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
Scope

- 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
Mandates

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

**Central/Eastern Europe**
- Austria > EAN-13
- Poland > EAN-13

**Asia Pacific**
- Taiwan > EAN-13, EAN-14, EAN.UCC-128

**North America / Latin America**
- Uruguay > EAN-13, EAN-8
Data Structures in Use Today

Data from 77 Countries / Regions represented in Baseline

<table>
<thead>
<tr>
<th>Code</th>
<th>Countries / Regions</th>
</tr>
</thead>
<tbody>
<tr>
<td>EAN-13</td>
<td>58 - 75%</td>
</tr>
<tr>
<td>EAN.UCC-128</td>
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<td>Code-128</td>
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</tbody>
</table>
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
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
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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