IDENTIFICATION RECOMMENDATIONS FOR REPRODUCTIVE HEALTH PHARMACEUTICAL PRODUCTS

REPRODUCTIVE HEALTH GLOBAL TRACEABILITY ADVISORY GROUP

Version 1.1, April 2017

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FOREWORD

In October 2015, USAID and UNFPA collaborated in calling on contraceptive suppliers to provide expert advice on implementing product identification standards to further efforts toward ensuring contraceptive security and patient safety through track-and-trace capabilities. The result was the Reproductive Health Global Traceability Advisory Group (RH GTAG), co-chaired by UNFPA and USAID. Group members include suppliers of implantable, injectable, and oral contraceptives, trade organizations, and other organizations whose work focuses on contraceptive commodity security.

Beginning in November 2015, the group met monthly to discuss the benefits, opportunities, and challenges of implementing standardized product identification and establishing traceability systems, to share developments in global and in-country efforts toward this goal, and to provide recommendations for the best path forward for procuring agencies and donors, such as UNFPA and USAID, in this area. The group's major output was the supplier recommendations in this report. Underpinning the recommendations was a unanimous call from suppliers to adopt global standards and for procuring agencies and donors to work collaboratively to adopt uniform procurement requirements. The next page provides a list of RH GTAG members who have participated in developing the recommendations for reproductive health pharmaceuticals. These recommendations are envisioned to be a major input for developing procurement requirements by USAID, UNFPA, and other agencies.

The co-chairs would like to thank everyone who has contributed to developing these recommendations over the past year. We would also like to extend our appreciation to members of the GS1 global health-care team for their support in the development process.

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ACRONYMS

AI..application identifier

GTIN ....global trade item number

HRI ....human readable interpretation

RH GTAG ....Reproductive Health Global Traceability Advisory Group

SSCC .... serial shipping container code

The Reproductive Health Global Traceability Advisory Group (RH GTAG) recommends the following specifications for packaging to facilitate identification and tracking of RH products. Also included are recommendations for the process and timeline for implementing the specified requirements. The RH products within the scope of these recommendations are oral, injectable, and subdermal implantable hormonal contraceptive methods. Medical device RH products are outside the scope of these recommendations. For identification and marking details in support of these requirements, refer to the GS1 General Specifications[1]. Appendix I provides a table of application identifiers (AIs).

1. GENERAL GUIDANCE

The barcode symbol data carriers referred to here and required for conformance to this procurement document are GS1 DataMatrix[2] and GS1-128.[3]

At the request of the procurement agency and before initial shipment, the vendor will submit actual samples of the barcode symbol (e.g., label, package) for review by the respective procurement agency. Barcode symbols should meet print quality "Grade C" (1.5 or above).[4] Should any barcode symbols be found defective or unreadable at the time of custody transfer to the procurement agency, the vendor should be contacted.

Barcode symbols, with their associated human readable interpretation (HRI), should be positioned according to accepted industry practice and as discussed below. As part of the regular manufacturing/production process, barcode symbol print quality and data content will be verified and graded in accordance with the appropriate sections within the GS1 General Specifications.[4]

The following sections provide the recommended packaging-level requirements. For additional packaging-level definition and details, refer to the GS1 General Specifications.

RH GTAG members have offered varying recommendations on the timeline(s) for implementing identification requirements. They have proposed a two-phased approach for implementation, with appropriate master data exchange executed in both phases. Where compliance is required, recommended timelines for implementing each phase are negotiable and should be determined based on discussions between the procurement agency and its trading partners that take into consideration potential delays due to regulatory registration, review, and approval. Procuring agencies should request voluntary implementation of all identifiers as soon as feasible.

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[1] http://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf.
[2] GS1 General Specifications – Section 5.7 Two dimensional barcodes – GS1 DataMatrix symbology. [3] GS1 General Specifications– – Section 5.4 Linear barcodes - GS1-128 symbology specifications.
[4] GS1 General Specifications – Section 5.5 Barcode production and quality assessment.

2. PROCUREMENT REQUIREMENTS

The following terminology will be used:

"Secondary packaging" refers to the intermediate level of packaging that holds one or more primary containers (e.g., cartons containing one or more items for consumption).

"Tertiary packaging" refers to upper levels of the packaging hierarchy. These may be, for example, cases that contain (one or usually) several items in their secondary packaging or pallets that contain (one or usually) several cases. Tertiary packaging may be used as either a logistic unit or as a trade item.
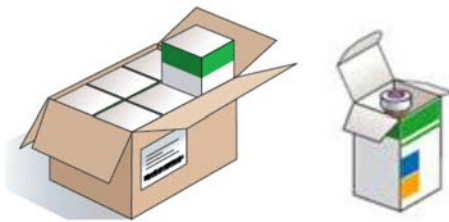
2.1 PROPOSED PROCUREMENT REQUIREMENTS FOR PHASE 1

Phase 1 requirements should be implemented immediately on a voluntary basis. The team recommended a three-year timeline for compliance after issuance by the procurement agency.

At the discretion of each manufacturer, additional information can be added to the electronically readable code using GS1 application identifiers and the HRI.

2.1.1 SECONDARY PACKAGING – MULTI-PACK AND/OR SINGLE-PACK CARTON

- The minimum GS1 identification key, AI, and HRI recommended for inclusion are:

    o AI (01) global trade item number (GTIN)
    o AI (10) batch/lot
    o AI (17) expiration date

- The recommended barcode symbol data carrier is the GS1 DataMatrix.

- Barcode symbols, with their associated HRI, should be positioned according to accepted industry practice.

2.1.2 TERTIARY PACKAGING – TRADE ITEM (PALLET OR CASE)

- The minimum GS1 identification key, AI, and HRI recommended for inclusion are:

    - AI (01) GTIN
    - AI (10) batch/lot
    - AI (17) expiration date

- The recommended barcode symbol data carrier is the GS1 DataMatrix or the GS1-128.

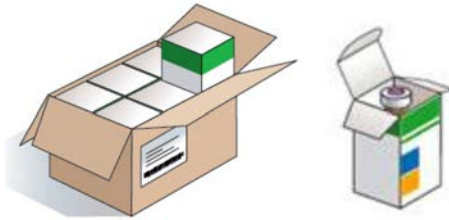## 2.2 PROPOSED PROCUREMENT REQUIREMENTS FOR PHASE 2

The benefits of serialized coding as envisioned in the second phase can be realized only if an information technology infrastructure has been established that enables interchange of transactional data between all supply chain partners involved. Therefore, the requirements reserved for Phase 2 implementation should be initiated by procuring entities once the benefits of implementation of the additional label position requirements and identifiers (serial number and serial shipping container code, or SSCC) and data can be realized within the entities' supply system.

At each manufacturer's discretion, additional information can be added to the electronically readable code using GS1 application identifiers and the HRI.

A summary table of requirements is provided in Appendix II.

2.2.1 SECONDARY PACKAGING – MULTI-PACK AND/OR SINGLE-PACK CARTON

- The minimum GS1 identification key, AI, and HRI recommended to be included are:

  - o AI (01) GTIN
  - o AI (10) batch/lot
  - o AI (17) expiration date
  - o AI (21) serial number

- The recommended barcode symbol data carrier is the GS1 DataMatrix.

- Barcode symbols, with their associated HRI, should be positioned according to accepted industry practice.

2.2.2 TERTIARY PACKAGING – TRADE ITEM (PALLET OR CASE)

- The minimum GS1 identification key, AI, and HRI recommended to be included are:

  - o AI (01) GTIN
  - o AI (10) batch/lot
  - o AI (17) expiration date
  - o AI (21) serial number

- The recommended barcode symbol data carrier is the GS1 DataMatrix or the GS1-128.

- Labels containing the barcode symbols, with their associated HRI, should be positioned on two faces of the tertiary packaging to enable ready access for scanning when the product is stored, stocked on shelves, or handled.

2.2.3 TERTIARY PACKAGING – LOGISTICS UNIT (PALLET OR CASE)

- The minimum GS1 identification key, AI, and HRI for inclusion is:

    - AI (00) SSCC

- The recommended barcode symbol data carrier is the GS1-128 linear barcode.

- Labels containing the barcode symbols, with their associated HRI, should be positioned on two faces of the tertiary packaging to enable ready access for scanning when the product is stored, stocked on shelves, or handled.

3. UNIQUENESS OF SERIAL NUMBERS AND SSCCS

Serial numbers must be generated by a deterministic or a nondeterministic randomization algorithm. The probability that the serial number can be guessed will be negligible – lower than one in ten thousand (1:10,000).

The character sequence resulting from the combination of the GTIN and the serial number will be unique to a given pack of a medicinal product until at least one year after the pack's expiry date or five years after the pack has been released for sale or distribution, whichever is the longer period.

The SSCC must remain unique and not be reallocated for a minimum of one year from the shipment date of the tertiary package (logistic unit) from the SSCC assignor to the trading partner in accordance with GS1 General Specifications.

4. DATA SUBMISSION

The original manufacturer or owner of the GTIN must provide information about the GTIN to the procuring agency. Also, the procuring agency will define which master data/product information it will need from the manufacturer or entity to which the GTIN has been licensed. This process may be facilitated manually or in an automated machine-to-machine fashion with the ability to keep the recipient of the data updated of any changes, updates, or deletions from the data source, through an electronic message, such as provided by the Global Data Synchronization Network.

APPENDIX 1. APPLICATION IDENTIFIERS[5,6]

Application Identifiers	Name	Format	Data Title
00	SSCC	N2+N18	SSCC
01	GTIN	N2+N14	GTIN
10	Batch or lot number	N2+X…20	Batch/lot
17	Expiration date (YYMMDD)	N2+N6	Use by or expiry
21	Serial number	N2+X…20	Serial

[5] For general information on application identifiers, see:
http://www.gs1.org/sites/default/files/docs/barcodes/GS1%20Application%20Identifiers.pdf.
[6] For detailed information on application identifiers including a complete list, see GS1 General Specifications, Section 3.

APPENDIX 2. GS1 IDENTIFICATION KEY AND APPLICATION IDENTIFIERS[7]

Level of Packaging	Phase 1[8]				Phase 2
	GS1 identification key and application identifiers				
	GTIN GS1 AI(01)	Batch/lot GS1 AI(10)	Expiry GS1 AI(17)	Serial number GS1 AI(21)	SSCC GS1 AI(00)
Secondary multi pack and/or single pack carton (always a trade item)	✓	✓	✓	✓	N/A
Tertiary case (trade item)	✓	✓	✓	✓	N/A
Tertiary case (logistic unit)[9]	N/A	N/A	N/A	N/A	✓
Tertiary pallet (trade item)	✓	✓	✓	✓	N/A
Tertiary pallet (logistic unit)[10]	N/A	N/A	N/A	N/A	✓

[7] See the latest version of the GS1 General Specifications for details, definitions, and use application.

[8] For information on implementation timelines, see Section 2.1, Proposed Procurement Requirements for Phase 1, and Section 2.2, Proposed Procurement Requirements for Phase 2.

[9,10] At a minimum the GS1 identification key SSCC AI(00) must be applied to any logistic unit. If the logistic item is also a trade item, then the GS1 GTIN AI(01) and other GS1 AIs noted can be added. For details, see the latest version of the GS1 General Specifications.

Identification Recommendations for Reproductive Health Pharmaceutical Products

Reproductive Health Global Traceability Advisory Group

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