UST-31 version 3 Principles of Identification of Medicinal Products for Human Use in the Czech Republic

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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, the marketing authorisation holder and other information required on the packaging of medicinal 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, this Guideline presents an overview of individual types of code identification of medicinal products. Various ways of allocating code identification have been gradually developed in response to the changing needs of their users and the development of legislation.

1. Marketing Authorisation Number

A marketing authorisation number is used to identify a medicinal product; in the Czech Republic, it is allocated to a specific strength and pharmaceutical form of the medicinal product. In compliance with Decree No. 228/2008 Coll., on marketing authorisation of medicinal products, as amended (hereinafter referred to as the "Marketing Authorisation Decree"), marketing authorisation numbers must be shown on the packaging of medicinal products and they are available from the web database of medicines of the State Institute for Drug Control (hereinafter referred to as the "Institute"), in the KLK Index, or in open data available from the website at www.sukl.cz.

In various EU countries, marketing authorisation numbers do not have a uniform format and the approach to their allocation has not been unified, either. While in some countries, marketing authorisation numbers distinguish each authorised presentation of the medicinal product, in others they distinguish individual authorised strengths and pharmaceutical forms of the medicinal product (in such a case, one marketing authorisation number identifies also various pack sizes or types of packaging). Some types of marketing authorisation numbers also allow for the derivation of so called global authorisation, i.e. authorisation of all medicinal products with the respective active substance for a particular marketing authorisation holder (but not in the Czech Republic).

As of the date of accession of the Czech Republic to the EU, i.e. 1 May 2004, marketing authorisations issued by the European Commission for products authorised through so-called centralised procedure came into force within 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 authorised medicinal products, or marketing authorisation numbers assigned by the European Medicines Agency in the case of centrally authorised medicinal products. The format and the principles of assigning these numbers are different.

1.1 Marketing Authorisation Numbers Assigned by the Institute

Prior to 1 December 2016, the marketing authorisation number was allocated together with the issuance of the marketing authorisation, since 1 December 2016, it is allocated as early as upon the receipt of the application for marketing authorisation. The marketing authorisation number hence serves as a unique identifier of the medicinal product in the course of the marketing authorisation procedure as well as after the marketing authorisation is granted.

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

[1] In the period prior to 1 January 1998, several strengths or several pharmaceutical forms of a medicinal product were included under a single marketing authorisation number. Because this method of allocation of marketing authorisation numbers no longer complied to legal regulations effective later on, these marketing authorisation numbers were adjusted, and the current character positions (C,

AA – indication group according to historical classification. This therapeutic classification is only indicative. It is used solely for the internal purposes of the Institute, it is not consistently linked to the ATC code system and it is not related to the reimbursement system of medicinal products. A list of these indication groups is available from the KLK list or open access data which are available from the website at www.sukl.cz.

BBBB – incremental number of the marketing authorisation application in the respective calendar year; prior to 1 December 2016, an incremental number of the marketing authorisation in the given calendar year.

XX – the last two digits of the year in which marketing authorisation application was submitted; prior to 1 December 2016, the last two digits of the year in which marketing authorisation was granted.

C or S/C – historical data distinguishing between medicinal products authorised prior to 1993 in Czechoslovakia, for which the marketing authorisation procedure took place in the Czech Republic (C) or in the Slovak Republic (S/C), and where the authorisations remained in force in the two new countries after the split of Czechoslovakia regardless of where the marketing authorisation procedure took place. The above-mentioned character positions were further used for the adjustment of marketing authorisation numbers issued prior to 1 January 1998, where multiple strengths or multiple pharmaceuticals forms were included under a single marketing authorisation number[2].

A marketing authorisation number is assigned to each medicinal product, i.e. to each strength and pharmaceutical form of the medicinal product, following the submission of the marketing authorisation application. In compliance with Section 26 of Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended (hereinafter referred to as the "Act on Pharmaceuticals"), an application for marketing authorisation may be filed only by a natural person or a legal person separately for each pharmaceutical form and strength of the medicinal product. In case the marketing authorisation procedure is approved, marketing authorisation is issued for each application, i.e. for each pharmaceutical form as well as for each strength of the medicinal product.

A marketing authorisation number of a product, which is the subject of parallel import, is composed of a marketing authorisation number of the reference product in the Czech Republic with the addition of a PI tag meaning parallel import, a sequence number of the application for parallel import authorisation in the given year and the year of submission of the application; prior to 1 January 2017, the PI tag was complemented with the sequential number of parallel import authorisation issued in the respective year for the respective medicinal product and the year of parallel import authorisation.

1.2 Marketing Authorisation Numbers of Centrally Authorised Medicinal Products

The marketing authorisation number assigned to a centrally authorised medicinal product indicates, *inter alia,* whether it is a product for human or veterinary use, the year of authorisation of the first presentation of the product, the sequence number of the authorisation of the first presentation of the product and the number distinguishing subsequently authorised presentations of the product (pharmaceutical form, strength, pack size and type of packaging). It has the following format: EU/A/BB/CCC/DDD:

EU – identification of a centrally authorised medicinal product

A – distinction of the medicinal product (1 – human medicine, 2 – veterinary medicine)

BB – year of authorisation

CCC – serial number of the authorisation

DDD – number of the product presentation

This type of the marketing authorisation number allows for the tracing of links between individual product presentations assigned to the global authorisation; however, it does not allow for the distinguishing of the

S/C) in the marketing authorisation numbers were amended (e.g. extension of the original marketing authorisation 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).

[2] In the period prior to 1 January 1998, several strengths or several pharmaceutical forms of a medicinal product were included under a single marketing authorisation number. Because this method of allocation of marketing authorisation numbers no longer complied to legal regulations effective later on, these marketing authorisation numbers were adjusted, and the current character positions (C, S/C) in the marketing authorisation numbers were amended (e.g. extension of the original marketing authorisation 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).

year in which the individual presentations were authorised, and it does not even indicatively point to the therapeutic area of the use of the product.

The marketing authorisation number of a product which is subject to parallel distribution, comprises of the marketing authorisation number of a centrally authorised medicinal product complemented with the letters "PD", meaning parallel distribution, the sequential number of the parallel distribution authorisation in the respective year, and the year of issuance of such authorisation; prior to 1 January 2017, the letters "PD" were complemented with the sequential number of the parallel distribution authorisation issued for the concerned medicinal product and the year of issuance of the parallel distribution authorisation. The data after the letters PD serve solely for the Institute's internal purposes, they do not form part of the marketing authorisation number and in the search database they are provided on a separate line under the marketing authorisation number.

2. SÚKL Code

SÚKL codes are used to distinguish each presentation of a medicinal product for the purposes of record-keeping and potential identification in the determination of prices and reimbursements from the public health insurance. SÚKL codes are therefore a unique symbol of each product presentation and they are assigned not only to products authorised nationally, through mutual recognition procedures or centrally, but also to medicinal products whose use is allowed under specific therapeutic programs (Section 49 of the Act on Pharmaceuticals refers), to foods for special medical purposes (FSMPs), parallel imports or parallel distribution of a medical product or taken-over authorisations of medicinal products. Separate SÚKL codes hence provide a more detailed distinction among the presentations of a medicinal product authorised under a single marketing authorisation number. Multiple SÚKL codes can be therefore assigned to a single marketing authorisation number issued by the Institute. In case of medicinal products authorised centrally, the marketing authorisation number of which already distinguishes the individual product presentations, a single SÚKL code is therefore allocated to a single marketing authorisation number. A similar course is followed in the allocation of codes to products the use of which is made possible through specific therapeutic programmes, foods for special medical purposes, parallel import or parallel distribution of a medicinal product or take-over of marketing authorisation of a medicinal product. A SÚKL code assumes the form of a randomly selected seven-digit number.

In respect of centrally authorised products, the Institute allocates codes after the publication of the concerned decision on the website of the European Commission.

In compliance with Annex 5 to the Marketing Authorisation Decree, SÚKL codes must be shown on the packaging of the medicinal product and they are available from the Institute´s web database of medicines, in the KLK Index or in open data available from the website at www.sukl.cz.

The Institute assigns SÚKL codes to each presentation of a medicinal product which has:

- a different presentation, i.e. pack size or type of packaging (e.g. bottle, blister);
- a practical importance with regard to the needs of the distribution chain and the medical field (e.g. radiopharmaceuticals, homeopathic products, allergens).

A new SÚKL code is assigned by the Institute to previously authorised products:

- When the name of the medicinal product changes
- When a new pack size is authorised
- When a new type of packaging is authorised
- In the case of parallel import
- In the case of parallel distribution
- When the authorisation is transferred onto a new marketing authorisation holder
- Upon take-over of the marketing authorisation

In the case of a transfer of the marketing authorisation onto a new marketing authorisation holder, a change in the name of the medicinal product or the type of packaging, the authorisation status of the original code

changes to “B”, i.e. the medicinal product complying with the labelling and documentation prior to the implementation of the variation to the marketing authorisation may continue to be marketed for the period of 180 days since the approval of the variation, and it may be distributed, dispensed, in case of selected pharmaceuticals sold, and used in the provision of medical services throughout its shelf-life. A medicinal product complying with the data and documentation following the implementation of the aforementioned variation is allocated new SÚKL codes and marketing authorisation status of “R”.

In respect of changes other than those specified above (e.g. change to the name or address of the marketing authorisation holder, change to the name of a centrally authorised medicinal product, transfer of marketing authorisation of a centrally authorised medicinal product), the Institute usually no longer allocates new codes to previously authorised medicinal products with previously allocated SÚKL codes.

The coding of medicinal product presentations was changed on 1 July 2007. Originally, codes were assigned to a 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).

In cases of specific therapeutic 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.

3. EAN Codes

The European article number or EAN serves particularly for the identification of medicinal products within the distribution chain and in pharmacies. In compliance with Annex 5 to the Marketing Authorisation Decree, EAN codes must be shown on the packaging of the medicinal product.

The allocation of EAN codes and their specification on the packaging is the responsibility of marketing authorisation holders, the Institute provides only for their record-keeping and publication. The Institute prefers 13-position EAN codes, but accepts also the types with 8 positions. EAN codes allocated in a country other than the Czech Republic are permissible. EAN codes may be obtained from the website at www.gs1cz.org.

A specific EAN code usually corresponds to a single SÚKL code, nevertheless it is acceptable to have several EAN codes for a single SÚKL code at one time. Situations where a single EAN code would identify medicinal product presentations distinguished by various SÚKL codes are not permissible.

Marketing authorisation holders report EAN codes to the Institute after their allocation. In order to safeguard a current overview of valid EAN codes for individual medicinal products, it is necessary for marketing authorisation holders to report the allocated EAN codes for all medicinal product presentations placed onto the market prior to the placement on the market proper.

Responsibility for the correctness of the EAN codes shall lie with the marketing authorisation holder; in case of specific therapeutic programmes with the approved distributor; in case of parallel imports with the approved importer.

Registered and missing EAN codes are published on the website at http://www.sukl.cz/ean-kody.

4. Other Coding Systems

Other coding systems are used to meet the practical needs of distributors, pharmacies and other persons handling medicinal products as well. These are e.g. PDK codes (**P**harm**D**ata **codes**), that are assigned by Pharmdata to individual medicinal products in connection with SÚKL codes (http://www.pharmdata.cz/ciselnik_pdk.htm).