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Pharmaceutical quality: big pharma also at fault

The 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 In 2008, batches of heparin from western pharmaceutical companies including Baxter and Sanofi Aventis were withdrawn from the US and European markets due to defective quality.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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Selected references from Prescrire’s literature search.

2- Prescrire Rédaction “Signaler au programme Éviter l’évitable: mode d’emploi” évitable. prescrire.org

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