and that more independent funding was needed (6). Will awareness of the problem and good intentions soon be followed by action?

©Prescrire

▶ Translated from *Rev Prescrire* **July 2018**
Volume 38 N° 417 • Page 545

Selected references from Prescrire's literature search

1- Prescrire Editorial Staff "Dangerous liaisons: patient groups and drug companies" *Prescrire Int* 2005; **14** (77): 111-112.
2- Prescrire Editorial Staff "Drug companies and patient groups: the influence of funding" *Prescrire Int* 2011; **20** (122): 306.
3- McCoy MS et al. "Conflicts of interest for patient-advocacy organizations" *N Eng J Med* 2017; **376** (9): 880-885.
4- Kopp E et al. "Patient advocacy groups take millions from drugmakers. Is there a payback?". khn.org accessed 9 May 2018: 15 pages.
5- Haute autorité de santé (HAS) "Publication des aides versées par les industries de santé aux associations de patients. Rapport 2013 portant sur les aides versées au titre de l'année civile 2013" October 2014: 11 pages.
6- Favereau E "Malades, nous devons nous imposer comme un contre-pouvoir (interview d'Alain-Michel Ceretti)" *Libération* 29 May 2017.

Drug companies' impunity from EU authorities

A routine inspection in 2012, carried out by the British Medicines and Healthcare Products Regulatory Agency (MHRA) on behalf of the European Medicines Agency (EMA), found that the company Roche had not analysed or reported more than 80 000 suspected adverse effects, involving 19 drugs, to drug regulatory agencies (1-3). Five years later, the European Commission pronounced its verdict on the matter: no big deal!

It is enough to admit one's guilt. After 5 years of investigation by the EMA, the European Commission absolved Roche on the pretext that the retention of information did not alter the harm-benefit balance of the 19 drugs concerned (2,3). The Commission endorsed the statements by the company that "*accepted all the inspection findings. It took them extremely seriously and fully understands the EMA's and Commission's concerns. It has worked diligently to remediate the deficiencies as quickly as possible and also to enhance the company's medical compliance and PV systems to prevent any recurrence*" (2). The proceedings were therefore stopped, and Roche will not have to pay the fine of nearly 700 million dollars that was at stake (3).

Given the financial stakes, it is understandable that Roche successfully sought leniency from the European authorities by adopting a humble and repentant attitude. On the other hand, this did not prevent the company from making a claim against the MHRA for not having warned it that a second inspection of its premises would form part of the ongoing European investigation, thereby preventing the company from "*asserting its right to silence*" (4). The company lost that lawsuit; it seems you can't win every time!

Why you can't win 'em all! The leniency of the European authorities seems out of step with civil law as it applies to ordinary people. Pharmaceutical firms, however, are very well protected by the European Regulation governing penalties for infringement. The European Commission can only impose a financial penalty if the infringement has "*substantial consequences for public health*" and if the companies do not co-operate during the proceedings brought against them (5).

This was the first application of this Regulation; its shortcomings were all too evident, as was the deliberately weak stance taken by the regulatory authorities.

©Prescrire

▶ Translated from *Rev Prescrire* **July 2018**
Volume 38 N° 417 • Page 538

Selected references from Prescrire's literature search

1- Prescrire Editorial Staff "Malfeasance on an industrial scale" *Prescrire Int* 2013; **32** (135): 32.
2- European Commission - Health and Food Safety Directorate General "Pharma investigation: Commission closes infringement procedure against Roche without penalty" 15 December 2017: 2 pages.
3- "Roche does not have to pay US$ 685 m fine" 20 December 2017. european-biotechnology.com accessed 27 March 2018: 2 pages.
4- "Roche v SOS for Health - Case n° CO/393/2014" 9 July 2014. The High Court of Justice Queen's Bench Division Administrative Court: 54 pages.
5- European Commission "Regulation (EC) n° 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) n° 726/2004 of the European Parliament and of the Council - consolidated" *Official Journal of the European Union* n° L 155, 15 June 2007: 17 pages.

COMING SOON...

NEW PRODUCTS

– Midostaurin in mastocytosis
– Dinutuximab beta for neuroblastoma

ADVERSE EFFECTS

– Drug-induced cholelithiasis
– Dolutegravir and pregnancy: neural tube defects

REVIEWS

– Febrile seizure in children
– Postpartum haemorrhage

OUTLOOK

– Psychostimulant use by medical students in France
– Non-occupational exposure to agricultural pesticides and Parkinson's disease

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