

Format of the Pricelist of reimbursed medicinal product and foods for special medical purposes, SÚKL, version 18.0

| No. | M/O | Label | Туре | Size | Name | Description |
|-----|-----|---------|------|------|----------------------------|---|
| 1 | Р | 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 | Р | NAZ | С | 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 | Р | 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 | Р | FORMA | С | 27 | Pharmaceutical form | Pharmaceutical form |
| 5 | Р | BALENI | С | 22 | Pack | Pack size |
| 6 | Р | CESTA | С | 15 | Route of administration | Route of administration |
| 7 | Р | DOP | С | 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 | Р | OBAL | С | 3 | Packaging | The immediate packaging of the MP, i.e. such form of packaging which is in immediate contact with the MP. |
| 9 | N | DRZ | С | 4 | MA holder | The abbreviation for the marketing authorisation holder. A common implemental index is available for the DRZ and ZEM DRZ fields. |
| 10 | N | 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 | N | RC | С | 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 | N | SOUBDOV | С | 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/yy or PD/xxx/yy |
| 13 | N | T_REG | C | 3 | MA type | Marketing authorisation (type of marketing authorisation: national, MRP, DCP, via centralised procedure, adopted MA, parallel import). |
| 14 | Р | 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; I – MP authorised under the emergency measure the Ministry of Health of the Czech Republic; P - food for special medical purposes; |

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| | | | | | | 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 | P | TCR | C | 3 | Price regulation type | The of price regulation applicable values: MCV - Maximum ex-factory price; OP - Regulation of the profit margin; the factory price is not subject to regulation under the Price Regulation of the Ministry of Health of the Czech Republic; OPN - Regulation of the profit margin by the amount of the nominal value according to the Price directive of Ministry of Health for the medicinal products paid according to Section 32c of Act No. 48/1997 Coll. |
| 16 | N | СР | N | 13,2 | Producer price | The producer price (CP) of the MP/FSMP, depending on the TCR field value, this may be either the maximum ex-factory price, or the announced producer price, or the temporary agreed maximum price of the medicinal product (symbol D in field LEG_CP). |
| 17 | N | LEG_CP | C | 1 | Producer price legal basis | The legal basis for the determination of the producer price of a MP/FSMP/STP; it may assume the following values: B – The maximum price determined or amended as per Section 32d of Act No. 48/1997 Coll; C - The decision on the maximum price determined or amended as per Section 32d of Act No. 48/1997 Coll has not become final yet and is preliminarily enforceable. D - The temporary price deregulation of a medicinal product based on an effective Written arrangement on price in public interest M - Determined under the emergency measure the Ministry of Health of the Czech Republic N - The specified price is the price determined or amended <i>ex lege</i>, for which the applicant may place the MP or FSMP on the market if their application has not been decided within timelines set forth by Act No. 48/1997 Coll., as amended. This price equals the price specified in the application for maximum price determination or reimbursement. The validity of this price is limited until an enforceable decision is issued on the matter; O - Announced producer price; P - Temporary ex lege reimbursement decrease, i.e. a temporary reimbursement decrease set forth by law; R - The price limit is based upon the last announced producer price, in cases where the medicinal product was re-classified by a price decision of the Ministry of Health of the Czech Republic to a maximum-price regulation, no maximum price has been determined for it todate; S - Determined or amended via an administrative procedure pursuant to Act No. 48/1997 Coll., as amended as a determined for it todate; X - The decision on the maximum price has not become final as yet and is preliminarily enforceable; |
| 18 | N | ODKAZ_CP | С | 20 | Grounds for CP determination | If the TCR field contains the "MCV" value, this field will contain the file no. of SÚKL administrative procedure or will be populated with the "MF" value, if the producer price has been set in compliance with existing legal regulations (price assessment of the Ministry of Finance). If the TCR field contains the "OP" value, this field remain blank. |
| 19 | N | UHR1 | N | 13,2 | Reimbursement | The amount of reimbursement of the medicinal product for the end consumer (JUHR1 incremented with the maximum profit margin as per the price regulation of the Ministry of Health of the Czech Republic and VAT) or medicinal products reimbursed ex lege pursuant to Section 15 para. 4 or Sections 30 para. 2 of Act No. 48/1997 Coll. |

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| 20 | N | JUHR1 | N | 13,2 | Core reimbursement | The amount of reimbursement of the medicinal product determined by SÚKL as per Section 39g, paragraph 4 of Act No. 48/1997 Coll. or determined as per transitory provisions of so called "technical amendment". |
| 21 | P | LEG_JUHR1 | C | 1 | Legal basis for core reimbursement | The legal basis for the determination of the amount and conditions of core reimbursement of a MP/FSMP from health insurance; it may assume the following values: The first temporary reimbursement of a highly innovative medicinal product as referred to by Section 39d of Act No. 48/1997 Coll.; The second temporary reimbursement of a highly innovative medicinal product as referred to by Section 39d of Act No. 48/1997 Coll.; <i>A - Ex lege</i> (statutory) reimbursement of MPs that contain an active substance listed under Section 15, paragraph 4 of Act No. 48/1997 Coll.; The amount and conditions of reimbursements determined pursuant to Section 32d of Act No. 48/1997 Coll.; C - The decision on the amount and conditions of reimbursement determined pursuant to Section 32d of Act No. 48/1997 Coll. D - the amount and conditions of reimbursement determined pursuant to Section 32d of Act No. 48/1997 Coll. has not become final to date, and it is preliminarily enforceable. D - the amount and conditions of the first temporary reimbursement of a highly innovative medicinal product included in the registry of orphan medicinal product has not become final to date, and it is preliminarily enforceable; F - The decision on the amount and conditions of the first temporary reimbursement of a highly innovative medicinal product has not become final to date, and it is preliminarily enforceable; F - The decision on the amount and conditions of the second temporary reimbursement of a highly innovative medicinal products released from the reserve stock system according to Section 77g of the Act on Pharmaceuticals (the increase of the UHR by a special profit margin determined by the Price directive in compliance with Section 39h paragraph 1 of Act No. 48/1997 Coll.) M - Etermined by Decree No. 63/2007 Coll. of the Ami |

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| | | | | | | T - Permanent reimbursement of a highly innovative medicinal product as per Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021 U - The winner of the reimbursement tender (RT) V - The MP is reimbursed ex lege within reimbursed care under Section 30 para. 2 of Act No. 48/1997 Coll., as amended in the least economically demanding presentation W – The MP is reimbursed ex lege within the reimbursed care under Section 30 para. 2 of Act No. 48/1997 Coll. It concerns medicinal products containing vaccines that are approved by the Ministry of Health based on the recommendation of the National Immunization Commission and published in the form of a notice in the Collection of Laws. X - The decision on the amount and conditions of permanent reimbursement of a highly innovative medicinal product under Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021, has not become final to date, and it is preliminarily enforceable; |
| 22 | N | ODKAZ_JUHR1 | С | 20 | Grounds for core reimbursement amount determination | Contains the file no. of SÚKL administrative procedure, or reference to statutory provision, or reference to a decree of the Ministry of Health determining the reimbursement in compliance with the aforementioned legal regulations. |
| 23 | N | LIM1 | С | 2 | Reporting limit | The method of reporting MPs/FSMPs to the health insurance company. A common LIM status value implemental index is available for the LIM1, LIM2, and LIM3 fields |
| 24 | N | OME1 | С | 40 | Prescribing doctor's specialization | The specification of prescription restriction based on the specialisation of the prescribing doctor. For a single MP/FSMP code it may assume several OME1 values. A common OME status value implemental index is available for the OME1, OME2, and OME3 fields. |
| 25 | Ν | IND1 | С | 1 | Indication restriction flag | Indication restriction (P). The DETIND1 implemental index is available for the indication restriction detail (indication or clinical condition conditioning the reimbursement of the MP/FSMP). In respect of medicinal products reimbursed <i>ex lege</i> pursuant to Section 30 of Act No. 48/1997 Coll., as amended, the particular provision of the Act is cited. |
| 26 | N | PUHR1 | C | 1 | Full reimbursement flag | The full reimbursement flag may assume the following values: I - the least economically demanding presentation of MPs fully reimbursed under the law; J - MPs where MFC <= UHR1. Note: Final sales under the pricing regulations of the Ministry of Health of the Czech Republic are disregarded. Where final sales for a higher price in compliance with a price regulation of the Ministry of Health of the Czech Republic is applied, the applied price for the end consumer may exceed the specified amount of reimbursement; M – MP containing vaccines approved by the Ministry of Health pursuant to Section 30 par. 2 of Act No. 48/1997 Coll. (Reimbursement agreements referred to under Section 39c, paragraph 2(d) of Act No. 48/1997 Coll. |
| 27 | N | JUHR1_PLATDO | D | 8 | Temporary reimbursement expiry date | The temporary reimbursement is determined for the period of 24 or 12 months pursuant to Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021 or for the period of 36 or 24 months pursuant to Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective from 31.12.2021. The field is populated with the expiry date of the temporary |

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| | | | | | | reimbursement. The amount and conditions of reimbursements of MP determined pursuant to Section 32d of Act No. 48/1997 Coll; are valid for the period specified in the decision. |
| 28 | N | SMLOUVY | Ν | 5,2 | Contracts | Designation of a contractual arrangement that may affect cost-effectiveness or impact on the budget, concluded between persons pursuant to Section 39f para. 2 of Act No. 48/1997 Coll. and which is decisive for granting or changing the amount and conditions of reimbursement of MP or FSMP in administrative proceedings. |
| 29 | N | DNC | С | 1 | Written arrangement on price in public interest | Identification of the maximum price (X) agreed between the health insurance company and the MA holder. If the calculated MFC is lower than the agreed maximum price announced by the health insurance company, the field will contain the "Y" value. |
| 30 | N | UHR2 | N | 13,2 | Second reimbursement | The amount of the second reimbursement of a medicinal product/FSMP determined by SÚKL pursuant to Section 39b, paragraph 11, or Section 39d of Act No. 48/1997 Coll. for the end consumer (JUHR2 incremented by the maximum profit margin as per the price regulation of the Ministry of Health of the Czech Republic and VAT) or medicinal products reimbursed ex lege pursuant to Section 30 para. 2 of Act No 48/1997 Coll. |
| 31 | N | JUHR2 | N | 13,2 | Second core reimbursement | The amount of the second core reimbursement of a medicinal product/FSMP determined by SÚKL pursuant to Section 39b, paragraph 11, or Section 39d of Act No. 48/1997 Coll. |
| 32 | N | LEG_JUHR2 | C | 1 | Legal basis for second core reimbursement | The legal basis for the determination of the amount and conditions of the second MP/FSMP core reimbursement from health insurance; it may assume the following values: The first temporary reimbursement of a highly innovative medicinal product as referred toby Section 39d of Act No. 48/1997 Coll.; The second temporary reimbursement of a highly innovative medicinal product as referred to by Section 39d of Act No. 48/1997 Coll.; D - the amount and conditions of reimbursements for medicinal product included in the registry of orphan medicinal products determined pursuant to Section 39d of Act No. 48/1997 Coll.; E - The decision on the amount and conditions of the first temporary reimbursement of a highly innovative medicinal product included in the registry of orphan medicinal product determined pursuant to Section 39d of Act No. 48/1997 Coll.; E - The decision on the amount and conditions of the first temporary reimbursement of a highly innovative medicinal product has not become final to date, and it is preliminarily enforceable; I - Ex lege is reimbursed (for symbols V and W in LEG_IUHR2) medicinal products released from the reserve stock system according to Section 77g of the Act on Pharmaceuticals (the increase of the UHR by a special profit margin determined by the Price directive in compliance with Section 39h paragraph 1 of Act No. 48/1997 Coll.) F - The decision on the amount and conditions of the second temporary reimbursement of a highly innovative medicinal product has not become final to date, and it is preliminarily enforceable; O - Reduction of reimbursement as part of government-approved measure to ensure financial stability of the health insurance system as per Section 39i, paragraph 3 of Act No. 48/1997 Coll.; P - Temporary <i>ex lege</i> reimbursement decrease, i.e. a temporary reimbursement decrease set forth by law; Q - Products whose reimbursement is directly affected by the reimbursement tender (RT), |

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| | | | | | | R - Medicinal products released from the reserve stock system according to Section 77g of the Act on Pharmaceuticals (the increase of the UHR by a special profit margin determined by the Price directive in compliance with Section 39h paragraph 1 of Act No. 48/1997 Coll.) S - Established or amended via administrative procedure pursuant to Act No. 48/1997 Coll., as amended as of 01 January 2008; T - Permanent reimbursement of a highly innovative medicinal product as per Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021 U - The winner of the reimbursement tender (RT) V - The MP is reimbursed ex lege within reimbursed care under Section 30 para. 2 of Act No. 48/1997 Coll., as amended in the least economically demanding presentation W - The MP is reimbursed ex lege within the reimbursed care under Section 30 para. 2 of Act No. 48/1997 Coll. It concerns medicinal products containing vaccines that are approved by the Ministry of Health based on the recommendation of the National Immunization Commission and published in the form of a notice in the Collection of Laws. X - The decision on the amount and conditions of permanent reimbursement of a highly innovative medicinal product under Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021, has not become final to date, and it is preliminarily enforceable; Y - The decision are teamount and conditions of permanent reimbursement of a highly innovative medicinal product under Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021, has not become final to date, and it is preliminarily enforceable; Z - Other increased reimbursement determined as per Section 39b, paragraph 11 of Act No. 48/1997 Coll. |
| 33 | N | ODKAZ_JUHR2 | С | 20 | Grounds for second reimbursement determination | Contains the file no. of SÚKL administrative procedure, or reference to statutory provision |
| 34 | N | LIM2 | C | 2 | Second reimbursemen reporting limit | The method of reporting MPs/FSMPs to the health insurance company. A common LIM status value implemental index is available for the LIM1, LIM2, and LIM3 fields. |
| 35 | N | OME2 | С | 40 | Prescribing doctor's specialisation | Specification of prescription restriction for the second MP/FSMP reimbursement based on the specialisation of the prescribing doctor. For a single MP/FSMP code it may assume several OME2 values. A common OME status value implemental index is available for the OME1, OME2, and OME3 fields. |
| 36 | N | IND2 | С | 1 | Indication restriction flag | Indication restriction (P) for the second reimbursement of an MP/FSMP. The DETIND2 implemental index is available for the indication restriction detail (indication or clinical condition conditioning the second reimbursement of the MP/FSMP). In respect of medicinal products reimbursed ex lege pursuant to Section 30 of Act No. 48/1997 Coll., as amended, the particular provision of the Act is cited. |
| 37 | N | PUHR2 | С | 1 | Full reimbursement flag | The full reimbursement flag may assume the following values: I - the least economically demanding presentation of MPs fully reimbursed under the law relevant to the ENNV2 field; J - for MPs which are fully reimbursed in case MFC <= UHR2. Note: Final sales under the pricing regulations of the Ministry of Health of the Czech Republic are disregarded. Where final sales for a higher price in compliance with a price regulation of the Ministry of Health of the Czech Republic is applied, the applied price for the end consumer may exceed the specified amount of reimbursement; M – MP containing vaccines approved by the Ministry of Health pursuant to Section 30 par. 2 |

| No. | M/O | Label | Туре | Size | Name | Description |
|-----|-----|--------------|------|------|--|--|
| | | | | | | of Act No 48/1997 Coll. (Reimbursement determined ex lege is equal to MFC.) U - MPs fully reimbursed under reimbursement agreements referred to under Section 39c, paragraph 2(d) of Act No. 48/1997 Coll. |
| 38 | N | JUHR2_PLATDO | D | 8 | Temporary reimbursement validity specified in the second reimbursement field | The temporary reimbursement is determined for the period of 24 or 12 months pursuant to Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021 or for the period of 36 or 24 months pursuant to Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective from 31.12.2021. The field is populated with the expiry date of the temporary reimbursement. |
| 39 | N | UHR3 | N | 13,2 | Third reimbursement | The amount of the third reimbursement of a medicinal product/FSMP determined by SÚKL pursuant to Section 39d of Act No 48/1997 Coll. for the end consumer (JUHR3 incremented by the maximum profit margin as per the price regulation of the Ministry of Health of the Czech Republic and VAT) or medicinal products reimbursed ex lege pursuant to Section 30 para. 2 of Act No. 48/1997 Coll |
| 40 | N | JUHR3 | Ν | 13,2 | Third core reimbursement | The amount of the third core reimbursement of a medicinal product/FSMP determined by SÚKL pursuant to Section 39d of Act No. 48/1997 Coll. |
| 41 | | LEG_JUHR3 | C | 1 | Legal basis for the third core reimbursement | The legal basis for the determination of the amount and conditions of the MP/FSMP core reimbursement from health insurance; it may assume the following values: The first temporary reimbursement of a highly innovative medicinal product as referred to by Section 39d of Act No. 48/1997 Coll.; The second temporary reimbursement of a highly innovative medicinal product as referred to by Section 39d of Act No. 48/1997 Coll.; The decision on the amount and conditions of reimbursements for medicinal product included in the registry of orphan medicinal products determined pursuant to Section 39d of Act No. 48/1997 Coll.; The decision on the amount and conditions of the first temporary reimbursement of a highly innovative medicinal product has not become final to date, and it is preliminarily enforceable; F - The decision on the amount and conditions of the second temporary reimbursement of a highly innovative medicinal product has not become final to date, and it is preliminarily enforceable; I – Ex lege is reimbursed (for symbols V and W in LEG_JUHR3) medicinal products released from the reserve stock system according to Section 77g of the Act on Pharmaceuticals (the increase of the UHR by a special profit margin determined by the Price directive in compliance with Section 39h paragraph 1 of Act No. 48/1997 Coll.; O - Reduction of reimbursement as part of government-approved measure to ensure financial stability of the health insurance system as per Section 39i, paragraph 3 of Act No. 48/1997 Coll.; P - Temporary <i>ex lege</i> reimbursement is directly affected by the reimbursement tender (RT), not equaling the reimbursement is directly affected by the reimbursement tender; R – Medicinal products released from the reserve stock system according to Section 77g of the Act on Pharmaceuticals (the increase of the UHR by a special profit margin determined by the Price directive in compliance with section 39h paragraph 1 of Act No. 48/1997 |

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|-----|-----|-------------|-------|------|--|--|
| | | | . 100 | | | as amended as of 01 January 2008; T - Permanent reimbursement of a highly innovative medicinal product as per Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021; U - The winner of the reimbursement tender (RT) V - The MP is reimbursed ex lege within reimbursed care under Section 30 para. 2 of Act No. 48/1997 Coll., as amended in the least economically demanding presentation; W –The MP is reimbursed ex lege within the reimbursed care under Section 30 para. 2 of Act No. 48/1997 Coll. It concerns medicinal products containing vaccines that are approved by the Ministry of Health based on the recommendation of the National Immunization Commission and published in the form of a notice in the Collection of Laws; X - The decision on the amount and conditions of permanent reimbursement of a highly innovative medicinal product under Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021, has not become final to date, and it is preliminarily enforceable; Y - The decisient product under Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021, has not become final to date, and it is preliminarily enforceable; Z - Other increased reimbursement determined as per Section 39b, paragraph 11 of Act No. |
| 42 | N | | | 20 | | 48/1997 Coll. |
| 42 | N | ODKAZ_JUHR3 | С | 20 | Grounds for third reimbursement determination | Contains the file no. of SÚKL administrative procedure. |
| 43 | N | LIM3 | С | 2 | Third reimbursement reporting limit | The method of reporting MPs/FSMPs to the health insurance company. A common LIM status value implemental index is available for the LIM1, LIM2, and LIM3 fields. |
| 44 | N | OME3 | С | 40 | Prescribing doctor's specialisation | Specification of prescription restriction for the third MP/FSMP reimbursement based on the specialisation of the prescribing doctor. For a single MP/FSMP code it may assume several OME3 values. A common OME status value implemental index is available for the OME1, OME2, and OME3 fields. |
| 45 | N | IND3 | С | 1 | Indication restriction flag | Indication restriction (P) for the third reimbursement of an MP/FSMP. The DETIND3 implemental index is available for the indication restriction detail (indication or clinical condition conditioning the third reimbursement of the MP/FSMP). In respect of medicinal products reimbursed ex lege pursuant to Section 30 of Act No. 48/1997 Coll., as amended, the particular provision of the Act is cited. |
| 46 | N | PUHR3 | С | 1 | Full reimbursement flag | The full reimbursement flag may assume the following values the least economically demanding presentation of MPs fully reimbursed under the law relevant to the ENNV2 field; J - for MPs which are fully reimbursed in case MFC <= UHR3. Note: Final sales under the pricing regulations of the Ministry of Health of the Czech Republic are disregarded. Where final sales for a higher price in compliance with a price regulation of the Ministry of Health of the Czech Republic is applied, the applied price for the end consumer may exceed the specified amount of reimbursement; M – MP containing vaccines approved by the Ministry of Health pursuant to Section 30 par. 2 of Act No. 48/1997 Coll. (Reimbursement determined ex lege is equal to MFC.) U - MPs fully reimbursed under reimbursement agreements referred to under Section 39c, paragraph 2(d) of Act No. 48/1997 Coll. |

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|-----|-----|--------------|------|------|---|--|
| 47 | N | JUHR3_PLATDO | D | 8 | Third reimbursement expiry date | The temporary reimbursement is determined for the period of 24 or 12 months pursuant to Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective until 31.12.2021 or for the period of 36 or 24 months pursuant to Section 39d, paragraph 4 of Act No. 48/1997 Coll., in the version effective from 31.12.2021. The field is populated with the expiry date of the temporary reimbursement. |
| 48 | N | RS | C | 6 | Reference group | The applicable reference group of the MP where the MP has been allocated a reference group by SÚKL when establishing the amount and conditions of reimbursement; it shall comprise of the applicable therapeutic group (TS), separator (/), sequence of the subgroup of products that are similar or that can cause confusion in the reference group (RS_P); the RS stipulated by a decree of the Ministry of Health of the Czech Republic under authority referred to under Section 39c, paragraph 1 of Act No. 48/1997 Coll. |
| 49 | N | TS | N | 3 | Therapeutic group | The applicable therapeutic group of the MP/FSMP if it has been allocated a therapeutic group by SÚKL when establishing the amount and conditions of reimbursement; the TS stipulated by a decree of the Ministry of Health of the Czech Republic under authority referred to under Section 39c, paragraph 1 of Act No. 48/1997 Coll. |
| 50 | N | TS_P | N | 2 | TS subgroup | The applicable subgroup of products that are similar or that can cause confusion within the TS of the MP/FSMP where an RS has been allocated by SÚKL when establishing the amount and conditions of reimbursement; the TS_P stipulated by a decree of the Ministry of Health of the Czech Republic under authority referred to under Section 39c, paragraph 1 of Act No. 48/1997 Coll. |
| 51 | N | ATC | С | 7 | Full ATC | Anatomical therapeutic chemical group. An ATC implemental index is available for the ATC field. |
| 52 | Ν | V_PLATOD | D | 8 | MA effective date | The effective date of the marketing authorisation. |
| 53 | N | 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. |
| 54 | N | NEOMEZ | С | 1 | Unlimited MA validity | Field to be completed (X) where unlimited validity of the marketing authorisation applies. |
| 55 | N | HL_UV_OD | D | 8 | Placement on the market | Date of initial placement of supplies of the medicinal product/ food for special medical purposes on the market or reinstitution thereof, to be reported by the MA holder/importer/ domestic manufacturer in compliance with Section 33 of the Act on Pharmaceuticals. |
| 56 | N | HL_UK_DO | D | 8 | Supply termination | Date of termination or discontinuation of supplies of the medicinal product/ food for special medical purposes onto the market, to be reported by the MA holder/importer/ domestic manufacturer in compliance with Section 33 of the Act on Pharmaceuticals. |
| 57 | N | DDDM | С | 5 | Amount of active substance in DDD | Defined daily dose – the amount of active substance – information as per WHO. |
| 58 | N | DDDJ | С | 4 | Unit of active substance amount in DDD | Defined daily dose unit – information as per WHO. |
| 59 | Ν | 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. |
| 60 | N | ODTD1 | N | 13,4 | Usual daily therapeutic dose for reimbursement | The usual daily therapeutic dose for reimbursement. |
| 61 | N | ODTDJ1 | С | 5 | Unit of active substance amount in ODTD1 | The usual daily therapeutic dose for reimbursement unit for ODTD1. |
| 62 | Ν | ODTDBAL1 | N | 11,4 | Number of ODTD1 in a MP pack | The number of usual therapeutic doses in a pack for ODTD1. |
| 63 | N | ODTD2 | N | 13,4 | Usual daily therapeutic dose for second reimbursement | The usual daily therapeutic dose for second reimbursement. |
| 64 | Ν | ODTDJ2 | С | 5 | Unit of active substance amount in | The usual daily therapeutic dose for second reimbursement unit for ODTD2. |
| 65 | Ν | ODTDBAL2 | Ν | 11,4 | Number of ODTD2 in a MP pack | The number of usual therapeutic doses in a pack for ODTD2. |
| 66 | Ν | ODTD3 | Ν | 13,4 | Usual daily therapeutic dose for | The usual daily therapeutic dose for third reimbursement. |

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|-----|-----|----------------|------|------|---|--|
| | | | | | third reimbursement | |
| 67 | Ν | ODTDJ3 | С | 5 | Unit of active substance amount in | The usual daily therapeutic dose for third reimbursement unit for ODTD3. |
| 68 | Ν | ODTDBAL3 | Ν | 11,4 | Number of ODTD3 in a MP pack | The number of usual therapeutic doses in a pack for ODTD3. |
| 69 | N | ZU_ODTD1 | N | 13,4 | Reimbursement for ODTD1 | Basic reimbursement of the active substance or reference group or MP, resp., in case of a temporary reimbursement for ODTD1, if it has been determined by SÚKL pursuant to Section 39c, paragraph 1 and paragraph 2 resp. to Section 39d of Act No. 48/1997 Coll |
| 70 | N | ODKAZ_ZU_ODTD1 | С | 20 | Grounds for ZU_ODTD1 determination | Contains the file no. of SÚKL administrative procedure. |
| 71 | N | ZU_ODTD2 | N | 13,4 | Reimbursement for ODTD2 | The second reimbursement of the active substance or pseudo-reference group or MP, resp., in case of a temporary reimbursement for ODTD2, if it has been determined by SÚKL pursuant to Section 39b, paragraph 11 resp. to Section 39d of Act No. 48/1997 Coll |
| 72 | N | ODKAZ_ZU_ODTD2 | С | 20 | Grounds for ZU_ODTD2 determination | Contains the file no. of SÚKL administrative procedure. |
| 73 | N | ZU_ODTD3 | N | 13,4 | Reimbursement for ODTD3 | Third reimbursement of a MP for ODTD3, if it has been determined by SÚKL pursuant to Section 39d of Act No. 48/1997 Coll |
| 74 | N | ODKAZ_ZU_ODTD3 | С | 20 | Grounds for ZU_ODTD3 determination | Contains the file no. of SÚKL administrative procedure. |
| 75 | N | DAT_CP | D | 8 | CP validity | The effective date of a producer price change. |
| 76 | Р | DAT_UHR | D | 8 | UHR validity | The date of change of the determination of the amount and conditions of reimbursement. |
| 77 | Р | ZAP1 | N | 13,2 | Eligible extra payment | An eligible extra payment for UHR1 under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, paragraph 1 of Act No. 48/1997 Coll. |
| 78 | Р | NEZAP1 | С | 1 | Limit eligibility symbol | A flag of the category of the pharmaceutical (eligibility for the limit) under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, paragraph 1 of Act No. 48/1997 Coll. The NEZAP implemental index is available for the NEZAP1 field. |
| 79 | N | ZAKL_ZAP1 | С | 1 | Eligible extra payment calculation base | Contains the "X" value only for MPs that form the basis for the calculation of the eligible extra payment under Section 16b, paragraph 1 of Act No. 48/1997 Coll. |
| 80 | N | ZAP2 | N | 13,2 | Eligible extra payment for second reimbursement | An eligible extra payment for UHR2 under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, paragraph 1 of Act No. 48/1997 Coll. |
| 81 | N | NEZAP2 | С | 1 | Limit eligibility symbol | A flag of the category of the pharmaceutical (eligibility for the limit) under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, paragraph 1 of Act No. 48/1997 Coll. The NEZAP implemental index is available for the NEZAP2 field. |
| 82 | N | ZAP3 | N | 13,2 | Eligible extra payment for third reimbursement | An eligible extra payment for UHR3 under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, paragraph 1 of Act No. 48/1997 Coll. |
| 83 | N | NEZAP3 | С | 1 | Limit eligibility symbol | A flag of the category of the pharmaceutical (eligibility for the limit) under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, paragraph 1 of Act No. 48/1997 |
| 84 | N | ZPVYD | С | 1 | Method of dispensing | Classification of the medicinal product for dispensing: F - The medicinal product may be dispensed without medical prescription; L - The medicinal product may be dispensed on the basis of a medical prescription prescribed by a doctor of a specialised competence, only for providers of healthcare services providing healthcare services in inpatient care setting; O - The medicinal product may be dispensed without medical prescription, but a restriction on the dispensing has been set (Section 39, paragraph 5 of the Act on Pharmaceuticals); P - The medicinal product may be dispensed without medical prescription, but a restriction on the amount of the medicinal product which may be dispensed to a single patient within a |

| No. | M/O | Label | Туре | Size | Name | Description |
|-----|-----|---------|------|------|---------------------------------------|--|
| | | | | | | predefined period of time has been set (Section 39, paragraph 5 of the Act on |
| | | | | | | Pharmaceuticals); |
| | | | | | | R - The medicinal product may be dispensed on medical prescription only; |
| | | | | | | V - Selected medicinal product. |
| | | | | | | In case of foods for special medical purposes, the method of dispensing is not specified, as decision- |
| | | | | | | making on the method of FSMP dispensing is not within powers od SÚKL. |
| 85 | Ν | RP40 | N | 13,2 | | Reserve field 40 |
| 86 | Ν | MFC | N | 13,2 | Final price | Final price – the price for the end consumer (producer price plus the maximum profit margin under |
| | | | | | | the price regulation of the Ministry of Health and VAT). |
| | | | | | | If the insurance company and the MA holder concluded an agreement on the maximum agreed price |
| | | | | | | for the product or assumed a valid obligation not to exceed the price assumed in a pricing tender |
| | | | | | | under Section 39 of Act No. 48/1997 Coll., as amended prior to the technical amendment, the |
| | | | | | | agreed price, lower than the MFC, will be specified in this field. If the calculated MFC is lower than |
| | | | | | | the agreed maximum price announced by the insurance company or the price assumed in the |
| | | | | | | pricing tender, the calculated MFC value will be specified in this field. |
| 87 | N | POCDAV | N | 13,0 | Number of vaccine doses | The number of vaccine doses in a pack |
| 88 | Ν | RP1 | С | 1 | | Reserve field 1 |
| 89 | N | RP6 | С | 15 | | Reserve field 6 |
| 90 | N | RP7 | С | 10 | | Reserve field 7 |
| 91 | Ν | DPH | N | 13,0 | Value-added tax rate | Contains a numerically expressed value-added tax rate. |
| 92 | Ν | RP9 | N | 13,2 | | Reserve field 9 |
| 93 | Ν | RP10 | С | 1 | | Reserve field 10 |
| 94 | Ν | RP11 | С | 20 | | Reserve field 11 |
| 95 | Ν | RP12 | С | 2 | | Reserve field 12 |
| 96 | Р | NAZ_REG | С | 70 | Name of the MP | Authorised name of the MP/FSMP/STP |
| 97 | Ν | RP14 | С | 1 | | Reserve field 14 |
| 98 | Ν | RP15 | С | 1 | | Reserve field 15 |
| 99 | Ν | RP16 | D | 8 | | Reserve field 16 |
| 100 | Р | POC_UHR | N | 13,4 | Total number of | Total number of reimbursements (reimbursements prices and conditions) established to the |
| | | | | | | MP/FSMP |
| 101 | Ν | RP18 | С | 5 | | Reserve field 18 |
| 102 | Ν | RP19 | N | 11,4 | | Reserve field 19 |
| 103 | Ν | RP20 | N | 13,4 | | Reserve field 20 |
| 104 | Ν | PAR_SK | С | 20 | Identification code of parallel group | Identifier of a parallel group of identical MP in compliance with Section 39b paragraph 9 of Act No. |
| | | | | | | 48/1997 Coll. |
| 105 | Ν | RP22 | N | 13,2 | | Reserve field 22 |
| 106 | Ν | RP23 | С | 1 | | Reserve field 23 |
| 107 | Ν | RP24 | N | 13,2 | | Reserve field 24 |
| 108 | Ν | RP25 | Ν | 13,2 | | Reserve field 25 |
| 109 | Ν | RP26 | С | 1 | | Reserve field 26 |
| 110 | N | RP27 | С | 20 | | Reserve field 27 |
| 111 | N | RP28 | С | 2 | | Reserve field 28 |
| 112 | N | RP29 | С | 40 | | Reserve field 29 |
| 113 | N | RP30 | С | 1 | | Reserve field 30 |

| No. | M/O | Label | Туре | Size | Name | Description |
|-----|-----|-------|------|------|------|------------------|
| 114 | Ν | RP31 | С | 1 | | Reserve field 31 |
| 115 | Ν | RP32 | D | 8 | | Reserve field 32 |
| 116 | Ν | RP33 | Ν | 13,4 | | Reserve field 33 |
| 117 | Ν | RP34 | С | 5 | | Reserve field 34 |
| 118 | Ν | RP35 | Ν | 11,4 | | Reserve field 35 |
| 119 | Ν | RP36 | Ν | 13,4 | | Reserve field 36 |
| 120 | Ν | RP37 | С | 20 | | Reserve field 37 |
| 121 | Ν | RP38 | Ν | 13,2 | | Reserve field 38 |
| 122 | Ν | RP39 | С | 1 | | Reserve field 39 |

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Field separator "I"

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 decimal)