



Regulatory Team

Princeton, NJ – November 29, 2005
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Objectives

- Organize the industry around a single position to influence future standards and regulations

- Work with existing healthcare industry organizations and healthcare lobbying groups in delivering the position of HUG
 - EU-Commission, Healthcare Ministries
 - AdvaMed, Eucomed
 - Others



- Standard Product Auto-Identification
- Medical Devices and Pharmaceuticals
- International, National, Regional Laws, Regulations, Standards



Deliverables

- Develop baseline of applicable laws, regulations, standards
 - Provide baseline to HUG Standards Development Team as input to the development of global GS1 standard as the industry response

- Assist HUG Communications Team to organize the education and lobbying around the preferred single solution to governmental agencies, healthcare organizations
 - Provide guidance on Healthcare organizations, governmental agencies and healthcare lobbying groups to approach



Baseline Represents 77 Countries / Regions

67 Countries with Requirements for
Pharmaceuticals

10 Countries with Requirements for
Medical Devices



Total of 27 Countries have some type of mandate for product Auto ID

Western Europe

- Greece > EAN-13
- Switzerland > EAN-13
- Spain > EAN-13, EAN.UCC-128
- Sweden > EAN-13, EAN.UCC-128
- Belgium > Code-128
- Germany > EAN-13, Code-39 (PZN)
- Italy > Code-39 (AIC)

Central/Eastern Europe

- Slovakia > EAN
- Slovenia > EAN-13
- Croatia > EAN-13
- Former Republic of Macedonia > EAN-13
- Yugoslavia > EAN-13, EAN-8
- Russia > EAN-13, EAN-8
- Ukraine > EAN-13, EAN-8



Mandates (continued)

Asia Pacific

- Australia > EAN-13
- Thailand > EAN-13
- Korea > EAN-13
- Iran > EAN-13
- Japan > EAN.UCC-128, EAN-13
- Hong Kong > EAN.UCC-128, HIBCC
- New Zealand > Proprietary

North America / Latin America

- USA > EAN.UCC
- Costa Rica > EAN.UCC
- Panama > EAN-13
- Brazil > EAN-13, EAN.UCC-128
- Mexico > EAN-13, EAN-8

Middle East/Mediterranean/Africa

- South Africa > EAN.UCC



Total of 11 Countries have some type of De facto Requirement for product Auto ID

Western Europe

- Ireland > EAN-13
- France > EAN-13, EAN.UCC-128
- Denmark, Finland, Iceland, Norway > EAN-13, EAN.UCC-128, (some proprietary)
- Portugal > Code-39

Asia Pacific

- Taiwan > EAN-13, EAN-14, EAN.UCC-128

Central/Eastern Europe

- Austria > EAN-13
- Poland > EAN-13

North America / Latin America

- Uruguay > EAN-13, EAN-8



Data Structures in Use Today

Data from 77 Countries / Regions represented in Baseline

EAN-13

58 - 75%

EAN.UCC-128

14

EAN-8

12

EAN.UCC

8

EAN-14

3

Code-39

3

Proprietary

3

HIBCC

3

Code-128

1



Opportunities

France – Healthcare Ministry

Need to move from proprietary coding scheme of Pharmaceutical Product Association. Migration process 2006 -2009 (EAN-13, EAN.UCC-128) considering data matrix

Italy – Healthcare Ministry

Requires identification system “bollino” Marketing Authorization Code. Pharmaceuticals must carry bar code known as “PARAF” according to specifications issued by Italian Ministry Health.

Netherlands – Dutch Healthcare

Extremely interested in the EAN Data Alignment Service, exploring possible alignment w/ Dutch DB for pharmaceuticals.

USA – FDA

Open issue 2004 white paper on anti-drug counterfeiting urging voluntary RFID tracking of drug pedigree by 2007.

Potential mandate for medical devices?



Next Steps

- Discuss and validate baseline in HUG Work Team breakout session
- Coordinate with Standards Development Team to use baseline as we move forward in standards development
- Continue to update and communicate baseline information
- Engage with HUG Work Teams in all phases moving forward



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