

Country specific information – Denmark

Content:

- **Barcodes for Primary package**
- **Non-pharmaceutical products**
- **Pricing of the Danish Vnrs**
- **New rules for already marketed packages**

Country specific information - Denmark

Barcodes for Primary package

Please note that Amgros requires bar codes for drugs supplied via tenders.

Read more on the homepage for Amgros

<https://levportal.amgros.dk/Stregkodemaerkning/Sider/Default.aspx>

Non-pharmaceutical products

The Nordic article numbers, Vnrs, are only allocated for **registered pharmaceuticals**.

All other products, such as medical devices and consumer products, use national numbers. The national numbers are given by the wholesalers Nomeco (sortiment@nomeco.dk) or Tjellesen Max Jenne (indkoeb@tmj.dk).

Pricing of the Danish Vnrs

Nordic article numbers, allocated for Denmark, are invoiced by Dansk Lægemiddel Information A/S.

New Vnrs are invoiced with an opening fee after assignment. Please note that the opening fee will be invoiced even if the Vnr should be withdrawn shortly after the assignment.

All active Vnrs are also invoiced annually. The annual fee is invoiced in the beginning of the calendar year.

New article numbers for already marketed packages

Marketed packages must receive a new Nordic article number if:

- The name of the medicine changes

New rules governing medicine packages

On 25 June 2016, the Danish Medicines Agency issued a new guideline on variations to marketing authorisations for medicinal products and a new executive order on product numbers for medicinal products. They replace guideline no. 126 of 16 December 2009 on variations to marketing authorisations for medicinal products and executive order no. 943 of 22 August 2011 on product numbers for medicinal products.

With the new guideline, the Danish Medicines Agency will ease the administrative and financial burden of implementing certain administrative variations. For example, if the marketing authorisation changes ownership or other changes are made to the company information. In future, the implementation process will provide greater flexibility combined with a relaxation of the product number requirement, which will facilitate the introduction of new (changed) medicine packages and reduce medicine wastage and supply issues.

The new rules will make it possible to have two versions of a medicine package in the market at the same time during an implementation period of a maximum of two years. Ahead of this, there will be a period of up to one year from the authorisation of the variation during which the marketing authorisation holder can prepare the implementation of the variation. This means that when the marketing authorisation of a medicinal product changes ownership – and if the medicinal product name is not changed simultaneously – it will be possible to have the old as well as the new packages in the market in Denmark at the same time. Moreover, the packages can have the same product number.

Note that the product number requirement is also eased for multi packages and large packages:

3.-(1) A multi-pack must be provided with a separate product number. Multi-pack means a package consisting of two or more identical packages of an authorised medicinal product (part-packs) that can also be sold separately.

(2) The individual part-packs of a multi-pack must be provided with a separate product number.

(3) The part-packs can carry the same product number as similar packages sold separately without having formed part of a multi-pack. This does not apply to prescription-only medicinal products for pets.

(4) As regards prescription-only medicinal products for pets, part-packs forming part of multi-packs of different sizes must carry a separate product number for each multi-pack size.

4.-(1) A large pack must be provided with a separate product number. Large pack means a package of medicine with a medicinal product for animals consisting of two or more inner packages that are not packed as unit packs, but which provides the medicinal product with sufficient protection against external influences.

(2) The individual inner packages of a large pack can be provided with a separate product number.

(3) As regards prescription-only medicinal products for pets that may be split up, the inner package must have a separate product number for each large pack size that the inner package forms part of.