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Decisions that put patients at risk

Celecoxib has been on the market under the brand name Celebrex° for about ten years for the treatment of rheumatic disorders, even though it is no more effective than non-steroidal anti-inflammatory drugs such as *ibuprofen*, and has more adverse effects (French edition n° 314).

Celecoxib is now approved for use in familial adenomatous polyposis, under the brand name Onsenal° (French edition n° 325). The EU authorities initially authorised Onsenal° in 2003, for use under "exceptional circumstances"; in particular, Pfizer was required to conduct an additional clinical trial (the CHIP study) (1). Seven years later, in 2010, this trial was still underway. The Onsenal° summary of product characteristics (SPC) still notes that: "*The effect of Onsenal-induced reduction of polyp burden on the risk of intestinal cancer has not been demonstrated*"; nevertheless, Onsenal° remains on the market (1).

Having authorised *etoricoxib* in 2009, after several years of wrangling (French edition n° 311 and *Prescrire Int* n° 108 page 158), drug regulatory agencies have once again failed to act in patients' best interests. Despite their mission to protect patients from harmful medicines, they authorise products that provide no therapeutic advantage over existing products and belong to drug classes that carry well-documented risks. In the case of Onsenal°, the company is creating false hope for patients, while the wait for effective prevention goes on.

Healthcare professionals must continue to inform and protect patients who are put at unnecessary risk as a result of irresponsible official decisions.

Prescrire

1- European Commission "SPC Onsenal" + "Specific obligations to be fulfilled by the marketing authorisation holder" 28 July 2010: 32 pages.