more or less explicitly and consciously, this blurring of roles is frequently not in the patients' best interests, because pharmaceutical companies are closer to the centre of power.

It would be better to replace such tacit agreement on compromise solutions with debates between the concerned parties, each clearly stating its interests and defending them passionately or even fiercely. Is open, explicit debate not a better way of airing and defending opposing interests than an implicit, vague consensus, reached behind closed doors?

## Unhealthily close links between the various experts or authorities

The Mediator° scandal and the debates it provoked made the general public aware of the concept of conflicts of interest: because influential individuals work both on behalf of the pharmaceutical industry and for the drug regulatory agency, they are simultaneously judging and being judged. Beyond the concept of conflicts of interest, drug regulatory agency decisions are also influenced by the unhealthily close links between their staff or experts and industry representatives.

Tacit compromise, possibly unconscious, but always kept secret, is a standard method of decision-making in these committees and working groups. They do not have to disclose the details of their discussions, their arguments, the evidence they used, or their votes. Especially when some internal rule or usual practice states that the goal is to reach "consensus". How many potential whistleblowers have been gagged by the pursuit of consensus?

**Too much biased consensus.** Consensus is even harder to break when the decision-makers, representing healthcare administrators, pharmaceutical companies, government, health professionals and even patients, have all known each other for a long time. They often obtained the same qualifications from the same universities, belong to the same socio-economic classes and the small circle of experts, etc. It would take real courage and motivation to dare to speak out in such meetings.

A decisive element for ensuring that cliquish, consensual decision-making does not become the norm, is the transparency of the meetings. But frequent and regular change in the various representatives who sit on the committees is also essential, extending recruitment to other circles and other countries.

At a different level, the same people can successively occupy positions of power in government ministries, pharmaceutical companies, drug regulatory agencies, then return to the pharmaceutical industry. This revolving door is often detrimental to patients and beneficial to the pharmaceutical industry. Going back and forth between these different positions is unacceptable.

## The truth, the whole truth

In addition to the necessary improvements to the practices of the pharmaceutical industry and regulators, the Mediator° scandal will only lead to lasting improvements if healthcare professionals, patients, experts and authorities change some of their attitudes: basing their actions on critical appraisal of scientific evidence; making shared, transparent decisions; paying more attention to adverse effects; avoiding the blurring of roles and unhealthily close links between those in authority.

Through the Mediator° scandal, *Prescrire* has become better known, achieved greater prominence, and has been able to promote some of the guiding principles it has upheld for the past 30 years, reflected in the following suggestions:

– to endeavour to give as small a role as possible to hope that is not grounded in solid evidence: to reach conclusions on the basis of evidence, i.e. after examining the facts, as opposed to assumptions and wishful thinking;

– to tell the truth to patients and the public: drug regulatory agencies and pharmaceutical companies should make all information publicly available;

– to tell the whole truth to patients who want to know: the evidence as well as any uncertainties;

– to criticise those who do not fulfil their role, whether they be politicians, pharmaceutical companies, drug regulatory agencies, educators, healthcare professionals, or patient advocacy groups;

– not to take a fatalistic view of the adverse effects of healthcare, but rather to constantly draw attention to them;

– not to seek consensus or close ties with other stakeholders in the healthcare system, in particular with its expert advisors or those in authority;

– to firmly uphold values and evidence, at the risk of sometimes being portrayed as overly dogmatic. This choice derives not from condemning the actions of specific individuals (within the pharmaceutical industry, drug regulatory agencies, etc.) but from seeking effective treatments, for the benefit of patients. It sometimes sets us against other societal stakeholders who have different or even opposing interests, some of which are very powerful.

As of 2011, The French edition of *Prescrire* is 30 years old and has 35 000 subscribers. Many healthcare professionals have long identified with its values and rely every day on the information it publishes to improve their professional practice and avoid similar tragedies.

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# European Medicines Agency: complete transparency needed

● **Trial protocols and raw data.**

The experience of two medical research scientists from the Nordic Cochrane Centre in Copenhagen shows that, as of 2011, the European Medicines Agency (EMA) still lacks transparency and works first and foremost for the pharmaceutical industry (1).

**The EMA obstructs access to clinical data.** In 2007, while the EMA was examining the marketing authorisation applications for *rimonabant* (formerly marketed under the brand name Acomplia°) and *orlistat* (Xenical°, Alli°), the two scientists requested the complete clinical trial reports and protocols of 15 placebo-controlled trials of these two drugs (1).

The scientists wanted to check the robustness of the results and measure any discrepancy between the published and unpublished data. The information requested *"was important for patients because anti-obesity pills are controversial. The effect on weight loss in the published trials is small, and the harms are substantial (…), and most of the drugs have been deregistered for safety reasons"* (1).

After several refusals from the EMA's director, who went as far as demanding evidence that the requested documents were of major public interest, the ▶▶



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► scientists lodged a complaint with the European ombudsman. The EMA persisted in refusing access to the data until the ombudsman accused it of *"maladministration"*. The EMA finally released the documents 3 years after the initial request and 2 years after marketing authorisation for *rimonabant* had been withdrawn.

This is not an isolated event (2,3). The EMA often uses the same pretexts to refuse *Prescrire*'s requests for access to clinical data, i.e. that the company's commercial interests must be protected or that a European review of the drug is underway (3). In May 2011, the EMA again refused to provide *Prescrire* with data on the risks of bladder cancer associated with *pioglitazone* (Actos°) (4).

**Demand transparency, in patients' best interests.** Access to assessment reports is not enough. What is needed is access to data covering all of the results and all of the trial protocols, as the Cochrane Centre scientists requested.

It is high time the EMA decided to hide nothing, be it from scientists, healthcare professionals or patients.

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**Selected references.**
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**3-** Prescrire Editorial Staff "Prescrire maintains its 5 complaints against the European Medicines Agency for refusal to provide information". english.prescrire.org accessed 7 July 2011: 2 pages.
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## QUERIES AND COMMENTS

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# Hay fever: why use the sublingual route for desensitisation?

*The allergologist community was astonished by the article "Hay fever and its treatments" published in la revue Prescrire (Fiches Info-Patients Prescrire – March 2010), which concluded that desensitisation was ineffective and risky (1). The French Society of Allergology (Société française d'allergologie, SFA) would like to refute this statement and to highlight a number of points».*

[Editor's note: in the following text, the subtitles in bold were added by Prescrire]

***A frequent problem; indisputable assessment.*** *"Allergic rhinitis is a global public health problem, affecting more than 500 million people worldwide. Its frequency is increasing, and has risen by a factor of 3 or 4 over the past three decades (2). Given the magnitude of this problem, experts of the ARIA group (Allergic Rhinitis and its Impact on Asthma) have been working in collaboration with the World Health Organization since 1999 to establish evidence-based guidelines (based on robust, controlled and randomised clinical trials) (2). They have concluded that allergen desensitisation (now called allergen-specific immunotherapy) is effective, in combination with other measures: allergen avoidance, symptomatic drug therapy (2). Several systematic reviews and meta-analyses published by the Cochrane Collaboration had already established the efficacy of allergen desensitisation in allergic rhinitis (see reference 3). The heterogeneity of the results of these studies was unavoidable, owing to design differences (allergen extracts, primary endpoints analysed, treatment duration, etc.). Large phase III trials were therefore necessary, and were conducted to evaluate two sublingual allergen-specific immunotherapy tablets containing grass pollens, in both adults (4,5) and children (6,7)".*

***Moderate effects, uncertain advantages, according to French authorities.*** *"The magnitude of the observed effect is large, superior to that of antihistamines and at least equal to that of nasal glucocorticoids. The French National Authority for Health (HAS) concluded that treatment provided a moderate benefit for patients. The rating for "added health benefits" is still under discussion, in light of new results demonstrating that a residual effect persists for two years after treatment cessation (8). What pharmacological treatment could redirect the immune response in such a specific and durable way?*

*Not only is the efficacy of sublingual allergen-specific immunotherapy now proven, its safety is also excellent (4-7). In addition, several earlier studies emphasised its potential preventive effect, reducing the risk of asthma onset (9) or sensitisation to new allergens (10)".*

**For the French Society of Allergology**
**M Migueres, F de Blay, JF Nicolas (a),**
**Members of the scientific board**
**P Demoly (a), President**

***a-*** *Conflicts of interest: M Migueres, F de Blay and P Demoly declared that they participated in pre-marketing clinical studies of injectable and sublingual allergen-specific immunotherapy. JF Nicolas declared no conflict of interest.*

The *Prescrire* article to which the letter from the French Society of Allergology refers is the *Prescrire Patient Info* sheet entitled "Allergic rhinitis: no routine desensitisation" published in French on the Prescrire website (www.prescrire.org). The information contained in this overview was drawn from several previous reviews conducted by *Prescrire*, including "Rhinite allergique saisonnière" and "Timothy pollen (standardised allergenic extract). Hay fever: 4 months treatment for 4 days' relief?" published in 2007 in French (2008 in English), and "5-grass pollen mix. 4 more grass species, but still no progress" published in June 2010 (2011 in English) (11-13).

Today, in mid-2011, what is the evidence supporting the efficacy of sublingual desensitisation?

### Several months' treatment for a few days' benefit

Seasonal allergic rhinitis (hay fever) is a benign condition, but the discomfort it



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