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Contact: Michael Levin-Epstein, Editor-in-Chief
The Food and Drug Law Institute
202-222-0897
mdl@fdli.org

FDLI Book Maps out Pharmacovigilance Provisions in More than Dozen Countries

Global Pharmacovigilance *Guidebook First to Compile International Laws, Rules*

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As recent events clearly indicate, the need to keep a close eye on pharmaceutical safety doesn't end with government approval to market the drug.

In March 2008, shipments of the blood thinner heparin made in China were discovered to be contaminated with excess sulfates often used to treat arthritis. The contaminated heparin caused dozens of deaths and hundreds of injuries.

In February 2009, the Food and Drug Administration accused Ranbaxy Pharmaceuticals, an Indian manufacturer of generic drugs, of falsifying data used to obtain regulatory approval for U.S. distribution.

These developments are just a few examples of why pharmacovigilance is now a global concern. Pharmacovigilance encompasses all phases of a product's lifecycle—from data supporting regulatory approvals to enter a market to periodic inspections of foreign manufacturing facilities to postmarketing surveillance and adverse event reporting — and beyond.

Many countries are working feverishly to developing their own sets of pharmacovigilance laws and regulations, and it's increasingly difficult for manufacturers to keep current on new requirements

With its new book, *Global Pharmacovigilance Laws & Regulations: The Essential Reference*, the Food and Drug Law Institute (FDLI) has made that job much easier. The comprehensive reference manual for pharmaceutical firms, medical device companies, life science attorneys, sales and marketing staff, compliance officers, regulatory affairs specialists and consultants lays out in user-friendly terms the pharmacovigilance laws and regulations for more than a dozen countries.

The 288-page book edited by Stephen L. Klinecicz, Global Head and Vice-President of Pharmacovigilance Sciences at the Benefit Risk Management division of Johnson & Johnson, Yueng Yueng Yap, senior legal counsel at Johnson & Johnson Law Department (Europe) and Adrian Thomas, Worldwide Vice-President for Health Economics & Pricing and Chief Safety Officer for the Johnson & Johnson companies, will be an invaluable resource to manufacturers of pharmaceutical products and compliance specialists alike.

The book covers the pharmacovigilance programs of these countries and entities:
Argentina, Australia, Brazil, Canada, China, Egypt, European Community, India, Japan, Mexico, Russian Federation, Singapore, Turkey and the United States.

For more information about the book, visit www.fdpi.org.

Media: To obtain a review copy of *Global Pharmacovigilance Laws & Regulations: The Essential Reference*, contact Michael Levin-Epstein, Editor-in-Chief, FDLI, (202) 222-0897; mdl@fdpi.org.

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