COPD DRUGS IN EUROPE – A COMPARISON OF MARKET ACCESS DECISIONS IN FRANCE, GERMANY, SWEDEN AND UK BASED ON THE PRISMAccess® DATABASE

INTRODUCTION:

Chronic obstructive pulmonary disease (COPD) is a type of obstructive lung disease, mainly caused by smoking or air pollution. Worldwide, COPD affects nearly five percent of the global population in 2015 and resulted in 2.0 million deaths, which is considered the fourth leading cause of death with rising numbers (1).

COPD is characterized by long-term air flow limitation and there is no final healing option yet possible, therefore the amount medical need is rising rapidly by experts (2).

In the last years various COPD Therapies have been developed and launched in Europe.

A key question remains if these novel therapies reach patients in terms of market access in various European countries and how the national HTA agencies have decided on these therapies.

METHODS:

- The international HTA-PrismAccess® database includes all decisions by market access authorities, among others France, Germany, Sweden and the UK.
- All decisions on therapeutic areas are flagged for “Chronic obstructive pulmonary disease (COPD)” and “Asthma” listed in these countries between January 1st, 2011 and October 11th, 2016 were considered for a systematic analysis for the HTA authorities France – Transparency Committee (HAS), UK – NICE, UK – SMR, Germany – G-BA and Sweden – TLV.
- Furthermore, listed in the national reference Table 1 are complying the national reimbursement grading systems.
- Additionally to the national rating, an overall comparable rating system is used, deciding all decisions into a traffic light system. While green and red are self-explaining, yellow means a restriction from a clinical, but also from an economic aspect. Therefore, for France and Germany, if there is an added benefit granted for the therapy in total, but at least in one subgroup a “no proven added benefit” was granted, then the therapy is assumed “yellow”. Such a grading system is available in the appendix table.
- Green – Recommended without limitation
- Yellow – Recommended with limitation
- Red – Not recommended

Table 1: Grading on therapeutics added benefit and the level of recommendation

<table>
<thead>
<tr>
<th>Decision Category</th>
<th>France</th>
<th>Germany</th>
<th>Sweden</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green – Recommended without limitation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Yellow – Recommended with limitation</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Red – Not recommended</td>
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RESULTS:

In total 75 decisions could be identified between 2011 and 2016.

- France (Transparency Committee) is leading with 20 decisions, followed by Sweden’s TLV 18 and the Scottish SMC with 10. Germany’s G-BA follows with 8 below England’s NICE with 2 decisions. Figure 1 shows the differentiation over time.

Figure 1: COPD and asthma decisions in the chosen countries sorted by year

In France, the transparency committee of HAS has overall decided 29 times. 21 decisions were approved without limitations, 3 recommended with limitations and 6 were not recommended.

The needed benefit SMR has been shown in Figure 2 was rated on 10 times substantial, 9 times moderate, but all 5 times non-substantial. For this actual added benefit ASMR recommended the application of ASMR III to all 5 non-substantial benefit assessments. The others received an ASMR of V or V for those who received a substantial SMR. See also Figure 3.

Asthma.

The Swedish TLV has overall decided 18 times. 14 decisions are approved without limitations (VIII), 2 approved with limitations and 2 approved with no limitations and conditions and 1 application was rejected by the TLV. Figure 5 shows the distribution of decisions in Sweden.

Figure 4: Distribution of decisions for COPD and Asthma drugs in Sweden

The German G-BA has overall decided 15 times. 12 decisions are approved without limitations (VIII), 2 approved with limitations and 1 application was rejected by the G-BA. Figure 6 shows the distribution of decisions in Germany.

Figure 5: Distribution of decisions for COPD and Asthma drugs in Sweden

CONCLUSIONS:

- The analysis showed differences in the assessment of COPD and asthma drugs between different national market access authorities in Europe.
- Reasons vary and need to be taken into account in future market access submissions.
- The unmet medical need is rated high by experts (2).
- In Germany a recommendation with limitation took place, because no dossier was presented clinical data.
- For five drugs, the decisions of the respective HTA bodies are different, as they reach from green over yellow to red. This applies for COPA, SIATGRA, METIc, RELVAR BLIspAIR and STRIVERD-Respimat.
- Reasons for the different level of recommendations are:
  - For the level of patient outcome was criticized: While England’s NICE still accepted the lock of data with the restriction of content or non-research, the French transparency committee did not – insufficient! In Sweden, the resubmission with additional data only before the rejection of ASMR. The German G-BA follows with 8 before England’s NICE with 2 decisions. Figure 1 shows the differentiation over time.

Figure 2: COPD and asthma decisions in the chosen countries sorted by year

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Figure 3: Requested ASMR for COPD and Asthma drugs in France

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