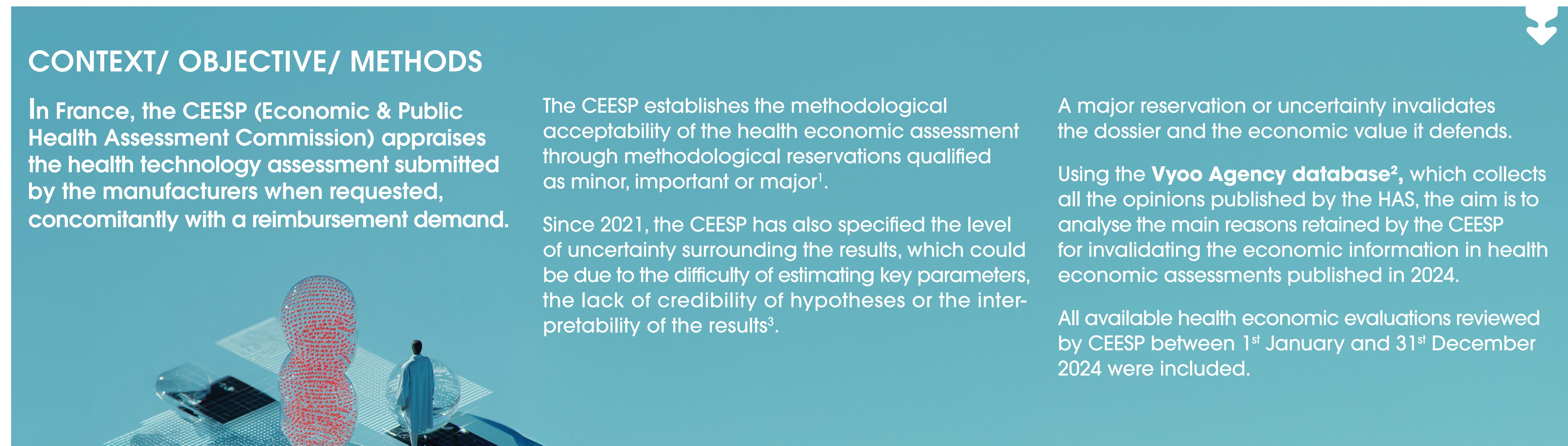


METHODOLOGICAL ACCEPTABILITY OF THE ECONOMIC ANALYSES ASSESSED BY THE HAS IN 2024

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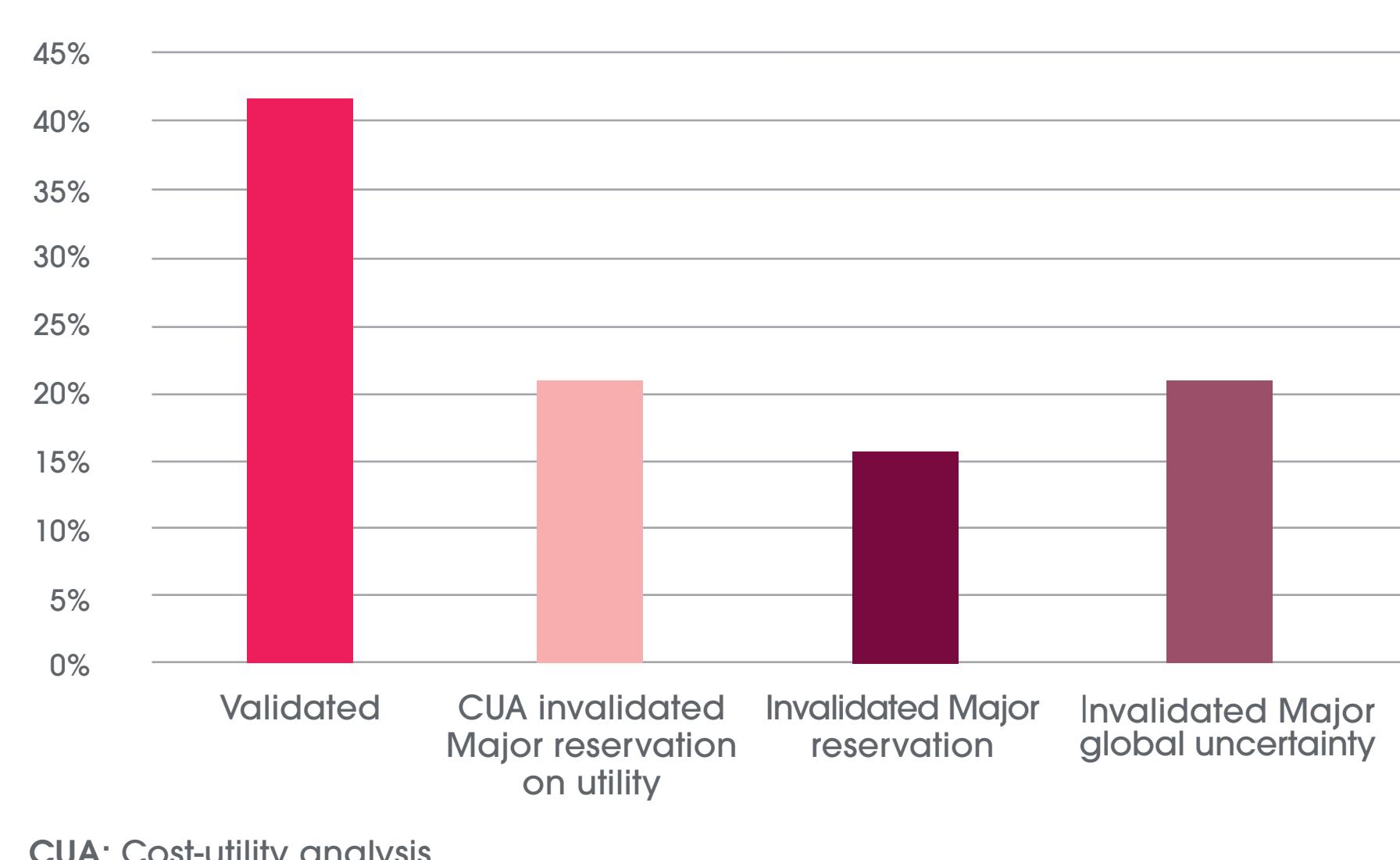
RESULTS

— 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.

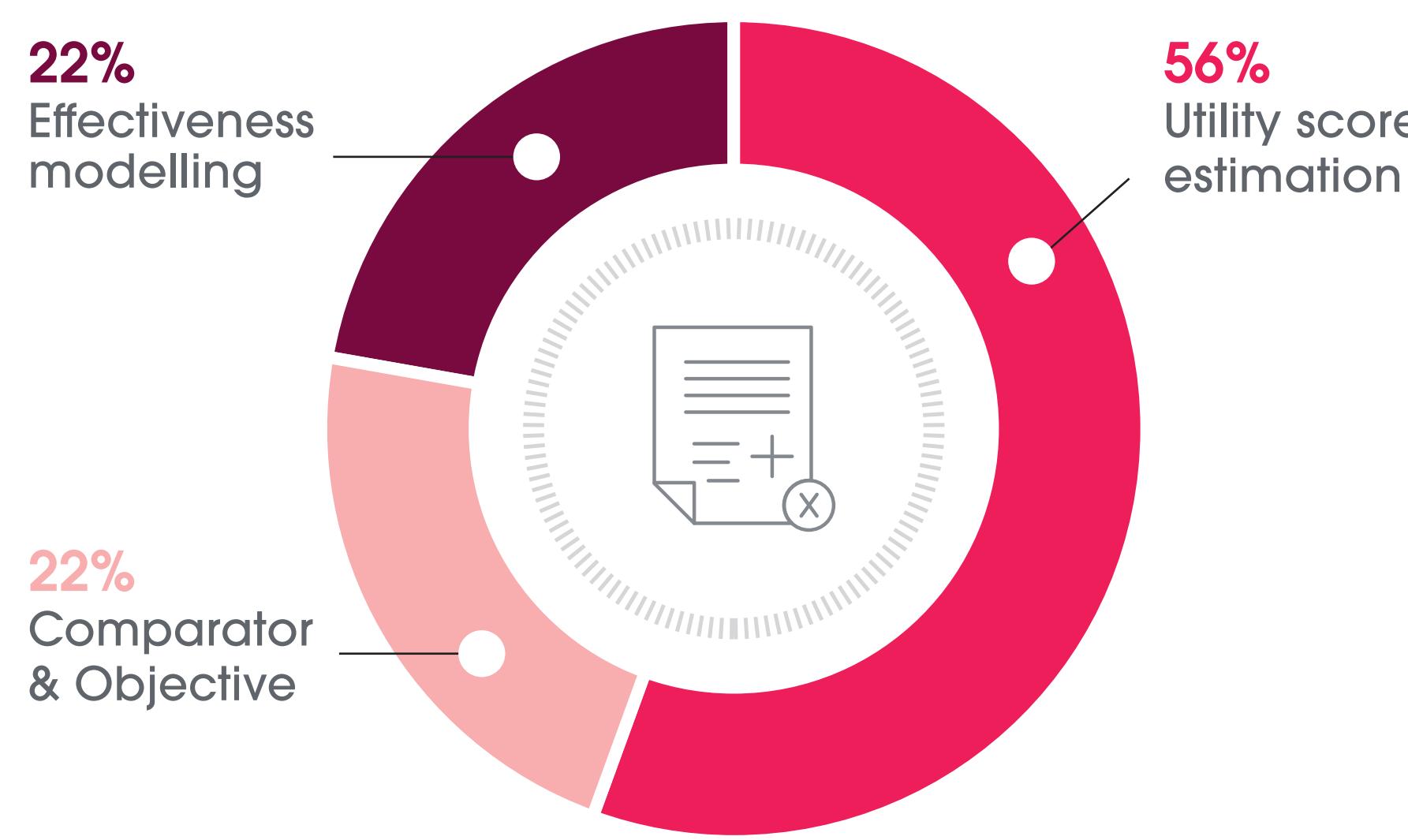
Four economic evaluations were invalidated due to major uncertainty.

FIGURE 1. CEEP CONCLUSIONS



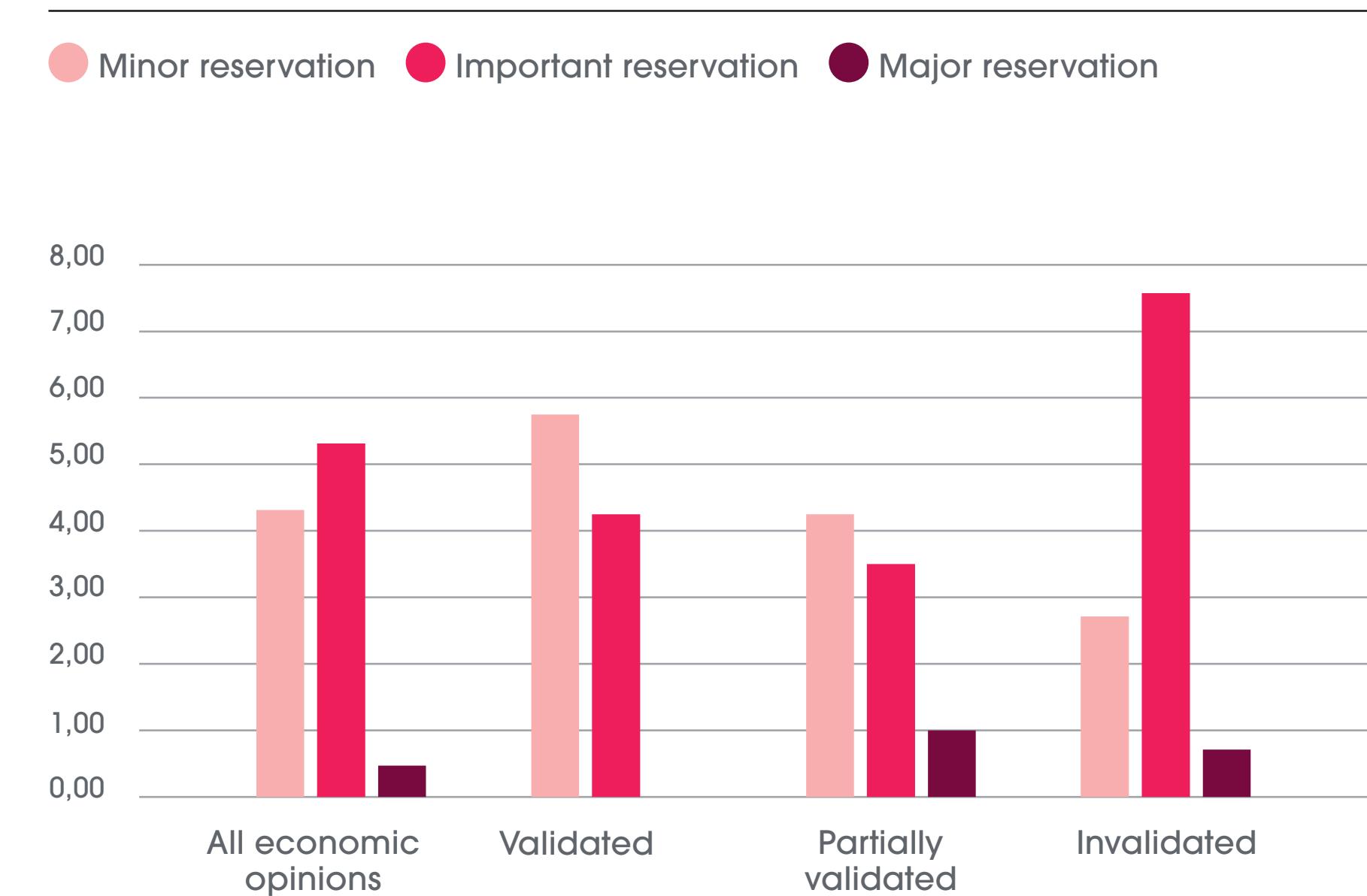
Major uncertainty were mainly supported by the context of rare disease (4 opinions, 3 of which on Orphan Drug).

FIGURE 2. MAJOR RESERVATIONS



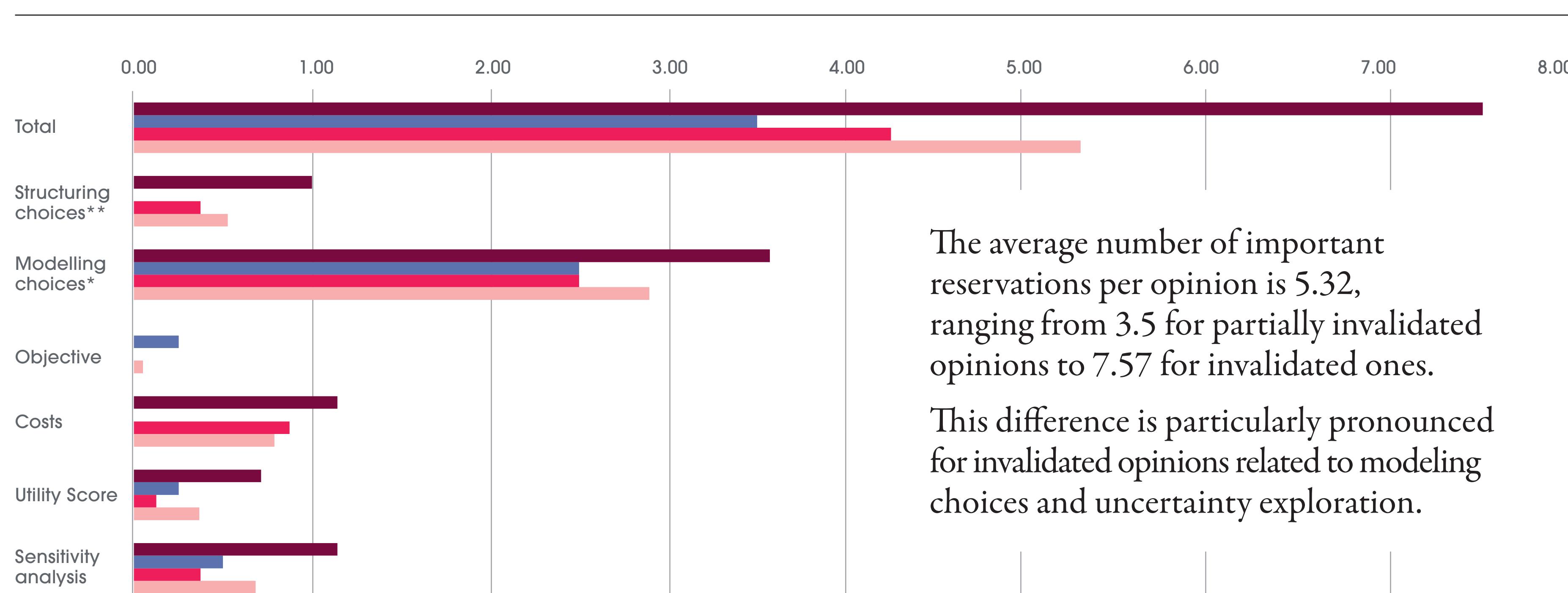
The major reservations concern the estimation of utilities (N=5) derived from external sources, the modelling of relative effectiveness (N=2), and the specification of objectives or comparators (N=2), which limit the scope of the conclusions by restricting the assessment's capacity to fully account for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

FIGURE 3. AVERAGE NUMBER OF RESERVATIONS ACCORDING TO CEEP 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.

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