Regulators visiting a Roche ($RHHBY) facility in the U.K. found a surprise lurking in the company's computer system: 80,000 uninvestigated adverse reaction reports from the U.S. The reports are on a hodgepodge of drugs made by the Swiss company and include more than 15,000 reports of deaths, with some of the notices dating back 5 years.

Given the reputation of the Germans for accuracy in record keeping, it is probably no surprise that the problem appears to lie with Genentech, its U.S. division.

The FDA tells The Wall Street Journal that it is working with the EMA to assess the impact. In a mea culpa statement provided to Pharmalot, the company acknowledged the colossal oversight, said it understands how the news might worry consumers, and said it was working to address the mistake. It said some of the reports can be traced to a Genentech "Patient Reimbursement Program in the U.S., which were not sent to the safety department for full evaluation, hence were not reported to the health authorities according to the applicable regulation."

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