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Astellas' lawsuit against Prescrire: French court rules that Prescrire did not "denigrate" Protopic[®] (tacrolimus)

● A Paris court handed down its ruling on 2 March, rejecting a suit brought by pharmaceutical company Astellas against the French journal *Prescrire*. At a time when French society is reeling in the wake of the scandal caused by weight-loss drug Mediator[®] (benfluorex), the 2 March ruling comes as very good news for healthcare professionals and for patients.

In its September 2009 French edition, *Prescrire* analysed a new indication for topical tacrolimus (Protopic[®], from Astellas) in the prevention of outbreaks of atopic eczema.

Prescrire concluded its 2009 article, which is a continuation of an in-depth review published in 2003, by saying that tacrolimus should be avoided in atopic

eczema, in view of its unfavourable harm-benefit balance.

The drug company Astellas Pharma filed suit against *Prescrire* on the grounds of "denigration", protesting against the "erroneous, or even deceitful, nature of certain critiques contained in the disputed article".

The Tribunal de Grande Instance de Paris delivered its ruling on 2 March, rejecting the suit brought by drug company Astellas. The judges indeed found that *Prescrire* "did not exceed the legitimate objective that it had set for itself, nor the expectation on the part of its subscribers to have access to a documented critical analysis on a subject which falls into the domain of public interest and healthcare safety".

What is at stake in a decision of this kind, as *Prescrire's* lawyers Jean Martin and Guillaume Prigent pointed out, is recognition of the right to information

and the right to criticise, unimpeded by the official position of health authorities, by the kind of censorship that Astellas was attempting to impose. This right must nonetheless be supported by rigorous and fully documented analysis, which the court recognised was indeed the case with *Prescrire's* article.

At a time when French society is reeling in the wake of the Mediator[®] scandal and the failings of its drug regulatory authorities, the 2 March ruling comes as very good news for healthcare professionals and for patients.

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INN-based prescribing: a good practice not widely adopted in France

● Too few French prescribers use international nonproprietary names (INNs).

The international nonproprietary name (INN), selected by the World Health Organization, is a drug's real name. INNs represent an independent and universal system of names for drugs that promotes proper use (1,2).

By using international nonproprietary names (INNs), health professionals can focus their attention on drugs' therapeutic properties and reduce the risk of potentially harmful confusion, especially for patients (1,2).

Fewer than 1 in 8 drugs prescribed using the INN system; strong regional disparities. The National Federation of French Mutual Health Insurers (Fédération nationale de la mutualité française, FNMF), the key organisation representing insurers, regularly examines the use of INNs in the prescription of

medicines (3). The rate of prescription using the INN was evaluated as a "proportion of prescriptions written for reimbursable drugs in metropolitan France, for out-patients" (3). In mid-2010, 12.4% of drugs were prescribed using the INN (13.7% of prescriptions among general practitioners and 5.2% among specialists) (a)(3).

Wide regional variations were noted: more than 15% of physicians in northern and western France used the INN system, compared to only 8.3% of physicians in southeastern France (3).

Mostly generics. Nearly 20% of generics were prescribed using the INN in February 2010, versus only 4.3% of drugs still under patent protection (4).

Note that the use of INNs has been mandatory for prescription of generic drugs in France since 2008 (3-5).

Think in terms of the "INN" first, whatever the drug. Efforts must be made at every level if the use of INNs is to be widely adopted by healthcare professionals, starting with university lecturers and clinician educators in hospital, as well as by government agencies and health insurers responsible for disseminating official information on drugs.

Brand names are too often used instead of INNs during initial training. In a 2006 survey of *Prescrire* subscribers, 33% of students in medicine and pharmacy replied that INNs were mainly used in their academic course work, but the rate was only 28% during their community-based clinical training and 2.6% during their hospital-based clinical training (6).

There is still a long way to go before prescribing using the INN becomes ►►

a- In comparison, 81% of prescriptions in the United Kingdom are based on INNs; UK physicians are made aware of the importance of using INNs during their training, and the British National Formulary (BNF) uses the INN system (refs 7,8). In Germany, only 35% of prescriptions are based on INNs (ref 8).