

Aventis Pasteur MSD and vaccine shortage

generics earlier. It makes one wonder whether the French authorities are really serious about promoting generics (b).

French prescribers must urgently adopt the INN system in order to circumvent these regulatory obstacles. This will also help focus attention on the drug substance that is being prescribed and dispensed.

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a- Marketing authorisations for generics authorised by the French medicines agency still include the words: "This drug is a generic of...", followed by the trade name of the originator drug. This is notably the case for the first omeprazole copy (ref 11).

b- A French professional journal recently pointed out that even though the zolpidem patent has not yet expired, a relevant group has already been created in the generics list; and, surprise, the medicines agency has registered Zolpidem Irex° (Sanofi's Stilnox° generic marketed by their affiliate Irex) - the only zolpidem copy currently on the French market (ref 12).

1- Prescrire Rédaction "La polémique sur la prescription en DCI est sans objet" *Rev Prescrire* 2000; 20 (209): 618-623.

2- Prescrire Rédaction "Prescription en DCI: un décret bienvenu mais compliqué" *Rev Prescrire* 2002; 22 (234): 818-819.

3- Prescrire Rédaction "Substitution: une réglementation inutilement complexe" *Rev Prescrire* 1999; 19 (198): 592-593.

4- Prescrire Rédaction "Répertoire de l'Afssaps: ça ne s'arrange pas" *Rev Prescrire* 2000; 20 (211): 752.

5- Prescrire Rédaction "Tarif forfaitaire de responsabilité: un début d'application" *Rev Prescrire* 2003; 23 (243): 661.

6- "Loi n° 2002-1487 du 20 décembre 2002 de financement de la Sécurité sociale pour 2003" *Journal Officiel* 24 December 2002 : 21482-21500.

7- Prescrire Rédaction "Doliprane° et Efferalgan° à la baisse" *Rev Prescrire* 2003; 23 (243): 670.

8- "Loi n° 2003-1199 du 18 décembre 2003 de financement de la Sécurité sociale pour 2004" *Journal Officiel* 19 December 2003 : 21641-21670.

9- Union nationale des pharmacies de France "Oméprazole: expiration du brevet" *Informations professionnelles* 16 April 2004: 1.

10- "Décret n° 2004-394 du 5 mai 2004 relatif à l'inscription au répertoire des groupes génériques et modifiant le code de la santé publique (deuxième partie: Décrets en Conseil d'État)" *Journal Officiel* 6 May 2004: 8104-8105.

11- Afssaps "RCP - Oméprazole Biogaran°" 24 March 2004: 6 pages.

12- Fontenelle N and Pouzaud F "Les ratés du Mopral" *Le Moniteur des Pharmacies* 2004; (2533): 8-9.

How long will Aventis Pasteur MSD continue to abuse physicians, pharmacists and their young patients?

It seems that the first important vaccine shortages occurred in 1997 (1-5). For more than 6 years now, despite letters announcing an end to these problems, nothing has changed: supplies of Tetracoq°, Pentacoq°, DT Polio° and Monovax° have an annoying tendency to dry up. The worst case is that of DT Polio° which cannot, in principle, be replaced with another product (although sales reps suggest using Revaxis°, which is twice as costly) (a). The result is a needless multiplication of appointments (the yearly visit and vaccination cannot be reliably programmed for the same day), sorely trying our patience.

Does this deplorable situation have to reach the attention of the national press before Aventis Pasteur MSD decides to act?

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a- The French medicines agency recently approved the use of Revaxis° instead of DT Polio°.

1- Nau JY "Pasteur Mérieux annonce une pénurie temporaire de vaccins pour nourrissons" *Le Monde* 8 January 1998.

2- Barré Ph "DT Polio et Pentacoq: la pénurie s'est installée" *Courrier de l'Ouest* 20 September 2000.

3- Prescrire Editorial Staff "Too many drug supply problems" *Prescrire Int* 2002; 11 (61): 159.

4- Denantes M "Rupture de stock" *Rev Prescrire* 2003; 23 (242): 633.

5- Boulanger S "Suggestion pour un palmarès" *Rev Prescrire* 2004; 24 (248): 234.



Selected letters addressed to physicians by Aventis Pasteur MSD (our translation from the French):

- "You will be aware of the supply problems with the DT Polio°, DTP Pasteur° and Pentacoq° vaccines, since the spring of 2000. These difficulties are linked to a formulation error, meaning that a batch could not be marketed. In an already difficult context of rising demand for the injectable polio vaccine, we also have to deal with a situation in which stocks are low. Given the time required to produce each batch, these difficulties [...] will take some time to resolve. We will keep you informed of the situation" (2 August 2000).
- "Regular provisions of DT Polio° vaccine are being planned, in order to re-establish a "safety stock" in wholesalers. This normalisation is underway" (31 July 2002).
- "We continue to dispatch regular information on the availability of our principal vaccines:
 - ROR Vax°: temporary supply difficulties; a shortage is likely during the second half of June. The situation should return to normal in July.
 - Tetravac-Acellulaire°: temporary supply difficulties; a shortage is likely during the second half of June. New batches of Tetravac-Acellulaire° are expected for July.
 - T Polio°: a lengthy supply interruption is likely. We are unable to say when regular supplies will return.
 - We are doing everything we can to resolve the current difficulties. They are transient, and the situation will return to normal shortly" (17 June 2003).
- "You will have noticed some supply difficulties with our DT Polio°, diphtheria, tetanus and inactivated polio vaccines in the last few weeks. Indeed, several batches that were to be available in September could not be released for technical reasons. It appears that we will not be able to provide supplies of DT Polio° vaccine before the second half of December 2003" (3 November 2003).