LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

This is a translation of the Danish executive order on product numbers for medicinal products (Danish title: Bekendtgørelse om varenumre til lægemidler). Only the Danish version has legal validity.

Executive order on product numbers for medicinal products[1]

The following is laid down pursuant to sections 83(2) and 104(3) of the Danish Medicines Act, see the consolidation act no. 506 of 20 April 2013:

1.-(1) Each individual pharmaceutical form, strength and package size of an authorised medicinal product must be provided with a unique product number, but see section 9.
(2) A package of medicine must be provided with a new product number if the medicinal product changes names.
(3) Subsection 2 does not apply to medicinal products that have been given a product number but are not marketed yet.

2. An allocated product number can only be used for one marketing authorisation number.

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.

5. Magistral medicinal products must be provided with a product number if they are listed in appendix 2 to the executive order on the reporting of information for medicinal product statistics.

6. The product number must be added to the package of medicine in such a way that it cannot be removed.

7.-(1) Product numbers for authorised medicinal products can be ordered from the Danish Medicines Agency or the institution authorised by the Danish Medicines Agency to allocate product numbers. The Danish Medicines Agency can provide information about where to order product numbers.
(2) No later than 14 days before a product number is to be used (the package is placed on the market), it must be reported to the Danish Medicines Agency. This also applies to product numbers for part-packs or inner packages. Reporting must be made electronically to Medicine Prices via DKMAnet.

8. If a package of medicine, which is being phased out or has been phased out and therefore permanently removed from Medicine Prices, should be marketed again at a later date, the package of medicine must be created with a new product number and notified as a new package to Medicine Prices via DKMAnet.

[1] The draft version of the executive order has been notified in accordance with Directive 98/34/EC of the European Parliament and of the Council (directive laying down a procedure for the provision of information) as amended by Directive 98/48/EC.

9. The executive order does not apply to medicinal products covered by

1) the executive order on homeopathic medicinal products,
2) the executive order on natural medicinal products and traditional herbal medicinal products,
3) the executive order on radiopharmaceuticals or
4) the executive order on vitamin and mineral preparations etc.

10. In special cases and on conditions established for each individual case, the Danish Medicines Agency may grant exemptions from the provisions of this executive order.

11.-(1) Any violation of sections 1-6, 7(2) or 8 is punishable by a fine.
(2) Companies, etc. (legal entities) will be held criminally liable under the provisions of Part V of the Danish Criminal Code.

12.-(1) This executive order enters into force on 25 June 2016.
(2) Executive order no. 943 of 22 August 2011 on product numbers for medicinal products is repealed.

Danish Medicines Agency, 22 June 2016

THOMAS SENDEROVITZ

/ Mette Aaboe Hansen