Prescrire's ratings of new drugs in 2022: a brief review

● Only 11 of the 124 new marketing authorisations analysed and rated in our French edition in 2022 represented a notable therapeutic advance for patients.

Every month, *Prescrire* publishes independent, comparative, systematic reviews of the latest developments in the European pharmaceutical market, including recent marketing authorisations for new active substances, new combinations, new pharmaceutical forms, and new indications. We also closely monitor news concerning adverse effects, market withdrawals (instigated by pharmaceutical companies or regulatory authorities), re-introductions of previously withdrawn products, re-evaluations of drugs already on the market, and the regulatory environment for health products. Our aim is to help subscribers distinguish between genuine advances and new products or new uses that are no better than existing treatments or that should never have been authorised, due to uncertainty over their harms or benefits or because they are clearly dangerous.

No major therapeutic advances in 2022. Prescrire examined 124 new marketing authorisations in 2022 in order to determine whether or not they advanced patient care (see the table opposite).

Thirty-four of these offered some degree of added benefit compared with existing treatments, at least for some patients, with 11 (9%) representing a notable advance (rated "Offers an Advantage"), and the remaining 23 (19%) a minimal advance (rated as "Possibly Helpful").

Half of the new authorisations we analysed in 2022 offered no proven advantages over existing treatment options (rated "Nothing New"). In 13 cases (10%), the harm-benefit balance could not be determined, because the clinical evaluation data provided insufficient evidence of their efficacy or potential serious adverse effects (rated "Judgement Reserved"). Finally, the evaluation data available on 14 authorisations (11%) showed them to be more dangerous than useful (rated "Not Acceptable").

A few new authorisations worth using. After the advances seen in 2021 with the first covid-19 vaccines, those observed in 2022 are far more modest, marking a return to the pattern generally seen before the pandemic.

A few new active substances are worth using, for example: *sacituzumab govitecan*, *tucatinib* and the combination of *pertuzumab* + *trastuzumab* for certain patients with breast cancer; as well as *nirmatrelvir* (combined with *ritonavir*) and *tocilizumab* for patients at risk of developing severe covid-19. The antibody *sotrovimab* was temporarily an advance for patients with covid-19, but not a durable advance due to the virus's variability. *Sodium oxybate* constitutes a notable therapeutic advance for children aged 7 years or older with narcolepsy, as was the case for adults.

Dose strengths ill-suited to the recommended doses. Some drugs *Prescrire* examined in 2022 are marketed at dose strengths that necessitate 2 to 4 injections in succession to achieve the recommended dose, for example: *bimekizumab*, supplied in pre-filled pens or syringes that contain 160 mg of the drug, yet the recommended dose for plaque psoriasis is 320 mg every 4 or 8 weeks (*Prescrire Int* n° 245); *natalizumab*, supplied in pre-filled syringes each containing 150 mg for subcutaneous administration, yet the recommended dose for multiple sclerosis is 300 mg per month (*Rev Prescrire* n° 464); and *tralokinumab*, marketed in pre-filled syringes containing only 150 mg of the drug, when the recommended dose is 600 mg, then 300 mg every 2 weeks, for certain patients with atopic dermatitis (*Prescrire Int* n° 239).

A few welcome restrictive measures at European level. A few welcome restrictive measures were taken in the European Union in 2022, in particular: the European Medicines Agency (EMA) issued a negative opinion on granting marketing authorisation for *aducanumab*, a drug with no demonstrated efficacy in Alzheimer's disease, leading the pharmaceutical company to withdraw its application (1); and authorisation for the use of *dapagliflozin* in type 1 diabetes was withdrawn. Authorisation for the use of *rucaparib* in relapsed ovarian cancer, recklessly granted in 2020 on the basis of a very tenuous evaluation, was finally revoked. And in late 2022, the EMA confirmed its earlier opinion recommending the withdrawal of products containing *amfepramone*. The dangers of this amphetamine have been known since the 1990s, and it had already been withdrawn in many countries, including France (2).

In contrast, *etifoxine* was not withdrawn from the European market, despite the fact that it has been known for many years to have an unfavourable harm-benefit balance.

In summary: a disappointing year. 2022 was a return to the bad old days for medicines in Europe. Therapeutic advances were few and far between. Most newly authorised products or indications offered no proven advantages over existing treatment options, or were excessively dangerous. And yet again, certain pharmaceutical companies gave too little consideration to the ease of use of their products, choosing to market them in pack sizes ill-suited to the doses to be administered.

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References **1-** EMA "Withdrawal of application for the marketing authorisation of Aduhelm (aducanumab)" 22 April 2022: 2 pages. **2-** EMA "EMA confirms recommendation to withdraw marketing authorisations for amfepramone medicines" 11 November 2022: 3 pages.

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Prescrire's ratings of new products and new indications over the past 10 years

PRESCRIRE'S RATING	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
BRAVO	0	1	0	0	0	0	0	1	0	0
A REAL ADVANCE	0	2	3	1	1	2	1	2	3	0
OFFERS AN ADVANTAGE	6	5	5	5	9	11	10	6	14	11
POSSIBLY HELPFUL	12	15	15	9	18	22	13	18	19	23
NOTHING NEW	48	35	43	56	45	50	61	55	51	63
JUDGEMENT RESERVED	9	10	6	5	4	5	9	17	12	13
NOT ACCEPTABLE	15	19	15	16	15	9	14	10	9	14
TOTAL	90	87	87	92	92	99	108	109	108	124

OFFERS AN ADVANTAGE

- *Apremilast* (Otezla°) for oral ulcers associated with Behçet's disease (*Prescrire Int* n° 237).
- *Atidarsagene autotemcel* (Libmeldy°) in metachromatic leukodystrophy (*Prescrire Int* n° 243).
- *Azacitidine* (Onureg°) as maintenance therapy in acute myeloid leukaemia (*Prescrire Int* n° 244).
- *Nirmatrelvir + ritonavir* (Paxlovid°) in covid-19 (*Prescrire Int* n° 244).
- *Sodium oxybate* (Xyrem°) in narcolepsy with cataplexy from 7 years of age (*Prescrire Int* n° 241).
- *Pertuzumab + trastuzumab* (Phesgo°) in certain breast cancers (*Prescrire Int* n° 237).
- *Sacituzumab govitecan* (Trodelvy°) in certain breast cancers (*Prescrire Int* n° 241).
- *Sofosbuvir + velpatasvir + voxilaprevir* (Vosevi°) in hepatitis C in adolescents (*Prescrire Int* n° 246).
- *Sotrovimab* (Xevudy°) in covid-19 (*Prescrire Int* n° 239).
- *Tocilizumab* (Roactemra°) in severe covid-19 (*Prescrire Int* n° 242).
- *Tucatinib* (Tukysa°) in certain breast cancers (*Prescrire Int* n° 239).

POSSIBLY HELPFUL

- *Aciclovir* solution (Aciclovir Accord°) in herpes virus or varicella zoster virus infections (*Rev Prescrire* n° 468).
- *Cannabidiol* (Epidyolex°) in epilepsy associated with tuberous sclerosis complex (*Prescrire Int* n° 242).
- *Casirivimab + imdevimab* (Ronapreve°) in early covid-19 (*Prescrire Int* n° 237).
- *Ceftazidime + avibactam* (Zavicefta°) in infections in infants and children (*Prescrire Int* n° 240).
- *Cenobamate* (Ontozry°) in focal seizures (*Prescrire Int* n° 244).
- Prolonged-release *potassium citrate and bicarbonate* (Sibnayal°) in distal renal tubular acidosis (*Rev Prescrire* n° 463).
- *Clopidogrel* (Plavix°) in combination with aspirin in ischaemic stroke (*Prescrire Int* n° 240).
- *Dobutamine* in pre-filled syringes (Dobutamine Sun°) in low cardiac output syndrome (*Rev Prescrire* n° 469).
- *Dolutegravir* (Tivicay°) in HIV infection from 4 weeks of age (*Prescrire Int* n° 240).
- *Fostemsavir* (Rukobia°) in multidrug-resistant HIV-1 infection (*Prescrire Int* n° 237).
- *Glecaprevir + pibrentasvir* (Maviret°) in hepatitis C from 3 years of age (*Prescrire Int* n° 244).
- *Ipilimumab* (Yervoy°) + *nivolumab* (Opdivo°) in certain inoperable pleural mesotheliomas (*Prescrire Int* n° 242).
- *Morphine* orodispersible tablets (Actiskenan°) in severe pain (*Rev Prescrire* n° 466).
- *Pegcetacoplan* (Aspaveli°) in certain patients with paroxysmal nocturnal haemoglobinuria (*Prescrire Int* n° 246).
- *Pembrolizumab* (Keytruda°) as 1st line treatment for advanced oesophageal cancers (*Prescrire Int* n° 243).
- *Pitolisant* (Ozawade°) in excessive daytime sleepiness linked to sleep apnoea (*Prescrire Int* n° 244).
- *Ravulizumab* (Ultomiris°) in paroxysmal nocturnal haemoglobinuria (*Prescrire Int* n° 242).
- *Rivaroxaban* (Xarelto°) in venous thromboembolism in children and adolescents (*Prescrire Int* n° 239).
- *Setmelanotide* (Imcivree°) in certain, very rare, genetic forms of obesity (*Prescrire Int* n° 244).
- *Sumatriptan* 3 mg/0.5 ml (Sumatriptan Sun°) in migraine (*Rev Prescrire* n° 468).
- *Tozinameran* (Comirnaty°) in the prevention of covid-19 in children from 5 years of age (*Prescrire Int* n° 236).
- *NVX-CoV2373 vaccine* (Nuvaxovid°) in the prevention of covid-19 in adults (*Prescrire Int* n° 238).
- *Venetoclax* (Venclyxto°) as 1st line treatment for acute myeloid leukaemia (*Prescrire Int* n° 243).

JUDGEMENT RESERVED

- *Adalimumab* (Humira°) in ulcerative colitis from 6 years of age (*Prescrire Int* n° 240).
- *Dapagliflozin* (Forxiga°) in chronic kidney disease (*Prescrire Int* n° 239).
- *Dupilumab* (Dupixent°) in severe childhood atopic eczema from 6 years of age (*Prescrire Int* n° 236).
- *Fostamatinib* (Tavlesse°) in refractory chronic immune thrombocytopenia (*Prescrire Int* n° 239).
- *Idecabtagene vicleucel* (Abecma°) in multiple myeloma (*Prescrire Int* n° 243).
- *Ipilimumab* (Yervoy°) + *nivolumab* (Opdivo°) in certain colorectal cancers (*Rev Prescrire* n° 464).
- *Methylphenidate* (Ritaline LP°) in attention deficit hyperactivity disorder in adults (*Rev Prescrire* n° 465).
- *Osimertinib* (Tagrisso°) in certain lung cancers (*Prescrire Int* n° 245).
- *Pegvaliase* (Palynziq°) in phenylketonuria (*Prescrire Int* n° 239).
- *Pembrolizumab* (Keytruda°) in certain breast cancers (*Prescrire Int* n° 244).
- *Risdiplam* (Evrysdi°) in spinal muscular atrophy (*Prescrire Int* n° 242).
- *Selpercatinib* (Retsevmo°) in certain lung or thyroid cancers (*Prescrire Int* n° 236).
- *Vosoritide* (Voxzogo°) in achondroplasia (*Prescrire Int* n° 245).

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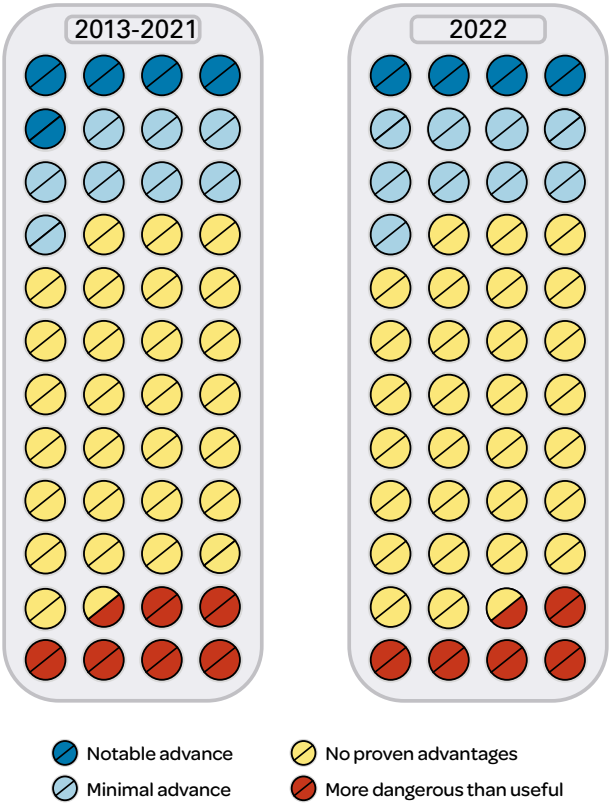
NOT ACCEPTABLE

- *Drospirenone + estetrol* (Drovelis°) for oral contraception (*Prescrire Int* n° 241).
- *Esketamine* (Spravato°) in depression with a high risk of suicide (*Prescrire Int* n° 238).
- *Icosapent ethyl* (Vazkepa°) in cardiovascular prevention (*Prescrire Int* n° 245).
- *Liraglutide* (Saxenda°) in obesity in adolescents (*Prescrire Int* n° 242).
- *Luspatercept* (Reblozyl°) in anaemia associated with myelodysplastic syndrome or with beta-thalassaemia (*Prescrire Int* n° 245).
- *Natalizumab* (Tysabri°) for subcutaneous use (*Rev Prescrire* n° 464).
- *Ozanimod* (Zeposia°) in multiple sclerosis (*Prescrire Int* n° 237).
- *Pemigatinib* (Pemazyre°) in cholangiocarcinoma (*Prescrire Int* n° 243).
- *Ponesimod* (Ponvory°) in multiple sclerosis (*Prescrire Int* n° 240).
- *Peanut protein* (Palforzia°) for oral desensitisation (*Prescrire Int* n° 238).
- *Relugolix + estradiol + norethisterone* (Ryeqo°) in uterine fibroids (*Prescrire Int* n° 244).
- *Roxadustat* (Evrenzo°) in anaemia associated with chronic kidney disease (*Prescrire Int* n° 245).
- *Opium tincture* (Dropizal°) in severe diarrhoea (*Rev Prescrire* n° 466).

Therapeutic advances in 2022 compared with the previous 9 years



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Prescrire's ratings

Our judgement is based on the therapeutic advance of the product in the relevant clinical situation. It considers not only the inherent value of each product in terms of its harm-benefit balance, but also its advantages and disadvantages relative to existing treatments. Note that the relative value of new products can vary from one country to another.

BRAVO
The product is a major therapeutic advance in an area where previously no treatment was available.

A REAL ADVANCE
The product is an important therapeutic advance but has certain limitations.

OFFERS AN ADVANTAGE
The product has some value but does not fundamentally change current therapeutic practice.

POSSIBLY HELPFUL
The product has minimal additional value, and should not change prescribing habits except in rare circumstances.

NOTHING NEW
The product is a new substance but with no evidence that it has more clinical value than other substances of the same group. It can be a me-too or a near me-too.

NOT ACCEPTABLE
Product without evident benefit but with potential or real disadvantages.

JUDGEMENT RESERVED
The editors postpone their rating until better data and a more thorough evaluation of the product are available.

Quality of information from pharmaceutical companies

In response to our systematic requests

Company provided detailed information including unpublished data and packaging items.

Company provided information limited to published administrative data or packaging items.

Company provided minimal information, mainly administrative and packaging items.

Company provided no information.

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