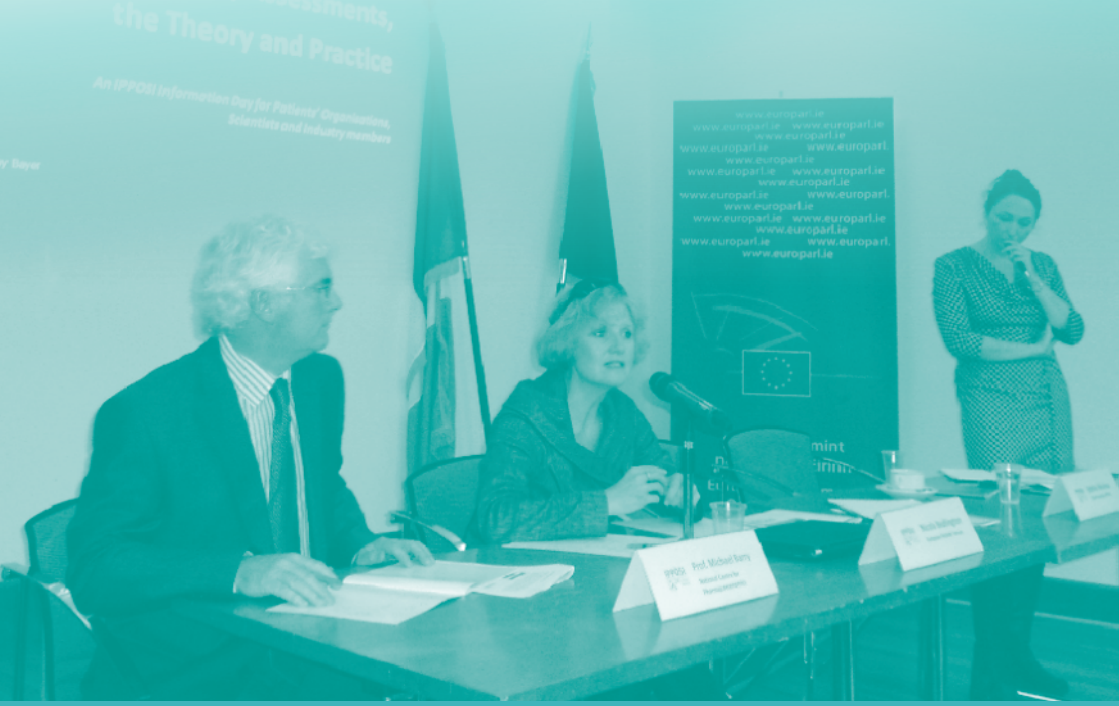
An IPPOSI Information Day:

Health Technology Assessments, the Theory and Practice

Held on Thursday 11th October, 2012
At EU Parliament Office, Molesworth Street, Dublin 2.

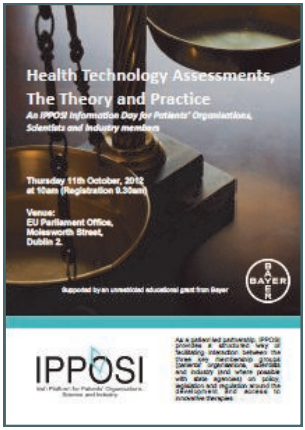
Outcome Report



IPPOSI patients science industry

The Irish Platform for Patients' Organisations, Science and Industry is a patient-led partnership which provides a structured way of facilitating interaction between patients' organisations, scientists, industry members and where possible state agencies. We seek to ensure patients in Ireland have prompt access to new and developing innovative therapies

IPPOSI held an information day on the process of Health Technology Assessments (HTA) in Ireland, in European Union House on the 11th of October 2012. IPPOSI members attending represented key individuals from leading patient organisations, clinicians, researchers and industry. The aim of the event was to explain how pharmaceutical products are assessed to further inform pricing and reimbursement decisions made by the HSE and/or the Department of Health. Health economics studies the medical, social, ethical, and economic implications of development, diffusion and use of health technology. National Health Economics centres are found in most EU countries with varying methods of assessment employed.



European Perspective

Nicola Bedlington, Executive Director, European Patient's Forum (EPF) presented on her organisation's survey which set out to identify the current situation, good practices in place and the challenges of patient involvement in HTA in European countries. The results should contribute to the process of informing and building the capacity of patient organisations, HTA agencies and HTA appraisal committees and decision-makers in Europe.

Ms Bedlington explained that meaningful patient involvement means that patients take an active role in activities or decisions that will have consequences for the patient community, because of their specific knowledge and relevant experience as patients. The involvement must be planned, appropriately resourced, carried out, and evaluated. The

EPF survey concluded that the dissemination stage is the stage that patients contribute the most in the EU, while there is very low patient involvement in the scoping stage. However, patients should be more involved in the early phases of HTA. Patient representatives input in HTA has the most impact in putting forward patients' needs in terms of *quality of life and providing a real life context* to the use of health technologies.

Irish Perspective

Professor Michael Barry, Clinical Director of the National Centre for Pharmacoeconomics began by introducing the principles of pharmacoeconomics and the methodology used in the HTA process in Ireland. He indicated that drug expenditure is a focus for cost containment of overall healthcare expenditure. Graphs provided in the presentation clearly highlighted the decrease in budget available to the HSE over recent years and the accompanying increase in the drugs bill. While efficacy of treatment and health outcome is important, the health economist seeks value for money and affordability. Prof Barry outlined that through the IPHA/HSE 2006 agreement, the HSE reserves the right to assess new and existing technologies (pharmaceuticals, diagnostics and devices) that may be high cost or have a significant budget impact on the Irish healthcare system. In Ireland, pharmaceutical companies seeking reimbursement of new products apply to the HSE and the National Centre for Pharmacoecomomics (NCPE). The product undergoes a rapid review in the NCPE and a decision is taken after 2-4 weeks as to whether the product needs a full HTA assessment. There were thirty five new products under rapid review in 2011, twenty did not need a formal assessment and fifteen required a formal assessment by the NCPE. The NCPE then advises the HSE whether assessments (formal or rapid) are positive and if so the decision to reimburse rests with the HSE.

Discussion and Recommendations

- Participants indicated that recent issues relating to access to new products took place when those products got stuck in the decision making part of the process (post HTA), accountability for decision making is currently a grey area. Prof Barry accepted that this is an issue in the current system but moves are afoot to have a clear decision-making pathway in the future.

- There is a need for a framework and methodology for patient involvement in HTA at EU level. The EPF will be doing some work in this area and Ms Bedlington agreed to share any such framework with IPPOSI and the NCPE.

- Some patient representatives raised concerns about access to orphan drugs and the fact that the Irish HTA system does not cater for them specifically unlike other EU countries. The English AGNSS model was alluded to as an example where ultra-orphan drugs are assessed in a different way and patients have an input.

- Patient organisations articulated a willingness to get involved in the HTA process at the earliest stage. Prof Barry agreed that this was an area the NCPE are interested in pursuing and thought that IPPOSI would be an ideal partner in linking his team with relevant patient groups as new applications arrive in to the NCPE office.

- HTA training of patients and patient organisations will be made available through the NCPE in the coming months. Patients participating in the HTA process need to be fully informed and in some cases training will be required.