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Advena Ltd are active members of the European Association of Authorised Representatives (EAAR) who have representatives on most of the major European policy making committees, including those for device vigilance, clinical trials, emerging technologies, IVD devices and there are contacts with the Global Harmonization Policy Committee for Europe. Appropriate information from these meetings will be reported in these reports.



Client's Update – November 2008

1 BUSINESS OPPORTUNITIES FROM UK TRADE AND INVESTMENT BODY

Poland - Medical Kits

The Military Hospital in Bydgoszcz has announced a tender for the supply of medical kits.

CPV: 33141620, 33182220, 33184300, 33184200, 33141320, 33141000

- medical kits,
- cardiac valves,
- artificial heart parts,
- vascular prostheses,
- medical needles,
- disposable non-chemical medical consumables and haematological consumables.

Poland - Digital Angiography Devices

The Voivodship Hospital in Jelenia Gora has announced a tender for the supply of digital angiography devices.

CPV: 33111721; Supply, installation and start-up of a stationary digital cardioangiographic apparatus.

2 CHINA

We are proposing a link-up with a Chinese regulatory consultancy so that our clients may proceed with registrations in this huge market. Once the agreement is set up we will provide more information. Any clients interested in this please let us know.

On the subject of China we have been informed that they have extended their central purchasing arrangements and these will have some effect to fix prices and favor local manufacturer's. It is considered, however, that more technologically innovative devices will not be affected..

3 AFRICA

Both Nigeria and Uganda have imposed bans on non auto-disable syringes except for use in certain applications. Conventional syringes may be confiscated and destroyed.

4 EUROPEAN STANDARDS

There has been the occasional confusion about the terms "*horizontal*" and "*vertical*" standards in the EU, so I will attempt to clarify.

There are level I, II and III standards;

- Level I: a general standard applicable to all medical devices, (now generally known as *horizontal standards*)
Examples of horizontal standards are;
 - quality system standards
 - biological and toxicological safety
 - risk management
 - clinical investigations
 - packaging
 - labelling and information supplied with devices.

- Level II: a group standard applying to medical devices with common features,
Examples;
 - sterilization
 - biological safety
 - toxicology
 - leachable substances
 - wound dressing testing
 - dental equipment and implants.
 - connectors

- Level III: product specific standards. (Now generally known as *vertical standards*.)
Examples of vertical standards are;
 - urinary catheters
 - drainage catheters
 - intravascular catheters
 - hypodermic syringes and needles
 - haemodialysers
 - extracorporeal circuits
 - blood gas exchangers
 - sphygmomanometers
 - non-woven compress test methods

- parenteral devices
- medical gloves

5 AUSTRALIA

It is reported that the Australian Regulatory Authority (TGA) will be consolidating a lot of their guidance documents into one document. It is unknown if there will be any changes in content and regulation but consultations are transparent and the new documents will be available for public comment on their web site.

6 CANADA

No particular news this month. Full information at:
<http://www.hc-sc.gc.ca/dhp-mpps/md-im/index-eng.php>

7 US NEWS

The US Congress recently passed the "Mercury Export Ban Act" to ban the export of mercury from the USA

7.1 DEFINITIONS RE. ADVENA'S U.S. OFFICE OFFICIAL CORRESPONDENT AND U.S. AGENT SERVICES;

The official correspondent is responsible for the registration and listing information for each establishment to which he/she is assigned. The official correspondent can:

- Create new registrations and listings
- Make changes, updates and cancellations to registrations and listings that have been assigned to them.
- Add their establishment(s) to listings previously entered for their owner/operator.
- View registration and listing information for the establishments which have been created by or assigned to them.

The responsibilities of the U.S. Agent are limited and include:

- Assisting the FDA in communications with the foreign establishment.
- Responding to questions concerning the foreign establishment's devices that are imported or offered for import into the United States.
- Assist the FDA in scheduling inspections of the foreign establishment; and,
- if the FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the U.S. agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

7.2 FDA FINAL RULES

Effective January 9, 2009 [Docket No. FDA-2004-N-0511] (formerly Docket No. 2004N-0556) RIN 0910-AF21 Obstetrical and Gynecological Devices; Designation of Special Controls for Male Condoms Made of Natural Rubber Latex

The Food and Drug Administration (FDA) is amending the classification regulation for condoms to designate a special control for male condoms made of natural rubber latex (latex). The special control for the device is the guidance document entitled "Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300." The

special control guidance document can be retrieved at <http://www.fda.gov/cdrh/comp/guidance/1548ref.html>.

7.3 FDA PUBLIC HEALTH NOTIFICATIONS

No notices posted in November.

7.4 FDA RECALLS/CORRECTIONS

Posted October 28, 2008: Thoratec HeartMate II Left Ventricular Assist System

Thoratec Corporation notified healthcare professionals of a worldwide correction of the HeartMate II Left Ventricular Assist System (HM II LVAS), of all serial numbers (having Catalogue No. 1355 or 102139), distributed since the beginning of clinical studies in November 2003. Over time, wear and fatigue of the percutaneous lead connecting the HeartMate II LVAS blood pump with the System Controller may result in damage that could interrupt pump function, require reoperation to replace the pump, and potentially result in serious injury or death. The estimated probability of the need for pump replacement due to percutaneous lead damage is 1.3% at 12 months, 6.5% at 24 months, and 11.4% at 36 months. Healthcare professionals with patients supported by a HeartMate II LVAS should assess the wear and fatigue of the percutaneous lead and provide proper instruction to patients on the management and care of the lead.

http://www.fda.gov/oc/po/firmrecalls/thoratec10_08.html

Posted November 6, 2008: Class 1 Recall: Tyco Healthcare Group LP (Covidien), ReliOn Insulin Syringes, 1cc, 31-Gauge

Covidien and FDA notified patients and healthcare professionals of a recall of ReliOn sterile, single-use, disposable, hypodermic syringes with permanently affixed hypodermic needles. The mislabeled syringe may result in patients receiving an overdose of as much as 2.5 times the intended dose, with serious health consequences, low blood sugar, and even death. These syringes are sold only by Wal-Mart or Sam's Club pharmacies under the ReliOn name. The recall applies only to lot number 813900. The product was distributed from Aug. 1, 2008 until Oct. 8, 2008, and includes 471,000 individual syringes in 4,710 boxes. FDA urges patients and health care professionals to check syringe packaging carefully for products with this lot number, not to use the product, and return the product to the pharmacy for replacement. The lot number can be found on the back panel of the 100 count syringe carton, or on the white paper backing of each individual syringe "peel-pack". <http://www.fda.gov/cdrh/recalls/recall-100908.html>.

Posted November 19, 2008: Class 1 Recall: Animas Corporation, Battery Caps Used with the OneTouch Ping System, Animas 2020 Insulin Pump, Animas IR1200 Insulin Pump, and Animas IR1250 Insulin Pump

There may be an intermittent loss of contact between the battery cap and the battery compartment in the pump which may result in the device resetting. This can cause the device to stop administering insulin, which could result in an excess level of glucose in the blood (hyperglycemia). Additionally, this failure may lead to user confusion in the amount of insulin administered, contributing to errors in future doses, which may result in lower than normal level of glucose in the blood (hypoglycemia). <http://www.fda.gov/cdrh/recalls/recall-080408.html>.

7.5 FDA NOTICES

November 17, 2008: [Docket No. FDA-2008-N-0571] Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Compliance With the Medical Device User Fee and Modernization Act of 2002, as Amended: Prominent and Conspicuous Mark of

Manufacturers on Single-Use Devices (formerly “Reprocessed Single-Use Device Labeling”)

The FDA is seeking comments for the following change: Section 2(c) of The Medical Device User Fee Stabilization Act of 2005 (Public Law 109–43) amends section 502(u) of the act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record.

Submit electronic comments on the collection of information to: <http://www.regulations.gov>.
Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this notice.

November 19, 2008: [Docket No. FDA–2008–N–0526] Global Harmonization Task Force, Study Group 1; Proposed and Final Documents; Availability

The Food and Drug Administration (FDA) is announcing the availability of proposed and final documents that have been prepared by Study Group 1 of the Global Harmonization Task Force (GHTF). These documents represent a harmonized proposal and recommendation from the GHTF Study Group that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe FDA’s current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. In particular, FDA seeks comments on the advantages and disadvantages of the approaches in the GHTF documents, particularly where they are not consistent with current practices for the manufacture of products in the United States.

Submit written or electronic comments on these documents by February 17, 2009 to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this notice.

7.6 U.S. CUSTOMS AND BORDER PATROL

No news

8 UK MHRA

UK MHRA have a new web page on obstetrics and gynaecology at:
<http://www.mhra.gov.uk/Safetyinformation/Healthcareproviders/Obstetricsandgynaecology/index.htm>

9 RECENT UK ALERTS

Dialysis, haemodialysis: filter - B Braun Medical Ltd - Diacap Ultra Dialysis Fluid and Online Filter, 7107366 and 7107365

Advice has been given by the manufacturer regarding the use of the device.

MDA/2008/081 - Frazier and Poole suction instruments used in surgery manufactured by ConMed Corporation

This Medical Device Alert (MDA) has been issued due to a risk of compromised sterility due to unvalidated method of packaging inspection.

Press release: "Tan jab" is an unlicensed medicine and may not be safe - warns medicines regulator

We are warning people not to use an unlicensed medicine called Melanotan which is being advertised and sold illegally as an injectable tan on the Internet and in some tanning salons and body building gyms.

Press release: UK medicines investigators take part in international operation to tackle illegal Internet medicines

The MHRA yesterday led an international operation, codenamed Pangea, in conjunction with INTERPOL and eight regulatory agencies worldwide to tackle the illegal sale and supply of medicines sold over the Internet.

MDA/2008/080 - Enteral feeding pump - ClearStar model M771 manufactured by Abbott Nutrition

This Medical Device Alert has been issued due to a risk of under-infusion due to cracking/breaking of an internal adapter bracket.

MDA/2008/079 - Mermaid, Dipper and Ranger bath hoists manufactured by Joerns Healthcare (part of Sunrise Medical Ltd)

This Medical Device Alert has been issued to highlight the risk of a fall from the hoist resulting in serious injury or death due to a lack of safety belt.

Airway devices: kit, tracheostomy - Teleflex Medical - Great Ormond Street Tracheostomy Cannula Set

Return of specified lots/batches of the device to the manufacturer or its representative.

IVF implantation devices: oocyte recovery needle - Smiths Medical International - Wallace Oocyte Recovery Needle

Return of specified lots/batches of the device to the manufacturer or its representative.

Monthly list of alerts is at;

<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/C ON2033928>

10 STANDARDS UP-DATE.

Please note that CEN Standards Committee TC 205 is recommending simple amendments to;

EN 20594-1:1993 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986)

EN 1707:1996 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Lock fittings

EN ISO 10555-1:1996 Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:1995)

EN 1060-1:1995 Non-invasive sphygmomanometers - Part 1: General requirements

EN 1060-2:1995 Non-invasive sphygmomanometers - Part 2: Supplementary requirements for mechanical sphygmomanometers

EN 1060-3:1997 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

EN 12470-1:2000 Clinical thermometers - Part 1: Metallic liquid-in-glass thermometers with maximum device

EN 12470-2:2000 Clinical thermometers - Part 2: Phase change type (dot matrix) thermometers

EN 12470-3:2000 Clinical thermometers - Part 3: Performance of compact electrical thermometers (nonpredictive and predictive) with maximum device

EN 12470-4:2000 Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement

EN 12470-5:2003 Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device)

EN 13867:2002 Concentrates for haemodialysis and related Therapies

EN 13726-1:2002 Test methods for primary wound dressings - Part 1: Aspects of absorbency

EN 13726-2:2002 Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings

EN 14079:2003 Non-active medical devices – Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

EN 13795-1:2002 Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Part 1: General requirements for manufacturers, processors and products

EN 13795-2:2004 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 2: Test methods

EN 13795-3:2006 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 3: Performance requirements and performance levels

Publications;

BS EN Publications	
BS EN ISO 8537:2008	Sterile single-use syringes, with or without needle, for insulin. Supersedes BS EN ISO 8537:1995
BS EN 13718:-	Medical vehicles and their equipment. Air ambulances.
BS EN 13718-1:2008	Requirements for medical devices used in air ambulances. Supersedes BS EN 13718-1:2002
BS EN 13718-2:2008	Operational and technical requirements for air ambulances. Supersedes BS EN 13718-2:2002
BS EN 60601:-	Medical electrical equipment.
BS EN 60601-1-3:2008	General requirements for basic safety and essential performance. Collateral Standard. Radiation protection for diagnostic X-ray equipment. Supersedes BS EN 60601-1-3:1995 which remains current.
BS Standards updated	
BS EN 60601:-	Medical electrical equipment.
BS EN 60601-2-33: 2002	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis.
British Standards withdrawn	
BS 4009:1991	Specification for artificial mastoids for the calibration of bone vibrators used in hearing aids and audiometers. Superseded by BS EN 60318-6:2008
New work started	
PD CEN/TR 12401	Dentistry. Guidance on the classification of dental devices and accessories.
BS EN 13795:-	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment.
BS EN 13795-1:2002/Amendment 1	General requirements for manufacturers, processors and products.
BS EN 13795-1:2002/Amendment 2	General requirements for manufacturers, processors and products.
BS EN 13795-2:2004/Amendment 1	Test methods.
BS EN 13795-3:2006/Amendment1	Performance requirements and performance levels.
BS ISO 14708:-	Implants for surgery. Active implantable medical devices.
BS ISO 14708-3	Implantable neurostimulators.
BS ISO 14708-4	Implantable infusion pumps.

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