A minority of patients likely to benefit.

In the Y1 trial, only 14 of the 48 patients completed the trial with a 50% reduction in seizure frequency. In the trial including 252 patients, the study population was not stratified according to failure of a previous treatment, undermining the strength of evidence provided by the results. In the non-comparative trial in 170 patients with “refractory” epilepsy, only 12 patients found topiramate monotherapy satisfactory. Topiramate therefore appears to have a positive risk-benefit balance in only a minority of patients.

Marketing authorisation can be granted regardless of the number of patients likely to benefit. Also, French Transparency Commission opinions do not take into account the size of the target population when estimating the ‘added therapeutic value’. In the present case, the Commission concluded that the ‘added therapeutic value’ was moderate. For our part, we concluded that topiramate offers an advantage.

In short, Thierry Moreau Defarges’ detailed letter in no way challenges our conclusions.