

ANALYSIS OF THE OUTCOMES OF THE HEARINGS OF THE TRANSPARENCY COMMITTEE IN FRANCE

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CONTEXT

In France, to access reimbursement and a price, medications must be evaluated by the Transparency Committee (TC). They are assigned a medical benefit (SMR), which defines a reimbursement rate, and an improvement of the medical benefit (ASMR), which will guide price negotiations. In the process, a draft opinion is issued by the TC. This draft opinion can be challenged by the applicant, leading to a hearing.

OBJECTIVES

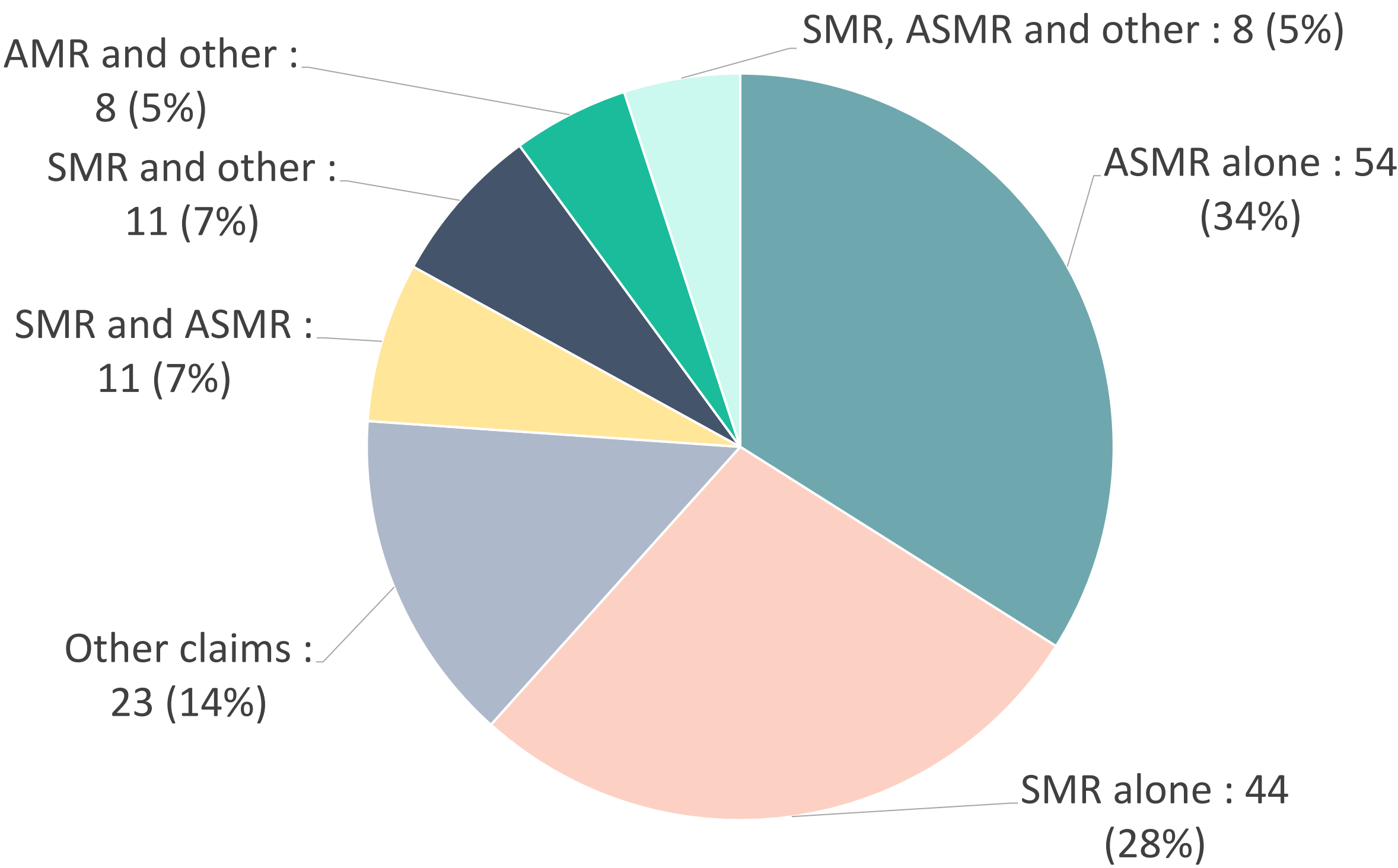
Our study consisted of a descriptive analysis of the hearings in order to identify the claims made and those that were successful, as well as the factors influencing the hearing’s outcome.

METHODS

We conducted a retrospective analysis of all TC hearings reports published between January 1, 2021, and December 31, 2023.

RESULTS

OVERVIEW OF CLAIMS AT THE HEARING



- Among 159 hearings conducted over the period covered by the analysis, the most represented therapeutic area was oncology (30%).
- Of these hearings, 75 targeted a change in SMR and 81 targeted a change in ASMR. A total of 117 drugs made only one claim at the hearing.
- The other claims (target population, comparators, etc.) represented only a small proportion of the claims made at the hearings (59 claims out of 50 hearings, often made in parallel with a claim on SMR or ASMR).

OUTCOMES OF THE HEARINGS

- 36% of the hearings lead to at least a partial modification of the initial opinion issued by the TC.
- No deterioration (downgrading) of the results of the initial opinion ASMR was observed in the analysis.
- SMR was improved in 37% of cases. In a significant number of cases an insufficient SMR could be changed to an important SMR (cf. table on the right).
- ASMR was improved in 31% of cases. Most improvements were from an ASMR V to an ASMR IV or ASMR IV to ASMR III. In only 2 cases, an ASMR V was upgraded to an ASMR III (cf. table on the right).

TABLE 1. SMR obtained after the hearing by SMR attributed in draft opinion

Initial SMR	SMR obtained			
	Insufficient	Low	Moderate	Important
Insufficient (n=42)	29 (69%)	5 (12%)	1 (2%)	7 (17%)
Low (n=12)	0	6 (50%)	6 (50%)	0
Moderate (n=21)	0	0	12 (57%)	9 (43%)

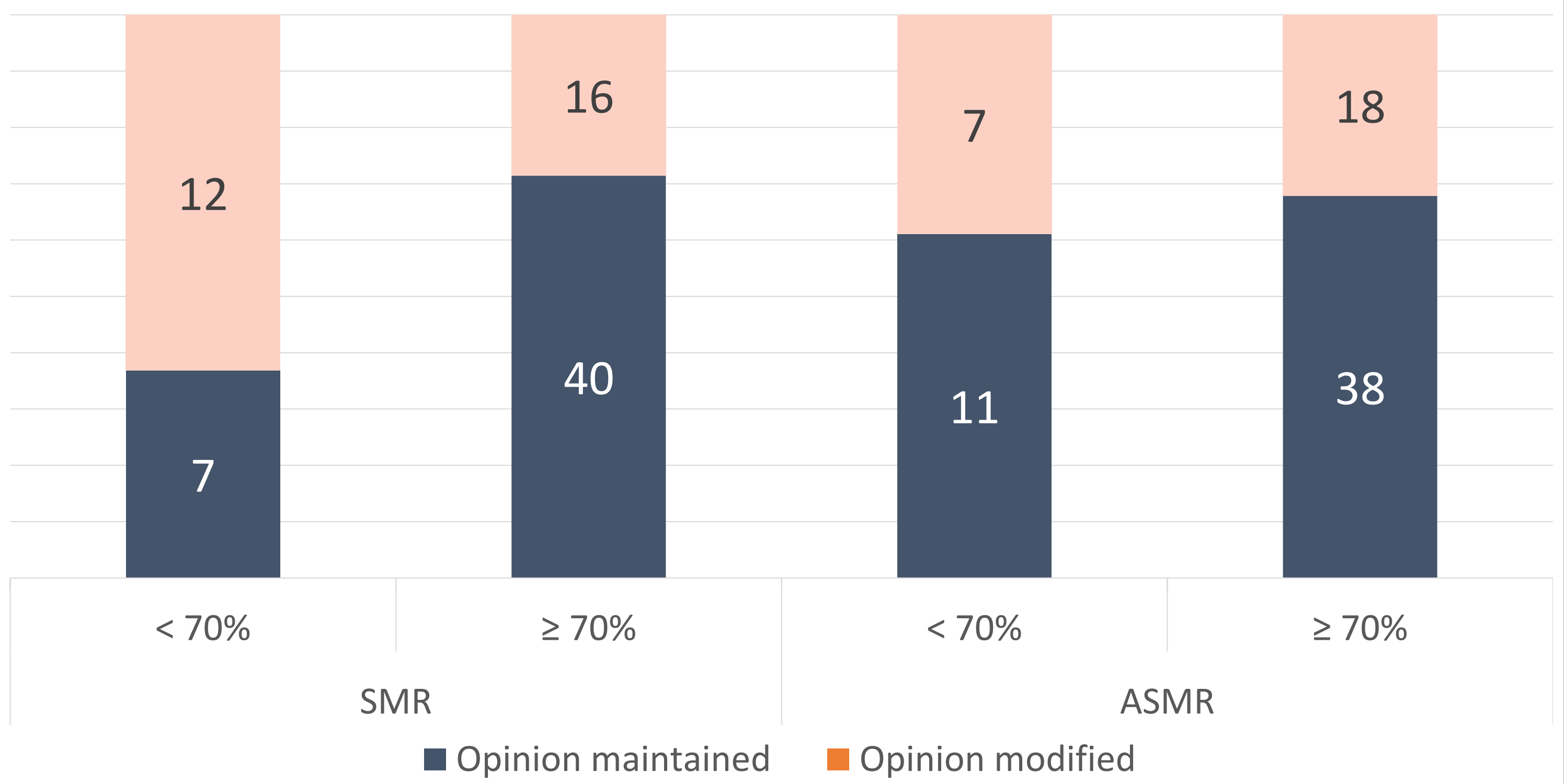
TABLE 2. ASMR obtained after the hearing by ASMR attributed in draft opinion

Initial ASMR*	ASMR obtained		
	V	IV	III
V (n=54)	36 (67%)	16 (29%)	2 (4%)
IV (n=20)	0	13 (65%)	7 (35%)

FACTORS POTENTIALLY PREDICTING OUTCOMES OF THE HEARINGS

- When the initial SMR had been attributed based on < 70% of votes, it was upgraded in 12/19 cases. When it had been attributed based on > 70% of votes, it was upgraded in 16/56 cases (figure 1 on the right).
- When the initial SMR had been attributed based on > 90% of votes, it could also be upgraded in 32% of cases (not shown on the figure).
- When the initial ASMR had been attributed based on < 70% of votes, it was upgraded in 7/18 of cases. When it had been attributed based on > 70% of votes, it was upgraded in 18/56 of cases (figure 1 on the right).
- When the initial ASMR had been attributed based on > 90% of votes, it could also be upgraded in 26% of cases (not shown on the figure).

FIGURE 1. MODIFICATION BY PERCENTAGE OF VOTES IN THE INITIAL OPINION



CONCLUSION

- The main learnings from this analysis are :
- Hearings could result in an upgrade of the appraisal in 36% of cases ; whereas there was no case of downgrading ;
 - In a significant number of cases an important SMR could be obtained while initial opinion was an insufficient SMR ;
 - An upgrade of the SMR and/or ASMR could be obtained even when the initial opinion was based on more than 90% of the votes.

