

202X - X.XXX.X

Appendix 2 Bar code requirements

Secondary packaging - regulatory requirements¹

For pharmaceuticals produced on or before 8 February 2019, it is a requirement that the secondary packaging is marked with either EAN 13- bar code or 2D (GS1 DataMatrix) bar code containing as a minimum an identification key.

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

Primary packaging - Amgros' requirements

For all pharmaceuticals for oral use, all pharmaceuticals for external use, as well as all pharmaceuticals for injection and for infusion, it is a requirement that the primary packaging is marked with a bar code. However, this requirement does not apply to tablets or capsules in blister sheets or other similar packaging in which tablets/capsules are single-dosed individually.

The bar code must either be an EAN 13 bar code or a 2D (GS1 DataMatrix) bar code and must as a minimum contain an identification key.

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

¹The 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.

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

Pharmaceuticals for infusion means:

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

1 January 2022

EXAMPLE