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Medicrime Convention Criminalizes Counterfeiting of Medical Products

Device manufacturers will be held accountable for the legitimacy of their products under the first binding international document to deal with counterfeit medical products.

The Council of Europe's Medicrime Convention introduces preventive and penal measures for the criminal counterfeiting of medical products on the national and international levels.

The convention, which includes 47 countries to date, criminalizes:

- Manufacturing of counterfeit devices;
- Supplying, offering to supply and trafficking in counterfeit devices;
- Falsifying documents; and
- Marketing of devices that do not comply with conformity requirements.

Adopted last month, the convention includes guidelines for national and international cooperation. A monitoring body will be created, with representatives from each member country, to implement the convention.

"The Council of Europe has long been concerned about the absence of harmonized international legislation, non-deterrent sanctions in proportionate to the harm caused to patients, and the involvement of criminal organizations which operate across borders," Swissmedic, the Swiss agency for therapeutic products, says.

Counterfeiting is a multibillion euro industry that is often linked to organized crime and drug trafficking, according to the Council of Europe.

Counterfeit medical products are more of a threat in developing countries. For instance, counterfeits make up less than 1 percent of the market value in developed countries but more than 50 percent in developing countries, according to the World Health Organization (WHO).

Much of the marketing of counterfeit devices is done online. The creation of the Medicrime Convention follows an international offensive against online distributors of counterfeit medicinal products that resulted in the October seizure of more than 1 million pills at an estimated \$2.6 million value.

Other countries and organizations are taking similar efforts to go after counterfeiters. The Anti-Counterfeiting Trade Agreement, for example, is being negotiated by Australia, Canada, the EU, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland and the U.S. (*IMDRM, November 2010*).

Similarly, the WHO has introduced initiatives to combat counterfeit products globally (*IMDRM, February 2009*).

The draft convention and related materials are available at www.coe.int/t/DGHL/StandardSetting/MediCrime/Default_en.asp. — Molly Cohen

IVD Market Remains Strong in Europe, But Budget Problems Hamper Growth

Although growth has slowed, the in vitro diagnostics (IVD) market remains strong in Europe, according to a report from the European Diagnostic Manufacturers Association (EDMA).

IVD revenues for 2009 grew 3 percent, down from 4.2 percent growth in 2008. Overall, IVD sales accounted for 0.8 percent of total 2009 healthcare expenditures in Europe, the trade group says.

The slowdown is not due to demand, which is increasing due to aging populations, patients that are more informed and the availability of improved technologies. More than 60 percent of the information in patients' files comes from IVD tests, EDMA says.

Rather, it attributes the slower growth to the economy and the increasing number of tests being done in private laboratories. While most IVD testing is still conducted in hospitals, the association notes that more hospitals are outsourcing testing to reduce their costs.

Additionally, several European countries are restricting testing volumes and reimbursements to balance their budgets, the report says. For example, Greece, Hungary, Norway and Romania had notable drops in IVD revenue due to budget cutbacks.

Government restrictions also have negatively affected IVD revenues in Germany and Italy, as well as the reimbursement for IVDs in Turkey. Despite its drop in reimbursement, Turkey has seen an increase in the volume of testing.

The IVD market increased slightly in Portugal and has been growing strong in Spain. But some of Spain's communities are looking at outsourcing hospital testing. In Madrid, new hospitals are to be built and managed by a temporary union of companies that will provide clinical analyses at a fixed price per patient, EDMA says.

Switzerland is unique in its level of IVD testing in doctors' offices, but it is reducing reimbursement for IVD testing to tackle budget deficits. In 2012, the country will introduce a new scheme that will reimburse hospitals according to a patient's medical condition, instead of individual testing, according to the report.

Late payment has been a problem for Italy and Portugal, but both countries have legislation in the works to solve that issue. Portugal also is creating new rules for negotiations for public tenders and the private sector. — Molly Cohen

US FDA Asked to Review New Data Relating to Dental Amalgam Safety

The U.S. Food and Drug Administration (FDA) should review new data to determine if dental amalgam should be reclassified, its Dental Advisory Panel recommends.

The request wrapped up a two-day advisory committee meeting last month in which advocates pressured the agency to ban the product or upgrade it from a Class II device. Advocacy groups claim dental amalgam, which is about 50 percent mercury, can cause serious health risks in certain doses and with certain populations.

The FDA has not indicated what its next step might be. But the odds that the status quo will be maintained diminished when Gary Ginsberg, a toxicology expert hired by the agency to analyze evidence presented in the petitions, questioned a key part of the regulation.

In finalizing its amalgam classification rule, the FDA based its safety level, or reference concentration (RfC), for mercury on a U.S. Environmental Protection Agency (EPA) measurement. However, further research has shown that the "current RfC appears to not be adequately protective," Ginsberg, a toxicologist with the Connecticut Department of Public Health, said at the workshop. "It would appear that several lines of evidence and calculation approaches lead to an RfC three to 10 times below that derived by" the EPA.

The FDA classified dental amalgam as a Class II device in 2009 and reclassified dental mercury from Class I to Class II. It also issued special controls for dental amalgam, mercury and amalgam alloy (*IMDRM, August 2009*).

Since then, the agency has received several petitions claiming the special controls and classification do not address the potential risk the devices pose to vulnerable populations, such as pregnant women, fetuses and young children. Those issues were raised again at the December advisory committee meeting.

But in arguing for the status quo, industry and dentists touted the cost effectiveness of amalgam and pointed to its years on the market as evidence of its safety. Dental amalgam has been on the U.S. market in its present form since the late 1800s. More than 50 million amalgam restorations are done each year in the U.S.

A ban or restrictive regulations "could adversely affect access to care in this county," William Spruill, president of the Pennsylvania Dental Association, said. Certain populations, such as fixed-income senior citizens, might not seek care if amalgam is not an option, he added.

Gary Price, CEO of the Dental Trade Alliance (DTA), agreed that banning amalgam or regulating it as a Class III device could have a wide impact on industry and ultimately patients if dentists were forced to use other alternatives to fill teeth. (DTA is an association of companies that provide dental devices and services to dentists and other oral care professionals.)

The composition and characteristics of dental amalgam allow it to be easily placed and make it less technique-sensitive than the most common alternatives. That makes it less costly than porcelain, gold crowns or onlays, Price told *IMDRM*. “Dental amalgam remains one of the leading dental materials for restoring teeth. Its durability, reliability, handling and low cost is still very relevant today,” he added.

The European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks has concluded that dental amalgam is safe for use in patients and that its overall risks and benefits are no greater than those of alternative restorative materials.

The committee’s 2008 review found no scientific evidence of adverse systemic effects or systemic disease associated with the use of dental amalgam. In addition, amalgam restorations tend to last longer than alternatives, which have a higher incidence of secondary caries.

The use of some alternative materials has been linked to cytotoxic and mutagenic effects, as well as allergies in patients and dental personnel, the committee pointed out in a 2008 report. “Far less information is available concerning exposure, toxicity and clinical outcomes for alternative materials,” the report says (*IMDRM*, August 2008). — Virgil Dickson

Experimental Radio License Proposed For Testing of New Wireless Devices

A proposed rule to create an experimental radio license to accelerate the development of wireless medical devices in the U.S. is playing to mixed industry reviews.

The U.S. Federal Communications Commission (FCC) proposed the rule to streamline its approval process for medical equipment so new devices can move from prototype to market in a shorter time.

The idea for the Experimental Radio Service (ERS) license for devices stems from a memorandum of understanding the FCC signed with the U.S. Food and Drug Administration at a public meeting last year. The agencies agreed to work together to improve the efficiency of regulatory processes for devices using broadband and wireless technology (*IMDRM*, August 2010).

In comments on the challenges facing wireless devices, trade association AdvaMed had asked both agencies to urge developers of standards for all wireless technologies to consider how communication devices may interact with medical devices (*IMDRM*, September 2010). The ERS license would

enable experimental devices to be tested and assessed for operational readiness in a real-world setting.

Both AdvaMed and the mHealth Regulatory Coalition applauded the FCC’s quick action. The experimental licensing would “nicely complement the investigational device exemption process the Food and Drug Administration has in place to allow medical innovation to be tested prior to clearance or approval for marketing,” coalition spokesman Bradley Thompson told *IMDRM*.

However, some industry experts say the rule does little to tackle the bigger challenges facing wireless technology. The proposed ERS license does not “address specific spectrum requests from devicemakers,” Tim Gee, principal at Medical Connectivity Consulting, told *IMDRM*.

Many of the comments made at last year’s joint public meeting “focused on the continued adoption of wireless communications by medical devices and what that means for manufacturers, providers and regulators,” he added.

Global Spectrum

Spectrum availability also was raised in comments submitted after the meeting. AdvaMed pointed out the need for worldwide wireless medical telemetry allocations, which are now the exception rather than the rule. Without international bands, manufacturers must develop unique devices for use in different countries, adding to the cost of product development, the association said.

Much of the FCC’s rule is still being fleshed out. Initially, the ERS licensing would be available for two types of medical technology: devices that use radio-frequency (RF) for ablation and devices that include at least one function that is implemented using RF wireless communications such as data transfer.

Since the program will be limited, the FCC is seeking comment on which companies should be eligible for the ERS licensing. “Should we restrict licensing to entities that meet specific criteria, such as accreditation by a particular certification body?” the agency asks. “Or should we instead require an entity, as part of its submission, to make an affirmative showing that it is engaged in the health care field and that it has sufficient resources and expertise to oversee tests conducted under the authority of a blanket license?”

Until these questions are answered, the FCC plans to require that facilities seeking an ERS license for a device demonstrate that they possess basic expertise in radio management. Under the rule, the license would be granted to the institution that creates and manages the testing environment as opposed to the manufacturers and researchers who may be conducting the tests.

The FCC has not set a deadline for comment. The rule is available at hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-10-197A1.pdf. — Virgil Dickson

Health Canada's Compliance Deadline Nears for Class I Device Software

Makers of Class I medical software must comply with Canada's Medical Devices Regulations by Feb. 1.

"Software that is intended to be used to view images, or other real time data, as an adjunct to the monitoring device itself, for the purpose of aiding in treatment or diagnosis of a patient, would be Class I medical devices," Health Canada (HC) says in a notice released last month that clarifies the differences between Class I and II software.

Class I software is exempt from the licensing requirements in Sections 26 through 43 of the Regulations. But manufacturers must make sure their software meets the remaining requirements, which focus on labeling, distribution records, problem reports, recall requirements, and safety and efficacy.

Class II software, which must be in compliance by Sept. 1, includes products that are an adjunct to a medical device and are involved in "data manipulation, data analysis, data editing, image generation, determination of measurements, identification of a region of interest in an image, or identification (by an alarm or alert) of results from a monitor that are outside of an established range," according to the notice.

Class II software must comply with Sections 10 to 20 and be labeled in accordance with specific requirements.

"The new HC requirements present a more consistent approach to medical device classification in Canada and should present no significant operational burdens for affected software manufacturers in terms of compliance," international device consulting firm Emurgo Group says.

The notice does not apply to software related to in vitro diagnostic (IVD) devices, including systems used to control IVDs or analyze their results. — Molly Cohen

To view the text of the deadline notice, [click here](#).

EU Regulators Struggling to Come Up With a Definition for Nanomaterials

Before devicemakers can expect guidance on nanotechnology, EU regulators must first decide what a nanomaterial is.

In grappling with the issue, the European Commission's (EC) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) acknowledges the complexity and uncertainties involved in trying to come up with a one-size-fits-all definition.

While size is critical to the definition, determining what that size should be and measuring it are challenges that must be addressed, SCENIHR says in an opinion released last month.

The committee recognizes safety evaluations and risk assessments of nanomaterials depend on a decisive definition. "With the expected increase in the applications of nanotechnology, there is an urgent need to identify what can be considered as a nanomaterial by clear unequivocal descriptions," it says.

While SCENIHR did not propose a definition, it offers a few conclusions:

- Since physical and chemical properties of materials can change with size, there is no scientific justification for a single upper and lower size limit that can be applied to all nanomaterials;
- No single methodology is applicable to all nanomaterials; and
- Size is universally applicable to define nanomaterials and is the most suitable measure.

"Not only is size itself important, but also the method used to measure it," the committee says. So in addition to developing a definition for nanomaterials, regulators need to develop and validate standardized methods to determine the size of the materials, along with the corresponding distribution, to ensure comparability of test results, it adds.

(See [Nanomaterials](#), Page 5)

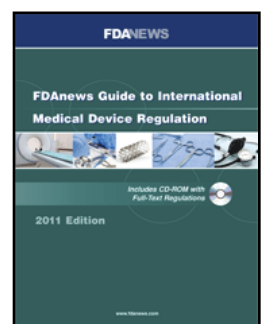
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Nanomaterials, from Page 4

The committee recommends a defined size range to facilitate uniform interpretation of a nanomaterial. It suggests 1 nm for the lower limit, with some exceptions to allow for specific entities such as grapheme, clusters and complex hybrid molecular structures. It also recognizes that the distinction, at this level, of molecules, nanoclusters and nanoparticles becomes unclear.

Setting the upper end of the size range is more difficult, SCENIHR says, as no scientific evidence favors a single upper limit. While an upper limit of 100 nm is commonly used, there is no justification for it, and it may be too limiting.

Instead, the committee suggests a three-tiered approach using intermediate thresholds: materials greater than 500 nm, those ranging from 100 nm to 500 nm and those from 1 nm to 100 nm.

In adopting a definition, SCENIHR advises the EC to consider an over-arching one that would include next-generation nanomaterials and would not become obsolete too quickly.

The committee also discusses other challenges in regulating nanomaterials. Current risk assessment methods, for instance, may be applicable for nanomaterials in general, but they may not be sufficient to address all the hazards involved. Thus, current assays may “need to be supplemented by additional tests, or replaced by modified tests, as it cannot be assumed that current scientific knowledge” has identified all potential adverse effects of nanoparticles, it says.

Agencies in the EU and the U.S. have been struggling with how to regulate nanotechnology for a few years. A 2008 UK environmental report called for urgent testing and regulation to control the rapidly developing field, and FDA scientists are trying to expand their knowledge in the field (*IMDRM, December 2008*).

Noting a lack of nanotech-specific regulations, the EC adopted a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research in 2008 aimed at minimizing the risk of environmental, health and safety consequences from the manufacture and use of nanotechnology (*IMDRM, March 2008*).

SCENIHR’s opinion on defining nanomaterials is available at ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_o_032.pdf. — Molly Cohen

MTAA: Australia Needs More Tools To Regulate Combo Technologies

Citing a range of new technologies that cross the line between devices and drugs, the Medical Technology Association of Australia (MTAA) is urging regulators to develop more tools to assess combination products.

Australia’s current system poses many challenges for co-dependent technologies, but the biggest issues are fragmentation,

lack of coordination and replication, MTAA says in response to a proposed methodology to assess combination products.

The methodology, proposed by Australia’s Department of Health and Ageing, focuses on a simple pairing of a diagnostic test with a drug. MTAA notes that the draft does not cover the many hybrid and co-dependent healthcare technologies available.

The department recognized that shortcoming when it released the draft, calling it “the first step in formulating a framework to manage the evidence and process issues involved in dealing with co-dependent technologies.”

It plans to use comments on the draft, which were due last month, to develop more comprehensive guidelines that can address more complex combination products.

MTAA offers numerous examples of co-dependent technologies that have faced regulatory challenges, including continuous glucose monitors connected to insulin pumps. The pump is reimbursed, but the monitor isn’t, which means the patient may have to pay for it. “As insulin pumps become technically more responsive to continuous glucose monitors, the clinical benefits of the working partnership of the two devices will have more to offer patients, and its lack of reimbursement will have greater impact,” the trade association says.

MTAA’s comments are available at www.mtaa.org.au/pages/images/MTAA_submission_to_DoHA_on_co-dependent_technologies_Dec_20104.pdf. — Molly Cohen

EC Sets Strict Timeline for Sponsors To Report Serious Adverse Events

Sponsors of clinical trials to support CE marking or an expanded use for a device must report any serious adverse event (SAE) that “indicates an imminent risk of death, serious injury or serious illness” within two days of learning about it, according to new guidelines from the European Commission (EC).

Sponsors have seven days to notify their national competent authorities (NCAs) of other reportable events. They also must implement a system to ensure trial investigators inform them of adverse events that occur during the study within three calendar days.

The same timelines apply to reportable events that occur in trials being conducted in countries outside Europe but under an EU clinical investigation plan, the guidelines say.

Under certain circumstances, NCAs may agree to more lenient reporting times. For instance, they may adjust the reporting requirements for trials in which the frequency of SAEs is expected to be high due to the progression of the disease involved, the guidelines say.

The guidelines are available at ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_7_3_en.pdf. — Molly Cohen

Devicemakers: Increase in AED Events Is Due to US FDA's Reporting Policy

An increase in the U.S. of serious adverse events tied to automatic external defibrillators (AEDs) may have less to do with faulty manufacturing issues than with industry confusion over the U.S. Food and Drug Administration's (FDA) medical device reporting (MDR) policy.

To address the issue, the agency plans to revamp its 1994 MDR guidance, Megan Moynahan, leader of the FDA's Cardiac Electrophysiology and Monitoring Devices Network, said last month at a public workshop on AEDs.

The FDA received more than 28,000 adverse event reports involving AEDs from January 2005 through May; the incidents include deaths, patient injuries and device malfunctions. Many of the reports can be attributed to a conservative reading of the agency's MDR policy, Derek Smith, a senior vice president at Philips Healthcare, said at the workshop.

For instance, devicemakers or AED users may submit an MDR when a defibrillator — sitting on a crash cart, in a wall cabinet or in a closet — signals it may need service. "Should a report be made in cases where the manufacturer has data showing the issue can be detected prior to emergency use?" Smith asked.

Aggressive Approach

Not knowing exactly what to report in such situations has led Philips to adopt an aggressive approach to MDRs over the past five years, he added. Others devicemakers at the meeting said they have similar policies.

Another quandary involves patient deaths. When a company investigates such an incident, it may not be able to get all the information necessary to assess whether the patient could have benefited from defibrillation therapy, Smith said.

"Because the reporting standard is 'may have caused or contributed to death or serious injury,' whether an event is reported depends more on how much information we were able to collect, rather than on the actual contribution of the defibrillator to the patient outcome," he added.

The volume of MDRs also could be tied to the increase of AEDs on the market over the past five years. Currently, about 1.5 million AEDs are in place around the world, workshop panelists said.

Human factors also may play a role, Brian Webster, CEO of Physio-Control, a division of Medtronic, said. For instance, some incidents have occurred when obsolete devices were used.

The American Hospital Association recommends a five-year lifespan for AEDs. However, one panelist noted that American Airlines reportedly has concluded an initiative to replace all its defibrillators, many of which had been in place for 10 years.

"They have the expectation the device will last for very long periods of time," Webster said. "How are we supposed to handle that?"

As financial pressures mount, the use of outdated AEDs could become a bigger problem. Hospitals, for example, are under increasing pressure to keep costs down, so they're trying to make their devices last longer, Mary Logan, president of the Association for the Advancement of Medical Instrumentation, said.

A new challenge stems from environmental legislation that forced suppliers of commercial off-the-shelf components used in AEDs to change the materials they use. The changes make the components less reliable in the long run, Webster said.

Despite the problems raised by devicemakers, Alford Taylor, director of the FDA's Division of Electrical & Software Engineering for devices, wouldn't let them completely off the hook. "There are a lot of the situations where deficient product design or poor engineering was a cause," he said.

Putting more funds into engineering systems up front "will pay off in the long run," he added.

The workshop was part of a new industrywide initiative the FDA launched in November. The agency plans to convene an advisory panel early this year to determine the appropriate AED approval pathway that promotes the best practices for design and testing.

The devices are considered Class III, but some have been cleared through the 510(k) process. The agency hopes to make a final decision on the classification this year. — Virgil Dickson

GHTF Revises Operating Procedures, Keeps English as Working Language

In revising its document production procedures, the Global Harmonization Task Force (GHTF) is sticking with English as its primary language.

All documents produced by GHTF's study and ad hoc work groups are to be in English, according to the revised operating procedures released last month by the task force's Steering Committee.

Translation of GHTF guidances is the responsibility of each individual member. However, the Steering Committee may ask study group members to review translations for accuracy and bring significant discrepancies to the attention of the translating party.

The organization's operating procedures have not been updated since May 2008 (*IMDRM, May 2008*).

The revisions are available at www.ghtf.org/documents/sc/sc_n3r11.pdf. — Mari Serebrov

EC Seeks to Use Enhanced Cooperation To Guide Future Patent Discussions

Despite a dispute over languages, the European Commission (EC) hopes to move forward this year with a unified patent system.

Recognizing that it cannot get unanimous agreement on a proposed European Community patent, the EC has appealed to the European Council to pursue a revised patent system through enhanced cooperation.

The push for a unified patent bogged down last year when the proposal called for the patent system to use English, French and German — the official languages of the EU. But Spain and Italy argued that such a system discriminated against their languages (*IMDRM, December 2010*). The problem was not resolved by a compromise to offer cost-effective translation services.

When the measure did not get the required unanimous support, several member states proposed enhanced cooperation, a last resort effort to continue discussing an important issue.

Currently, 12 member states have joined the enhanced cooperation: Denmark, Estonia, Finland, France, Germany, Lithuania, Luxembourg, the Netherlands, Poland, Slovenia, Sweden and the UK. Other member states may join at any time.

The EC's proposal to the council is available at ec.europa.eu/internal_market/indprop/docs/patent/COM%282010%29790-final_en.pdf. — Molly Cohen

Eucomed Offers Members Advice On Sponsoring Conferences

Devicemakers trying to comply with Eucomed's ethics code should only sponsor programs that are rigorously scientific or educational, the trade association says.

The content of sponsored programs must include current scientific information that is appropriate for healthcare professionals, according to an advisory interpretation provided by the Eucomed Compliance Panel.

Responding to devicemakers' requests for more guidance on third-party sponsorships, the independent panel gives the following recommendations:

- Faculty delivering the program must be competent and qualified to discuss the topic. If they are sponsored by Eucomed members, they must disclose that fact;
- Representatives of Eucomed members should not serve as faculty unless the program is part of a Eucomed member-sponsored satellite symposium;

- Program information and the identity of faculty must be available to Eucomed members in advance so they can determine the rigor and quality of the program;
- The program should not include leisure or sports events; and
- The program generally must involve full-day schedules of scientific and educational sessions. While half-day programs are permissible, the rest of the day cannot include nonscientific or noneducational activities.

The panel's recommendations are available at www.eucomed.be/Home/portal/press/press_releases/2010/~media/2E28E2AE799D48D895A9F141E803D062.ashx/. — Molly Cohen

US-S. Korea Trade Pact Promises Transparency for Devicemakers

A recent U.S.-South Korea free trade agreement is believed to be the first between the U.S. and another country to contain a section specifically for medical devices.

The agreement promises more regulatory transparency from S. Korea, whose government must propose regulations in a single official journal of national circulation as well as other channels.

Devicemakers will get the chance to comment, in most cases within 60 days, on regulations. All formal requests to the S. Korean government for the pricing or approval of devices for repayment should be completed within a reasonable, specified period disclosed to the applicant.

S. Korea has promised to make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

However, before the agreement is finalized, it must be approved by Congress and S. Korea's parliament. Ralph Ives, executive vice president of global strategy and analysis at AdvaMed, told *IMDRM* he hopes the agreement is finalized by mid-year.

The section of the agreement that deals with devices is available at www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file899_12703.pdf. — Virgil Dickson

Mexico Recognizes Equivalence With US and Canadian Devices

Devices already approved in Canada and the U.S. will have easier access to the Mexican market thanks to an agreement with Mexico's Federal Commission for Protection against Health Risks (COFEPRIS).

"The intent of the agreement is to expedite access to safe and effective medical devices for Mexican citizens," device consulting firm Emergo Group says. "Since a considerable

number of medical devices sold in Mexico are authorized in the U.S. and Canada and the safety standards of these countries are recognized to be equivalent ... COFEPRIS will recognize authorization in these countries as sufficient proof of safety and efficiency.”

The agreement, which became effective in late November, aligns equivalent regulations in the three countries that pertain to manufacturing and marketing authorization of devices, according to Santamarina Steta, a Mexican law firm.

“Benefits will apply to any medical device regardless of its country of origin or manufacture ... provided that it has been previously approved for its commercialization in the United States of America or Canada,” Santamarina Steta says.

Qualifying devices include Class I, II and III devices approved by the U.S. Food and Drug Administration and Class II, III and IV products approved by Health Canada, the Emergo Group says.

Applications for Mexican registration must include a summary of the product, inspection reports, certificate to foreign government and a classification report. Makers of Health Canada-approved products also must present licenses and a statement of approval.

Mexican registrations will be awarded within 30 days of the application, according to the Emergo Group.
— Molly Cohen

To view the text of the agreement (available only in Spanish), [click here](#).

Australian Device Group Pushes For Reforms in Procurement

Hoping to streamline the purchase of devices, the Medical Technology Association of Australia (MTAA) is proposing procurement reforms that would save public health resources and increase efficiency for the device industry.

Current differences in state purchasing agency structures and practices contribute to inefficiencies that result in a financial burden to device purchasers and suppliers, MTAA says in a position paper released last month.

Simplifying and standardizing government procurement of medical products would help in addressing the increasing pressure on health budgets, the organization says.

“Rather than trying to save through cutbacks and restrictions on the choice of products, bigger savings can be achieved on the operational side, including procurement, without compromising patient outcomes,” MTAA CEO Anne Trimmer says.

MTAA’s proposals include:

- A national alignment of public procurement processes for medical technology, using standardized terms and conditions and removing duplicative requirements;
- Improved governance arrangements to ensure transparency in the procurement process;
- Mechanisms to achieve best procurement practice; and
- Support for skills development for health procurement officials and increased understanding of the unique nature of medical technologies.

The position paper is available at [www.mtaa.org.au/pages/images/MTAA Position Paper on reforms to public health procurement December 2010.pdf](http://www.mtaa.org.au/pages/images/MTAA%20Position%20Paper%20on%20reforms%20to%20public%20health%20procurement%20December%202010.pdf). — Molly Cohen

Correction: An article in the December issue of *IMDRM* states that the FDA requires device facility inspections every two years for Class II devices, whereas Canada requires them every five to six years (*IMDRM, December 2010*).

However, a Health Canada official says manufacturers of Class II, III and IV devices marketed in Canada are subject to quality management systems audits on an annual basis.

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