A TREND TOWARDS THE INCREASED USE OF PATIENT ACCESS SCHEMES TO GAIN REIMBURSEMENT IN THE UK


Introduction

The UK is a free-pricing country, meaning manufacturers can set their own list price for pharmaceuticals, within reason. International reference pricing is where other countries set their price based on the prices published for other countries (e.g. an average across Europe). Since the UK is a free-pricing country and is referenced across Europe and beyond, setting a higher price in the UK as a first launch country may mean other countries subsequently set higher prices too.

However, when undertaking assessments for new drugs, the focus in the UK is on value for the NHS. To gain reimbursement in the NHS, manufacturers may have to offer a patient access scheme (PAS). PAS is a confidential agreement in which companies offer drugs at a reduced cost to the NHS, such that the NHS deems the drug to provide value for money and therefore becomes accessible to patients. Figure 1 outlines the process for applying to the Department of Health for a patient access scheme in the UK.

Our objectives are to:

1. Determine whether PAS in National Institute for Health and Care Excellence (NICE) and Scottish Medicines Consortium (SMC) appraisals has increased since 2014
2. Assess whether inclusion of a PAS is associated with the outcome in terms of a recommendation for reimbursement in the NHS.

Methods

MAP BioPharma maintains a database of European reimbursement recommendations, including NICE and SMC. All NICE and SMC appraisals between January 2015 and October 2017 were reviewed. NICE guidance that was terminated or withdrawn was excluded, along with SMC guidance resulting from a non-submission.

We hypothesised that the proportion of appraisals that include a PAS is increasing, which was tested using a one-tailed test. We further hypothesised that the inclusion of a PAS has an impact on whether the subsequent recommendation is positive or negative, which was tested using a two-tailed test.

Results

The number of NICE appraisals considered in the analysis increased from 35 to 72, from 2015 up to October 2017. Conversely, the number of SMC appraisals considered decreased year on year, from 105 in 2015, to 83 in 2016, and 57 appraisals by 2017 (Figure 2). The proportion of NICE and SMC appraisals that included a PAS significantly increased from 29% in 2015 to 64% in 2016 (p<0.0001) but not between 2016 and 2017, where the proportion reduced to 55%. In 2015, there were a greater proportion of appraisals with a PAS for NICE than SMC, but in 2017 this has switched such that the proportion of appraisals with a PAS is greater for SMC than NICE.

Over the period 2015-17, NICE appraisals with a PAS had a significantly higher positive recommendation rate of 95% compared to without a PAS (p<0.0001, Figure 3). On the contrary, submissions to the SMC were recommended in 74% appraisals with PAS and 87% without a PAS (p=0.006).

Conclusions

A PAS enables companies to maintain high published prices whilst providing value for money to the NHS. Conversely, in their recent Council conclusions, EU health ministers have expressed the desire for pricing transparency, whereby companies will be encouraged to voluntarily share information to enhance affordability across the EU. However, this analysis shows that there was a significant increase in the use of patient access schemes from 2015-16, although this has not continued in 2017.

In submissions to NICE, there is a significant positive association between inclusion of a PAS and a positive recommendation. This implies that inclusion of a PAS will increase the chance of a positive NICE recommendation. In submissions to SMC, there is a significant negative association between inclusion of a PAS and a recommendation. This implies that if you include a PAS, you have a lower statistical likelihood of a recommendation from the SMC but this is unlikely to be a predictive relationship as it is driven by other factors.

References: