

WORKING GROUP ON NEW AND EMERGING TECHNOLOGIES IN MEDICAL DEVICES (N&ET WORKING GROUP)

WORK PROGRAMME

Introduction

At the first meeting on 15 November 2005, the Working Group agreed to deal with new and emerging technologies according to the following 5 stage approach:

- a. Identification
- b. Definition
- c. State-of-the-art
- d. Assessment of existing regulations
- e. Recommendations for deficiencies

Working Programme

The Working Group has decided to work on two items:

1. Nanotechnology
2. Other New and Emerging Technologies

Output of the Working Group

1. Nanotechnology
Determination of adequacy of existing regulatory structure for medical devices made from, or incorporating, nanotechnology. Make recommendations to address any shortcomings identified.
2. Other New and Emerging Technologies
To compile a list of new and/or emerging technologies relevant for the field of medical devices.

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ADDENDUM TO WORKING PROGRAMME

Progress and anticipated actions after the meeting of 23 October 2006

1. Nanotechnology

a. Identification

The Working Group has identified nanotechnology as the first work item

b. Definition

As a definition for nanotechnology, the definition from the 2004 report of the UK Royal Society & Royal Academy of Engineering will be used. This definition was also adopted by the SCENIHR opinion and the reports from the Dutch RIVM.

c. State-of-the art

This item has been prepared by a small group of volunteers, who selected relevant examples of nanotechnology products, covering the broad range of possible applications. The basis for this selection was the RIVM report on the state-of-the-art of nanotechnology in medical applications and contributions from group members.

Important criteria for the inclusion of examples included the coverage of: different particle sizes, production of nanostructures bottom-up or top-down, MDD/IVD/AIMDD products, borderline products, and other criteria to be drawn up by the small group.

In the meeting of 29 March 2006 the Working Group analysed these 21 examples and drafted two shortlists of generic regulatory risk assessment issues: one for MD's/AIMD's and one for IVD's .

d. Assessment of existing regulations

Two group members/authors, assisted by some group members/commentators have drafted two separate documents. In these documents the question was answered whether the MDD/AIMDD, respectively the IVDD cover the generic risk assessment issues, and draft proposals to address deficiencies were made.

In the meeting of 23 October 2006 the Working Group concluded that in general the MDD/AIMDD and the IVDD are suitable to deal with (in vitro diagnostic) medical devices manufactured utilizing nanotechnology.

A point of discussion for the **IVDD** was whether diagnostics used on specimens that are potentially reintroduced into the body are within the scope of the IVDD.

This comes down to the interpretation of 'specimens derived from the human body' in art. 1.2b of the IVDD. This question was referred to the Commission for further consideration.

In the meeting of beginning 2007, discussions on the IVDD-document will be continued. Also the question, whether the generic risk assessment issue 'disposal into the environment' is covered, either by the MDD/AIMDD/IVDD or by other Community legislation, will be addressed.

e. Recommendations for deficiencies in MDD/AIMDD:

- i. New classification rule in the MDD: All devices incorporating or consisting of particles, components or devices of nanosize are in Class III unless they are encapsulated or bound in such a manner that they cannot be released to the patient's organs, tissues, cells or molecules.

The concept of "nanosize" needs some further consideration.

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- ii. To develop regulatory guidance, e.g. a MEDDEV document on specific risk analysis, risk management, possible regulatory pathways and clinical investigations.
- iii. To consider mandates for standardization
In the meeting of beginning 2007, the MDD/AIMDD-document will be further discussed and finalized.

2. Other New and Emerging Technologies

a. Identification

Application of terahertz radiation, telemedicine, micro-arrays and RFID were mentioned as new and emerging technologies for which the relevance in the medical device field should be considered. This is only a tentative list, on which the Working Group has not further elaborated.