JONES DAY | Pharmaceutical & Medical Device Regulatory Update
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JONES DAY

PHARMACEUTICAL & MEDICAL DEVICE REGULATORY UPDATE

Top News

Ministers of EU Countries Agree on Medical Device Package

On October 5, 2015, the European Council agreed on a general approach on two draft regulations aimed at amending and modernizing the EU regulatory framework on medical devices. The European Commission first proposed the updated regulations on medical devices and in vitro medical devices in 2012, and three years of discussions have followed. The decision allows the Luxembourg presidency to start talks with the European Parliament with a view to reach an agreement on the new medical device regulations. The first discussions are scheduled for October 13, 2015.

FDA Announces Inaugural Patient Engagement Advisory Committee

In an effort to further involve patients in the medical device development process, FDA's Center for Devices and Radiological Health recently announced it will form a new Patient Engagement Advisory Committee ("PEAC"). The committee will consist of nine voting members, one consumer representative, and, depending on the meeting topic, a varying number of temporary nonvoting members selected from a pool of industry-nominated individuals. The committee will advise FDA on issues such as agency guidance and policies, clinical trial or registry design, patient preference study design, benefit–risk determinations, device labeling, unmet clinical needs, available alternatives, patient-reported outcomes and device-related quality of life or health status issues, and other patient-related topics.

According to FDA, discussions with PEAC may help the agency "meet its public health commitment to improve patients' health and quality of life." The committee is accepting the first set of nominations through November 20, 2015 (later nominations will be considered as vacancies occur). ***Statements of interest and nominations may be submitted through October 21, 2015***.

CMS Posts Resources for 2016 Open Payments Reporting Cycle

On October 1, 2015, the Centers for Medicare & Medicaid Services ("CMS"), the agency that administers the Open Payments program, posted the teaching hospital list and key (de minimus) thresholds for calendar year 2016 reporting.

Open Payments requires applicable drug and device manufacturers to report annually regarding (i) direct and indirect payments and other transfers of value made to physicians and teaching hospitals (i.e., "covered recipients") and (ii) ownership and investment interests held in the company by physicians and their immediate family members. By October 1 of every year, CMS publishes a list of teaching hospitals to aid manufacturers in determining their reporting obligations under the program. For the 2016 reporting cycle, the number of teaching hospitals increased to 1,222 (from 1,203 for 2015). The key thresholds were also adjusted slightly upward based on the consumer price index.

New EU Clinical Trial Regulation Unlikely to Take Effect Until 2017

According to the New Clinical Trial Regulation No 536/2014 (the "Regulation"), the European Medicines Agency ("EMA") is responsible for the development and maintenance of a portal and database for the submission of clinical trial applications and authorizations within the EU. At the latest EMA Management Board meeting, the Board received an update on the timeline for the implementation of the clinical trial portal and database—a prerequisite for the new Regulation. Meeting minutes indicate that the system is planned to be available for an independent audit by the end of the third quarter of 2016. If the portal and database receive a favorable audit, the Regulation will come into effect by the end of 2017. From that point onward, the portal and database will be operational for sponsors and Member States to use for all new clinical trial applications in the EU, and the information from the database will be publicly available. During the meeting, the Board also endorsed the addendum to the functional specifications of the EU portal and database, which describes the practical implementation of the transparency rules of the European Clinical Trial Regulation.

EMA Provides Update on Publication of Clinical Trial Data

Last month, EMA published summaries and presentations of the discussions held at two recent meetings on the implementation of its policy on clinical data publication. EMA's policy on clinical data publication went into effect on January 1, 2015 and applies to clinical reports contained in all marketing-authorization applications submitted on or after this date. The first reports are expected in mid-2016. EMA's next steps in implementing this policy are to consult with both the European Ombudsman and the European Data Protection Supervisor this month. Industry expects EMA to publish two guidance documents regarding the identification and redaction of commercially confidential information in clinical reports for publication, and the anonymization of clinical reports.

Major Drug Company Releases Preclinical Data as Part of Crowd-Sourcing Challenge

As part of an open innovation challenge sponsored by Sage Bionetworks, AstraZeneca has released preclinical data from more than 50 molecules to support participants in developing predictive models of cancer drug combination synergy. Launched in September 2015, the Dialogue on Reverse Engineering Assessment and Methods ("DREAM") Challenge is an established crowd-sourcing effort exploring biology and medicine through computational science. The pharmaceutical manufacturer's data comprise more than 10,000 tested combinations that measure drugs' abilities to destroy cancer cell lines from colon, lung, breast cancer, and other tumors. In parallel, the Wellcome Trust Sanger Institute is making genomic data for the same lines available to DREAM Challenge participants.

Former Industry Executive to Lead Quality at FDA

FDA's Center for Drug Evaluation and Research ("CDER") recently announced that Michael Kopcha will serve as permanent director of the Office of Pharmaceutical Quality ("OPQ"). Kopcha formerly led research and development at Novartis Consumer Health, Inc. FDA formed OPQ in January 2015, which has been led by CDER Director Janet Woodcock. Kopcha is expected to assume the new role next month.

Other News

European Court Invalidates EU–US Data Protection Safe Harbor

FDA to Approve ANDAs on the Basis of Draft Labeling

Preamble of Proposed Rule Calls for Broader Review of FDA's 'Intended Use' Standard

FDA Orders Duodenoscope Manufacturers to Conduct Postmarket Surveillance at Hospitals

Harvard Study Questions FDA's Use of Expedited Programs

FDA Allows Genomics Company to Market Bloom-Syndrome Screening Test

FDA Approves Novel Autoinjection Device for Multiple Sclerosis Treatment

Federal Court Issues Permanent Injunction Against Laser Device Manufacturer

Austria's Finance Minister Urges EU to Include Health in All Policies

Regulatory Updates

FDA Extends Comment Period for CMC Guidance Document

In the October 6, 2015, *Federal Register*, FDA announced it is reopening the comment period for the "Established Conditions: Reportable Chemistry, Manufacturing, and Controls ("CMC") Changes for Approved Drug and Biologic Products; Draft Guidance for Industry." ***Comments are now due January 4, 2016***.

FDA Issues List of Approved PMAs

In the October 6, 2015, *Federal Register*, FDA published a list of premarket approval applications ("PMAs") that have been approved. This list is available through the agency's website.

FDA Announces FY2016 Fee Rate for Rare Pediatric Disease Priority Review Voucher

In the September 28, 2015, *Federal Register,* FDA announced the fee rate for using a rare pediatric disease priority review voucher for fiscal year 2016 ($2,727,000). The amount of the fee for using a rare pediatric disease priority review voucher is determined each year based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous fiscal year, and the average cost incurred in the review of an application that is not subject to priority review in the previous year.

FDA Proposes Rule to Clarify Regulatory Status of Products Derived from Tobacco and Amendments to Regulations Regarding "Intended Uses"

In the September 25, 2015, *Federal Register*, FDA provided notice of a proposed rule to describe the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the Federal Food, Drug, and Cosmetic Act ("FDCA"). In the same notice, FDA is proposing to amend its existing "intended use" regulations for drugs and devices. ***Comments are due November 24, 2015***.

FDA Requests Comments on Interim Results of Study of Workload Volume and Full Costs Associated with Review of Biosimilar Biological Product Applications

In the September 24, 2015, *Federal Register,* FDA announced the opportunity for public comment on the interim results of a study of the workload volume and full costs associated with the process for the review of biosimilar biological product applications (interim report). ***Comments are due October 26, 2015.***

FDA Classifies Oral Electronic Vision Aid

In the September 22, 2015, *Federal Register,* FDA announced the classification of the oral electronic vision aid into class II (special controls). FDA is requiring labeling, performance testing, software verification, and other methods to mitigate the identified risks, such as adverse tissue malfunctions, electrical shock, and software malfunction.

FDA Establishes Patient Engagement Advisory Committee

In the September 21, 2015, *Federal Register,* FDA announced the establishment of the Patient Engagement Advisory Committee. The committee will provide advice to the Commissioner of Food and Drugs or his/her designee on complex issues relating to medical devices, regulation of devices, and their use by patients. The committee may consider topics such as Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient-reported outcomes and device-related quality of life or health status issues, and other patient-related topics. ***Comments are due November 20, 2015***.

FDA Requests Individuals for Patient Engagement Advisory Committee

In the September 21, 2015, *Federal Register,* FDA requested nominations of individuals to serve as a voting consumer representative to the Patient Engagement Advisory Committee. FDA also requests that any consumer organization interested in participating in the selection of the voting consumer representative ***notify FDA by October 21, 2015***.

FDA Requests Nominations for Voting Members for the Patient Engagement Advisory Committee

In the September 21, 2015, *Federal Register,* FDA requested nominations for voting members to serve on the Patient Engagement Advisory Committee, Office of the Center Director, Center for Devices and Radiological Health. ***Nominations of qualified individuals should be submitted to FDA by November 20, 2015***.

FDA Requests Nominations of Individuals and Industry Organizations to Select Temporary Nonvoting Members on the Patient Engagement Advisory Committee

In the September 21, 2015, *Federal Register,* FDA requested that industry organizations interested in participating in the selection of a pool of nonvoting industry representatives to serve as temporary nonvoting members on the Patient Engagement Advisory Committee for the Center for Devices and Radiological Health notify FDA in writing. Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests ***must send a letter stating that interest to FDA by October 21, 2015***.

FDA Begins Implementing Authority on Destruction of Refused Drugs

In the September 15, 2015, *Federal Register,* FDA announced it is implementing its authority to destroy a drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission into the United States under the FDCA by issuing a rule that provides to the owner or consignee notice and an opportunity to appear and introduce testimony to the Agency prior to destruction. ***Effective October 15, 2015.***

FDA Issued the Following Draft and Final Guidance Documents:

Guidance for Industry: Acceptability of Draft Labeling to Support ANDA Approval, October 6, 2015, *Federal Register*.

Draft Guidance: M4E(R2): The CTD—Efficacy, International Conference on Harmonisation, October 2, 2015, *Federal Register*. ***Comments are due December 1, 2015***.

Draft Guidance for Industry: M7(R1) Addendum to ICH M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk; Application of the Principles of the ICH M7 Guidance to Calculation of Compound-Specific Acceptable Intakes, September 28, 2015, *Federal Register.* ***Comments are due November 27, 2015***.

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections:

- Guidance for Industry on Generic Drug User Fee Cover Sheet
- Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation
- Medical Device User Fee Small Business Qualification and Certification
- Substances Generally Recognized as Safe: Notification Procedure

FDA Announced that the Following Collections Have Been Submitted to OMB:

- Electronic User Fee Payment Request Forms
- Request for Samples and Protocols
- Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

EU Regulatory Notices

EU Agency Nominates New Executive Director

On October 1, 2015, the EMA's Management Board nominated Guido Rasi as the executive director of the Agency. Professor Rasi will be appointed following an October 13, 2015 hearing at the European Parliament, during which he will give a statement to the Committee on the Environment, Public Health and Food Safety. Deputy Executive Director Andreas Pott will continue to lead EMA operations and legally represent the Agency until the new executive director has officially assumed his duties.

EMA Consults on Guidance to Accelerate Development of Antibiotics

On September 28, 2015, the EMA released a draft guideline for public consultation on the use of pharmacokinetics and pharmacodynamics analyses in the development of antibiotics. The document aims to provide guidance for the conduct of robust analyses to facilitate and speed up the development of new antibiotics, in particular those targeting multi-drug resistant bacteria. The public consultation is open until March 31, 2016. In addition, EMA is organizing a workshop on November 12–13, 2015, with a broad range of stakeholders including academia, regulatory agencies, industry, and international experts to discuss the draft guideline. Attendance is by invitation only, but the workshop will be broadcast live on the EMA website.

EU Commission Publishes FAQs on European Reference Networks

On October 6, 2015, the European Commission published frequently asked questions on the procedural aspects on establishing European Reference Networks ("ERNs"). ERNs were established by Directive 2011/24/EU on the application of patients' rights in cross-border health care and are networks connecting health care providers and centers of expertise of highly specialized health care, for the purpose of improving access to diagnosis and treatment and enhancing the provision of high-quality health care.

European Commission, EMA, and WHO Step Up Cooperation

The European Commission and the EMA have agreed with the World Health Organization ("WHO") to share certain nonpublic information on the safety, quality, and efficacy of medicines already authorized or under review in the EU, or prequalified or under review by WHO. The aim of the new working arrangement is to strengthen communication between the respective organizations and make it easier to take action to protect public health.

EMA Consults on Draft Guideline on Immunogenicity Assessment of Biotechnology-Derived Therapeutic Proteins

On October 1, 2015, the EMA published a draft guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins for consultation. The document will replace the 2006 guideline on the same topic. ***Public comments are due January 31, 2016***.

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics

Sixth Annual Coalition Against Major Diseases/Food and Drug Administration Scientific Workshop, **October 15, 2015**, in Silver Spring, MD.

Public Meeting on Patient-Focused Drug Development for Nontuberculous Mycobacterial Lung Infections, **October 15, 2015**, in Silver Spring, MD. ***Comments are due December 15, 2015***.

Public Workshop titled "In Vitro Diagnostic Testing for Direct Oral Anticoagulants," **October 26, 2015**, in Silver Spring, MD.

Public Workshop titled "Osteoporosis Drug Development: Moving Forward," **November 4, 2015**, in Silver Spring, MD. ***Comments are due October 7, 2015***.

Public Meeting on Drug Interactions with Hormonal Contraceptives: Public Health and Drug Development Implications, **November 9, 2015**, in Silver Spring, MD.

Public Meeting on Labeling Lower-Dose Estrogen-Alone Products for Symptoms of Vulvar and Vaginal Atrophy, **November 10, 2015**, in Silver Spring, MD. ***Comments are due October 16, 2015***.

Public Workshop titled "Standards-Based Approach to Analytical Performance Evaluation of Next Generation Sequencing In Vitro Diagnostic Tests, **November 12, 2015,** in Silver Spring, MD.

Public Workshop titled "Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants, **November 13, 2015**, in Silver Spring, MD. ***Comments are due November 25, 2015***.

Public Meeting on Reauthorization of the Biosimilar User Fee Act, **December 18, 2015**, in Silver Spring, MD. ***Comments are due January 19, 2015***.

Medical Devices

Public Workshop titled "Non-Microbial Biomarkers of Infection for In Vitro Diagnostic Device Use," **October 16, 2015**, in Silver Spring, MD.

Advisory Committees

Arthritis Advisory Committee, **October 23, 2015**, in Silver Spring, MD.

Bone, Reproductive, and Urologic Drugs Advisory Committee, **November 3, 2015**, in Silver Spring, MD.

Anesthetic and Analgesic Drug Products Advisory Committee, **November 6, 2015**, in Silver Spring, MD.

Vaccines and Related Biological Products Advisory Committee, **November 13, 2015**, in Silver Spring, MD.

Joint Meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee and the Oncologic Drugs Advisory Committee, **November 18, 2015**, in Silver Spring, MD.

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee, **November 19, 2015**, in Silver Spring, MD.

Psychopharmacologic Drugs Advisory Committee, **December 1, 2015**, in Silver Spring, MD.

Pulmonary-Allergy Drugs Advisory Committee, **December 9, 2015**, in Silver Spring, MD.

For more comprehensive listings of FDA meetings, please visit these FDA web pages:
Meetings, Conferences, and Workshops (Drugs)
Workshops, Meetings, and Conferences (Biologics)
Workshops and Conferences (Medical Devices)
FDA Advisory Committee Calendar

Recent Notable Drug and Device Approvals/Clearances

FDA approves new injectable drug to treat schizophrenia (October 6, 2015)

FDA approves expanded indication for medical device to treat a form of brain cancer (October 5, 2015)

FDA approves Keytruda for advanced non-small cell lung cancer (October 2, 2015)

FDA permits marketing of new laser-based hearing aid with potential for broad sound amplification (September 29, 2015)

FDA approves two new drug treatments for diabetes mellitus (September 25, 2015)

FDA approves new oral medication to treat patients with advanced colorectal cancer (September 22, 2015)

FDA approves new drug to treat schizophrenia and bipolar disorder (September 17, 2015)

For additional information on drug and device approvals and clearances, please visit FDA's web pages on Drug Approvals and Databases (includes biologics) and Device Approvals, Denials, and Clearance.

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UPCOMING EVENTS

October 15–16, 2015: Colleen Heisey will moderate a panel discussion at the Medical Device Law 2015 Conference, cosponsored by the American Bar Association ("ABA"), Medical Device Manufacturers Association, and FDLI, in Washington, D.C.

October 24, 2015: Maureen Bennett will speak about *International Clinical Research Issues* at the ABA's Section of International Law fall meeting in Montreal.

December 2, 2015: Maureen Bennett will give a presentation on *International Clinical Research Issues* to the Boston Bar Association's Health Law Education Committee.

RELATED PRACTICES

FDA Regulatory & Compliance Counseling
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