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October 2012: NEHTA Communiqué on GTIN Use Best Practice in Australian Healthcare

Further to the guidelines provided in the GS1 'Healthcare GTIN Allocation Rules and GS1 General Specifications[1]' and subsequent international direction[2], the National E-Health Transition Authority (NEHTA) wishes to propagate safe and good practice in Global Trade Item Number (GTIN) use within the Australian Healthcare Industry. The position taken by NEHTA builds on, and is consistent with the global healthcare strategy, and is applicable to the allocation of GTINs to all levels of packaging for Regulated Healthcare Trade Items (pharmaceuticals or medical devices sold or dispensed in a controlled environment) bought and sold in Australia[3].

Whilst the philosophy and usage of GTINs is largely common from industry to industry, the nature of healthcare heightens the importance of some aspects of GTIN use. The misidentification of healthcare products can be of serious detriment to the safe delivery of healthcare and quality health outcomes for patients. Given this risk, reliable product identification in healthcare justifies an escalation in the care required, and a high level of vigilance in GTIN management to ensure exact product identification and authentication. This principle also applies to healthcare products supplied to multiple sectors e.g. healthcare and grocery.

NEHTA therefore recommends that Australian Healthcare suppliers adopt GTIN best practice and avoid GTIN re-use for Regulated Healthcare Trade Items.

In addition, suppliers should:

- Allocate a new GTIN in the following cases (in line with the recommendations in the GS1 Healthcare GTIN Allocation Rules):
  - when any medicine or medical device has been changed or;
  - when any medicine or medical device has been discontinued and replaced with a different product.
- Sequentially issue the entire range of GTINs allocated to their organisation
- Acquire new GTINs from GS1 should they exhaust their range of GTINs.

For more information about GTIN allocation, please refer to the GS1 'Healthcare GTIN Allocation Rules' available at http://www.gs1.org/1/gtinrules/index.php/p=static/t=healthcare or contact GS1 Australia's Healthcare Team on 1300 227 263.

NEHTA appreciates the ongoing support from the healthcare industry in maintaining the best standards for Australian healthcare.

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[1] The GS1 General Specifications describes the GS1 standards for GS1 Identification and GS1 Bar Codes
[2] Refer to: http://www.gs1.org/1/gtinrules/index.php/p=static/t=healthcare
[3] A regulated healthcare item would be something that is intended for therapeutic use and hence would meet the definition of a therapeutic good as defined by the Act. Any item that falls within this definition is either regulated by the TGA or declared not to be therapeutic goods. therapeutic goods means goods: (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be: (i) for therapeutic use; or (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii); and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include: (c) goods declared not to be therapeutic goods under an order in force under section 7; or (d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or (e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a standard (within the meaning of subsection 4(1) of the Food Standards Australia New Zealand Act 1991); or (f) goods (other than goods declared to be therapeutic goods under an order in force under section 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.