



# Regulatory Affairs

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GS1 Healthcare User Group (HUG)

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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

# Scope

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

# Deliverables

- Provide baseline of applicable laws, regulations, standards
- Provide baseline to HUG Standards Team as input to the development of one global GS1 standard as the industry response
  - Provide guidance on current baseline
- Assist HUG Communications Team 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

# Timeline

- August - Identify industry focus groups to approach
- August / September - Solicit input from industry organizations and membership companies
- September - Provide baseline set of applicable laws, regulations, standards at HUG meeting in Brussels

## Solicited input from Industry Organizations and Membership Companies:

- GS1 Leadership – Ulrike Kreysa
- Medtronic Quality, Regulatory, Legal and Standards Groups globally
- HUG Members
- Other Medical Device Companies from Medical Device Compliance Conference
- Contacts in the Industry

## Recruiting Opportunities:

- Medtronic Quality, Regulatory, Legal and Standards Groups globally
- GS1 Leadership – Ulrike Kreysa
- HUG Members
- Other Medical Device Companies from Medical Device Compliance Conference
- Contacts in the Industry





Healthcare

# Results

## Summary of Legal / Regulatory Requirements

- Track and Trace Regulatory Initiatives
- <http://www.nahit.org/hitsdir/pgEXT>

## GS1 Coding Systems for Pharmaceuticals, Medical Devices and Animal Health Products

Total of 74 Countries:

➤ 6 Countries Mandate auto-ID for Medical Devices

- Japan > EAN-128
- Hong Kong > EAN-128
- Sweden > EAN-13, EAN-128
- Russia > EAN-13, UPC, EAN-8
- Former Republic of Macedonia > EAN-13
- Mexico > Linear Bar Code

## Total of 74 Countries:

### ➤ 18 Countries Mandate auto-ID for Pharmaceuticals

- Brazil > EAN-13
- Belgium > Code-128
- Croatia > EAN-13
- Greece > EAN-13
- Hong Kong > EAN-128
- Iran > EAN-13
- Italy > Bollino w/Code-39
- Japan > EAN-13
- Mexico > Linear Bar Code
- Former Republic of Macedonia > EAN-13
- Russia > EAN-13, UPC, EAN-8
- Slovakia > EAN
- South Africa > EAN.UCC
- Spain > EAN-13, EAN-128
- Sweden > EAN-13, EAN-128
- Thailand > EAN-13
- Ukraine > EAN-13, EAN-8
- USA > EAN.UCC

## 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