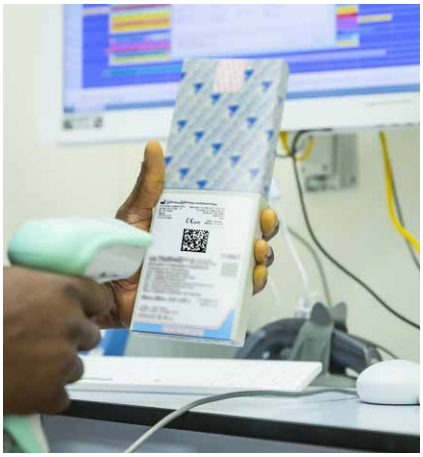
The Global Language of Business

Update the Healthcare GTIN Allocation Rules

Mission-specific working group: Collaborate with us to advance healthcare product identification.



What business challenges are being solved?

Healthcare product identification is critical to ensuring patient safety, regulatory compliance, and supply chain efficiency. Yet, evolving regulations and business processes have revealed gaps and inconsistencies in the current Healthcare GTIN Allocation Rules, causing challenges for stakeholders.

These include:

- **Confusion and divergence:** Misalignment between the Healthcare GTIN Allocation Rules and the broader GS1 GTIN Management Standard can lead to misinterpretation, errors, and inefficiencies.
- **Evolving scenarios:** New item identification scenarios not addressed in the current rules risk inconsistent implementation and operational challenges.
- **Global harmonisation:** Updates are needed to align with global standards and regulatory frameworks, ensuring seamless interoperability.

By refining the rules, we aim to create clarity, enhance usability, and ensure the healthcare community can confidently and consistently apply GTIN allocation rules across all products.

Impact

Adopting updated Healthcare GTIN Allocation Rules will:

- **Enhance clarity:** Provide clear, consistent guidance for GTIN allocation, reducing ambiguity and errors.
- **Protect investments:** Safeguard decades of industry investment in GS1-based solutions by adapting standards to evolving regulatory requirements.
- **Support innovation:** Enable alignment with regulatory frameworks, facilitating innovation and improving supply chain interoperability.

This initiative will ensure the GS1 standards remain the cornerstone of healthcare product identification, enabling safe, efficient, and reliable supply chains.

Background

Since its inception, GS1 Healthcare has championed global standards to prevent medical errors, combat counterfeit products, and improve supply chain efficiency. The Healthcare GTIN Allocation Rules have been instrumental in this mission, but recent updates to the GS1 GTIN Management Standard have highlighted areas requiring harmonisation.

New regulations and requirements, particularly in pharmaceutical and medical device sectors, necessitate clarification and updates to ensure global compliance. This project focuses on refining existing rules to better reflect real-world practices and provide clear, actionable guidance to stakeholders.

Why is this work needed?

This project is essential to ensure stakeholders have the tools they need to thrive in a dynamic regulatory environment while mitigating risks such as misaligned standards, fragmented implementations, and missed opportunities to harness harmonised global solutions for compliance and innovation.

Working Group objectives

The working group will focus on one main objective:

Define a broader solution: Develop best-practice approaches for GTIN allocation, ensuring alignment with international standards.

Who should join this Working Group?

We need a diverse range of experts to ensure the success of this initiative. Key participants include:

- **Healthcare manufacturers:** Pharma and medical device experts who understand real-world application.
- **Healthcare solution providers:** Those familiar with supply chain systems and processes.
- **Regulators:** Representatives who can align standards with compliance requirements.
- **GS1 Member Organisations:** Local champions for global implementation.

Expertise in item identification, regulatory frameworks, and supply chain logistics will be especially valuable.

How will the Working Group operate?

This working group will follow the GS1 Global Standards Management Process:

- **Define business requirements**—collect input from the industry and MOs
- **Refine and develop rules**—experts draft relevant standards and present them to industry and MOs for approval
- **Develop and approve**—standards are approved by the standards development community, ratified by GS1 governance bodies and published

Next steps

1. **Sign up for the Working Group** and join the Kick-Off meeting on Tuesday 13 May from 8:00-9:30 EDT / 14:00-15:30 CET. Register now and find more details here
2. **Contribute to the process:** Bring your expertise and insights to ensure the updated rules reflect the needs of the healthcare community.
3. **Help or questions?**
   Please contact: Neil Piper, neil.piper@gs1.org

Collaborate with us to advance healthcare product identification. Together, we can ensure safer, more efficient, and globally harmonised healthcare supply chains.

The GSMP is a community based forum for businesses facing similar problems to work together and develop global standards-based solutions to address them. Active GSMP participants represent industries ranging from retail and consumer goods to fresh foods, healthcare, transport and logistics, government and more—a healthy mix of business and technical people from nearly 60 countries.

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