

## Consultation of medical devices combined with human blood derivatives

### To whom is this news bulletin applicable?

Medical device manufacturers using human blood derivatives as specified in Annex I MDD, section 7.4 – only where the substance is liable to act upon the body with action ancillary to that of the device.

### What is required from manufacturers?

The documentation should be provided in CTD format. A guideline to the contents is to be found in MEDDEV 2.1.3 part B:

#### General information

- Description of the device (components, intended use)
- Justification for the use of blood derivatives (intended purpose, suitability of the substance, critical evaluation of alternatives)
- Critical evaluation of the results of the risk analysis (potential risk in relation to the expected benefit)

#### Qualitative and quantitative particulars of the constituents

- Description of the substance
- The amount included in the device
- If modifications were introduced, adequate description required

#### Description of method of manufacture

- Overall description of the device manufacturing process
- Process description for the substance is required

#### Controls of starting materials

- Specification of the blood derivate
- EU Pharm to be referenced (if applicable)
- National references (if applicable)
- Drug Master File(s)

#### Control tests carried out at intermediate stages of the manufacturing process of the medical device

- In-process controls (if applicable)

#### Control tests on finished products

- Qualitative test(s)
- Quantitative test(s)

#### Stability

- Desired function to be maintained during shelf life
- (Recommended storage conditions?)

#### Toxicity

- Toxicological profile of the substance
- New substance: results of toxicity tests (ISO 10993)

#### Reproductive function

- Toxicological profile of the substance
- New substance: results of toxicity tests (ISO 10993)

#### Embryo/fetal and perinatal toxicity

- Toxicological profile of the substance
- New substance: results of toxicity tests (ISO 10993)

#### Mutagenic potential

- Toxicological profile of the substance
- New substance: results of toxicity tests (ISO 10993)

#### Carcinogenic potential

- Toxicological profile of the substance
- New substance: results of toxicity tests (ISO 10993)
- To be considered: genotoxicity, chemistry, duration of exposure

#### Pharmacodynamics

- Intended action of the substance with regard to the medical device

#### Pharmacokinetics

- Description of the pattern of local and systemic exposure to the medicinal substance
- Maximum level and duration of exposure should be considered
- Potential level of exposure a safety concern?
- New substance: release characteristics, subsequent distribution, and elimination

#### Local tolerance

- Relevant results from ISO 10993 to be provided
- Where appropriate: relevant literature

#### Clinical documentation

- Clinical evaluation of the medical device is required. Relevant documents: see MEDDEV 2.7.1

#### Labeling

- Acc. MDD

#### What is assessed by the Notified Body?

TÜV SÜD Product Service as a Notified Body will establish an evaluation report that is to be submitted to the Competent Authority.

This report includes an assessment of the risk management, the risk to benefit analysis with regard to the intended use of the product, an evaluation of the sterilization process, inactivation of viruses and other new infectious agents, and the biocompatibility.

After consultation a final report will be compiled taking into account the comments of the competent authority and the results of the assessments performed by the product specialists for sterilization, biological safety, and other important product characteristics.

#### 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 or you are seeking scientific advice, please feel free to contact us.

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This Med-Info can be ordered at: [www.tuev-sued.com/mhs](http://www.tuev-sued.com/mhs)