MEDICAL DEVICES AGENCY
COMPETENT AUTHORITY (UK)

EC MEDICAL DEVICES DIRECTIVES

2 GUIDANCE NOTES FOR COMPLETION OF PCA 1 AND PCA 2

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DOCUMENTATION

PCA1 has been designed as a computer input form. PCA2 has been designed as a reference index. These forms help the UK Competent Authority record and assess the clinical investigation notification. For the completion of PCA1, the information should be entered directly into the boxes provided. Form PCA2 should be completed by entering in the relevant boxes the page numbers of the information provided with the notification.

Notification of the proposed clinical investigation is made by completing both forms PCA1 and PCA2 and sending the information together with the forms and fee to the address at the end of this document. For definitions of "low" and "high risk" see Guidance Document 1, Guidance Notes for Manufacturers on Clinical Investigations to be carried out in the UK; for scale of fees see enclosed leaflet.

HOW MUCH INFORMATION IS REQUIRED

PCA2 provides a check list of information that is required in order that the Competent Authority may make an informed judgement of the risk to public health when weighted against potential benefits of the device in order to assess the notification. The information requested includes some of the additional information that manufacturers are required to provide on request to the Competent Authority (see Active Implantable Medical Devices Regulations Schedule 4 paragraph 2 (2) and the Medical Devices Regulation 16(1)(A) which incorporates Annex VIII paragraphs 2.2 of the Medical Devices Directive); these items are marked with an *. By providing all relevant information with the notification, taking account of the risks associated with the design, manufacture and use of the device, the UK Competent Authority will be able to assess a notification within a shorter time. Guidance Document 1 provides further information.

PRESENTATION

All data submitted in support of a notification should be bound in an A4 folder if possible, with the pages numbered in sequence. This includes reprints, diagrams, tables and other data. A total of eight copies of each full submission are required.

Applications must ensure that the method of reproduction used allows for legible presentation of the text, including any relevant drawings with their captions.

All information must be in English. If any part of the supporting data is based on material in another language this must be translated. One copy of the original document in its original language should accompany the application.

DOCUMENTS TO BE KEPT AVAILABLE FOR THE UK COMPETENT AUTHORITY

In addition to the information listed in forms PCA1 and PCA2, other documents are required to be kept available for the UK Competent Authority, which may be requested if required (see Active Implantable Medical Devices Regulations Schedule 4 Section 3 (b) and the Medical Devices Regulations 16(1) (b) which incorporates Annex VIII, paragraph 3.2 of the Medical Devices Directive).

SPECIAL INSTRUCTIONS

HAZARDS (RISK ASSESSMENT)

In order to comply with the Essential Requirements, the risks associated with the design, manufacture and use of the device, must be identified and addressed. This may helpfully be provided in tabular form.

MEDICINAL SUBSTANCES

In the case of a drug-device combination details of a medicinal substance are required. In these circumstances the following information should be included:

- *identification of the medicinal substance(s);*
- *description of intended purpose(s);*
- *information on previous experience with the substance(s) in any country;*
- *a statement as to whether the medicinal substance(s) as sourced is contained in any medicinal product having a product license(s) and if so, the identification of such products.*

If a device is intended by the manufacturer to deliver a medicinal product, the following information should be included:

- *identification of medicinal product(s);*
- *description of intended purpose(s);*
- *a statement as to whether the medicinal product(s) has a product license(s).*

MATERIALS

For medical devices that utilise non-viable tissues or derivatives from animal origin the manufacturer should provide general details of the sourcing controls and identify the main processing steps intended to inactivate (or remove) viruses and transmissible agents.

STERILISATION

Applications by manufacturers for medical devices that are supplied sterile should contain a summary of the bioburden and environmental practices used during manufacture and an overview of the sterilisation process. The information should include:

- *the specification of the manufacturing environment;*
- *the monitoring programme of the manufacturing environment;*
- *the method(s) of sterilisation and the process parameters;*
- *a summary of the monitoring system of the sterilisation process;*
- *some packaging details;*
- *the sterilisation site (if different to manufacturing site), and*
- *an overview of the sterilisation validation data.*

Where the medical device is to be sterilised by the user, the manufacturer should include the user instructions and a summary of the validation studies performed to verify those instructions.

BIOCOMPATABILITY

For materials coming into contact with the patient it should be apparent from the risk assessment how hazards were identified and characterised, and how the risks arising from the identified hazards were estimated and justified in relation to anticipated benefits. Particular attention should be paid to biological safety issues, especially for devices containing new materials that will come into contact with patients or where established materials are used in a situation involving a greater degree of patient contact. For example, where particularly hazardous materials, such as ethylene oxide, may be present in the final device, the risk assessment should indicate why solutions avoiding the hazard have not been adopted. A description of how the biological safety of the device has been evaluated should be included. This should include the identity of the person(s) responsible for the risk assessment, a summary of the data examined and the basis for the judgment that the materials are suitable for the proposed use.

Guidance on the information appropriate for a biological safety assessment is given in Guidance Document 5 "Guidance on Biocompatibilty Assessment", available from the UK Competent Authority on request.

FURTHER INFORMATION

For further information on completion of proposed clinical investigation notifications, contact:

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