Labelling for Medical Devices

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Labelling for Medical Devices

Definition of Labelling

Written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or, accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

Note: Some regional and national regulations refer to 'Labelling' as 'Information supplied by the manufacturer' (Source – ISO 13485)

- Definition of Labelling
- Importance of Labelling
- Purpose of Labelling
- General Principles
- Label Data
- Language
- National Variation

Labelling for Medical Devices

Importance of Labelling – Why did GHTF look at this?

Safety

Information to the patient or user is critical to safe use

Promote Trade

Different labelling requirements in different jurisdictions can be a barrier to trade

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Safety

Information to the patient or user is critical to safe use:

"Labelling serves to communicate safety and performance related information to users of medical devices and/or patients as well as to identify individual devices."

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Promote Trade

Different labelling requirements in different jurisdictions can be a barrier to trade:

"Consistent worldwide labelling requirements would offer significant benefits to the manufacturer, user and/or patient, and to Regulatory Authorities."

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Purpose of Labelling

Clearly inform the user of:

- identity of the device (which device is it?)
- its intended use/purpose
- how it should be used, maintained and stored
- any residual risks, warnings or contra-indications

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SAFETY

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Purpose of Labelling

Whilst also promoting:

- labelling commensurate with the technical knowledge, experience, education or training of intended users
- use of symbols
- the avoidance of prescriptive country-specific requirements for labelling text, content, or the format of labels or labelling that offer no user or patient benefit

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TRADE (and SAFETY)

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General Principles

So in GHTF we set out some principles:

- Where to put the labeling/Information
- Single IFU if appropriate
- Medium, format, content readability and location
- Labelling of Simple devices
- Note on media (paper vs electronic)
- Residual risks
- Eliminate country specific labeling
- Symbols

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Label Data

And then we set out the data that achieves the safety aim while promoting trade:

- Identity: Name, address, lot number, etc.
- How to use the device
- Warnings, precautions and contra-indications
- Sterility
- Implantable Risks
- Use in combination
- Disposal
- Etc.
- Etc.

Labelling for Medical Devices

Language

Labelling should be:

- Appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s)
- Readily understood by the intended user
- Where appropriate, supplemented with drawings and diagrams
- Where the meaning of the symbol is not obvious to the device user, e.g. for a lay-user or for a newly introduced symbol, an explanation should be provided
- Provided that safe and correct use of the device is ensured, a Regulatory Authority may authorise labelling to be in one or more language(s) other than its national language(s)

Labelling for Medical Devices

National Variation

2.1 Rationale

Consistent worldwide labelling requirements would offer significant benefits to the manufacturer, user and/or patient, and to Regulatory Authorities. Eliminating or reducing differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

2.2 Purpose

"...the avoidance of prescriptive country-specific requirements for labelling text, content, or the format of labels or labelling that offer no user or patient benefit.

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Thank You For Listening

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