EUROPEAN CANCER ORGANISATION

Oncopolicy Forum 2011: Inequalities in Access to Cancer Drugs in Europe

Chairman Richard Sullivan, from King's Health Partners Integrated Cancer Centre, London, opened the session by asking delegates to vote on what they felt to be the key cause of inequalities in access to cancer drugs across Europe. In the vote, 42.2% cited the main cause as national funding and willingness to pay, 40.2% blamed drug affordability, 11.8% cited clinicians' non-adherence to guidelines, 3.9% blamed the health technology assessment process and 2% cited marketing authorisation as a key challenge.
In the second question the audience was asked what they felt to be key solutions for equitable access to drugs. In the vote 29.9% felt the solution to be greater reductions in the price of cancer drugs by industry, 26.2% felt greater enforcement of guideline-based protocols is needed, 22.4% cited the need for greater national funding, 15% felt quicker and greater harmony in European marketing authorisation is required, and 6.5% opted for reduction or removal of health technology assessments.

Health Technology Assessments, said **Måns Rosén**, from the Swedish Council on Technology Assessments in Health Care, need to include broad assessments of effects, risks, costs and social consequences of different interventions. In making decisions about affordability, comparisons between drugs and other interventions also need to be taken into account. The situation is complex - in Sweden, for example, three different government bodies make assessments – the Medicines Product Agency (drug approval), the Pharmaceutical Benefits Board (reimbursement decisions), and the SBU (health technology assessment).

Francesco Pignatti, from the European Medicines Agency (EMA), explained that the focus of the EMA is limited to the regulatory approval of new drugs (not other medical interventions) and once drugs reach the market, individual HTA authorities undertake funding appraisals in each country. The result is a complex situation where developers are required to satisfy the needs of multiple stakeholders. A current initiative that aims to bring about agreement on HTA methodologies amongst HTA bodies is the EUNetHTA.

Addressing the issue of why there is not a common European HTA system, **Bengt Jönsson**, from the Stockholm School of Economics, said this was because there is not a common European health insurance system. While it is easy to understand that willingness to pay may differ across European countries, said **Paolo Casali**, from the European Society of Medical Oncology, it is difficult to understand, from a clinical perspective, how efficacy assessments can differ between HTA authorities. The issue, explained Jönsson, is that when drugs first come to market full information is not available (from early development studies) about effects on quality of life and survival. HTA authorities are asked a question that cannot be answered with data available to regulators, and therefore they need to undertake their own assessments.

Defending the UK, a country where government willingness to pay for drugs is perceived as low, **Kathy Oliver**, from the International Brain Tumour Alliance, said a new Cancer Drugs Fund has recently been introduced in the UK covering payments for medications that either have not yet been approved by NICE or have been rejected. The problem with this scheme, however, is that there are variations between geographic areas regarding the specific drugs reimbursed, thus creating a postcode lottery. Oliver addressed the challenges faced by patients with rare cancers in accessing drugs. Altogether, there are four million people with rare cancers in Europe. Rare cancers represent a great opportunity for real innovation in drug development. But with much of the emphasis currently placed on prevention and screening, less funding is available for research. There is a need, said Oliver, to develop innovative approaches to the methodology and design of clinical trials, speeding up development of new drugs. For rare cancers R+D needs to define which drugs work in different populations, and to explore how patients can access off-label and near-label drugs.

In a recent survey one of the biggest issues identified by rare cancer patients was the cost of treatment. Governments, pharma and patient groups all need to explore the inequalities that patients with rare cancers face in accessing drugs. While there may currently be difficulties accessing single therapies, Oliver commented that there are likely to be even greater issues in the future when it comes to accessing combination therapies.

More and more tumours are being divided into subgroups, said Casali, making the rare cancer model more common. Resources are limited and choices will need to be made, with cancer technology assessments needing to take into account all the available options and not just focus on drugs.

Children face a different set of problems, said **Bruce Moreland**, from Birmingham's Children Hospital, UK, since drug companies are less interested in developing drugs in paediatric populations due to the small market share.

Addressing issues of whether treatment disparities might be due to medical oncologists not following guidelines, Casali felt recent moves to introduce evidence based guidelines have led to more clinicians around Europe prescribing the same treatments.

Speaking from a medical oncologist perspective **Nils Wilking**, from the University of Lund, said that the majority of health advances come from improving patient access to mature drugs rather than providing access to new high cost drugs. From the payers' perspective there is a need to consider how many "life years" different drugs deliver before allocating funds.
A problem for Europe, said Bengt Jönsson, is that the price of cancer drugs is largely determined in the US. In Europe the health expenditure of different countries can vary up to six-fold with cancer accounting for around 5 to 7% of all health care spending.
The good news is that higher drug prices stimulate R+D , which in turn leads to more new drugs reaching the market, but unfortunately not everyone has access, although with time generic drugs become cheaper.

A member of the audience from **Merck** raised the issue of the influence that the high failure rate of drugs in clinical trials has on pricing. In phase 3 final proof trials oncology drugs have an overall failure rate of 65%. Better methodologies are need, such as improved preclinical models, to eliminate unsuccessful drugs earlier in the development process.
Jönsson felt that prices need to be explained to patients, the general public and clinicians. One of the frustrations, he said, is that no one properly understands where current prices come from.

A delegate from Germany said that Avastin (bevacizumab) costs more in cancer than macular degeneration, due to the reasoning that patients die from cancer. Different doses were often used in different indications, Jönsson commented, thereby influencing cost. But there was no problem, he felt, from a point of principle in paying different amounts for drugs in different indications.

On the question of targeted therapy and personalised medicine, Oliver said that the move to treat more common cancers according to subgroups was likely to result in individual drugs being used for smaller populations of patients.

Regarding the evolving field of targeted therapy Sullivan concluded the discussion by asking panel members to suggest solutions. Rosén said there was a particular need for oncologists to collaborate in rare cancers. Casali felt the issue of personalised medicine should be addressed in guidelines. Pignatti said that drug development needs to be guided more by the biology of individual tumours; a move which he hoped would result in smaller trials with larger treatment effects.

Jonsson said that it would be necessary to put mechanisms in place to ensure that there was no variation in effective drug usage across Europe. Nils Wilking felt there to be a need for better collection of data on the 95% of cancer patients who do not participate in clinical trials.
Finally **Robin Grant**, from the Western General Hospital, Edinburgh, commented that for rare cancers there is a need to extend the life time of drug patents to take into account pharma's greater development costs, such as the increased length of time to recruit patients into trials.

A re-vote at the end of the session, on key causes of inequalities provided remarkably similar results to the first vote. 42.2% citing national funding/willingness to pay; 40.2% cost affordability; 11,8% clinicians prescribing/ not following guidelines; 3.9% health technology approval; and 2% lack of marketing authorisation.

The second vote on the question of key solutions to equitable access to drugs again was consistent, with the first vote, although there was a slight drop in the popularity of guidelines. In the vote 30.9% felt the solution to be greater reductions by industry in the price of cancer medicines; 22.7 % greater enforcement of guideline based protocols; 22.7% greater national funding; 17.3% felt quicker and greater harmony in European marketing authorisation; and 6.4% reduction or removal of health technology assessments.
At the end of the session 79.2% of the audience said they would not be prepared to cut budgets allocated for surgery, pathology, and radiotherapy even if this meant more money was made available for funding cancer medicines.

If you have any comments about any of the issues raised in this report or would like further information, please contact ECCO Public Affairs: EccoPublicAffairs@ecco-org.eu