Translated from ***Rev Prescrire*** **July 2011; 31 (333): 498**

Onsenal°: marketing authorisation withdrawn in the European Union

Company failed to supply required data

● **An example representative of the drawbacks of the insufficiently demanding marketing authorisation procedure.**

In late March 2011, European marketing authorisation for Onsenal° (*celecoxib*; Pfizer) was withdrawn at the company's request (1,2). Onsenal° had been marketed in France since late 2010.

This nonsteroidal anti-inflammatory drug, a "selective" cox-2 inhibitor, was authorised in the European Union for "*the reduction of the number of adenomatous intestinal polyps in familial adenomatous polyposis*", despite a negative harm-benefit balance (2,3). The efficacy of *celecoxib* in terms of colorectal cancer prevention has not been demonstrated, but its adverse effect profile is particularly unfavourable and includes haemorrhage and cardiovascular disorders (3). Marketing authorisation had been granted in 2003 under "*exceptional circumstances*" (**a**), with the company obligated to continue the assessment in order "*to provide further data*" (1,2).

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 It therefore asked that marketing authorisation be withdrawn (1,2).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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a- Marketing authorisation is granted under "exceptional circumstances" when epidemiological, scientific or ethical considerations mean that a drug cannot be fully evaluated (ref 4).

Selected references from Prescrire's literature search.

1- Commission européenne "Décision (...) retirant, à la demande du titulaire, l'AMM du médicament "Onsenal"" 24 March 2011 + "Annexe II-Onsenal" 28 July 2010: 6 pages in total.

2- EMA "Public statement on Onsenal (celecoxib)" 1 April 2011: 2 pages.

3- Prescrire Editorial Staff "Celecoxib: colorectal cancer: no preventive benefit" *Prescrire Int* 2006; **15** (81): 13-15.

4- Prescrire Rédaction "Dérogations à l'AMM "classique"" *Rev Prescrire* 2008; **28** (299): 696-701.

A drug's real name **INN** INTERNATIONAL NONPROPRIETARY NAME

Translated from ***Rev Prescrire*** **September 2011; 31 (335): 662**

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 "onazole" (1).

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Selected references from Prescrire's literature search.

1- WHO "The use of stems in the selection of INN. WHO/EMP/QSM/2009.3": 75-76.

2- Prescrire Rédaction "le suffixe du mois -conazole" *Rev Prescrire* 1991; **11** (112): 520.

3- "Substances names ending with conazole". Mednet.who.int accessed on 21 June 2011: 2 pages.

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.

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.

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