New GS1 Product Identification Standard - foundational for patient safety and supply chain improvements

Enables further effective and efficient harmonisation of bar code, RFID and traceability systems in healthcare worldwide

Brussels, Belgium, 21 January 2010 – GS1 Healthcare, the global, voluntary Healthcare user group, today announced the publication of the GS1 standard for the Automatic Identification and Data Capture (AIDC) of medical products. This voluntary standard provides industry stakeholders with a common set of data and data carriers for medical products at every packaging level, including specific guidance on selection and use of:

- Appropriate Product Identification Keys
- Additional product and production data, for example; lot number, expiration date, and/or serial number (where applicable)
- Data carriers including; linear bar codes, two-dimensional bar codes and Radio Frequency Identification (RFID) tags

"Sector-wide implementation of AIDC systems will improve patient safety, including reducing medication errors, fighting counterfeiting and enabling effective product recalls and adverse event reporting," said Mike Wallace, Director Global Standards and Serialization, Abbott, and Co-Chair of GS1 Healthcare, "It will also help remove inefficiencies throughout the Healthcare supply chain, allowing stakeholders to improve and integrate their processes."

"Implementing this standard will ensure that medical products can be unambiguously identified by anyone in the Healthcare supply chain," said Joe Pleasant, Chief Information Officer, Premier, Inc. and member of the Global Leadership Team of GS1 Healthcare, "The Healthcare sector must now leverage technology advances to create a more efficient and effective supply chain, bringing us one step closer to an efficient supply chain like those seen in other industries."

"We need a global vision: Healthcare is a global business where supply chain partners exchange goods and information. Country-specific non-standard requirements have a major impact on product assortment and on supply chain management," said Volker Zeinar, Global Coordination Auto-ID Affairs, B Braun and member of the Global Leadership Team of GS1 Healthcare, "Global standards are key success factors for process improvements for suppliers."

"Many countries have regulated product identification systems for medical product registration and reimbursement purposes," said Ulrike Kreysa, Director Healthcare, GS1 Global Office, "However, using these numbers for supply chain management purposes is sub-optimal. A GS1 Identification Key can be mapped to a national number in a national database by the brand owner. Over 65 countries already accept GS1 Identification Keys for medical products."

- more -

GS1 Standards ensure interoperability and compatibility and enable all stakeholders to efficiently and effectively comply with various identification, traceability and product catalogue requirements. Various authorities worldwide have developed, or are developing, regulations requiring automatic identification, serialisation and traceability systems in Healthcare to improve patient safety, including the European Commission, the US Food and Drug Administration, ANVISA (the National Health Surveillance Agency in Brazil), the Turkish Ministry of Health, the India Ministry of Health and Family Welfare. "This new standard provides a global framework taking all specific requirements for medical products into account," concluded Kreysa.

There were several notable developments, including:
- Recognition of the value of 2-dimensional bar codes, GS1 DataMatrix, to meet the specific requirements of the Healthcare supply chain, including the need to code more fixed and variable information, while maintaining a small size bar code (e.g., bar code at the unit of use level) and the need for direct part marking (e.g., surgical instruments). This bar code is targeted for use in hospitals and retail pharmacies.
- Confirmation that 14-digit GTIN will be used in non-retail applications.

For more information on the industry impact of these developments, see the position statements at www.gs1.org/healthcare/library.

"Over the last 3 years, more than 100 experts from every region of the world and representing every segment of the healthcare supply chain contributed to the development of this standard," said Grant Hodgkins, Alcon Laboratories, Inc., Co-Chair of the AIDC Application Standards work group and member of the GS1 Healthcare Global Leadership Team, "In over 150 meetings, or more than 4,500 contact hours, our teams carefully compiled the industry's business requirements, then designed and delivered global solutions to meet these challenging requirements. The Healthcare industry can now begin adoption efforts to realise the benefits already demonstrated in other sectors that use the GS1 System of Standards."

NOTES FOR EDITORS:

About GS1 and GS1 Healthcare
GS1 is a neutral, not-for-profit organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is driven by more than a million companies, who execute more than six billion transactions a day with the GS1 System of Standards. GS1 is truly global, with local Member Organisations in 108 countries, with the Global Office in Brussels, Belgium.
GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonisation. GS1 Healthcare consists of participants from all stakeholders of the Healthcare supply chain: manufacturers, wholesalers & distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. For more information, visit www.gs1.org/healthcare.

Contact: Jan Denecker, GS1 Global Office, jan.denecker@gs1.org, +32 2 788 78 36 (office)

# # #