HUG

Vaccines and Biologics Work group Close Out June 2006 HUG

Steve Hess Merck stephen_hess@merck.com (908) 423 7674

Bruce Cohen GSK bruce.x.cohen@GSK.com (919) 483-9375

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JAPAN

Implementation of Bar Code Labeling of Ethical Drugs
Additional requirements for *"Specific Biological Product"*

Comment period ends June 15 – Unique opportunity for the HUG

HUG agreed to change direction of Vaccine/Bio workgroup to respond

HUG has submitted comments

GS1-Japan to supply local support

Has arranged a meeting with Minister of Health office

Smallest unit of package

	Product	Expiry	Mfg #
BIO	YES	YES	YES
PHARMA	YES	NO	NO

Carton box holding multiples

	PRODUCT	EXPIRY	MFG #	QUANTITY
BIO	YES	YES	YES	YES
PHARMA	NO	NO	NO	NO

GS1 HUG

REQUIRED SYMBOLOBY

The following systems shall be used according to packaging forms and data to be indicated:

RSS-14 Stacked,

RSS Limited,

RSS-14 Stacked Composite Symbol with CC-A,

RSS Limited Composite Symbol with CC-A

CODE 128

AI REQUIREMENTS

Data element	Order	Application identifier
Product code	1	01
Expiration date	2	17
Quantity	3	30
Manufacturing No. or code	4	10

Letter Submitted

HUG

To: The Safety Division

Pharmaceutical and Food Safety Bureau

Ministry of Health, Labour and Welfare

Document of March 24, 2006

“Implementation of Bar Code Labeling of Ethical Drugs”

We thank you for the opportunity to review and comment on the above referenced document. The global Healthcare User Group, GS1 HUG™ (www.gs1.org/hug), comprises representation from major global pharmaceutical and medical device manufacturers (including Japanese manufacturers), wholesalers, hospitals, regulatory bodies and trade associations. The GS1 HUG™ is striving for global standards for automatic product identification and is currently working with a number of regulatory bodies.

The GS1 HUG™ Leadership team has reviewed this document in detail, together with other GS1 HUG members and we would like to provide our comments, which are listed in order of importance, some of which are recommendations for your consideration and some of which require further clarification. We are available to openly discuss these comments should you require clarification or additional information.

Ref. 2 Numbering of product codes and JAN codes

The GS1 HUG is concerned about the requirements for packaging level indicators. In the proposal, definitions are assigned to indicators 0, 1 and 2. The GS1 standards specify such indicators must be unique and do not have intelligence as this limits flexibility for alternate package configurations. We strongly recommend that the rule clarifies that packaging level indicators are not pre-assigned. The manufacturer determines the packaging level indicator and ensures that each is unique. GS1 HUG suggests that the table under section 3 (Changes of JAN codes) be updated to incorporate this approach for JAN code changes.

Ref. 4 Bar code symbol system

The GS1 HUG suggests that any of the approved open GS1 standard symbologies (including RSS, Data Matrix etc.) should be accepted. The market will drive the final selection from the approved standards.

Ref. 5 Order for indicating data elements and application identifiers

According to GS1 standards, Application Identifier AI (30) is used for a variable quantity, not a fixed quantity. AI (37) is to be used for a fixed quantity. The GS1 HUG strongly recommends that AI(30) and AI(37) are used as intended by GS1 standards. The case count field does not aid in preventing dispensing errors and therefore should not be within the scope of this proposed rule.

Ref. 7 (1) Others

This statement indicates two bar codes are required. The GS1 HUG recommends that only a single bar code is printed on any package unit .

Ref. 6 Timing for implementation of the New Bar Code Labeling (1)

It is unclear what products are classified as “specific biological products”. Is there a link to a database that can be shared? Is there logic to how specific biological products are identified?

Ref. ‘Ethical Drugs’

The wording ‘ethical drugs’ is used several times in the document.

The GS1 HUG understanding is that an ethical drug is intended for the hospital market only? Clarification of the terminology should be considered.

Ref.1. (1) Formulation package unit

Clarification is needed around definition of the ‘formulation package unit’. Kits or combination packs may contain a vial of active substance and a vial of liquid for dilution, packaged together. What is defined as the smallest unit of package? The GS1 HUG assumes that the “unit of use” package is considered the formulation package unit.

The GS1 HUG will give serious consideration to suggest that the QR code should be included by GS1 as a future open standard.

HUG COMMENTS TO JAPAN

The HUG is concerned about the requirements for packaging indicator level (example: meanings area assigned to indicators 0, 1 and 2 in Japan). Suggest that future rulemakings to clarify the ruling that Packaging level indicators are not fixed but indeed are flexible. The manufacturer will determine the packaging level indicator and ensure that each is unique. HUG suggests that table under section 3 (Changes of JAN codes) be updated to incorporate this approach for JAN code changes.

The HUG suggests that any of the approved open GS1 standard symbologies (ex: Datamatrix) should be accepted. The market will drive the final selection from the approved standards

According to GS1 standards AI 30 is used for variable quantity, not a fixed amount. AI 37 is to be used for fixed quantities. The HUG suggests that quantity become a voluntary item and driven by the market and not a regulatory requirement

HUG COMMENTS TO JAPAN

HUG recommends that only a single bar code be printed on any package unit

It is unclear what products are classified as “specific biological products”. Is there a link to a database that can be shared? Is there logic to how specific biological products are identified?

The HUG understands that an ethical drug is intended for the hospital market only?

Clarification is needed around definition of the formulation package unit. Kits/combi packs may contain a vial of active, a vial of diluent packaged together. What is defined as the smallest unit of package? The HUG assumes that the “unit of use” package is considered the formulation package unit.

The HUG suggests that the QR code be submitted for approval by GS1 as a future open standard.

Thanks to the leadership team and Medtronics

GS1 HUG

And Our Co- chair

HUG
Vaccine/Biological
Workgroup

Contact details

Steve Hess Merck **stephen_hess@merck.com**
(908) 423 7674
Bruce Cohen GSK **bruce.x.cohen@GSK.com**
(919) 483-9375