

# Brexit

The United Kingdom's announced exit from the European Union means that the European Medicines Agency (EMA) will most likely leave London.

Could the City, just a few underground stops away from the EMA offices, be influencing the EMA in its evaluation of the harm-benefit balance of drugs when it gives an opinion about European marketing authorisations (MAs)? Some of the European Public Assessment Reports give the impression that the EMA defends trade and puts the pharmaceutical industry's plans well ahead of patients' interests.

The EMA too often accepts inadequate evaluation. To cite a few recent examples, it accepted evaluations that lacked trials comparing the drug with the current standard of care (see *secukinumab* in psoriatic arthritis on p. 62 of this issue); that consisted of incomplete, fragmentary data (see *idarucizumab* in issue n° 177); or that hinged on minimal data and a statistically significant test, as was the case for *capsaicin*, a treatment for neuropathic pain that initially worsens pain (see page 65).

The EMA's relocation could be an opportunity for radical reform. Europe could then have an EMA that acts first and foremost in the interests of patients; an EMA that sets its sights on rigorous, independent examination of every aspect of applications before granting or refusing MAs, rather than on accelerated market access through adaptive pathways; an EMA that protects patients through its prudence before allowing a drug on the market and through proactive pharmacovigilance thereafter, rather than delegating this task to the company that markets the drug.

In summary, this could be an opportunity for the EMA to distance itself from financial interests, and focus on important patient interests instead.

## Prescire

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