AXON
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PROPOSAL MEDICAL DEVICES REGULATION CAPITA SELECTA

Combination Products Alliance
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health
food
technology

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Introduction + agenda

- Economic operators
- Conformity assessment (including classification and scrutiny)
- Notified bodies
- Market surveillance
- Vigilance

Economic operators

Proposal implements strict supply chain control mechanism

- Blueprint from general market surveillance regulation 765/2008
- As implemented in other specific instruments, e.g. toys and falsified medicinal products directive

- Goal: enlist supply chain in market surveillance by imposing autonomous obligations on the various stages of the supply chain

Economic operators: importers

Must ensure that:

1. the appropriate conformity assessment procedure has been carried out by the manufacturer;
2. an authorized representative in accordance with Article 9 has been designated by the manufacturer;
3. the EU declaration of conformity and the technical documentation have been drawn up by the manufacturer;
4. the device bears the required CE marking of conformity;
5. the device is correctly labeled and accompanied by the required instructions for use and EU declaration of conformity;
6. a Unique Device Identification has been assigned;

Economic operators: importers

Must furthermore:

1. Be able to identify any economic operator to whom they have supplied a device, any economic operator who has supplied them with a device and any health institution or healthcare professional to whom they have supplied a device for a period of five years;
2. Label the device with their contact details;
3. Take corrective action (a.o. recalls and report to authorities) autonomously;
4. Engage in post-market surveillance (among other things report complaints); and
5. Refuse to import devices of which he has reason to believe are not in conformity with the requirements.

Economic operators: distributors

Must verify that:

1. the product bears the required CE marking of conformity;
2. the product is accompanied by the information to be supplied by the manufacturer;
3. the manufacturer and, where applicable, the importer have complied

Economic operators: distributors

Must furthermore:

1. Label the device with their contact details;
2. Take corrective action (among other things undertake recalls and report to authorities) autonomously;
3. Engage in post-market surveillance (i.e., report complaints)

Economic operators: manufacturer activities

A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if he does any of the following:

(a) makes available on the market a device under his name, registered trade name or registered trade mark;
(b) changes the intended purpose of a device already placed on the market or put into service;
(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

Exclusion for translation and pack changes, but

- these must be subject to quality system
- manufacturer and authorities must be informed

Economic operators: qualified person

Manufacturers shall "have available" within their organisation at least one qualified person who possesses expert knowledge in the field of medical devices, "at least" responsible for

(a) that the conformity of the devices is appropriately assessed before a batch is released;
(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
(c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;
(d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.

Issues:
- "have available" – outsourcing possible?
- "at least" – what else is expected?

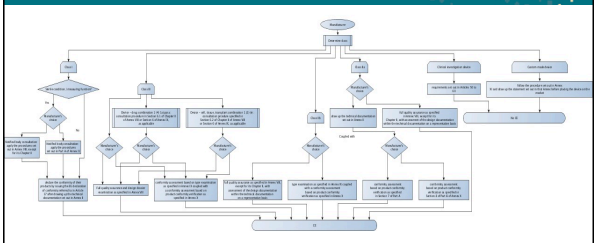
- Similar requirement for authorised representatives

Conformity assessment

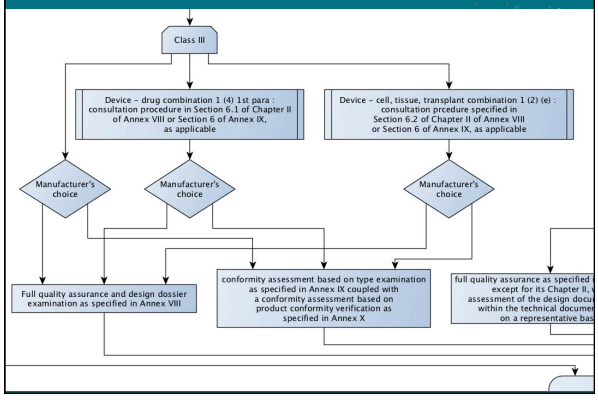
Essentials of system do not change but some quite radical changes

- Essential requirements can be amended by delegated act
- EU can mandate Common Technical Specifications
- Presumption of conformity by relying on harmonised standards will remain, but future of harmonisation is unclear
- Commission can tweak "modalities and procedural aspects" with a view to ensuring harmonised application of conformity assessment procedures by notified bodies

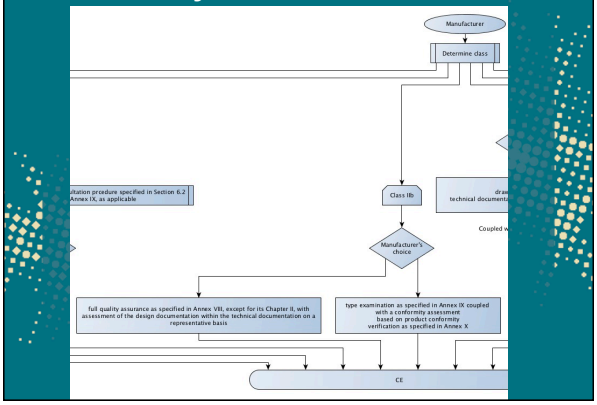
Conformity assessment routes overview



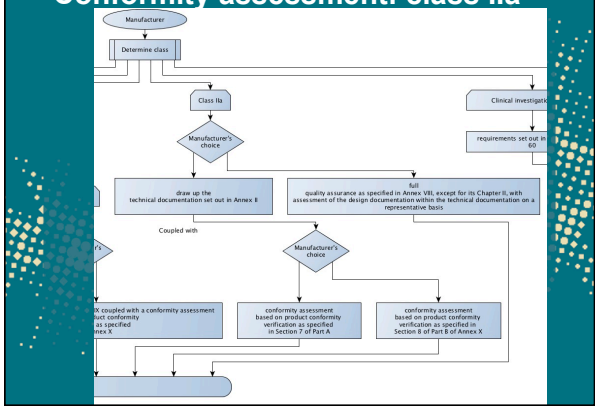
Conformity assessment: class III



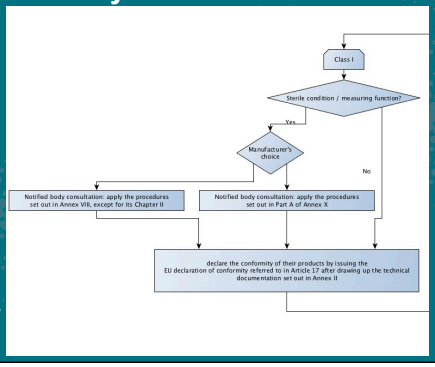
Conformity assessment: class IIb



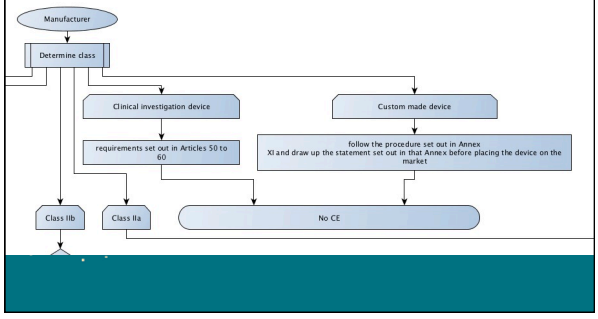
Conformity assessment: class IIa



Conformity assessment: class I



Conformity assessment: investigational and custom device



Scrutiny

Scrutiny procedure motivated by political decision to increase supervision of conformity assessment of high risk devices

- New MDCG will have the right to 'call' up files from notified bodies
- Procedure is not really well defined
- It's the thing that the industry is most sceptical about in the proposed MDR

Scrutiny

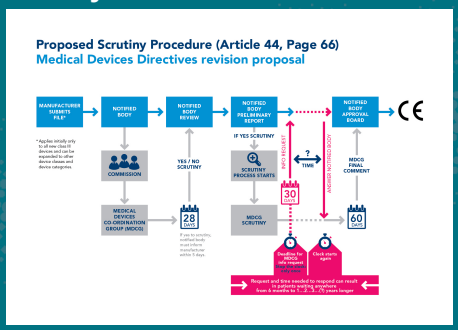
Scope

- Class III devices; and
- Other devices than class III, for a predefined period

Other devices if justified only by one or more of the following criteria:

(a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;
(b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;
(c) an increased rate of serious incidents reported in respect of a specific category or group of devices;
(d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;
(e) public health concerns regarding a specific category or group of devices or the technology on which they are based.

Scrutiny



Classification

- Basic classification logic stays the same
- Dispute resolution mechanism for disagreement manufacturer / notfied body : Member State competent authority regulating manufacturer decides
- Commission may intervene and decide for (class of) device(s), autonomously or by request Member State
- MDR contains mechanism to change classification for category or groups of devices or criteria in general – anticipate future up classification based on 'media-level'

Classification

New rules in MDR

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

Notified bodies

Transitioning to notified body accreditation 2.0:

- Designations under AIMD, MDD, IVD become void at the date of application of the regulation
- EC Certificates issued before MDR enters into force remain valid until expiration date
- EC Certificates issued after MDR enters into force become void 2 years after the date of application of the MDR
- Certificates against MDR can only be issued by notified bodies designated under MDR before the date of application of MDR

Aim: make notified bodies more of an extension of competent authorities' market surveillance paid by industry

Notified bodies

In the mean time

- Notified Bodies Code 3.0
  - Contains specifics on unannounced audits and many other interesting subjects
- Commission recommendation on unannounced audits in pipeline
  - Public end 2012, entry into force 2013
  - Will trigger applicability of Notified Bodies Code 3.0

Viglance and market surveillance

- Have their own chapter in the MRD now (chapter VII)
- Reflect the strong political desire to remedy the problems behind the PIP and metal-on-metal hips cases

Vigilance

- Vigilance incorporates vigilance MEDDEV 2.12/1
- Reporting via EUDAMED of
  - Serious incident
  - Corrective action
- Member States must take measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents

Vigilance

EUDAMED will contain

a) reports by manufacturers on serious incidents and field safety corrective actions;
b) periodic summary reports by manufacturers;
c) reports by competent authorities on serious incidents;
d) reports by manufacturers on trends;
e) field safety notices by manufacturers;
f) information to be exchanged between the competent authorities of the Member States and between them and the Commission

Accessible to competent authorities of the Member States, to the Commission and to the notified bodies; publicTBD

Vigilance

The competent authorities shall designate a coordinating competent authority to coordinate their assessments in the following cases:

a) where similar serious incidents related to the same device or type of device of the same manufacturer occur in more than one Member State;
b) where the field safety corrective action is being or is to be undertaken in more than one Member State

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the one of the Member State where the manufacturer has his registered place of business

Commission can harmonise formalities by delegated act

Market surveillance

General beefing up of surveillance, competent authorities

- to perform appropriate checks on the characteristics and performance of devices including, review of documentation and physical or laboratory checks on the basis of adequate samples;
- may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities
- may enter the premises of economic operators and take the necessary samples of devices; and
- may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary.

Market surveillance

- Many of the instruments proposed are not new
- Authorities must cooperate in market surveillance
- EUDAMED will comprise and automatically transmit

a) information in relation to non-compliant devices presenting a risk to health and safety
b) information in relation to compliant devices presenting a risk to health and safety;
c) information in relation to formal non-compliance of products; and
d) information in relation to preventive health protection measures.

- Mechanism for Commission to act against unjustified measures

Market surveillance

Member States can act to end non-compliance:

a) CE marking has been affixed in violation of the formal requirements;
b) CE marking has not been affixed to a device contrary to requirements
c) CE marking has been inappropriately affixed on a product that is not covered by MDR;
d) EU declaration of conformity has not been drawn up or is not complete;
e) information to be supplied by the manufacturer on the label or in the instructions for use is not available, not complete or not provided in the language(s) required; and
f) technical documentation, including the clinical evaluation, is not available or not complete.

Market surveillance

Member states can take provisional measures to remediate potential risk related to

- a device or
- a specific category or group of devices

if making available on the market or putting into service of such device or specific category or group of devices should be

- prohibited, restricted or made subject to particular requirements or
- that such device or category or group of devices should be withdrawn from the market or recalled

in order to protect the health and safety of patients, users or other persons or other aspects of public health

Commission confirm by implementing act, can adopt immediately applicable implementing acts

Money money money

- The Commission, the Member States and the designated EU reference laboratories will charge fees for various activities
- implementing acts to set the level and structure of fees

<u>Commission</u>
- EUDAMED registration fees
- Fees for scientific advice provided at the request of a manufacturer or notified body

<u>Member States</u>
- Fees for the designation and monitoring of notified bodies
- May levy fees for the activities based on MDR, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles

<u>EU Reference Laboratories</u>
- Fees for scientific opinions provided to notified bodies and manufacturers

Thanks for your attention

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