



Standards Implementation/ Regulatory Affairs

Roma IT
Jackie Rae Elkin and Tom Werthwine

The global language of business

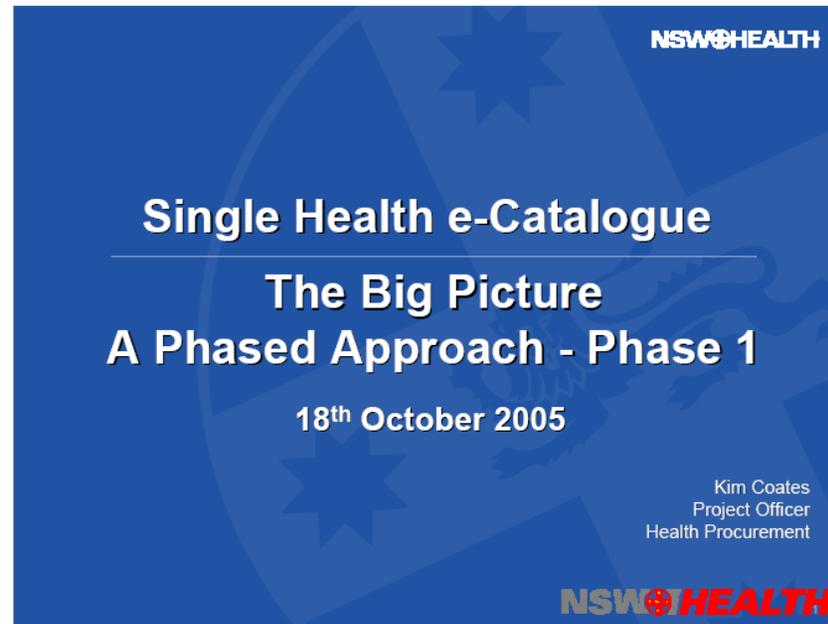
www.gs1.org

Why are we together ?



Regulations can be a hurdle to implementation...

Why are we together ?

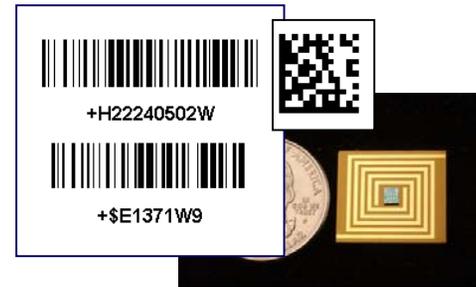


Regulations can accelerate implementation



Data

- Product identifier
- Lot no., Expiration date
- Unique identifier ("Serialization")
- Etc.



Carrier

- Bar Code
- RFID "Chip"
- Etc.
- Hardware to decode ("read")

Standard

- What data is included
- How data is organized
- How to decode data



What do we intend to do?

Assemble a team

Plan deliverables and milestones

Do the work

Measure progress

Produce results





Team Volunteers

Amgen
Cofares
GS1 France
GS1 Switzerland
GS1 UK
Boston Scientific
Hospira
Johnson & Johnson
Medtronic
Novartis
Premier





Standards Implementation/ Regulatory Affairs

Member Org

GS1 France

GS1 Switzerland

GS1 UK

Pharmaceutical

Amgen

Hospira

Johnson & Johnson

Novartis

Medical Devices

Boston Scientific

Hospira

Johnson & Johnson

Medtronic

GPO and Distribution

Cofares

Premier

Are we balanced ?



What do we intend to deliver ?

Let's look at the HUG mission and vision...



Our **mission** is to **lead** the healthcare industry to the effective utilization and development of global standards with the primary focus on automatic identification to improve patient safety.

Our **vision** is to become the single source for regulatory agencies and trade organizations (manufacturer, wholesaler, hospital and pharmacy) to seek input and **direction** for global standards in the healthcare industry.

How can we be effective ?

Let's look at the past....

In October 2001, HIDA declared EHCR is dead

(EHCR)

Efficient Healthcare Consumer Response

Is now replaced by

Electronic Healthcare Record

(EHCR)



So, we should change our focus from profit to patient

medication safety

Gary Hartley
Manager for
strategic initiatives
GS1 NZ

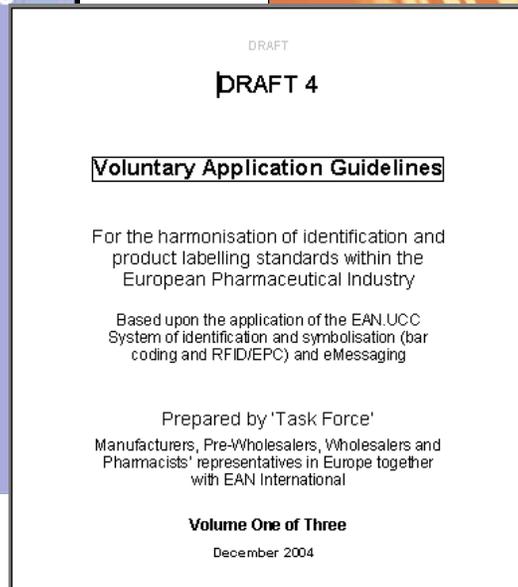
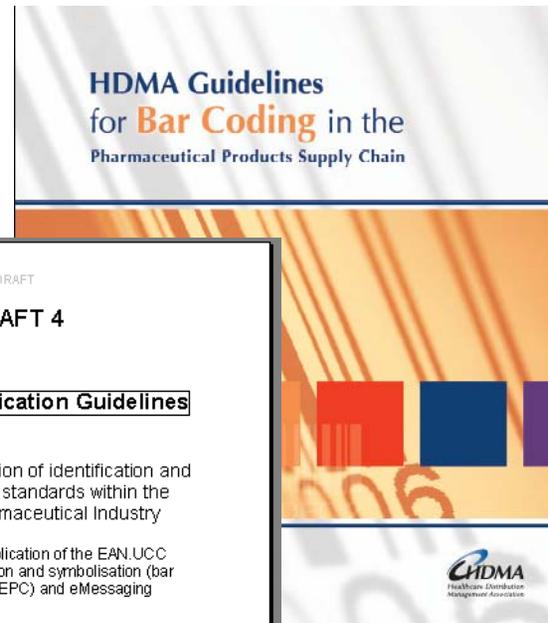
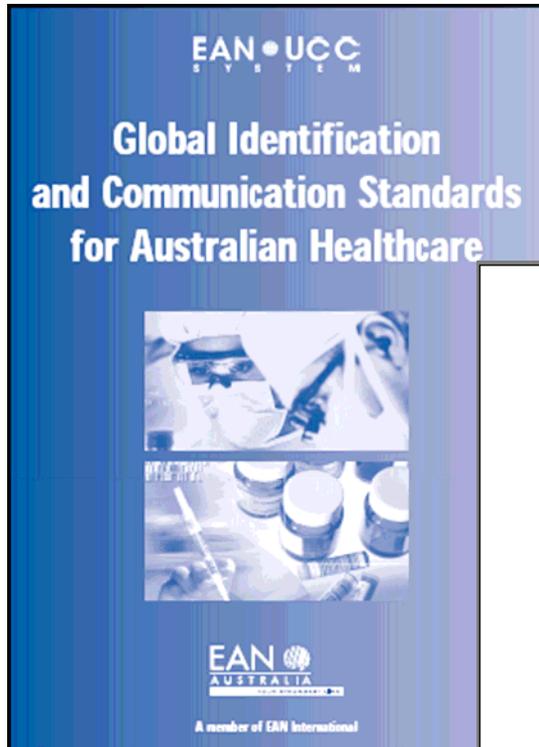


Scannable technology

Bar coded pharmaceuticals save lives

Research shows machine-readable product identification is key to preventing medical errors, improving patient safety, helping combat counterfeiting and lowering costs throughout the health sector. But GARY HARTLEY argues New Zealand has fallen behind the rest of the world in mandating bar codes on pharmaceuticals.

GS1 Staff suggests creating an Implementation Guide





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How would our Guide be unique ?



How “global” can we be?



*

*MVP-Seattle

Johnson & Johnson



*



Can the same guide apply to drugs and devices?

*Newsweek



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“It’s not about the bar code, it’s about the data.”

-- Karen Longe





How can we be effective ?

Let's look at the past and near present. . .

Product packaged and labeled for target market

UPC for US

EAN for Europe

FMCG bar coding for healthcare

Meat packing for healthcare

How can we be effective ?

Let's look at the future....

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LOT

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How can we be effective ?

Let's look at the future....

Create a work plan this week to define scope, objectives, and deliverables.

Know when we are done.



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