Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Digital Label

Leveraging technology to streamline access to information and reduce cost

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Global Medical Technology Alliance
Innovating for a Healthier World

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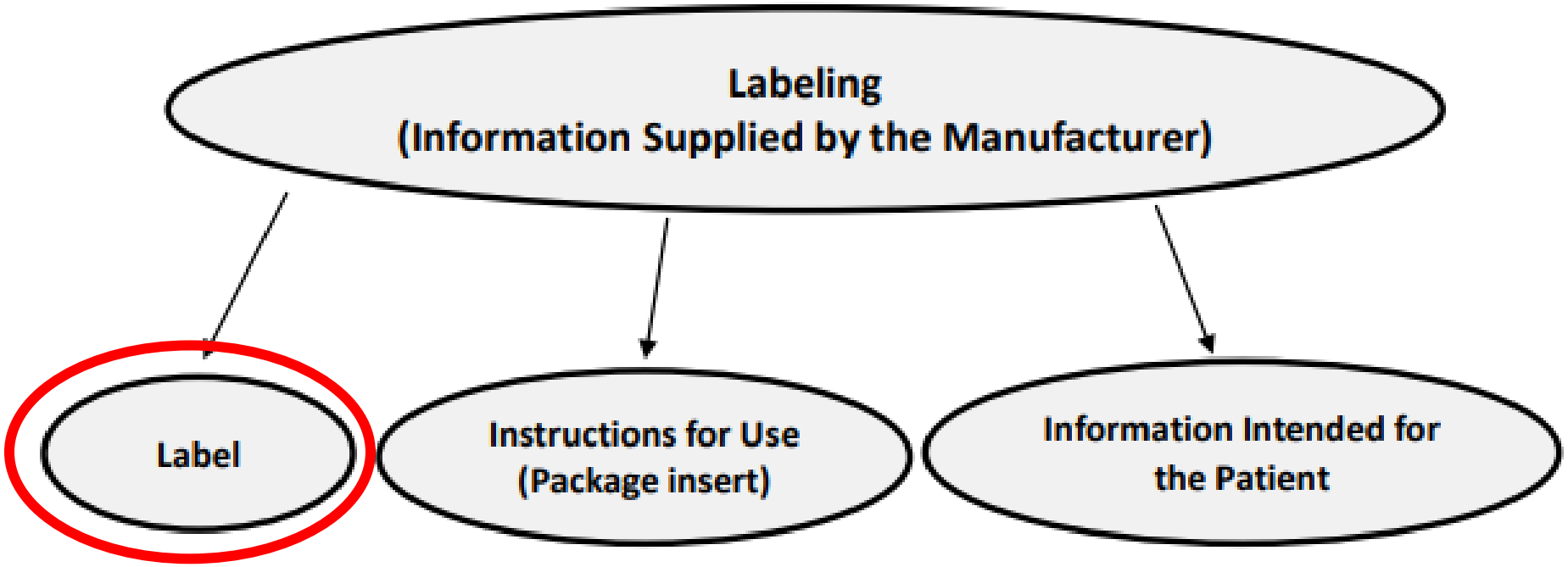
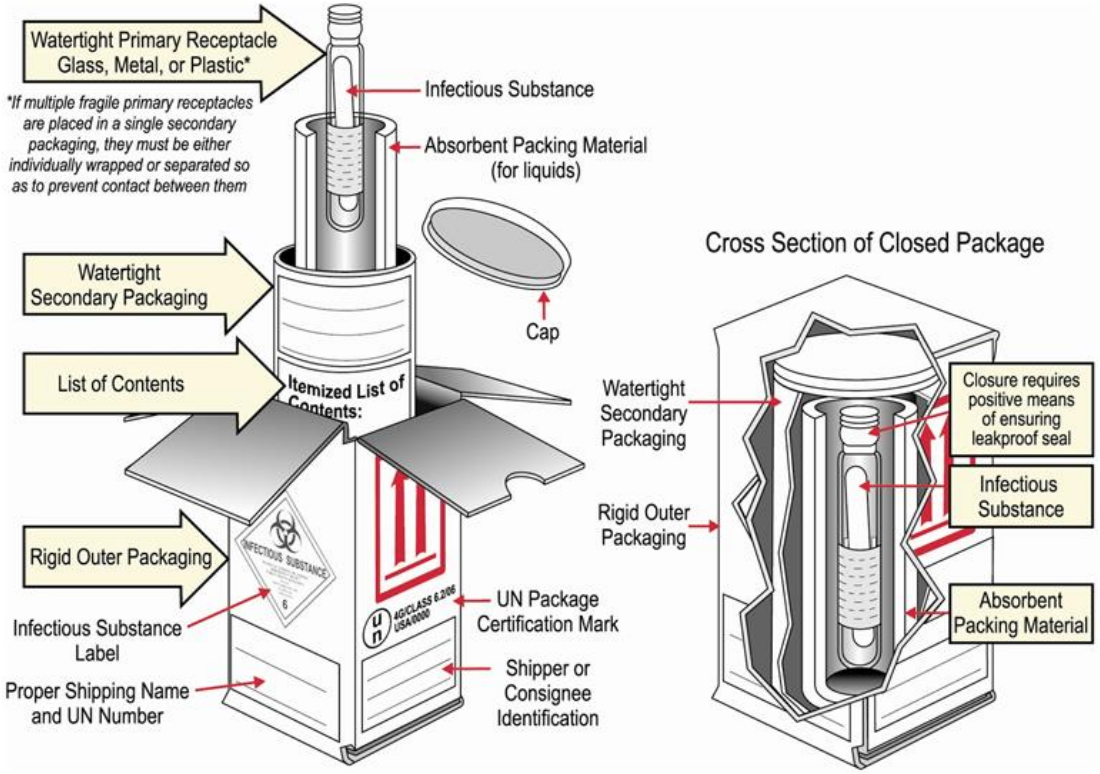
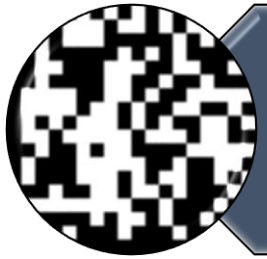
Focusing on:



What goes on the label? Key information:





Identify

Handle

Safety

Think about how the information is conveyed:

- Information must be clearly presented
- Uncluttered and easily accessible
- Ideally – language independent (symbols)

And yet, more regulations – more label requirements:

- Conformity marks
- Economic operators
- Local registration requirements…

Is this information needed on labels?

Conformity Marks

- Argument can be made that is relevant for consumers
- However, in all other cases information can just as effectively be provided in IFU or eIFU

Economic Operators

- Manufacturer should be on the label – essential part of identifying the device
- Other economic operators – are distracting on labels

Registration information

- Should never be on labels
- If absolutely needed other types of information provided by manufacturer should convey this (e.g. DoC)

Challenges of current labels:

Raising cost to serve

Proliferation of country specific label requirements

Lack of a harmonized approach on what is essential to be on the label

Difficulty to read specific information – small print and overcrowding of the label

Labelling changes can cause inefficiencies within the system and may impact product availability

What about a digital label? – What is it?

Digital **label**

Printed digital display on the product where additional prescribing, product information, country specific requirements for medical device can be displayed

Comes in the form of **barcodes, 2D data matrix, RFID, NFC, QR codes, blockchain, website link**

Examples of coded elements

UPC-A & E	I 2 of 5 (ITF)	Pharmacode	QR Code
EAN-8 & 13	Cod-a-bar	Data Matrix	Micro QR Code
EAN 128	Code 39	PDF-417	Human Readable
Code 128	GS1-RSS	Micro PDF-417	

Opportunities digital label offers:

Provides information to regulators and users in a format that is much clearer and avoids cluttered labels and packaging and information overload, as information can be better depicted electronically – **enhancing safety information**

Ensures rapid access to up-to-date information for health care professionals, hospitals, users, health authorities and other stakeholders

Can link the user to the latest electronic instructions for use (e-IFU) or an electronic implant card, if applicable

Can be used for **informing the authorities and users** on the registration status and on the economic operators **in their specific region** without the need for labelling the device packaging itself and confusion when multiple EOs are involved

Can accommodate a wider range of information to the user and inform the user on environmental sustainability for re-use, recycle and repurpose of e.g., packaging materials

Can improve supply management.

Digital labels reduce complexity of packaging line management and its associated activities which helps to reduce stock shortages, wastage, and improved access for patients

Can enhance sustainability goals. By eliminating paper labels, digital labelling improves environmental sustainability, reduces wastages and deforestation

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Benefits of a digital label:

Recommendations:

- Digitization of the regulatory system and acceptance of digital labels
- Consider limiting label requirements to elements that are essential for identification of the device and safety and allow for additional information to be accessed via a digital label
- Include stakeholders in the process

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Thank you!

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