

## Market Authorization of Combined Advanced Therapy Medicinal Products

Combinations of Advanced Therapy Medicinal Products with medical devices represent a new type of combination products requiring a fundamentally new approach for market authorization.

### To whom is this news bulletin applicable?

Medical device manufacturers using gene therapeutics or viable cells and tissues for the production of Advanced Therapy Medicinal Products.

### Definition - Advanced Therapy Medicinal Products

This new product group covers

- gene therapeutics,
- somatic cell therapeutics and
- tissue engineering products.

Gene and somatic cell therapeutics are defined by the Directive 2002/83/EC, Annex I part IV. Tissue engineering products have been described recently in the new Regulation on Advanced Therapy Medicinal Products that has been positively voted for by the European Parliament and Council in 2007.

By definition, tissue engineering products

- consist of viable cells or tissues that have been substantially manipulated,
- may include scaffolds and/or biologically active molecules and
- are used for the regeneration, repair or replacement of human tissue.

Excluded from this definition are products containing or consisting exclusively of non-viable

human or animal cells and/or tissues. This type of product may not contain any viable cells or tissues and does not act principally by pharmacological, immunological or metabolic action.

### Assessment and authorization procedure

As far as assessment and authorization of this new group of combination products is concerned, the European Parliament has adopted a completely new approach in the regulation. Basically, responsibility for approving the new type of combination products rests with EMEA, which will, however, commission a Notified Body to assess the medical device, taking essential requirements into account. The essential requirements are set forth in the revised Medical Devices Directives 93/42/EEC and 90/385/EEC.

- EMEA will apply this new consultation approach to all combination products which include a medical device not yet assessed by a Notified Body.
- Option 1: In this case, the agency will join with the manufacturer to decide on a Notified Body to carry out the assessment.
- Option 2: Another variant to the above approach is that the manufacturer has the medical device assessed by a Notified Body before submitting the authorization application to EMEA which must recognize the assessment result in its authorization decision.

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#### **What is required from manufacturers?**

1. Option: TÜV SÜD Product Service GmbH as Notified Body will establish an evaluation report that is to be submitted to the Competent Authority. The report is based on the assessment of a design dossier/technical file (see Med-Info Design Dossiers for detailed information). The report will focus on the assessment of the conformity of the device with the essential requirements detailed in the revised Medical Devices Directive 93/42/EEC and in the Directive for Active Implantable Medical Devices 90/385/EEC.
2. Option: Assessment prior to EMEA submission. Basically we will follow the same procedure which was set up for design dossier reviews for medical devices according to Annex II.4 of the Directive. The documentation shall address all relevant points as detailed in Med-Info Design Dossiers.

#### **What are the services provided by us?**

Our company brings together the scientific resources of over 200 experts for all types of active and non-active medical devices and in vitro diagnostics. Our experts contribute to national and international activities regarding standardization as well as harmonization of guidelines and legislation.

The successful application for market authorization depends on well-planned strategic decisions and meticulous and careful preparation of the documentation to be submitted. You may use the services of our experts for information prior to submission of the required documentation.

In addition we can provide scientific advice to companies for the development of new combination products.

#### **Links to informative websites:**

<http://www.emea.eu.int/>  
<http://www.pheur.org/>  
<http://www.pei.de/>  
<http://www.ich.org/>

**If there are any open questions, please feel free to contact us.**

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