A comparison of market access evaluations for new oncology therapies in France, Germany and the UK: An analysis using the Prismaccess database

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INTRODUCTION:

In recent years (2011 – 2014) various new oncology therapies were launched and evaluated by the different market access authorities.

The international Prismaccess database includes all evaluations and decisions by the respective authorities in France, Germany and the UK.

A research was carried out in PRISMACCESS database to identify opinions of national HTA-Agencies on oncology drugs “Tumors”:
- Transparency Committee (TC) – France
- NICE and SMC – United Kingdom
- GBA – Germany

METHODS:

- For all decisions for new oncology therapies which were evaluated by the authorities in France, Germany and UK has been systematically searched for.
- Selected criteria
  - ATC code L01; ATC code L02 (XTANDI AND ZYTIGA)
  - Antineoplastic drugs
  - New drugs and extension of indication
  - Period: from 2011 – 2014
- A comparison was executed with a focus on:
  - reimbursement decision
  - basis of decision
  - acceptance of submitted clinical endpoints
  - study designs
  - comparator
  - quality of life
  - indirect treatment comparison (ITC)

RESULTS:

In total there were 20 new oncology therapies being evaluated in the three countries.

<table>
<thead>
<tr>
<th>Drug name</th>
<th>ASMR</th>
<th>Added benefit</th>
<th>Recommendation</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARPILSA</td>
<td>V</td>
<td>Minor</td>
<td>Not recommended</td>
<td>Not recommended</td>
</tr>
<tr>
<td>ERIVERGE</td>
<td>V</td>
<td>Minor / No</td>
<td>Recommended</td>
<td>Recommended</td>
</tr>
<tr>
<td>GIOTRIF</td>
<td>V</td>
<td>Considerable / Minor / No / No</td>
<td>Recommended</td>
<td>Recommended</td>
</tr>
<tr>
<td>HALAVEN</td>
<td>V</td>
<td>Minor / Less</td>
<td>Not recommended</td>
<td>Not recommended</td>
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<tr>
<td>INLYTA</td>
<td>V</td>
<td>No / Minor</td>
<td>In development</td>
<td>Recommended</td>
</tr>
<tr>
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<td>Minor / No</td>
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<tr>
<td>KADCYLA</td>
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<td>Considerable / No / No</td>
<td>In development</td>
<td>Not recommended</td>
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<tr>
<td>PEJETA</td>
<td>II</td>
<td>Considerable / No / No</td>
<td>In development</td>
<td>Not recommended</td>
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<tr>
<td>PROVENGE</td>
<td></td>
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<td>In development</td>
<td>In development</td>
</tr>
<tr>
<td>STIVARGA</td>
<td>V</td>
<td>Minor</td>
<td>Suggested</td>
<td>Restricted</td>
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<tr>
<td>TAFILAR</td>
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<td>No</td>
<td>In development</td>
<td>In development</td>
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<tr>
<td>TEYSUNO</td>
<td>V</td>
<td>SMR insufficient</td>
<td>No ASMR</td>
<td>Restricted</td>
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<tr>
<td>VOTIENT</td>
<td>V</td>
<td>Significant / No</td>
<td>Not recommended</td>
<td>Not recommended</td>
</tr>
<tr>
<td>XALKORI</td>
<td>II</td>
<td>Significant / No</td>
<td>Not recommended</td>
<td>Not recommended</td>
</tr>
<tr>
<td>ZERFIGO</td>
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<td>Considerable / No</td>
<td>In development</td>
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<td>II</td>
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<td>In development</td>
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<td>Recommended</td>
<td>Recommended</td>
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<tr>
<td>XALTREX</td>
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<td>ZELBORAF</td>
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<td>Recommended</td>
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<tr>
<td>ZYTIGA</td>
<td>II</td>
<td>Considerable / No</td>
<td>Recommended</td>
<td>Restricted</td>
</tr>
</tbody>
</table>

CONCLUSIONS:

- In France 17 decisions were positive (ASMR II-V) and 1 insufficient (TEYSUNO).
- The 2 charts below show the link between ΔOS or ΔPFS and the level of ASMR granted.

In Germany 17 were positive in Germany (n=1 ‘significant’; n=8 ‘considerable’; n=7 ‘minor’; n=1 ‘non-quantifiable’ added benefit).
- Two products have been overall appraised negative (TAFILAR; TEYSUNO). In ten of the products for one or more subgroups the appraisal has been negative.
- The 2 charts below show the link between ΔOS or ΔPFS and the level of added benefit granted.

For UK there were 4 positive decisions made by NICE and another 6 have been positive in Scotland by SMC.
- Three products (ZELBORAF; ZYTIGA; TEYSUNO) have been appraised with restricted by SMC. Seven are in development at NICE. Four have been negative appraised by NICE and 8 by SMC.
- One product has been suspended by NICE.
- The 2 charts below show the link between ΔOS or ΔPFS and the level of recommendation or restriction granted.

For those therapies which have been appraised on different subpopulations we provided all added benefit values with their respective magnitude on subgroups.
- We can not add PROVENGE to the chart because this drug is in ‘development’ (France & UK) and the TC dossier (France) has not been submitted yet.
- ERIVERGE was not included due to a non-comparative study design.
- No significant difference between TEYSUNO and the COMPARATOR --> No ΔPFS or ΔOS was ascertainable thus it was as well not included.
- In case the assessment was positive (TAFILAR) by all agencies, in 2 more it was positive by all agencies if ‘restricted’ is accepted as positive (ZELBORAF; ZYTIGA).
- TEYSUNO has been the only one negative in all countries even though appraised as restricted by SMC.
- 26% (n=6) it was similar in all three countries (n=5 positive decisions; n=1 negative decision).
- In case overall survival was the primary endpoint the likelihood was higher in all countries for a positive decision.
- Key differences in terms of decisions were given in acceptance of ITCs, comparator as standard of care and ratings for cost-effectiveness.

Using the Prismaccess database the analysis shows that there might be key differences in terms of evaluation criteria between the three countries analyzed.
- In Germany a key focus is given on the appropriate comparator(s) and patient-relevant endpoints.
- In the UK and Scotland cost-effectiveness might trump a positive benefit assessment.
- In France the key drivers are not only the severity of the pathology (for tumours, 25% of SMR are not quantifiable).
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