# ISO DTS 23261

# REQUIREMENTS FOR ACCESSING DIGITAL MEDICINAL PRODUCTS INFORMATION BY USING THE EXISTING DATA CARRIER

# Where do we come from?

- **Austria**
- **Estonia** - using QR code on outer carton and/or PIL in accordance to CMDh guidance document on QR/2D codes
- **Norway** – using EAN code
- **Norway** – using APP for Health care professionals linking to abbreviated SPCs
- **Spain** – using existing barcode with the i-phone/Android
- **Singapore** – under discussion – 6 months pilot – use of QR/2D Data Amtrix code or sticker referring to HCP to the approved in HSA website
- **Belgium –** using QR code
- **Germany** with EFPIA - either via webpage or on a smart device by scanning a unique code
- **Canada** by Company X – scanning 2D code with mobile device
- **Company Y** – using web publishing technology

# Scope /1

- The aim of this technical specification is to allow **authorised / validated / trustworthy digital content**
  to be returned when the *supply chain data carrier* on the physical medicinal product packages is scanned. It further globally standardises means and requirements for interoperable and trustworthy access to digital information which supports manufacturer implementation, solution provider projects and users in their practice.

# Scope /2

- The technical specification will deliver further guidance on **more flexible use of digital information** by scanning the *supply chain data carrier* on the medicinal product packages.
  This might include access to
  - different languages, information about recalls, counterfeits, etc.
- Similarly, when **user's profile is leveraged** in the access to appropriate digital information -for example if user's profile is practitioner, or patient- then guidance will be provided to meet privacy constraints.
- Digital information exchange might include **adverse event reporting**, based on medicinal product's identification from *supply chain data carrier* (product code and/or batch).

# Scope /3

- Medicinal product packages are identified and provide a *supply chain data carrier* at secondary and primary packaging levels. The technical specification provides requirements for accessing same digital information from *supply chain data carriers* from the different packaging levels and with leveraging production information when available. For example, if *supply chain data carrier* includes batch/lot, digital information might include batch recall information, or specifically to that particular batch patient instruction, product colour / shape, ingredients. This does not prevent user to access more accurate information (eg. updated patient information).


# Scope /4

- Importantly, **security** aspects are addressed in the technical specification, which include trustworthiness of digital information, its integrity and completeness.

# Note

- This Technical Specification will include references to IDMP standards and regulated processes regarding medicinal product information.

# Ballot results

- 18 approval
- 2 negative
- 9 absentions

Total of 33 comments casted:

- Editorial : 1+1
- General : 8
- Technical : 23

Nominated experts from 9 countries (India, Iran, Japan, Netherlands, Norway, Philippines, Switzerland, UK, USA)

# Status

| Chapter | Status |
| --- | --- |
| Forword | Standard text |
| Introduction | Done |
| Scope | Done |
| Normative Ref | Done |
| Terms & Definitions | Done (might be expanded) |
| Accessing authorised dig cont | - |
| Accessing validated dig cont | - |
| Accessing trustworthy dig cont | - |
| Interactive access to dig cont | - |
| Considerations about privacy | - |
| Persistence of dig cont | - |

# Next steps

- Should be ready for November detailled review

# Contact

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