BORDERLINE ISSUES:

MDs / MPs / IVDs
....cosmetics?
....biocides?
....IT products?
....PPEs?

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MEDICAL DEVICE

Definition

- Instrument
- Apparatus
- Implant
- Machine
- Appliance
- Software
- Material
- Other similar or related article

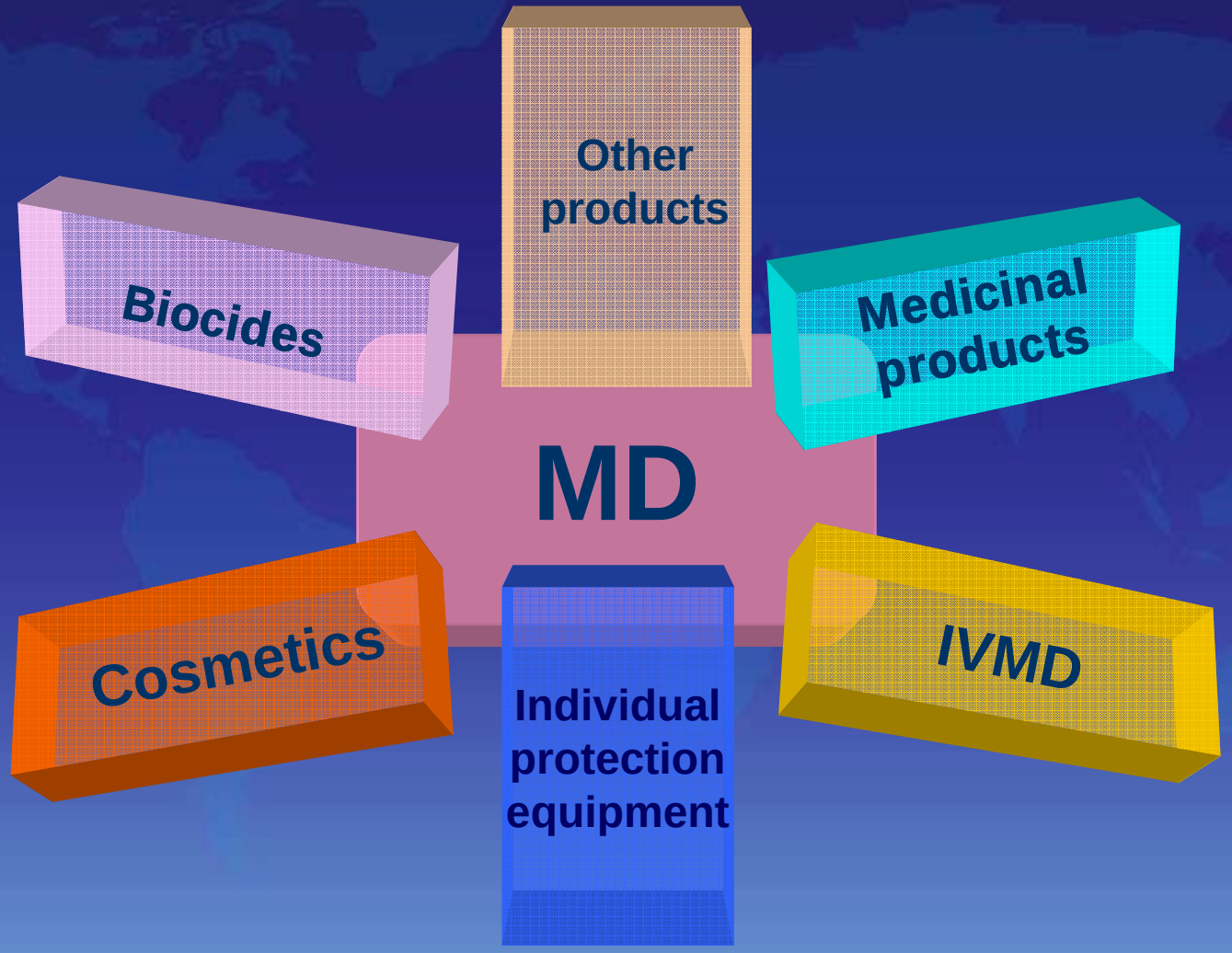
which doesn't achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

- Diagnosis
- Prevention
- Monitoring
- Treatment
- Alleviation
- Compensation

} disease / injury

- Investigation, replacement, modification, or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices

MEDICAL DEVICE
Borderline Issues



MEDICAL DEVICE
Borderline Issues

Is this product a medical device ?

MD

- **Medical purpose**
- **Principal intended action**

IN VITRO DIAGNOSTIC MEDICAL DEVICES: BORDERLINE ISSUES

A product cannot be an IVD under Directive 98/79/EC and a medical device under Directive 93/42/EC as the two directives are mutually exclusive.

A product is an IVD device, if it fulfils the clauses a) and b) of the Article 1.2 of Directive 98/79/EC:

1. intended use and properties as a medical device according to Article 1.2 a) and
2. intended use and properties as a IVD device according to Article 1.2 b)

thus a product must firstly be determined to be a medical device before determining whether or not it is an IVD, within the definitions contained in the directive 98/79/EC.

Essential Characteristics

The essential characteristics of an IVD, whether consisting of a single component or a combination, are that:

- ❖ its principal intended purpose is to provide information
  - concerning a physiological or pathological state or
  - concerning a congenital abnormality or
  - to determine the safety and compatibility with potential recipients or
  - to monitor therapeutic measures,
- ❖ the device is used *in vitro* for the examination of a specimen derived from the human body, and
- ❖ the information thus obtained is to be used for one or more of the medical purposes specified in Article 1.2 (a, b).

Medical Purpose

In order for a product to come within the scope of the MD Directives (incl. IVDD) it must be intended to be used for a medical purpose. If no medical purpose is intended by the manufacturer then the product is not MD.

Article 1.2 (h) of IVDD provides that the "**intended purpose**" is the use for which a device is intended according to the data (presumably, the information) supplied by the manufacturer on the labelling, in the instructions for use and / or in promotional material.

Examples:

- *Devices for detection of agents of biological or chemical warfare in the environment are not IVD's because such products have no medical purpose*
- *Devices intended to be used only in the course of law enforcement or other non-medical purposes, e.g. for detecting drugs of abuse/alcohol, are outside the scope of the IVDD*
- *A product for research use only which has no medical purpose*

Specimen Receptacles

Article 1.2(b) of the IVD Directive clearly states that specimen receptacles are considered as *IVD*'s. It defines specimen receptacles for this purpose as those devices that are specifically intended by the manufacturer to be for the primary containment and preservation of specimens derived from the human body for the purposes of in vitro diagnostic examination. This applies whether the product is vacuum type or not.

Examples:

- *Sample tubes, microbial transportation devices (tubes). Article 1 (2) b applies.*

Note: Specimen receptacles that come into contact with a patient are considered to fall within the scope of the MDD and not the IVDD.

Accessory: definition of "accessory" in Art 1.2 (c) of IVDD states that invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of MDD are not to be considered as accessories to *IVD*'s (e.g. lancets, pricking devices to obtain blood.

Products for General Laboratory Use:

Products for general laboratory use (non-IVD products) are not IVD's unless on the basis of its specific characteristics the manufacturer specifically intends such products to be used for in vitro diagnostic purposes.

Products for Research Use only:

A product for research use only which has no medical purpose, **cannot be a medical device and, therefore, cannot be an IVD medical device**

Devices for IVD Purposes with an Invasive Body Contact

If the principal intended purpose for the product is to be used in vitro for the examination of specimens derived from the human body for the purposes of providing information the IVD directive would apply (Art 2b).

<u>Examples:</u>

- *A device involving the vacuum suction of saliva into the integrated handle of a device which contains reagent material (e.g. for the detection of HIV).*
- *Mouth and other swabs having integrated reagents or reagent areas are IVD's because their principal intended purpose is to provide information relevant to the medical purposes specified in Article 1.2 (b).*

Kits Containing IVD's and Medicinal Products

As the medicinal product is concerned, it must have been granted a marketing authorization covering the actual use for which it is being included in the IVD kit and it must be labeled in accordance with the regulations relating to medicinal products. The IVD component of the kit must comply with all the applicable essential and other requirements of the IVDD (including the labeling requirements) and it must bear the CE marking.

Note: while the CE marking of the IVD content of the kit entitles it to free movement within the EEA (subject to language requirements), that is not so as regards the medicinal product.

Device or Medicinal Product?

In order to decide which regime (MDD or MPD) applies, the following criteria should be examined:

Step 1: The **intended purpose** of the product taking into account the way the product is presented

Step 2: The method by which the **principal intended action** is achieved. If the primary action is pharmacological, immunological or metabolic the product is pharmacological (*medicinal product*)

CRUCIAL

The principal intended action of a product may be deduced from:
- the manufacturer's labeling and claims,
- scientific data regarding mechanism of action

Primary Mode of Action

Medical devices may be assisted in their function by pharmacological, immunological or metabolic means, but as soon as these means are not any more ancillary with respect to the principal purpose of a product, the product becomes a medicinal product.

The claims made for a product, in accordance with its method of action may, in this context, represent an important factor for its classification as medical device or medicinal product.

Examples of Combination Products Classified as Medical Devices

- ✓ *catheters coated with heparin or an antibiotic agent,*
- ✓ *bone cements containing antibiotics,*
- ✓ *root canal fillers which incorporate medicinal substances with secondary action,*
- ✓ *blood bags containing anticoagulant or preservation agents,*
- ✓ *soft tissue fillers incorporating local anaesthetics,*
- ✓ *condoms coated with spermicides,*
- ✓ *electrodes with steroid-coated tip,*
- ✓ *wound dressings, surgical or barrier drapes with antimicrobial agent,*
- ✓ *intrauterine contraceptives containing copper or silver,*
- ✓ *drug eluting coronary stents.*

The Consultation Process

- is initiated by the Notified Body (application to a CA)
- is carried out by a Competent Authorithy
  - normally the CA that once approved the drug
  - all documentation to be supplied by the NB
- is not formally an application for a drug approval but should address the same issues
  - it is often a new drug delivery technique
  - local compared to systemic drug administration
  - local tolerance
  - new pharmacokinetics
  - new drug delivery time-frame
  - toxicity studies
- the NB decides (certificate or not) based on the CA's opinion

Examples of Medical Devices

- bone cement,
- dental filling materials,
- materials for sealing, approximation, or adhesion of tissues (e.g. cyanocrylates, fibrin-based adhesives not of human origin),
- sutures, absorbable sutures,
- soft and hard tissue scaffolds and fillers (e.g. collagen, calcium phosphate, bioglass),
- intrauterine devices,
- blood bags,
- systems intended to preserve and treat blood

Examples of Medicinal Products

- spermicidal preparations,
- gases intended to be used in anaesthesia and inhalation therapy
- topical disinfectants (antiseptics) for use on patients
- artificial tears,
- water for injections

Examples of MDs as „Accessory“

- ✓ contact lens care products (disinfecting, cleaning, rinsing and hydrating solutions...)
- ✓ disinfectants specifically intended for use with medical devices (e.g. endoscopes),
- ✓ lubricants specifically intended for use together with medical devices
- ✓ gases used to drive cryoprobes and surgical tools

Multipurpose disinfectants or sterilization agents are not covered by MDD; they will be covered by the directive on biocides (98/8/EC)

Information Systems and Medical Devices

Classification and Borderline Issue

Examples of Terminologies for Information Systems

- Medical information systems
- Patient record systems
- Health software
- Hospital information systems
- Electronic patient record

Why are we interested in this borderline issue?

Patient's SAFETY!

Events

- Lost X-ray pictures from the short term storage in a PACS *(Picture Archiving & Communication System)* system
- A hard disk failure put a centralized patient monitoring system to halt
- Poor user interface in a administrative system resulted in delay in cancer treatment
- A computerized medication list was presented with the wrong patient
- Poor overview capabilities in a computerized patient record resulted in administration of incorrect pharmaceuticals
- A computerized patient care record was supposed to indicate that a particular patient did not tolerate a specific pharmaceutical substance
- Use of different DICOM-standards in communicating PACS-systems resulted in identical CT scans for two patients

Medical IT-systems

Some facts (observations)

- ✓ Information regarding diagnosis, care and therapy is, to an increasing extent, handled by programmable systems
- ✓ Several IT-systems are often networked. Data is frequently generated in traditional Medical Devices and fed into an IT system
- ✓ The IT-systems are not always validated for the actual use

Devices and IT-systems

Observed trends

- ✓ Medical Information Systems are increasingly behaving like Medical Devices
- ✓ Electrotechnical Medical devices often incorporate information technology
- ✓ Ongoing platform fusion!

European regulations for MD's

National regulations (if any) for medical information systems

The borderline is disappearing!

Definition: Medical Device

….. any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

2007/47/EC

The definition in the revision make it even more clear by the inclusion of the word ”software” in the definition

Medical Device Software or Health Software

The standardization bodies have tried to formulate requirements for software used in healthcare:

- Medical Device Software
  – Software that should be regarded as MD and regulated as such
- Health Software
  – Non-regulated general software used in health care

Relation Between the Revised Directive 93/42/EEC Concerning MDs and Directive 89/686/EEC on Personal Protective Equipment (PPE)

Background

Some products can be qualified as PPE as well as MDs. These products are thus intended for **„dual use“**.
E.g., gloves with a medical purpose in the patient environment are MDs, but as they are also designed to provide protection to the user, they also fall into the definition of PPE

The legal situation **was** that double **„CE“** marking was <u>not allowed</u>

Revised Article 1 (6) MD Directive

Where the manufacturer wants to market a product as **MD** and also as **PPE**, the essential requirements of **both Directives need to be applicable**

The amendment means that dual use products (MD and PPE) are **covered by the MDD**

It allows manufacturers to submit their MD, intended for „dual use“ to a conformity assessment procedure under the MDD, which, as the product is also PPE, must include the relevant basic health and safety requirements of the PPE Directive

Thank you for your attention

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