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MedTech Europe Highlights Numerous Flaws, Needed Solutions for Brexit Plan

MedTech Europe is very concerned about the implications of a divergence in the regulatory framework for medical devices and in vitro diagnostics arising from Brexit.

The devicemaker group released a position paper suggesting possible ways to mitigate risks during the negotiation period between the UK and the European Union. The paper lists three challenges that could affect the supply of medical devices in both markets:

- Just-in-time delivery of parts or finished products could be hampered by a new customs regime;
- Refurbishment and repair services that would need to cross borders face significant cost and time hurdles; and
- Devices and IVDs could be subject to tariffs that would increase their manufacturing costs.

As the EU implements its new medical device and IVD regulations, the association is urging the UK to remain aligned with the

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FDA Proposes New Framework For Regenerative Medicine and Combo Products

The FDA's newly unveiled regenerative medicine framework contains guidance on when premarket review is required and how to expedite agency review — as well as a draft guidance on how devices used in the recovery, isolation and delivery of therapies will be evaluated as combination products.

Commissioner Scott Gottlieb said the field's rapid growth and complexity presents unique challenges to researchers, providers and the FDA — with more and more products being subject to premarket review.

Combination products based on regenerative medicine advanced therapies, or RMATs, are generally reviewed under a single

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EU27 regulatory system, saying that any divergence of regulatory systems, even in secondary legislation, would impact manufacturers and suppliers by adding costs and complexities in bringing products to market.

Notified bodies remain a particular area of concern as capacity is limited due to the greater workload associated with the new regulations.

"UK notified bodies are used for large amounts of CE marking activity and the risk to lose this capacity due to Brexit needs to be mitigated," said MedTech Europe CEO Serge Bernasconi.

Certificates Could Pose a Problem

The association suggested that certificates of conformity assessment to current regulations that were issued by UK notified bodies might be void earlier than in other EU27 countries, which would result in manufacturers facing delays in obtaining market authorization.

To mitigate this risk, the paper suggests recognizing existing valid CE Marking certificates issued by UK notified bodies until their expiration date. UK notified bodies could also remain within the existing EU network and continue to be designated to assess devices for the EU27 and UK markets, similar to the arrangement for Swiss notified bodies.

Other considerations outlined in the paper include authorized representatives that would no longer be able to operate from the UK, and manufacturers based only in the UK could lose access to the European market. Solutions could include mutual recognition agreements and custom arrangements to allow for products to cross borders without lengthy delays.

In addition, tariffs should not be placed on medical devices when they are being repaired in the UK and sent back to the EU and vice versa, MedTech Europe said, and the movement of dual-use goods between the UK and the EU27 countries should be permitted in new customs arrangements.

UK competent authorities could also lose access to various EU networks, such as the laboratory network established under the new EU directive as well as the Eudamed database. MedTech Europe suggests devising a framework for collaboration during the transition and post-Brexit.

Similar agreements should also be made for warehousing and manufacturing raw materials, unfinished products and animal material used for medical devices.

The majority of device companies in the UK and the EU are small to medium enterprises, and they may stagnate due to uncertainty surrounding regulations in the UK post Brexit, stakeholders suggested in earlier comments (*IDDM*, Sept. 25).

Read the MedTech Europe position paper here: www.fdanews.com/11-16-17-MTEBrexitpositionpaper.pdf.

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application, even if the RMAT and a specified delivery device are separately packaged but labeled for use together.

The draft details the attributes and intended uses that would result in a product being labeled a Class III device — although the agency says it has no predetermined list — and when a device may be limited to a specific intended use with only one particular type of cell.

If sponsors are submitting separate applications for the RMAT and device, fulfillment of regulatory requirements, such as clinical data or nonclinical performance data, may be streamlined to eliminate redundancy.

Over the next three years, the FDA intends to exercise enforcement discretion for certain products subject to review — to allow manufacturers time to comport with the guidance and determine if they need to submit a BLA.

The draft guidance on devices and combination products is available here: www.fdanews.com/11-16-17-DeviceEvalDraft.pdf. — Conor Hale

FDA Issues Final Guidance on Direct Marking Requirements for UDIs

The FDA released final guidance on requirements for direct marking of devices with unique device identifiers. The final document closely resembles the draft version issued in June 2015.

The guidance uses a Q&A format and includes four categories: Direct marking; UDI format; reprocessing; and exceptions to direct marking.

A permanently affixed UDI is required if the device is intended to be used more than once and reprocessed before each use. The only exception to this requirement is for Class I devices with a Universal Product Code on their label and packages.

The guidance states that the phrase "intended to be used more than once" refers to a devices that is "intended for repeated uses on or by different patients," whereas if it is "intended to be used more than once on or by the same patient…then the device does not need to be directly marked with a UDI."

A device would also be exempted from direct marking requirements if:

- Any type of direct marking would interfere with the safety or effectiveness of the device;
- The device cannot be directly marked because it is not technologically feasible; or
- The device has been previously marked under 21 CFR 801.45(a).

A device will be considered by the agency to be reprocessed "if it is intended to undergo high-level disinfection and/or sterilization before each use or between uses," the FDA said.

Manufacturers of Class II devices have until Sept. 24, 2018 to comply with the direct marking requirements. Producers of Class I and unclassified devices must comply by Sept. 24, 2020. Class III devices and those licensed under the Public Health Service Act were required to comply by Sept. 24, 2016, and life-sustaining and life-supporting devices, regardless of the class, were required to comply by Sept. 24, 2015.

Read the final guidance document here: www.fdanews.com/11-16-17-UDI.pdf.
— Ana Mulero

BRIEFS

Devicemaker Faked FDA Documents, Chinese Regulators Say

Chinese regulators assessed a fine of nearly $1.3 million on the manufacturer of a nasal cleaning and irrigation device that they suspect falsified U.S. FDA marketing-clearance documents to register the product as an import.

The regulators revoked the marketing registration for the product and said its manufacturer, TechWorld, may not reapply for registration for two years.

The fine includes approximately $257,000 that represents TechWorld's gain from marketing the device and a penalty of four times that amount.

Device Sales May Continue If Notified Body Doesn't, French Say

Sellers of medical devices in France can continue marketing their products after the entity that certifies them ceases operations until a valid certificate expires or for a year after the cessation, whichever comes first, French regulators said.

In the EU, some notified bodies have shut down or had their power to certify canceled by authorities. In such cases, device manufacturers should seek certification from a still-extant notified body as soon as possible, the regulators said.

The guidelines were agreed to at an October 2016 meeting of the EU Competent Authorities for Medical Devices.

First Proton Beam System Approved in Brazil

In a first for Brazil, medical device regulators approved a proton beam cancer treatment system.

The approved device is manufactured by Varian Medical Systems, headquartered in Palo Alto, California. The device can be applied to treatment of cancers of the head, neck, liver, lung and gastrointestinal system, regulators said.

NPPA to Revisit Price Controls On Coronary Stents in Early 2018

India's National Pharmaceutical Pricing Authority said it will revisit the ceiling prices imposed earlier this year on coronary stents.

In a Nov. 9 memorandum, NPPA indicated this may happen as early as January 2018.

The authority also set price caps for knee implants this year. Average prices were slashed by up to 85 percent for coronary stents and 70 percent for knee implants, industry lobbying group AdvaMed reported in a petition filed with the U.S. Trade Representative (*IDDM*, Oct. 23).

NPPA issued the new memorandum after it received a request from at least one international medical device manufacturer — Abbott Healthcare — to withdraw its coronary stents from the market because of "commercial unviability."

NPPA called on all stent importers and domestic stent manufacturers to provide any additional feedback on the matter by Dec. 13, 2017. — Ana Mulero

FDA Unveils 3-Tiered Approach To NGS Oncology Testing

The FDA is taking a three-tiered approach to next-generation sequencing oncology with a newly approved tumor profiling assay, the accreditation of the New York Department of Health as an FDA third-party reviewer, and the creation of the Class II regulatory pathway for these devices.

Memorial Sloan Kettering Cancer Center's qualitative in vitro diagnostic test — the Integrated Mutation Profiling of Actionable Cancer Targets (IMPACT) — was designed for identifying a larger number of genetic mutations, otherwise known as biomarkers, than any other test that the FDA has previously reviewed.

The insight gathered from IMPACT's detection of mutations in 468 unique genes will be used to guide treatment decisions as part of care plans for cancer patients.

Laboratories' NGS-based tests that have been approved by the NYSDOH will not require a separate 510(k) submission to the FDA. Other FDA third-party reviewers could also become eligible to make clearance recommendations to the agency for tests that are similar to IMPACT.

"The goal of allowing NGS-based tumor profiling tests to undergo review by accredited third-parties is to reduce the burden on test developers and streamline the regulatory assessment of these types of innovative products," FDA Commissioner Scott Gottlieb said. "As this field advances, we are modernizing the FDA's approach to the efficient authorization of laboratory tests from developers that voluntarily seek 510(k) clearance." — Ana Mulero

PEOPLE ON THE MOVE

STYR Labs appointed **John Siefert** as chief marketing officer. Prior to joining STYR Labs, Siefert was CEO of Virgo, a tradeshow and media company. STYR Labs is an artificial intelligence-based company that combines wearable technology, smart devices and apps to create personalized products.

LabVantage named **Bob Voelkner** as vice president of sales and marketing. Voelkner has 35 years of experience of laboratory information management products. Prior to joining LabVantage, he served as sales manager in the Americas for the LIMS division of Applied Biosystems. Previously, he spent seven years in senior sales roles at Thermo Fisher Scientific's Informatics and Services division. He began his career at Beckman Coulter as a senior software developer working on LIMS and chromatography data systems, progressing to director of global sales and marketing of its laboratory automation operations division.

Biolase appointed **Richard B. Lanman** to its board of directors. Lanman is currently chief medical officer at Guardant Health, a developer of non–invasive cancer diagnostics. A board-certified neurologist and physiatrist, he is the author of 45 articles published in peer reviewed scientific journals. Biolase develops laser systems for use in dentistry and medicine.

483 Roundup: FDA Targets Firms In Israel, the Netherlands, the U.S.

The FDA flagged two overseas facilities for inadequate medical device reporting and improper handling of nonconforming products, and cited a Florida devicemaker for numerous issues observed in a July inspection.

Lumenis: A medical device manufacturer in Yokneam, Israel failed to submit adverse event reports to the FDA within 30 days after becoming aware of numerous complaints that warranted them, the agency said.

According to a Form 483, FDA investigators who inspected the Lumenis facility from Jan. 30 to Feb. 2 observed that at least nine customer complaints should have been reported as MDRs.

These included complaints for patient burns caused by the firm's LightSheer Desire device; first and second degree burns caused by its LightSheer Duet device; and a patient extended surgery, stiches and open wound caused by a malfunction of its VersaCut+ Tissue Morcellator system.

Several months went by from the time that Lumenis became aware of these adverse events to when these were reported.

There was also a complaint from a patient who lost hair after receiving acne treatment with the M22 Acne Filter that the firm did not report as an MDR. Instead, it initiated a recall of the filters in November 2015, though the FDA wasn't made aware of that until April 2016.

In addition, the company's MDR procedure includes a requirement for maintaining a list of product malfunctions, but "management acknowledged that the list did not exist," the agency said.

Out of the 12 identified nonconformities, four were related to the firm's design procedures. For example, Lumenis failed to adequately document design validation results for its VersaCut+ device, and to revisit the design plans "as the design and development milestones and the responsibilities for implementation evolved," the investigators wrote.

The firm's procedures for CAPA actions, accepting incoming products, conducting quality audits, and identifying products during all of their lifecycle stages, as well as one of its approved process validation were also flagged as inadequate.

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Tips for Managing Nonconforming Product

Devicemakers must maintain procedures that inform employees how to identify nonconformances. Usually, this takes the form of marking the product or lot with a red tag or label, and then segregating it from the rest of the flow of material so it doesn't accidentally get distributed.

Next, companies need to make sure they have adequate documentation, which takes the form of quality records that keep track of every step of the process. They need to evaluate the nonconformances and execute a series of decisions, including whether disposition is necessary.

Devicemakers have to figure out what to do with the nonconforming material, with the evaluation step answering whether or not an investigation is needed. Then they have to decide who to notify, which means all responsible parties.

Documentation is essential here because the FDA will ask for a record of notification, the decision to investigate or not, what was discovered if an investigation was conducted, and what final decision the company reached about disposition and any corrective actions to keep the nonconformance from recurring.

A robust system of internal quality audits should include examination of nonconformance management procedures and their documentation. A quality management system that can spot and deal with nonconformances effectively can save devicemakers from production errors, recalls, product liability suits and especially FDA censure.

Excerpted from the FDAnews management report: ***Managing Nonconforming Product: A Devicemaker's Guide to Compliance***.

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FMI Medisch: FMI Medisch's manufacturing facility in Schiedam, The Netherlands drew a Form 483 over processes for reworking nonconforming products and accepting incoming products.

The rework activities were performed without an evaluation of whether they would lead to any adverse events, and they had not received the required approval, the agency's investigator found during an April inspection.

FMI also lacked documentation for procedures to control nonconforming products.

With regard to product acceptance activities, the inspection revealed that a sampling plan was being used for the inspection of incoming raw materials for manufacturing implantable devices for which there was no valid statistical rationale. The company also failed to document and maintain its acceptance activities in device history records.

Other nonconformities included an inadequate process validation procedure, and a lack of documentation for the monitoring and control parameters.

Applied Neuroscience: The FDA cited devicemarker Applied Neuroscience of Largo, Florida for failing to correct numerous nonconformities dating as far back as 2014.

Over the course of two days in July, the FDA conducted an inspection at the facility and observed that seven of eight issues identified were repeat deficiencies, including a lack of procedures for design control, as well as inadequate procedures for quality audits, adverse event reporting, and controlling purchased products and documents.

For example, no training was provided to the executive assistant who had been conducting quality audits at the facility, the investigator said.

Another repeat deficiency identified during the July inspection was the firm's procedure for management reviews, which was deemed inadequate because it did not include requirements for the review of the suitability and effectiveness of the quality system and for the results of the quality system reviews to be documented.

The lengthiest repeated deficiency related to inadequate procedures for CAPA actions. According to the investigator, the firm's procedure for establishing CAPA action requirements failed to adequately describe the requirements for analyzing quality data, investigating the root cause of an identified nonconformity, verifying or validating a CAPA action to ensure effectiveness, among others.

Inadequate complaint handling was the only new observation. The firm had not implemented its complaint handling procedure, which was found to be lacking a complaints definition, and a requirement to evaluate all complaints to determine which ones need to be investigated.

Read the Lumenis Form 483 here: www.fdanews.com/11-16-17-lumenisltd483.pdf.

Read the FMI Medisch Form 483 here: www.fdanews.com/11-16-17-fmimedischbv483.pdf.

Read the Applied Neuroscience Form 483 here: www.fdanews.com/11-16-17-appliedneuroscienceinc483.pdf. — Ana Mulero

Pioneering Digital Pill Receives FDA Approval

The FDA granted its first-ever approval to a prescription pill containing a sensor that verifies ingestion via electronic detection.

When activated by contact with stomach fluids, the sensor, imbedded in an Abilify (aripiprazole) MyCite antipsychotic tablet, sends a signal to a patch worn on the patient's skin, with the data transmitted to a smart phone application.

The system records the date and time of ingestion and additional information about the patient's activity level when the pill is taken. The patient can consent for a healthcare provider, family members or others to access that information through a web portal and can add more information, such as a report on mood.

Drugmaker Otsuka developed the product in combination with Proteus Digital Health, which makes the patch. The sensor is the size of a grain of sand and contains ingredients found in foods. It is digested by the patient.

The product is indicated for treatment of schizophrenia and bipolar disorder and as an add-on treatment for depression in adults.

Otsuka said it would offer Abilify MyCite to a select number of health plans and providers initially for use by patients they identify as suitable. The daily experience of those patients will be monitored to help determine how to move to a broader roll-out, the company said. — Gregory Roberts

CAMD Releases MDR/IVDR Implementation Roadmap

The EU's Competent Authorities for Medical Devices, the umbrella group through which the EU's national competent authorities work to enhance the single market for devices, released a new roadmap with a priority list of areas of focus for implementing the new European MDR/IVDR regulations.

Some of the actions categorized as high priorities include developing guidance on equivalence, well-established technologies and clinical evidence, classification guidance for IVDs, and industry guidelines for assigning unique device identifies (UDIs).

The roadmap also identifies over-arching and cross-cutting priorities, such as addressing uncertainties around how the new provisions will be implemented.

The priorities include:

- Clinical evaluation and clinical investigation;
- Performance evaluation and performance studies;
- Scope and classification;
- Notified bodies and conformity assessment;
- Post-market surveillance and vigilance for both MD and IVD;
- Eudamed and UDI;
- Market surveillance; and
- IVD-specific issues.

Read the CAMD roadmap here: www.fdanews.com/11-16-17-CAMDMDRegulation.pdf.

APPROVALS

Intellijoint Receives FDA Clearance for HIP System

Intellijoint Surgical received FDA clearance for revision total hip arthroplasty with its intellijoint HIP System.

The 3D mini-optical navigation system allows surgeons to evaluate existing arthroplasty components to make precise measurements for cup position, leg length and offset.

The device is indicated for use with Medacta's GMK Revision and GMK Hinge Knee systems, as well as the GMK tibial extension stems and offset.

FDA Clears Complete Blood Cell Count Analyzer

The FDA has granted premarket clearance and a waiver under the Clinical Laboratory Improvement Amendments of 1988 to Sysmex America for its complete blood cell count test.

Broadened access to the XW-100 automated hematology analyzer for patients at least 2-years-old in additional healthcare settings such as

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non-traditional laboratories, will allow for faster availability of results, the agency said.

The analyzer provides results from a complete blood count test more quickly than the standard 24-hour delivery.

Grifols Wins FDA Approval For Fibrin Sealant

Grifols won the FDA's approval for its Fibrin Sealant for surgical use in adults, the company announced in a Securities and Exchange Commission filing.

The device is composed of the plasma proteins fibrinogen and human thrombin.

Grifols said the U.S. approval will allow it to expand its range of plasma-derived products. The sealant will be manufactured at the Grifols facility in Barcelona, Spain.

Stryker Receives Humanitarian Device Exemption for Neuroform Atlas Stent

Stryker Corporation received FDA approval for the Neuroform Atlas Stent System for marketing under a humanitarian device exemption.

The device is a small nitinol stent that is used in conjunction with metal coils to pack weakened blood vessel sacs in the brain.

The system can be used with neurovascular embolic coils for the treatment of wide neck, intracranial, and saccular aneurysms.

Beckman Coulter Assay Wins CE Mark

Beckman Coulter Diagnostics received a CE Mark for a new high-sensitivity troponin (hsTnI) assay that aids in diagnosing myocardial infarction in patients presenting with chest pain or other ischemic symptoms.

The assay will allow hospitals to develop fast-track protocols leading to early discharge for patients with suspected myocardial infarction, the company said.

The assay can be used with the Access 2, DxI and Beckman Coulter's family of Access immunoassay systems.

One Drop Receives Regulatory Approval in Canada

One Drop received Health Canada's approval for its One Drop Chrome, a Bluetooth-enabled blood glucose monitoring system that syncs directly with the One Drop Mobile app.

The system is available as part of One Drop's Premium and Plus subscription plans.

The device wirelessly transmits blood glucose data directly to the cloud via the One Drop Mobile app for iOS and Android.

DT MedTech Wins FDA Clearance For Ankle Replacement System

DT MedTech's Hintermann Series H2 total ankle replacement system received 510(k) clearance from the FDA.

The device is indicated for use with bone cement to treat ankle arthritis in either primary or revision surgery of ankle joints damaged by systemic arthritis of the ankle, primary arthritis, and secondary arthritis.

The Hintermann Series H2 is for patients with a failed total ankle replacement or non-union/mal-union of the ankle arthrodesis, if sufficient bone stock is present.

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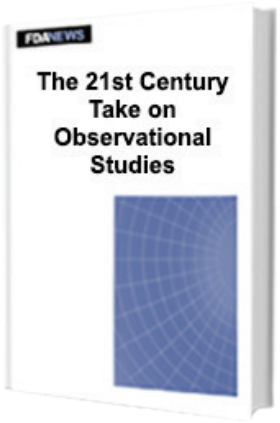

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