Trend analysis of SMC decisions - what factors influence the likelihood of positive, restricted and negative recommendations?


Objectives

Since its formation in 2002, the Scottish Medicines Consortium (SMC) has evaluated over 1000 health technology assessment (HTA) submissions of new medicines or indications for use in Scotland. Unlike most HTA agencies which evaluate only selected products, the SMC evaluates almost all products receiving European marketing authorization, and aims to do so within 3 months of product launch. Any product that receives marketing authorization but does not submit to the SMC receives an automatic non-recommendation. The SMC have, therefore, assessed more clinical and cost-effectiveness evidence for medicines than any other HTA organization in the world. Trends in SMC guidance were analyzed to provide insights on likely recommendations of new products as manufacturers navigate the UK market.

Methods

All analyses were based on a validated, longitudinal MAP BioPharma database of all published guidance from 2002 to 2014. SMC recommendations following full submission, resubmissions or abbreviated submissions were reviewed and then subdivided into British National Formulary (BNF) categories to provide some insight into the considerations that companies should include in their strategic plans.

Results

From 2002 to 2014, the SMC has published guidance following 608 full submissions, 232 abbreviated submissions, 157 non-submissions, 158 resubmissions and 5 independent review panels (IRP) (Figure 1). The proportion of products not recommended fell from 40% in 2007 (n=98) to only 17% in 2014 (n=84) (Figure 2). Products falling into the malignant disease (MD) and immunosuppression BNF category were most commonly submitted (20% of submissions, n=197) with a fairly steady approval rate of 55% (42%-65%) up to 2003 but then drastically improving to 82% in 2014 (n=22). Overall approval rates from 2002-2014 according to BNF category are shown in Figure 3.

Figure 1: Number of different types of submissions

Figure 2: Number of submissions [on bars] and distribution of recommendation

Figure 3: Number of submissions to the SMC in 2002 to 2014 and the subsequent distribution of recommendations by BNF category

Figure 4: Recommendation rates for the 6 BNF categories most commonly evaluated by the SMC in the last 5 years: [central nervous system (CNS); malignant disease (MD); musculoskeletal and joint disease (MS, joint); cardiovascular disease (CVD)]

Four of the six categories most commonly submitted to SMC have seen an increase in recommendation rates in the last 5 years (Figure 4). Conversely, treatments for the endocrine system have recently seen a reduction in recommendation rates whilst recommendations of MD and immunosuppressive treatments were steady in 2010-2013 then substantially increased in 2014.

Conclusions

The approval rate of new medicines appears to have increased in recent years and may have been influenced by recent reforms in the SMC process, which aimed to improve patient access to effective therapies, including cancer treatments. Recent changes implemented by the SMC may provide hope to companies preparing to navigate the SMC process with oncology, immunosuppressive, infection or musculoskeletal products, but companies with gastrointestinal or nutrition products should explore additional analyses to maximize market access opportunities in Scotland.

Whilst the inclusion of patient and clinician engagement (PACE) meetings add an important perspective in the decision making process for end-of-life, orphan and ultra-orphans products, it does add 2-3 months to the timelines for appraising new products and indications. This is an important consideration as evidence submissions will consequently be required up to 6 months ahead of marketing authorization in order to ensure timely guidance in Scotland.

References:
2. SMC recommendations obtained from the SMC website: https://www.scottishmedicines.org.uk/SMC_Advice/Advice_Directory

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