

# Regulatory Affairs

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### Objectives

- Organize the industry around a single position to drive future standards and influence regulations around auto identification of healthcare products
- Work with existing healthcare industry organizations and healthcare advocacy groups in delivering the position of HUG
  - Healthcare Ministries, Regulatory Agencies
  - >AdvaMed, Eucomed, and other trade associations



### Scope

Auto-Identification in Healthcare

Medical Devices and Pharmaceuticals

International, National, Regional Laws, Regulations,
 Standards





#### Deliverables

- Maintain global reference of applicable laws, regulations, standards
- Provide guidance to HUG membership including governmental agencies and healthcare trade associations
- Specific responses to authorities regarding public policy



## Regulatory Baseline

	GS1 Healthcare User Group													
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### **Working Communication**

Actively engaged in communication and dialogue with Healthcare Ministries, Regulatory and Governmental Agencies

#### **Examples:**

\*Ministry Health Labor Welfare – Japan

\*Spain Ministerio de Sanidad y Consumo, Madrid

Italian Healthcare Ministry

\*UK Department of Health

Australia National Blood Authority

New Zealand Ministry of Health

Public Health Agency Canada

\*United States - Food and Drug Administration China - State Food and Drug Administration





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