Access to newly licensed medicines

Scottish Melanoma Group, the Scottish Dermatology Society Skin Cancer Group and affiliated clinicians

We write to you on behalf of the Scottish Melanoma Group, the Scottish Dermatology Society Skin Cancer Group, and affiliated clinicians who are responsible for the care of patients with melanoma in Scotland, specifically to express our views and concerns to the Health and Sport Committee Inquiry on access to cancer medicines.

We are grateful to the Scottish Government for their continued investment in the National Health Service and in health and social care in Scotland. We acknowledge that there are many competing areas for investment within healthcare and we appreciate the challenges of meetings these demands in the current financial climate. However, we believe that access to cancer medicines is a critical area requiring specific investment to ensure equitable treatment with patients in the other nations of the United Kingdom and within the European Union. This is particularly the case for patients with advanced melanoma.

The annual number of new cases of melanoma has increased steadily since the 1970s and malignant melanoma is currently the 5th most common cancer in the UK with the Central belt of Scotland having the highest incidence within the UK along with the South West of England. Despite the advances in early detection of melanoma, approximately 200 people die from melanoma in Scotland every year. When melanoma has advanced beyond the skin and regional lymph nodes, chemotherapy has historically been used but to little effect.

The last 1-2 years have witnessed a revolution in melanoma therapies with the culmination of renewed global research efforts, including researchers and patients from Scotland, leading to two new licensed agents that have transformed the management of this disease. Vemurafenib blocks abnormal B-RAF genes (found in approximately 50-60% of melanoma cases) and ipilimumab exploits the immune system to target cancer cells. Both have demonstrated striking activity with responses in up to 80% of patients and improved survival compared to chemotherapy. If these two agents are unavailable to patients in Scotland, then our patients will only have the option of chemotherapy - demonstrably inferior treatment compared with other developed nations, who have not restricted use of the new drugs.

We remained concerned that our patients will be disadvantaged by the current systems determining access, the Scottish Medicines Consortium (SMC) and Individual Patient Treatment Requests (IPTRs) for the following reasons:

- There has been no increase in the QALY (Quality Adjusted Life Years) cost limits with inflation since the inception of the SMC in 2001, despite the significant increases in the costs of healthcare provision in the interim.
- This mechanism of assessment (QALY) is biased in favour of low-cost interventions that yield long-term survival, thereby disadvantaging patients treated with palliative intent to yield significant, but more modest, improvements in survival but with significant symptomatic improvement.
The QALY under-estimates the better survival made over a series of incremental improvements over several clinical trials with addition of sequential therapies as each intervention is considered in isolation.

The cost-effectiveness assessments include the costs of all supportive care and staff time rather than just the cost of the new therapeutic agent which again is less favourable to interventions that result in a modest absolute, but a large percentage, improvement in survival (especially where there was no previously available standard of care) which typically occurs in patients with malignant disease.

We suspect that the stated number of patients who are unable to access these new agents through the IPTR process is an under-estimate:

- Frequently if the therapy is not approved for funding by the SMC then neither is the companion molecular diagnostic so that the appropriate sub-group of patients based on molecular profile cannot be identified and so exceptionality cannot be demonstrated and submission cannot be made.
- We know that many clinicians do not submit time-consuming IPTRs as there is a perception of low chance of approval.
- Although clinicians may occasionally access these new drugs at no cost without IPTR via the medicines being made available by the sponsors of clinical trials in which the clinicians are participating, this is not a sustainable way to access therapies that our patients require.

Finally, it is very likely that the current lack of access to cancer medicines will have a significant negative impact on clinical research. Already, clinical researchers have been unable to participate in clinical trials in which the recognised optimal standard of care is not available in Scotland but is available in other countries of the UK and elsewhere. Participation in a clinical trial in which the standard of care is provided at no cost is a mechanism to access these medicines for our patients. Lack of ability to participate will ultimately compromise clinical research further since trial participation will be dictated by ability to access medicines rather than by clinical scientific enquiry. Inevitably, this will lead to a drift of active researchers to relocate to other countries in the UK, with consequent detriment to patients, to clinical academic research, and to medical education in Scotland. Clearly the drain of clinical academic resource will be of major detriment to the Life Sciences sector and the knowledge economy of Scotland.

We implore the Committee to give consideration to these issues and especially to the tragedy that we now, for the first time, have significant life-giving treatments for melanoma patients, yet have no access to these in Scotland.

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