cancer Society. Other key contributions came from Dr Ambrose McLoughlin, Secretary General of the Department of Health, Prof Orla Hardiman, Consultant Neurologist, Dr Fergus O’Ferrall, Adelaide Lecturer in Health Policy and Gina Menzies, Medical Ethicist.

Chairing the roundtable discussion, Eibhlin Mulroe, CEO of IPPOSI outlined how IPPOSI has led the debate on this issue since 2008. She drew attention to two IPPOSI meetings and subsequent reports which explored the emerging Health Technology Assessment (HTA) process in Ireland.

The first report was published in the wake of the Health Act 2007 entitled ‘Access to New Medicines and Technologies in the Era of Health Technology Assessments (HTA)’. The second was published in 2011 entitled ‘Health Technology Assessment, where are we now?’

Ms Mulroe said that while the HTA process is accepted by all our stakeholders as a transparent process whether undertaken by the NCPE or HIQA, the decision-making process to reimburse needs clarity. Patients and the public need to know who the decision maker is and what the criteria for that decision includes as the HTA is only one element. Orphan drugs were highlighted as an example of where the HTA cannot be the only consideration.

There is consensus that, until recently, Irish patients were among the first in Europe to gain access to new treatments and therapies. However in recent years challenges have emerged in access to new and often expensive treatments. The issues faced by Irish patients currently were identified as follows:

- New treatments are approved (HTA) by the NCPE, but then no decision is taken by the HSE on reimbursement. The treatment is effectively “on hold” in the system preventing patient access.
- Patients are added to waiting lists or are denied access to innovative treatment if they live outside the hospital’s catchment area.
- Some approved treatments are being replaced by off-label alternatives, patients are not always aware of the alternatives.

Contributors agreed that it would be unacceptable for Irish patients to be denied access to treatments while patients elsewhere in Europe have access. The availability of new treatments and technologies was agreed to be a vital component of a good health service.
THE DECISION MAKING PROCESS

Following the contributions by the patients’ organisations at the Roundtable, it became clear that transparency and clarity in the decision making process was lacking. There was an acceptance that the metrics used by the National Centre for Pharmacoeconomics are acceptable and were described as ‘fair’. However, on reviewing a table (see table 1) from the NCPE website outlining the process, there was agreement that the process of HTA is clear, but the decision-maker at the end of the process is not widely known or clear to the patients.

Table 1, (www.ncpe.ie)
THE RESOURCES ALLOCATED TO AND USED BY THE HEALTH SYSTEM

Clinicians face an ethical dilemma in resource allocation. On the one hand they are patient advocates seeking to get the best treatment to the patient and on the other, particularly those in the public sector; they are becoming the gatekeepers of resources.

There was an acknowledgment by patient representatives that tough decisions had to be made. However some contributors challenged an emerging view that resources were so constrained that they face difficult choices.

One patient representative said that their members should have access to all approved and licensed treatments as deemed suitable for them by their clinician. They felt that this was the only way to give patients the best opportunity to have a good quality of life, and allow them to work, contribute to the economy, enjoy family life and society in general.

An Ethical Dilemma

Advances in medical technology and drug therapies in all areas of medicine have greatly improved healthcare outcomes and at the same time produced new ethical dilemmas including the following:

- How much should a civilized society spend to save or enhance a life? What is the answer? – Whatever it takes or is there a limit?

- If the state effectively ends a life by refusing treatment that is available, could this course of action be considered as involuntary or passive euthanasia?

- Can one put a cash value on a human life or on a period of human life?

The ensuing discussion around these questions and statements only highlighted the clear need to further develop ethical guidance for those ‘gatekeepers’. They are responsible for making treatment decisions every day for their patients, but now have the added resource considerations to bear in mind.
THE IMPACT ON THE DEVELOPMENT OF NEW TREATMENTS AND THERAPIES

Throughout the discussion on the difficulties in accessing innovative treatments, the potential impact on the development of new treatments and therapies arose as a concern for all present. One patient organisation involved in funding research said it would be a crime if new treatments, in part funded by Irish people, were not then available to Irish patients.

There was general concern that if a therapy emerges for some rare conditions, it may never prove to be cost effective due to the low number of patients involved. Therefore a treatment could be approved clinically but not reimbursed.

On the issue of the clinical trials process, a speaker involved in clinical trials described the process as ‘very long and expensive’ and said it was often about designing something that fulfills regulatory requirements rather than asking other questions about cost and access. Another speaker said that we needed to broaden the skill sets used in the process by including health economists, statisticians and epidemiologists. Expanding on this issue of the clinical trials process, it was suggested that the Irish Medicines Board (IMB) begin a discussion at a European level to seriously consider how the clinical trials process can be reformed. The process needs to be shorter while still ensuring patient safety. As a result of a shorter process, the costs to be recouped by the sponsors are reduced which can only have a positive impact on the cost effectiveness of treatments.
ROUNDTABLE RECOMMENDATIONS REACHED BY IPPOSI MEMBERS

Arising from the roundtable meeting, the following recommendations were reached by IPPOSI members:

- Transparency and clarity on the decision making process on access to new treatments and therapies.
- Define at all stages of the process, who the decision maker is and the methodology and timelines to which they are working. The Transparency Directive should be adhered to in this context.
- Patients should have a role in the process and there should be a right of appeal
- Orphan drugs, particularly ultra orphan drugs, must be considered using different criteria, due to the low number of patients involved and the high cost of treatment
- Patients receiving an off-label treatment have a right to be informed of this and they should have access to the alternative approved treatment
- Ethical guidance should be provided to prescribers who make difficult decisions in the context of the patient and budget constraints.
- At European level and alongside the review of the Clinical Trials Directive, the Irish Medicines Board (IMB) should engage the EU in seriously considering proposals to shorten the clinical trials process while still ensuring patient safety. The costs of clinical trials must be reduced thereby reducing the cost of treatments.
Kathleen O’Meara - Head of Advocacy & Communications, Irish Cancer Society
Kathleen O’Meara leads the advocacy team at the Irish Cancer Society where she gives expression to the advocacy mission of the Society in the area of cancer prevention, screening, research and fighting tobacco. She served as a member of Seanad Éireann for ten years where she was her party’s spokesperson on Childcare and a member of the All Party Committee on the Constitution and on Justice. Prior to her time in the Oireachtas Kathleen was an accomplished radio and television journalist.

Ava Battles - CEO, MS Ireland
Ava Battles is a qualified health psychologist with 13 years’ experience in the community and voluntary sector. As CEO of MS Ireland she is responsible for overseeing the delivery of a range of services and resources to the MS Community in Ireland. Ava has previously worked as the National Training and Research Manager at the Irish Society for the Prevention of Cruelty to Children (ISPCC), as Director of Services with Brainwave - The Irish Epilepsy Association and CEO of the Carmichael Centre for Voluntary Groups. She is currently a board member of the Neurological Alliance Ireland.

Anna Moran - External Affairs Manager, Fighting Blindness
Since 2006, Anna has worked with Fighting Blindness, an Irish patient-led organisation whose vision is to cure blindness, to support those living with sight loss and to empower patients. She holds the role of External Affairs Manager and is responsible for managing all aspects of the research portfolio of the organisation, Anna holds a graduate degree from Trinity College, Dublin along with a postgraduate qualification from Griffith College, Dublin.

Other Guest Contributors to the discussion

Dr. Ambrose McLoughlin - Secretary General, Department of Health
Dr. Ambrose McLoughlin has been recently appointed as the new Secretary General at the Department of Health. He holds a Masters in Business Administration from University College Cork and a Bachelor of Dental Science from National University of Ireland / Dublin Dental School. Dr Ambrose has over 30 years’ successful experience in the Health Service from Practitioner Level to Chief Executive. He has previously served as Chief Executive of the Pharmaceutical Society of Ireland (PSI), the pharmacy regulator and as CEO of the North Eastern Health Board (NEHB).

Prof Orla Hardiman—Consultant Neurologist
Prof Hardiman is a Clinical Professor of Neurology at Trinity College Dublin and a Consultant Neurologist at Beaumont Hospital. Her primary research interests include the epidemiology and pathogenesis of motor neurone disease and she is internationally recognised for her work in this area. She has also maintained a clinical interest in the pathogenesis and treatment of migraine. Dr Hardiman is known for her interest and advocacy in health service development with an emphasis on delivery of a fair and transparent system of care for all based on medical need.