Draft position on barcodes/ packaging *Single Unit Packages of Varying Formulations* (EAG)

Position of NVZA, June 2015

The 'Nederlandse Vereniging van Ziekenhuisapothekers' *('Dutch hospital pharmacists' association, NVZA) takes the view that all medication used in hospitals should be available in Single Unit Packages (known as EAG).*
One of the most important requirements of this type of packaging is the presence of the correct barcode.[1] This makes it possible to record the administration of medication electronically, which significantly contributes to greater safety in this area.
For more information, please contact the secretarial offices of the NVZA:

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1. A worldwide standard

The healthcare sector is preparing to put the GS1 Data Matrix on all medications. This symbol is very small and contains a great deal of information. This is necessary because:

- As well as identification, there is a need for additional information about the product, such as expiry date and batch number.
- The symbol must be put directly on the product and therefore needs to be very small. The GS1 Data Matrix meets these conditions.

European legislation in this area is currently under preparation and all parties are expected to comply with these new laws by 2018.

2. Policy

The NVZA is aiming to have all medication available in EAG. In order to achieve this objective, the NVZA is proposing the following starting points:

- Uniform coding, taking national and international standards in the trading of medication into account.
- Use of EAG (this is a simplification of the *Single Unit Supply Packages* (known as EAV)). Because of the minimal requirements that the EAG must meet, it is being made easier to apply this type of packaging in primary healthcare.
- Reaching agreement with all partners in the healthcare sector in achieving a speedy transition. This means both ensuring that the products are available and the use of these products in hospitals, as intended.

2.1 Aiming to increase in scale by replacing EAV packaging by EAG, for the following reasons:

- Usability in primary and secondary healthcare
- In line with international developments.
- Reducing the definition of EAG to its essence.
- Limiting the requirements that apply to EAG to an absolute minimum.
- Communicating the importance of EAG among other organisations and manufacturers.

[1] The word 'barcode' is used for the sake of convenience. This refers to a code that can be read by a machine, such as a Data Matrix.

- Meeting national and international standards in the trading of medication.

Notes: The NVZ (Netherlands Association of Hospitals) has emulated the decision of the NFU (the Netherlands Federation of University Medical Centres) to use the international GS1 coding system as standard. Both organisations have made this decision in order to increase patient safety and improve logistical efficiency. This has led to Z-Index deciding to introduce a link in the G-standard with the GS1 identification code (Global Trade Item Number, GTIN). The barcodes of EAG packaging should therefore be based on the GS1 standards.

3. Requirements of EAG packaging

Packaging can be defined as EAG if the medication is packaged per single unit, for use within every link of the logistical channel, up to the moment of its consumption by or its administration to the patient. Each single unit package can clearly be identified visually and by means of a barcode.

This is subject to the following requirements:

1. Packaging: packaged as single unit and can be opened/used without the use of any tools or instruments.
2. Labelling: for each unit the following items are present: name of substance + strength + expiry date + batch number + (if necessary) method of administration
3. At the single dose level at least, a barcode in GS1 Data Matrix format including GTIN, expiry date, and batch number.
4. The GS1 standard is used at the primary (single dose), secondary, and tertiary level (case/shipper) packaging. **See notes**.

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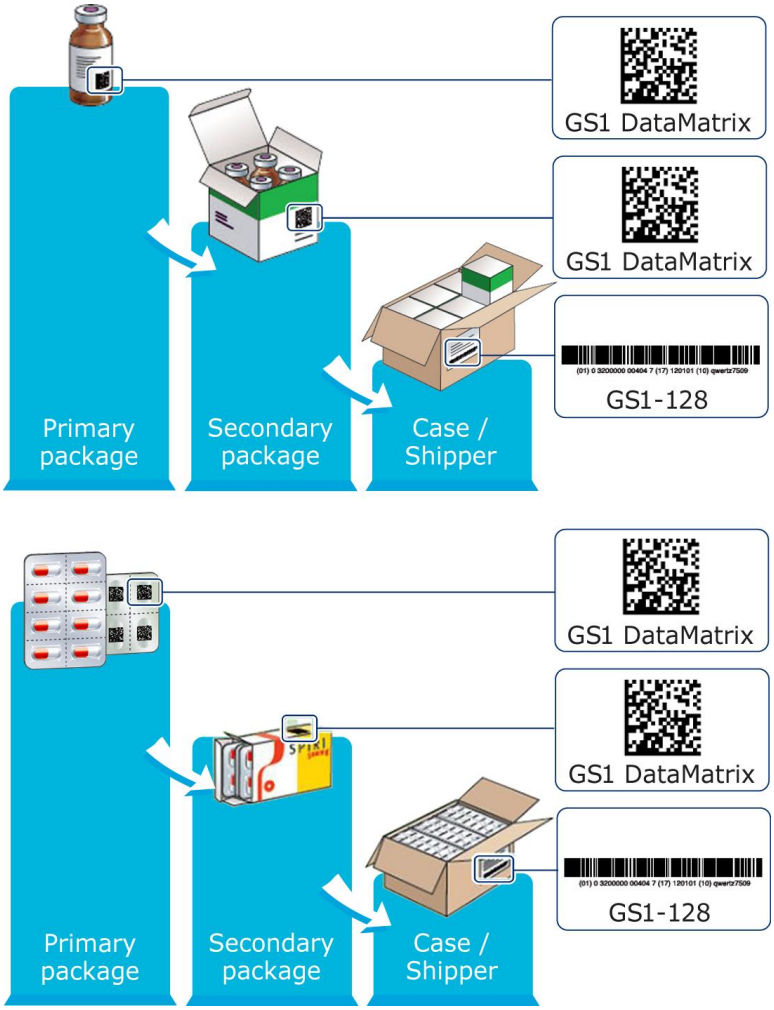
Notes: The international healthcare sector has explicitly opted for the barcode technology of the GS1 Data Matrix. As well as the GTIN, the 'expiry date' and 'batch number' data can be included in this symbol. The barcode is small enough to be printed on every cell.



Primary packaging – the 'single dose' or EAG
On the primary packaging, you use the GS1 Data Matrix
Data in the bar code: Global Trade Item Number (GTIN), batch number, and expiry date

Secondary packaging
On the secondary packaging, you use the GS1 Data Matrix
Data in the barcode: Global Trade Item Number (GTIN), batch number, and expiry date

Case/shipper
On the trade unit, you use the GS1-128
Data in the barcode: Global Trade Item Number (GTIN), batch number, and expiry date

Note: European legislation (Falsified Medicines Directive) may require additional information such as a serial number on secondary and tertiary packaging.

For more information on coding, the barcodes, the data in the barcode, the location of the barcode on packaging, or technical or other support, we refer you to GS1 Netherlands (www.gs1.nl).