Státní ústav pro kontrolu léčiv
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No.	M/O	Label	Type	Size	Name	Description
1	M	KOD	C	7	SÚKL code	The code of the medicinal product (hereinafter referred to as "MP") allocated by SÚKL to the presentation of the MP as part of the marketing authorisation (MA) of the MP or allocated to a non-authorised MP included in a specific therapeutic programme (hereinafter referred to as "STP") or allocated to food for special medical purposes (hereinafter referred to as "FSMP").
2	M	NAZ	C	70	Name of the MP	The name of the MP, FSMP or STP as referred to by SÚKL guideline REG-29, version 4, in compliance with Directive 2001/83/ES.
3	M	SILA	C	24	Strength	The strength of the MP, i.e. the contents of active substances expressed quantitatively with a view to a unit of dose, volume or weight, depending on the pharmaceutical form.
4	M	FORMA	C	27	Pharmaceutical form	Pharmaceutical form
5	M	BALENI	C	22	Pack	Pack size
6	M	CESTA	C	15	Route of administration	Route of administration
7	M	DOP	C	75	Specification of the MP	MP name supplement, which clearly defines the presentation of the MP, comprising of an integration of its pharmaceutical form, pack size, and strength. This item of the List is further specified in the items CESTA, FORMA, BALENI and SILA.
8	M	OBAL	C	3	Packaging	The immediate packaging of the MP, i.e. such form of packaging which is in immediate contact with the MP.
9	O	DRZ	C	4	MA holder	The abbreviation for the marketing authorisation holder. A common implemental index is available for the DRZ and ZEM DRZ fields.
10	O	ZEMDRZ	C	3	Holder´s country	An abbreviation of the country of the marketing authorisation holder's registered office; for medicinal products included in specific therapeutic programmes and for foods for special medical purposes this shall mean the abbreviation of the country of the manufacturer's/importer's registered office. A common implemental index is available for the DRZ and ZEM DRZ fields.
11	O	RC	C	16	MA number	The marketing authorisation number, which identifies a group of presentations of a medicinal product for which the marketing authorisation has been issued.
12	O	SOUBDOV	C	11	Parallel import identifier	The identification number of parallel import, which is associated with the respective reference product as per the MA number; usually in the following format: PI/xxx/tyty.
13	O	T_REG	C	3	MA type	Type of marketing authorisation **CMS** – Registration by the mutual recognition procedure (MRP) or decentralised procedure (DCP) with the Czech Republic as the concerned member state (CMS) **EUR** – Registration by centralized procedure (except for orphans) **NAR** – Registration by national procedure **ORP** – Orphan medicinal products **PRE** – Adopted marketing authorisation **RMS** – Marketing authorisation by mutual recognition procedure (MRP) or decentralised procedure (DCP) with the Czech Republic as the reference member state (RMS) **SDI** – Parallel distribution **SOU** – Parallel import

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No.	M/O	Label	Type	Size	Name	Description
14	M	S_REG	C	2	MA status	Status of the marketing authorisation, the basic values being as follows: **B** – Following an implemented variation thereto, the product may be marketed for the period of 6 months and used until its expiry date, not exceeding the MA expiry date; **C** – Revoked marketing authorisation with permitted final sale of the medicinal product; the product is to be recalled prior to the timeline specified in the decision on marketing authorisation revocation; **F** – Specific therapeutic programme authorised by the Ministry of Health of the Czech Republic upon SÚKL's recommendation; **P** – FSMP; **R** – Authorised MP; **Y** – Marketing authorisation which ceased to be valid; the product is to be recalled prior to the timeline specified in the decision.
15	M	MCV	N	13,2	Maximum ex-factory price	Maximum ex-factory price of the medicinal product/food for special medical purposes
16	M	LEG_CV	C	1	Maximum ex-factory price legal basis	The legal basis for the determination of the producer price of the MP/FSMP/STP; it may assume the following values: **N** – The stated price is the *ex lege* established or amended price at which the applicant may market the MP or the FSMP, if no decision on their applications has been adopted within the timelines set forth by Act No 48/1997 Coll., as amended. This price equals the price stated in the application for maximum price determination or change thereof. This price shall be effective until an enforceable decision is issued on the matter; **P** – Temporary *ex lege* price decrease, i.e. a temporary price decrease set forth by law; **M** – Determined by the Ministry of Finance of the Czech Republic pursuant to Act No 265/1991 Coll. and Act No 526/1990 Coll. prior to 31 December 2007; **S** – Determined or amended via an administrative procedure pursuant to Act No 48/1997 Coll., as amended as of 01 January, 2008. **X -** The decision on the maximum price has not become final as yet and is preliminarily enforceable
17	O	ODKAZ_MCV	C	20	Grounds for max. ex-factory price	Contains the file no. of SÚKL administrative procedure.
18	O	ATC	C	7	Full ATC	Anatomical therapeutic chemical group. **An ATC implemental index is available for the ATC field.**
19	O	V_PLATOD	D	8	MA effective date	The effective date of the marketing authorisation.
20	O	V_PLATDO	D	8	MA expiry date	The expiry date of the marketing authorisation, unless unlimited validity has been granted pursuant to Section 34 of the Act on Pharmaceuticals.
21	O	NEOMEZ	C	1	Unlimited MA validity	Field to be completed (X) where unlimited validity of the marketing authorisation applies.
22	O	HL_UV_OD	D	8	Placement on the market	Date of initial placement of supplies of the medicinal product on the market or reinstitution thereof, to be reported by the MA holder in compliance with Section 33 of the Act on Pharmaceuticals.
23	O	HL_UK_DO	D	8	Supply termination	Date of termination or discontinuation of supplies of the medicinal product onto the market, to be reported by the MA holder in compliance with Section 33 of the Act on Pharmaceuticals.
24	O	DDDM	C	5	Amount of active substance in DDD	Defined daily dose – the amount of active substance – information as per WHO.
25	O	DDDJ	C	4	Unit of active substance amount in DDD	Defined daily dose – unit – information as per WHO.

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26	O	DDDBAL	N	11,4	DDD count in MP pack	The number of defined daily doses in a pack – where DDD has been established by WHO.
27	O	DAT_MCV	D	8	Max. ex-factory price validity	Effective date of the change to the maximum ex-factory price.
28	O	RP1	C	1		Reserve field 1
29	M	NAZ_REG	C	70		Authorised name of the MP/FSMP/STP
30	O	PAR_SK	C	10	Identification code of parallel	Identifier of a parallel group of identical MP in compliance with Section 39b paragraph 9 of Act No. 48/1997

Code page 1250 WIN
CZ Field separator “|”

The “M/O” column identifies mandatory and optional fields in the List
The “Type” column identifies the format of the fields as follows: "C" – character attribute
"N" – numeric attribute
"D" - date in the “ddmmyyyy” format
The “Size” column identifies the scope of the fields. The format of numeric fields is identified as “x,y” (“x” positions, incl. the decimal point, of which “y” are decimals)

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