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Sledljivost medicinskih pripomoļkov

Medical device traceability

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CEN REPORT

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Medical device traceability

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

The EU Commission has requested consideration should be given to the preparation of a standard (or other procedural documents) for the purpose of identifying wherever possible, the route to be followed by medical devices when they have been placed on the market so that, in particular for safety related issues, rapid identification of the patient who is treated with a particular device may be obtained.

Within the CEN Healthcare Forum Forum Task Group *Traceability* it has been recognized that traceability to the patient is not a possibility for all devices. Moreover, as a large part of the links to the patient take place outside the control of the manufacturer this was considered not to be a suitable subject for the development of a harmonized standard under the Medical Device Directive 93/42/EEC. However it was judged to be a suitable subject for a CEN report.

Introduction

With many devices, a malfunction may result in death or rapid deterioration of health of the patient. It is important to allow rapid links to such devices. However, it is necessary to assess the need for and extent of traceability for all types of devices.

1. Scope

This technical report provides recommendations for procedures that should be followed to establish, as far as possible, a traceability route for medical devices which have been placed on the market.
It is understood that the procedures to be described in this report will be more detailed in relation to high-risk devices when the need has been identified to trace devices as far as the actual patient.

For lower risk devices this report provides recommendations for elements of procedures to be transmitted by manufacturers to the members of a distribution chain, to achieve an appropriate level of traceability, perhaps of batches of products in some cases, sufficient to withdraw or inform purchasers or users of information regarding such identified products.

2. Definition

For the purpose of this technical report, the following definitions apply:

Traceability:
The procedure by which it may be possible to establish the distribution route of one or more identified medical devices from the time it/they leave(s) the manufacturer's premises, via intermediary bodies, up to the end user or the patient if possible.

High-risk devices:
For the purposes of this report, a high-risk device is one for which insufficient traceability or inability to identify quickly any patient treated there with could result in severe harm to one or more patients.

This may include implantable devices, life supporting or life sustaining devices, devices intended to administer or exchange energy in a potentially hazardous way, devices intended to administer or remove medicines, body liquids or other substances to or from the body in a manner that is potentially hazardous.

3. The Distribution Chain

For all medical devices there is a chain, which commences with the manufacturer and ends with the patient. Between the manufacturer and the patient there may be a number of intermediate links. These may include any of the following links:

From (A) Manufacturer/Authorised representative
To (B) Single or multiple distributors
To (C) Dealer or sub-agents or patient associations
To (D) regional hospitals - bulk purchasing departments
To (E) Individual hospitals/clinics/nursing homes/hospital pharmacies
To (F) Medical professional/health care professional
To (G) Patient

No single party controls, or can be expected to control, all links in this chain. Effective traceability requires the diligence and co-operation of all parties involved. These are only examples, and any combination or sequence of the above may be appropriate between manufacturer and patient.

4 Traceability/review of the concept

The risk of loosing traceability should be analysed during a risk management process. The eventual extent of traceability might be established as follows:

4.1 Devices other than high-risk devices

When appropriate in view of the device concerned the aim is to ensure continuity between the links of the chain such that traceability of one or more medical devices will be effective up to level D or E or as far as level F where applicable.
Each of the existing links within the chain is responsible for establishing and maintaining the procedure, which will ensure correct recording, retention and transfer to the next level of the minimum data set of traceability (see 4.3)

4.2 High Risk Devices

The aim is to establish communication between the links of the chain such that the tracking of the medical device will be effective to the appropriate level in the chain, this could be to level E or F or when appropriate to level G, the patient.

Each of the existing links within the chain is responsible for establishing and maintaining the procedure, which will ensure correct recording, retention and transfer to the next level of the minimum data set of traceability (see 4.3).

4.3 Minimum data set for traceability

- Manufacturer/Authorised representative - Name and address,
- Product identification - Model name & number as appropriate,
- Product manufacturing lot or serial number,
- Quantity of products transferred to the next link in the chain,
- Name and address of the next link in the chain.
- Date of shipment

Any other pertinent information (e.g. date of use, patient identity and address) may also be recorded where found necessary.
It is not to be forgotten that any initiative taken in this regard must comply with the provision of the regulation on data privacy protection. This may have an impact on the procedure and the type of information to be handled.

Note:
In the case of some specific devices, the manufacturers may provide an identification document, or other means (patient identification card), which may help the recording process of the data set for traceability.

Bibliography

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices.

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

Guidelines on good distribution practice of medicinal products for human use, 94/C63/03.

ISO/FDIS 16054 Implants for surgery – Minimum data sets for surgical implants.

prEN ISO/DIS 14971 Medical devices – Application of risk management to medical devices.

EN 46001 Quality systems – Medical devices – Particular requirements for the application of ISO 9001.

EN 46002 Quality systems – medical devices – Particular requirements for the application of ISO 9002.

ISO 13485 Quality systems – Medical devices – Particular requirements for the application of ISO 9001.

ISO 13488 Quality systems – medical devices – Particular requirements for the application of ISO 9002.