

Introduction

- Since 2013, France has required economic evaluation for healthcare products and technologies presumed to be innovative and likely to have significant impact on health insurance expense (1)
- The economic opinion development process includes a contradictory phase in which manufacturers can submit written observations and/or request a hearing with CEESP to seek amendments to its conclusions (2)
- Manufacturers must comply with a 10-day deadline to submit written observations or request a hearing. The claims made by manufacturers requesting a hearing may only pertain to the conclusions and must be limited to elements that have already been submitted to CEESP (2)
- Following this phase, the CEESP conclusion may be modified

Objective

- The objective of this research was to assess the impact of written observations and/or participation in a hearing on CEESP's final conclusions by determining the occurrence of modifications in these conclusions and evaluating the extent to which these modifications align with manufacturers' claims and the subjects of discussion

Results

- Overall, 158 CEESP meeting minutes published between 2013 and 2024 were reviewed (3). Among them, 31 cases of written observations and 45 cases of hearing were identified. However, detailed information on these results was only available in meeting minutes published from 2020 to 2021 onward (**Table 1**)
  - The number of observations may seem low compared with what might be expected. It is assumed that since 2020, CEESP minutes only detail the written observations that required a second submission to CEESP with requests relating to product assessment criteria. Before 2020, written observations were not mentioned in the minutes

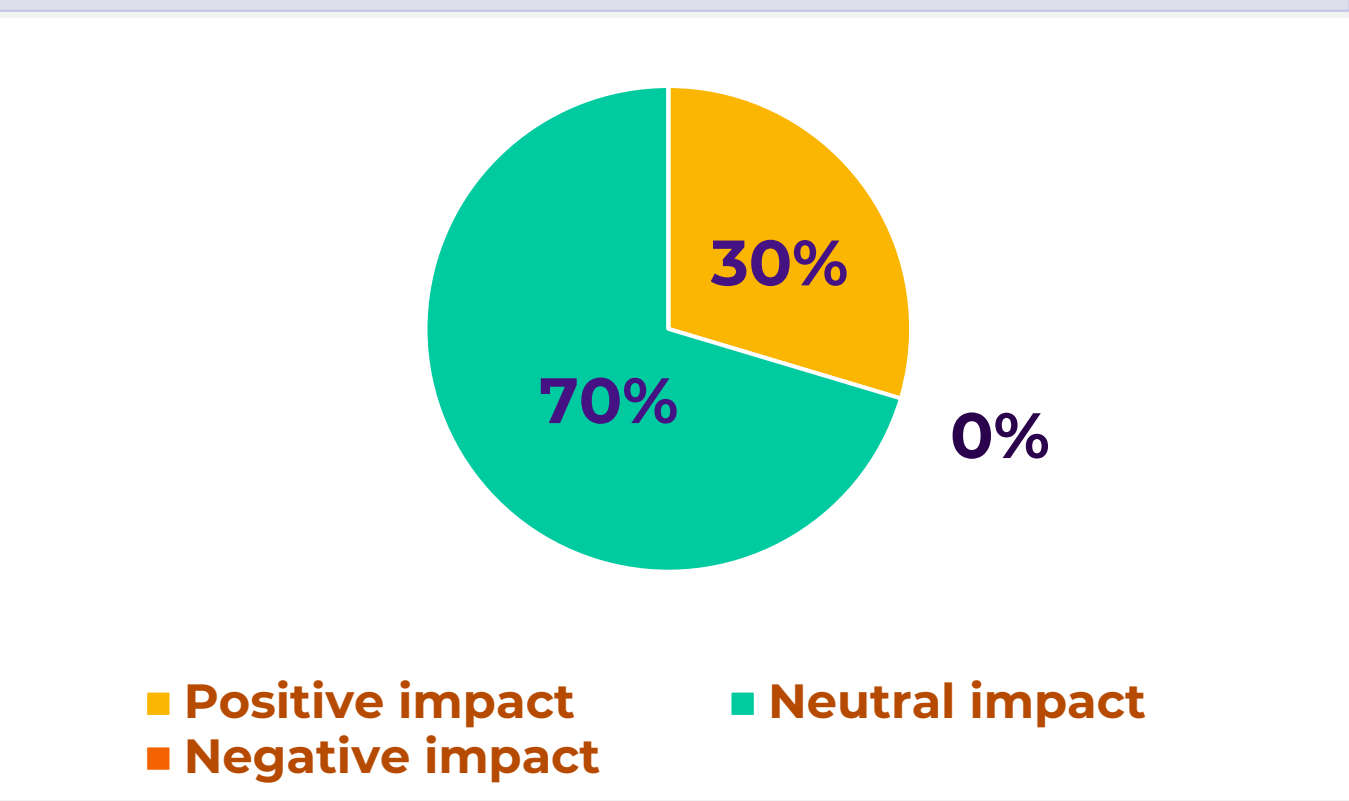
Table 1. Number of written observations and hearings by year of publication

Type of opinion	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total
Written observation	-	-	-	-	-	-	-	4	6	9	9	3	31
Hearing	1	6	8	1	4	3	7	2	6	3	3	1	45
Total published	-	17	23	19	18	20	24	24	27	28	19	14 <sup>a</sup>	233

Written observations

- A total of **70** CEESP meeting minutes published between **January 2021** and **July 2024** were reviewed. From these meeting minutes, **27** cases of written observations were identified
- Among these cases, **30%** showed a positive impact on the initial conclusions (n=8)
- A neutral impact was observed in **70%** of cases, with no changes in the CEESP's conclusions (n=19)
- There were no cases with a negative impact

Figure 1. Impact of written observations on CEESP conclusions



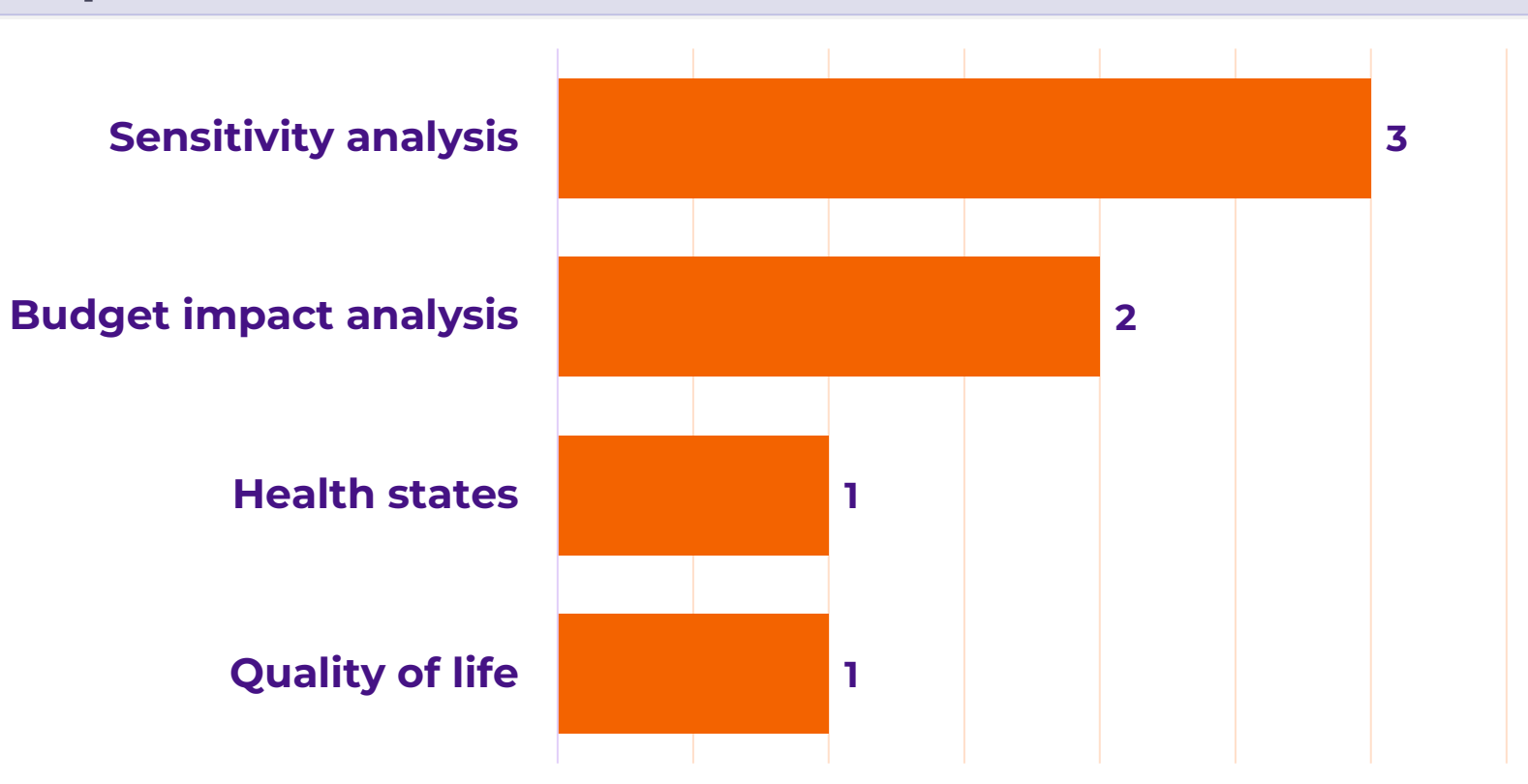
- Positive results included **reclassification** of important reservations as minor ones, associated **reformulations** in **6** of 8 cases, and the **removal of an important reservation** in **2** cases
- A neutral impact was considered in **8** cases where conclusions were **reworded**, in **8** cases where conclusions were strictly **unchanged**, and in **3** cases where reservations were **reformulated** (**Figure 2**)

Figure 2. Distribution of positive and neutral effects of observations on CEESP conclusions



- The **reclassification** of important reservations as minor reservations was associated with the following subjects (**Figure 3**):
  - Sensitivity analysis in **3** cases
  - Budget impact analysis in **2** cases
  - Measurement and valuation of health states in **1** case
  - Quality of life in **1** case

Figure 3. Subject of reservations requalified from important to minor



Methods

- The complete set of CEESP meeting minutes published between 2013 and July 2024 was reviewed (3). A double extraction was conducted to isolate the results of the hearings and written observations when sufficient information was available in the minutes, mainly from 2020 onward
- For each opinion assessed in a contradictory phase, the manufacturer's claims, the CEESP's post contradictory phase conclusions, and the impact of these modifications were collected. The impacts were classified as positive, negative, or neutral, based on the changes in the conclusions
- A positive impact was represented by a modification favorable to the manufacturer, which may have involved a positive reclassification of the level of reservation(s) or the removal of reservation(s); a negative impact was associated with an addition of reservations, whereas a neutral impact translated no important modifications or only rewordings in CEESP's conclusions
- Rewording of reservations was not considered a modification of the conclusions, as specified by the CEESP
- The data extracted from the meeting minutes included therapeutic area, type and number of reservations obtained, and subject discussed during the contradictory phase
- Because of the lack of detail in the available data published between 2013 and 2020, a focus was placed on the periods from January 2021 to July 2024 for written observations and from January 2020 to July 2024 for hearings, corresponding to the periods in which the CEESP's meeting minutes were the most detailed

Hearings

- A total of **86** CEESP meeting minutes published between **January 2020** and **July 2024** were reviewed. From these meeting minutes, **15** cases of hearings were identified
- Where sufficiently detailed data were available, the subjects leading to hearing requests were analysed to identify the most common reasons for such requests (**Figure 4**)
- The hearings had the following results on CEESP conclusions (**Figure 5**):
  - A change in CEESP's final conclusions compared with the draft opinion was observed in **20%** of the cases (n=3)
  - In **80%** of cases without impact on results, CEESP's final conclusions remained unchanged (n=12)
- All cases with no change in CEESP conclusions were classified as having a neutral impact. Of these cases, a reformulation of reservations was observed in 4 instances
- Particular interest was placed on the 3 cases of hearings resulting in changes/modifications in CEESP conclusions
  - Positive impact** was identified in **2** hearing cases
  - Only **1** hearing case with a **negative impact** was observed
- The manufacturers' claims, results of the hearing, impact of the results, and subjects discussed are presented in **Table 2**

Figure 4. Top subjects for hearing requests

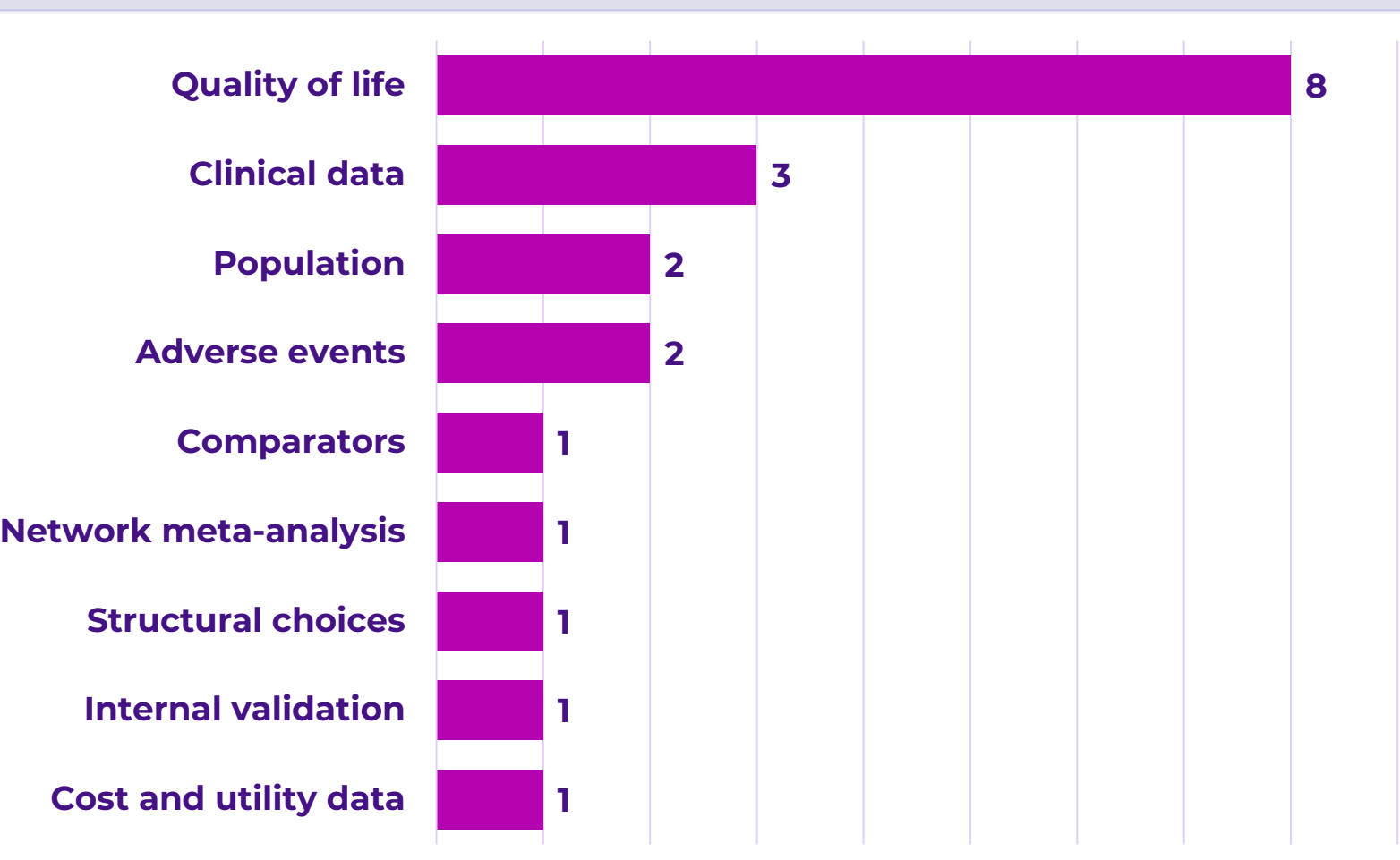


Figure 5. Impact of hearings on CEESP conclusions

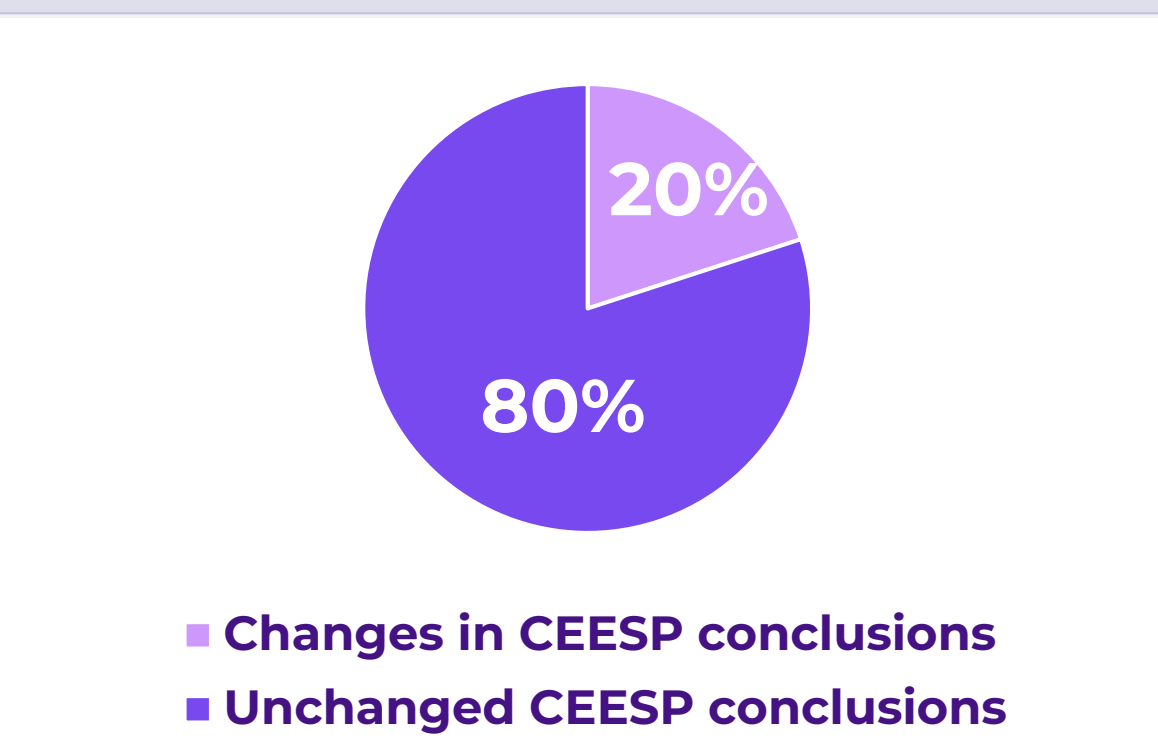


Table 2. Changed CEESP conclusions post-hearing

Product	Manufacturer claims	Hearing results	Impact	Subject of hearing
Onasemnogene abeparvovec	Reclassification of 2 important reservations as minor	Addition of an important reservation	Negative	Quality of life
Ciltacabtagene autoleucel	Reclassification of a major reservation	- Reformulation of major reservation - Reclassification of 2 important reservations as minor	Positive	- Population - Adverse events - Quality of life
Cannabidiol	Reclassification of 2 important reservations as minor	Reclassification of 2 important reservations as minor	Positive	- Clinical data - Cost and utility data

Conclusions

- The main limitation of this study was that the analyses were conducted based on the available information, with only the meeting minutes from 2020 to 2021 onward providing sufficient detail, which limited the scope of the analyses. Nevertheless, positive outcomes were observed in 30% of cases for written observations and in 67% of cases for hearings, with only a single instance of a negative outcome recorded overall
- Contradictory phases are of significant interest for manufacturers, although changes in the level of validity of the opinion are relatively uncommon. However, these phases offer a valuable opportunity for dialogue, enabling manufacturers to present and defend their position, which can promote better alignment with the CEESP and often lead to reformulations

Abbreviation: CEESP, French Economic and Public Health Committee  
\*Opinions published up to September 2024

References: 1. Décision n°2013.011/DC/SEESP du 18 septembre 2013 du collège de la Haute Autorité de santé relatif à l'impact significatif sur les dépenses de l'assurance maladie déclenchant l'évaluation médico-économique des produits revendiquant une ASMR ou une ASA de niveaux I, II ou III; 2. Étapes d'élaboration d'un avis économique: [https://www.has-sante.fr/upload/docs/application/pdf/2013-08/etapes\\_delaboration\\_desavis\\_deficience.pdf](https://www.has-sante.fr/upload/docs/application/pdf/2013-08/etapes_delaboration_desavis_deficience.pdf); 3. Agenda of CEESP meetings: [https://www.has-sante.fr/jcms/prd1\\_2989758/fr/agenda-de-la-has](https://www.has-sante.fr/jcms/prd1_2989758/fr/agenda-de-la-has)

