Review of efficiency opinions published by the Economic and Public Health Assessment Committee (CEESP)

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BACKGROUND

- In France, since 2013, pharmaceutical companies seeking reimbursement for innovative products claiming an improved medical benefit (ASMR) level III or higher and with significant impact on health expenditures (turnover > €20 million 2-year post-commercialization) are required to submit an economic analysis to the French National Authority for Health (HAS).
- The Economic and Public Health Assessment Committee (CEESP) evaluates the economic analysis and publishes efficiency opinions (EOs).[1]
- This study aimed at synthesizing the outcomes of these EOs.

METHODS

- All the EOs released by the CEESP until 26th June 2021 were collected from the HAS' website.[2]
- The following data from each EO were extracted : type of demand, **therapeutic area**, type of population, population size, ASMR claimed, ASMR obtained, **ICER**, number of concerns (minor, important and major), therapeutic alternative, life threatening condition, budget impact analysis, **CEESP conclusion about analysis methodology validation**, etc.).
- The main outcome of interest was the ICER validated by the CEESP; if several ICERs were available, the lowest one (€/QALY) was considered.

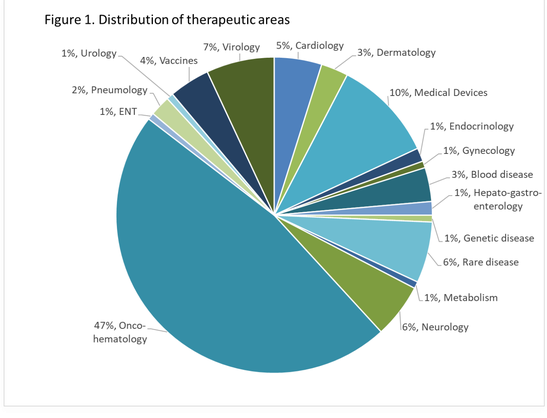
RESULTS

- Overall, 144 EOs have been collected.

Therapeutic areas

- Almost half of the opinions published evaluate onco-hematology products (Figure 1).

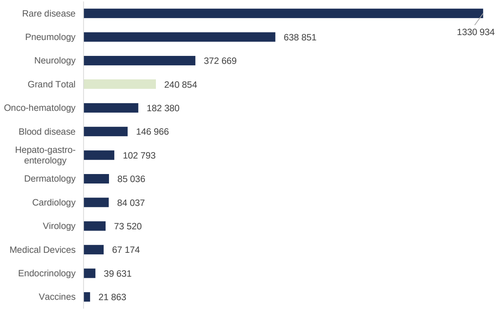
Figure 1. Distribution of EOs by therapeutic area



Mean ICERs

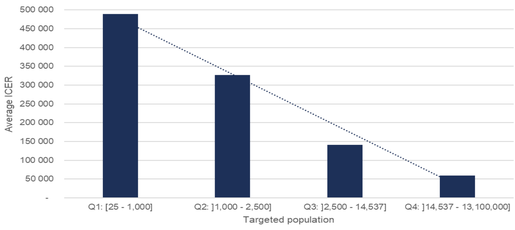
- The highest ICERs in EOs are reported in EOs related to rare diseases, pneumology and neurology (Figure 2).

Figure 2. Mean ICER (€/QALY gained) by therapeutic area



- Regardless of the therapeutic area:
  - The mean ICER increased from €214,883/QALY in 2014-2017 to €274,904/QALY in 2018-2021 (+28%).
  - The mean ICER of EOs for which the ASMR obtained is similar to the ASMR claimed is >2 times higher compared to EOs for which the ASMR obtained is different (467,038 €/QALY vs. 211,828 €/QALY).
  - The mean ICER of EOs for which the vital prognosis is compromised in the indication is >2.5 times higher compared to EOs for which it is not the case (285,547 €/QALY vs. 105,870 €/QALY).
  - The mean ICER seems to be influenced by the population size estimation, as shown in Figure 3.
  - The mean ICER seems to decrease with the number of therapeutic alternatives rises (€491,114/QALY when no therapeutic alternative vs €263,499€/QALY when there is one alternative and €190,252€/QALY when there is >1 alternative).

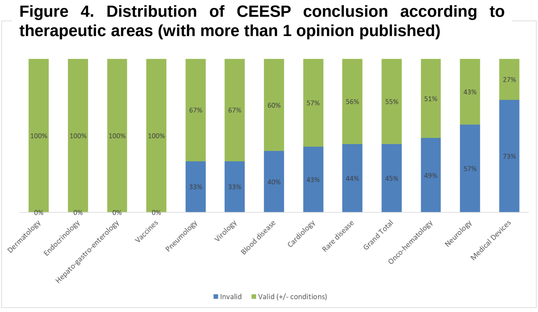
Figure 3. Mean ICER (€/QALY) by target population size



CEESP conclusion about analysis methodology validation

- Figure 4 presents the distribution of CEESP conclusion on company's submission, by therapeutic area with ≥1 EO published.

Figure 4. Distribution of CEESP conclusion according to therapeutic areas (with more than 1 opinion published)



- Overall, the company economic evaluation was invalidated by the CEESP in 43% of cases (62 EOs). Of note, this rate varied between 35% in the period 2014-2017 and 53% in the period 2018-2021 (+51%).
- Among the 144 EOs, 1288 concerns were reported, including 692 minor (54%), 507 important (39%) and 89 major (7%).
- The size of the targeted population size also seems to influence the validity of the EO. The mean population size is 8 times higher when the EO is validated (220,255) than when it is invalidated by the CEESP (27,071).
- The presence of a major concern does not seem to impact the ICER (€207,232 if at least one major concern vs €235,670 if no major concern).
- A difference between ASMR obtained and claimed is associated to 44% of invalidity, vs. 32% when ASMR are similar.
- About 50% economic evaluation were invalidated in the case of life-threatening conditions, vs. 22% when not.
- Finally, the ICER does not seem to have an impact on the validity of the EO by the CEESP.

DISCUSSION

- The highest ICERs can be observed:
  - in certain therapeutic areas (e.g. rare diseases, pneumology, neurology or onco-hematology),
  - when the ASMR obtained is the one claimed (may suggest higher awareness of the product value as assessed by HAS),
  - for small population sizes,
  - when no therapeutic alternative is available,
  - when mortality is a key element of the indication.
- The size of the targeted population or a difference between ASMR claimed and obtained also seem to be drivers of the validation status.
- It seems important to note that no trend between major concern and the ICER was observed.
- The trend of the mean ICER to increase with time could be partly explained by the variations of the parameters listed above.

CONCLUSIONS

- This analysis shows that in France, ICERs submitted by pharmaceutical companies to the CEESP are increasing over the past years, while at the same time, the economic evaluations are increasingly challenged by the CEESP.
- The reasons of this evolution are numerous and complex.
- A statistical analysis involving a regression model could help to better understand these trends.

REFERENCES
1. HAS. Rapport d'activité 2020 - Commission évaluation économique et de santé publique (CEESP).
2. HAS. Site officielle – WEB PAGE - https://www.has-sante.fr/jcms/p_3149875/fr/avis-economiques-rendus-par-la-commission-d-evaluation-economique-et-de-sante-publique-ceesp

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