Comparison of time to reimbursement recommendations of (orphan-) oncology drugs in Europe

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OBJECTIVE

- Differences in time between EMA marketing authorization (MA) and reimbursement evaluations (i.e. “time-to-recommendation”), and the likelihood of acceptance for (orphan-) oncology drugs across European countries exist.
- In this study, the decision-making process was evaluated, from EMA approval to reimbursement recommendations.
- Scope:

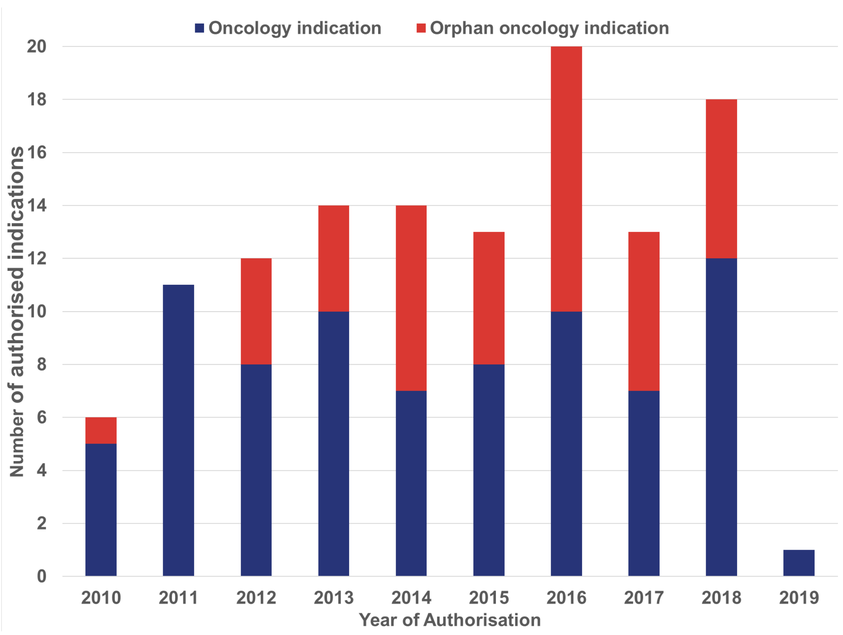
METHODS

- Orphan-oncology and oncology drugs approved by EMA between January 2010 - January 2019 were selected.[1]
- A database was created containing the dates of EMA approval and HTA reimbursement recommendations, and the type of recommendation (yes/restricted/no).[2-5]
- Median time-to-recommendation was calculated per indication and country
- Ranking of reimbursement decisions and type of recommendation were analysed and compared.
- Indications were compared among the HTA agencies to assess factors influencing the decision-making process

RESULTS

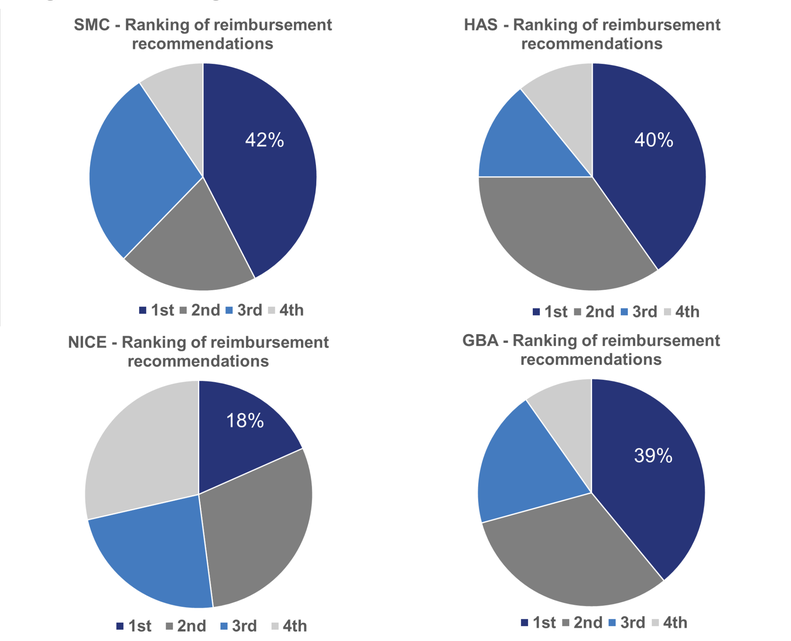
- In total, 94 drugs for 122 indications received marketing authorisation by EMA. Between 2010-2019 an increase of EMA approvals for oncology indications was observed, especially for orphan-oncology indications (see Figure 1).

Figure 1: Marketing authorisation for indications over time



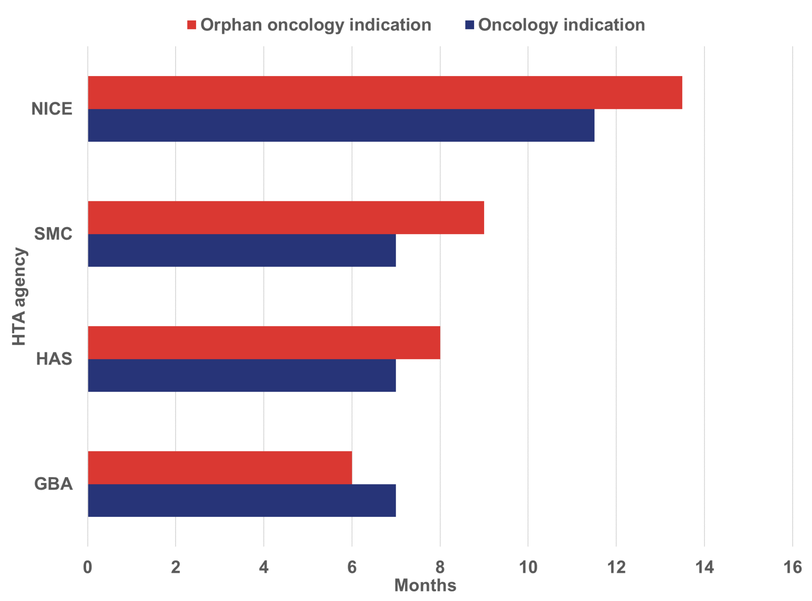
- Figure 3 presents that SMC was first to publish reimbursement recommendations in 42% of the cases, followed by HAS (40%; corrected by number of recommendations per country).

Figure 3: Ranking of reimbursement recommendations



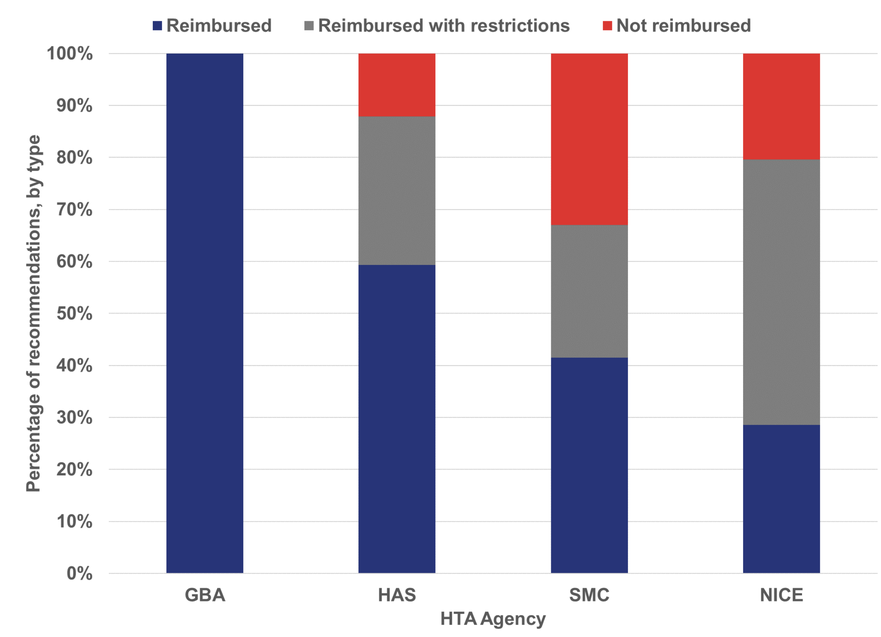
- The median time-to-recommendation was shorter for orphan-oncology indications (6 months) than oncology indications (7 months) in Germany, while the opposite was the case in France, UK and Scotland (see Figure 2).

Figure 2: Median time to reimbursement (months)



- SMC had the lowest positive recommendation rate (67%), followed by NICE (80%). However, for 2/3 of the positive recommendations of NICE were restricted the EMA indication for reimbursement (see Figure 4).

Figure 4: Type of recommendation per agency



- A total of six indications were compared among the HTA agencies to assess factors influencing the decision-making process (see Table 1).
- In most cases, the clinical benefit was the main driver of the reimbursement recommendation.
- Two types of restrictions were observed, restrictions were applied to the approved EMA indication and managed entry agreements were made to control access.
- Further analysis is needed to evaluate the impact of decision-making factors.

Table 1: Factors influencing decision-making process and outcomes – cases of indications with different outcomes between agencies

Drug and indication	Agency and recommendations			
EMA indication				
Pomalidomide *R/R multiple myeloma who have received ≥2 prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy*	✗	✗	✓	✓
Ibrutinib *Previously untreated chronic lymphocytic leukemia*	✗	✗	✓	✓
Olaparib *Platinum-sensitive relapsed BRCA-mutated high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer in response to platinum-based chemotherapy*	✓	✗	✓	✓
Ixazomib *Multiple myeloma who have received ≥1 prior therapy*	✓	✗	✓	✓
Nintedanib *Previously treated locally advanced, metastatic, or locally recurrent non-small cell lung cancer*	✓	✓	✗	✓
Olaratumab *Advanced soft tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin*	✓	✓	✗	✓

✓ Reimbursed
✓ Reimbursed with restrictions
✗ Initial negative recommendation, reimbursed upon resubmission
✗ Not reimbursed

CONCLUSIONS

These results indicate that time needed for reimbursement recommendations of orphan-oncology and oncology indications differ across the EU countries. GBA tend to make quicker recommendations on orphan-oncology indications than the other agencies. SMC seems to be first in providing reimbursement recommendations. NICE restricts the most EMA indications for reimbursement. Factors influencing this recommendation-making process are being studied to enhance the understanding of reimbursement trends in orphan-oncology and oncology products.

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