Global Monitoring of Medicine Safety

Pharmaceutical companies distribute their medicines globally and collect data on the use of their medicines in each country where the use of a medicine is approved. The industry and its medicinal products are highly regulated by governmental entities known as regulatory agencies or regulatory authorities.

In the U.S., for example, the Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of medicines. In the European Union (EU), these activities are carried out by the European Medicines Agency (EMA) and the local regulatory agencies in the individual EU member states. This is achieved through:

- Reviewing clinical research and consulting with experts to decide whether or not to approve a new medicine,
- Providing safety information on approved medicines,
- Overseeing the safety information generated on a product during its lifetime and any changes that need to be made to the safety information as a result,
- Inspecting facilities where medicines are tested or manufactured, and
- Carrying out safety reviews of a product when necessary.

In the U.S., laws governing medicines are found in the Food Drug and Cosmetic Act [21 U.S.C. 301 et seq.] as well as other statutes. In addition to laws, the FDA has the power under law to create regulations, which are published in the Federal Register and in the Code of Federal Regulations. The FDA also issues Guidances, which specify the agency’s current thinking and preferences on laws and regulations. While nonbinding, these Guidances are generally followed by the industry.

In the EU, the EMA evaluates and supervises the approval and use of medicinal products that are centrally approved in the EU (a process whereby a single application leads to an EU-wide approval). In addition, products that are not centrally approved are evaluated and supervised either by individual national regulatory authorities, or by a group of member states’ regulatory authorities, with one of the member states acting as the “reference member state” and leading the process (known as the decentralised or mutual recognition procedures).

EU legislation is more complicated than in the U.S., because it derives from treaties and agreements between 27 different sovereign countries (Member States). The EU pharmacovigilance laws are specified in Regulations (laws directly applicable to all Member States, without the need for additional implementation at the national level); and Directives (which bind Member States to implement the contents of the Directive into their national laws within a certain time period). There are also Guidance documents on pharmacovigilance (which, although not law themselves, should be complied with), one such document being Volume 9a of the Rules Governing Medicinal Products in the European Union - Pharmacovigilance. New pharmacovigilance legislation that was passed in late 2010, for implementation in 2012, significantly changes the way that safety information is reported and monitored in the EU. For more information, visit http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000492.jsp.

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For more information on medicine safety, please visit: www.pfizer.com/medicinesafety
Pharmaceutical companies must report safety information about their medicines to the FDA and other regulatory agencies (or health authorities) worldwide. Different languages, time zones, regulatory requirements, and reporting documents complicate the process considerably. Having an internationally standardized safety reporting procedure can help improve the quality of post-approval safety information and streamline the gathering and reporting of information to regulators around the world. With the goal of achieving a level of standardization, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH),* which brings together representatives of the regulatory agencies of Europe, Japan, and the U.S., has developed recommendations for harmonized post-approval safety processes. These standards include elements designed to help assure post-approval medicine safety, such as: identifying and describing safety signals, investigating signals through observational/pharmacoepidemiologic studies, interpreting safety signals, and developing a pharmacovigilance plan. However, ICH recommendations require country-level implementation and do not over-ride national legislation.

*www.ich.org/

**Examples of Regulatory Agencies**

- FDA (United States)
  > [www.fda.gov](http://www.fda.gov)
- EMEA (European Union)
  > [www.emea.europa.eu](http://www.emea.europa.eu)
- Pharmaceuticals and Medical Devices Agency (PMDA) within the Ministry of Health, Labor and Welfare (MHLW) (Japan)
- AFSSAPS (France)
  > [www.afssaps.fr](http://www.afssaps.fr)
- BfARM (Germany)
  > [www.bfarm.de/DE/Home/home_node.html](http://www.bfarm.de/DE/Home/home_node.html)
- MHRA (United Kingdom)
  > [www.mhra.gov.uk/index.htm](http://www.mhra.gov.uk/index.htm)
- Health Canada (Canada)
  > [www.hc-sc.gc.ca/index_e.html](http://www.hc-sc.gc.ca/index_e.html)
- TGA (Australia)