How do Post-Registration Studies Impact Drug Evaluation by the Transparency Committee?

Exploring Context and Analyzing Results

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Context & Objective

- Post-registration studies may be requested by the Transparency Committee (TC) when it issues an opinion on a drug and is faced with uncertainties about its use in current practice, its clinical benefit or its adverse effects.
- These "real-life" studies may have several objectives: to provide information on the product's efficacy in current practice or on its tolerability; to provide information on its conditions of prescription or use, on its impact on quality of life, on morbidity and mortality, or on the healthcare system; or to provide data on patient compliance with treatment.

Method

- Scope: opinion published with an EPI requested by the TC and the results of which are not yet available & opinion published with results of EPI evaluated by the TC
- Timeframe: 2016 to 2024
- Criteria: TC opinion date, Level of SMR & ASMR, Role in therapeutic strategy, Clinical package requested, Expected evaluation time and Actual assessment time

Results

- 106 opinions with an EPI requested by the TC
- 81 opinions with results of EPI evaluated by the TC

Specialties for which an EPI has been requested by the TC

Figure 1. Number of EPI requested per year

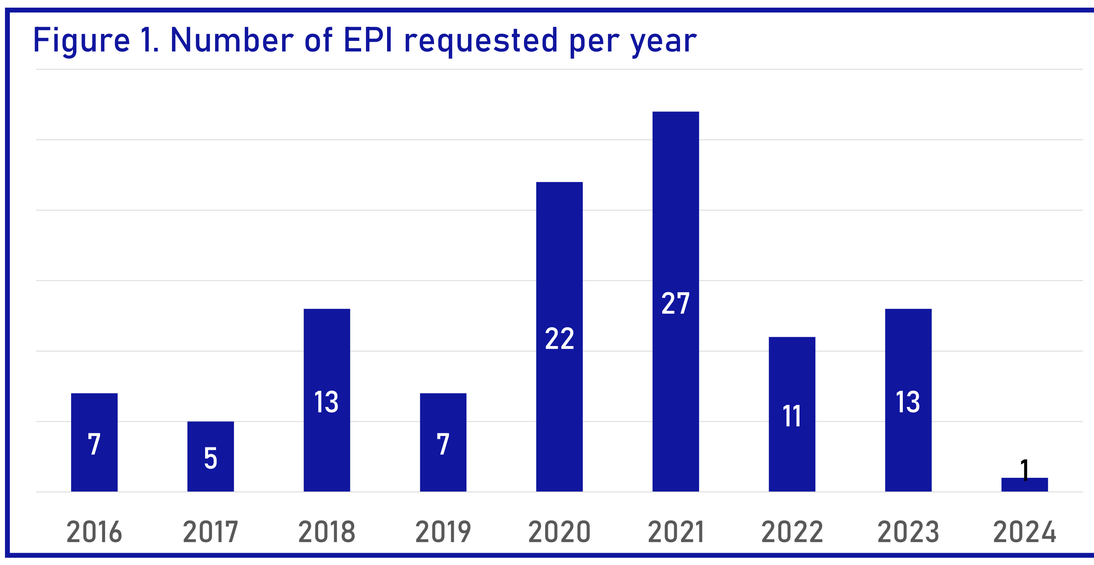
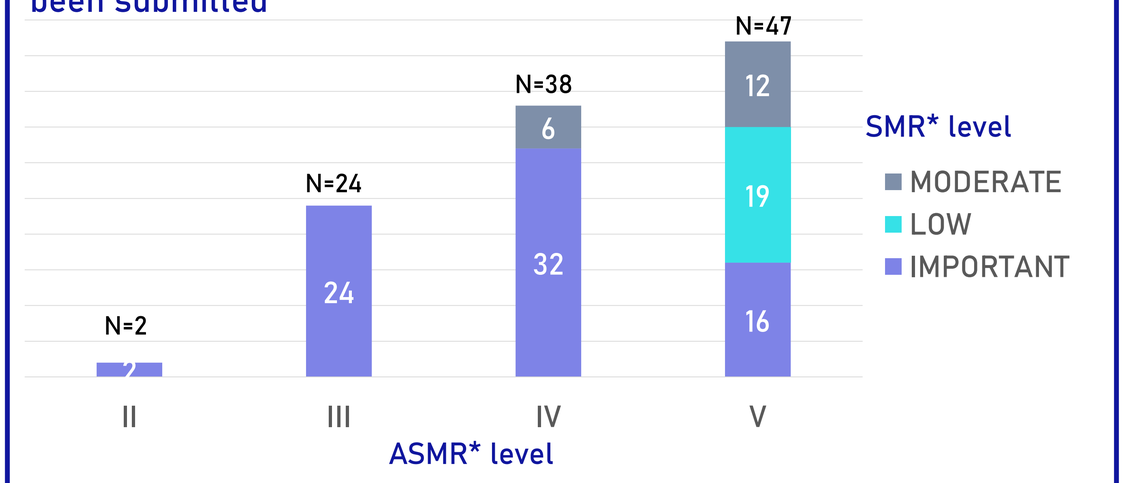


Figure 2. SMR and ASMR of drugs for which an EPI application has been submitted



* 5 opinions included 2 levels of SMR and/or 2 levels of ASMR

Figure 3. Request to set up a register and expected evaluation time of drugs for which an EPI has been submitted

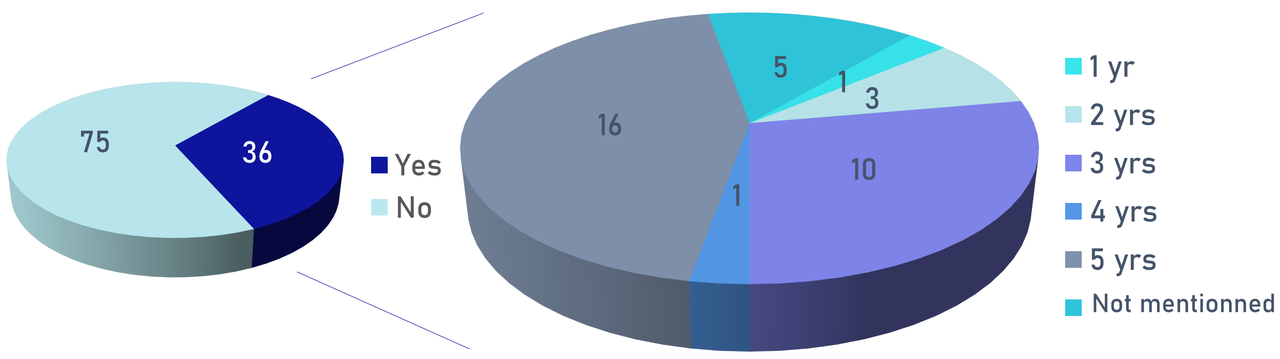


Table 1. Conditional* SMR of drugs for which an EPI has been submitted

SMR	SMR conditional	No SMR conditional
Important	1	73
Moderate	1	16
Low	3	17
Total	5	106

5 opinions included 2 levels of SMR and/or 2 levels of ASMR
* When the Commission states in its opinion that it conditions the maintenance of the SMR level on the re-evaluation of the product on the basis of new data.

Specialties for which results of EPI has been evaluated by the TC

Figure 4. Number of EPI evaluated per year

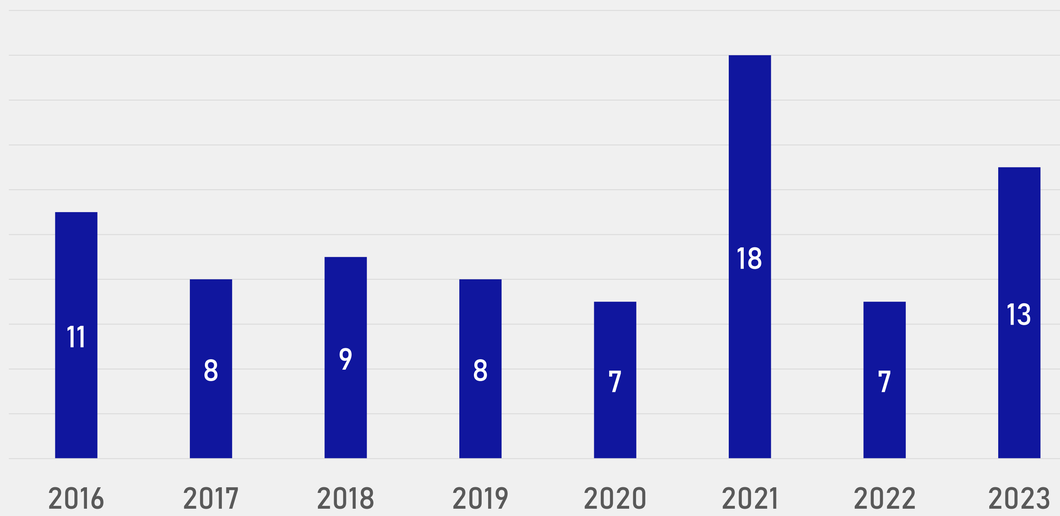


Figure 5. Deadlines for final results

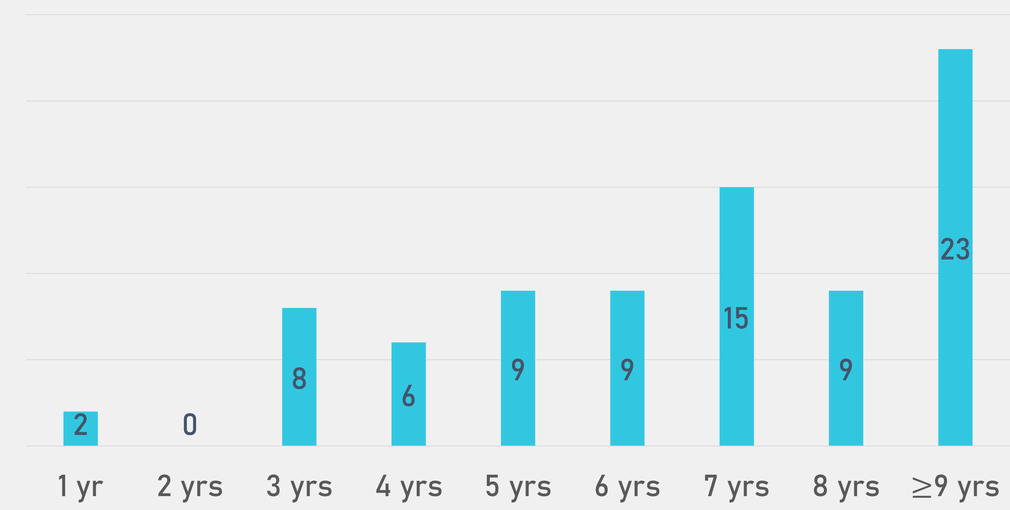
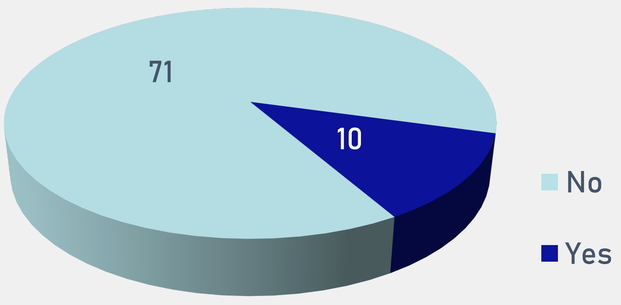


Table 2. SMR, ASMR and role in therapeutic strategy of drugs for which results of EPI has been evaluated

	SMR	ASMR	Therapeutic strategy
Not changed	72	76	74
Upper than the initial assessment / In favor of the laboratory's claim	7	2	5
Lower than the initial assessment / Disagrees with the laboratory's claim	2	3	2

Figure 6. Continued demand for EPI



Conclusion

- The 106 requests for EPI formulated between 2016 and 2024 concerned drugs with improved medical benefits in 57% of cases.
- The majority of EPI confirmed the SMR level (89%), ASMR level (94%) and place in the therapeutic strategy (91%) attributed to the product.

SMR, CB, clinical benefit
ASMR, CAV, clinical added value

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