Onsenal®: marketing authorisation withdrawn in the European Union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In late March 2011, European marketing authorisation for Onsenal® (celecoxib; Pfizer) was withdrawn at the company’s request (1,2).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 It therefore asked that marketing authorisation be withdrawn (1,2).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.

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

Translation 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).

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