GS1

The Global Language of Business

Implementation Reality Session
Point of Care Scanning

A Pharmaceutical Manufacturer's Perspective

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What Roche did so far?

GS1 DataMatrix with GTIN

🇩🇰 **AMGROS Requirement in Denmark** (except for blisters)

🇨🇭 Voluntary implementation for **all injectables in Switzerland**

🇪🇺 Voluntary implementation for **infusion solution vials for all EU countries** (centrally registered products)

Pictures for illustrative purposes only. Do not reflect the actual layout for the specific market.
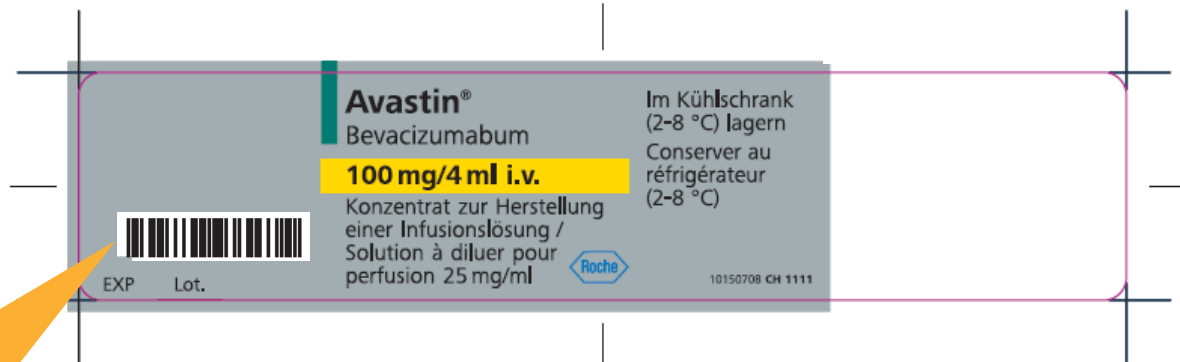
It's about collaborating and leveraging opportunities

- In 2010, Roche had to redesign its vial labels following technical issues. We took the opportunity to include a **GTIN encoded in a GS1 DataMatrix** where space allowed (65% of vials labels).

- In 2011, Roche collaborated with GS1 Switzerland to implement GTIN in GS1 DataMatrix on the labels of all its **injectables** for the Swiss market.

- 2012: Roche signed a **joint recommendation** with other Swiss pharmaceutical manufacturers and Swiss hospital associations to providing guidance for the implementation of single unit coding.

- Starting in 2012, Roche refurbished its packaging lines for the implementation of serialization. At the same time, an **online printing equipment for primary packaging** has been installed on 60% of the lines (90% for labels, 20% for blisters).
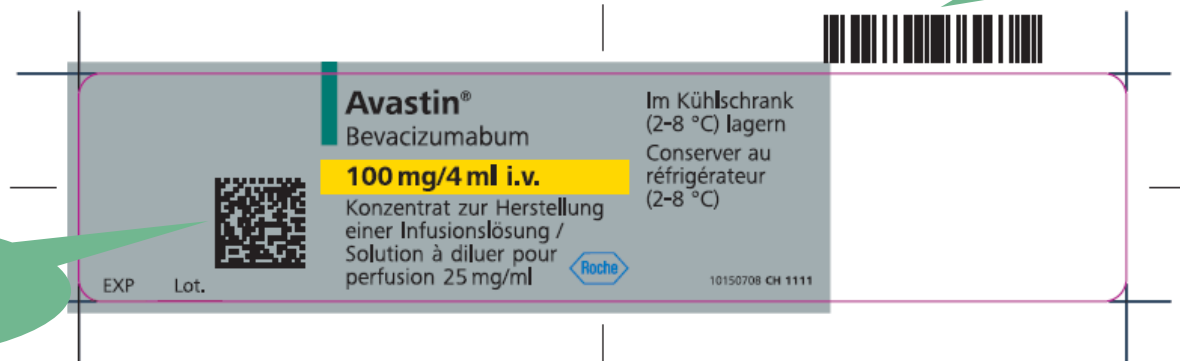
Vial Label Layout Adaptation

Before

Barcode for internal identification

Barcode for internal identification

After

GS1 DataMatrix with GTIN

Phased Deployment Approach at Roche, using GS1 DataMatrix

Labels (bottles, parenterals, syringes)

Blisters (single unit)

	Labels (bottles, parenterals, syringes)	Blisters (single unit)
1 element (static)	GTIN only	GTIN only (per cavity)
GS1 DataMatrix content 3 elements (variable)	GTIN + Expiry date + Batch number	GTIN + Expiry date + Batch number (per cavity)

Phased Deployment Approach at Roche, using GS1 DataMatrix

1a. GTIN only (static) on labels

- Easy to implement if label format and text font size allow
- **Implemented on 35% of Roche labels (65% for vials)**

1b. GTIN only on single unit blisters

- Does not require online printing equipment (part of artwork)
- Blister format and text font size to be checked
- Anti-reflection lidding foil material (readability for scanner)

2a. GTIN + Exp + Lot on labels

- Requires online printing equipment
- Label format and text font size to be checked
- **90% of Roche packaging lines equipped**

2b. GTIN + Exp + Lot on single unit blisters

- Requires online printing equipment
- Blister format and text font size to be checked
- Anti-reflection lidding foil material
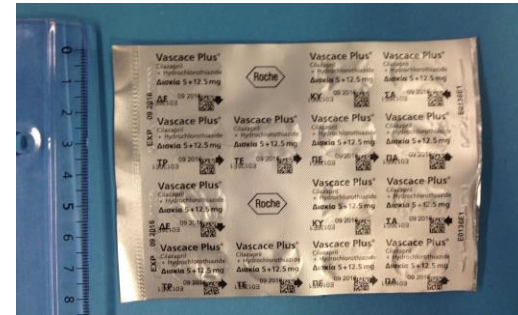- **20% of Roche packaging lines equipped**

Technical Constraints

- Very small containers

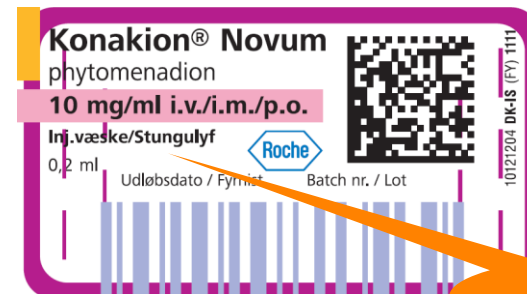
- Reflecting lidding foil of blister

- Amount of text and font size

Font size: 5 pt

- What is more important? Text or barcode…?

Font size: 3.25 pt

Technical Constraints, User Expectations

- Readability of barcode on syringes with safety device

- GTIN on bottle = 50 tablets, not 1 tablet!

- GTIN on multi-dose vials = full content, not single dose!

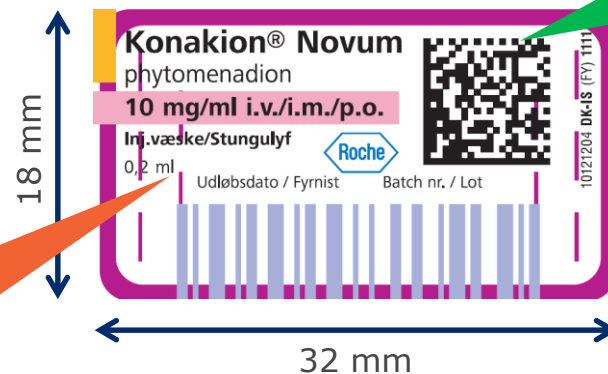- GTIN on non single-unit blister = 21 capsules, not 1 capsule!

Solving the Barcode vs. Text Dilemma

Example: Konakion ampoule label, 32x18 mm

I want to be able to read the barcode!

I want to be able to read the text!

Internal Challenges and Roadblocks to further Roll-Out

Solve Technical Issues

- Technical challenges requiring new label formats and enhanced lidding foil non-reflective material require **substantial investments** to be solved.

Implement Processes and Systems

- Line equipement alone is not sufficient to allow single unit coding. All **surrounding processes and systems** must be in place (IT, master data, label change management)

Prioritize Project Internally

- Single Unit Coding projects at manufacturers are **competing** with other regulatory-driven projects and might get de-prioritized in case they do not directly impact regulatory compliance.

Next steps & Take Home Messages

- Advocate for the use of **GS1 standards**

- Need to find a **common and strong position** on this topic between industry and hospital associations (like EAHP) to provide clear and harmonized recommendations (GS1 is the ideal platform!)

- Need to **engage with health authorities** to increase awareness on the importance of point of care scanning and help us solving the dilemma between barcode, text and font size on labels

- More and more leading hospitals worldwide introduce barcode requirements for **tender orders** → strong incentive for manufacturers, provided requirements are consistent and harmonized

- Regulators all over the world start to be receptive and to discuss **requirements for single unit coding** (Netherlands, Taiwan) → this will make the projects move forward at manufacturers

Thank you!