c. CIOMS

CIOMS is an international, nongovernmental, organization established jointly by WHO and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949. It provides a range of guidance on issues ranging from bioethics, health policy, drug development and use, and international nomenclature of diseases, as well as on assessing and monitoring adverse events (337).

d. The CIOMS I Form

This concerns adverse events that occur outside the United States. For reporting these AEs to the FDA, drug companies can use either an international form (CIOMS I form) or FDA Form 3500A (338). However, for adverse events that occur within the United States, drug companies must use FDA Form 3500A, and must not use the CIOMS I Form. The CIOMS I form is available in electronic format (339).

There is only the CIOMS I form (there do not exist CIOMS II or CIOMS III forms). The CIOMS I form is used for both pre- and postmarketing reporting. Reporting is mandatory only for the Marketing Authorization Holder, but voluntary for consumers and physicians (340). In Great Britain, the MHRA will accept information filled out on a CIOMS I form by a member of the public or healthcare professional, as long as it has the four minimum reporting requirements: a patient identifier, suspect drug, suspect reaction, and reporter details, however in practice, this route for reporting safety issues in Great Britain is rarely used (341).

Investigators need to be aware of different reporting requirements in the United States and in Europe. According to one commentator, in Europe, it is the case regulators accept the ICH concept that manufacturers should report only those events that the reporting physician or the manufacturer believe have a causal relationship with a drug (342). However, the United States has been slow to adopt these standards, and prefers companies to report all adverse experiences, irrespective of the likelihood of a causal relationship (Fig. 25.7).

e. Postmarketing Surveillance

Postmarketing safety reporting to the FDA can use a format mandated by the FDA (Periodic Adverse Drug Experience Report; PADER) or, with permission, can utilize the Periodic Safety Update Report (PSUR) format (343). The PSUR provides an update of

[337]Castle GH, Kelly B. Harmonization is not all that global: divergent approaches in drug safety. Food Drug Law J. 2008;63:601–22.

[338]U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for industry. Postmarketing safety reporting for human drug and biological products including vaccines; March 2001.

[339]Drug safety reporting duties in Switzerland. Swissmedic, Hallerstrasse 7, CH-300 Bern 9 (document dated May 13, 2009).

[340]Andrews EB. E-mail of April 1, 2011.

[341]Heffer S. E-mail of April 1, 2011.

[342]Castle GH, Kelly B. Global harmonization is not all that global:divergent approaches in drug safety. Food Drug Law J. 2008;63:601.

[343]U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for industry. Providing regulatory submissions in electronic format—postmarketing periodic adverse drug experience reports; June 2003 (16 pp.).