

CONFORMITY ASSESSMENT OF „ADVANCED MEDICAL DEVICES“

Jan Petrik

Definition – 93/42/EEC, Art. 1, para 2, a)

„**MEDICAL DEVICE**“ means 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:

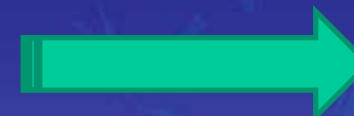
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

... 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

Combined Products for „Advanced Therapy“

Combined products already regulated:

- MD + medicinal products (a)
- MD + non viable animal derivatives (b)
- MD + blood or plasma derivatives (c)



Combined Products(a)

- **Directive 93/42/CEE (MD)**
- **Directive 2001/83/EEC**
- **Directive 2004/27/EEC**

Combined Products(b)

- **Directive 93/42/EEC**
- **Directive 2003/32/EC (BSE/TSE)**

Combined Products(c)

- **Directive 93/42/CEE (MD)**
- **Directive 2000/70/EEC**

Combined Products(a)

- 1) **MD + MP 93/42/EEC Art. 1.3, MD&MP form a single integral product2001/83/EEC**
 - 2) **MD + MP 93/42/EEC Art. 1.3, MD intended to administer MP93/42/EEC + 2001/83/EEC**
 - 3) **MD + MP 93/42/EEC Art. 1.4, MD incorporates MP with ancillary action93/42/EEC (Rule 13)**
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- 1) **No CE Mark; e.g. pre-filled insulin syringes MEDDEV 2.1/3 rev.2, Sec. C**
 - 2) **CE Mark; e.g. pre-fillable syringes**
 - 3) **NB seeks a mandatory scientific opinion from MP-CA (safety, quality, usefulness) MEDDEV 2.1/3 rev.2, Sec. B**

Combined Products(c)

- **MD + blood or plasma derivatives ...**
93/42/EEC Art. 1.4.a NB seeks a mandatory scientific opinion from the European Agency for the Evaluation of Medicinal products (EMA) about quality and safety

Advanced Therapy (Medicinal) Products

Lacking, Overlapping & Transitional Issues



Regulation (EC) No. 1394/2007

- Introduction and Scope
- Exceptions and Combination Products
- CAT and Procedures

Transitional Law

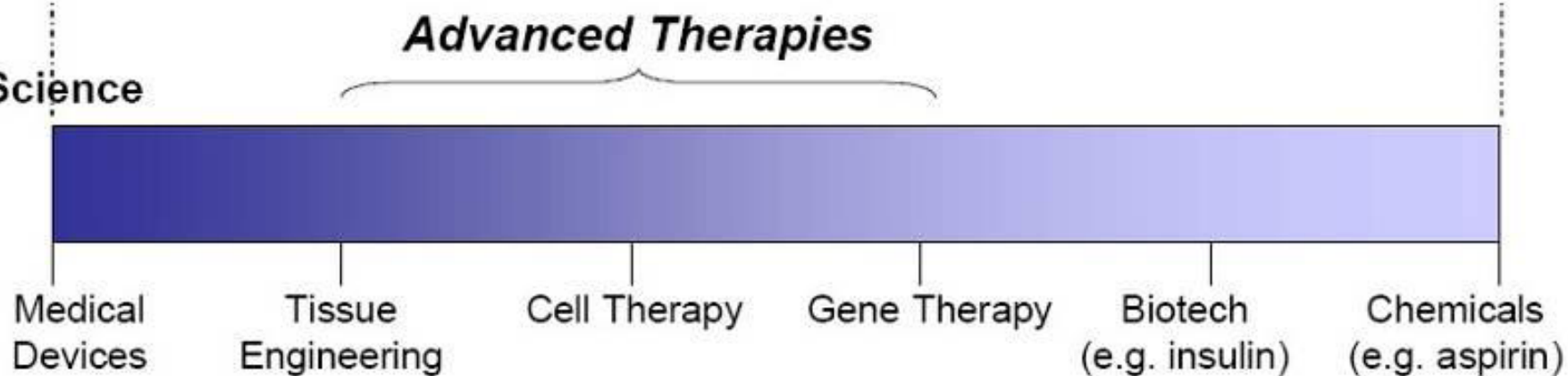
Directive 2004/23/EC

- Cells and Tissues

Legislation



Science



Scope of Reg. 1394/2007

- Is an ATP a medicinal product because it is an ATP?
- Or is a medicinal product an ATP because it is an ATP?

What about products without primary mode of action to be defined as:

- Pharmacological
- Metabolic
- Immunological


New Article 1.4.a (2001/83/EC):

- Advanced therapy medicinal product: *product as defined in Article 2 of Reg. 1394/2004*

Exemptions from the scope of Reg. 1394/2007... (1)

- ATPs prepared on a **non-routine** basis according to **specific quality standards** and used within the same member state in a **hospital** under the **exclusive professional responsibility** of a medical practitioner, in order to comply with an **individual prescription** for a **custom made** product for an **individual patient**,
- **“Individual ATP”**
 - Borderline issues
 - Authorization and regulation by the national competent authorities
 - Standards of ATP regulation

Exemptions from the scope of Reg. 1394/2007... (2)

- Products containing **non-viable human or animal cells/tissues** are **excluded** from the definition if they do not act by pharmacological, immunological, metabolic means 
- **“non-viable cell and tissue products”**
 - No ATP
 - No medicinal product
 - Medical device?
 - Human: excluded from Directive 92/43/EEC2004/23/EC(?)
 - Animal: Yes2003/32/EC

Combined Products

- Any “**advanced**” aspect turns medicinal product or medical device into ATP
- Borderline issues
- Overlapping issues:
 - Evaluation of **device component** by notified body
 - Evaluation as a **medicinal product**

Combined ATM Products

...Regulation (EC) No. 1394/2007/EC Art. 2, para 1.d

Combined advanced therapy products:

ATMPs are those that:

- ✓ Contain as integral part **one or more MD or AIMD**
- ✓ Cells/tissues contained are **viable**; or
- ✓ Cells/tissues contained are **NON viable but their action can be considered primary**

Combined ATM Products

...Regulation (EC) No. 1394/2007/EC Art. 2, para 2

Where an ATMP contains **viable cells / tissues** the **pharmacological, immunological or metabolic action shall be considered as the principal product's mode of action**

Specific Provisions for MD combined in ATMP

- MD which forms part of an ATMP shall meet the essential requirements laid down in Annex I to 93/42/EEC
- AIMD which forms part of an ATMP shall meet the essential requirements laid down in Annex 1 to 90/385/EC

Specific Provisions for MD combined in ATMP

In addition to the requirements laid down in Art. 6(1) of Reg. (EC) No. 726/2004, **applications** for the authorization of an ATMP containing MDs, bio-materials, scaffolds or matrices **shall include:**

- a description of the **physical characteristics and performance** of the product, and
- a description of the **product design methods**, in accordance with Annex I to Directive 2001/83/EC.

Assessment Procedure

...Art. 9 of ATMP 1394/2007

- **Final evaluation** of the ATM Product by EMEA
- The application shall include evidences of MD conformity to **essential requirements** referred in Art. 6
- The application shall include (where applicable) results of MD/AIMD part **assessment by NB**
- EMEA **shall recognize** those results (may request for more information)
- If the application does not include NB assessment conclusions related to MD/AIMD, EMEA **shall seek an opinion** on device conformity to NB identified by a manufacturer, **unless** CAT for medical devices decides that involvement of NB is not required.

Actually not Regulated Products

- **Combined products including human but not cellular derivatives** (apart from blood/plasma derivatives)
- **Combined products containing non-viable human cells/tissues having an action that is not considered as “primary”**



Thank you for your attention

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