

# METHODOLOGICAL ACCEPTABILITY OF THE ECONOMIC ANALYSES ASSESSED BY THE HAS IN 2024

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## CONTEXT/ OBJECTIVE/ METHODS

In France, the CEESP (Economic & Public Health Assessment Commission) appraises the health technology assessment submitted by the manufacturers when requested, concomitantly with a reimbursement demand.



The CEESP establishes the methodological acceptability of the health economic assessment through methodological reservations qualified as minor, important or major<sup>1</sup>.

Since 2021, the CEESP has also specified the level of uncertainty surrounding the results, which could be due to the difficulty of estimating key parameters, the lack of credibility of hypotheses or the interpretability of the results<sup>3</sup>.

A major reservation or uncertainty invalidates the dossier and the economic value it defends.

Using the **Vyoo Agency database**<sup>2</sup>, which collects all the opinions published by the HAS, the aim is to analyse the main reasons retained by the CEESP for invalidating the economic information in health economic assessments published in 2024.

All available health economic evaluations reviewed by CEESP between 1<sup>st</sup> January and 31<sup>st</sup> December 2024 were included.

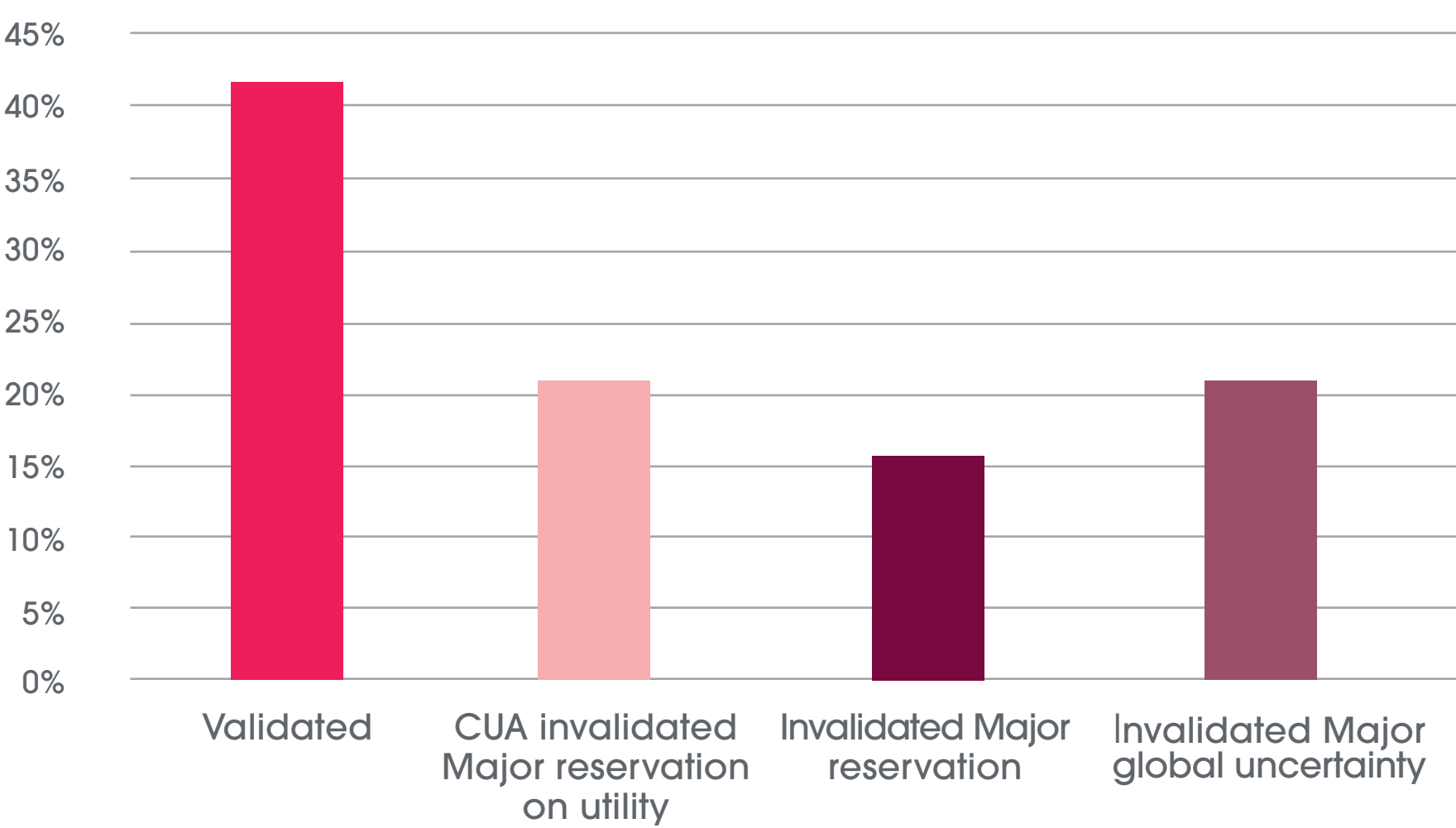
## RESULTS

— In 2024, 19 appraisals were disclosed 7 of which were completely invalidated, and 4 cost-utility were invalidated – without an invalidation of the ICER expressed as cost per life year gained.

Nine major methodological reservations were stated, invalidating 3 economic evaluations and 4 cost-utility analysis.

Four economic evaluations were invalidated due to major uncertainty.

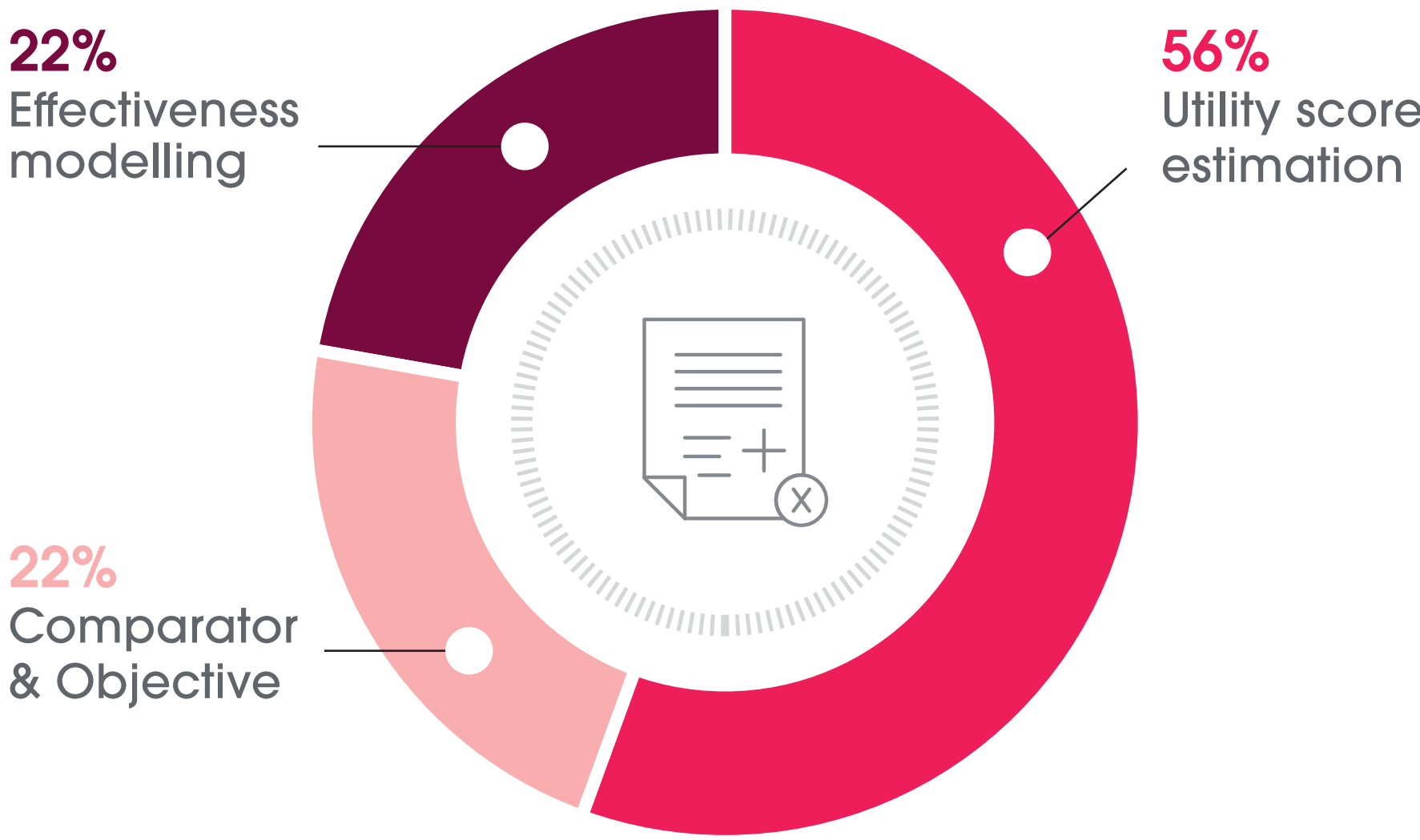
FIGURE 1. CEESP CONCLUSIONS



CUA: Cost-utility analysis

Major uncertainty were mainly supported by the context of rare disease (4 opinions, 3 of which on Orphan Drug).

FIGURE 2. MAJOR RESERVATIONS



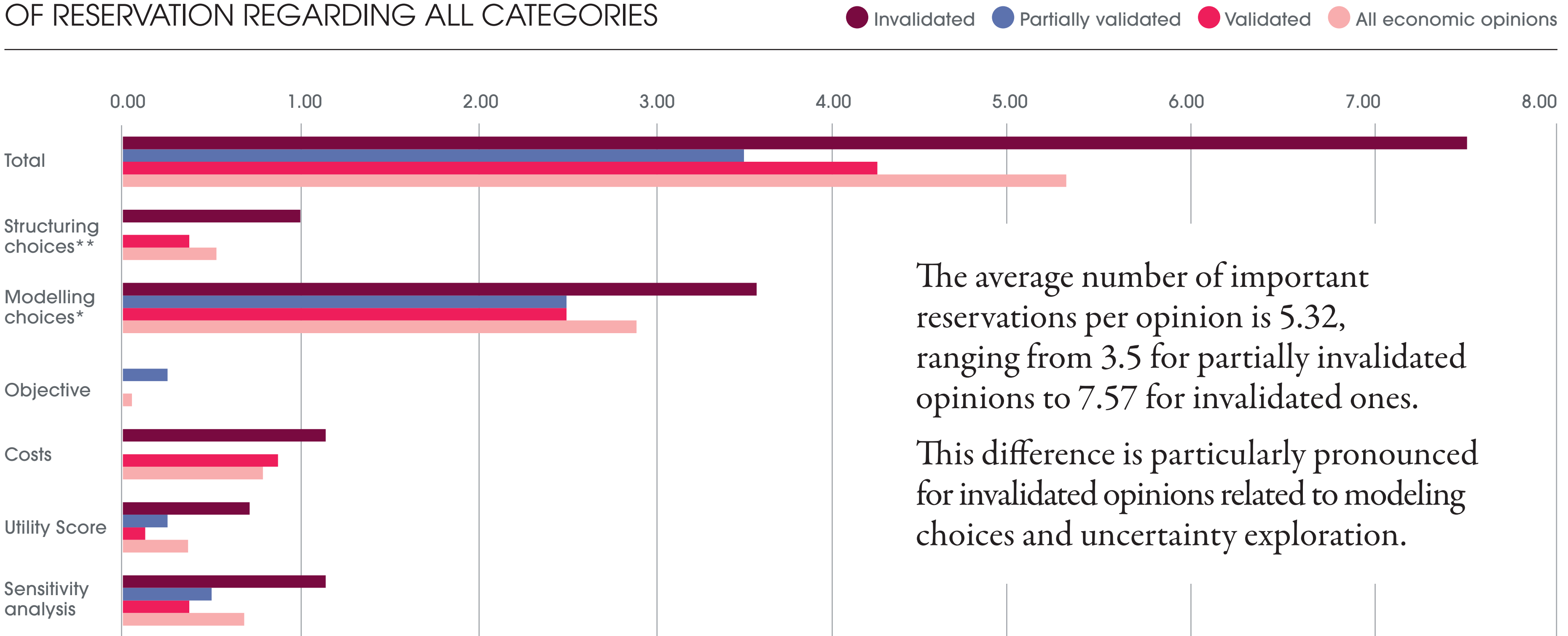
The major reservations concern the estimation of utilities (N=5) derived from external sources, the modelling of relative effectiveness (N=2), and the specification of objectives or comparators (N=2), which limit the scope of the conclusions by restricting the assessment's capacity to fully account for all relevant treatment alternatives.

FIGURE 3. AVERAGE NUMBER OF RESERVATIONS ACCORDING TO CEESP CONCLUSION



The number of minor reservations is higher for validated economic evaluations. In all, invalidated dossiers account for around 50% of important reservations versus 35% for validated dossiers and 15% for partially validated. This last category is the one with the highest average number of major reserves

FIGURE 4. DISTRIBUTION OF IMPORTANT AVERAGE NUMBER OF RESERVATION REGARDING ALL CATEGORIES



The average number of important reservations per opinion is 5.32, ranging from 3.5 for partially invalidated opinions to 7.57 for invalidated ones. This difference is particularly pronounced for invalidated opinions related to modeling choices and uncertainty exploration.

## CONCLUSION

In 2024, only 42% of cost-utility analysis were validated. This is less than in 2023 (64%). However, with cost-effectiveness analysis (cost per life year), 63% of economic evaluations were likely to provide economic information

useful in the decision-making process in France. Increasing the number of validated assessments is a key issue to ensure economic information can be fully used in pricing negotiations.

References  
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2. Vyoo Agency efficiency database. Online subscription only : <https://efficiency.vyoo-agency.com/>  
3. CEESP Doctrine. [https://www.has-sante.fr/upload/docs/application/pdf/2021-09/doctrine\\_de\\_la\\_ceesp.pdf](https://www.has-sante.fr/upload/docs/application/pdf/2021-09/doctrine_de_la_ceesp.pdf).