Rating therapeutic advance: third comparison of Prescrire's drug ratings with those of the French HAS

● A comparative analysis of drug ratings assigned by Prescrire and France's National Authority for Health (HAS) reveals that the main differences between them concern the weight assigned to presumed innovation and to advances in ease of use.

New is not necessarily better, including in the pharmaceutical sector.

Every month, Prescrire aims to help improve the quality of patient care and make it easier for healthcare professionals to sift through the multitude of new products or indications, by rating the extent to which they represent an advance over existing treatment options (see also "Prescrire's drug ratings in 2025: a brief review", pp. 101-103) (1). France's National Authority for Health (HAS) produces its own ratings of the clinical benefit (CB) and clinical added value (CAV) of drugs, largely with the purpose of helping the public authorities make decisions about reimbursement and whether to approve a drug's use in hospitals and other healthcare institutions, as well as to support price negotiations (2).

Prescrire has conducted a comparison between its own ratings and those of the HAS for the period 2019-2023, following previous comparisons for the periods 1999-2004 and 2009-2014 (3,4). This analysis examined and compared the ratings assigned to 510 products or indications.

Overall, analysis of Prescrire's ratings shows that only a small number of new products (10%) constituted a notable therapeutic advance over the period 2019-2023 (rated as "Bravo", "A real advance" or "Offers an advantage"). 17% of the new products represented a minimal advance (rated as "Possibly helpful"). The majority (53%) provided no advantages over existing options, and some (8%) were even considered more dangerous than beneficial. The remaining 12% were considered to have uncertain therapeutic value (rated as "Judgement reserved") (see table below).

This comparative analysis of the Prescrire and HAS ratings for the period 2019-2023 found fewer differences between their respective ratings than in the previous comparison published in 2015.

The ratings differed in about half of cases, mostly for products that were rated by Prescrire as "Not acceptable" or "Possibly helpful". The Prescrire rating was higher than the HAS rating in 13% of cases, mostly for new products that advanced patient care because they were easier to use than existing treatment options. The HAS rating was higher than the Prescrire rating in 33% of cases, mostly for anti-

Comparison of the ratings assigned by Prescrire and France's National Authority for Health (HAS) for the period 2019-2023 (a)

Prescrire \ HAS	CAV I (major)	CAV II (substantial)	CAV III (moderate)	CAV IV (minor)	CAV V (none)	Insufficient CB	Total
Bravo	1	–	–	–	–	–	1 (0.2%)
A real advance	–	3	–	–	–	–	3 (0.6%)
Offers an advantage	–	2	23	15	7	–	47 (9%)
Possibly helpful	–	1	23	31	31	–	86 (17%)
Nothing new	–	–	16	56	187	13	272 (53%)
Not acceptable	–	–	-	8	22	12	42 (8%)
Judgement reserved (b)	–	2	19	20	14	4	59 (12%)
Total	1 (0.2%)	8 (2%)	81 (16%)	130 (25%)	261 (51%)	29 (6%)	510 (100%)

HAS and Prescrire ratings similar
HAS rating higher than Prescrire rating
HAS rating lower than Prescrire rating

CAV: clinical added value; CB: clinical benefit

a- This table shows the ratings given to drugs evaluated in *La Revue Prescrire*, our French edition, between January 2019 (*Rev Prescrire* n° 423) and December 2023 (*Rev Prescrire* n° 482).

b- The HAS's regulations do not allow it to reserve judgement in cases where a drug's harm-benefit balance is uncertain. It is therefore impossible to determine whether its "CAV V" and "insufficient CB" ratings are higher or lower than Prescrire's "Judgement reserved" rating.

neoplastic drugs, last-resort antibiotics and drugs used in rare diseases for which treatment options are limited. Often, the evaluation data were uncertain or constituted low-level evidence; in such cases, Prescrire advised caution, while the HAS opted to reward "innovation" by taking a gamble that the new drug would advance patient care.

IN SUMMARY The Prescrire and HAS ratings tallied in half of cases. Compared with Prescrire, the HAS tended to reward "innovation", which sometimes led it to overestimate the extent to which a drug would advance patient care. This was the case, in particular, for drugs used to treat cancer or rare diseases, for which patients and healthcare professionals have very few effective options. But in many of these cases, much remained unknown about the drug in question, and rating it as a therapeutic advance was a gamble, taken on behalf of patients, sometimes exposing them to the risk of serious adverse effects but uncertain clinical benefits. The HAS assigns less weight than Prescrire to advances in ease of use, even though these are valued by patients and healthcare professionals. Prescrire will continue to act first and foremost in the interest of patients, by highlighting any therapeutic advance for which there is sufficient evidence, and by warning healthcare professionals, and thereby patients, about drugs that are more dangerous than beneficial.

► Excerpt from *Rev Prescrire* January 2026
Volume 46 N° 507 • Pages 60-65

Selected references from Prescrire's literature search

1- Prescrire Editorial Staff "Prescrire's ratings of new drugs in 2024: a brief review" *Prescrire Int* 2025; **34** (269): 102-104.

2- HAS "Transparency Committee doctrine. Principles of medicinal product assessments and appraisal for reimbursement purposes" 2 December 2020: 28 pages.

3- Prescrire Editorial Staff "Comparative advantages of new drugs: French Pharmacoeconomic Committee is not sufficiently demanding" *Prescrire Int* 2015; **24** (166): 303-307.

4- Prescrire Rédaction "Amélioration du service médical rendu (ASMR): en France, la Commission de la transparence n'est pas assez exigeante" *Rev Prescrire* 2004; **24** (256): 859-864.

EMA: proposed Key Information Section in the package leaflet

● Prescrire provided its feedback on the European Medicines Agency's proposed inclusion of a Key Information Section in the package leaflet of medicinal products.

In May 2025, Prescrire responded to a consultation by the European Medicines Agency (EMA) on the inclusion of a "Key Information Section" in the package leaflet (1).

Prescrire expressed its support for the addition of such a section, which should include information about treatment indications and benefits, contraindications, both common and serious adverse effects, dosing and treatment duration, how the medicine is given, warnings and precautions, how to report adverse effects and, finally, information on the harm-benefit balance, compared to standard treatment where one exists (1).

Like the rest of the package leaflet, this section should undergo patient/user testing to assess its readability and comprehensibility (1).

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Volume 46 N° 508 • Page 150

References 1- Prescrire Editorial Staff "Prescrire final response to EMA Consultation on a potential Key Information Section in the Package Leaflet (...)" 21 May 2025: 6 pages.