A comparison of HTA decisions in France and Germany for new treatment options in oncology in 2019

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Introduction

- In Germany and France, the recommendation of new medicines is based on assessment of the clinical benefit that these new agents may offer to patients (**Table 1**).
- Understanding recent trends in HTA outcomes across these organisations may inform market access strategies for oncology treatments in development.

Table 1: Summary of HTA processes in Germany and France

• Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) commissions the evaluation of new medicines by the Institute for Quality and Efficiency in Health Care (IQWiG)[1].	• Haute Autorité de Santé (HAS) assesses new medicines to gauge the actual benefit (SMR) and the improvement of medical benefit (ASMR) versus the relevant comparator[3].
• IQWiG impartially evaluates added therapeutic benefit, and the G-BA makes a final decision on the extent of added benefit[1].	• SMR determines the reimbursement rate: medicines with important SMR have the highest reimbursement rates while medicines with insufficient SMR are not recommended for reimbursement[3].
• Medicines with no added benefit are included in a reference price cluster, whereas manufacturers of medicines with added benefit can engage in price negotiations[2].	• ASMR ranges from I (major improvement) to V (no improvement) and is used for pricing and market access[3] negotiations.

Objectives

- This research aims to analyse trends in health technology assessment (HTA) outcomes published by the G-BA (Germany) and HAS (France) for oncology treatments between 2017 and 2019.

Methods

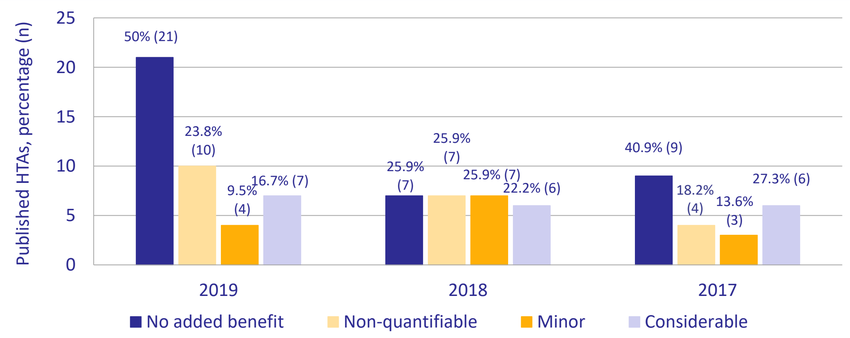
- The SIRIUS Oncology HTA Database contains published clinical and economic data from over 1200 HTA decisions for oncology treatments approved by the European Medicines Agency.
- The SIRIUS Oncology HTA Database was used to perform a retrospective analysis of assessments by the G-BA and HAS in 2019.
- Comparison was also made with trends in HTA outcomes between 2019, 2018, and 2017.

Results

G-BA outcomes 2017-19

- The G-BA published guidance from 42 oncology treatments in 2019, an increase from 27 treatments in 2018 and 22 treatments in 2017 (**Figure 1**).
- No added benefit was reported for a greater proportion treatments in 2019 (50%) compared with 2018 (25.9%) and in 2017 (40.9%).
- The proportion of treatments reported to provide minor added benefit in 2019 was lower in 2019 (9.5%) than 2018 (25.9%) and 2017 (13.6%).
- The proportion of treatments reported to provide a considerable added benefit was also lower in 2019 (16.7%) compared with 2018 (22.2%) and 2017 (27.3%).

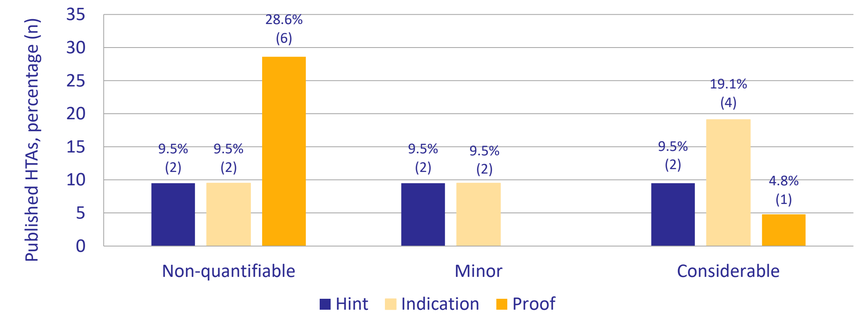
Figure 1: Outcomes from G-BA oncology HTA decisions 2017-19



G-BA extent of added benefit in 2019

- Proof of added benefit was described in 33.3% of G-BA assessments with non-quantifiable, minor, or considerable added benefit (**Figure 2**).
- Proof of added benefit was described for only 1/7 treatments with considerable added benefit but more frequently for treatments with non-quantifiable added benefit (6/10).
- A hint or indication of added benefit was determined for all treatments with minor added benefit (4/4 assessments) and most treatments with considerable added benefit (6/7 assessments).

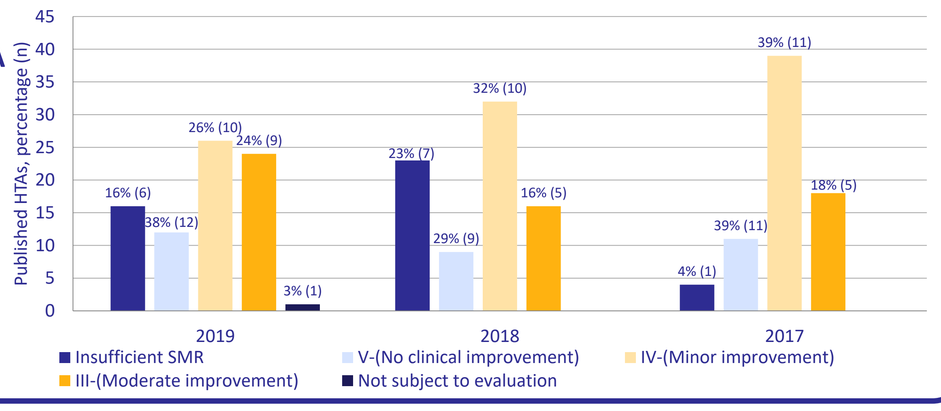
Figure 2: G-BA added benefit assessments 2019



HAS outcomes 2017-19

- HAS published guidance for 38 oncology treatments in 2019, an increase from 31 in 2018 and 28 in 2017.
- Insufficient medical benefit (SMR) was reported for 16% of oncology treatments in 2019, lower than the proportion in 2018 (23%) (**Figure 3**).
- Minor improvement in medical benefit (ASMR IV) was reported for 26% of treatments in 2019, a lower proportion than 2018 (32%), and 2017 (39%).
- Moderate improvement (ASMR III) was reported for 24% of treatments in 2019, higher than both 2018 (16%) and 2017 (18%).
- No treatments showed an important or major improvement (ASMR II or I).

Figure 3: Outcomes from HAS oncology HTA decisions 2017-19



Comparison of HAS and G-BA outcomes in 2019

- HTA reports were published by both HAS and G-BA for 23 oncology treatments in 2019.
- Outcomes were similar between the two organisations; drugs with high added benefit ratings from the G-BA tended to have ASMR ratings of IV or III from HAS (**Table 2**).
- Notably, rucaparib[4] and radium-223 dichloride[5] each received an ASMR rating of IV, and enzalutamide[6] received an ASMR rating of III from HAS, however, all 3 treatments were concluded to provide no added benefit by the G-BA[7,8,9].
- In the case of enzalutamide, the HAS outcome (ASMR III) was largely driven by an almost 22-month gain in metastasis free survival in the pivotal PROSPER clinical trial with enzalutamide versus placebo[6].
- Based on the PROSPER results, the G-BA concluded that an added benefit of enzalutamide versus the comparator could not be proven due to overall survival data being immature and uncertainty around metastasis free survival as an endpoint[7].

Table 2: Comparison of HAS and G-BA outcomes 2019

G-BA \ HAS	Insufficient SMR	ASMR V	ASMR IV	ASMR III
Considerable	-	-	Liposomal cytarabine-daunorubicin	Durvalumab Pembrolizumab* Nivolumab Trametinib Dabrafenib
Minor	-	-	Daratumumab Venetoclax Cabozantinib	Apalutamide
Non-quantifiable	-	Gemtuzumab ozogamicin	-	Pembrolizumab (NSCLC, melanoma)
No added benefit	Rucaparib (3rd line) Lenvatanib Ribociclib	Dacomitinib Encorafenib Brigantinib Ribociclib**	Rucaparib (maintenance) Radium-223 dichloride	Enzalutamide

*NSCLC, <50% PD-L1;
**In the absence of symptomatic life-threatening visceral disease in the short term

Conclusions

- The number of HTAs published for oncology treatments by HAS and the G-BA has increased between 2017 and 2019.
- Higher proportions of HAS assessments in 2019 resulted in ASMR rating of IIII compared with recent 2018 or 2017; however a lower proportion received an ASMR of IV.
- No HAS assessments between 2017 and 2019 resulted in an ASMR rating of II or I.
- The proportion of G-BA assessments reporting no added benefit in 2019 was almost double that reported in 2018.
- The proportion of G-BA assessments reporting non-quantifiable added benefit fluctuated between 2017 and 2019.
- The proportion of G-BA assessments reporting a minor or considerable added benefit decreased between 2017 and 2019.
- The majority of treatments with added benefit reported by the G-BA show a hint or indication of added benefit.
- Outcomes of G-BA and HAS assessments are generally consistent.
- Discrepancy in the outcome of assessment for enzalutamide was due to the G-BA requirement for mature overall survival data.

References

1. G-BA (2018) https://www.g-ba.de/
2. Wenzl M, Paris, V. Pharmaceutical Reimbursement and Pricing in Germany. 2018.
3. HAS (2018) https://www.has-sante.fr/portail/jcms/fc_1249588/fr/accueil
4. HAS (2019) https://www.has-sante.fr/jcms/p_3112630/en/rubraca
5. HAS (2019) https://www.has-sante.fr/jcms/p_3080449
6. HAS (2019) https://www.has-sante.fr/upload/docs/evamed/CT-17551_XTANDI_PIC_EI_Avis2_CT17551.pdf
7. G-BA (2019) https://www.g-ba.de/downloads/40-268-5744/2019-05-16_AM-RL-XII_Enzalutamid_D-411_TrG.pdf
8. G-BA (2019) https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/446/#dossier
9. G-BA (2019) https://www.g-ba.de/beschluesse/3990/

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