Onsenal®: marketing authorisation withdrawn in the European Union

Company failed to supply required data

In early 2011, the company had still not provided these data, because of slow enrolment in the trial. It therefore asked that marketing authorisation be withdrawn (1,2).

This is an example representative of the failings of current EU health policies: marketing authorisation is increasingly granted on the basis of insufficient data. Yet, even with the simplified procedure, companies often fail to fulfil their obligations.

Selected references from Prescrire’s literature search.
2- EMA “Public statement on Onsenal (celecoxib)” 1 April 2011: 2 pages.

Quality of information from pharmaceutical companies

In response to our systematic requests
- The product is a major therapeutic advance in an area where previously no treatment was available.
- The product is an important therapeutic innovation but has certain limitations.
- The product has minimal additional value, and should not change prescribing habits except in rare circumstances.
- The editors postpone their rating until better data and a more thorough evaluation of the drug are available.
- Product without evident benefit but with potential or real disadvantages.

The INN of another antifungal drug derived from miconazole, bifonazole, does not include the key stem -conazole, but simply the letters “onazole” (1).