MDD Revision Update: Impact on UK Medical Device Companies

Neil Adams, Medical Devices Operations and Delivery Director
22 October 2013
…… Consider the Current Regulatory Landscape

• Commission Recommendation on UDI
• PIP fallout
  • Commission Implementing Regulation (EU) No 920/2013
    • On the Designation and Supervision of Medical Device and AIMD Notified Bodies
    • On the audits and assessments performed by notified bodies in the field of medical devices
  • Commission Recommendation 2013/473/EU
    • On the audits and assessments performed by notified bodies
    • Includes unannounced audits
  • Clinical data, Post Market Surveillance and Post Market Clinical Follow up
  • Enforcement
  • Central oversight and Co-operation
• Generalists to Specialists
• Cost of the Compliance Infrastructure
Overview

- Look a few years ahead at the proposed MDR
- Consider the immediate impact of
  - Commission Implementing Regulation (EU) No 920/2013 on the Designation and Supervision of Medical Device and AIMD Notified Bodies
  - Commission Recommendation 2013/473/EU on the audits and assessments performed by notified bodies (unannounced audits already covered)
- Mention anything surprising at today’s MHRA IVD Strategy Group Meeting
- Anything from yesterday’s EP plenary session vote MDR and IVDDR amendments
26 September 2012

Proposal for a
REGULATION OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL
on medical devices, and amending Directive
and Regulation (EC) No 1223/2009
The Commission says the new regulations...

- Build on the strengths of existing directives ...
  - Support innovation
  - Rapid access to market
  - Balance between pre- and post-market control
  - Cost-effective
  - SMEs
- ... but adapt and improve, especially in terms of
  - Health and safety
  - Internal market
  - Transparency
  - Trust and confidence in the European Regulatory System
A Key Feature: Delegated and Implementing Acts

• Proposal empowers the Commission to adopt
  • Implementing acts to ensure uniform application of the Regulation
    • Member State Committee must give positive opinion on Commission Proposals
  • Delegated acts to complement the regulatory framework for medical devices over time
    • Commission publishes the Delegated Act
    • European Parliament or Council have two months to object

• Serious centralisation of power
  • Too much say some Member States and MEPs

• Very useful tools to adapt to technical progress
Implementing Acts: Positive MS Opinion Required

• Commission can:
  • Establish regulatory status of products: does a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device'?
  • Adopt Common Technical Specifications: where no harmonised standards exist or where relevant harmonised standards are not sufficient
  • Establish and regularly update a list of categories or groups of single-use devices for critical use which may be reprocessed...
  • Lay down the modalities necessary for the development and management of Eudamed
  • Set NB application process, scope acceptability criteria and competency codes, and Notified Body De-Designation process
  • Change medical device classification criteria, conformity assessment procedures, certificates of free sale, field safety corrective action procedures
  • Procedures for dealing with non-compliant and compliant devices presenting a risk to health and safety
  • ...... and more
Delegated Acts: EP and MS Two months to object

• Commission can
  • Adopt delegated acts in the light of technical progress and taking into account the similarity between a medical device and a product without a medical purpose
  • Adapt the definition of nanomaterial in view of technical and scientific progress and taking into account definitions agreed at Union and international level
  • Amend or supplement data requirements, documentation and procedures
    • the general safety and performance requirements set out in Annex I, the information supplied by the manufacturer; the technical documentation set out in Annex II; the minimum content of the EU declaration of conformity; amend the information to be submitted as set out in Part A of Annex V, the minimum requirements in Annex VI needed for the assessment of specific devices, or categories or groups of devices; the classification criteria set out in Annex VII; the conformity assessment procedures; the minimum content of the certificates; the requirements for the documentation to be submitted with the application for the clinical investigation
  • Determine the devices, categories or groups of devices whose identification shall be based on the UDI system
  • Set out the structure and the level of the fees MS can charge NBs
  • ...... And more
Scope

• Scope Additions
  • Products utilizing non-viable human tissues or cells unless they are covered by the Advanced Therapy Medicinal Products (ATMP) – e.g. syringes prefilled with human collagen
  • Certain products with no medical purpose, but, similar devices in characteristics and profiles – e.g. non-corrective contact lenses, implants aesthetic purposes

• Scope Exclusions
  • Products containing viable biological substances
  • Food covered by other EU regulations (slimming products) – devices now excluded from food regulations
  • EC empowered to confirm regulatory status of product(s)
Standards and Common Technical Specifications

• Presumption of compliance using harmonized standards increased to include process and conformity assessment standards
  • QMS, risk management, clinical investigation, clinical evaluation and post–market clinical follow-up
• Allows the EC to mandate common technical specifications (CTS)
Obligations of Authorized Representative, Importers, Distributors

• Manufacturer designates by written mandate a single authorized representative confirmed in writing by the authorized representative
  • Prescriptive requirements for authorized representative
  • Written process for changing authorized representative
• General obligations of importers & distributors
  • Confirm: conformity assessment, authorized representative, technical documentation, devices CE Marked, labeled in accordance with regulation
  • Identify themselves, registration, storage & transportation, records, complaints, responsibilities
• Relabeling / repackaging devices
  • Assumes responsibilities of the manufacturer
Single Use Devices and Reprocessing

• Considered to be the manufacturer
• Reprocessing of single-use devices for critical use is prohibited (intended for surgically invasive procedures)
• EC has power to change definition of devices for critical use
• Removal of OEM’s name from label
• National provisions may be maintained or introduced
Manufacturer - Qualified Person

- Manufacturers need a qualified person available within their organisation who has medical device expertise
  - Either education requirements plus two years medical device RA / QA experience or five years medical device RA / QA experience
- Protected when properly fulfilling responsibilities
- Responsibilities include
  - Statements regarding clinical investigation devices essential requirement compliance and protection of subjects
  - Conformity of devices confirmed before batch release
  - Technical documentation and declarations of conformity are current maintained
  - Reporting obligations are met
- EU Representatives shall also have qualified person
  - Expert knowledge of EU medical device regulations
Identification within the Supply Chain

• Economic operators shall identify the following (available to CA’s):
  • Economic operator to whom they supplied a device
  • Economic operator who supplied them a device
  • Any health institution or healthcare professional to whom they have supplied a device
Implant Card

• Manufacturers of implantable devices shall provide implant card for particular patients
  • Identifies device implanted including UDI
  • Warning, precautions, measures to be taken with reciprocal interference with external influences (e.g. compatibility with diagnostic devices)
  • Information on expected life cycle and follow-up
CE marking of conformity

• New requirement – when CE Marking is used in promotional material the notified body number must also be identified
Parts and components

- New requirement for suppliers of parts or components
- Responsibility to determine the part or component does not adversely affect the safety and performance of the device
  - Substantiating evidence available to CA’s
- Part or component that significantly changes the performance or safety characteristics of a device shall be considered a device in its own right
Electronic System of Registration of Devices and Economic Operators

• The EC will set up and manage an electronic system
• Manufacturers will submit information in electronic means
• Importers will submit information in electronic means
  • All changes updated within one week
• Accuracy confirmed at least every 24 months
• Data shall be publically available
• Fees may be collected
Notified Bodies

• Significant new requirements regarding the designation, competence, scope, monitoring and maintenance of notified bodies
• Requirement to issue certificates and status in database
• Procedure for changing notified bodies
• Current notified bodies will need to apply for and achieve designation under the new regulation
  • National Authority shall notify to the EC, MS and MDCG
  • Scopes of NB’s will be competence specific

Already here: Commission Implementing Regulation (EU) No 920/2013
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Likely Classification Changes up to Class III

- AIMD and accessories
- Spinal disc replacement implants and implantable devices that contact the spinal column
- Devices incorporating nanomaterial
- Devices intended for aphaeresis
- Devices intended to be ingested, inhaled or administered rectally or vaginally and are wholly or partially absorbed by or dispersed in the human body
Conformity Assessment

• Notified bodies shall notify the Commission and MDCG of new applications for class III devices
• Notified body shall rotate the members of the audit team (no more than three years per auditor)
Unannounced Visits

• Notified body shall randomly perform unannounced factory inspections and if appropriate suppliers / subcontractors

• Notified body shall establish a plan for unannounced factory inspections which shall not be disclosed to the manufacturer

• Within the context of unannounced factory inspections the notified body shall check an adequate sample of devices from production to verify compliance with technical file

  • Notified body could take samples from the market and verify compliance with technical file

**Already here: Commission Recommendation 2013/473/EU**

**Covered this morning**
Clinical Evaluation & Clinical Investigation

- Regulation combines and incorporates current guidance on clinical evaluation and clinical investigation
- Significant requirements on clinical
  - General requirements – sponsor responsibilities
  - Application
  - Registration
  - Electronic system
  - Post market clinical investigation requirements
  - Substantial modification
  - Sponsor information obligations regarding suspension / termination
  - Event reporting

Much already here: Commission Recommendation 2013/473/EU
European MS Co-operation

• Competent authorities (CA)

• Medical Device Coordination Group (MDCG)
  • Oversight and contribute: NB designation / Class III certification / Guidance / Assist CA’s (vigilance, clinical investigations) / Assist EC / Harmonization

• Scientific Advisory Board (SAB)

• European Union Reference Laboratories (EURL)
  • EC will facilitate access to manufacturers and NB’s to advice provided by SAB and EURL’s

• Union shall support the establishment of registers for certain devices to evaluate long term safety and performance
Budgetary Implications: Costs

• Development of the Eudamed database (one-off costs and maintenance)
• Commission staff organising and participating in 'joint assessments' of notified bodies
• National assessors participating in 'joint assessments' of notified bodies
• Commission staff supporting the MDEG and its sub-groups
• Commission staff managing the Regulation and developing the delegated / implementing acts
• Organisation of meetings of the MDEG and its sub-groups, of the advisory committee on borderline issues, and of the Committee under Regulation 182/2011, including reimbursement of the members appointed by the Member States
• Reporting members of the MDEG preparing opinions on notified bodies' preliminary conformity assessments of high risk devices
• Organisation of meetings of the Scientific Advisory Committee, including reimbursement of its members
• The functioning of the EU reference laboratories
• Participating in international regulatory cooperation
Budgetary Implications: Finding the Money

• The Commission, the Member States or and the designated EU reference laboratories will charge fees for various activities
• The Commission will use implementing acts to set the level and structure of fees
• The Commission
  • Fees for the registration of medical devices in the central database
• The Member States
  • Fees for the designation and monitoring of notified bodies
  • Transfer a portion to the Commission to finance the 'joint assessments' and the scrutiny mechanism for high risk devices
• EU Reference Laboratories
  • Fees for scientific opinions provided to notified bodies and manufacturers
2012 View of Best Case Timelines

- **EU Presidency**
  - European Commission: Draft the legal text
  - European Commission: Publish the Proposal
  - EU Parliament and Council: 1st Reading: Assess and amend the Proposal
  - EU Parliament and Council: 2nd Reading: Negotiate agreeable text
  - Member States: Implement
  - Jul – Dec 2011
  - April 2012
  - 2012 / 2013
  - 2013 / 2014
  - 2014

- **Denmark**
- **Cyprus / Ireland**
- **Lithuania / Greece**
- **Italy**

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Timelines: Current Status

**EU Presidency**

**European Commission**
- Draft the legal text
  - Jul – Dec 2011

**European Commission**
- Publish the Proposal
  - April 2012
  - September 2012

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**EU Parliament and Council**
- 1st Reading: Assess and amend the Proposal
  - 2012 / 2013

**EU Parliament and Council**
- 2nd Reading: Negotiate agreeable text
  - 2013 / 2014

**Member States**
- Implement
  - 2014
MDR is for the Future; What now?

• Commission Implementing Regulation (EU) No 920/2013
  • On the Designation and Supervision of Medical Device and AIMD Notified Bodies
  • On the audits and assessments performed by notified bodies in the field of medical devices
• Commission Recommendation 2013/473/EU
  • On the audits and assessments performed by notified bodies
  • Includes unannounced audits
Key Features of Implementing Regulation (EU) No 920/2013

• Changes substantially the procedure for designating Notified Bodies
• Five year designation period
• Joint Assessment Teams:
  • Four representatives: European Commission expert (FVO, Dublin), designating authority of the EU Member State in which the notified body is established and designating authorities of two other EU Member States
  • Following an on-site audit, all four produce a report each; made available by the Commission, upon request by other EU Member States
  • Designating authority of the EU Member State where the notified body is located decides on designation, taking account of the recommendations from the other members of the joint assessment team and any other EU Member State
• Now have the right to undertake unannounced audits of Notified Bodies at their locations (not manufacturer witnessed audits)
• Instructs Designating Authorities to have the sufficient number of competent personnel
Implementation

- FVO has full time people assessing Notified Bodies
  - Looks like it will become the de facto centre of excellence for auditing Notified Bodies
- All existing Notified Bodies subject to renewal by 14 October 2016
- MHRA have a plan for its five UK Notified Bodies over the next three years
  - Will give each NB three months’ notice
- Surveillance at least 12 months if over >100 clients
- Extensions and renewals will follow the same procedure as a new designation
- Joint assessments will increase workload of MHRA in other Member States
- Some Designating Authorities may be challenged by need for sufficient competent resource
- Compliant Notified Bodies should not be affected significantly
  - Some debate about employment of medical practitioners
  - NBs will need in-house technical expertise
- These provisions should appear in the new regulation unless there is a major change in regulatory process
Key Points: Commission Recommendation 2013/473/EU on NB Audits and Assessments

• Instructs Notified Bodies to Perform Unannounced Audits
  • Covered this morning
• Provides specific advice to Notified Bodies on requirements for Medical Device Clinical Evaluation and Post Market Clinical Follow-up
• Provides specific advice to make sure Notified Bodies do not provide any exceptions for outsourced production compared to in-house production
  • Must include the most important subcontractors and suppliers in the conformity assessment procedures
Product and Quality System Assessments

• Annex I Product Assessment: Design Dossier examination or Type Examination
  • Reinforces Current Good Practice
• Annex II Quality System Assessment
  • Mainly Reinforces Current Good Practice, apart from impact on Own Brand Labellers
  • Gives advice in case of outsourcing of the production via subcontractors or suppliers
  • Critical subcontractors or crucial suppliers may be suppliers of suppliers or even suppliers further down the supply chain
  • Notified bodies should refrain from signing arrangements with manufacturers unless they receive access to all critical subcontractors and crucial suppliers and thus to all sites where the devices or its crucial components are produced, regardless of the length of the contractual chain between the manufacturer and the subcontractor or supplier
Product and Quality System Assessments: OBLs

- Own Brand Labels as UK knows it have gone
- MHRA to update Bulletin 19 on Own Brand Labels
- OBL only clients will now get an audit: a site visit and they must have their own quality system
- MHRA do not require a full product listing scope for QMS certificates, but the manufacturer must have, and the Notified Body must verify, a clear unequivocal product identification system, from which the Notified Body can base the certificate scope
- Notified Body should look at technical file
  - Maybe a STED type file for technical documentation will suffice
- Need updated MHRA bulletin to clarify requirements
BSI’s Medical Device Experts NB 0086 and NB 0535 Summer 2013

... and 130 QMS Auditors
## Medical Device Experts in Notified Body 0086 2008 and 2013

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... and 130 QMS Auditors

- 25% of the EU’s Certificates?
- Every manufacturer visited
- Our performance monitored
- Real sanctions available
- Contribute to improve the system for all
Conclusions

• Commission Implementing Regulation (EU) No 920/2013 and Commission Recommendation 2013/473/EU and the proposed MDR and IVDDR will:
  • Increase the workload and competency requirements in Competent Authorities
  • Increase the workload of Notified Bodies

• The Commission, Member States, Notified Bodies and Manufacturers must all resource to meet the needs of the changing landscape
  • Manufacturers move from involvement to commitment

• For Notified Bodies
  • Notified Bodies need competence in-house
  • Must minimise conflict of interest

• For Regulatory Consultants
  • Many changes and increased oversight will increase need for regulatory affairs expertise in every size of company
  • Choose notified bodies with critical mass and in house expertise
    • “Virtual notified bodies” a thing of the past

• For everyone
  • There is a lot of talking and amending to do before the new regulations become reality
Today’s Developments in Brussels and London

• MHRA IVD Strategy Group Meeting
• EP plenary session vote MDR and IVDDR amendments
Thank you

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