



Standards Implementation

GS1 HUG Meeting, November 2005
Tom Werthwine

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Standards Implementation Work Group

To answer the question:
“Is this true ?”

If not, then, “why not?”

If true, then, “How far do we
have yet to go ?”

HEALTHCARE GOES
FOR GLOBAL
EAN•UCC STANDARDS

The most implemented, most requested, best supported
identification and communication standard in healthcare
logistics and supply processes.



Standards Implementation Work Team

Objectives

- Define - Healthcare goes for GS1 Standards
- Measure - Implementation Baseline Online Survey
- Analyze - At GS1 HUG Princeton Meeting
- Improve - TBD
- Control - TBD





HUG Implementation Baseline Survey Results (summary)

David Buckley

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Background

Survey Conducted 10 to 25 November 2005

GS1 Healthcare User Group - Implementation Baseline

MEDICAL DEVICES - For the PALLET package level, which bar code symbol(s) are used?

- GS1 Datamatrix
- RSS (Reduce Space Symbology)
- RSS with Composite
- EAN/UPC (covers EAN-8, EAN-13, UPC-A & UPC-E)
- GS1-128 (previously known as UCC/EAN-128)
- ITF-14
- Datamatrix
- Code 39
- Code 128
- Other

MEDICAL DEVICES - For the PALLET package level, what DATA do you encode in the bar code?

- GTIN (e.g., AI 01)
- Expiration Date (e.g., AI 17)
- Lot or Batch Number (e.g., AI 10)
- Serial Number (e.g., AI 21)
- SSCC (e.g., AI 00)
- HIBCC primary UPN
- HIBCC secondary
- National Registration Number (e.g., PZN in Germany)
- Other



16 replies, all results presented as averages

- SMITHS MEDICAL
- Pfizer
- Medtronic, Inc.
- Boston Scientific
- Cook
- B. Braun
- Hospira
- Terumo Europe N.V.
- Novartis Pharma AG
- ABBOTT
- GlaxoSmithKline
- BD (Becton Dickinson)
- Merck
- Alcon Laboratories, Inc.
- Pall Medical
- Becton Dickinson

NOTE: Results refined for Medical Devices & Pharma





Background: Sorry Everyone

- The answers pertaining to the Pharmaceuticals are no because we only manufacture medical devices. The answers should be Y/A, however the system would not allow anything but yes / no
- Your review might give wrong overall impression since a Pharma-only company is also obliged to answer questions on medical devices. Questions otherwise are device related and need to answer yes/no to the questions. The system does not allow the supplier to answer. Otherwise, please forward the questions to the supplier and we will provide a copy of the result!
- [We] do not manufacture pharmaceuticals therefore please disregard the pharmaceuticals section.
- We are a medical device manufacturer and don't provide pharmaceuticals. Some bar coded however most shelf packs have GS1 labels that may or may not have secondary information. On the unit packaging, we try to GTIN bar code the packaging. Some may don't have them due to space constraints.

Sorry!



Survey Design – KEY LEARNINGS

- **Need more respondents - both inside and outside GS1 HUG membership**
- **Healthcare is not one market with two segments - Pharma and Med Device : Healthcare is diverse**
- **We need to target the survey to avoid confusion**
- **We need to cover other GS1 service offerings**



Medical Devices

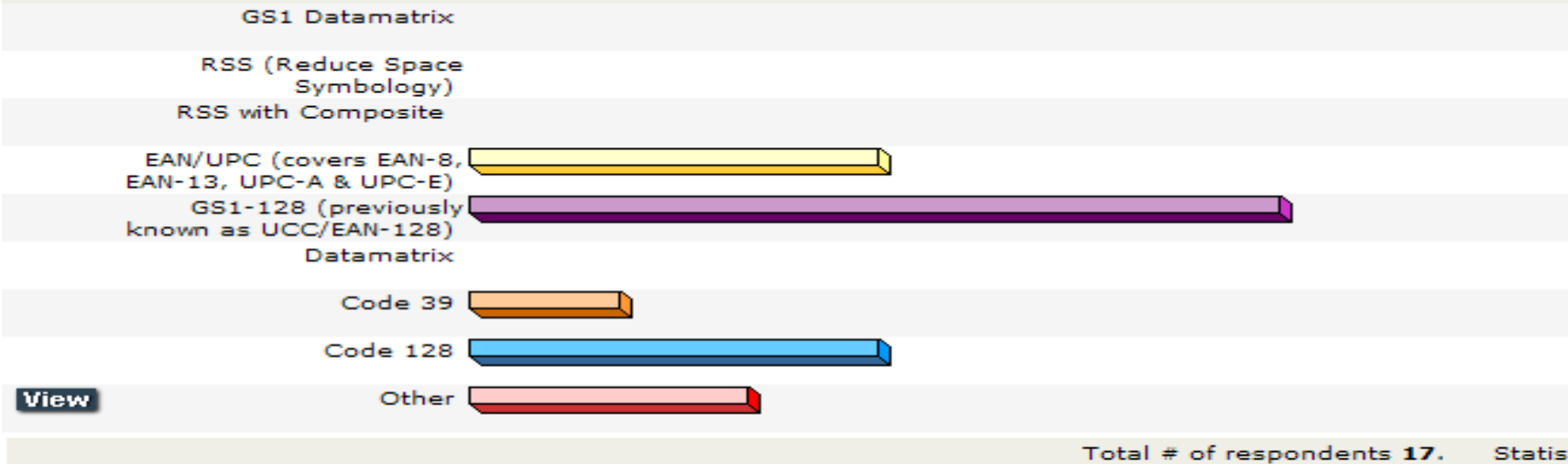
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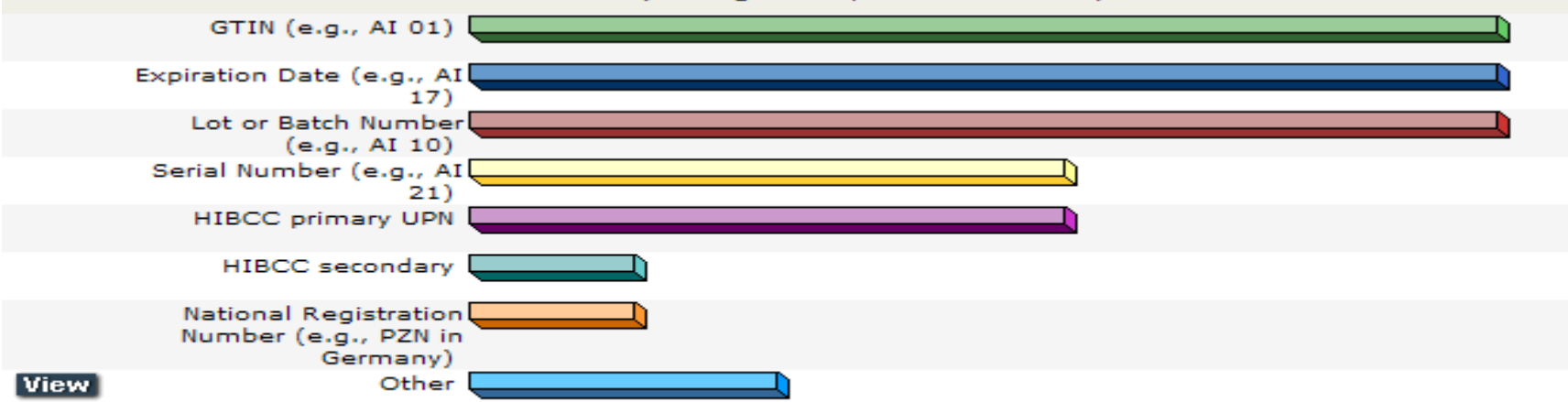


Medical Devices – Unit of Use

MEDICAL DEVICES
For the UNIT OF USE package level, which bar code symbol(s) are used?



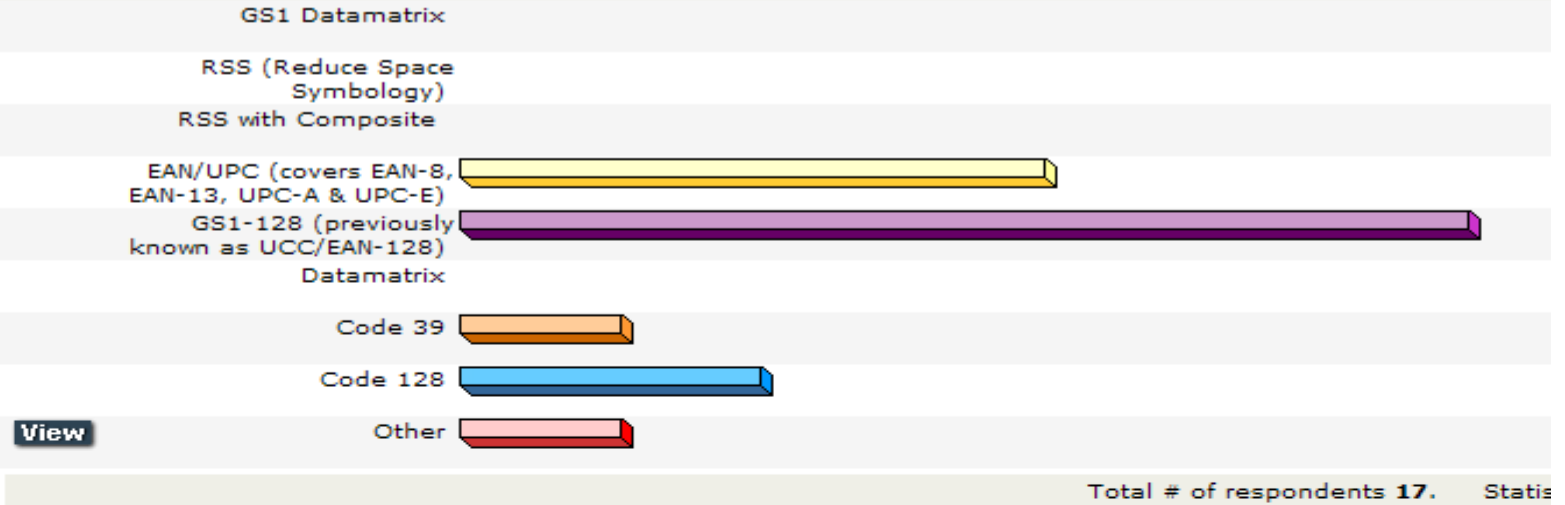
MEDICAL DEVICES - For the UNIT OF USE package level, what DATA do you encode in the bar code?



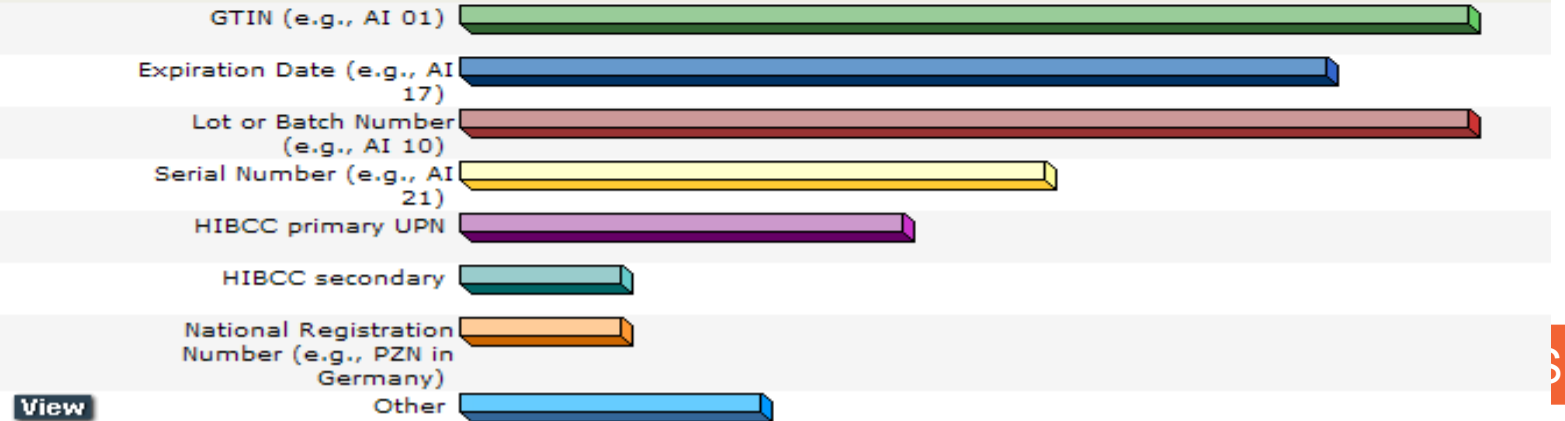


Medical Devices – SKU

MEDICAL DEVICES - For the STOCK KEEPING UNIT (SKU) / SHELF PACK package level, which bar code sym



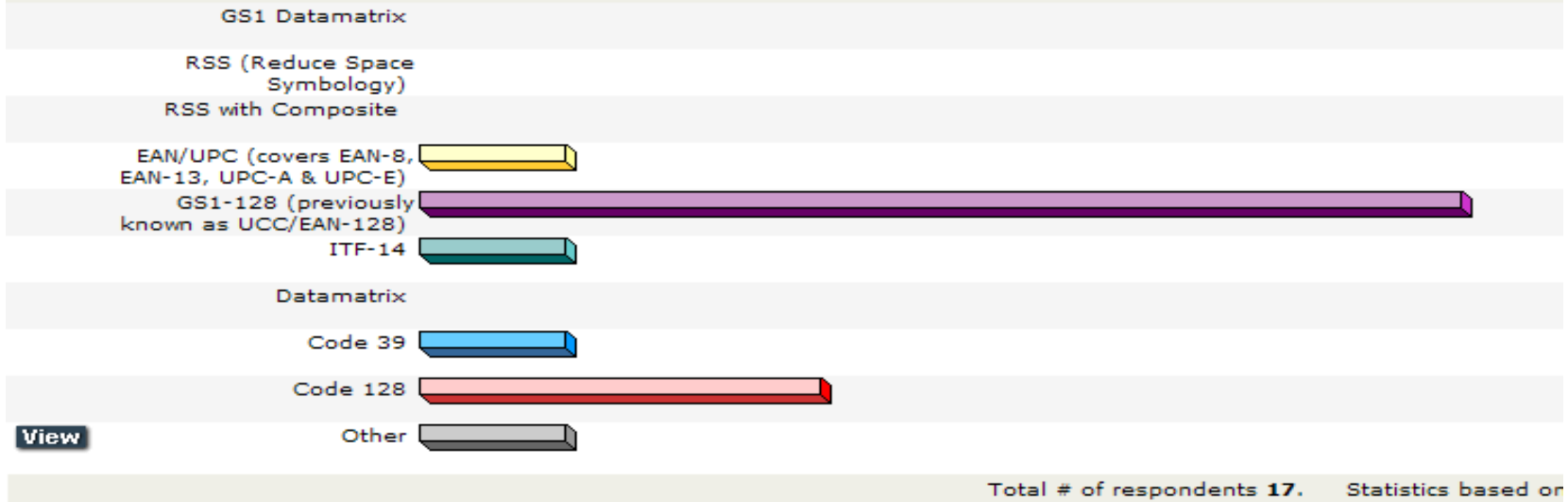
MEDICAL DEVICES - For the STOCK KEEPING UNIT (SKU) / SHELF PACK package level, what DATA do you encode?



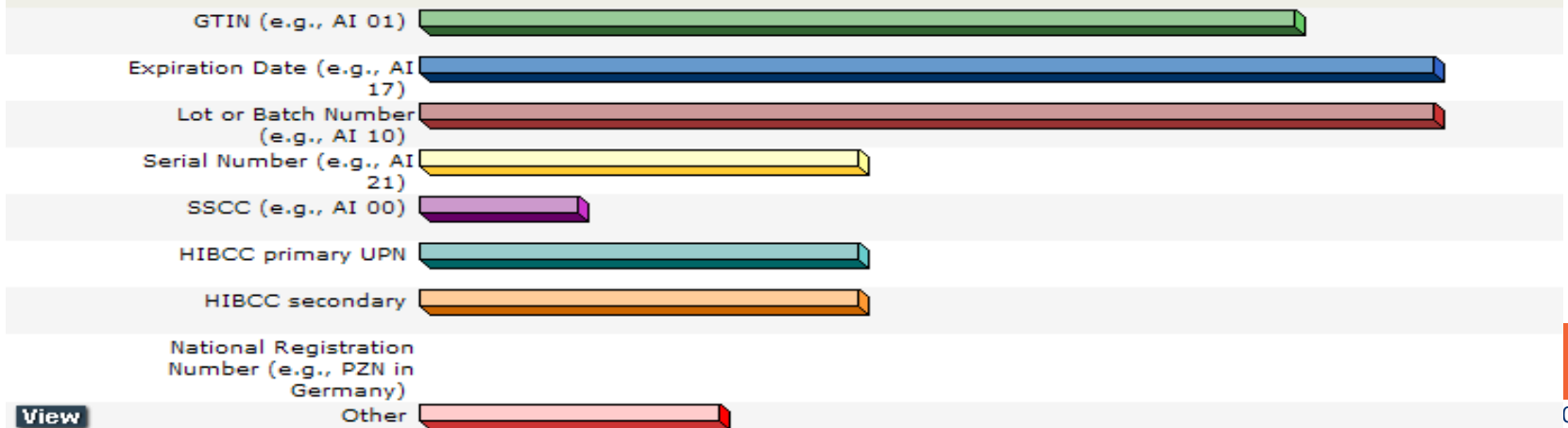


Medical Devices – SHIPPER or CASE

MEDICAL DEVICES - For the SHIPPER or CASE package level, which bar code symbol(s) are used?



MEDICAL DEVICES - For the SHIPPER or CASE package level, what DATA do you encode in the bar code?

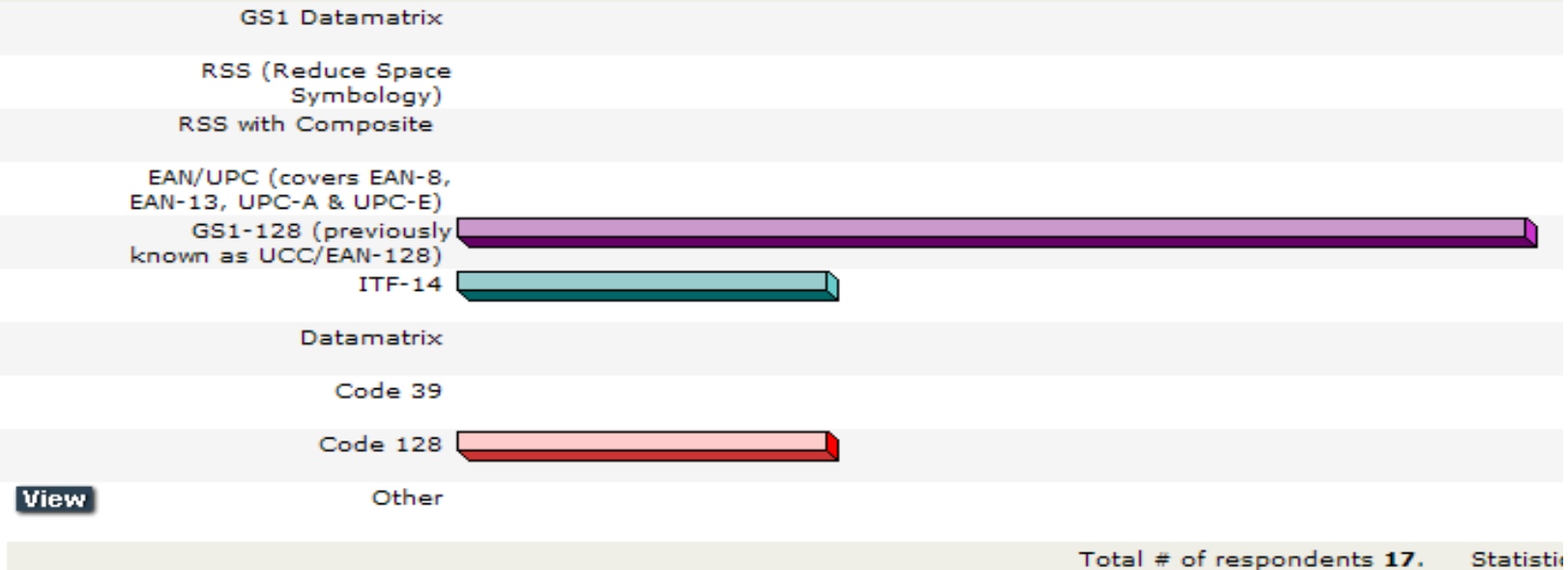




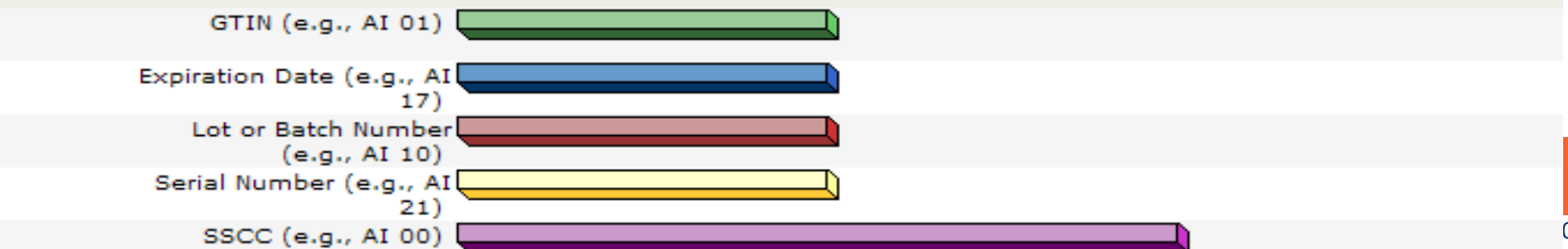
Medical Devices – Pallet

NOTE: Only five companies Bar Code Pallets

MEDICAL DEVICES - For the PALLET package level, which bar code symbol(s) are used?



MEDICAL DEVICES - For the PALLET package level, what DATA do you encode in the bar code?





Medical Devices – KEY LEARNINGS

- **The predominant bar code used is code 128**
- **The predominant data are GTINs**
- **HIBCC usage is still significant**
- **Only 5 respondents bar code pallets**
- **RSS has made no inroads**
- **Use of serial numbers lags behind use of lot / batch**



Pharmaceuticals

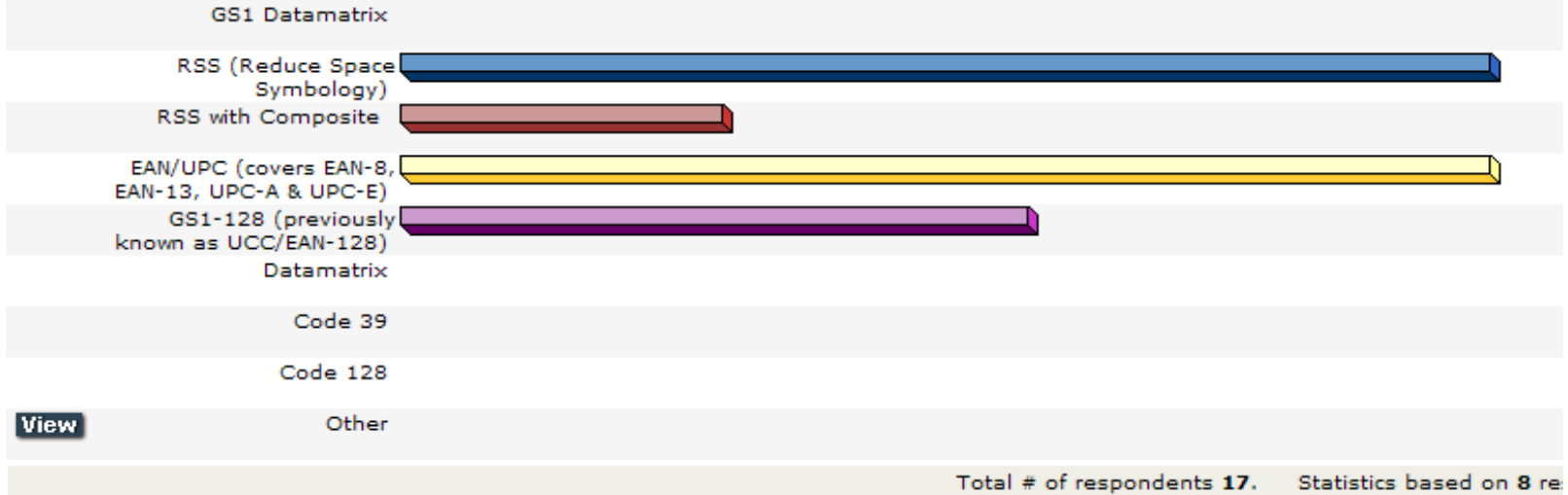
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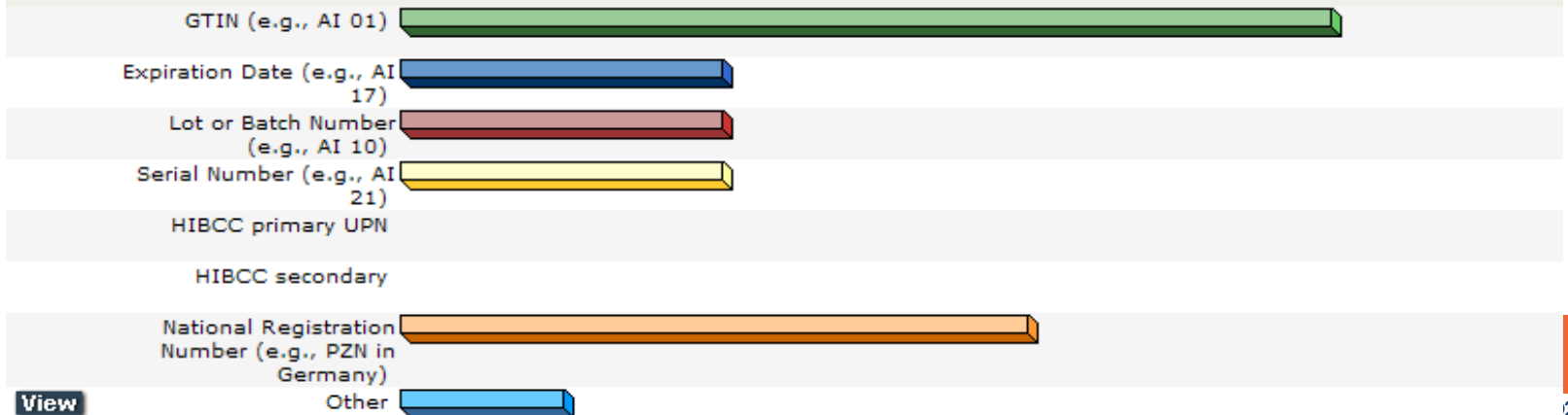


Pharmaceuticals – Unit of Use

PHARMACEUTICALS - For the UNIT OF USE package level, which bar code symbol(s) are used?



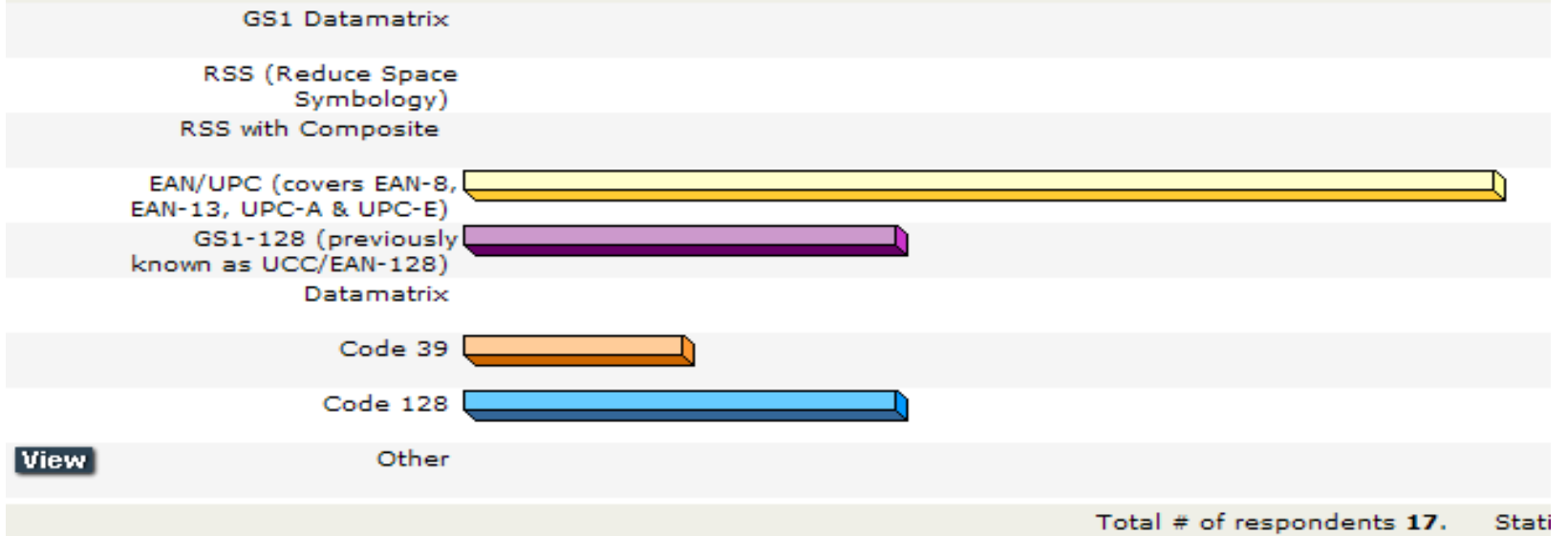
PHARMACEUTICALS - For the UNIT OF USE package level, what DATA do you encode in the bar code?



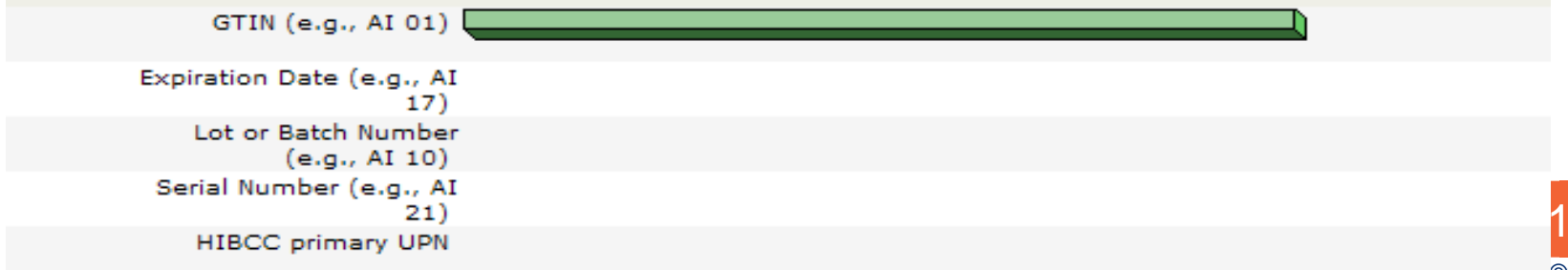


Pharmaceuticals – SKU

PHARMACEUTICALS - For the STOCK KEEPING UNIT (SKU) / SHELF PACK package level, which bar code sy



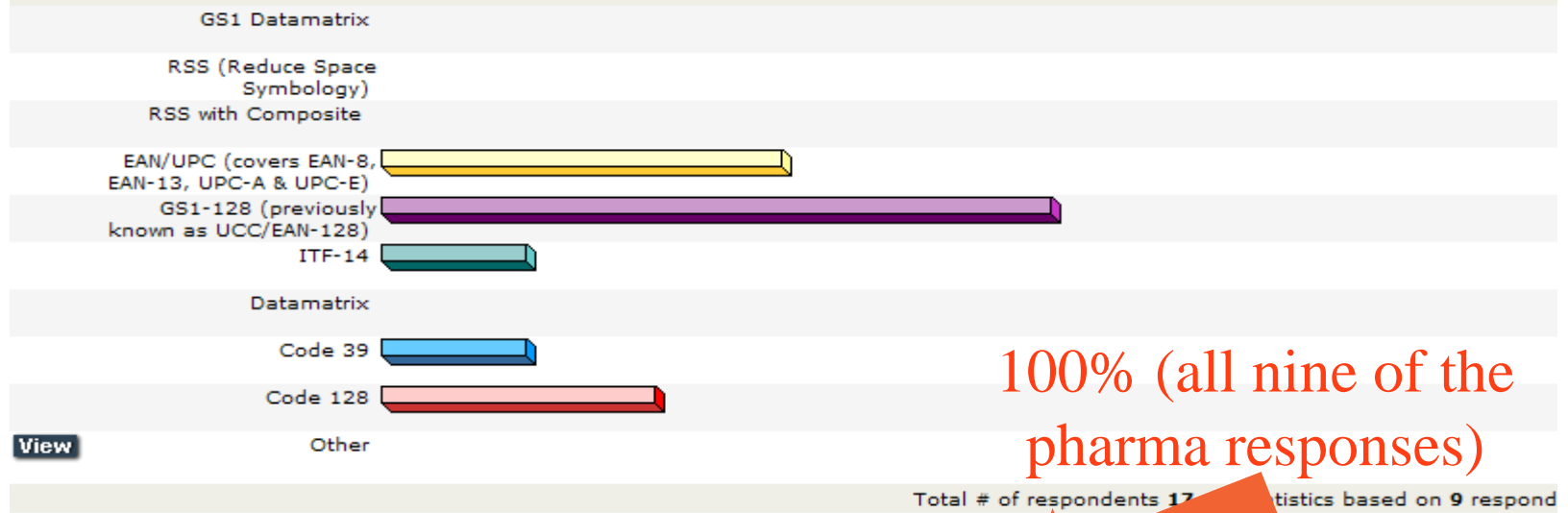
PHARMACEUTICALS - For the STOCK KEEPING UNIT (SKU) / SHELF PACK package level, what DATA do you code?



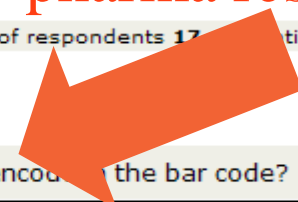


Pharmaceuticals – SHIPPER or CASE

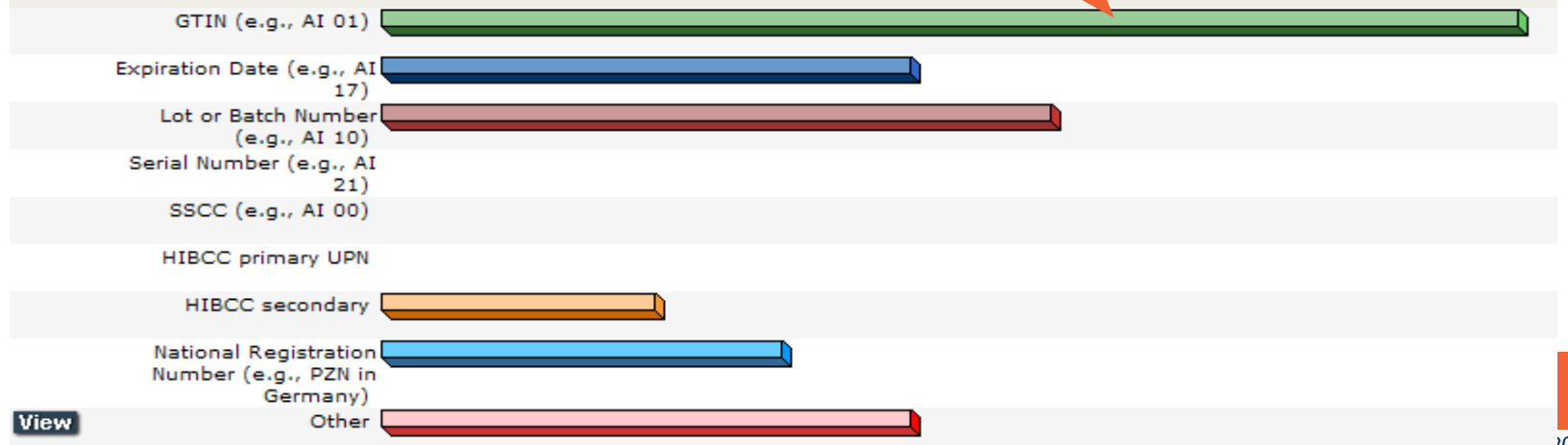
PHARMACEUTICALS - For the SHIPPER or CASE package level, which bar code symbol(s) are used?



100% (all nine of the pharma responses)



PHARMACEUTICALS - For the SHIPPER or CASE package level, what DATA do you encode in the bar code?

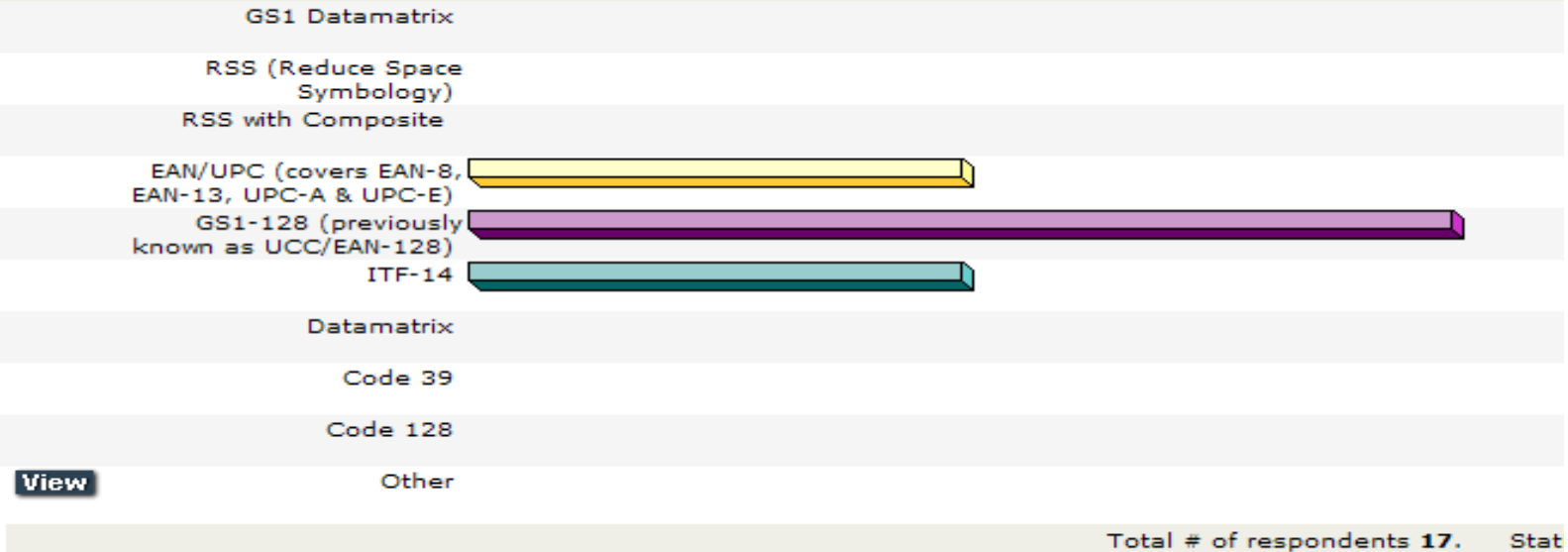




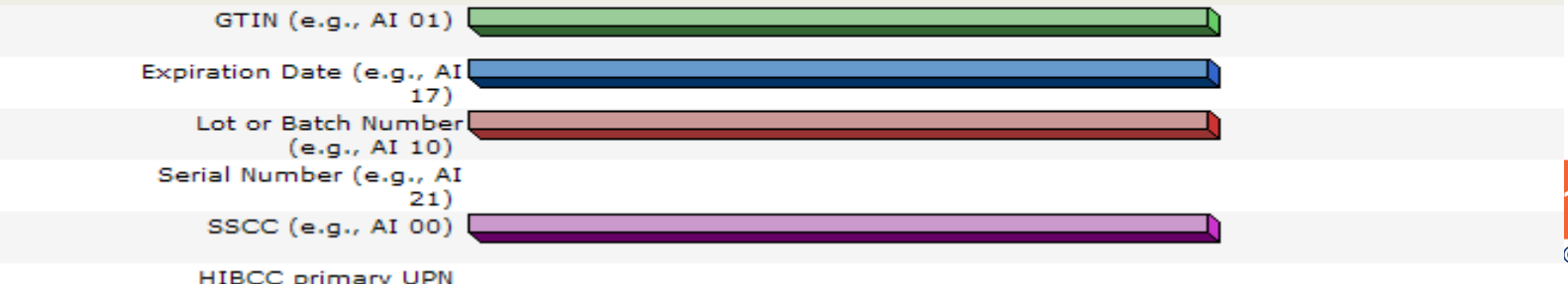
Pharmaceuticals – Pallet

NOTE: Only four companies Bar Code Pallets

PHARMACEUTICALS - For the PALLET package level, which bar code symbol(s) are used?



PHARMACEUTICALS - For the PALLET package level, what DATA do you encode in the bar code?





Pharmaceuticals – KEY LEARNINGS

- **RSS usage significant at unit of use level of packaging**
- **The predominant data are GTINs**
- **HIBCC usage minimal**
- **Only 4 respondents bar code pallets**



GENERAL

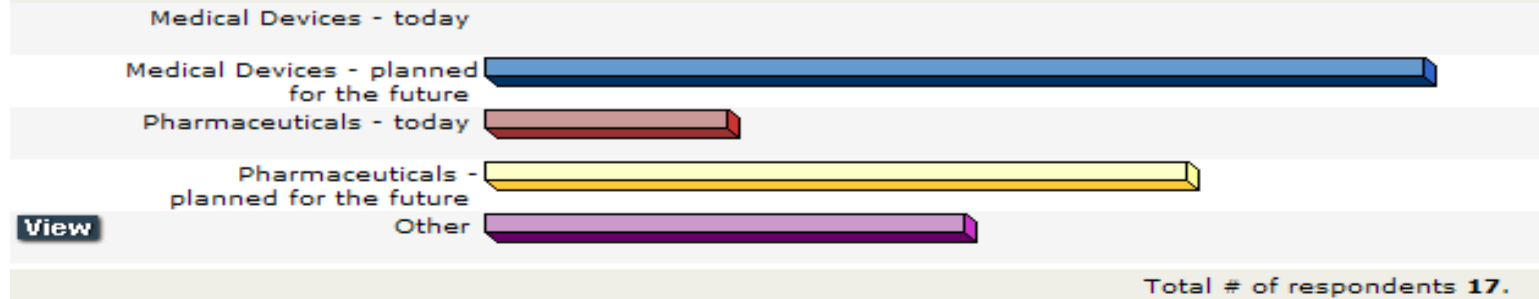
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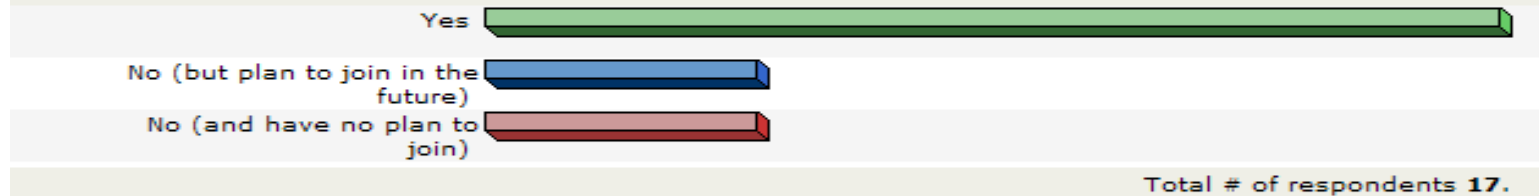


RFID

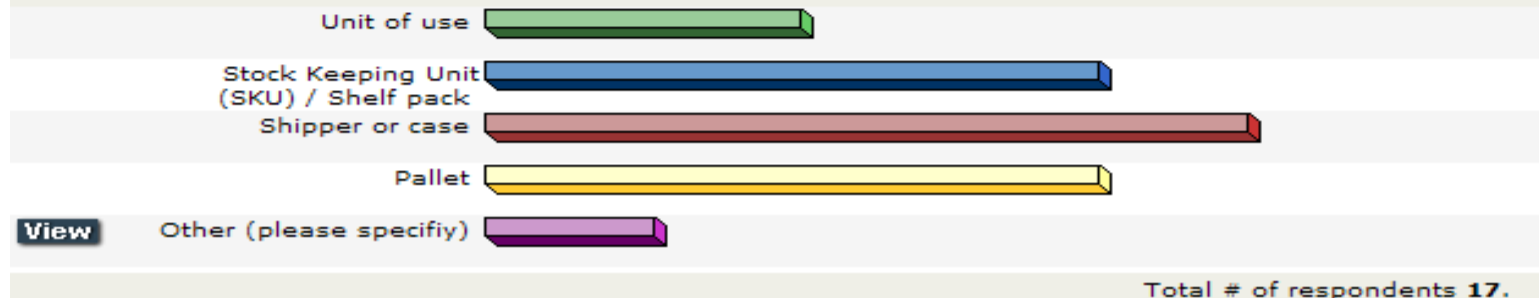
RFID is used, or planned to be used, for which items:



RFID - Is your company a member of EPC?



RFID tags are used for which packaging levels in your company?





Bar Codes for Regulatory Reasons

- **NO – Seven**
- **YES – Nine:**
 - Japan
 - FDA and some individual European countries.
 - Bar Code designed to meet Regulatory requirement for each marketed country.
 - FDA
 - US- FDA
 - FDA EU EFPIA
 - EAN128 is used to provide regulatory tracing capability at LOT level and shelf pack.
 - We use US as baseline. Barcodes changed for specific markets. - Germany -Spain -Brazil -Chile -Italy -Australia -Canada
 - Italy, Japanese requirement to meet JFMDA rules.
- **Unsure how to answer – One:**
 - Regulations drive much of what we do. We must comply.



General – Selected Comments

- We are at a very early stage with RFID and will not consider it for the large range of sterile, small, low cost product lines. For the unit of use there are many situations where there is not enough space to include the GS1-128, but we put it at the next level of labelling. We are being increasingly asked to provide a peelable bar code and for China dual (2 the same) bar codes, which will add to the product cost. We try wherever possible to have "global" packaging rather than country specific packaging.
- I answered the above on behalf of our US market. To try and do so for other markets would be difficult...
- Practices vary by country. My response was global and may not be very valuable for this survey
- We anticipate the need to bar code all unit packaging, however, some of our product's packaging is not conducive to bar codes and we may need to redesign our unit packaging to apply the bar code efficiently.



CONCLUSIVE KEY LEARNINGS

Target key segments and expand base of respondents

Identify key opportunities

The product itself e.g. surgical instruments ?

Pallets - Is the survey skewed ?

Serialized GTINs as a precursor to RFID ?

Other GS1 offerings e.g. GLNs ?



Where do we go from here ?

Invitation - Moving Ahead session

Invitation - Surgical Marking session

Expand and refine survey

Target

AdvaMed Members

Eucomed Members

PhRMA Members

Others ?



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