The Global Language of Business

Public Community Review:

Identification of Repackaged Medicinal Products for dispensing purposes - Survey

Review period: Until 28th January 2022

Reviewer details (please add your information below)

Name: _____

Job Title: _____

Organisation: _____

Email address: _____

Introduction

There is a need to for clear guidance regarding how to identify repackaged medicinal products – both patient specific and non-patient specific. This is because it is common practice that primary and secondary packages are fully unpacked, or unpacked to the primary package, and subsequently repackaged to create a new package, often for a specific patient to support dispensing purposes. Repackaging is often done by a hospital, service provider or retail pharmacy, including for long term care. Lack of harmonised identification prevents easy and trusted registration of what products, at what time, have been repackaged and dispensed and used by the patient. Ultimately this breaks traceability.

We are working to produce recommendations to enable globally harmonised implementation of standards for stakeholders to identify and barcode repackaged medical products.

Recommendations in the scope of our work are for:

- The identification and data capture with GS1 standards of the:
    1) repackaged single / multiple unit(s) (not patient specific)
    2) repackaged single / multiple medicinal product dose (patient specific)
    3) collected single and multiple medicinal product dose(s) (logistics units created for transport)
    4) the prescription bag (patient specific)
- The identification and data capture to support safe and efficient dispensing and administration processes by the healthcare provider.
- The identification of the prescription, repackaging machine, and patient identification.

Products in scope of this guideline are:

- All medicinal products (prescription/Rx + OTC).
- All medicinal forms like solids, semi-solids, and liquids. This includes pills, vials, ointments, injections, and nebules.

Out of scope of this guideline are:

- Reconstituted products.
- Compounded products.

These products are out of scope because guidance is already offered as part of the Healthcare GTIN Allocation Rules.

2.1 GS1 standards

GS1 standards provide the common language to identify, capture and share supply chain data ensuring important information is accessible, accurate and easy to understand.

In healthcare, harmonised implementation of GS1 standards in business and clinical processes enables interoperability, optimal quality, and healthcare delivery efficiency to benefit patients. This will lead to enhanced patient safety and supply chain efficiency, through ensuring improved identification and traceability of medical devices and medicines.

Identification and data capture of repackaged products for dispensing purpose

3.1 Repacked single / multiple unit(s)

The repackaged single / multiple unit(s) is repackaged centrally by a healthcare provider or third-party for the healthcare provider to ease dispensing. This product is not personalised and thus could be repackaged by the repackager at any time and delivered directly when an order by a healthcare provider is sent. While repackaging, the intended recipients are not known.

Medicinal products that are traded items are often pills or capsules, but can also be other forms of medication, including liquids (e.g., syrup packaged into a medicine cup sealed and repackaged), powders, vials, or ampoules.

A third party repackager or healthcare provider has two options to repack a medicinal product:

- a medicinal product that is without primary packaging
- a medicinal product where the primary package remains

3.1.1 Questions for your input

- The table below asks questions regarding the recommendations on how to identify repackaged units for dispensing purposes. Please indicate whether you agree or disagree. We would also encourage comments, especially where you may not agree with the recommendation(s) being proposed.

Title	Description	Recommendation	Agree Y/N	Comments
Identification of a medicinal product that is **without primary package**	When the medicinal product is fully unpacked, including removing any primary packaging (packaging immediately surrounding the medicinal product), and repackaged, the responsibility for the product now lies with the repackager. The repackaged single unit / multiple unit(s) is like any other product traded in healthcare, needing a globally unique identifier.	This identifier should be in line with GS1 standards and within the GS1 standards this identifier is called a GTIN - Global Trade Item Number As the repackaged single / multiple unit is considered a new traded item, a new GTIN, Global Trade Item Number (GTIN), needs to be assigned to the repackaged single unit.		
Identification of a medicinal product **when the primary package remains**	Sometimes the primary package of the medicinal product remains. In situations where the primary packages that are being repackaged for dispensing purposes and **already have an identifier allocated by the brand owner (a GTIN) assigned.** a. **The primary package has an identifier allocated by the brand owner** (a GTIN), and the GTIN is encoded in a data carrier on the primary package OR the primary package has a GTIN, but the GTIN is not encoded in a data carrier on the primary package.	A new identifier needs to be assigned to the repackaged single or multiple medicinal product. This is to help differentiate the original primary package(s) from the repackaged medicinal product. The identifier (GTIN) assigned to the repackaged single / multiple unit(s) is assigned by whoever is responsible for the specifications of the repackaged		

		single unit (contract giver, e.g., pharmacy or hospital who has responsibility or the third-party repackager).		
	Sometimes the primary package of the medicinal product remains. In situations where the primary packages that are being repackaged for dispensing purposes and **already have an identifier allocated by the brand owner (a GTIN) assigned**. b. **When the healthcare provider repackages the primary package (within their facility)** and this only for their internal dispensing purposes, and the repackaged single unit / multiple unit(s) remains within the healthcare provider's **closed loop processes**. For this scenario, the same principles are relevant as described above.	It is unnecessary to assign a new GTIN to the repackaged single unit, as long as the repackaging has not impacted the product's form, fit or function or performance characteristics. This means the brand owner allocated GTIN can be applied on the new dose packaging surrounding the primary package. For repackaged multiple units, a new GTIN must be assigned by the hospital as a new trade item has been created.		
	Sometimes the primary package of the medicinal product remains. In situations where the primary packages that are being repackaged for dispensing purposes and **already have an identifier allocated by the brand owner (a GTIN) assigned.** **c. The primary package does not have GTIN.** A dose package is created and surrounds one or many primary package(s) (that do not have an identifier allocated by the brand owner, a GTIN).	A new GTIN must be assigned by whoever is responsible for the specifications of the repackaged single or multiple unit (contract giver, e.g., pharmacy or hospital who has responsibility or the third-party repackager).		
Additional information to be included in the barcode	From a safety perspective, there is a strong recommendation for extra product attribute information to be printed in the barcode on the repackaged single unit / multiple unit(s) that will be used in addition to the product identifier.	Recommended data to be included: • Expiration date - The expiration date is the date that determines the limit of consumption or use of a product. • Batch number - Associates a product with information the manufacturer considers relevant for traceability of the product. • Date of manufacturing / production date (optional) - The production date is the production or assembly date determined by the manufacturer. Extra attribute information like strength should be captured in a database easily accessible to the healthcare provider dispensing or administering repackaged medicinal product.		

Repackaged single unit / multiple unit(s) secondary or logistic item	For storage and transportation purposes, the repackaged single unit / multiple unit(s) might be collected and packaged in : a. Secondary product packaging (a larger package that is considered a traded item) for example a roll of dose packages or a box containing dose packages. OR	When the repackaged single / multiple unit(s) secondary packaging is a trade item, a GTIN must be assigned.		
	For storage and transportation purposes, the repackaged single unit / multiple unit(s) might be collected and packaged in: b. A logistic item (a unit created purely for transportation efficiency) for example a roll of dose packages or a box containing dose packages.	A logistic item should also be identified in line with GS1 standards and within the GS1 standards this identifier is called a Serial Shipping Container Code (SSCC) which can be assigned any combination of products created into a unit for logistics or shipping. The extra product attribute information applied in barcodes for secondary packaging or logistics units should reflect what is on the repackaged single unit / multiple unit(s) package.		

3.2 Single and multiple medicinal product dose

Single

A 'single medicinal product dose' is one dose of one medicinal product (e.g., paracetamol), but there could be more or less than one item of that medicinal form, e.g., half, one, 1.5 tablets. The medicinal product could also be a liquid drawn into a syringe in a vial or glass bottle, an ampoule, ointment in a cup, etc.

The single medicinal product dose package is created for dispensing purposes and is for a specific person for a specific date and moment in the day (e.g., 8 am, 1 pm and 6 pm). The product is dispensed by a pharmacist after prescription by a doctor, often in the hospital or in care homes.

Multiple

A 'multiple medicinal product dose' means more than one distinct medicinal product (e.g., paracetamol and omeprazole). There could be more or less than one item of each medicinal product, e.g., half, one, 1.5 tablets. In other words, there may be in one medication administration (one moment of intake) several pharmaceutical dose forms from different medicinal products in one container.

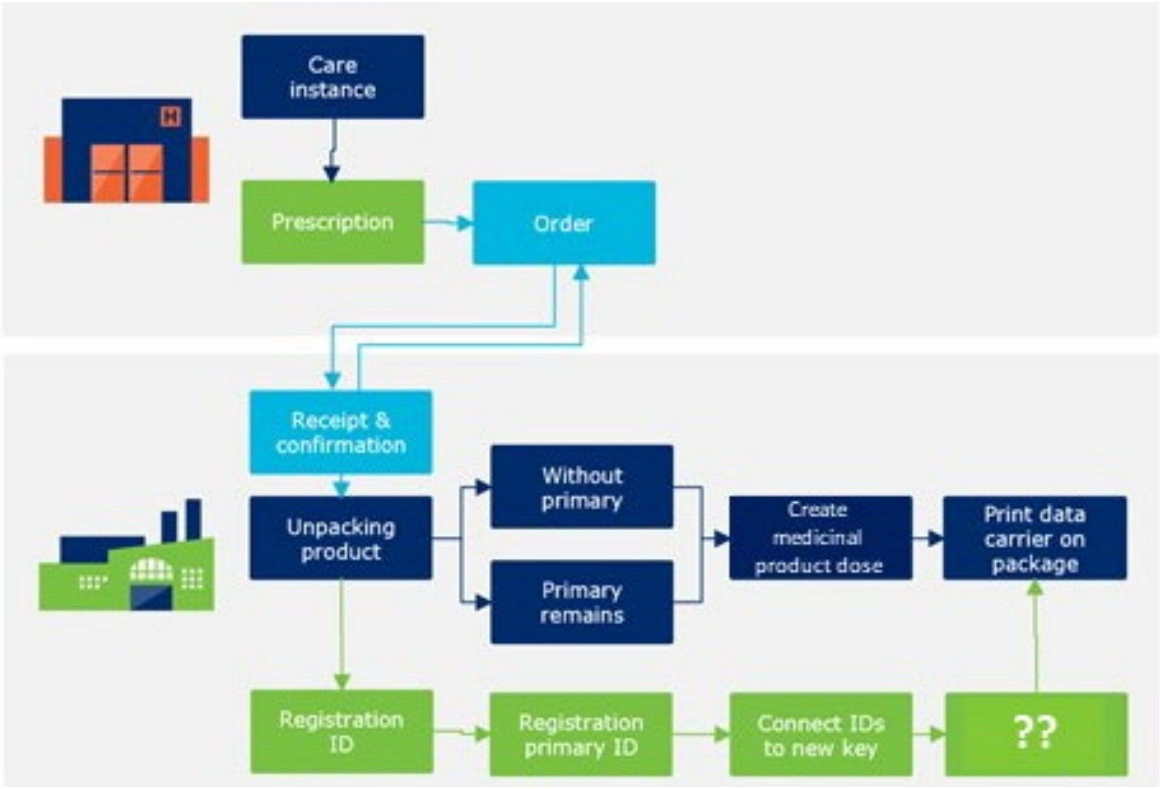
- Note that in some countries this is also referred to as a repackaged multiple unit.
- Note that this is distinct from a multi-dose when there are multiple doses of a medicine in one unit, e.g., when eye drops have multiple doses in it.

The multiple medicinal product dose package is for a specific person for a specific date and moment in the day (e.g., 8 am, 1 pm and 6 pm). The product is dispensed by a pharmacist after prescription by a doctor, often in the hospital or in care homes.

An example is shown below.

3.2.1 Process

The figure below shows the process steps in scope:



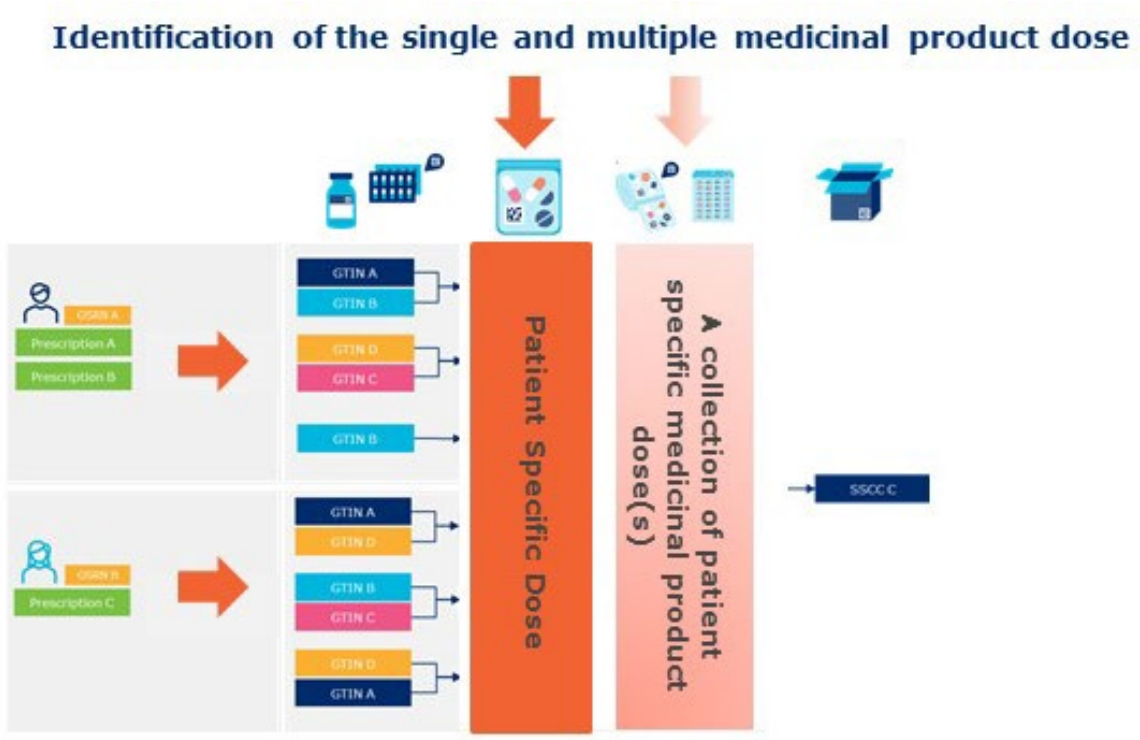
3.2.2 Questions for your input

Does this flow chart **accurately represent the process steps** for creating repackaged single and multiple product doses?

Questions	Y/N/Partially	Comments
Is this flowchart **accurate and appropriate**?		
Are there any **steps missing** from this process?		
Are there any **unnecessary (superfluous) steps** in this process?		

3.2.3 Identification of the single and multiple medicinal product dose

We are seeking community feedback as to the appropriate identification option(s) to be selected and used for the "Identification of Medicinal Products – Patient Specific Dose" – please refer to the graphical depiction below.



3.2.4 Question for your input

What information do you believe needs to be **included in barcode on a single or multiple medicinal product dose**?

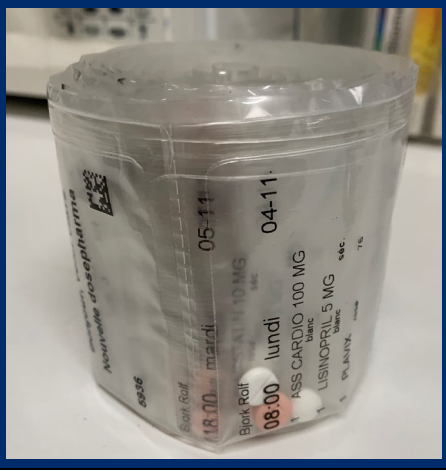
Data	Yes – Mandatory / Yes – Optional / No	Comments
A non-serialised identifier, simply identifying the dose, i.e., doses sharing the same contents may have the same identifier.		
A serialised identifier i.e., a unique identifier for each dose.		
Identification of the prescription used as the instruction to create the dose.		
Identification of the patient to whom this to be given		
Expiry date of the dose (as defined by repackager)		

Data	Yes – Mandatory / Yes – Optional / No	Comments
Packaging date (as defined by repackager)		
Batch of the dose (as defined by repackager)		
Intended date and time of dose use (as defined by prescription)		
Other data		

3.3 Collected single and multiple medicinal product dose

The collected single and multiple medicinal product dose is a collection of the repackaged doses. These are collected in a roll or box that contains doses for a more extended period, e.g., a week and may be for a single patient or for multiple patients. The rolls or boxes are dispensed by a pharmacist after prescription, often in the hospital or in care homes. Examples are shown below.

The collected single and multiple product dose needs to be identified for traceability purposes.

Large blister of multiple medicinal product doses	Large roll of multiple medicinal product doses
	

Multiple collected single and multiple medicinal product dose rolls or blister packages could be packaged and shipped together from the repackager to the healthcare provider. To enable communication about the entire shipment, it is possible to build a parent-child relationship.

3.3.1 Questions for your input

Do you agree with the following statements regarding **identification and barcoding of collected single and multiple medicinal product doses**?

Questions	Y/N/Partially	Comments
Each roll or blister (logistic unit) needs to be identified		
This logistic unit identifier should be in line with GS1 standards		

Questions	Y/N/Partially	Comments
Where there are multiple rolls or blisters grouped together to create a larger unit for shipping purposes, this should also have an identifier.		

Within the GS1 standards the identifier for logistics and transportation packages is called the Serial Shipping Container Code (SSCC).

3.4 Prescription bag

Primary and/or secondary and/or repackaged products packages are packaged together in a sealed bag or carton at a central location to easy dispensing. The bag or carton might contain medicinal products for a longer period (e.g., a week or month) and can contain different types of medication. This bag is often dispensed by the retail pharmacist after prescription by a doctor and is used at home or in care homes.

3.4.1 Questions for your input

Do you agree with the following statements regarding **identification and barcoding of prescription bags**?

Questions	Y/N/Partially	Comments
The prescription bag needs to be identified to enable easy identification of products contained within the bag and verification of dispensing of the right bag to the right patient by the pharmacist.		
Because the prescription bag is not considered a trade item and is essentially a package to support easy transportation of medicinal product packages, it should be considered a logistic unit.		
Where there are multiple rolls or blisters grouped together to create a larger unit for shipping purposes, this should also have an SSCC.		
Each logistic unit needs to be identified in line with GS1 standards.		

Within the GS1 standards the identifier for logistics and transportation packages is called the Serial Shipping Container Code (SSCC).

3.5 Identification of the repackaging robot

The repackaging robot can be fixed in place or mobile and it is used to create the repackaged single unit, or the repackaged single or multiple medicinal product doses, and the collected single and multiple product doses. The repackaging robot can be owned by the healthcare provider/hospital facility, or by a third-party repackager.

3.5.1 Questions for your input

Do you agree with the following statements regarding **identification of repackaging robots**?

Questions	Y/N/Partially	Comments
When an asset (repackaging robot) needs to be uniquely identified it should be in line with GS1 standards.		

Within the GS1 standards the identifier for fixed assets is called the Global Individual Asset Identifier (GIAI).

3.6 Identification of reusable transportation packages and the doses contained within

The single or multiple medicinal product doses are often distributed and dispensed in a reusable transportation **plastic box or Webster pack**. This reusable package is considered an asset and needs an identification number to trace the reusable packaging for inventory control of that packaging and to locate the packaging in various locations for financial recording.

3.6.1 Questions for your input

Do you agree with the following statements regarding **identification of reusable transportation packages and the doses contained within?**

Questions	Y/N/Partially	Comments
Reusable transportation packages such as a Webster pack or plastic box are considered assets		
These need an identification number to trace the reusable packaging for inventory control of that packaging and to locate the packaging in various locations for financial recording.		
That identifier should be in line with the GS1 standards.		
The doses contained within the reusable packages are to be identified as per the repackaged single and multiple medicinal product dose recommendations.		

Within the GS1 standards the identifier for returnable assets is called the Global Returnable Asset Identifier (GRAI).