Cross Party Group on Cancer in the Scottish Parliament

Meeting, Wednesday 6 June 2012, 5.30pm

Present:

Malcolm Chisholm MSP, Co-convener [Chair]
Nanette Milne MSP, Co-convener
Richard Simpson MSP
Leigh Smith, MASScot
Angela Timoney, SMC
Gavin Lewis, Roche
Vicky Crichton, Cancer Research UK
Peter Hastie, Macmillan Cancer Support
Phil Atkinson, Health Policy Scotland
Suzanne Spencer, Cancer Research UK Ambassador
Kerry Napuk, Edinburgh and Lothians Prostate Cancer Support Group
Mike Shaw, Edinburgh and Lothians Prostate Cancer Support Group
Maureen Black, Scottish Government
Fiona Hamill, Janssen
Greg Stevenson, Roche
Stella MacPherson, SCAN
Jim Swift, Health Inequalities Alliance
Richard Walker, MSD
Aileen Bryson, Royal Pharmaceutical Society
David Cameron, University of Edinburgh/ NHS Lothian
Alistair Monro, Janssen
Gillian Knight, CCTT
Iain Brotchie, Royal Pharmaceutical Society
Mark Parsons, NoSCAN
Kate Morgan, Myeloma UK
Karen Bell, Cancer Research UK
Annie Anderson, University of Dundee
Kate Seymour, Macmillan Cancer Support
Diane Thomson, Pfizer
Karen McNee, James Whale Fund
Tracey Bowden, Pfizer
Sandra Auld, ABPI

Apologies:

Alison McInnes MSP
Elaine Smith MSP
Bob Doris MSP
Gus Ironside, Brain Tumour UK
Peter Phillips, SCAN
Prof. Bob Steele, Scottish Cancer Foundation
John Sleith, REHIS
Sarah Muir, Cancer Research UK
Suzanne Fernando, Cancer Research UK Ambassador
Val Lee, CIS Oncology
Dr Liz Forbat, Cancer Care Research Centre
Shirley Fife, NHS Lothian
Dr Christine Campbell, University of Edinburgh

Kathryn Quinn, NHS Fife
Mandy Forbes, NHS Fife
Marianne Nicholson, NHS Grampian
Alex Little, NHS Dumfries and Galloway
Dr Alison McCallum, NHS Lothian
Mhairi Simpson, RCN
Bill Paton, Napp
Heather Cubie, NHS Lothian
Jacquie Forde, Health Inequalities Alliance
Leslie Horne, Edinburgh and Lothians Prostate Cancer Support Group
Prof Alan Rodger
Elspeth Atkinson, Macmillan
Ellen Finlayson, CLIC Sargent
Lynne Barty, Brain Tumour Action
Frances Reid, Target Ovarian Cancer
Martin Coombes, ABPI
Dr Colin Selby, NHS Fife
Dr Alex Holme, NHS Lothian
Emma Anderson, Bowel Cancer UK
Janette Wilkins, Sanofi

Agenda

Malcolm Chisholm welcomed attendees to the meeting.

1 Minutes of last meeting

The minutes were approved as a true record of the meeting.

2 Access to cancer drugs

Gavin Lewis, Director of Strategic Pricing and Health Economics, Roche UK - current issues and Value Based Pricing for medicines

Mr Lewis began by stating that Value Based Pricing (VBP) is often misunderstood, and seen as more complex than it is. He outlined its creation following an OFT report into pricing which concluded that the current medicines pricing system – the Pharmaceutical Price Regulation Scheme (PPRS) – does not relate to value. This idea was embraced by Andrew Lansley MP, and taken forward when he became Health Secretary. Mr Lewis argued that VBP may already be in operation, since the OFT report only considered the PPRS, and did not taken into account the impact of Health Technology Assessment (HTA) bodies such as SMC or NICE. These bodies implicitly send a message to industry about value through their use of a cost per QALY (Quality Adjusted Life Year) threshold. This threshold is generally believed to be approximately £20k-£30k per QALY. VBP is seen as a solution, but there is confusion about what problem it's trying to solve – value for money, patient access, incentivising innovation, managing budgets or improving health outcomes.

A report by Professor Mike Richards on variations in drug usage, which clearly showed a lag in the UK compared to other European countries, was very influential in driving this agenda, and the creation of the Cancer Drugs Fund was seen as a bridge to VBP.

The drivers outlined in the UK DH's consultation paper on VBP are improving outcomes and stimulating innovation. Mr Lewis noted that VBP will only apply to new medicines licensed from 2014 onwards – existing medicines will be managed through a traditional renegotiation of the PPRS in 2014. The consultation also reaffirms the place of NICE in assessing value of medicines. The consultation is also looking at the use of modifiers to take wider societal concerns into account when assessing value.

Mr Lewis explained that currently NICE and SMC are unable to renegotiate a price with a company once it has been set through PPRS, so this will be a new step. Mr Lewis also mentioned that the QALY threshold is currently subject to new research, through an MRC commissioned project by York University, and that initial ideas suggest that it may be set too high.

Mr Lewis highlighted a number of issues of concern, including the importance of the global situation in pricing, the tight timescales for implementation of VBP, the importance of confidentiality for companies and the need for a stable future for existing medicines under PPRS. He noted that if the UK is seen to be an outlier in terms of price, then patient access will not improve.

He also pointed out the opportunities to modify the way the QALY is used, to deal with the challenges of multiple indications and to improve data systems to accurately measure medicines utilisation.

Mr Lewis closed by stating that VBP is an evolution of the current system which offers the opportunity to refine the way in which medicines are made available on the NHS.

Professor Angela Timoney, Chair, Scottish Medicines Consortium – SMC: what we do and how we work

Professor Timoney opened using the metaphor of the ship Discovery, which was built in Dundee and taken to the Antarctic by Captain Scott. She noted that, like SMC, it is flexible and surprisingly small. Prof. Timoney outlined that the SMC is a partnership between the NHS, pharmaceutical companies and patient groups, all of whom have different views on access to medicines but work together to find the best solution. SMC's core activity is undertaking rapid health technology appraisal (HTA) of all new medicines. They also horizon scan to help Boards assess service needs and to forward plan.

SMC advises NHS Board Area Drug and Therapeutics Committees (ADTCs) on all new medicines, new formulations and new indications, and they aim to provide advice within 3-6 months of marketing authorisation. Prof. Timoney noted that these timescales are challenging, but cited a recent BMJ publication which showed these timescales compared favourably to those of NICE. Prof, Timoney outlined the process which takes a medicine from initial findings to the point where it is considered for use on the NHS, and noted that the high numbers of drugs which fail to make it to market means that companies must recoup their R&D costs through those that do. SMC relies on data from companies which is collected through clinical trials.

Prof. Timoney described the 'three hurdles' for marketing approval – quality, safety and efficacy, and explained that SMC then looks at relative effectiveness

(i.e. compared to the current treatment in Scotland) and cost effectiveness. SMC uses QALYs (along with most HTA systems across the world), and although there is no fixed threshold, a cost per QALY of under £20,000 is generally considered acceptable value for money. For a medicine with a cost per QALY between £20,000 and £30,000 SMC might accept this if the medicine gives significant benefits over existing treatments. Over £30,000 would have to be justified. Prof. Timoney noted that one of the benefits of the QALY is its applicability to any disease, and the fact that it takes into account improvements in both quality and quantity of life. SMC can make one of three recommendations: accepted for use, accepted for restricted use (usually to a sub-set of patients, or to use by certain prescribers) and not recommended for use.

Prof. Timoney highlighted that SMC has a multidisciplinary membership and a geographical spread, and that all members have to make declarations of interest, and will not take part in any discussions where there is a conflict.

Prof. Timoney then outlined the process by which SMC makes its decisions, with the new drugs committee looking at it first and getting input from clinical and economic experts, then passing their recommendation to the full SMC for consideration. She also noted that in around 50% of cases, the SMC will receive a Patient Interest Group Submission. The final SMC decision goes to Board ADTCs and companies before being made public. SMC assesses around 80-90 produces each year, and companies can resubmit at any time, as many times as they like with new data. Across all disease areas 35% of products are accepted, 36% restricted and 29% not recommended.

Prof. Timoney then outlined the process post-SMC, where ADTCs can decide whether to add approved treatments to their formularies. She noted that IPTRs would only be used in cases where SMC had not recommended a product.

Prof. Timoney also addressed the issue of orphan treatments, where SMC recognises that smaller trials may be used as evidence, and will accept greater uncertainty and possibly a greater cost per QALY. She noted that the acceptance rate for orphan drugs is 61% as opposed to 75% for all submissions, showing that SMC does approve orphan treatments. She also outlined the modifiers used by SMC, which apply to all medicines and include those products which treat a life threatening disease, which substantially increase life expectancy and/ or quality of life, which can reverse rather than stabilise the condition, or which bridge to definitive treatment.

Finally, Prof. Timoney noted that when a company decides not to submit to SMC, the medicine will automatically be ‘not recommended’ and encouraged companies to engage with the process.

Leigh Smith, Melanoma Action and Support Scotland – experiences of making a patient group submission to SMC

Leigh Smith outlined her experience of making a patient group submission to SMC. She noted that guidance is available on the SMC website, and that SMC has run two half day study groups for patient groups who may wish to make submissions, which were very helpful. She also mentioned that SMC’s Public

Involvement Officer had been very supportive. Ms Smith noted that the information available on the SMC website was encouraging and suggests that Patient Interest Group (PIG) submissions are taken seriously by SMC. She noted that at SMC meetings, a member of SMC's Public and Patient Involvement Group reads a summary of the PIG submission.

Ms Smith then talked through the various questions asked on the PIG form. She noted that psychological symptoms can be just as devastating for patients as the physical ones, but that these are difficult to capture in a form. It was noted that many melanoma patients are younger, and may have young families to consider. The existing treatment is from the 1970s, and while it does work very well for some patients, there are currently no alternative treatments available on the NHS.

Ms Smith noted that the form requests that groups consult with their members. For MASScot this was easy as they are small and in regular contact with their members. She also noted that SMC encourages the inclusion of anonymised patient stories to demonstrate their case. She highlighted that there were no questions relating to patients' contribution to society and the wider impact their illness and potential death would have on their family.

Overall, Ms Smith worried that the process had been a waste of time since she knew that the high cost of the treatment would likely lead to SMC rejecting it. She called for SMC to be empowered to be able to negotiate with the company on price. She also noted that MASScot are not supportive of calls for cancer to be treated differently to other conditions, but want patients to be able to access effective treatments without having to consider difficult decisions about paying for private treatment. Ms Smith closed by calling for a solution to be agreed so that acceptable prices can be negotiated, and treatments made available to those who would benefit from them.

Malcolm Chisholm thanked all three speakers for their insights. The discussion was then opened to the full group for discussion.

Questions were asked about SMC is funded and to whom is it is responsible. Prof. Timoney explained that members come from within the NHS, and that SMC is accountable to NHS Boards' ADTCs.

Concerns were raised about whether stricter requirements for outcomes data were unfairly disadvantaging cancer drugs as opposed to other disease areas where survival can't be measured, and which are non-fatal. Prof. Timoney explained that SMC's aim is to have a process which can look equitably across all diseases and that for some that will mean using surrogate markers. In these cases SMC use the drug agency criteria. It was also noted that sometimes surrogate markers have to be used when trials are ended early.

A question was raised about the impact of VBP in Scotland, and how it will interact with existing HTA arrangements. Gavin Lewis stated that it would still be possible for Scotland to maintain a separate HTA process post VBP if they chose to, but that may not optimal. Prof. Timoney agreed that Scotland needed to be involved in discussions to shape VBP, and said she understood that the Scottish Government is in contact with the UK Government on this issue.

A discussion followed about whether patients with different treatment histories should be treated differently. It was noted that decisions about cost effectiveness are made at an average level. Many members of the group expressed concern at the idea of a treatment 'quota' and felt that if a treatment might benefit a patient, and had been judged cost effective, then they should have access to it, regardless of what other previous treatment they had received.

A further question was raised about the impact of patient interest group submissions, and Prof. Timoney stated her concern that Ms Smith had felt it hadn't been worth it. She reassured the group that while patient interest group submissions may not be the deciding factor, they will all be taken into account, and assist SMC in their deliberations.

A discussion followed about the appropriateness of the QALY, and potential other factors which might be taken into account such as societal factors. The group also discussed whether there was enough evidence of what the public believes in relation to these factors, including valuing different stages of life differently. It was felt that while some evidence does exist, it may not yet be robust enough to change practice, and that this is an area where further work is required. It was noted that there is a perception that the QALY does benefit common conditions and that getting approval for rarer or end of life treatments is harder. Questions were raised about how quality of life is measured and how the patient voice is heard in this. This is mainly collected through trials and there are a number of agreed ways to do this.

It was also noted that it is the case that fewer cancer medicines are currently available to patients in Scotland than in England and other EU countries. A suggestion was made that Scotland could build on the work done by NICE looking at public attitudes and solve the issue of availability in an appropriate way.

Finally, the group discussed the way in which patient interest group submissions are considered by SMC. Prof. Timoney clarified that the full submission is included with papers, then the PAPIG rep reads a summary at the meeting. The group debated whether patients themselves should be able to attend, although the challenges of this were acknowledged.

3 Scotland Against Cancer

Malcolm Chisholm noted that the conference had been very successful. Vicky Crichton thanked those who had attended, and advised that the report of the conference is currently being produced and that it will come to the group for discussion at the next meeting.

4 AOB

Sue Spencer highlighted Cancer Research UK's *The Answer is Plain* Campaign, and asked members to sign the petition in support of plain packaging of tobacco products.

5 Date of next meeting

The next meeting of the group will be Wednesday 12th September at 5:30pm. The agenda will be circulated to members once it is confirmed.