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It's official... but not infallible

Evaluation of first-line *maraviroc* therapy for HIV infection is examined on pages 252-254 of this issue, even though this is an off-licence use in Europe. We took this unusual step because first-line use of recent antiretroviral drugs is controversial.

We have very little follow-up with these new drugs, whereas the efficacy of older antiretrovirals on viral load and CD4+ T lymphocytes is known to correlate with a marked reduction in morbidity and overall mortality. In particular, nothing is known of the long-term adverse effects of recent antiretroviral drugs, which could potentially outweigh their benefits compared to existing options.

The company that sells *maraviroc* has obtained a licence extension for first-line use in the United States, whereas the European Medicines Agency finally rejected this appli-

cation, a decision endorsed by the European Commission.

Confronted with the same uncertainties and the same set of clinical data, the US and EU regulatory authorities came to different decisions. Official decisions, including marketing authorisation, are not scientific truths but human, often controversial, and reversible choices.

Marketing authorisation is an important factor for informed treatment choices by patients and healthcare professionals, but clinical data are more trustworthy than regulatory decisions.

This applies to all official decisions, including court rulings: see the example of ketoprofen gel on page 204 of *Prescrire International* issue 109 and in the coming issue.

Official does not mean infallible.

Prescrire