MEDICAL DEVICE LABELLING

Medical device labelling includes all information provided by a manufacturer, such as symbols, instructions, and warnings, intended to ensure the device is used safely and effectively. This information can be on the device itself, its packaging, or in accompanying documents like leaflets or user manuals. Key requirements often include the manufacturer's details, intended use, warnings, and unique identifiers like the Unique Device Identification (UDI) system.

Key components of medical device labeling

- **Manufacturer's information:** Name and address of the manufacturer, packer, or distributor.
- **Device identification:** The name of the device, along with batch codes, lot numbers, or serial numbers.
- **Intended use:** What the device is for, including indications for use, intended user, and kind of patient it is intended for.
- **Warnings and precautions:** Any necessary warnings, restrictions, or precautions for safe and effective use.
- **Sterility:** If the device is sterile, the label must state "STERILE" and how it was sterilized.
- **Expiration and manufacturing date:** The expiration date is crucial if applicable. If not, the date of manufacture must be provided.
- **Special instructions:** Handling and storage requirements, instructions for single-use only, or indications for custom-made devices.
- **Unique identifiers:** Systems like the UDI assign a unique identifier to track and identify devices.
- **Symbols:** Standardized symbols, like those from EN ISO 15223-1, are used to convey information concisely.

Why labeling is important

- **Safety:** It provides critical information to ensure the device is used safely and correctly, minimizing the risk of harm.
- **Regulatory compliance:** Government bodies like the FDA and EU MDR have strict regulations that manufacturers must follow to get a device to market.
- **Identification:** It helps identify the device and its manufacturer, which is vital for tracking and recall purposes.
- **Harmonization:** Consistent worldwide labelling requirements offer benefits to manufacturers, users, and regulatory authorities.

Label vs. Labelling

The U.S. Food and Drug Administration (FDA) develops and administers regulations under authority granted by laws passed by Congress that apply to food, drugs, cosmetics, biologics,

radiation-emitting electronic products, and medical devices. Labelling regulations pertaining to medical devices are found in the following Parts of Title 21 of the Code of Federal Regulations (CFR).

- General Device Labelling - 21 CFR Part 801
    - Use of Symbols - 21 CFR Part 801.15
- In Vitro Diagnostic Products - 21 CFR Part 809
- Investigational Device Exemptions - 21 CFR Part 812
- Unique Device Identification - 21CFR Part 830
- Good Manufacturing Practices - 21 CFR Part 820
- General Electronic Products - 21 CFR Part 1010

The Federal Food, Drug and Cosmetic Act (FFDCA) is the law under which the FDA takes action against regulated products. Specifically:

Section 201(k) defines 'label' as a:

- 'display of written, printed, or graphic matter upon the immediate container of any article...'

The term 'immediate container' does not include package liners. Any word, statement, or other information appearing on the immediate container must also appear 'on the outside container or wrapper, if any there be, or the retail package of such article, or is easily legible through the outside container of wrapper.'

Section 201(m) defines 'labelling' as:

- 'all labels and other written, printed, or graphic matter

(1) upon any article or any of its containers or wrappers, or

(2) accompanying such article' at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.

The term 'accompanying' is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. 'Accompanying' also includes labelling that is brought together with the device after shipment or delivery for shipment in interstate commerce.

Advertising

According to an appellate court decision: "Most, if not all advertising, is labelling. The term 'labeling' is defined in the FFDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."