Inspectie voor de Gezondheidszorg
Ministerie van Volksgezondheid,
Welzijn en Sport

C: Mandatory notification of clinical investigations with medical devices

The manufacturer is responsible for ensuring that a clinical investigation with a medical device is notified to the Inspectorate in accordance with Article 13.1 of the Medical Devices Decree (BMH).

- ✓ *If the clinical investigation involves use of medical devices with CE marking, and the investigation concerns the same application of the medical device as indicated in the relevant conformance evaluation procedure, the clinical investigation does not need to be notified to the competent authority (the Inspectorate).*

Notification of a clinical investigation involving the use of a medical device must be made using the statement referred to in Annex VIII to Directive 93/42/EEC. Various documents must be added to the statement. The Inspectorate additionally requires some documents necessary in accordance with Dutch legislation. Below there is an overview of the documents that must be submitted to the Inspectorate.

1) Registration form

To speed up the processing of your registration and to ensure its correct entry in the European Eudamed database, the Inspectorate requests you to fill in the registration form and to attach it to your notification. You should send your notification digitally to the Inspectorate's information desk at meldpunt@igz.nl.

The form is subject to change in the event of revision of Annex 7 to MEDDEV 2.7/2. If the investigation already has a Eudamed number issued by another Member State, you should state the previously issued Eudamed number on the form to enable the Inspectorate to correlate the registrations.

2) Data allowing identification of the device in question.

This information may have been included in the investigator brochure; refer to item 4. Refer to that information where applicable.

3) The Clinical Investigation Plan (CIP).

The CIP must cover all aspects of the proposed investigation, including but not confined to inclusion and exclusion criteria, objectives, participating centres, intended number of included patients, and so on. For more information, refer to the **ISO 14155** standard.

4) The investigator's brochure (IB).

This may also be the Investigational Medical Device Dossier (IMDD). The document must include all technical specifications of the product, risk assessment, and the results of any preclinical research (the list is not exhaustive). For more information, refer to the **ISO 14155** standard.

5) Proof of liability insurance by the manufacturer

- ✓ *Note that the manufacturer's obligation to take out liability insurance, as mandatory*

*under Section 13 (3b) of the Medical Devices Act (WMH), is **not** the same as the*

mandatory insurance for investigation subjects under the Medical Research (Human Subjects) Act (WMO). The Medical Devices Act (WMH) makes it obligatory for the manufacturer to take out – prior to the commencement of the clinical investigation – insurance that covers its liability for damage caused by the investigation involving the use of the medical device. Proof of this insurance needs to be provided with the notification.

6) Documents used to obtain informed consent.

These are the Dutch "Patient Information Form" (PIF) and the Dutch "Informed Consent Form" (ICF) that can be found at http://www.ccmo-online.nl.

- ✓ *These documents must reasonably and neutrally describe the risks to which a patient will be exposed when participating in the clinical investigation. An exhaustive list of potential risks that will occur seldom if ever is not necessary. However, the most relevant, realistic and/or serious risks must be disclosed. These risks must not be presented in a context capable of giving a patient the idea that the risks are negligible. Attention must further be drawn to the circumstance that as yet there is only limited clinical experience with the medical device or the intended application, and that consequently there may be (serious) unforeseeable side-effects. Patients must be properly informed of any alternatives.*

7) Statement indicating whether or not the device incorporates – as an integral part – a substance or a human blood derivative referred to in Section 7.4 of Annex I (93/42/EEC) or in item 10 of Annex I (90/385/EEC).

8) Statement indicating whether or not the device is manufactured utilizing tissues of animal origin as referred to in Directive 2003/32/EC.

9) Positive opinion of the Ethics Committee concerned and details of the aspects covered by its opinion.

- ✓ *In the case of research covered by the Medical Research (Human Subjects) Act (WMO), a positive opinion from a competent Ethics Committee in conformity with that Act will suffice. In the case of clinical investigation involving the use of medical devices not covered by the Medical Research (Human Subjects) Act (WMO), this request remains fully in force and the law still requires, under Article 13 (3a) of the Medical Devices Act (BMH), a positive advice from a competent Ethics Committee.*

10) If applicable under the procedures of participating centres: the approval of the Executive Board / Board of Directors of each participating centre.

With this, the Inspectorate adheres to the provisions made in the CCMO Directive (2012).

11) Name of the medical practitioner or other authorized person and of the institution responsible for the investigations.

A reference to the CIP or the registration form will suffice if the information contained therein is complete.

12) Place, starting date and scheduled duration for the investigation

A reference to the appropriate section in the CIP will suffice if the information contained therein is complete.

13) Statement that the device in question conforms to the essential requirements apart from the aspects covered by the investigations and that, with regard to

these aspects, every precaution has been taken to protect the health and safety of the patient

This Statement of Conformity usually contains all elements mentioned above and is signed by a duly authorized person on behalf of the manufacturer.

This page belongs to the subject "Clinical Investigations with medical devices" on www.igj.nl.