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Fingolimod (Gilenya°): EMA's lack of transparency spells danger for patients

The European Medicines Agency (EMA) refused to supply Prescrire with data on cases of death following the first dose of *fingolimod* (*Gilenya°*). Below are a summary of the press release issued by *Prescrire* on 20 February 2012, and an update detailing EMA'S latest refusal.

- *Fingolimod* (Gilenya°) is an immunosuppressant authorised since March 2011 by the European Medicines Agency (EMA) for certain patients with multiple sclerosis.
- The pre-marketing evaluation data already revealed cardiac arrhythmia, among other disorders. In April 2011 *Prescrire* recommended limiting use of *fingolimod* to rigorously supervised clinical trials.
- In December 2011, the US Food and Drug Administration (FDA) reported the sudden death of a patient within the first 24 hours of taking *fingolimod*.
- On 22 December 2011, in response to the FDA alert and faced with the EMA's silence, *Prescrire* asked the EMA for a review of the serious adverse effects of fingolimod and for the initial European Periodic Safety Update Report (PSUR).
- On 23 January 2012 EMA informed *Prescrire* that its request for information dated 22 December was rejected, on the grounds that a European re-evaluation of fingolimod was under way: the re-evaluation had been initiated 3 days earlier.
- On 7 February 2012, *Prescrire* reiterated its information request, this time to the EMA Director Guido Rasi.
- Once again the European Agency is refusing to provide patients and healthcare professionals with important information on adverse effects. They give the benefit of the doubt to drug companies rather than to patients, and dispense information about adverse effects only sparingly.
- It is high time that the EMA get back to its primary mission: protecting patients' health, which should take precedence over protecting the financial interests of pharmaceutical companies.
- UPDATE: on 27 February EMA's Director reiterated the Agency's rejection of Prescrire's request for information on *fingolimod*.

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