

Full Issue of Drug Industry Daily

Jan. 16, 2015

FDA Recommends Assessing New Drugs for Driving Impairment

The FDA is asking drugmakers to evaluate all new psychoactive and other drugs for their potential to impair a patient's driving ability and provide warning labelling if needed.

In draft guidance issued Thursday, the agency said driving impairment should be analyzed in a tiered assessment that begins during phase 1 trials. The first step in that assessment should be determining whether a proposed new psychoactive drug has any effects on the central nervous system.

Pharmacological and toxicological studies set the baseline for whether a drug has CNS effects. Epidemiological studies should be used to discover whether related drugs already in use have shown a tendency to impair driving or whether the patient population for a drug is especially vulnerable to driving impairment.

Even a small impact on the CNS in phase 1 studies may warrant further and more focused analysis of potential driving impairment, the agency says.

In phase 2 and 3 clinical trials, the FDA recommends drugmakers look for specific adverse events associated with impaired driving.

Finally, behavioral studies using driving simulators, or actual motor vehicles, should be used to evaluate a drug's impact on driving when the drugmaker has reason to suspect the drug will interfere with a patient's ability to drive.

While the guidance focuses on the impairing potential of psychoactive drugs, because they are obvious candidates to cause impairment, the FDA cautions that nonpsychoactive drugs should be assessed as well.

And, the agency cautions, drugmakers should not restrict their tests to measuring drowsiness or alertness, but should also look for any tendency of a drug to increase risk-taking by a patient, impair motor function, decision making or reaction time, alter perceptions of speed, or other side effects that could impair driving.

If performed, driving impairment tests should be included under clinical trials in the labelling section of an NDA or BLA, the FDA says.

See the guidance here: www.fdanews.com/01-15-2015-Drugs-and-Driving.pdf. – Bryan Koenig

FDA Warns Healthcare Providers of Practice Saline Administered to Patients

Non-sterile saline solution meant only for training purposes and not use in humans has found its way to healthcare facilities and been incorrectly administered to patients in at least seven states, where it's been linked to at least one death and has prompted the FDA to urge clinics, hospitals and other healthcare providers to check their saline stock.

More than 40 patients have been known to have been administered Practi-0.9% sodium chloride solution, a simulated IV saline solution manufactured by San Diego-based Wallcur. Many adverse events have been linked with administration of the practice solution, including fever, chills, tremors, headache and at least one death, although it's unknown if that death is directly related to the saline, the FDA said in a safety alert.

The adverse events have been reported in Florida, Georgia, Idaho, Louisiana, North Carolina, New York and Colorado, according to the FDA.

Wallcur has initiated a voluntary recall of its saline and the FDA is urging clinicians and staff to check any products for labels that say "Wallcur," "Practi-products," "For clinical simulation," or "Not for use in human or animal patients," according to the alert. Wholesalers, distributors and suppliers are also asked to check their stock.

It's unclear how the practice solution was shipped to healthcare facilities. The FDA said that it is currently investigating.

Healthcare providers have struggled recently with an ongoing shortage of saline ([DID, Sept. 12, 2014](#)). The FDA has been working with manufacturers to increase supply, the agency said. Wallcur did not respond to a request for additional comment by press time.

See the FDA warning notice here: www.fdanews.com/01-15-2015-Saline-Safety-Warning.pdf. – Bryan Koenig

NICE Expands Sovaldi Recommendations

The UK's health cost-benefit watchdog is recommending Gilead Sciences' blockbuster hepatitis C cure, Sovaldi, be offered through the National Health Service to patients with three additional types of hepatitis C beginning in July.

National Institute for Health and Care Excellence had originally recommended the drug in combination with peginterferon alfa and ribavirin for adults with genotypes 1, 2 and 3 hepatitis C virus, it is now recommending expanding the indications to cover patients with genotypes 4, 5, and 6 who also have liver cirrhosis ([DID, Aug. 15, 2014](#)).

Cost-effectiveness analyses showed that providing Sovaldi (sofosbuvir) to patients with the expanded indications would fall at the high end of NICE's acceptable range, but in final draft guidance NICE found that those patients represent a significant amount of unmet medical need. These patients will also be required to take peginterferon alfa and ribavirin.

A 12-week course of Sovaldi costs \$53,300 in the UK, far less than its \$84,000 price tag in the U.S. Stakeholders now have the opportunity to make any appeals on the final draft. NICE expects to release a finalized guidance next month.

Read the final draft at www.fdanews.com/01-15-15-Sovaldifinaldraft.pdf. — Lena Freund

India Approves 28 Clinical Trial Proposals, 7 Trial Waivers

India's health ministry has given the go-ahead for 28 clinical trials, 14 of which are international studies, a continuation of the rebounding number of studies in the country.

The ministry also approved local trial waivers for seven other products – five drugs, a biologic, and a medical device – meaning those products can go forward for approval by the Drugs Controller General relying on data from trials conducted in other countries.

The seven products include hepatitis C drug Sofosbuvir, prostate cancer drug Enzlutamide, lymphoma drug Vorinostat, tuberculosis drug Bedaquiline, leukemia drug Clofarabine, hemophilia B drug Rixubis, and Sapien xt-Transcatheter heart valve with Novaflex+ Transfemoral kit.

The regulatory action on the trials is a positive sign for India's clinical trials industry, says Vince Suneja, CEO of TwoFour Insight Group, but he expects the industry will not fully recover until the Supreme Court resolves a lawsuit filed by the activist group Swasthya Adhikar Manch over trial-related deaths and malpractice in Indian clinical trials.

At least 2,374 people died in trials for unregistered drugs between 2007 and 2012, according to the Alliance for Human Research Protection. Revelation of trial deaths prompted strict government regulations in 2012, and the number of trials plummeted. The total number of trials conducted in 2013 was 107, compared to a high of 500 trials in 2010 ([DID, July 24](#)). —Jonathon Shacat

IOM: Governments, Industry Must Plan for Trial Data Sharing

The Institute of Medicine is calling on clinical trial sponsors and governments to develop plans for substantially greater sharing of clinical trial data.

In a report containing sweeping recommendations for both industry and regulators, the IOM calls on governments to create guidance for industry that mandates data sharing and establish the technologies and standardized data formats to allow greater sharing.

In addition, regulators should develop datasets that do not contain confidential information so they can be more readily shared, with a goal of making data for approved studies of all products available to the public no more than 30 days after regulatory action or 18 months after study completion.

Sponsors, the report recommends, need to commit to data sharing by removing confidential information from clinical trials reports and developing data-sharing plans at the outset of trials that address how and when data will be distributed.

The data sharing plans need to establish how data will be shared in compliance with all international privacy laws, and incorporate the information into informed consent documents.

The IOM recommendations were created by a panel of medical societies, universities, pharmaceutical companies and the FDA. The report was sponsored by drugmakers, the FDA and the NIH to help develop a consensus on data sharing issues.

Get the report at <http://iom.edu/Reports/2015/Sharing-Clinical-Trial-Data.aspx>. —Lena Freund

Uhl Named Permanent Director of Office of Generic Drugs

The FDA has named Kathleen Uhl permanent director of the Office of Generic Drugs (OGD), where she has served as acting director since March 2013.

Uhl was named acting director of the office, which is charged with overseeing and approving all generic drug products, after the departure of Gregory P. Geba, who was OGD director for only about nine months ([DID, March 14, 2013](#)).

Uhl has more than 30 years of regulatory and medical policy, scientific, and government experience. She was an integral part of OGD's reorganization and expansion, and oversaw implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA).

Uhl joined FDA in 1998 as a medical officer in clinical pharmacology review. She has served in several leadership roles, including senior advisor to OGD director, OMP deputy director, and assistant commissioner of women's health and director of the Office of Women's Health, Office of the Commissioner.

FDANEWS

Customer Service

(888) 838-5578 • +1 (703) 538-7600

customerservice@fdanews.com

Executive Editor: Meg Bryant

(703) 538-7634

mbryant@fdanews.com

Ad Sales: Jim Desborough

(703) 538-7647

jdesborough@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431
Phone: (888) 838-5578 • +1 (703) 538-7600 • Fax: +1 (703) 538-7676

www.fdanews.com

Reporters: Lena Freund, Robert King, Kellen Owings, Bryan Koenig,
Jonathon Shacat

President: Cynthia Carter; **Content Director:** Dan Landrigan

Copyright © 2015 by Washington Business Information Inc. All rights reserved. ***Drug Industry Daily*** (ISSN 1541-6607), an executive briefing on the regulation of pharmaceuticals, is published daily, 250 issues, for \$1,995. Photocopying or reproducing in any form, including electronic or facsimile transmission, scanning or electronic storage is a violation of federal copyright law and is strictly prohibited without the publisher's express written permission. Subscribers registered with the Copyright Clearance Center (CCC) may reproduce articles for internal use only. For more information, contact CCC at www.copyright.com or call (978) 750-8400.

Copyright ©2015. All Rights Reserved.

FDANews 300 N. Washington St., Suite 200, Falls Church, VA 22046, USA.

Phone (703) 538-7600 – Fax (703) 538-7676 – Toll free (888) 838-5578

www.fdanews.com