Rules on determining the prices of medicinal products for human use

AGGREGATED DATA

Official Gazette of the Republic of Slovenia, no. 32/2015, 15/2016, 19/2018
Official consolidated text valid on the day: 28 March 2018
Valid from: 24 March 2018
The document can be accessed at the IUS-INFO portal

I. GENERAL PROVISIONS

Article 1

These Regulate:
- The criteria, method and procedure for determining maximum allowed prices and exceptional higher allowed prices of medicinal products for human use that are financed from public funds or earmarked to be financed from public funds (hereinafter: prices of medicinal products);
- The criteria, procedure and method for changing or coordination (hereinafter: coordination) of maximum allowable prices and exceptionally allowed higher prices of medicinal products;
- The mandatory elements of the application for determining of maximum allowable price and exceptionally allowed higher price of a medicinal product;
- The level of marketing at which prices of medicinal products are determined or changed;
- The method for publishing and communicating medicinal product prices;
- The period of validity of maximum allowable price and exceptionally allowed higher price of medicinal products.

Article 2

Beside the definitions and terms set out in Article 6 of the Medicinal Products Act (Official Gazette of RS, no. 17/14; hereinafter: the Act), these Rules also utilise the following terms:

1. Party subject to determination of prices of medicinal products (hereinafter: subject) shall be:
- The holder of marketing authorisation for a medicinal product or its representative;
- The holder of authorisation for import or input of a medicinal product, for the medicinal product that is not authorised for marketing and is classified into the list of essential or indispensable medicinal products pursuant to the Act;
- The holder of temporary marketing authorisation for a medicinal product that is not authorised for marketing and is classified into the list of essential or indispensable medicinal products pursuant to the Act;
- The holder of authorisation for input of a parallel imported medicinal product;
- The holder of certificate of received notification on parallel distribution of medicinal product based on the provisions of Article 118 of the Act.

2. The maximum allowed price of a medicinal product is the price determined pursuant to these Rules and may be used in wholesale.

3. The exceptionally allowed higher price of a medicinal product is the price determined pursuant to these Rules and may be used in wholesale, which is higher than the maximum allowed price of a medicinal product.

4. The comparative price of a medicinal product is established pursuant to:
- Prices of medicinal products in comparative countries, calculated from publicly available data, or
- Prices of medicinal products in other EU member states (hereinafter: EU) and countries signatories of the Agreement on the European Economic Area (hereinafter: EEA).

5. The manufacturer's element of the wholesale price (hereinafter: PEP) is a structural part of the maximum allowed wholesale price of a medicinal product or exceptionally allowed higher wholesale price that represents administratively recognized costs of the medicinal product manufacturer, calculated from the comparative price of a medicinal product.

6. The marking "CIP buyer" denotes that the wholesale price of a medicinal product includes administratively recognized costs of the manufacturer, transportation and insurance of goods to the end buyer and share for covering the costs of wholesale.

7 Administratively recognized costs of the manufacturer are the costs of manufacturing of medicinal products the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (hereinafter: JAZMP) recognizes pursuant hereto when determining wholesale prices of medicinal products.

8. Market presence of a medicinal product in the Republic of Slovenia means presence of a medicinal product, established pursuant to Article 24 of the Act.

9. Market presence of a medicinal product in comparative countries means the listing of such a medicinal product in publications detailed in Paragraph two of Article 11 hereof.

10. Market presence of a medicinal product in other EU member states and signatories of the EEA Agreement means the listing of such a medicinal product in online resources of bodies competent for pricing and payment of medicinal products from the public funds of such countries.

11. Total annual turnover of a medicinal product in value in all its pharmaceutical forms and strength is the overall annual value of funds from mandatory health insurance and
copayments, including pharmacy services and value added tax in a calendar year.

12. Total annual turnover of a medicinal product in quantity is the overall annual number of packages of a medicinal product in all pharmaceutical forms and strengths marketed in wholesale in a calendar year.

13. Total annual turnover of a medicinal product at the level of manufacturer in terms of value is the overall annual value of sales of a medicinal product in all its pharmaceutical forms and strength in a calendar year in accordance with data reported by the party subject to price determination to the JAZMP pursuant to Article 24 of the Act.

14. An original medicinal product is a medicinal product that has been granted marketing authorisation regardless of the type of procedure in accordance with:
- Article 44 of the Act or paragraph 3 of Article 8 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code related to medicinal products for human use (OJ L 311, 28. 11. 2001, p. 67), last amended by 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1), (hereinafter: Directive 2001/83/EC).
- Article 47 of the Act or Article 10a of Directive 2001/83/EC, if the subject possesses the rights of original manufacturer;
- Article 49 of the Act or Article 10b of Directive 2001/83/EC or
- Article 50 of the Act or Article 10c of Directive 2001/83/EC prior to expiry of data protection.

15. Form in electronic form means the form in an electronic template downloaded from the JAZMP website.

16. Calculative elements of the manufacturing cost of a medicinal product are costs of materials, labor and energy and other operating charges.

Article 3

(1) Notwithstanding the terms defined in Article 6 of the Act, the present Rules also utilise the following terms:

1. A generic medicinal product is a medicinal product that has, regardless of the type of procedure:

a) acquired marketing authorisation pursuant to:
- Article 45 of the Act or Paragraph one of Article 10 of Directive 2001/83/EC or
- Article 52 of the Act or Article 10b of Directive 2001/83/EC or

b) Acquired marketing authorisation pursuant to:
- Paragraph six of Article 45 of the Act or Paragraph three of Article 10 of Directive 2001/83/EC;
- Article 47 of the Act or Article 10a of Directive 2001/83/EC or
- Article 50 of the Act or Article 10c of Directive 2001/83/EC prior to expiry of data protection of the original medicinal product, whereby the subject does not possess evidence on the primary origin of the medicinal product in the sense of the provisions of the above Item hereof.

2. A similar biological medicinal product is a medicinal product that has acquired marketing authorisation pursuant to Paragraph 6 of Article 45 of the Act or Paragraph four of Article 10 of Directive 2001/83/EC and corresponds to the definition under item 58 of Article 6 of the Act.

(2) Terms set out in the above paragraph shall apply mutatis mutandis to medicinal product that are financed by public funds or are intended to be financed by public funds and do not have marketing authorisation in the Republic of Slovenia, but do have:
- Authorization under the third Paragraph of Article 20 of the Act;
- Authorisation for import or input of a medicinal product, for the medicinal product that is not authorised for marketing and is classified into the list of essential or indispensable medicinal products pursuant to the Act;
- Marketing authorisation for parallel imported medicinal product; or
- Certificate of received notification on parallel distribution of medicinal product based on the provisions of Article 118 of the Act.

Article 4

These rules set out the wholesale prices of medicinal product without VAT CIP buyer.

II. DETERMINATION OF MAXIMUM ALLOWED AND EXCEPTIONALLY ALLOWED HIGHER PRICES OF MEDICINAL PRODUCTS

Article 5

(1) Maximum allowed prices of medicinal products are determined on the basis of:

1. Comparison of prices in comparative countries;

2. Comparison of prices in other EU member countries and countries signatories of the EEA Agreement, if the medicinal product is not marketed in comparative countries or

3. Comparison of prices in other European countries, if the medicinal product is not marketed in countries listed in Items 1 and 2 above.

(2) Exceptionally allowed higher prices of medicinal products are determined on the basis of criteria, procedures and method detailed herein.

Article 6

(1) The effective date of the highest allowed price of a medicinal product shall be set out by a decision and shall not exceed 90 days from reception of complete application. If a decision is not issued in the above period, the effective date for the prices shall be a day after expiry of said period.

The effective date of the exceptionally allowed higher price of a medicinal product shall be set out by a decision. If a decision on the proposed exceptionally allowed higher price of a medicinal product is not issued within 90 days of reception of a complete application or within an extended 60 day period, the effective date for such a price shall be a day after expiry of the above periods.

(3) When JAZMP foresees a 60 day extension of the deadline due to an excessive number of applications, it shall issue a decision on extension prior to expiry of the 90 day deadline referenced above.

(4) If the decision detailed in Paragraphs one or two above is not issued within the deadlines set out herein, the medicinal product may be marketed at the proposed price until a new decision is issued on the basis of the application submitted within the deadlines set out in Paragraph one of Article 23 hereof.

Article 7

(1) A maximum allowable price of a medicinal product shall remain in force until a new maximum allowable price for the same medicinal product has been established.

(2) Notwithstanding the former paragraph, the maximum allowed price of medicinal product shall cease to apply on the 30th day from the date of deadline for submission of applications in accordance with first paragraph of Article 23 hereof, provided the applicant does not submit an application in the above deadline.

(3) The determined exceptionally allowed higher price of medicinal product shall remain in force for a maximum duration of one year.

Article 8

(1) If marketing authorisation for a medicinal product is transferred onto another subject, the previously determined price shall continue to apply to the medicinal product and a new application for determination of a maximum allowable price or extraordinary allowed higher price is not necessary if price is to remain as is.

(2) The party subject to price determination shall submit to JAZMP all the data pertaining to the transfer of authorisation within fifteen days of receiving a decision on said transfer.

1. Criteria, procedure and method for determination of maximum allowed prices of medicinal products.

Article 9

(1) Subjects shall submit an application to JAZMP for the determination of prices in written and electronic form for medicinal products detailed in Paragraph one of Article 158 of the Act that are financed from public funds or intended for financing from public funds.

(2) The application referenced above shall consist of a filled out B1 form, enclosed as Appendix 1 hereto, in electronic pdf and xls form. The application shall be supplemented by documentation evidencing the data listed on the application.

(3) The party subject to price determination, which is a public institution established in the Republic of Slovenia, and:
- Is not a manufacturer, shall also provide JAZMP with documentation showing the sales price of the manufacturer at which said public institution established in the Republic of Slovenia is purchasing the medicinal product;
- Is the manufacturer of the medicinal product, either partially or in full, shall also provide JAZMP with specifications and sums of calculated elements of the production price of the medicinal product.

Article 10

Maximum allowed prices of medicinal products shall be determined on the basis of calculated PEP values, which shall not exceed the maximum allowed PEP value and an added share or fixed amount to cover the costs of wholesale (hereinafter: wholesale margin), in accordance with the calculation of the wholesale price of the medicinal product from Appendix 3, which is a constituent part of these Rules.

Article 11

(1) The PEP value shall be calculated based on the comparative price of medicinal products.

(2) Comparative prices of medicinal products shall be calculated on the basis of prices of medicinal products financed from public funds in comparative countries Austria, France and Germany (hereinafter: comparative countries). Determination of the PEP value shall be made on the basis of latest issues of printed or electronic publications or appropriate online resources listing comparative prices of medicinal products and date of data capture:
- Austria: Erstattungskodex, issued by Hauptverband der osterreichischen Sozialversicherungstrager (publication or online resource), calculation from retail price of medicinal product;
- France: Vidal, issued by Vidal France (direct online resource or resource licensed from issuer), calculation from retail price of medicinal product or application of the UCD standard in cases where the retail price is not set and the medicinal product is exclusively or predominantly used within the scope of services of persons performing healthcare activities at a secondary or tertiary level;
- Germany: Lauer-Taxe, issued by Lauer-Fischer GmbH (electronic publication or online resource); or price list ABDA Datenbank, issued by Bundesvereinigung Deutscher Apothekerverbande (electronic publication or online resource); calculation from wholesale price of medicinal product, taking into account the lowest wholesale price applicable to public financing of medicinal product.

(3) Notwithstanding the previous paragraph, data on medicinal products in the comparative country of Austria, which are not listed in the Ersattungskodex publication, shall be gained from the Warenverzeichnis publication, issued by Osterreichische Apotheker-Verlagsgesellschaft m.b.H. (online resource), calculation from retail price of medicinal product, financed from public resources, without VAT.

(4) Prices from publications of comparative countries shall be calculated for each comparative country in the following manner:
- Prices for Germany shall be recalculated using Equation 1 which is enclosed in Appendix 2 hereof;
- Prices for France shall be recalculated using Equation 2 and Table 1 which are enclosed in Appendix 2 hereof;
- Prices for Austria shall be recalculated using Table 2 which is enclosed in Appendix 2 hereof.

(5) Notwithstanding the above paragraph, in cases of medicinal products that are in comparative countries sold directly to healthcare service providers, thus bypassing wholesalers, subjects shall utilise prices listed in relevant publications as comparative prices.

(6) In cases of circumstances detailed in the above paragraph, subjects shall provide:
- A statement of the existence of such a method of sale of medicinal products;
- Recalculation of price pursuant to these Rules, taking into account the actual wholesale price and substantiation for each of these countries; and
- Evidence of actual wholesale price which, if it is in the form of a payment document, shall not be older than three months.

Article 12

(1) PEP value of original medicinal products shall be determined on the basis of the comparative price of a medicinal product, which is the lowest calculated price of an original medicinal product in any of the comparative countries. If the medicinal product is marketed in only one or two comparative countries, only recalculated prices from such countries shall be considered. The PEP value of an original medicinal product may not exceed 100 percent of the comparative price.

(2) PEP value of generic medicinal products shall be determined on the basis of generic medicinal products in comparative countries in the following manner:
- If a generic medicinal product is marketed in all comparative countries, the comparative price of the medicinal product shall be the average of median values of recalculated prices in these countries. The median value of recalculated prices in each comparative country is the arithmetic mean of the highest and lowest recalculated price. If only one generic medicinal product is marketed in a country, only the recalculated price of that medicinal product shall be considered. The PEP value of a generic medicinal product shall not exceed 72 percent of the comparative price;
- If a generic medicinal product is marketed in two comparative countries, the comparative price of a medicinal product shall be the average of median values of recalculated prices in these two comparative countries. The median value of recalculated prices in each country is the arithmetic mean of the highest and lowest recalculated price. If only one generic medicinal product is marketed in a country, only the price of that medicinal product shall be considered. The PEP value of a generic medicinal product shall not exceed 72 percent of the comparative price;
- If the generic medicinal product is marketed in only one comparative country or there is no generic medicinal product marketed in comparative countries, the PEP value of a generic medicinal product shall not exceed 68 percent of the comparative price of the original medicinal product detailed in the above paragraph;
- If a generic medicinal product is marketed in only one comparative country and there is no original medicinal product marketed in said country, the comparative price of a medicinal product shall be the average of the highest and lowest recalculated price in said country. If only one generic medicinal product is marketed in a country, only the price of that medicinal product shall be considered. The PEP value of a generic medicinal product shall not exceed 72 percent of the comparative price.

(3) PEP value of a similar biological medicinal product shall be determined on the basis of the comparative price of such a medicinal product, which is, when:

- The same biological medicinal product is marketed in comparative countries, the lowest recalculated price of the same medicinal product in any of the comparative countries. If the medicinal product is marketed in only one or two comparative countries, only recalculated prices from such countries shall be considered. The PEP value of a similar biological medicinal product shall not exceed 92 percent of the comparative price;
- The same similar biological medicinal product is not marketed in comparative countries, equal to the median of manufacturer’s prices for the similar biological medicinal product in all other EU member countries and countries signatories of the EEA Agreement in which the medicinal product is marketed according to data of the subject. If the number of such countries is even, the comparative price of a

medicinal product shall be established as the median value of manufacturer's prices in two countries in the middle of the price range. The PEP value of a similar biological medicinal product shall not exceed 92 percent of the comparative price.
- The same similar biological medicinal product is not marketed in comparative countries, other EU member countries or countries signatories of the EEA Agreement, the comparative price of such a medicinal product shall be established as the comparative price of the reference biological medicinal product the medicinal product in question is similar to. The PEP value of a similar biological medicinal product shall not exceed 68 percent of the comparative price. If there are differences in the effectiveness of the medicinal product, data on differences in medicinal product effectiveness listed in the European public assessment reports (EPAR) or documents of bodies competent for assessment of healthcare technologies in EU member states shall also be considered and calculated using the following equation:

PEP (BSM) = PEP (RBM)*0.68* (share of BSM efficiency according to EPAR),
whereby the following elements shall have the following meanings:

PEP (SBMP) - PEP of similar biological medicinal product

PEP (RBM) - PEP of reference biological medicinal product.

Article 13

(1) In case of a varying number of dosages per package, comparable packagings in terms of the number of units shall be considered separately for each comparative state. The comparative price of a medicinal product shall then be recalculated to the number of dosage units of the medicinal product of the Person subject to price determination.

(2) The comparative price of medicinal products shall be established separately for each comparative state for each separate pharmaceutical form. If no comparable pharmaceutical form is present in comparative countries, a similar pharmaceutical form may be used for comparison (eg. tablets and lozenges), whereby pharmaceutical forms with controlled release of active substances cannot be compared to pharmaceutical forms with rapid release.

(3) The comparative price of medicinal products shall be established separately for each strength.
If the strength in question is not present in any comparative country, a reasonable recalculation of prices of other strengths shall be used.

Article 14

The PEP value of parallel imported or parallel distributed medicinal product shall be determined by comparing the calculated prices of the medicinal product to the authorisation of which the authorisation holder for parallel import of medicinal products or holder of the certificate pursuant to Paragraph three of Article 118 of the Act, whereby the comparative price of a parallel imported or parallel distributed medicinal product shall equal the calculated price of the medicinal product to which the reference is made. The PEP value may not exceed 100 percent of the comparative price.

Article 15

(1) Notwithstanding the provision of the second paragraph of Article 9 hereof, the application, in case there is no generic or original medicinal product in the comparative country, shall contain the following components:
- Substantiated proposal for the maximum allowed wholesale price of the medicinal product;
- Data on the previously applicable wholesale price of the medicinal product or the maximum allowed wholesale price of medicinal product and its structure (the share covering production costs, including those arising from the requirements of the competent bodies based on the provisions regulating

medicinal products, prices of medicinal products, coverage from health insurance and wholesale costs), if it was determined;
- Data on producer prices and wholesale prices of medicinal products without value added tax CIP buyer in other EU Member States or in the signatories of the EEA Agreement or, if the medicinal product is not present on the market of these countries, adequate data for other European countries in which the medicinal product is present on the market, according to the subject's data, indicating the source on the form B3 from Annex 1 hereof in the electronic form in pdf and xls format;
- Data on the financing of a medicinal product from public sources in other EU Member States or signatories of the EEA Agreement in which the medicinal product is present on the market, to the best knowledge of the subject;
- Evidence on data in the application.

(2) The PEP value is determined as the median of producer prices based on the subject's data in other EU Member States or signatories of the EEA Agreement in which the medicinal product is marketed, to the best knowledge of the subject, and financed from public funds. If the medicinal product is not present on the markets of the EU Member states and the signatories of the EEA Agreement, the PEP value is determined as the median of producer prices in other European countries in which the medicinal product is present on the market.

(3) The maximum allowed price of the medicinal product shall equal the PEP value referred to in the previous paragraph hereunder topped by the maximum wholesale margin, in accordance with the table in Annex 3 which is attached hereto as a constituent part.
Rules on determining the prices of medicinal products for human use

2. Criteria and elements for determining exceptionally allowed higher prices of medicinal products.
Article 16

(1) The subject may submit an application for the determination of an exceptional higher allowed price of a medicinal product in the following cases:
- The maximum allowed price has been determined for a medicinal product or the subject has simultaneously submitted to JAZMP an application for the determination of both the maximum allowed price and the exceptional higher allowed price of the medicinal product;
- There is no medicinal product on the market of the Republic of Slovenia with the same active substance, pharmaceutical form and strength whose valid price was lower than the proposed exceptionally allowed higher price of medicinal product;
- There is no medicinal product on the market of the Republic of Slovenia with the same therapeutic indication and the same pharmacological mechanism, whose valid price was lower than the proposed exceptionally allowed higher price of medicinal product; and
- The value of the total annual turnover of the medicinal product in all its pharmaceutical forms and strengths, taking into account their price, valid on the day of application, does not exceed 400,000 Euros for the previous calendar year or the value of the total annual turnover does not exceed 100,000 Euros for the previous calendar year, provided that the value of the total annual turnover for the previous calendar year did not exceed the growth index of 150 at the annual level.

(2) Notwithstanding the provision of the fourth indent of the preceding paragraph, the subject may submit an application for the determination of the exceptional higher allowed price if the total annual turnover of the medicinal product exceeded 400,000 Euro in the last calendar year and when there is no adequate substitute medicinal product on the market.

(3) The application for determination of exceptionally allowed higher price shall be submitted to JAZMP in two hard copies and in electronic form.

(4) The application for the determination of the exceptional higher allowed price for the medicinal products not listed as essential or indispensable as referred to in Article 17 of the Act shall include:

- The grounds supporting the claim that the maximum allowed price pursuant to the criteria set out by this Rules does not allow the subject to ensure market supply in the Republic of Slovenia, including data on actual costs that additionally encumber the medicinal product and are the basis for the request to allow an exceptional higher allowed price;
- Informative calculation of the maximum allowed wholesale price of the medicinal product based on criteria specified herein; on Form B1 from Annex 1 hereof in .pdf and .xls formats;
- A calculation of the proposed exceptionally allowed higher allowed price of the medicinal product, provided on form B2 from Attachment 1 hereof in pdf and xls formats;
- Data on the volume of sales of all pharmaceutical forms, strengths and packagings of this medicinal product in the Republic of Slovenia for the period of the last three years since the submission of the application, stating the anticipated volume of sales for the medicinal products that have been on the market for a period shorter than the required one, or that are only coming on the market;
– Data on producer prices and wholesale prices for the same medicinal product financed from public funds and data on quantity turnover for the same medicinal product in other EU Member States or the signatories to the EEA Agreement in which, according to the subject's information, the medicinal product is marketed, indicating the source, or data on the medicinal products not marketed in the EU Member States or the signatories of the EEA Agreement for other European countries where the medicinal product is marketed, provided on form B3 from Attachment 1 hereof in xls format;
- Analysis of influence on public funds for medicinal products for which more than 10 years have passed since the addition of the last therapeutic indication into the marketing authorisation in EU member countries or countries signatories of the EEA Agreement, and pharmacoeconomic analysis for other medicinal products, both of which shall be prepared on the basis of data for the Republic of Slovenia or data from other EU member countries or countries signatories of the EEA Agreement which is duly translated using correct methodology and information relevant to the Republic of Slovenia;
- Assessment of the relative therapeutic value of the medicinal product or appropriate pharmacoepidemiological data including relevant data for the Republic of Slovenia.

(5) For the medicinal products with a retail turnover of all pharmaceutical forms, strengths and package sizes on the market in the Republic of Slovenia not exceeding 50,000 Euro at the annual level in the previous calendar year, no analyses or data referred to in the sixth and seventh indents of the preceding paragraph need to be submitted with the application.

(6) For medicinal products without marketing authorisation but with authorisation for import or entry or temporary marketing authorisation, which are included in the list of essential and indispensable medicinal products stipulated by Article 17 of the Act, no data from the fifth, sixth and the seventh indent of the previous paragraph need to be attached to the application.

Article 17

Upon deciding on the exceptionally allowed higher price of a medicinal product, JAZMP shall consider the following:
- Opinion of the Committee under indent four of Paragraph five of Article 4 of the Act (hereinafter: the Committee);
- Established public interest in the field of healthcare;
- Established assessment of risk arising from any disturbances in the supply of the relevant medicinal product with an economic substantiation, or evidenced, unavoidable and disproportionate costs arising from fulfilment of public service obligations.

Article 18

(1) In its opinion, based on the data contained in a complete application, data on the medicinal product and other information that shows the state of professional and scientific development, JAZMP states its opinions on:

- The significance of the medicinal product within national healthcare priorities,
Rules on determining the prices of medicinal products for human use
taking into account its urgency, importance and irreplaceability;
- The risk to public health that may arise from a disrupted supply of the medicinal product, including the economic aspect;
- Impact on public finance because of approved extraordinary allowed higher price of medicinal product.

(2) The Committee evaluates the data submitted in a complete application based on these Rules and issues an opinion that comprises of its findings in the form of points, whereby the following criteria are considered:

1. Relative therapeutic value, which means added effectiveness through the improvement of health outcomes (assessed with a grade ranging from 1 to 5 points, indicating to what extend does the Committee agree with the merits of the request for the determination of an exceptional higher allowed price for the medicinal product);

2. Cost efficiency of the medicinal product or presence of appropriate financial and economic merits in comparison to other possible treatments (assessed with a grade ranging from 1 to 5 points, indicating to what extend does the Committee agree with the merits of the request for the determination of an exceptional higher allowed price for the medicinal product);

3. Balance between the proposed exceptional higher allowed price for the medicinal product and the prices of the relevant medicinal product in other EU Member States or the states signatories to the EEA Agreement, taking into consideration the key characteristics of the compared markets, namely:

- 5 points - proposal more than 10 percent below median price of medicinal product on comparative markets;
- 4 points – proposal between 5 and 10 percent below the median price of the medicinal product on the compared markets;
- 3 points - proposal between 0 and 5 percent below median price of medicinal product on comparative markets;
- 2 points - within 5 percent over median price of medicinal products on comparative markets;
- 1 point – more than 5 percent over the median price of the medicinal product on the compared markets;

4. Existence of specific factors relevant for the placement of the medicinal product in question in national healthcare programs in accordance with given priorities and ethical aspects (assessed as the rate of Committee agreement with the substantiation of the request for determining an exceptionally allowed higher medicinal product price, between 1 and 5 points).

(3) When assessing applications for medicinal products without marketing authorisation, which do have authorisation for entry or import of medicinal products or temporary marketing authorisation and are placed on the list of essential or indispensable medicinal products referenced in Article 17 of the Act, the Committee shall consider criteria detailed in Items one and four of the previous paragraph.

Article 19

(1) In its opinion, the Committee states its views on the items detailed above and the proposed amount of the extraordinary allowed higher price of a medicinal product in one of the following manners:

1. By a positive opinion the Committee proposes the exceptionally allowed higher price of medicinal product as proposed in the application if the points detailed in Paragraph 2 of the above Article amount to 18 or more for medicinal products with due marketing authorisation or authorisation for a parallel imported medicinal product and 10 or more for medicinal products with no marketing

authorisation, but do have authorisation for entry or import or temporary marketing authorisation and are placed on the list referenced in Article 17 of the Act, or

2. By a positive opinion the Committee proposes the exceptionally allowed higher price of medicinal product which is lower than that proposed in the application, in the amount calculated by the equation:

PEP(DPEHAP) = PEP(MAP) + DT/MT * (PEP(PPEHAP)-PEP(MAP)) *
(min(PEP(median(ER)) / PEP(PPEHAP); (PEP(PPEHAP) - PEP(MAP)) /
max(PEP(median(ER)); PEP(MAP))),

whereby the following elements shall have the following meanings:

PEP(DEAHP) – determined PEP of extraordinary allowed higher price

PEP(PEAHP) – proposed PEP of extraordinary allowed higher price

PEP(MAP) – PEP of maximum allowed price

DT – achieved points

MT – possible points

PEP(median(ER)) – median of producer prices in the EU Member States or countries signatories of the EEA Agreement, where the medicinal product is marketed, namely:

- If data from only two states is available, the arithmetic mean of the prices in these two countries shall be used;
- If data from only one country is available, data from this country shall be used;
- If this country is the Republic of Slovenia, the maximum allowed price shall be used.

3. The Committee gives a positive opinion and proposes that the exceptional higher allowed price for the medicinal product be set in the amount determined and substantiated by the Committee, whereby the results of the assessments referred to in paragraph two of the preceding Article are also considered proportionately;

4. By a negative opinion the Committee proposes that an exceptionally allowed higher price not be set for the relevant medicinal product.

(2) If the Committee issues a negative opinion, such opinion must be substantiated, stating the definitions referred to in paragraph one of the preceding Article and the number of the points achieved in the evaluation of data provided in the application referred to in paragraph two of the preceding Article.

Article 20

(1) JAZMP identifies the public interest in the field of health, considering the presence of the medicinal product on the market in the context of national health priorities and taking into account the data on the medicinal product, its use, costs of treatment in comparison with the costs of treatment with the medicinal products for the same indication area within the same therapeutic group of medicinal products and in the field of the relevant pharmacotherapy, obtained on the basis of the protocols on data exchange between the Institute of Public Health of the Republic of Slovenia (hereinafter: NIJZ) and Health Insurance Institute of Slovenia (hereinafter: HEALTH INSURANCE INSTITUTE OF SLOVENIA).

(2) JAZMP may in the process of establishing public interest also obtain a second opinion on the presence of public interest in the medicinal product concerned in the scope of health care programmes financed from the regional expanded expert committee or a clinical department or three statements of specialists practicing medicine in the area of relevant pharmacotherapy.

Article 21

Prior to deciding on the maximum allowed price for a medicinal product and the exceptional higher allowed price for a medicinal product, JAZMP may request from ZZZS the data on the impact of the proposed price on public expenditure at the level of individual medicinal products, groups and the entire field of the relevant pharmacotherapy.

III. COORDINATING THE MAXIMUM ALLOWED PRICES OF MEDICINAL PRODUCTS AND EXCEPTIONALLY ALLOWED HIGHER PRICES OF MEDICINAL PRODUCTS

Article 22

The maximum allowed prices of medicinal products are coordinated with the provisions of these Rules twice annually

Article 23

(1) For purposes of coordination, the subjects shall establish the maximum allowed prices of medicinal products in accordance with the criteria specified herein and submit an application for coordination of maximum allowed prices to the JAZMP, in the period:
- 1 March to 1 April of the current year; and
- 1 September to 1 October of the current year, including.

(2) Application for coordination of maximum allowed prices shall contain a request for determination of coordinated maximum allowed price of a medicinal product, list of products and proposed maximum allowed prices of medicinal products with calculation given on Form B1 from Annex 1, in written and electronic form.

(3) The following issues of the prescribed publications shall be used in the application for coordination of maximum allowed prices of medicinal products:

1. In the period referred to in the first indent of the first paragraph hereunder:
- Austria: Erstattungskodex: The issue of 1 January of the current year or Warenverzeichnis: data from a web source with the date of acquisition in February of the current year;
- France: Vidal, date of acquisition in February of the current year;
- Germany: Lauer-Taxe or ABDA Datenbank: issued on 15 February of the current year;

2. In the period referred to in the second indent of the first paragraph hereunder:
- Austria: Erstattungskodex: The issue of 1 January of the current year and amendment of 1 July of the current year, or Warenverzeichnis: data from a web source with the date of acquisition in August of the current year;
- France: Vidal, date of acquisition in August of the current year;
- Germany: Lauer-Taxe or ABDA Datenbank: issued on 15 August of the current year.

(4) The maximum allowed prices of medicinal products shall be coordinated in the manner specified hereunder also in the period when the marketing authorisation for a medicinal product has already expired and the medicinal product can be marketed, pursuant to the Act, until its expiry date but not longer than 18 months.

(5) JAZMP may reduce the exceptionally allowed higher prices and maximum allowed prices of medicinal products prior to the expiry of their validity on the basis of an application submitted by the subject in written or electronic form in pdf and xls format, in which the following shall be listed:

- Proposed reduced maximum allowed price of medicinal product on Form B1 or proposed reduced exceptionally allowed higher price on Form B2 from Annex 1 hereof and
- Date of enforcement of the proposed reduced price.

IV. PUBLISHING AND FORWARDING OF PRICES;

Article 24

(1) The JAZMP shall at least once a month publish the maximum allowed prices of medicinal products and extraordinary allowed higher prices of medicinal products which it has determined in accordance herewith on its website by specifying the following:

- National identifier of medicinal products;
- Name and presentation of the medicinal product;
- General name of the medicinal product;
- Classification marking of the medicinal product;
- Name of the subject;
- Maximum allowed price of a medicinal product or exceptionally allowed price of a medicinal product;
- Date of entry into force of the price of the medicinal product;
- Medicinal product dispensing regime;
- Medicinal product status (original, generic or biosimilar);
- Other relevant data.

(2) Notwithstanding the first paragraph, the maximum allowed price shall not be published without the subject's consent in the case of the first Paragraph of Article 16 hereof and when the exceptionally allowed higher price of medicinal product had not been determined.

(3) JAZMP shall once a year report to the European Commission the applicable maximum allowed prices and extraordinary allowed higher prices of the medicinal products.

(4) At least once a month, JAZMP shall submit to the Institute, the ministry responsible for health (hereinafter: the Ministry) and the IVZ the maximum allowed prices of medicinal products and extraordinary allowed higher prices of medicinal products together with PEP values and percentages of comparative price in the electronic form.

(5) JAZMP shall submit data on medicinal products under Paragraph two of Article 7 to ZZZS until 25 April or 25 October of the current year.

(6) ZZZS shall submit wholesale prices, agreed on the basis of the first paragraph of Article 159 of the Act and dates of entry into force to JAZMP and the Ministry at their request.

(7) NIJZ shall provide JAZMP, the Ministry and ZZZS with data on the use of medicinal products and their costs at least once annually.

(8) JAZMP shall provide the Ministry with data acquired from the public body established in the Republic of Slovenia pursuant to Paragraph three of Article 9 hereof, within 30 days of receiving such information or upon each coordination of the maximum allowed price of a medicinal product, the subject of which is a public body established in the Republic of Slovenia.

Article 25

The subjects shall notify maximum allowed prices and exceptionally allowed higher prices of the medicinal products devised in accordance herewith to business entities with authorisation for wholesale trade in medicinal products or authorisation for production of medicinal products and concluded agreements on cooperation with them, immediately or not later than within eight days after determining the maximum allowed prices and exceptionally allowed higher prices of the medicinal products and at least three business days prior to their first use on the market.

V. TRANSITIONAL AND FINAL PROVISIONS

Article 26

Applications received until the day of enforcement hereof, for which no price had been determined, shall be subject to the present Rules.

Article 27

Rules on the determination of prices of medicinal products for human use (Official Gazette of the Republic of Slovenia, nos 102/10, 6/12, 16/13 and 71/13) shall cease to apply on the date the present Rules enter into force.

Article 28

These Rules shall enter into force on the next day after their publication in the Official Gazette of the Republic of Slovenia.

APPENDIX 1

A		SUBJECT:								**Issue number:**				**Appendix 1**	
B		SUBJECT:	**FORM B1 FOR CALCULATING MAXIMUM ALLOWABLE WHOLESALE PRICE OF MEDICINAL PRODUCTS**							Lauer-Taxe (online resource or electronic issue)					
C										ABDA Datenbank					
										Vidal (online resource or resource licensed from issuer)					
Copy empty form			Date of data preparation:							Erstattungskodex (publication or online resource)					
F										Warenverzeichnis (online resource)					
1		Medicinal product code	Proprietary name of proposed medicinal product, strength, form and packaging	ATC	No. of basic units	Valid MAP	Originator - Generic	Comp. price per bas. unit	Comparative price	Percentage of comp. price	PEP (€)	Wholesale share (€)	Prop. MAP (€)	Index	Date of presence on market
2		1	2	3	4	5	6	7	8=7*4	9	10=8*9/100	11	12	13=12/5*100	14
3	**0**														
4	0	Comparative state	Proprietary name of proposed medicinal product, strength, form and packaging	No. of basic units	Price from publication	Comparative price *	Comparative price per bas. unit*								
5	0	16	17	18	19	20	21 =20 / 18								
6	0	Austria 1													
7	0	Austria 2													
S	0	France 1								Legend:					
9	0	France 2								PEP - The manufacturer's element of the wholesale price					
10	0	Germany 1								MAP - maximum allowed wholesale price of medicinal product					
11	0	Germany 2								*	data for comparative states				

Signature of responsible person:

A	SUBJECT:								**Issue number:**			**Appendix 1**		
B	SUBJECT:	**FORM B2 FOR CALCULATING EXCEPTIONALLY ALLOWED HIGER WHOLESALE PRICE OF MEDICINAL PRODUCTS**							Lauer-Taxe (online resource or electronic issue)					
C									ABDA Datenbank					
Copy empty form		Date of data preparation:							Vidal (online resource or resource licensed from issuer)					
									Erstattungskodex (publication or online resource)					
F									Warenverzeichnis (online resource)					
1	Medicinal product code	Proprietary name of proposed medicinal product, strength, form and packaging	ATC	No. of bas. units	Valid EAHP	Originator - Generic	Comp. price per bas. unit	Comparative price	Percentage of comp. price	PEP (€)	Wholesale share (€)	Prop. EAHP (€)	Index	Date of presence on market
2	1	2	3	4	5	6	7	8=7*4	9	10=8*9/100	11	12	13=12/5*100	14
3														
4	Comparative state	Proprietary name of proposed medicinal product, strength, form and packaging	No. of basic units	Price from publication	Comparative price *	Comparative price per bas. unit*								
5	16	17	18	19	20	21=20 / 18								
6	Austria 1													
7	Austria 2													
P	France 1								Legend:					
9	France 2								PEP - The manufacturer's element of the wholesale price					
#	Germany 1								MAP - maximum allowed wholesale price of medicinal product					
#	Germany 2								*	data for comparative states				

Signature of responsible person:

Appendix 1											
Form B3											
LISTING OF MEDICINAL PRODUCT PRICES IN EU/EEA MEMBER STATES OR OTHER EUROPEAN COUNTRIES											

Subject:
Date (dd.mm.YYYY):
Medicinal product name and packaging:
Working code:

Table a. Prices in EU/EEA Member States

MEMBER STATE	manufacturer price EUR	wholesale price EUR	no. of units*	sales in 000 units	note***
Austria					
Belgium					
Bulgaria					
Cyprus					
Czech Republic					
Denmark					
Estonia					
Finland					
France					
Greece					
Croatia					
Ireland					
Iceland					
Italy					
Latvia					
Liechtenstein					
Lithuania					
Luxembourg					
Hungary					
Malta					
Germany					
The Netherlands					
Norway					
Poland					
Portugal					
Romania					
Slovakia					
Slovenia					
Spain					
Sweden					
United Kingdom					

Table b. Prices in other European countries

STATE	manufacturer price EUR	wholesale price EUR	no. of units*	sales in 000 units	note***
Albania					
Andorra					
Belarus					
Bosnia and Herzegovina					
Montenegro					
Kosovo					
Rep. of Macedonia					
Moldova					
Monaco					
Russia					
San Marino					
Serbia					
Switzerland					
Turkey					
Ukraine					
Vatican					

* number of doses in packaging

**actual annual sales of medicinal products expressed in 000 of sold units-packages

***sequential number of note; subjects submit notes on a separate sheet with marked sequential numbers from tables (a) or (b) of this form

APPENDIX 2

A:
Equation 1 Calculation of comparative price - Germany Recalculation from retail prices (source: Lauer Taxe or ABDA Datenbank)

Comparative price (Germany) = MAX (C - 38.50 ; (C - 0.70) / 1.0315) EUR, where:

C - wholesale price in Germany (from EK data field in the publication Lauer-Taxe or data field [Apo_Ek] in the publication ABDA Datenbank);
MAX (a; b) - the higher of items a and b.

B:

Table 1. Factor values for calculation of comparative price (France) from published retail prices of medicinal products (source: Vidal - online resource or resource licensed from issuer) with regard to relevant price ranges in the column marked C [EUR].

C [EUR]	f2	f3	f1
0-2.45	0.0000	0.30	1.1000
2.46-29.72	-0.2199	0.00	1.2808
2973-179.19	2.7334	0.00	1.1518
179.20-524.33	6.4628	0.00	1.1268
524.34-1676.93	6.4822	30.06	1.0600
1676.94-	97.3822	30.06	1.0000

Equation 2
Comparative price (France) = (C/f4 - f2 - f3) / f1 where:
C - retail price of medicinal product with VAT (France) from publication (France: Vidal (online resource or resource licensed from issuer)
f1, f2, f3 - factor values for recalculation from Table 1
f4 - value of recalculation factor (f4 = 1,021)

C:

Table 2. Calculation of comparative price - Austria. Recalculation from retail prices (source: Erstattungskodex - publication or online resource, or Warenverzeichnis - online resource).

Insurance price in EUR	Calculation factor	Calculation of comparative price
C	f	Formula
up to 9.58	0.6320	C * f
9.59	0.6408	C * f
9.60 – 13.69	0.6488	C * f
13.70	0.6540	C * f
13.71 – 18.38	0.6584	C * f
18.39	0.6643	C * f
18.40 – 26.99	0.6704	C * f
27.00	0.6780	C * f
27.01 – 39.59	0.6856	C * f
39.60	0.6963	C * f
39.61 – 76.06	0.7070	C * f
76.07	0.7135	C * f
76.08 – 76.79	0.7200	C * f
76.80	0.7347	C * f
76.81 – 122.99	0.7493	C * f
123.00 – 123.01	0.7652	C * f
123.02 – 141.59	0.7811	C * f
141.60	0.7948	C * f
141.61 – 170.99	0.8085	C * f
171.00	0.8232	C * f
171.01 – 216.82	0.8379	C * f
216.83	0.8437	C * f
216.84 – 219.99	0.8496	C * f
220.00	0.8657	C * f
220.01 – 370.99	0.8817	C * f
371.00	0.8906	C * f
371.01 – 377.03	0.8995	C * f
from 377,04	1.0390	C/f - 23.74 EUR

APPENDIX 3

Calculation of wholesale price of medicinal product.

Wholesale price of a medicinal product is calculated using the relevant equation so that the manufacturer's price element is increased by the wholesale share, which is a sum of a fixed and variable part:

Wholesale price of medicinal product = PEP + P1 + MIN (PEP * P2 ; P3) EUR,

where:
- wholesale price of medicinal product: maximum allowable price or exceptionally allowed higher price;
- PEP: manufacturer's element of price
- P1 + MIN (PEP * P2 ; P3): wholesale share;
- MIN (a;b): smaller of the a and b values in parentheses in the equations
- P1 fixed part of wholesale share
- P2 maximum allowed percentage of PEP value for calculation of the variable part of the wholesale share (%)
- P3 maximum allowed value of the variable part of wholesale

Values of parameters P1, P2 and P3 in the above equation are:
- P1 0.50 EUR
- P2 1.1 %
- P3 27.00 EUR

(Published 8 May 2015) (1) Rules amending the Rules on determining the prices of medicinal products for human use (Official Gazette of the RS, no. 15-514/2016), published 26 February 2016, in force as of 27 February 2016, also state:	Article 2 Applications for determining the maximum allowed price and extraordinary allowed higher price of medicinal products, received up to the day of enforcement hereof, for which no price had been determined before that date, shall be subject to the rules in force until the date of enforcement hereof."

(2)Rules amending the Rules on determining the prices of medicinal products for human use (Official Gazette of RS, no. 19-827/2018), published on 23 March 2018, in force as of 24 March 2018	