The United Kingdom embarked on healthcare system reform in 2010 which promises to radically change the way pharmaceuticals are priced and reimbursed. The reform bill, already approved by the House of Commons and currently being reviewed by the House of Lords, may undergo additional changes; however, these changes are unlikely to impact the part of the bill dealing with the introduction of value based pricing (VBP).

VBP is due to be introduced from 1 January 2014, when the current PPRS scheme expires. Under VBP, originator drugs coming onto the market after 1 January 2014 will have their prices set at a level that corresponds to the benefit they bring to the healthcare system, individual patients and society. The end of free pricing is cause for serious concern for pharmaceutical companies and may encourage them to change the priority given to the UK in their launch sequencing strategies.

This study seeks to evaluate and forecast the impact on market access for pharmaceuticals in the United Kingdom following the introduction of VBP.

SMC advice and final NICE guidance issued between 1 June 2010 and 31 May 2011 were assessed to determine the number and outcome of total appraisals, of Single Technology Appraisals (STAs), and of appraisals based on a manufacturer submission. The current length of a NICE review and the time required to provide guidance under the NICE Scientific Advice Programme were also considered.

Once VBP is introduced in the United Kingdom, all new originator drugs entering the market and all new indications of existing medicines will be reviewed. This will make the process similar to that currently used in Scotland where all newly-approved originator medicines and new indications have their cost effectiveness reviewed in order to determine whether they should be recommended for reimbursement. Therefore, the current number of reviews conducted by the SMC in Scotland will serve as a good predictor of the number of reviews expected after the introduction of VBP. Original SMC reviews are a better predictor of the number of likely VBP reviews over a 12 month period than the total number of SMC reviews (which also includes reviews following a manufacturer resubmission).

A comparison between the number of SMC reviews and the number of NICE reviews allows us to see how many more appraisals are likely to be conducted following the introduction of VBP in comparison to the number of NICE STAs under the existing system. The comparison between the SMC and NICE in terms of reviews is also ideal because the two agencies are at any time faced with the same sample of medicines (due to the simultaneous marketing authorisation across the UK).

Over the 12-month period, the SMC reviewed a total of 101 new drugs or indications, of which 18 were resubmissions, so a total of 83 original reviews were performed. In contrast NICE – which only reviews treatments it is commissioned to review by the DH – conducted 28 STAs. The number of SMC original reviews conducted was 2.96 times higher than the number of STAs conducted by NICE.

Some 47% of SMC drug reviews resulted in positive guidance – rising to 58% among reviews based on a manufacturer submission.

The average length of a NICE technology appraisal can be as much as 18 months (Source: Alastair Wittington, Network Director, South East London Cancer Network). However, NICE scientific guidance can be provided in as little as 15 weeks (Source: Joanne Holden, Technical Advisor, NICE).

We expect that under value based pricing, the time required to complete a review would be closer to the current time required for the provision of scientific guidance by NICE.

Pharmaceutical market access in England and Wales will potentially improve following the introduction of VBP as more products are reviewed in a more timely manner. Three times more originator medicines or new indications will be reviewed in comparison to the number currently reviewed by NICE. The average length of an appraisal under VBP could be just 15 weeks – 19.2% of the time currently required. These developments will be positive for the pharmaceutical industry as access to reimbursement for new medicines will be possible earlier than is currently the case in England and Wales. On the negative side, manufacturers would be expected to offer products at an acceptable price – calculated in accordance with yet-to-be-finalised criteria – in exchange for gaining reimbursement.