Access to newly licensed medicines

Merck Serono

Merck Serono is pleased to have this opportunity to contribute to the Health and Sport Committee’s enquiry to this topic. We would like to focus in particular on the IPTR process, where our experience is confined to the availability of chemotherapeutic treatments for colorectal cancer.

During our time supporting clinicians and Local Health Boards implementing SMC 543/09 from February 2010, we have been able to observe the impact of the IPTR process on clinically led availability of chemotherapeutic agents in colorectal cancer and these observations are detailed below.

The reason for the IPTR process

It is unclear to us what the IPTR process fundamentally seeks to do. It is either:

1. To provide access to a medicine without SMC approval in a near unique clinical setting where the patient’s extraordinary individual condition clearly require access to this medicine in a setting that was not considered by SMC. It would be expected that many of these applications would be unlicensed indications.

2. Or it is a system used to obtain supply of a medicine for a clinical circumstance where the standard of care has failed and the clinical judgement of the patient’s requirement for further treatment includes this otherwise unavailable medicine.

There would seem to us to be confusion in clinical circles in Scotland as to which of these 2 alternatives applies and clarification needed.

From our experience, it appears the IPTR process is behaving as per option 1 above. We have compared clinically led supply outside NICE guidance in England versus that of IPTR funded availability in Scotland. In the case of cetuximab, we have seen greater than 800 patients funded for metastatic colorectal cancer in comparison to 6 patients thus far funded via the IPTR process in Scotland that we are aware of.

We believe the purpose of the IPTR process should be made clearer to clinicians within NHS Scotland. At the present time both clinicians and patients would seem to believe that the IPTR process would allow similar access to medicines as other systems do in England. For biological agents used in the treatment of metastatic colorectal cancer is this not the case.

Implementation of the IPTR process

There are a number of issues arising from the current implementation of the IPTR process that if remedied and/or simplified could lead to a more clinician and patient friendly process.
1. Improving the transparency of the process

Feedback we have had informally from clinicians suggests the approval process and particularly the objective way an application had been reviewed are not clear. In addition, the appeal process appears to demand considerable effort from both clinician and patient, which may not be possible, especially is the patient is particularly unwell.

2. Complexity and non uniformity of application forms between Local Health Boards

Again, feedback we have had from clinicians is that the paperwork and data required are considerable, and considered excessive. Also the application requirements and the constitution of the application forms appears to vary between Local Health Boards. Unifying data requirements would help ease the process considerably.

3. Publically available audit of the IPTR process by Local Health Boards

There are high approval figures quoted for the rate of successful funding via the IPTR process. It is possible given the perceived complexity of the process that many applications are actually not made, and thus the headline approval figure might be misleading. Systematic audit of the process by Local Health Board will help determine how the systems are working and the true level of approvals, allowing the process to be continually refined.

In summary, our experience of the IPTR process is that despite considerable clinical demand for access to medicines via this process, the IPTR process itself using the example of metastatic colorectal cancer treatments, does not appear to be providing this access to Scottish colorectal cancer sufferers, leading to both patient and clinician frustration. We offer a number of recommendations that if implemented should improve this situation.

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