2023 Prescrire 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 preparing the articles published in the Marketing Authorisations section of our French edition. Prescrire's Information Awards focus on the level of transparency that companies have exhibited over the year in response to our requests for information and documentation.

What information does Prescrire request from pharmaceutical companies, and why? In addition to the information Prescrire gathers through a systematic search of the scientific literature and documentation provided by health authorities, we systematically ask pharmaceutical companies to send us data on their drugs, from marketing authorisation through to post-marketing surveillance.

We primarily ask for data on efficacy and adverse effects, packaging items, the conditions under which patients can access the drug, its reimbursement status in France, the planned date of its market introduction or the reasons for its market withdrawal.

We request all of this information in order to provide healthcare professionals with updated scientific knowledge with which to evaluate the harm-benefit balance of the drug in question, promote the correct use of drugs and help ensure patient safety, and also to share practical information about availability, reimbursement and so on.

Transparency very often limited. Prescrire requested information from 89 pharmaceutical companies in 2023.

Six of them earned a place on the 2023 Information Awards Honours List, by responding with detailed documentation that addressed every aspect of Prescrire's requests. Four of them were rated as "Outstanding" for sending particularly useful information and documents in a timely manner: Amryt Pharmaceuticals, EG Labo, Ever Pharma, and Theravia (formerly Cell Therapies Research & Services).

The pharmaceutical companies on the 2023 Information Awards Honours List chose to be open, and demonstrated that transparency is feasible, by providing documents or information that are not publicly available, such as:

– Clinical study reports (CSRs), which contain details on the protocols and results of clinical trials, especially on adverse effects;
– Periodic safety update reports (PSURs), which enable a better understanding of the drug's adverse effects;
– 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 about when their monopoly will end, and when generic versions of the drug can be marketed;
– Information about the date the drug will enter the market;
– Packaging items.

Conversely, 13 pharmaceutical companies chose to withhold information from Prescrire. They failed to respond to repeated requests, some claiming that they do not have time, while others clearly indicated their choice not to provide information to Prescrire. These companies received an information "Red Card" (see figure).

Transparency: not just a principle, but a duty for drug companies. Pharmaceutical companies hold a wealth of documents that they usually make inaccessible to the public, in particular certain evaluation data. European citizens have the right to access clinical data on which marketing authorisations are based. Evaluation data are not confidential data. In fact, the European Ombudsman considered the argument that disclosure of clinical study reports could undermine companies' commercial interests to be unfounded. The European Medicines Agency (EMA) itself deemed as "releasable" documents containing clinical data received in connection with European evaluations, such as PSURs and CSRs. And when the EMA was challenged by pharmaceutical companies for having divulged these data, the European Court of Justice ruled in the EMA's favour. Pharmaceutical companies have a duty to provide medical information, and this includes a responsibility to share clinical data.

It is possible to provide high-quality information, but it remains the exception. In 2023, some pharmaceutical companies showed that a commitment to openness and a company policy of transparency are possible. They serve as examples for all the others to follow.

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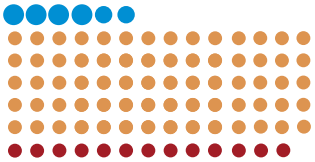
Of the 89 companies we contacted for information



- **6 companies made the Honours List**
- **70 companies not on the Honours List not given a Red Card**
- **13 companies given a Red Card**

Honours List

Outstanding:
Amryt Pharmaceuticals, EG Labo, Ever Pharma, Theravia (formerly Cell Therapies Research & Services)

Followed by:
Arrow Génériques, Lundbeck

Red Cards

Alk-Abelló, Amgen, Bayer Healthcare, Bristol-Myers Squibb, Genzyme (Sanofi Group), Incyte Biosciences, Janssen Cilag, Kyowa Kirin Pharma, Menarini, MSD, Sanofi Aventis (Sanofi Group), Vifor Fresenius Medical Care Renal Pharma, X.O.

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