

202X - X.XXX.X**Appendix 2 Barcode Requirements**

Secondary packaging - regulatory requirements¹

For pharmaceuticals produced on or after 9 February 2019, it is a requirement that the secondary packaging be marked with 2D (GS1 DataMatrix) barcode containing GTIN, expiry date, batch/lot number and serial number.

Primary packaging - Amgros' requirements

Amgros requires a barcode on the primary packaging for all medicines for oral use, external use as well as injection and infusion.

The barcode must either be an EAN 13 barcode or a 2D (GS1 DataMatrix) barcode and must as a minimum contain an NTIN or a GTIN.

Pharmaceuticals for oral use means:

- Tablets or capsules
- Oral fluids and drops

Pharmaceuticals for external use means:

- Ointments, creams, or gel
- Cutaneous liquids

Pharmaceuticals for injection means:

- Injection fluid
- Injection fluid concentrate
- Powder for injection
- Injection fluid in pre-filled syringe

Pharmaceuticals for infusion means:

- Infusion fluid
- Infusion fluid concentrate
- Powder for infusion fluid

The following medicines are exempt from the requirement for a barcode on the primary packaging:

- Tablets or capsules in blister sheets or other similar packaging in which tablets/capsules are single dosed individually.
- Pre-filled single-dose containers (e.g., pre-filled pens/syringes) that are intended for use for one dose/patient and where multipacks of the drug in question do not exist.

1 January 2023

¹ The paragraph "Secondary packaging - regulatory requirements" is only provided as courtesy information for the Supplier and does not provide an exhaustive list of the regulatory requirements, nor, therefore, any exemptions from or modifications of the law. Amgros is therefore not responsible for any errors or omissions in the text. The Supplier remains responsible for compliance with the law in the area