

UST-31 Version 2 Principles of identification of medicinal products for human use in the Czech Republic

This guideline replaces UST-31 Guideline Version 1 with effect from 24 July 2013.

The State Institute for Drug Control (hereinafter referred to as the Institute) adopted a change in the existing system of assigning SÚKL codes for medicinal products with effect from 1 July 2007. Until then, codes were assigned to the so-called "sub-presentation" of a medicinal product, i.e. to the manufacturer. The codes are now assigned to the marketing authorization holder.

Several types of information assigned to individual products are used for unambiguous identification of medicinal products in the Czech Republic and the European Union. In addition to the name of the product, identification of the marketing authorization holder and other information required on the packaging of products, several types of codes are used to identify, simplify and refine the handling of the products. As the orientation in the mechanisms of the allocation and significance of these codes is often subject to uncertainties and assumptions, we present in this guideline an overview of individual types of code identification of medicinal products which can be encountered by operators and persons handling medicinal products. Various ways of allocating code identification were gradually developing in response to the changing needs of their users and the development of legislation. A difficulty occurring in changes in access to the code identification lies in the fact that changes of their format usually require adjustments to the software of the code users, and therefore they are coordination-intensive when there are large numbers of users of various drug databases.

1. Marketing Authorization Number

Marketing authorisation numbers are used to identify medicinal products, which have been granted a marketing authorization, and to facilitate the overview of authorized products. They are mandatory (according to Decree No. 228/2008 Coll., on Registration of Medicinal Products) on the packaging of the medicinal product and can be found on-line at SÚKL website (www.sukl.cz) - Medicines - Outputs from the Database - SÚKL Code List - KLK.dbf.

In different EU countries, marketing authorisation numbers do not have a uniform format and the approach to their allocation is not unified either. While marketing authorisation numbers distinguish each authorized medicinal product presentation in some states, only different marketing authorizations are distinguished in other states. In this case, one marketing authorisation number identifies various package sizes or types of packaging. A relationship to global marketing authorization, i.e. the registration of the first presentation of the medicinal product with the given active substance for a specific authorization holder, can be derived from some types of marketing authorisation numbers.

On the date of accession of the Czech Republic to the EU, i.e. on 1 May 2004, marketing authorizations issued by the European Commission to the products registered through so-called EU centralized procedure came into force in the territory of the Czech Republic. Therefore, in the Czech Republic either marketing authorisation numbers assigned by the Institute can be seen in the case of validly authorized medicinal products or marketing authorisation numbers assigned by the European Medicines Agency in the case of centrally authorized medicinal products. The format and the principles of assigning these numbers are different.

Marketing authorisation numbers assigned by the Institute

Marketing authorisation numbers issued by the Institute are structured AA/BBBB/XX-C or S/C 1). Individual parts of the marketing authorisation numbers indicate:

AA - indication group according to historical classification. This therapeutic classification is only indicative. It is used solely for internal needs of the Institute, it is not consistently linked to the ATC code system, it is not related to the reimbursement system for medicinal products and therefore is insignificant for persons

handling medicines. A list of these indication groups is available at www.sukl.cz - Reviews and Lists – KLK Code List and EAN Codes – KLK Code List – ISV.DBF

BBBB - accession number of the marketing authorization in the given calendar year

XX - last two digits of the year

C, or S/C respectively - historical data distinguishing between medicinal products, for which the marketing authorization procedure took place in the Czech Republic (C) or in the Slovak Republic (S/C) respectively until 1993 in Czechoslovakia, while the authorizations remained in force in the two new states after the split of Czechoslovakia regardless of where the marketing authorization procedure took place. At present, the above written rules are used for adjusting marketing authorisation numbers issued before 1 January 1998 unless multiple strengths or more dosage forms¹⁾ were included under a single marketing authorisation number.

A marketing authorisation number is assigned to each medicinal product for which a separate marketing authorization has been issued, specifically with accession numbering during the given calendar year. Cases, for which a separate marketing authorization is issued, are derived from Section 26 of Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, as amended (Act on Pharmaceuticals), and are based on the provisions of the European Parliament and Council Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended.

1. A natural or a legal person applies for registration separately for each dosage form and strength of a medicinal product.
2. After a successful procedure, a marketing authorization is granted based on such an application and it is characterized by the relevant marketing authorisation number.
3. A separate marketing authorization is issued for each dosage form and each strength of the medicinal product¹⁾.
4. A separate marketing authorization is issued for each different name of the medicinal product. Multiple names within one authorization are not permitted.

Therefore, it is not possible to trace any connection between individual strengths, dosage forms or developmental variations of a product of one holder containing the same active ingredient based on marketing authorization numbers issued by the Institute.

The marketing authorization number distinguishes a parallel imported medicinal product. A marketing authorization number of a product, which is the subject of parallel import, is composed of a marketing authorization number of the reference product in the Czech Republic with the addition of a PI tag meaning parallel import, a sequence number of the authorization issued for the given medicinal product (regardless of the dosage form, strength, package size, country from which it is imported etc.) and the year of authorization of parallel import (e.g. 59/001/95-C/PI/001/05).

The same rule applies for parallel distribution. A marketing authorization number of a product, which is the subject of parallel import, is composed of a marketing authorization number of the centrally authorized reference product with the addition of a PD tag meaning parallel distribution, a sequence number of the authorization issued for the given medicinal product (regardless of the dosage form, strength, package size, country from which it is imported etc.) and the year of authorization of parallel import (e.g. EU/07/032/001/PD/001/12).

Marketing authorization numbers of centrally authorized medicinal products

The marketing authorization number assigned to centrally authorized medicinal products indicates whether it is a product for human use, a veterinary medicine or an orphan (products for treatment of rare diseases). It also includes the first year of authorization of the first presentation of the product, the sequence number of the authorization of the first presentation of the product and the number gradually distinguishing the subsequently authorized presentations of the product (dosage form, strength, package size). It has the following format: EU/A/BB/CCC/DDD:

A - Indicates the nature of the medicinal product (1 - human medicine, 2 - veterinary medicine, 3 - orphan)

BB - Year of authorization

CCC - Serial number of authorization

DDD - Number of the product presentation

This marketing authorization number allows tracing the connections between individual product presentations assigned to the global authorization; however, it does not allow distinguishing in which year the individual presentations were authorized, and it does not even at the slightest indicate the therapeutic area of the use of the product (e.g. EU/1/04/285/001).

2. SÚKL Code

SÚKL codes are used to distinguish each medicinal product presentation allowed to be placed on the market in the Czech Republic. SÚKL codes are therefore a unique symbol of each product presentation and they are assigned not only to products properly registered nationally or centrally, but also to medicinal products whose use is allowed under specific treatment programs (Section 49 of the Act on Pharmaceuticals), and to foods for special medical purposes (FSMPs). In practice, this means that separate codes are used to further distinguish medicinal product presentations registered under a single SÚKL marketing authorization number. Multiple SÚKL codes can be therefore assigned to a single marketing authorization number issued by the Institute. SÚKL codes are assigned on the basis of Section 32 (5) of the Act on Pharmaceuticals also to centrally authorized products and since the EU marketing authorization number already distinguishes different presentations of the product, one SÚKL code is assigned to one EU marketing authorization number. A similar procedure is used in the assignment of codes to products whose use is allowed under specific treatment programs and FSMPs.

The Institute assigns codes to centrally authorized products after the publication of the authorization at <http://ec.europa.eu> and <http://www.ema.europa.eu>. Lists of new centrally authorized products and new package sizes of previously authorized products have been available since May 2004 at www.sukl.cz (Reviews and Lists - Overview of changes in marketing authorizations for medicinal products). Since May 2004, centralized products have been also part of the KLK Code List of SÚKL.

SÚKL codes are not stated on the packaging of medicinal products but they can be found in the KLK Code List issued by the Institute and are regularly published on-line once a month.

The Institute assigns codes based on the below rules and the information available and provided to it.

A separate SÚKL code is assigned to each product presentation which has:

- a different marketing authorization number
- a different presentation (package size, packaging)
- a practical importance with regard to the needs of the distribution chain and the medical field (examples: radiopharmaceuticals, allergens, authorization before and after the change, parallel import, parallel distribution).

The aim of the Institute is not to assign codes unnecessarily, and - if possible - to address more detailed distinction in another way - for example, by using the EAN code.

The SÚKL code has the form of a randomly selected 7-digit number.

The SÚKL code is used to distinguish:

1. strengths and dosage forms (in the case of national authorization, even the marketing authorization number represents distinction here)
2. different package sizes of the product
3. different types of packaging of the product (e.g. blister, bottle)
4. different presentation with regard to the method of dispensing, if distinguished by the manufacturer

5. parallel imported products, i.e. it is differentiated, whether a product is imported under the responsibility of the marketing authorization holder or within parallel imports
6. parallel distributed products

A new code is assigned by the Institute to already authorized products:

- 1) When the name of the product changes (a completely new name or a significant change)
- 2) When a new package size is authorized
- 3) When a new type of the inner packaging is authorized
- 4) In the case of parallel import
- 5) In the case of parallel distribution
- 6) When the authorization is transferred onto a new holder.

In the case of a transfer of the marketing authorization holder, a change in the name of the medicinal product or the type of packaging, the authorization status of the original code changes to B, i.e. the medicinal product is intended for final sales before the change is made and the product with the implemented change will have new codes and the authorization status R.

The coding of medicinal product presentations was changed on 1 July 2007. Originally, codes were assigned to the so-called "sub-presentation" of a medicinal product, i.e. to the manufacturer. Now, every medicinal product presentation has a unique code (1 code from n-codes currently assigned to sub-presentations), i.e. based on the holder. Medicinal product presentations, which were omitted from the list of the codes within the Code Conversion, received the Q flag to distinguish their final sale from a final sale due to a change in the medicinal product (authorization status B, see above). In cases of specific treatment programs and foods for special medical purposes, the Institute continues to assign codes to so-called medicinal product "sub-presentation", i.e. to the manufacturer.

A new code is not assigned by the Institute to already authorized products with assigned codes:

1. When extending the name of the product, if information regarding the package size, strength, dosage form or the marketing authorization holder are added
2. When the name or address of the marketing authorization holder is changed
3. When the name is changed or the authorization is transferred in the case of centrally authorized products

A special approach is chosen to assign codes to the following categories of medicinal products.

Coding of homeopathics

A separate code is assigned only to each dosage form and individual dilution levels or dilution ranges. If any dilution level is transferred to over-the-counter sale, the Institute shall assign a new code.

Coding of allergens

In the past, codes were assigned to a set of allergens regardless of individual presentations. Therefore, individual allergens in previously authorized products are not distinguished from each other by SÚKL codes.

Coding of radiopharmaceuticals

A separate code is assigned to each dosage form and at the request of the marketing authorization holder also to individual activities, or a range of activities.

In case of any ambiguity in the assignment of codes, it is possible to contact the Institute:

- In the case of national authorizations at: helena.moravcova@sukl.cz, lydie.liskova@sukl.cz
- In the case of centralized authorizations at: helena.moravcova@sukl.cz, lydie.liskova@sukl.cz

3. EAN codes

They are mainly used for the identification of medicinal products in their handling by the distributors and in pharmacies. These are codes assigned by the EAN CZ Centre and are generated by the manufacturer. This code in the form of a bar code is placed on the packaging of the medicinal product. After the allocation, the marketing authorization holders notify the Institute of the code and the Institute records it in the database of medicinal products. Principles of the allocation of codes are listed at www.ean.cz. A list of reported EAN Codes is published by the Institute in the code list which is available at <http://www.sukl.cz/ean-kody> (Reviews and Lists – EAN Codes). Details regarding the reporting of EAN Codes to SÚKL are also published there.

4. Other coding systems

Other coding systems are used to meet the practical needs of distributors, pharmacies and other persons dealing with medicines. These include PDK codes that are assigned by Pharmdata to individual medicinal products in connection with SÚKL codes. These codes are also used to identify medicinal products if an EAN code has not been assigned to them, and they are also used to identify other products.

¹⁾ In the period before 1 January 1998, more strengths, or more dosage forms of a product were included under a single marketing authorization number. Because this method of allocation of marketing authorization numbers no longer complies with legislation and mainly complicates internationally harmonized EU authorization procedures, these previously issued marketing authorization numbers are being adjusted. For these purposes, modification of the current alphabetic positions (C, S/C) are used in the marketing authorization number (e.g. extension of the original marketing authorization number 41/1454/01-C to 41/1454/01-A/C and 41/1454/01-B/C, or 43/1454/01-S/C to 43/1454/01-A/C and 43/1454/01-B/C. More information from SÚKL regarding this renumbering published at www.sukl.cz.