

► In summary, it is difficult to talk about errors, but through discussing them, we obtain relief and above all, find it useful: we can learn from past errors to improve future practice.

**Improving professional practice through personal, then collective reflection.** The Preventing the Preventable workshop organised during the 2010 *Prescrire* Encounters meeting showed that healthcare professionals are eager to discuss quality of care and methods for improvement, and the ideas came fast and furious.

At the beginning of the workshop, 30 participants said they found it difficult to talk about errors, 35 found it easy, and 21 did not express an opinion. At the end of the workshop, when asked about the impact of the workshop on their incentives and disincentives to talk about errors, about 15 participants did not answer, nobody claimed to be more reluctant than before, 3 said they were still as reluctant, 51 were motivated, and 23 were more motivated than at the beginning.

Reporting an error or a near-miss to *Prescrire*'s Preventing the Preventable programme is the first step in taking an active approach to improving one's professional practice (2).

The role of *Prescrire*'s Preventing the Preventable programme is to link these individual contributions to collective action; the objective is to provide better patient care, and to promote the idea of continuous quality improvement, which depends on the analysis of professional practice, vigilance and the participation of all those involved, for the benefit of patients.

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#### Selected references from *Prescrire*'s literature search.

- 1- *Prescrire* Rédaction "La valeur pédagogique de l'erreur" *Rev Prescrire* 2005; **25** (267 suppl. Éviter l'évitable): 913.
- 2- *Prescrire* Rédaction "Signaler au programme Éviter l'Évitable: mode d'emploi". *evitable.prescrire.org*
- 3- *Prescrire* Editorial Staff "Reporting of errors by healthcare professionals" *Prescrire Int* 2010; **19** (109): 230-234.
- 4- *Prescrire* Editorial Staff "Analysing an adverse event in primary care: a multidisciplinary, collaborative process" *Prescrire Int* 2011; **20** (121): 274-278.
- 5- Ishikawa K "Diagrammes cause-et-effet". In: "La gestion de la qualité. Outils et applications pratiques" Dunod, Paris 1984: 25-36.

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## Pharmaceutical quality: big pharma also at fault

**T**he issue of pharmaceutical quality sometimes makes the news. It is generally a generic manufacturer or a drug company based in a developing country that is accused of marketing drugs that fail to meet quality standards. But the biggest pharmaceutical companies in the world have also been found to be at fault.

**Inadequate control of raw materials.** In 2008, batches of *heparin* from western pharmaceutical companies including Baxter and Sanofi Aventis were withdrawn from the US and European markets due to defective quality. The raw material, imported from China, was defective and caused serious allergies and deaths in the US (a) (1). But quality control problems are not limited to subcontractors in developing countries.

**Poor manufacturing practices.** GlaxoSmithKline (GSK) was fined 750 million dollars in 2010 for serious flaws in the manufacturing process at its Puerto Rico plant, which mainly supplies the US market (b). The manufacturing problems identified by inspectors from the US Food and Drug Administration (FDA) between 2001 and 2005 are enlightening: the manufacturing processes for Kytril® (*granisetron*) and Bactroban® (*mupirocin*) failed to ensure the sterility of the products; sustained release tablets of Paxil® (*paroxetine*) contained no *paroxetine* and had no sustained release mechanism; Avandamet® tablets (*rosiglitazone* + *metformin*) contained too little or too much of the active ingredients; different products were found in the same bottle; etc. (2).

GSK is not the only culprit; in 2010, the FDA issued a formal warning to Bristol Myers Squibb (BMS), demanding that the company correct deficient procedures in one of its production plants (3).

**In summary.** Pharmaceutical companies want to play many roles in society, ranging from health educator to health partner. They need to be constantly reminded that their fundamental, day-to-day role is to produce high quality drugs with a favourable harm-benefit balance, and to ensure there is no interruption in the supply of medications to community and hospital pharmacies.

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a- For a special report on this subject see <http://pharmacritique.20minutes-blogs.fr/heparines-chinoises-lovenox-prion-chondroiteine/> (French only).

b- Many US pharmaceutical companies have set up production plants in Puerto Rico (a self-governing Caribbean commonwealth in association with the US), which offers substantial tax incentives (ref. 4,5).

#### Selected references from *Prescrire*'s literature search.

- 1- *Prescrire* Rédaction "Héparines: contamination, allergies et décès" *Rev Prescrire* 2008; **28** (297): 497-498.
- 2- Department of Justice "GlaxoSmithKline to plead guilty & pay \$750 million to resolve criminal and civil liability regarding manufacturing deficiencies at Puerto Rico plant" 26 October 2010. [www.justice.gov](http://www.justice.gov) accessed 21 July 2011: 2 pages.
- 3- Food and Drug Administration "Warning letter 10-SJN-WL-06" 30 August 2010. [www.fda.gov](http://www.fda.gov) accessed 21 July 2011: 2 pages.
- 4- "Welcome to Puerto Rico!" [www.topuertorico.org](http://www.topuertorico.org) accessed 21 July 2011: 4 pages.
- 5- "Pharmaceutical industry association of Puerto Rico. Industrial incentives". [www.piaapr.org](http://www.piaapr.org) accessed 21 July 2011: 2 pages.

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