Translated from ***Rev Prescrire*** **December 2004; supplement to the French edition: The drug price explosion: 912-913**

The flagrant example of atorvastatin

The case of the cholesterol-lowering statins clearly exposes the complexity of drug pricing in France.

First marketed in France in spring 1998, Tahor° (atorvastatin) came in at number 9 on the list of total drug refunds in the first half of 1999, before rising to 5th place in 1999 and 2nd place in 2000 and 2001 (1,2). With 6.9 million boxes refunded in 2001, atorvastatin outstripped both pravastatin (Elisor° and Vasten°, 6.8 million boxes) and simvastatin (Zocor° and Lodales°, 5.8 million boxes) (2).

Inadequate basic and continuous education. There is no good medical reason why atorvastatin should be the most widely prescribed statin in France. On the contrary: the SPCs for Zocor° and Lodales° state that simvastatin is effective in secondary prevention of cardiovascular mortality, while the Elisor° and Vasten° SPCs state that pravastatin is effective in both secondary and primary prevention of cardiovascular mortality (3,4), whereas neither effect has been documented with Tahor°.

Why, then, are French prescribers so infatuated with a recent and insufficiently evaluated statin? Certainly not because it represents an innovation that doctors want to encourage: atorvastatin is simply a "me-too". And why have the strenuous efforts made by the manufacturers of simvastatin and pravastatin to evaluate their drugs gone unrecognised?

One reason is poor initial and continuing education on therapeutics in France. Another is the propagation of simplistic ideas based on a "positive class effect". But this was undermined by the notorious case of cerivastatin, which is the only statin to have been withdrawn from the market, because of a particularly high risk of rhabdomyolysis (5).

A huge promotional campaign. Even before Tahor° hit the French market in 1998, a major promotional campaign had prepared the terrain. The medicines agency even felt moved to ban a journal supplement promoting atorvastatin in 1996, pointing out that drugs could only start to be publicised after their effective market release (6).

In 1998 a French judge fined Parke-Davis for claiming in an advertisement that Tahor° 10 mg was a "*major advance in the management of hypercholesterolemia*", stating that the drug had not shown any effect in terms of cardiovascular prevention (7).

In 1998 our pharmaceutical representative monitoring network identified a curious new sales pitch, based on "*the best-ever commercial launch in the United States!*" (8).

Note that the high sale price of Tahor° helped fund the aggressive advertising campaign.

An astonishingly high price. The French financial ombudsman (*Cours des Comptes*) expressed his surprise at the high sale price granted for Tahor°: "*In expanding markets such as those for proton pump inhibitors and statins, the arrival of new "me-toos" has been encouraged by relatively high prices, i.e. generally close to those requested by manufacturers. Thus, the two dose strengths of a new statin approved for refunding in 1998 were granted a mean daily treatment cost almost equal to that of the most expensive statin and far above that of another statin marketed a short time before, even though the first dose strength offered no improvement in medical benefit and the second offered only a minor improvement*" (9).

When setting drug prices, the French economic committee on health products applies a complex set of rules based on the unit dose, the dose regimen, and sales volume, intended to control the progression of drug sales, especially for similar products (10). In the case of Tahor°, the Committee responded to the ombudsman in the following terms: "*With regard to the statin approved for refunding in 1998, the "standard" dose was granted a price more than 9% below that of the last comparable statin to be registered. Relative to the standard dose, the higher dose, which was the first of its type and therefore not comparable with an existing statin, was granted a far lower price per unit of active substance*" (9).

It remains that the 5.2 million boxes of Tahor° refunded by the French health insurance system in 2000 amounted to 186 million euros, while the 4.3 million boxes of Zocor° amounted to 149 million euros, i.e. a lower mean price per box (34.6 euros versus 35.7 euros) thanks to "standard" and "strong" dose manipulations (1).

Limitations of existing price controls. The ombudsman also pointed out that the economic Committee "*accepted, for a statin* [editor's note: this clearly referred to Tahor°], *both in 1999 and in 2000, not to accumulate the price reductions that would have resulted from the rules that the Committee had itself dictated*" (9). The national health insurer added disapprovingly: "*It seems necessary to ensure that the total cost of statin reimbursement should increase little, if at all, in future. Unfortunately, in the view of the economic Committee, this solution does not appear feasible. This reflects the essential limits of the system of conventions, which is required to encourage manufacturers and requires major concessions to be made if companies are to agree*" (9).

Price reductions, at long last. Following the publication of several studies showing that drug costs had exploded in 2000-2001, mainly owing to a limited number of very expensive products, the French authorities decreed a number of price cuts in summer 2001. Besides old drugs providing inadequate medical benefit, the prices of about 80 recent preparations were also cut. The ten sharpest cuts involved five statins, including Tahor°: the price of the strong dose fell by 20% and that of the standard dose by 13% (by almost as much as Zocor°: 13.9%).

Conclusion: flimsy rules. The case of Tahor° illustrates how a simple me-too can become a major commercial success in France, due to aggressive promotion, inadequate education of prescribers, and inconsistent decisions by the authorities responsible for medicines.

©Prescrire Editorial Staff

1- Medic'assurance maladie - Les médicaments remboursés par le Régime général d'assurance maladie au cours du 1er semestre 1999 et du 1er semestre 2000" Cnamts, Paris 2001: 62 pages. Cited in: "La dépense pharmaceutique en 2000 selon Medicam" *Rev Prescr* 2001; **21** (223): 855-856.
2- "Medic'am – Les médicaments remboursés par le Régime général d'assurance maladie au cours des années 2000 et 2001" Cnamts, Paris 2002: 131 pages. Cited in "Medic'am 2001: la déferlante de Celebrex°" *Rev Prescr* 2002; **22** (231): 625.
3- French datasheet compendium "Dictionnaire Vidal", Vidal, Paris 2002.
4- Prescrire Editorial Staff "Some statins are more equal than others" *Prescr Int* 2002; **11** (57): 2.
5- Prescrire Editorial Board "Roulés dans la farine" *Rev Prescr* 2001; **21** (221): 641.
6- Decision of 21 May 1996 published in the *Journal Officiel* on 23 July 1996: 11133. Cited in: "Vingt-trois nouvelles interdictions de publicités" *Rev Prescr* 1996; **16** (167): 776-777.
7- Prescrire Rédaction "atorvastatine-Tahor°" *Rev Prescr* 1998; **18** (190): 803-805.
8- Prescrire Editorial Board "Échos du Réseau - Monsieur plus" *Rev Prescr* 1998; **18** (180): 34.
9- Cour des comptes "La sécurité sociale" Paris 2001: 633 pages.
10- Comité économique des produits de santé "Rapport d'activité année 1999" Paris 2000: 49 pages.

Downloaded from english.prescrire.org on 09/10/2026
Copyright(c)Prescrire. For personal use only.