EARLY ACCESS REFORM IN FRANCE: DESCRIPTIVE ANALYSIS OF EAP DECISIONS TWO YEARS AFTER THE REFORM

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CONTEXT

Early access program (EAP) was reformed on July 1, 2021. The Transparency Committee (TC), which is responsible of reimbursement decision, issue an opinion whereas the final decision is taken by the College of the HAS.

OBJECTIVES

Our study consisted of a descriptive analysis of EAP decisions taken since the reform.

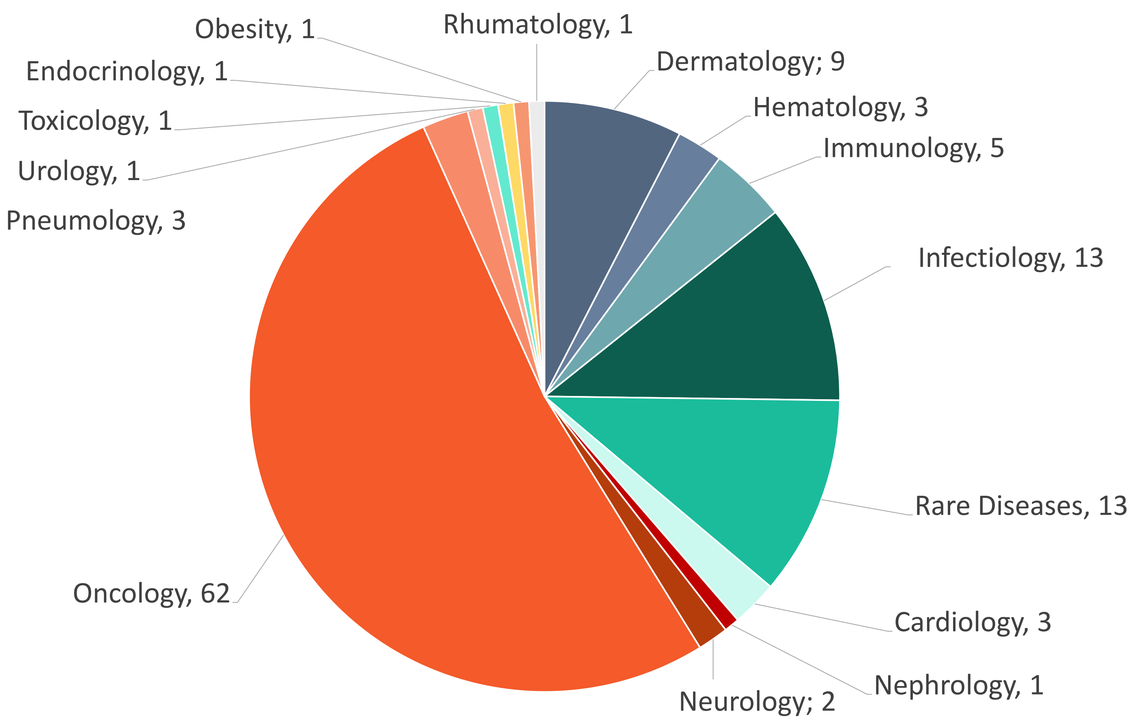
METHODS

We conducted a retrospective analysis of all HAS decisions published between July 1, 2021, and May 31, 2023.

RESULTS

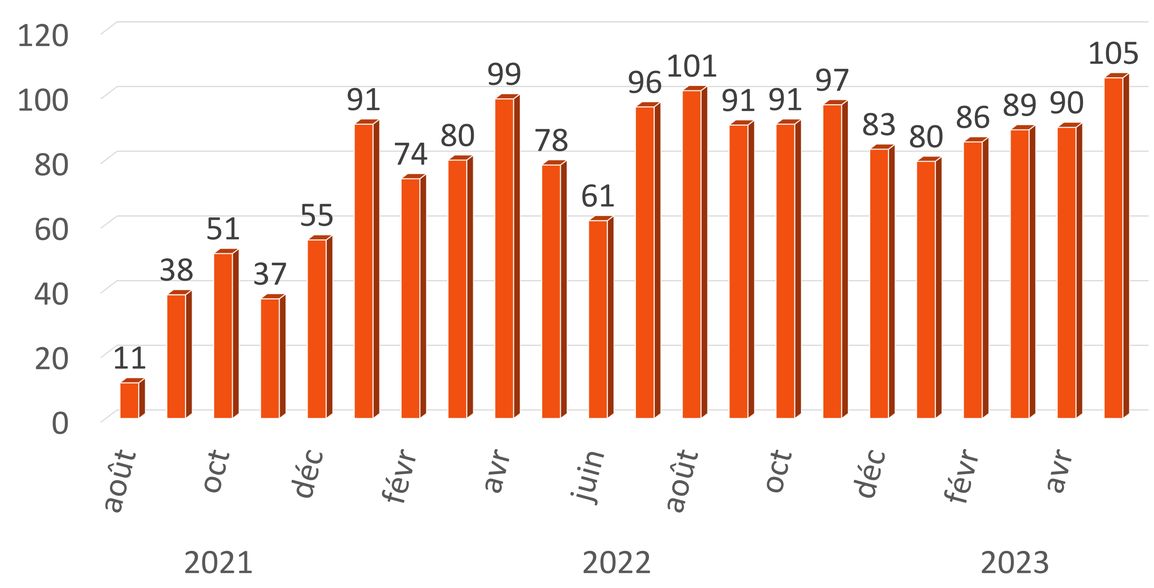
- Among 119 EAP decisions published, 41% concerned medicines without marketing authorization (MA) and 59% concerned medicines with a MA.
- The most represented therapeutic area was oncology (52%).

FIGURE 1. THERAPEUTICS AREAS OF PRODUCTS EVALUATED FOR EAP



- The average time from dossier submission to EAP decision publication was 81 days and remained stable between 2022 and 2023 (88 days versus 89 days) compared to 2021 (42 days). The average time of evaluation is longer for products without MA (93 days) compared to products with MA (73 days).

FIGURE 2. AVERAGE TIME (IN DAYS) BETWEEN DOSSIER SUBMISSION AND PUBLICATION OF EAP DECISION



- Most evaluated medicines (75%) had comparative results at the time of their evaluation.

TABLE 1. TYPES OF DATA AVAILABLE FOR THE EAP ASSESSMENT

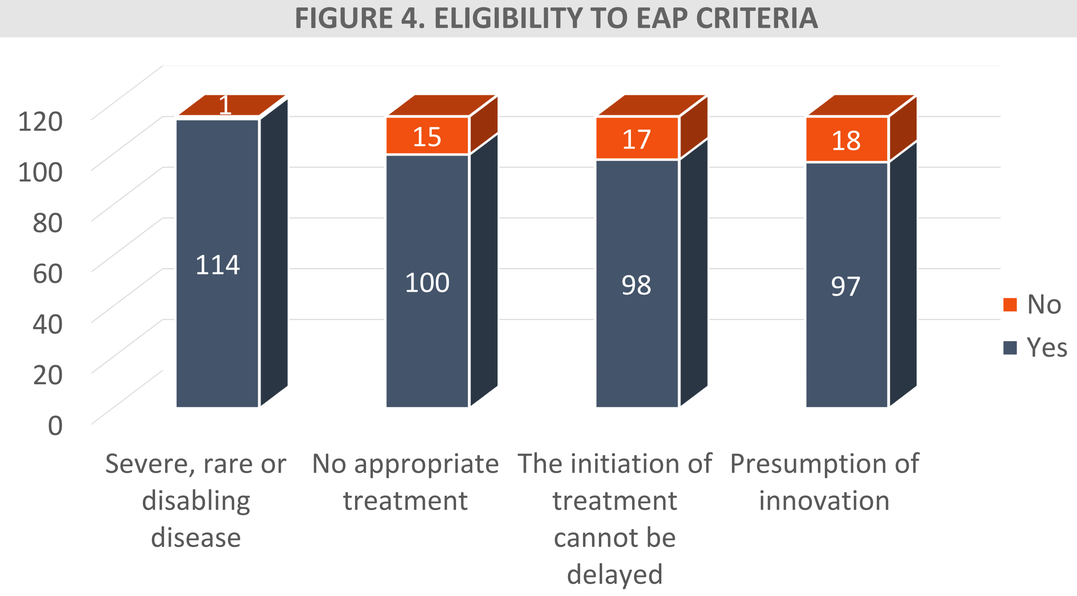
Non-comparative study	**25%**
Phase I	1%
Phase I/II	8%
Phase II	11%
Phase III	1%
Other (literature review, early access data, observational study, compassionate use)	4%
Comparative study	**75%**
Phase I	2%
Phase I/II	1%
Phase II	4%
Phase II/III	5%
Phase III	63%

- EAP was granted for 94/119 (79%) of treatments.

FIGURE 3. EAP DECISION

- Efficacy and safety have not been demonstrated for 5 drugs without MA.
- The severe, rare or disabling nature of the disease was recognized for almost all the EAP evaluations (114/115). The lack of a presumption of innovation, the possibility of deferring treatment and the identification of appropriate treatment, and were responsible of denial for 16%, 15% and 13% of the EAP assessments, respectively.

FIGURE 4. ELIGIBILITY TO EAP CRITERIA



CONCLUSION

Since the reform, evaluation for EAP is conducted according to TC requirements and became a very important preparatory step for reimbursement. Pharmaceutical companies must ensure consistency between EAP and reimbursement dossiers and think about their market access strategy earlier.

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