

Guidance on using NTIN in EPCIS visibility events

Executive summary

In order to ensure full supply chain interoperability, **GS1 Healthcare strongly recommends use of a Global Trade Item Number (GTIN) as the product code for both supply chain and reimbursement purposes.**

Background

An increasing number of countries has adopted the GTIN for both pharmaceutical product identification and reimbursement purposes. This is a globally interoperable approach, assuring harmonisation of a product's unique identifier across international borders (for example, across the European Union (EU) as required by the EU Falsified Medicines Directive). It also facilitates the sharing of joint packages in multiple countries, which is common practice today.

The least interoperable approach is to embed the national number into a so-called National Trade Item Number (NTIN) instead of using a GTIN. Unlike GTINs, NTINs typically lack a company prefix and therefore cannot be identified by brand owner, nor can NTINs in a database be queried by brand owner. The **use of an NTIN is not recommended by GS1 Healthcare** and should only be considered where all other alternatives have been evaluated and excluded. This option should only be accepted in single or specific markets and will considerably limit the use of multi-market packaging.

Nonetheless, countries where the NTIN is deeply embedded in the systems or which are currently on a migration path from NTIN to GTIN for product identification may require clarification regarding the use of an NTIN in EPCIS events.

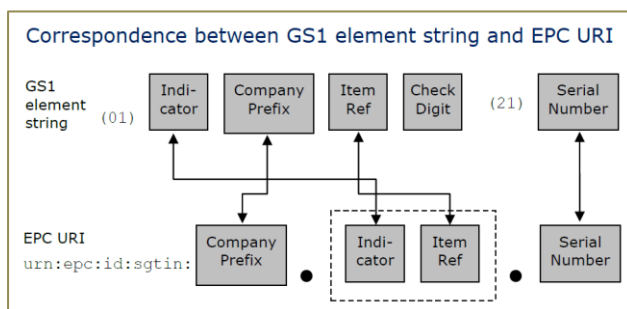
SGTIN for encoding GTIN & serial number in EPCIS

When used in EPCIS events, the combination of a GTIN and serial number – AI(01) and AI(21) – is encoded as a "Serialised Global Trade Item Number" (SGTIN), in the form of a "pure identity" Electronic Product Code Uniform Resource Identifier (EPC URI), as defined in GS1's [EPC Tag Data Standard \(TDS\)](#).

The SGTIN consists of the following elements:

- The **GS1 Company Prefix (GCP)**, assigned by GS1 to a managing entity.
- The **Item Reference**, assigned by the managing entity to a particular object class. The SGTIN's Item Reference is derived from the GTIN by concatenating the **Indicator Digit** of the 14-digit GTIN and the Item Reference digits, and treating the result as a single numeric string. *Note that the GTIN check digit is not included in the SGTIN EPC URI.*
- The **Serial Number**, assigned by the managing entity to an individual object.

SGTIN EPC URI syntax: `urn:epc:id:sgtin:CompanyPrefix.ItemRefAndIndicator.SerialNumber`



For example, this GS1 element string:

`(01)00614141123452 (21)400`

...is encoded as this SGTIN EPC URI:

`urn:epc:id:sgtin:0614141.012345.400`

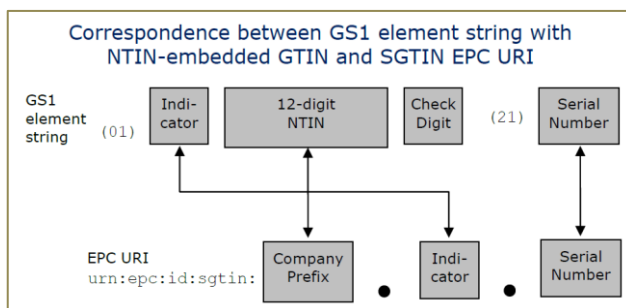
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Encoding NTIN in EPCIS

In countries where it has not been possible to use a GTIN, a nationally controlled number may have been embedded into a GTIN structure, creating a National Trade Item Number (NTIN). However, this will result in incompatibility with other industry standards, and prohibits reciprocity of packaging because the country using them generally does not permit GTINs/NTINs from other countries.

Unlike a GTIN, an NTIN does not include a company prefix, and therefore cannot be used to identify the product manufacturer or brand owner. For the same reason, **NTINs in a database (such as an EPCIS repository) cannot be searched or queried by product manufacturer or brand owner.** This would make it extremely difficult to reliably locate manufacturer-specific products scattered across the supply chain, for example by means of a standing EPCIS query for automatic notification about events pertaining to the entire portfolio of products from a given organisation.

An NTIN can be paired with a serial number and “embedded” in an SGTIN for use in EPCIS events. However, because it typically does not include a GS1 Global Company Prefix (GCP), in order to be encoded as an SGTIN in EPC URI syntax for EPCIS events, **an NTIN must be encoded as a “one-off” GTIN with a GCP length of 12 digits.**



For example, this NTIN-embedded GTIN and serial number:

(01)04150567890128 (21)xyz

...is encoded as this SGTIN EPC URI:

urn:epc:id:sgtin:415056789012.0.xyz

Recommendations

GS1 Healthcare strongly recommends use of a Global Trade Item Number (GTIN) as the product code for both supply chain and reimbursement purposes.

Regulatory authorities are encouraged to not require the inclusion of a national number in the unique identifier. GS1 Healthcare and its global members invite the respective national authorities to liaise with local stakeholders to establish clear and explicit guidance on the identifier to be used to implement regulatory requirements in their country. European regulators should also take into account the current use of GTINs in most of the EU member states.

Benefits of GTIN for product identification

Since their introduction in retail, GTINs have saved industry billions of Euros in supply chain efficiencies through harmonised interoperable processes. GS1 standards are increasingly used to achieve similar savings within the Healthcare sector, while at the same time helping to provide safer care. The McKinsey report “Strength in unity” shows the significant savings which are possible. Use of the GTIN for product identification to meet the requirements of anti-counterfeiting regulations (such as the FMD) can be leveraged to realise these benefits.

For additional details, please refer to the following GS1 Healthcare discussion papers:

- [Implementation of the EU Falsified Medicines Directive with GS1 standards](#)
- [Product identification in healthcare](#)
- [Identification and marking of multi-market packs for pharmaceutical products](#)