THE PRESCRIRE AWARDS FOR 2022

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2022 Prescrire Drug Awards

Every month, *Prescrire*'s Editorial Staff help our readers decide which of the multitude of newly authorised products or indications are worth adding to their list of useful treatment options, and which are to be avoided. We do this by conducting systematic analyses of the relevant evaluation data available on new drugs, new indications, new pharmaceutical forms and new dose strengths authorised in Europe or in France. European authorisations account for the majority, and these are the focus of our English edition, *Prescrire International*. The 2022 Prescrire Drug Awards are based on the analyses published in the Marketing Authorisations section of our French edition in 2022.

Prescrire's multidisciplinary team has been conducting and publishing independent drug analyses for 42 years, free from the influence of any companies or organisations involved in the healthcare sector.

No Pilule d'Or in 2022, and only two drug awards

None of the drugs examined by Prescrire in 2022 represented a major therapeutic advance worthy of a Pilule d'Or (Golden Pill Award). Only two drugs received an award, one earning a place on the Honours List and the other a place on the Noteworthy list.

Honours List: nirmatrelvir + ritonavir (Paxlovid°) in covid-19: fewer complications in symptomatic patients at risk of developing severe disease. A 5-day course of the combination of *nirmatrelvir (a Sars-CoV-2 protease inhibitor)* + *ritonavir* (an inhibitor of the cytochrome P450 isoenzyme CYP3A4) was compared with placebo in a double-blind randomised trial in 2246 adults with covid-19 who had had symptoms for 5 days at most, but showed no signs of severe disease. Most were infected with the Sars-CoV-2 Delta variant, and they all had at least one risk factor for developing severe covid-19 (mainly obesity, hypertension or diabetes). Only 22% of them were aged 60 years or over. None of the patients had been vaccinated against covid-19, but half of them had anti-Sars-CoV-2 antibodies, indicating prior infection with this virus. In the month following the start of treatment, 0.8% of patients in the *nirmatrelvir* + *ritonavir* group were hospitalised, versus 6% in the placebo group ($p<0.0001$).

Epidemiological data from a later period suggest that *nirmatrelvir* + *ritonavir* reduces the risk of hospitalisation or death due to covid-19 in adults when the Omicron variant is predominant, including in those vaccinated against covid-19. These data provide lower-quality evidence than the results of the single trial available, but they are consistent with the trial data, which is not surprising given that the mechanism of action of this combination is independent of the spike protein mutations that characterise the different Sars-CoV-2 variants. Very little is known about *nirmatrelvir*'s adverse effects. Treatment with *nirmatrelvir* + *ritonavir* is difficult to manage due to the risk of major drug interactions and the risk of overdose in patients with renal impairment.

The combination of *nirmatrelvir* + *ritonavir* was developed sufficiently rapidly to reduce the number of hospitalisations and limit the burden placed on hospitals by covid-19, especially when infection rates were at their highest, thus earning it a place on the 2022 **Honours List**.

Noteworthy: azacitidine (Onureg°) as "maintenance" therapy in acute myeloid leukaemia: substantially longer survival. The cytotoxic drug *azacitidine* was evaluated as oral "maintenance" therapy in acute myeloid leukaemia in a single double-blind randomised placebo-controlled trial in 472 patients, aged 55 years or over, enrolled within 4 months of achieving remission. Median survival in the *azacitidine* group was longer than in the placebo group: 25 months versus 15 months.

Azacitidine can cause serious adverse effects, including haematological and gastrointestinal disorders, dyspnoea, pericarditis and necrotising fasciitis.

Azacitidine (Onureg°) was awarded a place as a **Noteworthy** drug because of the substantial increase in survival it offers a group of patients whose prognosis is poor. It failed to earn a place on the Honours List due to the severity of its adverse effects, which reduce patients' quality of life, and because these trial results have yet to be confirmed in another trial.

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2022 Pilule d'Or/Golden Pill

A Pilule d'Or (Golden Pill) is awarded to drugs that represent a major therapeutic advance in a particularly poorly served field.

Not awarded in 2022

2022 Honours List

Drugs included on the Honours List constitute a clear advance for some patients compared with existing therapeutic options, albeit with limitations.

Paxlovid° (*nirmatrelvir + ritonavir*)
Pfizer

In adults with mild to moderate symptomatic covid-19, at risk of developing severe covid-19 (Prescrire Int n° 238 and 244).

Noteworthy in 2022

Drugs deemed "Noteworthy" provide a modest improvement in patient care.

Onureg° (*azacitidine*)
Bristol-Myers Squibb

In acute myeloid leukaemia, as "maintenance" therapy (Prescrire Int n° 244).

2022 Information Awards

Prescrire's annual Information Awards are based on the quality of the documentation and information provided by pharmaceutical companies in response to requests by Prescrire's Editorial Staff. We use this documentation when analysing new products or new indications and preparing the articles published in the Marketing Authorisations section of our French edition. Prescrire's Information Awards focus on the transparency or secrecy companies have exhibited over the year in response to our requests for information and documentation.

What documentation and information do we request from pharmaceutical companies? The information which pharmaceutical companies hold on their drugs, from the earliest stages of development to data collected after their market introduction (or in some cases after their market withdrawal), is important for health care and patient safety.

Prescrire primarily asks pharmaceutical companies to send us information concerning: efficacy and safety data; packaging items; and the conditions under which patients can access the drug, in particular whether it is reimbursed (by the French national health insurance system), the planned date of its market introduction or the reasons for its market withdrawal. We compare and contrast the data thus obtained with those gathered from the other sources we consult as part of a systematic search for information, including health authorities and the scientific literature.

Six companies honoured for their transparency. Prescrire requested information from 92 pharmaceutical companies in 2022. Six of them chose to be open, which they demonstrated by providing detailed, appropriate documentation in response to our requests. These companies earned a place on the 2022 Information Awards Honours List. Three of them – Arrow Génériques, EG Labo and Rhythm Pharmaceuticals – were rated as "Outstanding", because they sent us particularly useful, detailed, explanatory documents and information in an extremely timely manner, sometimes without being asked.

All of the companies on the 2022 Information Awards Honours List supplied documents or information that are not publicly available, such as:

– Clinical study reports (CSRs), containing details on the protocols and results of clinical trials.

– Pharmacovigilance documents that are not in the public domain, which pharmaceutical companies submit to health agencies on marketed drugs, or agencies' assessment reports on these documents. These detailed pharmacovigilance data improve our understanding of the drug's risks outside the clinical trial setting.

– Documentation submitted to the French National Authority for Health (HAS) to request eligibility for reimbursement by the national health insurance system or approval for use in hospitals. These documents contain useful clinical and administrative data.

– Information concerning the timeline for the market introduction of generic drugs and market withdrawals.

All of these companies acted in patients' interests by helping inform healthcare professionals about their drugs through Prescrire's analyses.

But the vast majority of companies chose secrecy. Many more pharmaceutical companies responded to Prescrire's requests by sending too little information, too irregularly or too late. These companies (13 of the 92 companies we contacted in 2022) received an Information Red Card, indicating persistent and multiple deficiencies in the provision of information.

Some companies did not respond at all to Prescrire's requests, including several companies that market vaccines, a therapeutic field in which greater transparency might help reduce some people's distrust of vaccines.

Other companies failed to respond in a timely manner or omitted the most important or sensitive data.

And some companies only responded to our repeated requests once our article had been published. Only then did they send us the documentation on which they based their rebuttal of Prescrire's analysis.

Continue to demand transparency until it becomes a principle. Drug companies and agencies hold a wealth of documents analysing detailed clinical data but, as of 2022, it is clearly still difficult, if not impossible, for healthcare professionals and independent teams such as Prescrire to gain access to them. The few pharmaceutical companies that respect the principle of transparency show that it is feasible. It is high time the rest of the industry viewed this principle as a priority.

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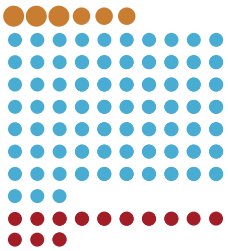
Prescrire Information Awards

Of the 92 companies we contacted for information



6 companies made the Honours List

73 companies not on the Honours List but not given a Red Card

13 companies given a Red Card

Honours List

Outstanding: Arrow Génériques, EG Labo, Rhythm Pharmaceuticals

Followed by:
Bioprojet Pharma, Delbert, Pharmanovia

Red Cards

Amgen, Bayer Healthcare, Gedeon Richter, Incyte Biosciences, Janssen Cilag, Menarini, MSD, Pfizer, Pharma Blue, Sanofi Aventis, Sanofi Pasteur, Shionogi, Zentiva