

Many of these “informers” probably don’t realise the stakes involved. After all, many of the commonly used marketing tools described above are taken verbatim from a pharmaceutical marketing textbook and from drug company websites (4-7,9). But most healthcare professionals who participate in these activities probably see an opportunity to take part in what are presented as simple scientific studies (10).

It is never too late to take off the blinkers and react...

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a- Information generated by GERS is only distributed to its members, with the exception of an analytical document called *Pharmagers*, which is also provided to the French Economic Committee for Healthcare Products (CEPS) within the framework of the policy agreement on drug regulation (ref 4).

b- Cegecim also produces Santestat software designed for community pharmacies (ref 7).

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Selected references from Prescrire’s literature search.

1- Prescrire Rédaction “Le poids important de la promotion dans le budget des firmes pharmaceutiques” *Rev Prescrire* 2006; **26** (268): 69.

2- Prescrire Rédaction “Industrie. Les milliards de la promo” *Rev Prescrire* 2001; **21** (214): 145.

3- Prescrire Rédaction “Dépenses marketing des firmes: encore plus” *Rev Prescrire* 2009; **29** (308): 457.

4- “Veille stratégique et contrôle de la politique marketing”. In: Serre MP et Wallet-Wodka D “Marketing des produits de santé” Dunod, Paris 2008: 281-292.

5- IMS Health “Company information”. www.imshealth.com accessed 25 June 2009: 12 pages.

6- GERS “Qui sommes nous? Nos missions”. www.gie-gers.fr accessed 25 June 2009: 2 pages.

7- Cegecim “Activités”, “Métiers”, “Professionnels de santé”. www.cegecim.fr accessed 25 June 2009: 6 pages.

8- “Revue de Presse du jeudi 16 May 2002. Cegecim reprend le CAM” *Pharmaceutiques* 2002. www.pharmaceutiques.com accessed 25 June 2009: 1 page.

9- Cessim “Qui sommes nous?”. www.cessim.org accessed 25 June 2009: 1 page.

10- Cegecim “Thalès on line - L’observatoire épidémiologique en temps réel”. www.lsimedical.com accessed 5 August 2009: 8 pages.

Translated from *Rev Prescrire* March 2010; 30 (317): 213

Pharmacovigilance: an opportunity for the European Commission to put patients’ interests first

● Subcontracting pharmacovigilance to drug companies is dangerous.

As of 2010, responsibility for pharmaceuticals in Europe will no longer lie with the European Commission’s Directorate General for Enterprise and Industry, but rather with its Directorate General for Health and Consumers (DG SANCO) (a)(1).

This transfer was needed to make public health, rather than the competitiveness of European pharmaceutical companies, the priority of the European Commission’s drug policy. But this symbolic gesture is not enough. The new arrangement will be judged on results, starting with the Commission’s pharmacovigilance package.

Pharmacovigilance: back to the drawing board. The European Commission’s pharmacovigilance proposal, which had its first reading in the European Parliament in spring 2010, may represent a major step backward in pharmacovigilance in Europe. In particular, it proposes that Member States will be able to choose one of two approaches: healthcare professionals would be able to report adverse effects to the public pharmacovigilance system... or only to pharmaceutical companies, thus depriving the public system of direct access to valuable scientific data that could be processed and enriched (2,3).

Drug companies play a prominent role at every stage in the Commission’s proposal: from the collection of adverse event reports to re-evaluation of the risk-benefit balance of drugs, even allowing them to propose changes to the wording of the official product information to the health authorities (2,3).

The Commission’s proposal also paves the way for premature marketing authorisations to become the norm, justified by the requirement for post-marketing risk management plans. The Commission is also proposing to get rid of the requirement that pharmacovigilance activities be publicly funded, in spite of their obvious public interest (2,3).

An opportunity to put patients first. Having transferred responsibility for pharmaceuticals to a different Directorate General, the European Commission has an excellent opportunity to show that it finally accepts that medicines are not just another consumer product: by putting patients’ interests first and abandoning the most dangerous of its pharmacovigilance proposals.

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a- *Prescrire*, the Medicines in Europe Forum and other civil society stakeholders have long been requesting this change (ref 1).

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Selected references from Prescrire’s literature search.

1- ISDB and Medicines in Europe Forum “Medicines under the SANCO’s competence: An opportunity to put public health first” Letter to JM Barroso dated 1st December 2009: 1 page.

2- ISDB and Medicines in Europe Forum “Pharmacovigilance in Europe: the European Commission’s proposals endanger the population” www.isdbweb.org: 11 pages.

3- European Commission “Proposal for a directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use”. <http://eur-lex.europa.eu> accessed 8 December 2009: 65 pages.