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European Council Divided on Reprocessing, Could Slow Press for 'Trialogue' Debate

Members of the Council of Europe are at odds over whether to allow reprocessing of single-use devices, and the disagreement could upend efforts to pass device reform legislation before EU elections in May.

At a Dec. 10 meeting to discuss the proposed device and IVD regulations, member states were divided over the issue of whether reprocessing should be allowed — with Germany, Croatia and Slovakia supporting reprocessing of single-use devices and most other states urging that it be left up to the individual states' discretion, according to a Dutch briefing document on the session.

Erik Vollebregt of Axon Lawyers in the Netherlands says the Council seems willing, however, to live with the European Commission's original proposal, which would require reprocessors to "satisfy the obligations incumbent on manufacturers" and prohibit reprocessing of single-use devices for critical use, such as implants.

The reprocessing issue is proving a sticky wicket in moving the Council to "trialogue" discussions with the Commission and Parliament, and Vollebregt says it will be up to the Council's incoming president to "close the deal" before May elections.

Premarket Scrutiny

The other big issue is the proposed EU-level premarket scrutiny mechanism, which industry and many member states see as overly burdensome. "My thoughts mirror the Dutch and UK position, which basically say we need more [postmarket surveillance] and less frontloaded [premarket approval], and we need to adopt a regulation that will do what it is supposed to rather than increase administrative costs and complexity and delay market access," Vollebregt tells *IMDRM*. He would prefer to scuttle the current proposals if it means getting a more industry-friendly regulation down the road.

As the Council's presidency shifts from Lithuania to Greece this month, Vollebregt questions whether the Greeks have enough clout to speed the legislation through the member states. "In this case, however, it is in everyone's interest, because we should rather accept some new iteration on this project than be stuck with unripe legislation that will not do what it is supposed to do," he says.

Gert Bos, head of regulatory and clinical affairs at BSI, says the Council's meeting shows that "there still are a lot of technical debates needed to get to unified positions." The good thing is that Greece has agreed to prioritize the work so as not to delay the trialogue unnecessarily, he adds.

In a press briefing following the meeting, Commissioner for Consumer Protection Neven Mimica said EU lawmakers have already demonstrated "political will" by adopting the proposed measures. "It is now up to member states to take the discussion forward to ensure adoption under the current legislature," he said, adding this task should be given "utmost urgency."

Mimica acknowledged that the proposed framework won't prevent all instances of fraud and malpractice, but said it should allow member state authorities and the Commission to identify fraud "in time, much faster than has been the case."

The current legislative session ends June 30. In practice, many parliamentarians will go to their countries by April to work on reelection, Bos notes. "But at a slower pace, the work will continue till June and a vote could indeed take place in that month if all the stars align," he says. — Nick Otto

Japanese Law Sets Wheels in Motion For Device Regulatory Framework

As 2013 wound down, lawmakers in Japan pushed through drug overhaul legislation, paving the way for a distinct regulatory regime for medical devices and raising industry hopes that long-awaited device regulations won't be far behind.

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The following documents covered in this issue of the *International Medical Device Regulatory Monitor* are available for download at www.fdanews.com/IMDRMdocs.

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Philip Agress, AdvaMed's senior vice president for global strategy and analysis, says the trade group has been pressing Japanese officials for years to adopt a separate regulatory framework for devices. Currently, devices and in vitro diagnostics are regulated under the country's drug laws, "and that doesn't necessarily work well for devices," he tells *IMDRM*.

The Law Ensuring the Quality, Efficacy, and Safety of Drugs, Medical Devices, etc. brings several key changes to industry, including the expansion of private sector third-party certification for high-risk devices. Under the current system, only low-risk products can be reviewed by third parties, with special control devices requiring Pharmaceuticals and Medical Devices Agency review.

Third-party entities, such as notified bodies, would have to meet specified standards, yet to be defined. The law also calls for rules and regulations to be established on such issues as the transfer of marketing authorization from one individual or entity to another and cancellation of certification by the health minister.

The current licensing and approval system for devices will be replaced with a registration system that, according to Agress, will be more like a notification process. Implantable devices currently designated by the PMDA will be subject to reevaluation under the criteria of the new law, and a use results surveys performed.

The law establishes a risk-based classification system for medical devices. Class I "general" medical devices would require simple notification to the PMDA. Class II "controlled" devices would need third-party certification. And Class III and IV "specially controlled" devices would require third-party certification and review and approval by the PMDA.

QMS Audits Streamlined

Leasing of specially controlled devices will be subject to licensing or notification, even if the devices are leased free of charge. And standalone diagnostic programs, such as an MRI workstation, will be regulated as medical devices.

Meanwhile, quality management system audits of manufacturing and control methods will be streamlined under the reform law and conducted on a product-group basis, the unofficial summary says. Devices belonging to product groups that met PMDA standards in previous QMS audits would be exempt from future audits. Further, QMS audits by prefectural offices would be eliminated

and replaced by audits conducted by the PMDA and third-party certifiers.

Nobuo Uemura, director of the PMDA's Office of Medical Devices III, has said the legislation aims to make device safety measures more practical and reasonable. In an effort to meet an agency goal of cutting device review times by 30 percent, the PMDA earlier this year relaxed stability testing reporting requirements for some devices (*IMDRM*, March).

Now that the Diet has approved the law, Japan's Ministry of Health, Labour and Welfare has a year to issue a series of notices and ordinances prior to its taking effect. "Industry will be discussing intensively with the Ministry some of the key issues that they'll be working on," Agress says, but he doesn't see any red flags to be concerned about. — Nick Otto

Year in Review: Devicemakers Ride Regulatory Roller Coaster Into 2014

Regulatory affairs folks had little time to relax in 2013, with heated debates over the future of EU device regulations, new controls in Japan and a proposed regulatory framework in India. And that's just the tip of things. During the year, Malaysia got busy implementing its new device law and Brazil eased the process for device registration. Members of the International Medical Device Regulators Forum cemented plans for a January launch of a single-audit pilot program, and the U.S. Food and Drug Administration finalized rules for unique device identification. Use this review to reflect on developments in 2013 and prepare a winning business strategy in 2014.

EU Device Reforms: The European Commission's proposed medical device and IVD regulations hit some bumps along the way, but have finally made it to the coveted "trialogue" conversations between European Parliament, Council of Ministers and the Commission.

Throughout the year, industry kept up a chorus of opposition to a centralized premarket mechanism for high-risk devices under the aegis of the European Medicines Agency, saying it would destroy the EU's competitive edge vis-à-vis the U.S. In October, the Parliament approved language limiting the EMA's involvement with notified bodies to only "special notified bodies" anointed to do conformity assessment of Class IIb, III and other high-risk devices.

In addition to the device and IVD overhauls, lawmakers introduced a data protection bill that would impose new hurdles on companies wanting to transfer data out of the EU for approval purposes in other regulatory jurisdictions. The measure would also require patients' consent to profile them when needed to pursue a contract or for other reasons.

Notified Bodies: Improving the performance of notified bodies was a priority in the EU during 2013. A recent report by the Notified Body Operations Group found "generally satisfactory" levels of compliance with legal requirements and best practices, but a number of issues with organizational requirements and quality management systems.

As lawmakers wrangled over premarket controls, the European Commission adopted new rules clarifying the criteria notified bodies must meet to operate in the EU and the tasks they must perform when they audit and assess device facilities. A pilot audit of 11 notified bodies, conducted jointly by the commission and EU member states, resulted in two suspensions pending correction of deficiencies.

Regulatory Changes in Asia: During the summer, India's health minister introduced a bill to overhaul the country's 73-year-old drugs law and establish a first-ever comprehensive regulatory framework for devices. The legislation called for a Central Drugs Authority overseen by a council of permanent secretaries from related ministries to regulate both drugs and medical devices. It also would have extended new clinical trial compensation rules to device trials. Stricter compensation policies, first announced in January, drew backlash from industry and the research community. The U.S. National Institutes of Health said it would withdraw from clinical trial research in India due to uncertainties posed by the requirements.

The Central Drugs Authority bill was short-lived, however. The Departmental Committee on Health and Family Welfare, in Parliament's upper house, rejected the concept of a council running the agency in favor of a chief drug controller general of India at the secretary level.

Even before the committee's December report, Amy Hariani, director and legal policy counsel for life sciences at the U.S.-India Business Council, gave the bill low odds of getting passed, saying other, more controversial issues were on lawmakers' agendas.

In China and South Korea, government officials reacted to growing concerns about food and health product safety by elevating their regulatory authorities to cabinet level. The China Food and Drug Administration issued guidelines urging devicemakers to step up use of

adverse event reporting systems, beefed up inspections of device clinical trials and tightened controls of IVD reagents. The CFDA also drafted measures to fast-track approvals of novel medical technologies.

Korea's new Ministry of Food and Drug Safety announced six medtech priorities, including establishing an advanced safety control system and supporting the development of high value-added technologies.

In Malaysia, regulators were busy implementing the 2012 device regulations, issuing guidelines on registration and good distribution practice, and outlining criteria for device installation and acceptance criteria. And at year's end, industry cheered Japan's adoption of legislation establishing a distinct regulatory regime for medical devices (*see story, page 2*).

Collaboration Down Under: Efforts to merge Australia's and New Zealand's medical product authorities continued to progress, with the creation of a joint warning system in March to notify the public of potential safety issues with regulated goods. The decade-long effort to create a trans-Tasman regulatory scheme stems from a 2003 treaty between the two countries. The plan derailed in 2007 when New Zealand's Parliament failed to pass implementing legislation, but was revived in June 2011.

MDSAP: On a more global scale, the International Medical Device Regulators Forum formalized plans for the Medical Device Single Audit Program. A pilot involving U.S., Canadian, Australian and Brazilian regulators is set to launch this month. Companies that score high on an audit in one of the participating countries would not have to undergo audits by regulators in the other countries.

Rollout of the pilot will begin the selection of MDSAP auditors. Initially, the pool of applicants will be limited to the 14 auditing organizations recognized by the Canadian Medical Devices Conformity Assessment System, most of which are also notified bodies. Devicemakers will be able to apply to participate in the MDSAP pilot in June. Regulators in the EU and Japan, which are also IMDRF members, are not participating in the pilot.

UDI: After multiple missed deadlines, the U.S. Food and Drug Administration in September published its final rule on unique device identification, dramatically changing how devicemakers label their products.

Industry praised the rule, saying concerns about placement and implementation had been addressed. The FDA also eased the time frames for implementation, allowing Class III companies to extend the one-year deadline by another year and giving Class II and Class I manufacturers three years and five years, respectively, to set up a UDI system.

Scandals and Bribery: While regulatory sunshine was a key theme in 2013, the year also shed light on corporate transparency. Alleged corruption at drug giant GlaxoSmithKline sparked a massive probe by Chinese officials into unscrupulous activities across the drug and device industries (*see story, page 10*).

In Brazil, officials signed a law aimed at stemming corporate bribery of government officials in all business sectors. Legal experts called the legislation "game changing." Companies found guilty of offering bribes face fines of up to 20 percent of their gross annual revenue from the previous year, or a maximum of about US $30 million. The government also has authority to suspend or dissolve a company's operations and confiscate its assets.

Brazil's Anvisa also yielded to industry complaints over lengthy delays to register products, agreeing to accept GMP certificates from recognized foreign authorities in lieu of a BGMP. — Nick Otto

Canada Proposes Stiffer Requirements, Fines to Guard Against Unsafe Devices

Legislation introduced last month by Canada's health ministry would require medical device companies to revise product labels to reflect new risk information, including updates on pediatric warnings, and conduct further tests when issues arise around vulnerable populations, such as children and the elderly.

Specifically, the government could require marketing authorization holders to "compile information, conduct tests or studies or monitor experience in respect of the therapeutic product … and provide the [Health] Minister with the information or the results of the tests, studies or monitoring."

The Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) also calls for mandatory reporting of serious adverse device incidents by healthcare institutions and stiff new penalties for unsafe products, including jail time and fines up to about US $4.7 million per day versus the current $4,700. Courts could impose steeper fines against companies and individuals that intentionally marketed unsafe products.

The bill, C-17, applies to medical devices, prescription and over-the-counter drugs, vaccines, gene

therapies, cells, tissues and organs. It was introduced Dec. 6 by Minister of Health Rona Ambrose.

"Canadians deserve to have confidence that the medicines they use are safe," Ambrose said. This measure will "help ensure that no drug that is unsafe is left on store shelves," she added.

MEDEC, Canada's device industry association, was still reviewing the proposal and had not formulated an opinion at press time.

In addition to strengthening adverse reaction reporting requirements and ramping up penalties for unsafe products, the bill would enable Health Canada to respond more quickly to newly identified health risks with demands for labeling changes or product recalls. For example, the agency could require a devicemaker to add new risk information to a label or to change the brand name or packaging to avert patient injury.

Devicemakers would also need to inform Health Canada of any risks, labeling changes or recalls associated with a product that have taken place outside Canada.

Health Canada would have the authority to order recalls of products that pose an "imminent or serious" health risk. Alternatively, instead of removing a harmful product from the market, the agency could ask the manufacturer or user to implement a corrective action plan while the product remains in place, the bill says.

To reduce red tape and speed adoption of science-based decisions, the bill would give Health Canada new authority to reference technical standards, lists, guidelines or other documents in regulations. "Currently, the contents of these kinds of documents or lists are found within the regulations and can only be changed with a regulatory amendment," the agency said.

MP Terence Young, whose daughter, Vanessa, died from a heart attack while taking a prescription drug that was pulled from the market due to safety risks, called the bill a "quantum leap in protecting vulnerable patients and reducing serious adverse" events.

Certain provisions of Vanessa's Law, such as increased fines and jail times, would take effect immediately upon royal assent, Health Canada said. Other reforms would require new regulations, subject to public review and feedback.

View the bill at www.fdanews.com/ext/resources/files/12/12-13-VanessasLaw.pdf. — Meg Bryant

EC Pilot Looks to Speed Coverage Of Promising New Technologies

The European Commission is launching a pilot program to help devicemakers better understand the kinds of clinical evidence health technology assessors need to make coverage decisions, in the hopes of avoiding last-minute conflicts as companies bring products to market.

During the pilot, HTAs and companies will engage in direct discussions about the HTA's requirements for efficacy and cost-effectiveness, as well as the type of evidence — design of trials, duration, type of events/endpoints, comparators — needed for regulatory approval, a Dec. 2 call for interest states.

Devicemakers will get nonbinding advice on product development, while being enlightened about different HTA and regulatory requirements across the EU, "so as to help design a robust global development programme," the document says.

The pilots — to be conducted by the Shaping European Dialogues, or SEED, Consortium under a Commission contract — will initially involve three novel devices. Candidates may include procedures and/or diagnostics, in conjunction with other technologies or alone. Applicants should note whether the development stage is before or after exploratory, proof of concept or performance trial. Seven pharmaceuticals will also undergo multi-HTA early dialogue.

Six to seven HTA bodies will participate in each early dialogue. The pilots are scheduled to begin in March and run through January 2015.

The SEED Consortium comprises 14 national and regional HTA entities led by France's Haute Autorité de Santé. The pilots echo U.S. efforts to encourage early dialogue between device developers, the U.S. Food and Drug Administration and Centers for Medicare & Medicaid Services, which determines which new technologies the government will fund. Last month, the agencies extended for two more years a parallel review pilot, saying they need for more time to evaluate the program's effectiveness.

The Commission's call for interest will remain open until October. Applications received after candidates are selected may be considered for a reserve list in the event one of the participants halts product development, SEED says.

View the notice at www.fdanews.com/ext/resources/files/01/01-14-SEED.pdf. — Meg Bryant

NICE Recommends NHS Coverage Of Novel Heart Disease Device

The UK's cost-benefit watchdog is recommending that the government pay for operations with a new device that repairs complex aneurysms and dissections of the thoracic aorta, because the technology could reduce the need for additional procedures and the associated risk of serious complications.

JOTEC's E-vita open plus is a single-use, one-piece polyester fabric tube that combines a conventional vascular graft attached with an endovascular stent graft, allowing simultaneous treatment of the ascending aorta and the arch and descending aorta. In reviewing the clinical data, the National Institute for Health Care and Excellence's Medical Technologies Advisory Committee concluded that use of the E-vita endoluminal stent system would provide benefits compared with standard care options in a small group of patients with disease of the ascending aorta, aortic arch and the proximal descending aorta.

Specifically, the device was approved for patients with aneurysms or acute aortic dissections that require repair of the aortic arch and ascending aorta if the disease extends less than 10 cm into the descending aorta.

Current treatment of complex aneurysms and dissections of the thoracic aorta involves one of two two-stage "elephant trunk" procedures or "debranching" the head and neck vessels from the aortic arch by means of a surgical anastomosis between the ascending aorta and the head and neck vessels using a vascular graft. With the debranching technique, the endoluminal stent graft may be inserted during the same operation or a subsequent one.

Because there is no need for a second operation with the E-vita open plus and the risk of complications is reduced, outcomes for patients are improved and overall treatment costs should be reduced, the committee says. NICE estimates the JOTEC device could save the National Health Service from US $36,000 to $46,000 per patient at 10 years post-procedure compared with current practices.

To support its coverage bid, JOTEK relied on observational data gathered from 2005 through 2010 on 274 patients with complex aortic disease at eight European centers. While calling the clinical evidence "limited," the committee deemed it "sufficient, when taken together with clinical expert advice."

View NICE's guidance at www.fdanews.com/ext/resources/files/12/12-23-13-NICE.pdf. — Nick Otto

IMDRF Issues Final Guidance on UDI, Software as a Medical Device

Devicemakers must include all of the core data elements for the Unique Device Identification Database except those marked "optional," according to a harmonized guidance on UDI. Data elements marked "if applicable" are mandatory in the UDID if the information appears on the product label, the International Medical Device Regulators Forum says.

The guidance, issued last month, lists 25 core data elements. Only two of those — additional product description and URL for additional information, such as electronic IFU — are optional. Nine of the data elements fall into the "if applicable" category.

Data for device identifiers must be available in the database at the time the product is launched. This provision, also contained in the U.S. Food and Drug Administration's UDI final rule, has drawn criticism from industry, which says it could delay market entry of new devices (*see story, page 8*). The guidance finalizes a draft issued last spring (*IMDRM*, May 2013).

To achieve global harmonization, regulators must implement UDI systems "without regional or national differences," IMDRF stresses. To this end, countries should not modify the UDID core data elements and submissions should be via the Health Level Seven International (HL7) structured product label and web-based interface, the guidance says.

Further, a UDI applied to a device anywhere in the world should be recognized globally and meet the UDI requirements of any markets where the product is sold, the document adds.

In discussing UDI's benefits, the final guidance says it will facilitate the "unambiguous identification" of devices through distribution and use — strengthening the draft's reference of "adequate identification." The guidance also expands on adverse event reporting to include field safety correction actions.

IMDRF also finalized a set of harmonized definitions on device software. The document defines "software as a medical device," or SaMD, as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical devices." It also clarifies the various tasks that medical software may perform and changes to SaMD.

The issuances come on the heels of four other final documents, including requirements for auditing

organizations that wish to participate in the Medical Device Single Audit Program (*IMDRM*, December 2013).

View the UDI guidance at www.fdanews.com/ext/resources/files/12/01-14-IMDRF_UDI.pdf. The guidance on SaMD is at www.fdanews.com/ext/resources/files/12/01-14-IMDRF_SaMD.pdf. — Meg Bryant

U.S. UDI Guidance Brings Calls For Timeline Extensions, Clarity

The U.S. Food and Drug Administration's final guidance on unique device identification should allow for submission of UDI data elements within 10 days of commercializing a device, rather than requiring that they be in the Global UDI Database before market launch, AdvaMed says. The trade group warns that the higher hurdle could lead to lost sales.

"Medical devices should be available for commercialization and distribution immediately upon receipt of FDA market authorization," the group says in comments on draft UDI guidance issued earlier this year (*IMDRM*, October 2013).

AdvaMed notes that UDI data submitted via the electronic submissions gateway may not be posted immediately, or even on the same day the device receives authorization. The group anticipates posting delays due to the system validation process, outages, transmission issues, gateway issues, untimely acknowledgment receipts and other issues.

Adding to the potential for market delays is the fact that listing numbers, product codes and market authorization numbers are not always available before FDA market authorization, or they may change, AdvaMed says.

AdvaMed also suggests keeping private the required field for "device exemption from premarket submission." If the field is made public, other companies or watchdog groups could search for products on the market without a 510(k) or PMA. This "could lend itself to companies informing on each other if they perceive a business disadvantage from someone playing looser with Part 807 requirements," the group says.

The FDA's final UDI rule and draft guidance, published in September, change how devicemakers label their products. UDIs must include two distinct identifiers:

- The device identifier, which lists the specific version or model of the device; and
- The production identifier that more precisely identifies the specific device through information such as lot or batch, serial number or expiration date.

But the draft guidance lacks clarity on the scope of products for which data must be submitted, Merck says. In particular, the company would like the FDA to elucidate the guidance's applicability to combination products or standalone software devices.

Clarity Sought on GUDID Testing

The draft's section on HL7 SPL submission testing requirements lacks clarity as well, says GE Healthcare. The company urges the agency to provide more information on the GUDID testing requirements, which it recommends be released as soon as possible so that companies can do their testing before the Class III compliance deadline — Sept. 24, 2014. AdvaMed believes the implementation time frame should be extended beyond that date.

Industry also takes issue with the "data entry notes" instructions in Appendix B, which require tracking the history of device changes beyond the requirements for the FDA Unified Registration and Listing Systems database. "This is overly burdensome and does not add value for users of the database," the group contends. And adding this data retrospectively for all primary device identification records would take significant resources at the initial data submission, it adds. AdvaMed recommends entering the listing number that corresponds to the FDA premarket submission number, rather than all previous listing numbers.

Further, some of the data elements required in Appendix B are inconsistent and create conflicting requirements with the UDI rule, Boston Scientific writes. The devicemaker recommends modifying the guidance and database to ensure consistency with 21 CFR 830.

The FDA should also clarify whether there will be a process for editing typos in DI attributes, which, under the draft guidance, can't be edited after the grace period ends, AdvaMed says. GE recommends that the grace period for correcting information in the published record be extended from seven to 10 calendar days.

AdvaMed urges the FDA to allow another opportunity for public feedback after the agency has a "meaningful dataset" of DI records. — April Hollis

AHWP Steps Up Adoption Of Global Device Standards

The Asian Harmonization Working Party has released a strategic framework aimed at bringing medical device regulation of member nations in line with recommendations of the Global Harmonization Task Force, now known as the International Medical Device Regulators Forum.

The *Strategic Framework for 2012-2014: Foreseeable Harmonization Horizon* is intended to serve as a guide for various AHWP activities, including organizational presence and partnership, expansion, training and capacity building, and the regulatory convergence goal. The framework includes a four-pronged implementation plan: membership expansion; training and capacity building; key harmonized areas based on GHTF principles and AHWP guidance; and enhanced global partnerships between AHWP and other international organizations.

AHWP wrapped up the year with a raft of draft guidances. The documents, adapted from GHTF guidances, cover:

- Nonconformity grading system for quality management systems;
- Regulatory framework for in vitro diagnostics;
- Essential principles of IVD devices;
- Summary technical documentation for demonstrating conformity to the essential principles for IVDs;
- Comparison of the GHTF STED format and the common submission dossier template for medical devices and IVDs; and
- Adverse event reporting for the manufacturer or authorized representative.

The draft documents can be found on the AHWP's website at www.ahwp.info. — Nick Otto

India Offers Detailed Guidance On Registration, Import of IVDs

India's Central Drugs Standard Control Organization has issued detailed guidance on submission requirements for the registration, reregistration and import of notified in vitro diagnostic kits and import of non-notified kits, with the aim of facilitating application reviews and easing transition to electronic submissions.

According to CDSCO, the use of esubmissions "may happen in the near future."

To register or reregister an IVD, companies should include the standard cover letter, authorization letter, fees and power of attorney information. The information may be provided in a single file, with the plant master file and device master file submitted in separate files, the final guidance says. In the case of

reregistration, a copy of the registration certificate should accompany the application.

Other documents required for registration/reregistration include the wholesale license for sale or distribution of drugs; manufacturing license issued by the state drug licensing authority, if the test kit is imported; free sale certificate; ISO 13485 certificate; CE full quality assurance certificate, if applicable; CE design certificate, if applicable; declaration of conformity; performance evaluation report; evaluation report by regulator in country of origin on three consecutive batches; product insert, in English; original colored labels and pack size; requirements for the site and device master files; specimen batch test report for at least three consecutive batches; detailed test report on components; shelf life, specificity and sensitivity; and sort copy of dossier summary sheet in word format.

"All certificates submitted should be within the validity period and should have at least six months valid period at the time of submission of application," CDSCO notes.

Submission requirements for import of notified and non-notified kits are similar to those for registration/reregistration. Each of the four types of notification requires a specific form.

The guidances are already in effect. View the guidance on registration/reregistration of IVD kits at www.fdanews.com/ext/resources/files/01/01-14-IndiaIVDreg.pdf, the guidance on import of notified kits at www.fdanews.com/ext/resources/files/01/01-14-IndiaIVDimport.pdf and the document on import of non-notified kits at www.fdanews.com/ext/resources/files/01/01-14-InidaIVDlicense.pdf. — Nick Otto

China Escalates Corruption Crackdown With Public Shaming, Market Ban

China's National Health and Family Planning Commission announced "severe" new measures aimed at barring device- and drugmakers convicted of bribery from selling their products in the domestic market — for as long as four years in some cases.

The "Establishing commercial bribery record in drug/device purchase and sales" rule, issued Dec. 27 and effective in March, updates a 2007 rule on commercial bribery.

The new rule follows a plan to publicly shame drug companies that knowingly market unsafe or inferior healthcare products by publishing executives' names on a government "blacklist."

Devicemakers found guilty of bribery will have the record of their misdeeds published on the provincial NHPFC office's website. Within a month of that airing, the national NHPFC will be notified and it, too, will post the record, explains Juliet Zhu, with L.E.K. Consulting's Shanghai office. Bribery records include information such as company name, address, legal representative, name, title, incident and verdict.

Public or government-funded health organizations that accept bribes will be not be allowed to purchase products from the offending company for two years in the province where the offence occurred, Zhu says. Companies found guilty of bribery twice in five years will be barred from selling their products to publicly funded healthcare institutions nationwide for an additional two years.

The new rule also requires purchasing contracts to include an "integrity sales contract," which illustrates the sales representative's commitment to ethical business standards.

The rule follows the Dec. 26 publication of a code of conduct on physician interactions with sales reps. Among other things, the code prohibits doctors from

participating in promotional activities and accepting industry kickbacks.

Zhu likens the code to a "moral guidance" for physicians. Combined with the updated bribery rule, it underscores an "escalating" government commitment to stamp out graft and other illegal business practices, she says. — Nick Otto

Disputes Over U.S. Sunshine Act Reporting Could Trigger Audit

Medtech companies could wind up in the crosshairs of U.S. government auditors if the payments they report under the Physician Payment Sunshine Act are frequently disputed by doctors and teaching hospitals.

The rule took effect Aug. 1 and the first reports are due by March 31. The Centers for Medicare & Medicaid Services will begin publishing the data on a public website in September 2014. While the law mainly targets U.S. companies, it also applies broadly to foreign manufacturers that have plants or offices within the U.S., either directly or through an authorized representative, including a sales agent.

Although CMS will not comment on how it intends to enforce compliance with the new law, it will probably view disputes and discrepancies as warning signs that a devicemaker does not have adequate reporting systems in place, says Lisa Murtha, a partner at Dentons law firm.

Under the transparency law, physicians and academic medical centers have 45 days to review and either certify or dispute a manufacturer's reported payments before the information becomes public. Manufacturers will be notified of any dispute and offered an opportunity to resolve the dispute within 15 days of the end of the 45-day period. If the dispute isn't resolved, CMS will publicly report the company's reported amount, but mark it as disputed.

Discrepancies between amounts reported by manufacturers and doctors in conflict-of-interest disclosures to teaching hospitals or research sites can also draw CMS scrutiny, Murtha says.

She advises devicemakers to notify physicians and teaching hospitals in advance that they intend to report a payment and what the amount will be, in order to resolve disputes before they reach CMS' attention.

Device companies should retain receipts for payments, canceled checks or some sort of proof of payment for every amount reported under the Sunshine Act, Murtha says.

She also urges manufacturers to have clear policies in place regarding what type of payments can be made and for what purposes, who has the authority to make these payments and what disclosure mechanisms will be used to track and report payments.

Jennifer Geetter, a partner at McDermott Will & Emery, recommends that companies develop an audit response strategy and then rehearse it. Key personnel should be trained in how to handle an audit and a point person should be designated to respond when an auditor appears on the government's behalf, she adds.

As the deadline for reporting draws near, CMS is attempting to clarify some aspects of the rules. The agency noted recently, for instance, that devicemakers do not need to report repairs or training provided under warranty or the names of third parties, such as contractors, that indirectly provide a research payment to a doctor or other entity covered under the law.

Minimum Thresholds Raised

On the must-report list are payments made outside the U.S. and donations provided to a teaching hospital's foundation at the request of, or on behalf of, a physician. For journal reprints, the value should be based on the cost the manufacturer paid to acquire the reprint, CMS says.

The agency has raised 2014's minimum reporting threshold on gifts and payments from US $10 to $10.18 for individual payments, and to $101.75 for aggregate payments, up from the 2013 limit of $100. The thresholds track the U.S. consumer price index and are adjusted annually.

The Sunshine Act requires devicemakers and drugmakers to disclose all payments to physicians and teaching hospitals. U.S. Rep. Robert Andrews (D-N.J.) has asked CMS to revise its rules to exempt food served at events connected to continuing medical education from the reporting requirements.

The agency has published Q&A guidance clarifying aspects of the transparency law, available at https://questions.cms.gov/faq.php?id=5005&rtopic=2017. For more information on the act, visit www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html. — Melissa Winn, Robert King, Johnathan Rickman

IN BRIEF

CFDA Simplifies Reregistration

The China Food and Drug Administration last month issued a notice laying out scenarios for simplified reporting when reregistration of a medical device is necessary. For example, reregistration due to an address change will not require the submission of registered product standards and test reports. This will reduce the reporting burden on companies and free the CFDA up to focus on reregistrations involving more substantive product and technical changes, the agency says. The CFDA also issued a draft notice on reregistration requirements for medical device software. Both notices are available on the agency's website.

Team-NB Completes First Member Audits

A first round of member audits by the European Association for Medical Devices of Notified Bodies found no violations of the group's code of conduct, which became mandatory in April 2013. Team-NB Director Françoise Schlemmer said plans are to audit every member over a three-year period, averaging about 10 audits per year.

UK's NICE Plans Medtech Briefings

The National Institute of Health and Care Excellence will begin publishing medtech innovation briefings in early 2014. The briefings — produced by NICE's Medical Technologies Evaluation Programme, which also produces guidance on new technologies — will cover the nature of the device, its indications, costs of using the device, and a review of supporting evidence. NICE stressed that the briefings will not include recommendations or guidance.

Vietnam Issues Device Requirements

Vietnam's Ministry of Health has issued a decree specifying requirements for the manufacture, sale, services, information and advertising of medical devices. The decree also covers quality management systems and technical personnel in manufacturing plants. Comments on the Decree on Medical Devices are due by Feb. 4. It is slated to take effect July 1.

Feedback Sought on Malaysia Regs

Legislation establishing a device regulatory framework in Malaysia took effect just six months ago, and the Medical Device Authority wants to hear from stakeholders on how implementation and the transition to establishment licensing and device registration is going. The agency has hired Frost & Sullivan Malaysia to analyze several issues, including: single versus multiple authorized representative(s) to represent devicemakers operating outside Malaysia; licensing of establishment by local manufacturer, authorized representative, importer or other entity that carries out multiple roles; and registration of devices by regulators recognized by the MDA. Interested parties can write to healthcare.survey@frost.com.

Argentine Devicemakers Sign COCIR Code

GE, Philips, Siemens and Griensu S.A. signed the COCIR Code of Conduct covering their Argentina units. The pact represents the first signing of code in Latin America. COCIR Secretary General Nicole Denjoy said the group has "been working consistently for a number of years to extend [the code's] geographical reach, particularly to BRIC countries." The code was launched in 2009 and has been widely adopted across Europe.

Saudi Arabia: Imports Need DOC Certificate

Effective Jan. 3, importers and authorized representatives must apply for a Declaration of Conformity certificate for each shipment of medical devices authorized for sale in Saudi Arabia. Applicants must supply the manufacturer identification number assigned by the Saudi Food and Drug Administration, the name of the authorized representative or importers, device marketing authorization number, device description, quantity, SFDA listing number and serial/batch numbers.

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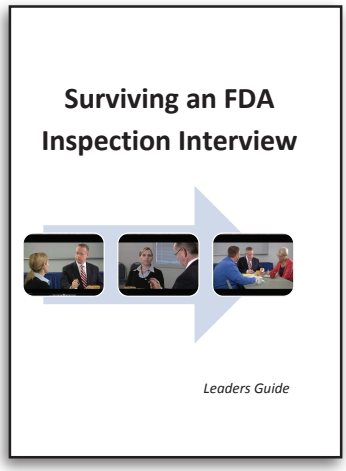

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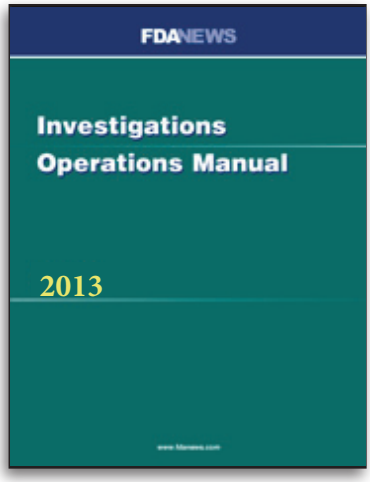

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