THE PROPOSED MEDICAL DEVICES REGULATIONS

How will it affect your business?

March 2014

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Who We Are

- We are a global compliance, quality & operational consulting firm committed to delivering measurable results for our clients.
- We are committed to helping our clients achieve their compliance & performance goals to capitalize on business opportunities.
- We are a global full-service firm who serve our Life Science clients through:
  - Deep technical knowledge
  - Broad insight into the industry
  - Operational know-how

Compliance & Quality Service Areas

- Risk Management
- Validation (all forms)
- New Products & Facilities
- CAPA / Complaints
- GMS/Cost of Quality
- Supplier Quality
- Warning Letter Remediation

Quick Facts

- Founded in 1984
- Operate six offices globally (Indianapolis, IN (HQ); Boston, MA; Exton, PA; San Jose, CA; Nottingham, UK & Solothurn, CH)
- Quick Facts
  - Founded in 1984
  - Operate six offices globally (Indianapolis, IN (HQ); Boston, MA; Exton, PA; San Jose, CA; Nottingham, UK & Solothurn, CH)
  - Execution focused & served
  - 8 of the top 10 pharmaceutical companies
  - 6 of the top 10 biopharmaceutical companies
  - 4 of the top 5 medical device companies
  - Currently serving 40+ clients - big brand names, PE & VC firms
  - Double digit compounded growth each year for last 3 years

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THE PROPOSED MEDICAL DEVICES REGULATIONS

Session 1 – The Current Medical Device Directives
Session 2 – Proposed New Regulations
Session 3 – Implications of the Changes
Session 4 – Notified Body Changes
Session 5 – Competent Authorities
Session 6 – Q and A Session

Session 1

- The Current Medical Device Directives
1: THE CURRENT MEDICAL DEVICE DIRECTIVES

- **93/42/EEC Medical Device Directive**
  - Divides devices into 4 classes based on
    - Duration of use
    - Degree of invasiveness
    - Active or non-active
    - Classes are: I IIa IIb III

- **90/385/EEC Active Implantable Medical Devices Directive (AIMDs)**

- **98/79/EC In Vitro Diagnostic Medical Device Directive (IVDs)**
1: THE CURRENT MEDICAL DEVICE DIRECTIVES

- **93/42/EEC**
  - The Medical Devices Directive
  - 23 Articles
  - 12 Annexes

- **90/385/EEC**
  - The Active Implantable Medical Device Directive
  - 17 Articles
  - 9 Annexes
  - No risk classes – all devices are regulated as Class III in the MDD
1: THE CURRENT MEDICAL DEVICE DIRECTIVES

- 98/79/EC
  - The In Vitro Diagnostics Directive
  - 24 Articles
  - 10 Annexes
    - Devices classified by lists in annex II
  - 4 types of device listed:
    - List A: blood typing, HIV, HEP, etc.
    - List B: specified genetic marker testing
    - Self-testing kits for home use
    - Any other not listed above!
1: THE CURRENT MEDICAL DEVICE DIRECTIVES

- Manufacturer's Self Certification:
  - MDD 93/42/EEC: **Class I non-measuring, non-sterile only**
  - AIMDD 90/395/EEC: **not allowed for any device**
  - IVDD 98/79/EC: **Anything not listed or for self-testing!**
    - Otherwise there has to be Notified Body assessment of the device before it can be CE marked and placed on the market

Session 2

- Proposed New Regulations
2: PROPOSED NEW REGULATIONS

A. Proposed Regulation on Medical Devices:
This combines the requirements of MDD 93/42/EEC and AIMDD 90/385/EEC


B. Proposed Regulation on In-vitro Medical Devices:
To replace IVDD 98/79/EC


Important point:

- A DIRECTIVE has to be transposed into the laws of the individual states (now 28 in number) – in the UK this is the Consumer Protection Act

- A REGULATION comes into force in all EU states without the need for modification
2: PROPOSED NEW REGULATIONS

Some Background:

- PIP Breast Implant – incorrect specification of material which was “hidden” from auditor
- Metal on metal total hip replacements – insufficient post-market surveillance and clinical follow-up when soft tissue swelling was identified

The examples quoted have helped strengthen some elements of the new proposed regulations but it was always the intention of the European Commission to update the Directives to account for:
- New technology, e.g. Nanotechnology, new IVD tests
- “Messy” patchwork of legislation, 3 directives, unincorporated amendments, e.g. 2005/50/EC
2: PROPOSED NEW REGULATIONS

- **Medical Devices** Proposed Regulations:
  - Key points:
    - 97 Articles over 99 pages
    - 16 Annexes over 73 pages
    - Articles are divided into 10 chapters
    - Correlation table to show correspondence between article in the Regulation and the articles in 93/42/EEC and 90/385/EEC
    - Does not cross-reference the annexes!

- **Chapter contents:**
  - Chapter I  Scope and Definitions
  - Chapter II  Placing on Market, CE Marking, etc.
  - Chapter III Identification, Traceability, Device registration, European databank
  - Chapter IV  Notified Bodies
  - Chapter V  Classification and Conformity Assessment
2: PROPOSED NEW REGULATIONS

Chapter contents:

- Chapter VI Clinical Evaluation and Investigations
- Chapter VII Vigilance and Market Surveillance
- Chapter VIII Medical Device Coordination Group, etc.
- Chapter IX Confidentiality, data protection, etc.
- Chapter X Final Provisions

Annexes:

- Annex I General Safety and Performance – replaces “Essential Requirements”
- Annex II Technical Documentation
- Annex III Declaration of Conformity
- Annex IV CE Mark
- Annex V Format for UDI
- Annex VI Notified Body Requirements
2: PROPOSED NEW REGULATIONS

- Annexes:
  - Annex VII: Classification Rules
  - Annexes VIII to XI: Conformity assessment routes
  - Annex XII: Certificates
  - Annexes XIII, XIV: Clinical Evaluation, PMCF, Clinical Investigations
  - Annex XV: Devices “not for a medical purpose”
  - Annex XVI: Table of references to 93/42/EEC and 90/385/EEC

So what is new and what will be the same?

- The new items will be discussed in more detail later, but the new regulation still has:
  - 4 classes of device, but with a few reclassifications
  - Notified Body Assessments for anything other than Class I, non-sterile, non-measuring
- Same CE Mark
- Same Technical Documentation requirements (mostly)
- Same Essential Requirements (mostly)
- Same Risk Management requirements
2: PROPOSED NEW REGULATIONS

- Additional Legislation Required

- There are several areas (at least 10!) in the proposal which refer to “implementing acts” – this is where further legislation is needed to bring these into effect.

The main items are:

- Listing the single-use devices which could be reprocessed
- Setting up the UDI system
- Class III safety summary: definition of elements
- Central Clinical Investigation data
- Central Vigilance System set-up
- Central PMS system set-up
- Other provisions to enable the MDCG activities
In Vitro Diagnostic Devices Proposed Regulations:
- Key points:

Same Chapter structure as the other new proposal
- What else is new?
  - Definition of “Near Patient Testing”, which imposes similar obligations to “self testing”
  - Classification to be risk-based with 4 classes A B C D, which mirrors the Medical Device Directive and new proposed Regulation

BREAK AND REFRESHMENTS
Session 3

Implications of the Changes for manufacturers

3: IMPLICATIONS OF THE CHANGES

Some key areas to consider:

- Reclassification of some devices
- Single use devices and reprocessing
- Invasive/implantable devices without a medical purpose
- Qualified Person
- UDI and Traceability
- Vigilance system
3: IMPLICATIONS OF THE CHANGES

- MEDICAL DEVICES: Reclassification of some devices:
  - Classification rules are similar to before, but some significant examples of change:
    - IVF and ART non-invasive devices can be IIb
    - Spinal implants to be Class III
    - Total and partial joint replacements to be Class III
    - Devices recording diagnostic images to be IIa
    - Nanomaterial devices to be Class III
    - Apharesis devices to be Class III
    - Devices which are rectally or vaginally administered and absorbed to be Class III

- IN VITRO DEVICES: Complete re-write of the rules:
  - Classes A B C D based on risk
    - "Near Patient" devices - where test is performed without sending the samples to a lab - regulated like self testing devices
  - IVD Manufacturers need to examine the impact of this on their specific devices as there is no direct equivalence to the classification system in 98/79/EC
3: IMPLICATIONS OF THE CHANGES

- Single use devices and reprocessing
  - There has been much debate about the fact that devices intended for single use have been reprocessed (e.g. decontaminated, refurbished) and then reused
  - The proposed regulations say:
    1. A “re-processor” becomes the Legal Manufacturer of the re-processed device
    2. Devices for “critical” use: safety must be demonstrated and the Commission will establish a list of such devices
    3. Individual Member States can prohibit transfer from one state to another or complete prohibition!

3: IMPLICATIONS OF THE CHANGES

- Invasive/implantable devices without a medical purpose
  - It has been recognised that there are devices which have not been regulated as they do not fall within the existing definitions
  - The new proposal lists items which, although they have no “medical purpose”, are to be regulated:
    - ALL contact lenses, including cosmetic
    - All implants for modification of the anatomy
    - Facial and other dermal or mucous membrane fillers
    - Liposuction equipment
    - Invasive laser equipment
    - Intense pulsed light equipment
3: IMPLICATIONS OF THE CHANGES

- Qualified Person (Article 13)

  **Qualifications:** Formal Qualification (university degree or equivalent in science, engineering, etc.) plus >2 years regulatory or quality experience

  OR >5 years professional experience in regulatory or quality

  This also applies to Authorised Representatives

  **Responsibilities:**
  - Conformity assessment for batch release
  - Keeping Technical Documentation and D of C up-to-date
  - Fulfilment of Vigilance and Reporting requirements
  - Statement of conformity and safety for Clinical Investigational devices
3: IMPLICATIONS OF THE CHANGES

- UDI and Traceability (Article 24 or 22 for IVD)
  - This is a new requirement to have a Unique Device Identifier with the following information:
    - Quantity in pack
    - Batch number
    - Expiry date
    - Product identifier (product, size, volume, etc.)
    - Name and address of Manufacturer
    - EUAR name and address (if applicable)
    - GMND code or other internationally recognised identifier
    - Storage instructions
    - Warnings
    - Etc., Etc.

- To do all this will require a bar code for the information
- On small devices this will need to be a 2-D code
- There has been partial introduction of a UDI system in the USA starting with the highest risk devices
- In Europe there are still many debates going on about what system to adopt as there are many national "vested interests"
3: IMPLICATIONS OF THE CHANGES

- Vigilance system (Chapter VII)
  - Written to emphasise the importance of Incident Reporting and PMS
  - No surprises as Notified Bodies and Competent Authorities were already ensuring adherence to the MEDDEV guidance
  - This guidance has now been incorporated into the proposed regulations
  - Biggest change is the centralisation of the data through the EUDAMED database – unsure yet how this will work in practice

Session 4

- Notified Body Changes
4: NOTIFIED BODY CHANGES

- Two items of special interest:
  - Issuing Certificates
  - Unannounced Visits

Issuing Certificates (Annex XII or XI for IVD)

- The proposal intends to ensure that all certificates are to the same standard and therefore contain the following:
- Notified Body – Manufacturer – Unique Number – Date of issue and expiry – Device identification – manufacturing facilities (if applicable) – Annex reference for conformity – ref. to standards, tests or audit reports – NB’s conclusions – any limitations – legally binding signature
- Most NBs issue certificates bearing this information already but not all certificates currently contain the same information
4: NOTIFIED BODY CHANGES

- **Unannounced Visits (Annex VIII, 4.4)**
  - Already allowed for in existing Directives – no need for the new regulations to be approved
  - Commission Recommendation 2013/473/EU of 24 Sep 2013 emphasised the role of NBs in continuing surveillance of the manufacturers and defines the unannounced inspections requirement
  - NBs will carry out unannounced audits and take samples for testing where appropriate
  - **This is happening already** (BSI will start for real in April 2014)

Session 5

- **Competent Authorities**
5: COMPETENT AUTHORITIES

- High Risk Devices and centralised database
- Competent Authority recommendations

5: COMPETENT AUTHORITIES

- High Risk Devices and centralised database (Article 44)

  - For Class III devices:
    - Notified Body informs the Commission of application by manufacturer
    - Notified body supplies draft ER summary and IFU and estimated date of completion of assessment
    - Commission transmits the information immediately to the MDCG
    - MDCG may (within 28 days) ask the NB for more information
    - MDCG may submit comments to the NB within 60 days
    - NB takes account of any comments
    - The Commission may make public certain data
5: COMPETENT AUTHORITIES

- Competent Authority recommendations:
  - The Competent Authorities are all feeding their recommendations to the Commission, based on comments by the manufacturers.
  - In the UK, the MHRA has taken comments from the ABHI and is in discussions on possible changes to the proposals.
  - Most of these changes are likely to be concerning the centralisation of data and how the requirements can be implemented, including the need for a common UDI.

AND FINALLY.....

- When is all this happening?
  - Draft proposals are still under discussion.
  - The council of the EU is most likely to consolidate the texts in October/November 2014.
  - Then they have to go through the Second Reading by the European Parliament (with new MEPs!).
  - Then they go through the Second Reading by the Council.
  - At which stage the Regulations may be adopted.
  - If not, there is a further "Reconciliation" procedure.

- The conclusion is that they are unlikely to come into force until mid 2015 after which there will be a transition period of at least 18 months.
- Manufacturers need to start planning to be ready to comply by the end of 2016.