Recast of MDD – what do we expect?

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Agenda

1. The medical device directives
2. Commissions Joint Plan for Immediately Action
3. Notified bodies
4. Draft for new regulations on medical devices
The current directives (1)

- The first common European regulation of medical devices – more or less without changes for 20 years

- Well known administrative principals for product regulation that supports safety, innovation, marked access and predictability

- A common European regulation do grant safety, innovation and technological knowledge compared to national regulations

  but the regulation needs to be adjusted to new technologies, new safety requirements and new scientific knowledge
The current directives (2)

- Supervision and control on notified bodies
  - non-uniformity in quality and thoroughness in the competent authorities requirements for notification and the control/audits of notified bodies

- Post-market surveillance
  - Non-uniformity in planning and administration of post-market surveillance between member states.

- Transparency and traceability
  - No common EU overview of products and no common, standardized tool for traceability
The current directives (3)

- Co-operation with medical/technical expertise
  - Medical and technical expert are not involved in the regulatory and decision making process in a structured manner

- Administration of the regulatory system
  - No technical, scientific or logistic systems to support the co-operation between member states
  - No IT tools/systems to regulate the flow of information within the system
  - No consolidated scientific and medical expertise to support decision making

Resulting in an uneven administration of the legislation
Joint action plan (1)

Background

PIP breast implants:
- Use of industrial silicon, no laboratory test was made, audits by notified bodies was always pre-announced
- The PIP case was used as a “stress test” in the Commissions draft for new medical device legislation

The cases involving Metal-on-Metal (MoM) hip implants and vaginal MESH also accentuated the need for action.
Joint action plan (2)
Notified bodies

Notified bodies:

- Significant divergences between member states on designation and monitoring of notified bodies
- Significant divergences in quality and depth conformity assessment performed by notified bodies
- The power to do unannounced audit has not been used by notified bodies
- Notified bodies do not always have access to their clients incident reports

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Voluntary joint assessment pilot program in 2013:

- Audit teams consisting of designating NCA, experts from other designating NCAs and FVO
- Notified bodies in 22 out of 23 countries has been audited (last audit is expected to take place third quarter of 2014)
- 22 out of 23 countries has made assessors available for joint assessment
- All assessment resulted in identification of non-conformities
- Major non-conformities was identified in approximately half of the countries
- For major non-conformities notified bodies was obliged to undertake corrective actions. In serious cases temporary suspension or limitation of scope was imposed. One complete designation was made
- Most common non-conformities identified was related to; staff qualification, quality/depth of review of clinical evaluation and sampling of technical files

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Joint action plan (4)
Notified bodies

The requirements laid down in the directives are very general. This is reinforced by:

- Implementing regulation (920/2013) on designation and supervision entered into force 24th of September 2013

- First implementing measure concerning notified bodies since the directive entered into force in 1993.
Joint action plan (5)
Notified bodies

According to the implanting regulation:

- designation is made by designating team; designation NCA, two other NCA and Commission

- audits of notified bodies shall be made every 12 months (large NB) or 18 months (small NB)

- the notified body shall have the necessary administrative, technical, clinical and scientific personnel with technical and scientific knowledge and sufficient and appropriate experience within its organization
Joint action plan (6)
Notified bodies

- Commission shall investigate cases concerning fulfillments of the requirements for a notified body

- If a notified body no longer meets the requirements Commission shall inform NCA requesting them to take action or take action themselves

- Detailed requirements for notified bodies control both pre- and post-marketing
  - incl. unannounced audits at manufactures

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Commissions recommendations on audits and assessments made by notified bodies entered into force on the 24th of September 2013

- The recommendation provide guidelines to facilitate a consistent assessment when notified bodies are doing:
  - Product assessment
  - Quality system assessment
  - Unannounced audits (should be made at least every third year)

- The recommendation do not set out new requirements, but clarify the requirements set out in the directives
Market surveillance:

- Survey made by the Commission showed divergences between surveillance made by member states, e.g.
  - Focus on national manufacture
  - Different items in focus, e.g. labelling and packaging
  - Use of vigilance data
  - Cooperation with customs
  - Reactive or proactive (often reactive)

- Conclusion is that member states should have focus on:
  - Documentary check, physical and laboratory checks and visit to the premises of economic operators

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Joint action plan (9)
Coordination, communication and transparency

Coordination of member states activities:
- Coordination of efforts when an increase in frequency of vigilance reports is identified
- Monthly vigilance teleconferences
- Coordination of inspections and audits

Communication and transparency:
- Commission recommendation (2013/172) on Unique Device Identification to ensure that systems within Europe are compatible
- Set up of “implant registers” to ensure a an effective collection of mid- and long-term data on safety and performance
- Implementation of reporting systems for health care professionals and patients
New regulation(1)
Focus on high-risk devices

High-risk devices:

Art. 44 scrutiny procedure:

- Notified bodies shall inform Commission (MDCG) on applications for conformity assessment of class III medical devices

- MDCG can require a summary of the preliminary conformity assessment

Medical Device Coordination Group (MDCG) consisting of delegates from all NCA and Commission
New regulation (2)
Focus on high-risk devices

- MDCG shall give a justified scientifically valid health reason for scrutiny
- MDCG can request for more documentation, samples or on-site visits at the manufactures premises

Principle of equal treatment shall be duly taken into account
Clinical evaluation:

- Data from clinical investigation becomes mandatory for implantable devices and class III devices.

- The use of equivalent data will no longer be considered as sufficient justified as an alternative to clinical data;
  - In case of minor changes to a manufacturer's own devices, equivalent data can be justified.

**High-risk products** → a summary of the clinical evaluation should be made public available.
New regulation(4)
Post-marketing clinical follow-up

Post-marketing follow-up:

- Documentation of surveillance plan
- Procedures to keep the post-marketing surveillance plan updated
- Pro-active approach to clinical follow-up
  - collection and evaluating of clinical data from use in humans

Focus on pre-marketing clinical evaluation or on post-marketing clinical follow-up?
New regulation (5)
Transparency and traceability

Transparency and traceability:

- Unique Device Identifier (UDI):
  - Implementation gradually and proportionate to the risk class of devices (implants -> class III -> ....)

- EUDAMED:
  - Extension of database to hold even more data on vigilance, market surveillance, UDI information etc.
Market Surveillance:

- Economic operators must be able to identify who supplied them and to whom they have supplied medical devices.

- Reporting of serious incidents and corrective actions via EUDAMED:
  - Coordination authority in case of similar incidents or corrective actions.
  - The responsibility of the coordinated authority is clarified.

- Member states shall encourage reporting from healthcare professionals, users and patients.
New regulation (7)
Market surveillance

- Member states shall make a risk assessment on incidents and corrective actions
- Market surveillance activities to include checks on characteristics and performance of devices
- Coordination of market surveillance activities between member states and Commission (work-sharing)
- Information between member states on output from market surveillance (EUDAMED)
- Detailed procedures for handling of cases on non-compliance and cases of risk to health and safety