

**Position Paper on
Clinical Regulations applicable to Medical Devices
15 January 2007**

Background

Eucomed’s attention has been drawn to the extension of the scope of directives 2001/20/EC and 2005/28/EC on clinical investigations of medicinal products to medical devices during their transposition in some European Member States.

1. Different regulatory regimes

Community regulations governing medicinal products and medical devices do not follow the same regulatory regime.

Unlike Directive 65/65/EEC, the Medical Devices Directives 93/42/EC and 90/385/EEC follow the New Approach principles.

As a result, a set of harmonized standards offering presumption of conformity with the essential requirements of these Directives was produced and adopted.

EN/ ISO /14155 is the harmonized standard covering clinical Investigations for medical devices.

Eucomed welcomes some administrative aspects of Directives 2001/20 /EC and 2005/28/EC such as the simplification of applications to Ethics Committees.

However, application of a medicinal product directive to medical devices would, given the difference in the regulatory regimes, be in conflict with established Community directives and regulations for medical devices.

2. Different technologies

The heterogeneity of medical devices, which encompass products as different as thermometers and implantable pacemakers, renders the application of a medicinal product regulation to medical devices impractical and unnecessary.

3. Principal differences are described below

A. Differences in regulatory regimes

| Medical Technologies and Devices | Medicinal Products |
|---|---|
| <ul style="list-style-type: none"> ◆ recent regulations: part of the European ‘New Approach’ ◆ CE Marking ensures product | <ul style="list-style-type: none"> ◆ long established EU legislation ◆ regulations based on pre-market approval/licensing |

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| <p>conformity with Essential Requirements</p> <ul style="list-style-type: none"> ◆ assessment, controls and requirements increase in proportion to potential risk, the highest level requiring prior market design and clinical evaluation ◆ all pre-market clinical investigations are subject to prior notification to Member State Competent Authorities ◆ Notified Bodies are appointed by the Member States to certify the conformity assessment procedures | <ul style="list-style-type: none"> ◆ all pharmaceutical products are subject to prior market approval ◆ pharmaceutical products are registered centrally by EMEA (European Medicines Evaluation Agency) and/or the Member States ◆ Clinical Trials are centrally registered by EMEA: EUDRA-CT database. |
| <ul style="list-style-type: none"> ◆ a harmonized standard EN ISO 14155, offering presumption of conformity with the directives covers Clinical investigation of medical devices for human subjects ◆ differences between medical devices and medicinal products recognized by GHTF SG5 in the various draft documents. | <ul style="list-style-type: none"> ◆ Good Clinical Practice for medicinal products is detailed in ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) |

B. Differences in technologies

| Medical Technologies and Devices | Medicinal Products |
|---|---|
| <ul style="list-style-type: none"> ◆ traditionally based on mechanical, electrical and materials (physics) | <ul style="list-style-type: none"> ◆ traditionally based on pharmacology and chemistry |
| <ul style="list-style-type: none"> ◆ industry is made up of a few large companies and a big number of very small companies. The industry is very diverse. | <ul style="list-style-type: none"> ◆ Industry is primarily constituted of large corporations, mostly multinationals |
| <ul style="list-style-type: none"> ◆ products engineered to perform certain functions based on specific performance and safety requirements; the therapeutic effect can in many cases be patient triggered or automatically adapted to the patient's condition | <ul style="list-style-type: none"> ◆ product development by trial on active substances selected on the basis of safety and efficacy |
| <ul style="list-style-type: none"> ◆ effective by mechanical and/or electrical action; mainly pharmacologically inactive | <ul style="list-style-type: none"> ◆ pharmacologically active; effective when absorbed into the human body |
| <ul style="list-style-type: none"> ◆ continuous and rapid innovation based on new science, technology and available materials | <ul style="list-style-type: none"> ◆ continuous innovation and some improvements based on new science and technology; discovery of active substances with long term evaluation to determine effects and side-effects |
| <ul style="list-style-type: none"> ◆ short product life cycle for each device iteration due to continuous | <ul style="list-style-type: none"> ◆ extensive product life cycle with 'prescription-only' often moving to |

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| <p>incremental improvements; often user related/driven, opposed to a long implant life for some devices.</p> <ul style="list-style-type: none"> ◆ short amortization period ◆ more stringent patient specific traceability is imposed to track long-term effects of implants | <p>OTC (“over the counter”) allowing for a long amortization period</p> |
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4. Eucomed Position

Eucomed would like to remind Member States that the extension of the scope of directives 2001/20 /EC and 2005/28/EC on clinical investigations of medicinal products to medical devices by national transposition is

- In conflict with the Community law for medical devices
- Impractical due to the different nature of these products
- Unnecessary as the current regulatory regime adequately ensures the safety and performance of medical devices

Eucomed is working with the CEN technical committee and with ISO TC 194 and national standardization bodies for the revision of the harmonized standard for clinical investigations EN/ISO /14155, so that the standard recognizes differences between medical devices and medicinal products. National Competent Authorities are encouraged to participate via their local standardization body.

The same fundamental approach is being followed by GHTF SG5 to differentiate the requirements of devices from those for medicinal product as defined in ICH documents.

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