

2009 Prescrire Information Awards



The Information Awards focus on the quality of the information provided to *Prescrire* by the pharmaceutical companies whose products we examined in the New Products section of our French edition during the previous year (in 2009: issues 303 to 314).

Prescrire's review articles dealing with new drugs and indications are based on a thorough literature search for documents relating to the drug's pre-approval assessment, especially clinical trial reports.

In addition to textbooks and bibliographic databases, editors search the websites of drug regulatory agencies (a), health economics institutions, health technology assessment agencies and other institutions specialising in the relevant therapeutic field. We also search other independent journals belonging to the International Society of Drug Bulletins (ISDB), and any independent institutions that have evaluated the drug in question.

Assessing drug company transparency. We also request relevant information from the companies that market each drug we analyse in France, to ensure that we take into account all documents, including unpublished data, used to justify marketing approval or to modify an existing marketing authorisation. Such unpublished data (for example, clinical reviews) may be held by the drug regulatory agency that examined the application and by the company that obtained marketing authorisation.

As with the other *Prescrire* Awards, a systematic and totally independent process is used to grant the Information Awards (rules available on our website, at www.english.prescrire.org).

Rewarding accountable companies. Some drug companies respond to our requests for information in a timely manner and provide us with thorough and relevant documentation, including unpublished data.

These companies are mentioned on the Honours List. Fewer generic manufacturers are included on the list since *Prescrire* decided not to examine all new generics (b)(1).

The companies rated as "Outstanding" provided us with exhaustive and detailed information without delay, sometimes without being asked.

What do unhelpful companies have to hide? Other drug companies either fail to respond to our requests for information or provide only limited

data. They tend to delay their response as long as possible, i.e. only after publication of the opinion of the French Transparency Committee (that assesses the comparative effectiveness of new drugs and provides advice on drug reimbursement), or of the price in the *Journal Officiel* or after the launch of their advertising campaign. They may also omit the most relevant data, claiming to be too busy, that the administrative services are too slow or that the clinical data in question are confidential.

Other companies withhold information as a kind of retaliation because they did not like one of our earlier product reviews. Few pharmaceutical companies persistently withhold information. For patients' sake, we hope that refusal of transparency or lack of respect for the independence of the editorial staff of *Prescrire* and its subscribers do not constitute reasons for withholding information.

"Red cards" for withholding information are a way of highlighting persistent shortcomings in the provision of information by certain drug companies and a way of encouraging more openness.

Take into account drug company transparency when choosing a drug. A drug company's commitment to transparency is the fifth factor to be taken into account when choosing a drug, after efficacy, safety, convenience and price. When two drugs are otherwise indistinguishable, then it is in patients' and healthcare profession-

als' best interests to select the product marketed by a company that puts its cards on the table and does not hide information, including the limitations of their products.

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a- Drug regulatory agencies release some clinical and administrative data to healthcare professionals and patients by publishing their public assessment reports, post-marketing follow-up data, and detailed reasons for changes made to marketing authorisation, and through rapid online publication of summaries of product characteristics (SPCs). The European Medicines Agency (EMA) and the French Health Products Safety Agency (Afsaps) still have some way to go.

b- We continue to contact generic manufacturers to ask for administrative information, particularly about patents and marketing of generic drugs.

1- Prescrire Rédaction "Mieux faire face à l'avalanche de copies" *Rev Prescrire* 2007; **27** (280): 106.

Whenever we examine a new drug, the article is accompanied by one of four pictograms rating the transparency of the company concerned for their response to our requests for information about their product (see this issue p. 67).

Honours list (in alphabetical order)

- **Outstanding** : Janssen-Cilag and Sanofi Pasteur MSD
- **Followed by** : Bouchara-Recordati, EG Labo, GlaxoSmithKline, Leo, Mundipharma, and Nycomed

Red cards (in alphabetical order)

- **Amgen, Bayer Schering, Lilly, Menarini, Pfizer, Sanofi Aventis, Servier, and Teva Pharma**