Access to newly licensed medicines

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As a group of senior oncologists (Research Network / Clinical Academic leads) from 3 Scottish cancer centres we wish to submit our evidence to the above enquiry.

Firstly, we wish to acknowledge that we understand that many of the new cancer drugs are expensive and dialogue with the pharmaceutical companies regarding ‘sensible’ pricing should continue. We also understand that the Scottish Government is working in a climate of increasing financial constraint, but this is no different from many other European countries, and therefore this alone cannot be used as an excuse for cancer patients in Scotland to be placed at a disadvantage from those in other similar countries.

One recent example illustrates the current situation for Scottish cancer patients. Malignant melanoma is a skin cancer whose incidence has risen dramatically over the past 30 years, particularly in Scotland, where world-leading research has been conducted. Recently, the treatment of advanced melanoma has been revolutionised with the licensing of B-raf inhibitors and ipilimumab to treat this previously drug-resistant disease. These drugs, welcomed worldwide as a significant breakthrough, are not available to people treated in Scotland. The refusal to approve these medicines undermine 30 years of worldwide research efforts and is totally demoralising for both researchers and patients alike. These decisions attract worldwide attention to the Scottish NHS cancer services for all the wrong reasons, a situation not of any benefit to Scottish patients or the Scottish Government.

The 2011 Scottish Life Science Strategy ‘Creating Wealth, Promoting Health’ 2020 vision sets the aim of doubling the economic contribution made by Scotland’s Life Science Industry by 2020. If the current situation remains with regard to poorer access to new medicines, it will negatively impact on this aspiration, due to a drift in oncologists from within Scotland conducting less innovative research. In addition, due to Scotland in many situations no longer treating patients with the standard of care used in other parts of the world, Scotland may well not be able to take the lead or even to take part in global clinical research studies, NCRN clinical trials or many other commercial trials which require the standard therapy in such trials to be what is approved by the regulators, but which is increasingly not the standard of care in Scotland. Amongst other detriments, inability to partake in such studies will deprive the NHS of the financial savings from company-funded drug supply, as well as the overall loss of investment in the Scottish economy. This risks a knock on effect in terms of international funders reviewing investment across the whole of science including Scotland’s strongholds in areas such as basic science and translational medicine, where Scotland has led the way for many decades.
This reverse in fortune will occur despite the CSO investment into infrastructure to support clinical trials and Scotland’s clinical trials metrics which show impressive achievements in terms of set up time to start clinical trials. However, where the standard of care is not used, oncologists have no experience in using such treatments and if there is no chance of a medicine being adopted post approval, this will significantly impact on clinical trial opportunities. Ultimately, this will impact negatively on our clinical cancer research infrastructure (ECMCs, CTUs CR-UK Centres) causing inability to generate inflow of resources to Scotland, cessation of our ability to attract high quality clinical and research trainees, and will compromise Scotland’s ability to be leaders in clinical cancer research within the UK and beyond.

This spiralling effect - where cancer is merely the paradigm for other chronic conditions such as cardiovascular disease - will impact on other major areas of strategic focus for Scotland’s economy.

The Scottish Medicine Consortium was an important and welcome mechanism introduced to equalise access to medicines across Scotland. However, some aspects require urgent review: The criteria for assessing clinical effectiveness have not changed in terms of cost per QALY since the SMC’s inception. Even inflation is not taken into account, unlike most other areas of the NHS. One of the issues is that for cancer, calculation of the Cost per QaLY may be based on the overall survival data from the clinical trials but most studies are not designed for this use of the data and estimates may therefore be wrong. Conversely, for many other areas of medical research data on the actual patient survival is not available and is assumed. This means that the cost/QALY approach often does not adequately measure cost-effectiveness, which again disadvantages cancer medicines. This is supported by a report produced by The Office of Health Economics which found that if the acceptance rate of all submissions to SMC were analysed around two thirds were accepted by SMC but if only cancer submissions were included in the analysis two thirds were declined. In addition, the value of medicines in the wider societal sense is not considered. Other HTA bodies have included ‘end of life’ criteria but the SMC have not considered such a change. The current system inevitably disadvantages cancer patients in Scotland – a situation that must change.

The Individual Patient Treatment Requests (IPTR) process does grant access to unapproved drugs for small numbers of cancer patients but this approach is not a satisfactory solution for a number of reasons. Furthermore the number of such IPTR requests made vastly under-represents the actual number that could be submitted for a variety of reasons:

- Many health boards will often not even consider an IPTR for an indication if SMC has made a negative decision, irrespective of the individual patients’ circumstances, in contrast to the other areas of the UK where a drug rejected by NICE can be made available via the Cancer Drugs Fund
Some clinicians do not need to submit an IPTR when their cancer centre is participating in a clinical trial that provides free drug (subsidising the NHS and supportive of earlier comments regarding importance of trials participation). A specific example of this was the recent SEARCH study sorafenib + erlotinib or placebo) in Hepatocellular carcinoma (HCC) where the Beatson West of Scotland Cancer Centre was the second highest recruiting site worldwide, treating over 20 patients in approximately 18 months, and so no IPTR submissions were necessary as drug supply of sorafenib was accessed through this commercially-sponsored study.

Busy oncologists find the whole process burdensome, bureaucratic, usually negative and lacking in transparency, so are disincentivised to pursue this process in their already over-committed professional lives.

Occasionally clinicians cannot submit an IPTR as they do not have the funding for the molecular diagnostic to be able to ascertain whether the patient is eligible for the particular cancer medicine in question. An example of this is seen in the use of trastuzumab in HER2+ gastro-oesophageal cancer where the diagnostic test is not funded so it is impossible to identify the 15-20% of patients who are highly likely to benefit from this agent (comparable to the benefit observed in breast cancer). It is particularly shocking when we are made aware of cancer patients forced to leave their home in Scotland so they can access this medicine in other parts of the UK.

As stratified medicine becomes the norm for the optimal, progressive treatment of cancer and other diseases, smaller more niched medicines will be approved together with a diagnostic molecular test. For Scottish patients to benefit from these significant strides in understanding cancer biology, it is clear an urgent review of the SMC process is required. Molecular diagnostics will become integral to standard of care for any cancer patient and therefore the SMC should address this as part of its review.

There is also evidence that shows when the IPTR is used as a means to access newly licensed medicines it leads to inequality of care, as across the 14 Health Boards different decisions are made. This is a clearly unsatisfactory state of play for all concerned and negates one of the principle aims/functions of the SMC.

We are aware that other parts of the UK have looked at alternative measures to fund cancer medicines and improve access for patients, such as the Cancer Drugs Fund (CDF). Evidence demonstrates that this has helped many English patients but has not resolved the issue of equity of access. The CDF was introduced as a temporary measure and we believe a much more robust solution is required, providing an opportunity for Scotland to lead the way with a fairer, sustainable system.
In summary, the solution to the current inequality of access to new cancer medicines lies in an urgent review of the current processes and a revised more equitable, transparent process being put in place with appropriate input from all key stakeholders. We believe that this must involve a co-ordinated approach between European health care funders and the pharmaceutical industry to ensure that there is agreement about what is an affordable price for innovative medicines for patients with cancer, particularly those that offer improved survival where there was little hope before.

We implore the Scottish Government to find the modest amount of extra money required for effective newly licensed cancer medicines so that patients in Scotland may receive the benefits of decades of research often led by many of Scotland’s foremost researchers in this field. The consequences of not addressing this system will be devastating to the patient and potentially to the Scottish economy, particularly when taken in the context of the recent Statement of Intent from Scottish Government ‘Our Vision: Scotland is a world leading centre for innovation in health through partnership working between Government, NHS Scotland, industry and the research community’

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