Protecting patients

In December 2019, *Prescrire* published its annual review of drugs to avoid, for the eighth time (free download at english.prescrire.org). This new review shows that many drugs remain authorised for years despite an unfavourable harm-benefit balance – and that is just the tip of the iceberg. For many new drugs which are not included, marketing authorisation remains poorly justified as a result of inadequate initial evaluation.

When a drug is authorised through the centralised European procedure following a favourable opinion from the European Medicines Agency (EMA), this marketing authorisation is imposed on all member states of the European Union. This decision can be called into question by a national drug regulatory agency, but the European authorities hold the balance of power and the European authorisation applies to all member states. At the EMA, however, commercial interests are often better defended than the interests of patients.

How then can patients and community resources be protected? In France, the Transparency Committee of the National Authority for Health (HAS), which provides recommendations on reimbursement by the national health insurance system, can exert some leverage by advising against reimbursement of drugs, even if they have been authorised in the European Union. It plays an important role in access to drugs and it can sometimes be stubborn. For example, it repeatedly issued negative opinions because of the lack of evidence that gliflozins (SGLT2 inhibitors) reduce the complications of type 2 diabetes, whereas these oral hypoglycaemic drugs carry a risk of amputation, ketoacidosis, and necrotising fasciitis of the perineum (see p. 72 of this issue).

That is not the only example. In 2019, France's Transparency Committee issued eight opinions of this type. The reasons were inadequate risk assessment, uncertain efficacy, or an unfavourable harm-benefit balance. This last reason was invoked in 2018 with regard to Lartruvo° (*olaratumab*) for soft tissue sarcoma. One year later, the European authorities justifiably withdrew the marketing authorisation for this drug (see p. 82). Another example is *padeliporfin* in prostate cancer (see p. 74). Reassessment of old drugs has also led this Committee to issue some unfavourable opinions regarding reimbursement (see p. 68).

We welcome this protective action by the Transparency Committee in France, while emphasising that withdrawal of marketing authorisation, or taking a drug off the market, is a better way to protect patients, at both the national and European levels, rather than merely not supporting its reimbursement in one of the member states.

Prescrire

▶ Translated from *Rev Prescrire* **December 2019**
Volume 39 N° 434 • Page 881

EDITORIAL