Evaluate before authorising

In 2013, the initial evaluation in support of the marketing authorisation for *insulin degludec* (Tresiba°) warranted a cautious approach. The data showed that it had similar efficacy to other long-acting insulins but suggested it may increase the risk of cardiovascular events.

Yet despite this safety signal, the European Medicines Agency (EMA) recommended the marketing authorisation, which the European Commission promptly granted. The US Food and Drug Administration (FDA), on the other hand, rejected the application and requested a specific trial in thousands of patients to evaluate the cardiovascular risk in greater depth.

The pharmaceutical company complied with the FDA's request. And on the basis of results showing no particular cardiovascular risk, the FDA subsequently approved the drug (see pp. 64-66).

This outcome may appear to support the EMA's stance. But the EMA had chosen an incautious approach, exposing numerous patients to a potentially dangerous drug that had no tangible advantages to justify such a gamble. Knowing that once marketing authorisation has been granted, years can go by before studies of sufficient methodological quality are obtained (see *Prescrire Int* n° 190, p. 54). And knowing that even once a drug is proven to have severe or even fatal effects, it often takes months, if not years, to withdraw its marketing authorisation (*Prescrire Int* n° 184, p. 195).

Patients, and society in general, have a legitimate right to expect a drug's adverse effects to have been thoroughly evaluated before it is authorised and before it is used.

Prescrire

▶ Translated from *Rev Prescrire* **November 2018**
Volume 38 N° 421 • Page 804

EDITORIAL