

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

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## 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.

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## 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