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Trends in HTA recommendations from the UK and Germany - a comparison of G-BA, SMC and NICE single technology appraisal decisions


Objectives

The analysis was conducted to compare trends in recommendations for orphan and non-orphan products reviewed by the Scottish Medicines Consortium (SMC), the National Institute of Health and Care Excellence (NICE) and the Gemeinsamer Bundesausschuss (G-BA) via the Arzneimittelmarkt Neurordnungsgesetz (AMNOG) process, and identify disease areas that may be particularly challenging for manufacturers planning European product launches. Identifying the likelihood of recommendations in the UK versus Germany may also support planning for sequencing across the EU.

Methods

All analyses were based on a validated, longitudinal MAP BioPharma database of all published guidance from 2001 to 2014 (2011 to 2014 for Germany based on the introduction of AMNOG)\(^1\)-\(^4\). All guidance was categorized according to Table 1. Only products with EU Orphan designation were assigned orphan status\(^5\). Analysis of recommendations by disease area was conducted by classification into British National Formulary (BNF) categories to establish if there are disease areas where the likelihood of recommendation is different between the UK and Germany.

Table 1: Categories for recommendations in the UK and Germany

<table>
<thead>
<tr>
<th>“Recommended”</th>
<th>Unable to recommended</th>
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<tbody>
<tr>
<td>• NICE positive and restricted recommendations</td>
<td>• NICE negative recommendations</td>
</tr>
<tr>
<td>• SMC positive and restricted recommendations</td>
<td>• SMC non-submissions and negative recommendations</td>
</tr>
<tr>
<td>• G-BA major, minor and considerable additional benefit decisions</td>
<td>• G-BA no-benefit or unquantifiable benefit</td>
</tr>
</tbody>
</table>

Results

SMC, NICE and G-BA have published 1160, 157 and 105 recommendations since their formation, respectively. Recommendations from the UK were higher in 2014 compared to previous years. Recommendations from the UK increased in 2012-2014 (59% to 74%) but decreased from G-BA (52% to 41%). The overall recommendation rate in the UK is significantly greater than Germany (63% vs. 46%, p=0.0006). The G-BA and NICE have reviewed a similar number of orphan products but both have reviewed a very small proportion compared to the SMC (SMC 130, NICE 22, G-BA 16). Overall, G-BA has recommended more orphan products (63%) than NICE (55%) or SMC (43%). The recommendation rates for orphans in Germany has remained consistent (range 60%-67%) but the UK recommendations for orphans have fluctuated dramatically (Figure 1).

Treatments for malignant disease and immunosuppression formed the largest category of submissions (SMC n=244, NICE n= 75, G-BA n=37) and had a significantly higher recommendation rate in Germany compared to the UK (68% vs. 50%, p=0.05). Statistically significant differences in recommendations between the UK and Germany were also found between endocrine treatments (74% vs. 29%, p=0.0002), eye treatments (74% vs. 20%, p=0.012) and infection products (82% vs. 55%, p=0.033) (Figure 2). Due to the low number of appraisals of orphan products, no significant differences were observed between recommendations from the UK and Germany for any one BNF category. Although based on a small number of observations, it appears products for the central nervous or endocrine system and nutrition and blood products have greater chance of success in Germany than the UK (Figure 3).

Conclusions

This analysis illustrates that the UK market may be easier to access than the German market but the scale of the challenge depends on the BNF category of the product. Products in the malignant disease and immunosuppression category have a much higher chance of success in Germany compared to the UK, along with endocrine, eye and infection products. NICE and G-BA have both reviewed a small number of orphan products so predicting the outcome of a new orphan product appraisal may be premature, however it appears that the German appraisal system is more favorable to orphan products. This is perhaps not a surprising result given that NICE do not have a different appraisal process or special considerations for orphan products whereas, in Germany, the AMNOG law protects orphan products from receiving a no-benefit assessment when annual revenue is less than 50 million euros.

The next stage of analysis will consider trend analysis when accounting for: SMC resubmissions; re-reviews of NICE technology appraisals and multiple technology appraisals; and reviews of guidance published by G-BA.

References:
2. SMC recommendations obtained from the SMC website: https://www.scottishmedicines.org.uk/SMC_Advice/Advice_Directory
3. NICE recommendations obtained from the NICE website: http://www.nice.org.uk/guidance/published\#type=ta
4. G-BA recommendations obtained from the G-BA website: https://www.g-ba.de/informations/nutzenbewertung/

Figure 1: Proportion of positive recommendations in the UK and Germany

Figure 2: Proportion of positive recommendations in the UK and Germany by BNF category

Figure 3: Proportion of positive recommendations in the UK and Germany for orphan products by BNF category