Onsenal°: marketing authorisation withdrawn in the European Union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 It therefore asked that marketing authorisation be withdrawn (1,2).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.

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

A drug’s real name

INN

INTERNATIONAL NONPROPRIETARY NAME

COMMON STEM -conazole

The international nonproprietary names (INN) of antifungal drugs derived from miconazole end in -conazole (1,2).

On 21 June 2011 there were 42 substances of this type on the World Health Organization (WHO) list of INNs (3). Thirteen of them are marketed in France, for topical application (cutaneous, vaginal, etc.), oral administration or injection, namely econazole, fenticonazole, fluconazole, isoconazole, itraconazole, ketoconazole, miconazole, omoconazole, oxiconazole, posaconazole, sertaconazole, tioconazole, and voriconazole.

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

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Selected references from Prescrire’s literature search.
3- “Substances names ending with conazole”. Mednet.who.int accessed on 21 June 2011: 2 pages.

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Company provided detailed information including unpublished data and packaging items.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 administrative and published data.

Company provided minimal information, mainly administrative data.

Company provided no information.

Prescrire's ratings

Our judgement is based on the therapeutic advance of the new product. It considers not only the inherent value of each product in terms of its risk-benefit balance, but also its advantages and disadvantages relative to existing products available in France. 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 innovation but has certain limitations.

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

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

NOTHING NEW: The product may be a new substance but is superfluous because it does not add to the clinical possibilities offered by previous products available. In most cases it concerns a me-too product.

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

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

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