Digital Label

Leveraging technology to streamline access to

information and reduce costs

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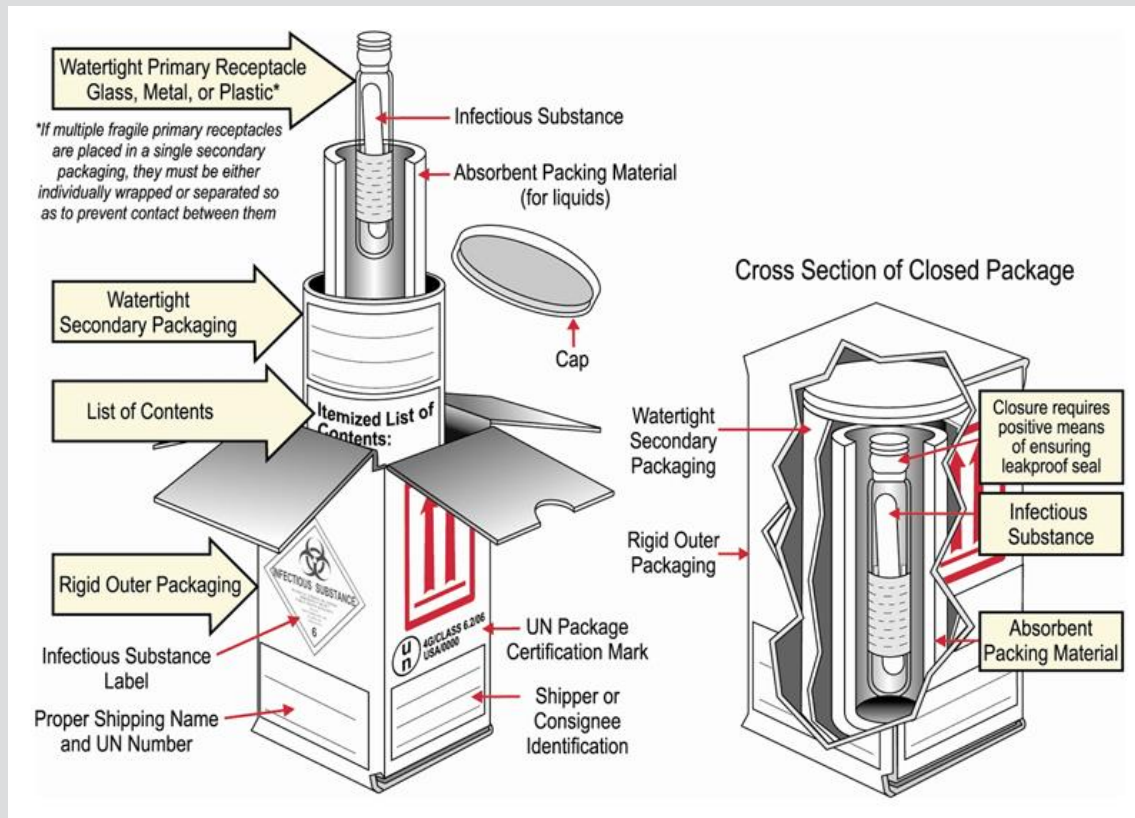**26 September 2023**

Focusing on:
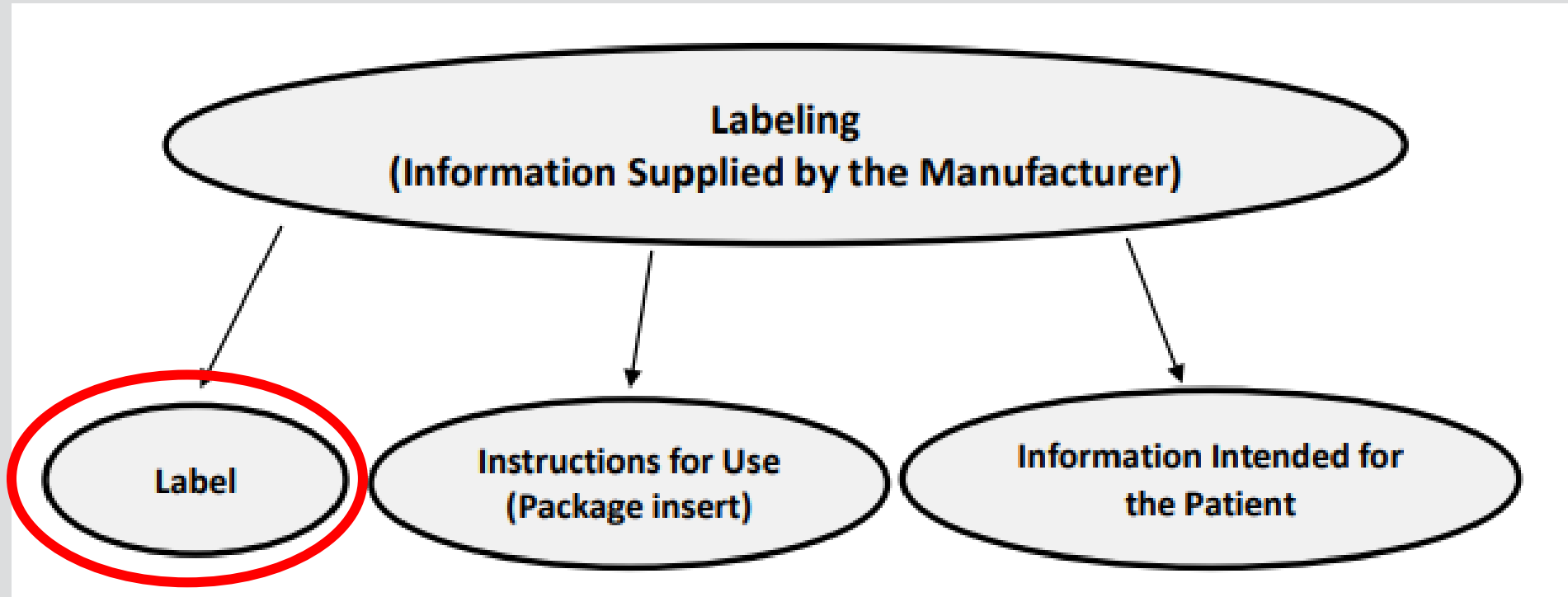
What is in a label? – Key information:

Identify

Handle

Safety

And yet - more regulations – more label requirements:

Conformity Marks

Economic operators

Local registration information…

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 is a digital label?

Digital **label**

Printed digital display on the product where additional prescribing, product information, country specific requirements for medical device can be displayed
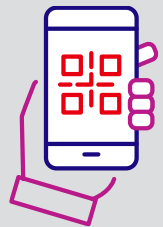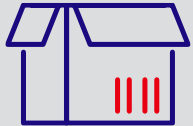
Comes in the form of **barcodes, 2D data matrix, RFID, NFC, QR codes, blockchain, website link**

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 PV000001
Code 128	GS1-RSS (01)04512345678906	Micro PDF-417	

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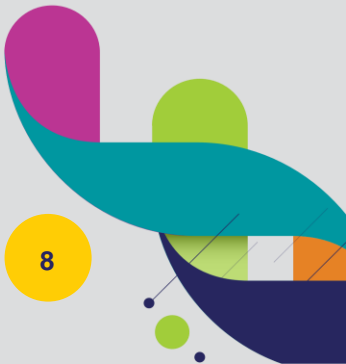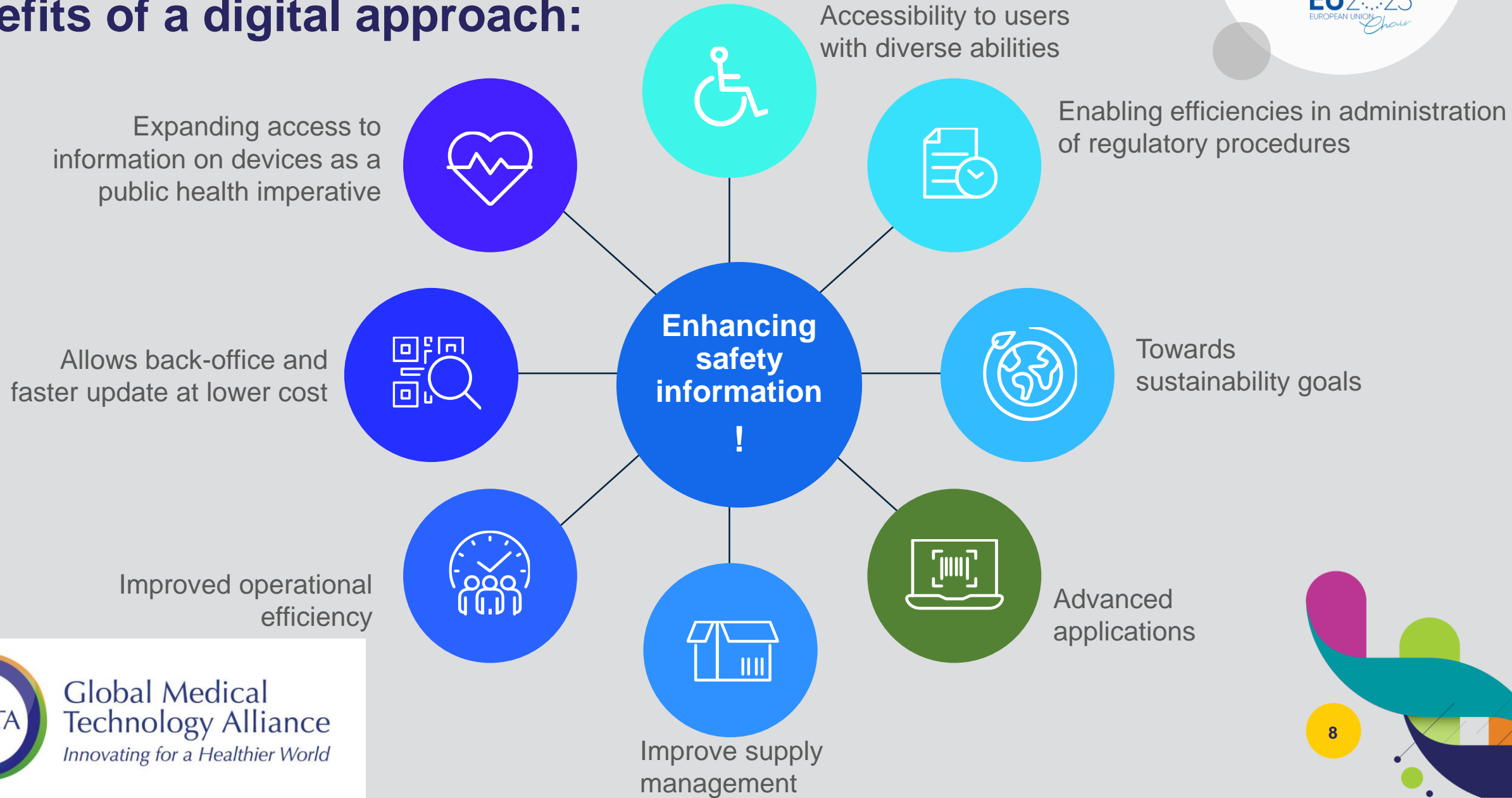
Can enhance sustainability goals. By eliminating paper labels, digital labelling improves environmental sustainability, reduces wastages and deforestation

Benefits of a digital approach:

Accessibility to users with diverse abilities

Enabling efficiencies in administration of regulatory procedures

Expanding access to information on devices as a public health imperative

Enhancing safety information !

Towards sustainability goals

Allows back-office and faster update at lower cost

Improved operational efficiency

Advanced applications

Improve supply management

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Recommendations:

- Digitization of the regulatory system and acceptance of digital labels

- Agree and align on what is the KEY information that needs to be on the label (device identification and safety perspective)

  - Limit label requirements to those 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 to enable additional information to be made available to users via a digital label

THANK YOU / QUESTIONS

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