Johnson & Johnson MEDTECH

Opportunities for Modernizing Regulatory Policy on Labeling

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Agenda

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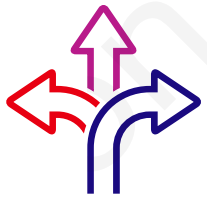
The Rising Cost to Serve

Inflation is rising and is higher than projected



The cost and operational implications of COVID have had **significant implications for industry**

It is **no longer sustainable** for suppliers to absorb such costs

Governments need to consider **the impact of rising inflation, increasing costs** and **labelling on the global supply chain**

Eliminating country-specific label requirements and direct part marking, and moving toward e-labeling should be seen by Governments as a **starting point for reducing such costs**

On the Current Labeling System

Prone to disruption

Processes for labelling products are complicated and require time for review and approval

Labels **can go out of date quickly** if information is updated

May not reflect the latest health authority approved label

Variable time lag between approval and actual appearance in the pack

Physical label **may not be** the latest **approved version**

No need to label devices with extra markings

Registration status of medical devices are available on health authority websites; meaning extra marking is not needed

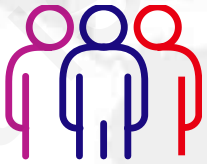
In a digital age, **extra markings are no longer needed**

On Country Specific Labelling

The impact of requiring **country specific marks,** license numbers, Economic Operators and environmental info on labels should be assessed

New labelling requirements create potential **logistical issues,** such as the need to manufacture **country specific inventory**

This would require updating both the **package labels** and the **instructions for use**

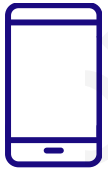


Country specific labelling not only **increases the cost of the device** before it comes to market, but also means that most of these costs are likely to be **passed on to the end user**

In turn making technology **more expensive in markets** that have a country specific requirement

The Cost of Direct Part Marking

Direct part marking on **medical technology** can have a huge impact on global supply chains and must be avoided



If Governments require direct part marking, there would be a huge cost associated with **keeping the devices**

The estimated cost of direct part marking for a single market to be around 20 % of total labelling cost, **tens of millions USD**

There is also the challenge with **physical space** on the device itself given a **global market**

Direct part marking would also require the engineering of **new machinery and manufacturing equipment** alongside additional verification and validation, **delaying access to the market even further**

This may create not only a **substantial economic burden** but also significant costs to customers and users

And may inadvertently cause smaller suppliers and contractors to **pull out of the market** or no longer supply to the market in question, further impacting on availability of innovative devices

What is E-labelling?

Stands for **electronic labelling**

Printed digital display on the product where additional prescribing or product information(1) for consumer products or Instructions for Use (IFU) for a drug or medical device can be displayed

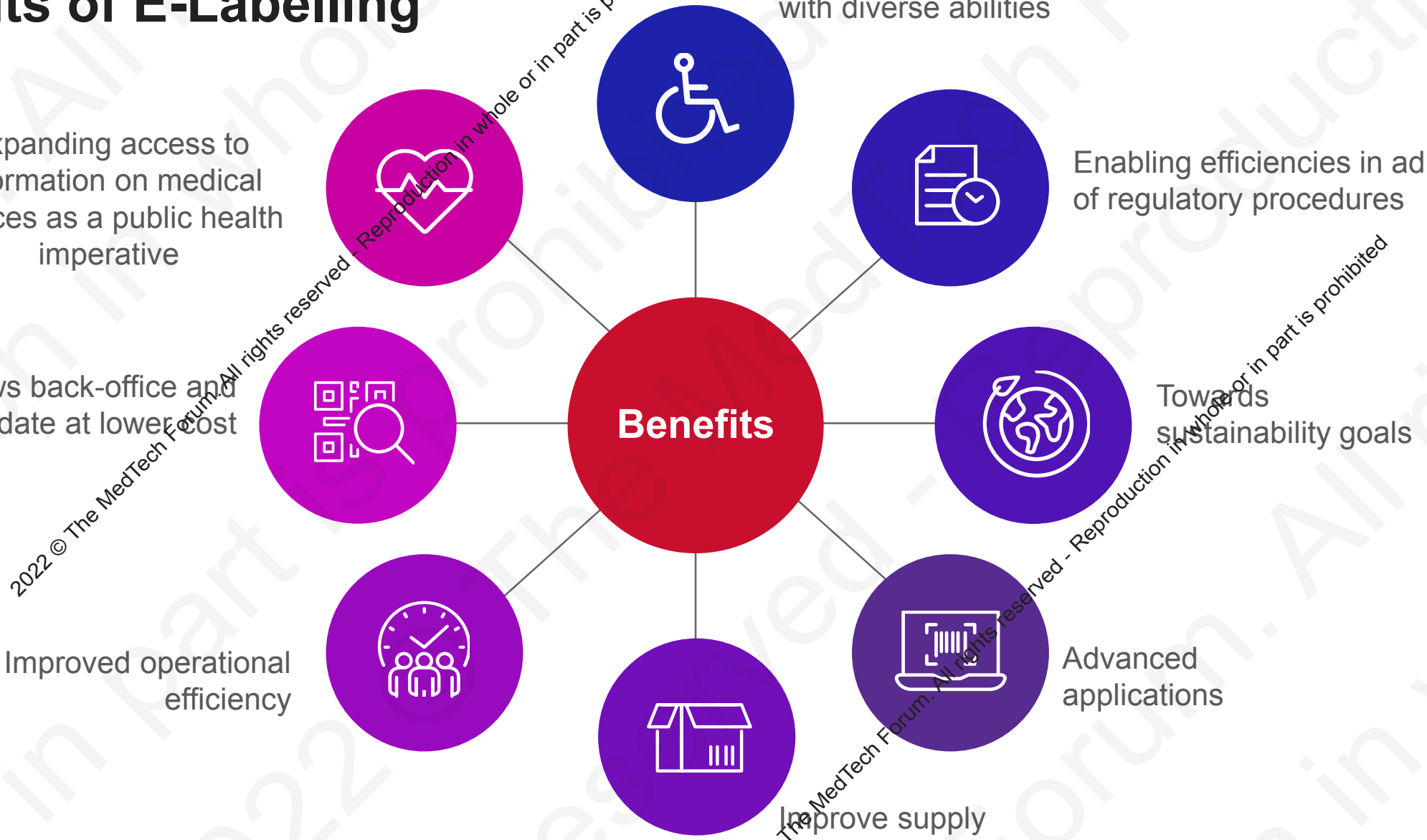
Comes in the form of **barcodes, 2D data matrix, RFID, NFC, QR codes, blockchain, website link**

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	

(1) The prescribing or product information (PI) of a medicine or medical device in most countries of the world includes the package leaflet for patients and the summary of product characteristics (SmPC) for healthcare professionals or Instructions for Use (IFU) for medical devices.

Benefits of E-Labelling



Call to Action

Digitisation of the regulatory system should be one of the Governments highest priorities in order

Regulatory approaches that **minimise unnecessary regulatory and economic burden** on all stakeholders involved should be developed and implemented to ensure timely access to **safe, effective**, and **innovative Medical Technology**

Healthcare systems are not immune to inflationary costs and Governments should attempt to **reduce the high cost** to serve by **digitising the regulatory system**

There is no need to apply a direct part mark to medical devices to ensure a **robust supply chain**

E-labelling is a viable option for labelling a medical device that is approved for use in the market without placing a mark on the package label

E-labelling **supports the sustainability agenda** by eliminating unnecessary paperwork and administrative burden

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Q&A

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