UST-32 version 2 EAN CODE REPORTING AND REGISTRATION

This guideline supersedes the original guideline UST-32 version 1.
Effective date: 17.9.2009

The State Institute for Drug Control (SÚKL) hereby notifies the marketing authorisation holders of the duty to label all authorised medicinal products with the European Article Numbering (EAN) Code, as implied by the provisions of Section 37, paragraph 1 of Act No 378/2007 Coll., as amended, and its implementing decree (Decree No 228/2008 Coll. Section 3, paragraph 6 (a) 6).

Authorised medicinal products released for circulation and not labelled with the EAN Code or labelled with another Code than the one recorded in the SÚKL registry shall be considered defective by SÚKL with the relevant consequences for the manufacturer/marketing authorisation holder and the qualified person of the manufacturer responsible for the release of the batches with the defective labelling. Please note that the labelling of a medicinal product with the EAN Code is an important part of the product identification in the distribution chain and that an incorrect labelling may cause confusion. That is why labelling with EAN Codes is considered a manufacturing operation, is subjected to the principles of Good Manufacturing Practice, and in some cases defective labelling may also trigger an action against the defective product.

The allocation of EAN Codes and its statement on the labelling is the responsibility of marketing authorisation holders and relevant manufacturers.SÚKL ensures only the registration of the EAN Codes and their publication. SÚKL publishes the Codes in separate files on its website. The files contain both the lists of inserted SÚKL Codes for individual medicinal products and the relevant EAN Codes pertaining thereto (PROPRIETARY MEDICINAL PRODUCTS and HOMEOPATHIC PRODUCTS) and a list of products with effective authorisation and missing EAN Codes. These files are intended as a means of control for the MA holders to see whether the notified EAN Codes are correctly maintained in the SÚKL database.

In order to ensure that the list of effective EAN Codes for individual medicinal products is kept up-to-date it is necessary for marketing authorisation holders to provide to SÚKL the following information for all marketed presentations prior to the placement of the product into circulation:

- Newly allocated EAN Codes for authorised medicinal products identified by separate SÚKL Codes or, where relevant, for new batches which are placed onto the market initially, unless these presentations have already been allocated EAN Codes and these EAN Codes have been registered by SÚKL;
- Any changes to the EAN Codes; changes may be implemented only if the concerned EAN Code has not been allocated to a batch of a medicinal product which has already been placed onto the market.

A new EAN Code has to be reported also if an import of a foreign-language batch has been authorised for the product (the foreign-language batch has to be distinguished from the authorised presentation).

SÚKL prefers the 13-digit type of EAN Codes, but with a view to the practical needs of marketing authorisation holders it also accepts 8-digit EAN Codes. EAN Codes allocated in countries other than the Czech Republic are acceptable.

Although, for the purposes of surveillance over medicinal products, it is ideal for one EAN Code to correspond with one SÚKL Code, SÚKL allows for one SÚKL Code to have several EAN Codes at one time. It is not acceptable for one EAN Code to identify presentations of a medicinal product distinguished by various SÚKL Codes. Amendments and changes to EAN Codes shall not be considered variations to marketing authorisation.

Please report the EAN Code by completing the following table in EXCEL.

Sample of the EXCEL table:

Marketing authorisation holder SÚKL Code	Product name	Pharmaceutical form	MA number	EAN Code	EAN Specification

1. The table shall provide the EAN Codes for all product presentations (SÚKL Codes) with the status of marketing authorisation of R, B, Q, which are intended for placement onto the market in the Czech Republic.
2. You may register several EAN Codes for a single SÚKL Code under the item EAN Code, providing each EAN Code in one row of the list.
3. If an EAN Code is transferred for use with another medicinal product or medicinal product presentation, it is also necessary to specify the original SÚKL Code.
4. The file with the notified EAN Codes – company name and date.

Please send your notifications to the e-mail address **informatika@sukl.cz** or in writing (label your delivery with the words "EAN Codes") to the following address:

Státní ústav pro kontrolu léčiv
Sekce informatiky
Šrobárova 48
100 41 Praha 10

Once an EAN Code is reported, SÚKL will provide the reporter with an electronic confirmation of the inclusion of the EAN Code to the SÚKL database.
Should you have any queries, please contact Ms Marie Ješátková at **marie.jesatkova@sukl.cz** .