1323. Rules of Reimbursement

Pursuant to the tenth and eleventh paragraph of Article 23.c and Article 26 of the Health Care and Health Insurance Act (Official Gazette of the Republic of Slovenia, no. 72/06 – official consolidated text, 114/06 – Act Regulating Adjustments of Transfers to Individuals and Households in the Republic of Slovenia – ZUTPG, 91/07, 76/08 and 62/10 – Exercise of Rights to Public Funds Act – ZUPJS, 87/11 and 40/12 – Fiscal Balance Act – ZUJF) and Item 1 of the first paragraph of Article 70 and the first paragraph of Article 71 of the Articles of Association of the Health Insurance Institute of Slovenia (Official Gazette of the Republic of Slovenia nos. 87/01 and 1/02 – corr.) the General Meeting of the Health Insurance Institute of Slovenia, at its 13th meeting held on 3 April 2013, adopted the following

R U L E S of Reimbursement

I. GENERAL PROVISIONS

Article 1
(Areas covered by the Rules)

(1) These Rules stipulate:
1. Detailed procedure and criteria for reimbursed medicinal products;
2. Detailed procedure and criteria for non-reimbursed medicinal products;
3. Conditions and procedure for determining the restrictions in prescribing or dispensing individual medicinal products;
4. Costs of procedure;
5. The manner, procedure and criteria for determining the highest recognised value for each group of interchangeable medicinal products;
6. Detailed procedure and conditions for determining therapeutic groups of medicinal products and their highest recognised values;
7. Criteria, conditions and procedure for reaching an agreement on the prices of medicinal products with the Health Insurance Institute of Slovenia (hereinafter: the Institute); and
8. Records on reimbursed medicinal products, the highest recognised value for each group of interchangeable medicinal products, and therapeutic groups of medicinal products and their highest recognised values.

(2) The Institute puts medicinal products on the list, changes them between individual lists, excludes them from the list, lays down limitations to prescribing or dispensing individual medicinal products, and determines the therapeutic groups of medicinal products based on the expert opinion of the Reimbursement Committee from Article 32 hereof.

1. Article 2
2. (Terms)
3.

(1) The terms used herein shall have the following meaning:
1. "Budget Impact Analysis" is an analysis evaluating in detail the budget impact of the introduction and use of a new method of treatment paid for by the health insurance system.
2. "Sensitivity Analysis" is an assessment of impacts of unreliability in evaluation parameters under assumptions underlying the pharmacoeconomic model in a cost- effectiveness analysis and a cost-utility analysis.
3. "Cost Analysis" is a type of economic analysis that only takes into account the cost of treatment regardless of its outcome.
4. "Cost-Effectiveness Analysis" is a type of economic analysis that compares the costs of treatment expressed in monetary units and its outcomes expressed in units of clinical outcomes such as additional years of life.
5. "Cost-Utility Analysis" is a sub-type of cost-effectiveness analysis in which the treatment outcome is expressed in units of humanistic outcomes such as quality-adjusted life-year (QALY) based the patient’s subjective assessments of the quality of their health.
6. "Cost Minimisation Analysis" is a type of economic analysis that only takes into account the cost of treatment because there is no difference in its outcomes.
7. "Hospital" is a provider of health care services engaging in specialised hospital treatment or specialised outpatient activity at the secondary or tertiary levels of health care.

8. "Hospital Medicinal Product" is a medicinal product that can only be dispensed at a hospital due to its properties.
9. "Price of Medicinal Product" is the applicable price of a medicinal product agreed or set in accordance with the law on medicinal products and forming the basis for charging the medicinal product to health insurance or health care providers.
10. “Defined Daily Dose” is the unit used by the World Health Organisation for the consumption of medicinal products.
11. "Discount rate" is the rate used to calculate the present value of future cash flows.
12. "Value Added of a Medicinal Product" is the medicinal product's value expressed by its relative therapeutic value or economic advantage compared to a comparator.
13. "Galenic medicinal product" is a medicinal product for human use, as specified in the law on medicinal products.
14. "Generic Medicinal Product" is a medicinal product as specified in the law on medicinal products.
15. "Authorisation Holder" is a general term for a marketing authorisation holder for a medicinal product or its representative in the Republic of Slovenia, a holder of marketing authorisation for a parallel entered or imported medicinal product, a holder of authorisation for entry or import of a medicinal product included in the list of essential medicinal products for human use and a holder of positive opinion of the European Medicines Agency on a parallel distributed medicinal product.
16. "Non-Reimbursement" means excluding a medicinal product from the cover provided by compulsory health insurance because it is no longer reimbursed in accordance with Article 3 hereof, does not meet the criteria laid down in Article 5 hereof or one of the criteria laid down in Article 16 hereof is met.
17. "Exceptionally Allowed Higher Price" is a price as specified in the law on medicinal products.
18. "Health Care Provider" is a natural or legal person that has signed a contract with the Institute to provide health care.
19. "Public Agency" means the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices.
20. "Final Treatment Outcome" means the outcome relating to the time of extension of life for the treated disease or the time until recurrence.
21. "List of Medicinal Products" is a common term for positive and intermediate lists of prescription medicinal products and the list of hospital medicinal products.
22. "Magistral medicinal product" is a medicinal product for human use, as specified in the law on medicinal products.
23. "Substitute Medicinal Product" is a medicinal product without a marketing authorisation in the Republic of Slovenia but having a special authorisation for entry or import that can substitute a reimbursed medicinal product with the same active substance in the case of interrupted supply.
24. "Substitute Treatment Outcome" means a clinical outcome result on the basis of which the effectiveness of treatment can be assumed, (value of blood pressure, cholesterol, glycogenic haemoglobin, hospitalisation, etc.).
25. "Maximum Allowed Price" is a price as specified in the law on medicinal products.
26. "Highest Recognised Value (HRV)“ is the price standard defined by the Institute for a medicinal product in a group of interchangeable medicinal products and a therapeutic group of medicinal products covered by compulsory insurance in full or in relevant percentage, depending on the act regulating health care and health insurance (hereinafter: the Act) and reimbursement or otherwise of a medicinal product.
27. "New Medicinal Product" means that no medicinal product with the same active substance has been reimbursed so far.
28. "Restricted Dispensing" means that a pharmacist in a pharmacy may dispense a medicinal product to the debit of compulsory health insurance only within the set limitations.
29. "Restricted Prescription" means that a physician may prescribe a medicinal product to the debit of compulsory health insurance only within the set limitations.
30. "Code of Reimbursed Medicinal Product" means a combined code which includes the code of the list of medicinal products and the percentage financed by compulsory health insurance and potentially also the code of a medicinal product with restricted prescription or dispensing and the code of a medicinal product with set HRV.
31. "Code of Medicinal Product from the List of Hospital Medicinal Products" is a combined code including the list code and possibly the code of a medicinal product with restricted prescription and the code of a medicinal product with set HRV.
32. "Similar Biological Medicinal Product" is a medicinal product as specified in the law on medicinal products.

33. "Procedure" is a common term for the process of listing, relisting, excluding from the list of medicinal products and the process of determining or changing the restriction of prescribing and dispensing conducted on the basis of these Rules.
34. "Relisting" is a change in the listing from one list of medicinal products to another.
35. "Adjustment of Pharmacoeconomic Analysis" is a methodological adjustment of an analysis made for one of the Member States of the European Economic Area to the Slovene territory with Slovene input data.
36. "Comparator" is a medicinal product used as the benchmark for a medicinal product in the procedure to determine the relative therapeutic value and in pharmacoeconomic analyses.
37. "Comparative Form of Medicinal Product" means different pharmaceutical forms with comparative release and the same application.
38. "Comparative Dose" is a dose of medicinal product which, based on the data from the Summary of Product Characteristics and professional literature, results in a comparative clinical effect in view of the comparator.
39. "Recommended Dose" is a maintenance dose of the medicinal product for an adult weighing 70 kg for a specific therapeutic indication.
40. "Incremental Cost-Effectiveness Ratio – ICER" is the incremental cost-effectiveness or utility ratio of a new treatment method compared to the standard treatment in the Republic of Slovenia.
41. "Listing" is deciding on reimbursement of a medicinal product.
42. Relative Therapeutic Value" of a medicinal product is the difference between the effectiveness of two or more medicinal products or therapeutic procedures which represent comparable alternatives for the achievement of desired outcome of treatment in the regular clinical practice. A medicinal product with the same therapeutic indication is used to determine the relative therapeutic value and other medicinal products in the pharmacological-therapeutic group are also included in the comparison, especially the selected medicinal products from the therapeutic guidelines and other most frequently used medicinal products.
43. "List of Interchangeable Medicinal Products with HRV" is the list of the Institute which contains the highest recognised values of classified medicinal products from the list of interchangeable medicinal products published by the Agency.
44. "Therapeutic Indication of Medicinal Product" is the disease or condition specified in the Summary of Product Characteristics which the medicinal product can cure or improve.
45. "Therapeutic Group of Medicinal Products" is a group of medicinal products determined by the Institute that are classified in the positive and intermediate lists of medicinal products with the same therapeutic indication, which may include individual medicinal products, combined medicinal products and various pharmaceutical forms of a medicinal product.
46. "Prescription Medicinal Products" are medicinal products included by the Institute on the positive or intermediate list of medicinal products, prescribed by the personal or referring physician and dispensed in pharmacies.
47. "Orphan Medicinal Product" is a medicinal product used for treating a rare illness which obtained the status from the European Medicines Agency.
48. "Treatment" is a health care service that includes the medicinal product.
49. "Health Care Institution" is a health care provider.
50. "Health Insurance" is a common term for compulsory and complementary health insurance.
(2) Designations and abbreviations in these Rules shall have the following meaning:
1. "ATC" means anatomic-therapeutic-chemical listing of medicinal products;
2. "B" means a medicinal product from the list of hospital medicinal products;
3. "C" in the designation of the list means a medicinal product with the highest recognised value;
4. "EAHP" means exceptionally allowed higher price;
5. "N" means a non-reimbursed medicinal product;
6. "MAP" means maximum allowed price;
7. "HRV" means the highest recognised value;
8. "P" means the positive list of prescription medicinal products;
9. "V" means the intermediate list of prescription medicinal products;
10. "*" asterisk in the listing means a medicinal product with limited prescription or dispensing.

4. Article 3
5. (Subject of listing)
6.

(1) The following medicinal products shall be listed:
1. Medicinal products with marketing authorisation in the Republic of Slovenia;

2. Medicinal products with authorisation for parallel import;
3. Medicinal products with a positive opinion from the European Medicines Agency for parallel distribution;
4. Medicinal products from the list of essential medicinal products for human use which have not been granted marketing authorisation but a special authorisation for entry or import;
5. Substitute medicinal products;
6. Galenic medicinal products for human use; and
7. Magistral medicinal products.
(2) A hospital medicinal product shall be listed if the price of its recommended dose exceeds EUR 5,000 per person in one year to the debit of health insurance.

7. Article 4
8. **(List of medicinal products)**
9.

(1) Prescription medicinal products are listed to the positive list of medicinal products or the intermediate list of medicinal products.
(2) Hospital medicinal products are included in the list of hospital medicinal products.
(3) Medicinal products are listed with their proprietary names, except for magistral medicinal products.

10.

11.

12. II. CRITERIA FOR MEDICINAL PRODUCT LISTING AND RELISTING

13.

14. Article 5
15. (Criteria)
16.

In the process of listing and relisting, medicinal products are assessed on the basis of the following criteria:
1. Significance of medicinal product in terms of public health;
2. Health care programme implementation priorities;
3. Therapeutic significance of the medicinal product;
4. Relative therapeutic value of a medicinal product;
5. Assessment of pharmacoeconomic data on the medicinal product;
6. Evaluation of ethical aspects;
7. Health care programme priorities; and
8. Data and assessments from reference sources.

17. Article 6
18. (Significance for public health and health care programme priorities)
19.

(1) The priorities in the area of prevention and treatment of persons and conditions considered significant for the assessment of significance of individual medicinal products in terms of public health, health care programme implementation priorities and health care programme priorities are:
1. Set out in Article 23 of the Act;
2. Specified in the resolution concerning the national health care plan; or
3. Defined in the documents of the World Health Organisation on the priority health care programmes in Europe.
(2) In the assessment from the previous paragraph hereunder, the significance of the areas not specified in the documents referred to in the previous paragraph hereunder is also taken into account when they are significant for public health.

20. Article 7
21. (Therapeutic significance of the medicinal product)
22.

(1) In terms of therapeutic significance, a medicinal product is defined as:
1. Medicinal product with a proven positive effect on final treatment outcomes;
2. Medicinal product with a proven positive effect on substitute treatment outcomes; or
3. Medicinal product with a positive effect on the quality of life.

(2) When assessing the therapeutic effect of a medicinal product, the level of medicinal product recommendation in the Slovenian therapeutic guidelines or the guidelines of the European expert associations is taken into account:
1. Class I: the medicinal product is convincing and without any doubt effective, which is why it must be used;
2. Class IIa: evidence on effectiveness of the medicinal product is inconsistent; however, evidence that it is effective prevails, which is why its use is recommended;
3. Class IIb: there is not enough evidence on the effectiveness which is why the use of the medicinal product is only recommended in special cases; or
4. Class III: there is no evidence of clinical effectiveness of the medicinal product which is why the use is not recommended.

23. Article 8
24. (Relative therapeutic value of a medicinal product)
25.

In terms of relative therapeutic value, the medicinal product is defined as:
1. A medicinal product with new therapeutic value in case it is used for treating or preventing a disease for which no effective treatment has existed so far; or
2. A medicinal product with new therapeutic value in case the following issues are involved, compared to the comparator:
a) more favourable impact on the final treatment outcome,
b) more favourable impact on the substitute treatment outcome,
c) effective treatment of disease symptoms,
d) an improved safety profile of the medicinal product; or
e) a more patient-friendly use of the medicinal product.

26. Article 9
27. (Estimate of pharmacoeconomic data on the medicinal product)
28.

(1) The Institute shall assess the medicinal product based on a pharmacoeconomic analysis and a budget impact analysis, which shall be presented for the first three years of cover by health insurance.
(2) The cost-efficiency or usefulness analysis conducted or adapted for Slovenia shall use as the basis for assessing the medicinal product also the incremental cost-effectiveness ratio as the ratio between incremental cost and incremental effectiveness or utility for the new and the standard treatment as determined by a resolution of the Management Board of the Institute based on the planned funds under the compulsory health insurance for medicinal products, as specified in the Institute's budget.
(3) The budget impact analysis shall use as the basis for assessing the medicinal product the aspect of planned compulsory health insurance funds for medicinal products, as specified in the Institute’s budget.

29. Article 10
30. (Types and results of pharmacoeconomic analyses)
31.

(1) The preparation of pharmacoeconomic analyses referred to in the previous article hereof may apply:
1. A complete evaluation with an analysis of costs and treatment outcomes; or
2. A partial evaluation with a cost analysis.
(2) The following pharmacoeconomic analyses can be used as the basis for assessing the pharmacoeconomic data:
1. Cost-effectiveness analysis;
2. Cost-utility analysis;
3. Cost-cutting analysis; or
4. Cost analysis.
(3) As a rule, the results of the pharmacoeconomic analyses are expressed as:
1. The incremental cost-effectiveness ratio between the new and the standard treatment for an additional year of quality-adjusted life years; or

2. The incremental cost-effectiveness ratio between the new and the standard treatment for an additional year of life or the time until disease progression or the number of prevented medical conditions; or
3. Comparison of costs of the new and the standard treatment at the annual level.

32.

33. Article 11

34. (Aspect of pharmacoeconomic data)

35.

(1) The pharmacoeconomic analysis is carried out from the aspect of health insurance. An analysis can also be conducted from the social aspect, particularly if significant difference is expected between the social aspect and the aspect of health insurance. In such case, both aspects must be shown separately.
(2) The budget impact analysis is carried out from the aspect of health insurance.

36.

37. Article 12

38. (Content of pharmacoeconomic data)

39.

(1) The pharmacoeconomic analysis must include the following items:
1. Basic data on the analysis:
a) the party ordering the analysis,
b) the party conducting the analysis,
c) disclosure of potential conflict of interests of the contractor,
2. Key starting points of the analysis, including:
a) the purpose of the analysis,
b) the aspect,
c) the therapeutic indication,
d) the target population,
e) common or standard treatment,
f) treatment with a new medicinal product,
g) list of comparators,
h) a comparison of the safety profile of the new and the common treatment,
i) period to which the analysis refers,
j) a description of the input data (costs, epidemiological data, data on effectiveness),
k) sources of input data, together with the strengths, weaknesses, source reliability and selection criteria for studies and files,
l) data collection process,
3. Analysis type;
4. A description of the model and its validation in the case of a model analysis;
5. A clear record of treatment outcomes, clinical and humanistic (quality of life);
6. Source of information on treatment outcomes (systematic overview of literature or meta-analysis);
7. Discounting the cost or outcome of treatment;
8. Analysis assumptions;
9. Sensitivity analysis;
10. Results with comments;
11. Methodology of transfer into Slovenia, in the case of a foreign analysis;
12. Summary of the analysis; and
13. In the case of a model analysis, the computer model in an electronic table with non-protected contents.
(2) The recommended fixed discount rate under Item 7 of the previous paragraph hereunder shall equal three to five percent and vary between nought and eight percent in the sensitivity analysis.
(3) The budget impact analysis must include the following items:
1. Introductory information:
a) epidemiological data (prevalence and incidence of disease, age, gender and risk factors) for Slovenia, if data exist, otherwise from foreign sources,
b) clinical data (description of pathology, progressing of disease and existing treatment possibilities),
c) economic data (relevant pharmacoeconomic analyses),
2. Description of the new treatment compared to the standard treatment, including potential changes in the treatment implementation;
3. The budget impact analysis (taking into account the aspect of health insurance);

4. Method and form of analysis:
a) determining the population (by years, taking into account all known measures, such as restricted prescription, stimulated demand, adverse effects),
b) integration of new medicinal product in the treatment processes,
c) period to which the analysis refers,
d) model description,
e) description of input data,
f) sources of data, together with the strengths, weaknesses source reliability and selection criteria, studies and files,
g) data collection process,
h) description of the method(s) for compiling the analysis; and
5. Results:
a) presentation of the impact of the introduction of a new medicinal product on health insurance expenses by year, based on pessimistic, optimistic and medium version;
b) presentation of annual cost of the introduction of a new medicinal product (total cost and cost by item), based on pessimistic, optimistic and medium version,
c) sensitivity analysis, if conducted,
d) graphic presentation of model, if used,
e) indication of used assumptions of the model, if used, and
f) computer model in the form of checklists in an electronic table, with non-protected contents, if used.
(4) The form E from Annex 1 hereto can be used for the presentation of an analysis of cost reduction or a cost analysis.

40. Article 13
41. (Mandatory pharmacoeconomic data)
42.

(1) Pharmacoeconomic data with the cost-effectiveness analysis or cost-utility analysis and budget impact analysis, compiled or adjusted for Slovenia, are a mandatory enclosure to the application in the case of:
1. A new medicinal product;
2. A new therapeutic indication of a reimbursed medicinal product;
3. Relisting; or
4. Determination or change to the restriction on prescribing or dispensing.
(2) In the case under the previous paragraph hereunder, i.e. adjustment of a pharmacoeconomic analysis, the original analysis or its translation into Slovenian or a language understandable to the Institute shall be a mandatory enclosure to the application.
(3) In the case of a medicinal product under the first paragraph hereunder the foreseen total turnover of which does not exceed 500,000 euros to the debit of health insurance in all strengths and forms in the budget impact analysis for the first three years of financing, it shall be sufficient if the original analysis in the original language or its translation into Slovenian or a language understandable to the Institute, conducted in one of the Member States of the European Economic Area, is attached to the application instead of the pharmacoeconomic analysis under the first paragraph hereunder.
(4) If the medicinal product under the first paragraph hereunder exceeds the total amount of 500,000 euros to the debit of health insurance before or after the expiry of the three-year period, the marketing authorisation holder shall be obliged to submit a pharmacoeconomic analysis in accordance with the first paragraph hereunder within six months of receiving a request from the Institute to do so. If the marketing authorisation holder fails to submit the analysis within the specified deadline, the Institute shall initiate the procedure for non-reimbursement of the medicinal product.
(5) For a medicinal product under the first paragraph hereunder without significant differences in effectiveness and safety compared to the comparator, a cost-cutting analysis or a cost analysis will be attached to the application under the first paragraph hereunder.
(6) All required analyses for medicinal products hereunder shall be based on the results of publicly available meta-analyses or high-quality randomised studies. If required, any additional data may be derived from observation studies. If not enough real data are available, modelling methods can also be used for the analysis.

43. Article 14
44. (Evaluation of ethical aspects)
45.

The ethical aspect is considered as a criterion mainly in the assessment of medicinal products for the treatment of severe or rare illnesses.

46. Article 15
47. (Data and estimates from reference sources)
48.

In the scope of data and assessments from reference sources, data from expert and scientific publications, therapeutic guidelines, findings and estimates of reference expert associations, data and guidelines of the World Health Organisation and other institutions and bodies competent for prices of medicinal products and public financing as well as data from other publicly available sources shall be taken into account.

49. Article 16
50. (Criteria for non-reimbursement)
51.

Notwithstanding Article 5 hereof, the following medicinal products shall not be reimbursed:
1. Not disclosing the same or added value in the therapeutic or economic sense compared to the reimbursed medicinal products in the same therapeutic group; or
2. Used for alleviating the symptoms or treating medical conditions that are less significant from the point of view of public health; or
3. Used in treating medical conditions that can be regulated or treated merely by changing the way of living.

52. III EXCLUSION FROM THE LIST OF MEDICINAL PRODUCTS
53.
54. Article 17
55. (Exclusion from the list of medicinal products)
56.

(1) A medicinal product shall be excluded from a list of medicinal products or if it is no longer the subject of listing under Article 3 hereof, does not meet the criteria from Article 5 hereof or when one of the criteria from the previous article is met.
(2) Notwithstanding the previous paragraph hereunder, a medicinal product can be excluded from the list of medicinal products based on a written consent of the marketing authorisation holder obtained beforehand, if the medicinal product is not available in the Slovenian market for more than one year, which the Institute verifies based on the data on its taking and the data that the authorisation holder is obliged to submit to the Institute.

57. IV RESTRICTED PRESCRIPTION AND DISPENSING
58.
59. Article 18
60. (Restricted prescription and dispensing)
61.

(1) The institute may define or change the restrictions on prescribing and/or dispensing a listed medicinal product in the process of listing or relisting. A restriction can refer to:
1. Population group entitled to receive the medicinal product, defined by age or other population characteristics;
2. Indication area for which the medicinal product may be prescribed; one or more approved therapeutic indications may be selected from the summary of product characteristics; treatment duration can also be limited in the scope of indication area,
3. The disease severity for which the medicinal product may be prescribed,
4. Type of specialisation of the physician entitled to prescribe the medicinal product, i.e. clinical specialty or a group of specialised physicians entitled to prescribe medicinal products;

5. Mandatory previous approval by an expert committee which decides on the prescription of specific medicinal products obtained with biotechnological procedures;
6. Time or quantity restriction of dispensing;
7. The hospital which, in accordance with an approval from the ministry of health, performs a health programme with the medicinal product.
(2) The text of the restriction on prescribing or dispensing is published on the website of the Institute together with the listing or relisting. A medicinal product with restricted prescription or dispensing shall be marked with an asterisk next to the list code.

62.

63.

64. V. PROCEDURE

65.

66. Article 19

67. (Initiation of procedure)

68.

(1) The marketing authorisation holder may submit to the Institute an application for listing, relisting and deciding on or changing of the restriction on prescribing or dispensing.
(2) The health institution may address to the Institute an initiative for starting the procedure. The Institute shall inform the health institution in writing of the acceptance or rejection of the initiative. If the initiative is accepted, the procedure is continued as in the case of application and a decision from Article 34 hereof is issued.
(3) The Institute may initiate the procedure upon its own initiative.
(4) The Institute shall inform of the initiative from the second and the third paragraphs hereunder the marketing authorisation holder to whom the initiative refers or the pharmacy producing the galenic medicinal product. The marketing authorisation holder or the pharmacy shall submit to the Institute upon its written request the relevant documentation needed for the Institute's decision. Otherwise, the Institute shall decide on the basis of evidence available to it.

69.

70. Article 20

71. (Types of applications and initiatives)

72.

(1) The application or initiative for listing a medicinal product can refer to:
1. A new medicinal product;
2. A new therapeutic indication of a reimbursed medicinal product;
3. New combination of medicinal products;
4. Similar biological medicinal product;
5. Generic medicinal product and parallel entry or import or parallel distribution;
6. New form, strength or packaging of a reimbursed medicinal product;
7. A medicinal product from the list of urgently needed medicinal products for use in human medicine;
8. Substitute medicinal product;
9. Galenic medicinal product or
10. Magistral medicinal product.
(2) An application can also refer to:
1. Relisting; and
2. Determination or change to the restriction on prescribing or dispensing.
(3) An initiative can also refer to:
1. Relisting,
2. Determination or change to the restriction on prescribing or dispensing; and
3. Exclusion from the list of medicinal products.

73.

74. Article 21

75. (Application)

76.

(1) The application shall contain data on the marketing authorisation holder, technical and expert data on the medicinal product specified herein and the decision on the maximum allowed price or exceptionally allowed higher price.
(2) The application is sent to the Institute in printed copy and on an electronic data carrier.

(3) If the marketing authorisation holder or its representative change during the procedure, the application shall be supplemented with the data on the new marketing authorisation holder or its representative and the evidence on this change within eight days of the change.
(4) Data and documents in the application shall be sent to the Institute organised in the order as specified for each type of application hereunder and in the manner specified in individual type of application.

77.

78. Article 22

79. (Initiative)

80.

(1) The initiative must contain data on the health institution which addresses the initiative to the Institute, the data on the medicinal product to which the initiative refers and the expert explanation of the proposal.
(2) The initiative shall be submitted to the Institute in written or electronic form.
(3) Unless stipulated otherwise herein regarding individual issues related to the initiative, it shall be subject to the same provisions hereof as those applying to the application.

81.

82. Article 23

83. (Application for a new medicinal product, new therapeutic indication, relisting and determination of or change to limitations of prescribing and dispensing)

84.

(1) An application for listing of a new medicinal product or a new therapeutic indication of a reimbursed medicinal product, an application for relisting and an application for determination of or change to restrictions on prescribing or dispensing shall contain the following data and documents:
1. Cover letter (form A in Annex 1 hereto);
2. Application summary (form B in Annex 1 hereto), containing:
a) data from the summary of product characteristics (B.1.),
b) data on the treatment (B.2.),
c) expert justification (B.3.),
d) possible inclusion in the expert guidelines and the level of recommendation (B.4.),
e) rate of reimbursement from public funds in the EU Member States and potential other countries and potential limitations of prescription and dispensing (B.5.),
f) data on the marketing (B.6.),
g) data on the price (B.7.),
h) data on the cost of medicinal product (B.8.),
i) data on the impact on health care services (B.9.),
j) data on the pharmacoeconomic research (B.10.),
k) data on the budget impact analysis (B.11.),
l) potential proposal by the marketing authorisation holder (B.12.),
m) data and estimate from reference sources (B.13),
3. Documents (form C in Annex 1 hereto):
a) authorisation (C.1.),
b) decision on MAP or EAHP (C.2.),
c) evidence on potential status of an orphan medicinal product (C.3.),
d) certificate that the costs have been paid (C.4.),
e) authorisation, in case the applicant or proposer of initiative is a legal or natural person applying for the listing on behalf of the marketing authorisation holder (C.5.), and
4. Additional expert documentation (form D in Annex 1 hereto):
a) summary of product characteristics approved by the Public Agency or the European Medicines Agency (D.1.),
b) European Public Assessment Report (EPAR) if the medicinal product is registered according to the centralised procedure (D.2.),
c) clinical research referred to in the application summary (D.3.),
d) pharmacoeconomic analysis (D.4.),
e) budget impact analysis (D.5.).
(2) The application under the previous paragraph hereunder shall also contain the treatment protocol, the inclusion and exclusion clinical criteria and medicinal products or treatments already used for the same therapeutic indication, and data on the effectiveness of the new treatment compared with the existing treatment.

85. Article 24
86. (Application for a new combination of medicinal products)
87.

Application for reimbursing a new combination of medicinal products shall contain the following data and documents:
1. Cover letter (form A in Annex 1 hereto);
2. Application summary (form B in Annex 1 hereto), containing:
a) data from the summary of product characteristics (B.1.),
b) data on the treatment (B.2.),
c) expert justification (B.3.),
d) rate of reimbursement from public funds in the EU Member States and potential other countries and potential limitations of prescription and dispensing (B.5.),
e) data on the marketing (B.6.),
f) data on the price (B.7.),
g) data on the cost of medicinal product (B.8.),
h) pharmaceutical particulars (B.10.3),
i) potential proposal by the marketing authorisation holder (B.12.),
j) data and estimate from reference sources (B.13),
3. Documents (form C in Annex 1 hereto):
a) authorisation (C.1.),
b) decision on MAP or EAHP (C.2.),
c) evidence on potential status of an orphan medicinal product (C.3.),
d) certificate that the costs have been paid (C.4.),
e) authorisation, in case the applicant or proposer of initiative is a legal or natural person applying for the listing on behalf of the marketing authorisation holder (C.5.), and
4. Additional expert documentation (form D in Annex 1 hereto):
a) summary of product characteristics approved by the Public Agency or the European Medicines Agency (D.1.),
b) European Public Assessment Report (EPAR) if the medicinal product is registered according to the centralised procedure (D.2.),
c) clinical research referred to in the application summary (D.3.).

88. Article 25
89. (Application for similar biological medicinal product)
90.

Application for reimbursing a similar biological medicinal product shall contain the following data and documents:
1. Cover letter (form A in Annex 1 hereto);
2. Application summary (form B in Annex 1 hereto), containing:
a) data from the summary of product characteristics (B.1.),
b) expert justification (B.3.),
c) rate of reimbursement from public funds in the EU Member States and potential other countries and potential limitations of prescription and dispensing (B.5.),
d) data on the marketing (B.6.),
e) data on the price (B.7.),
f) data on the cost of medicinal product (B.8.),
g) potential proposal by the marketing authorisation holder (B.12.),
h) data and estimate from reference sources (B.13),
3. Documents (form C in Annex 1 hereto):
a) authorisation (C.1.),
b) decision on MAP or EAHP (C.2.),
c) evidence on potential status of an orphan medicinal product (C.3.),
d) certificate that the costs have been paid (C.4.),
e) authorisation, in case the applicant or proposer of initiative is a legal or natural person applying for the listing on behalf of the marketing authorisation holder (C.5.), and
4. Additional expert documentation (form D in Annex 1 hereto):
a) summary of product characteristics approved by the Public Agency or the European Medicines Agency (D.1.),
b) European Public Assessment Report (EPAR) if the medicinal product is registered according to the centralised procedure (D.2.),

c) clinical research referred to in the application summary (D.3.).

91. Article 26
92. (Application for generic medicinal product and medicinal product with authorisation for parallel import or parallel distribution)
93.

(1) The application for reimbursing a generic medicinal product, a combined generic medicinal product and a medicinal product with authorisation for parallel import or parallel distribution shall contain the following data and documents:
1. Cover letter (form A in Annex 1 hereto);
2. Application summary (form B in Annex 1 hereto), containing:
a) data from the summary of product characteristics (B.1.),
b) expert justification (B.3.),
c) data on the marketing (B.6.),
d) data on the price (B.7.),
e) data on the cost of medicinal product (B.8.),
f) potential proposal by the marketing authorisation holder (B.12.),
3. Documents (form C in Annex 1 hereto):
a) authorisation (C.1.),
b) decision on MAP or EAHP (C.2.),
c) certificate that the costs have been paid (C.4.),
d) authorisation, in case the applicant or proposer of initiative is a legal or natural person applying for the listing on behalf of the marketing authorisation holder (C.5.); and
4. Additional expert documentation (form D in Annex 1 hereto):
a) summary of product characteristics approved by the Public Agency or the European Medicines Agency (D.1.),
b) European Public Assessment Report (EPAR) if the medicinal product is registered according to the centralised procedure (D.2.).
(2) The application for reimbursing a medicinal product with authorisation for parallel import or a positive opinion of the European Medicines Agency for parallel distribution shall be prepared pursuant to the previous paragraph hereunder, except for Item 3.a, where the authorisation for parallel import or a positive opinion of European Medicines Agency for parallel distribution shall be enclosed.

94. Article 27
95. (Application for a new form, strength or packaging of a reimbursed medicinal product)
96.

(1) The application for new form, strength or packaging of a reimbursed medicinal product shall contain:
1. Cover letter (form A in Annex 1 hereto);
2. Application summary (form B in Annex 1 hereto), containing:
a) data from the summary of product characteristics (B.1.),
b) expert justification (B.3.),
c) rate of reimbursement from public funds in the EU Member States and potential other countries and potential limitations of prescription and dispensing (B.5.),
d) data on the marketing (B.6.),
e) data on the price (B.7.),
f) data on the cost of medicinal product (B.8.),
3. Documents (form C in Annex 1 hereto):
a) authorisation (C.1.),
b) decision on MAP or EAHP (C.2.),
c) evidence on potential status of an orphan medicinal product (C.3.),
d) certificate that the costs have been paid (C.4.),
e) authorisation, in case the applicant or proposer of initiative is a legal or natural person applying for the listing on behalf of the marketing authorisation holder (C.5.), and
4. Additional expert documentation (form D in Annex 1 hereto):
a) summary of product characteristics approved by the Public Agency or the European Medicines Agency (D.1.),
b) clinical research referred to in the application summary (D.3.).

(2) If the new form of the medicinal product affects the cost of treatment compared to the reimbursed form, the application referred to in the previous paragraph hereunder shall also contain the pharmacoeconomic data from Section B.10.3 from Annex 1 hereto.

97. Article 28
98. (Application for medicinal product from the list of essential medicinal products and for substitute medicinal product)
99.

The application for reimbursing a medicinal product from the list of essential medicinal products for human use and a substitute medicinal product shall contain the following data and documents:
1. Cover letter (form A in Annex 1 hereto);
2. Application summary (form B in Annex 1 hereto), containing:
a) data from the summary of product characteristics (B.1.),
b) expert justification (B.3.),
c) data on the marketing (B.6.),
d) data on the price (B.7.),
3. Documents (form C in Annex 1 hereto):
a) authorisation (C.1.),
b) decision on MAP or EAHP (C.2) and, for the substitute medicinal product, the wholesale price;
c) evidence on potential status of an orphan medicinal product (C.3.),
d) authorisation, in case the applicant or proposer of initiative is a legal or natural person applying for the listing on behalf of the marketing authorisation holder (C.5.); and
4. Additional expert documentation (form D in Annex 1 hereto) including the Summary of Product Characteristics in Slovenian or a language understandable to the Institute.

100.
101. Article 29
102. (Initiative for galenic medicinal product)
103.

An initiative for reimbursing a galenic medicinal product shall contain the following data and documents:
1. Cover letter (form A in Annex 1 hereto);
2. Application summary (form B in Annex 1 hereto), containing:
a) data from the patient information leaflet (B.1.),
b) expert justification (B.3.),
c) data on the marketing (B.6.),
d) data on the price (B.7.),
e) data on the cost of medicinal product (B.8.),
f) any proposal by a health care institution (B.12.), and
3. Additional expert documentation (form D in Annex 1 hereto) including the patient information leaflet.

104.
105. Article 30
106. (Initiative for magistral medicinal product)
107.

An initiative for reimbursing a magistral medicinal product shall contain the following data and documents:
1. Cover letter (form A in Annex 1 hereto); and
2. Application summary (form B in Annex 1 hereto), containing:
a) expert explanation of the health care institution stating the therapeutic indication and prescription (B.3.1., B.3.12.),
b) data on the price: framework calculation together with pharmacy service,
c) potential proposal of a healthcare institution (B.12.).

108.
109. Article 31
110. (Processing of applications and initiatives)
111.

(1) The Institute shall process complete applications and initiatives. An application or initiative shall be deemed complete if it contains all data and documents stipulated herein. If an application or initiative

is incomplete, the Institute shall, within five days of receiving it, ask the marketing authorisation holder or the healthcare institution to supplement it.
(2) The Institute may, based on submitted and obtained data, request from the authorisation holder or the health care institution additional data and analyses significant for further decisions.

112.

113. Article 32

114. (Reimbursement Committee)

115.

(1) In the process specified in the second paragraph of Article 1 hereof, the Institute shall decide on the basis of an expert opinion from the Reimbursement Committee (hereinafter: the Committee). Members of the Committee shall be appointed by the Management Board of the Institute for a four-year term.
(2) The Committee shall be an expert and independent body consisting of experts in the field of medicine and pharmacy, with knowledge in clinical pharmacology, and other experts with systemic knowledge in the area of medicinal products. The Committee members shall perform their work in compliance with the code of medical ethics and the applicable regulations.
(3) The Committee shall adopt its Rules of Procedure.

116.

117. Article 33

118. (Additional expert opinions)

119.

In the process and when determining therapeutic groups of medicinal products, the Institute may obtain opinions from professional associations, clinics or individual experts in medicine, pharmacy or other areas.

120.

121. Article 34

122. (Decision)

123.

(1) The Institute shall issue the decision on reimbursement or non-reimbursement no later than within 90 days of receiving the complete application. This deadline can be extended only in case the Agency has determined the maximum allowed price prior to the expiry of 90 days. The process of determining the maximum allowed price in accordance with the provisions regulating the prices of medicinal products and the process of reimbursement of medicinal products, including the implementation of reimbursement may together not last more than 180 days.
(2) Notwithstanding the previous paragraph hereunder, the Institute shall issue a decision on reimbursing a galenic medicinal product within 180 days of receiving a complete initiative.
(3) The Institute shall issue a decision on relisting or a decision on rejecting the relisting, a decision on non-reimbursement of medicinal products and a decision on the determination or change of restrictions on prescribing or dispensing, or a decision on rejecting the determination or change of restrictions on prescribing or dispensing within 180 days of receiving a complete application or initiative.

124. Article 35

125. (Explanation)

126.

The decision under the previous article hereunder shall be explained with the statement that this was the subject of listing under Article 3 hereof, indicating the reasons based on the criteria specified in Articles 5 and 16 hereof, including the expert opinions on which the decision is based.

127.

128. Article 36

129. (Appeal and judicial protection)

130.

(1) The marketing authorisation holder or the pharmacy may lodge an appeal against a decision in accordance with Article 34 hereof. An appeal should be submitted within 30 days following the service of the decision under Article 34 hereof. The appeal shall be lodged with the Institute, which forwards it to the ministry of health within five days of receiving it. An appeal shall not stay the execution of such decision.

(2) A decision on the appeal shall be adopted by the minister of health within 60 days of receiving of the appeal by the Institute.
(3) The marketing authorisation holder or the pharmacy may contest the decision of the minister of health referred to in the previous paragraph hereunder within 30 days of receiving the decision by filing a lawsuit in an administrative dispute to the Administrative Court of the Republic of Slovenia.

131.

132.

133. VI. COSTS OF PROCEDURE

134.

135. Article 37

136. (Costs of procedure)

137.

(1) The marketing authorisation holder shall pay the costs of procedure in accordance herewith. The costs of procedure shall be paid upon the submission of the application into the account of the Institute.
(2) Depending on the type of application, the costs of procedure shall be as follows:
1. For reimbursement of a new medicinal product: EUR 2,000,
2. For reimbursement of a new therapeutic indication of a reimbursed medicinal product: EUR 1,500,
3. For reimbursement of a new combination of medicinal products: EUR 1,000,
4. For reimbursement of a similar biological medicinal product: EUR 500,
5. For reimbursement of a generic medicinal product, combined generic medicinal product and a medicinal product with authorisation for parallel import or parallel distribution: EUR 300,
6. For reimbursement of new forms and strengths of reimbursed medicinal products: EUR 500,
7. For reimbursement of a new packaging of reimbursed medicinal products: EUR 300,
8. For relisting: EUR 1,000; and
9. For the determination or change to the restricted prescription or dispensing: EUR 1,500.
(3) The costs of procedure from the previous paragraph hereunder shall refer to one medicinal product with one working code. The costs of procedure shall be increased by EUR 25 for each additional working code.
(4) The costs of procedure shall not be paid in the case of reimbursing a:
1. Medicinal product from the list of urgently needed medicinal products for human use;
2. Substitute medicinal product;
3. Galenic medicinal product; and
4. Magistral medicinal product.

138. VII. THERAPEUTIC GROUPS OF MEDICINAL PRODUCTS

139.

140. Article 38

141. (Determining therapeutic groups of medicinal products)

142.

(1) The Institute shall determine upon its initiative therapeutic groups of medicinal products among the medicinal products included in the positive and the intermediate list of medicinal products. The basis for inclusion of a medicinal product in a therapeutic group of medicinal products is therapeutic indication and the criteria under Article 5 hereof.
(2) The medicinal product with the most favourable treatment cost-effectiveness ratio based on the prices of reference doses of medicinal products included in the therapeutic group shall be set for every therapeutic group of medicinal products.
(3) When determining a medicinal product from the previous paragraph, only the active substances or combinations of active substances of the medicinal product shall be taken into account which achieve the market share calculated based on the following formula:
minimum market share = 100% / (n + 1),
where:
n – the number of active substances or combinations thereof in a therapeutic group of medicinal products.
The market share of active substances of a medicinal product or combinations thereof shall be calculated from the data of the Institute on dispensed medicinal products, expressed in defined daily doses, available in the last 12 months.

(4) A therapeutic group of medicinal products can be divided into classes of reference doses with regard to the strength of medicinal products (hereinafter: the Class). If a medicinal product from the second paragraph hereunder is not represented in all classes, other medicinal products are defined, so that all specified medicinal products are within HRV in all strengths.
(5) If no significant difference exists between medicinal products in a therapeutic group of medicinal products or a Class as regards effectiveness, safety, pharmaceutical forms and method of administering, the medicinal product with the most favourable treatment cost-effectiveness ratio shall be the one with the lowest price of a reference dose at a time the HRV is set for a therapeutic group of medicinal products or Class.
(6) If a therapeutic group features a medicinal product which is advantageous as regards the insured person due to its pharmaceutical form in the sense of method of administering or clinical properties, value added shall be determined and expressed as a percentage of the price of a reference dose. Value added may not exceed the percentage that would result in a higher HRV than the price of medicinal product based on the data, applicable upon the preparation of the resolution from the eighth paragraph hereunder on the therapeutic group, according to the procedure for determining the HRV from Articles 39 to 43 hereof.
(7) Value added of a combined medicinal product included in a therapeutic group of medicinal products is defined as the difference between the sum of HRV of individual active substances and the HRV of the combined medicinal product without value added, defined based on the data, applicable upon the preparation of the resolution from the eighth paragraph hereunder on the therapeutic group, according to the procedure for determining the HRV from Articles 39 to 43 hereof. Value added is expressed as percentage of price of a comparable dose. If the HRV of a combined medicinal product without value added exceeds the sum of HRV of individual active substances, value added is not specified. If HRV cannot be calculated for an individual active substance, the price of medicinal product is used. If no medicinal product with the active substance of the combined medicinal product is reimbursed, the price shall be set on the basis of a comparator in the Republic of Slovenia or the European Union.
(8) The therapeutic groups of medicinal products and any changes thereof shall be determined by a decision of the Institute's Management Board.

143.

144. VIII. HRV

145.

146. Article 39

147. (Data for determining HRV)

148.

(1) Data valid on the first business day of the month in which the HRV is set shall be used to determine the HRV in accordance with Articles 40 and 41 hereof.
(2) The basis for determining the HRV is prescription medicines only, based on the national code, the share of dispensed packaging of which reached at least 0.5% in the group of interchangeable products, a therapeutic group of medicinal products or its class in the last month. The Institute shall take into account the latest available monthly data on dispensed medicinal products from the previous paragraph.

149.

150. Article 40

151. (Determining HRV for groups of interchangeable medicinal products)

152.

(1) The Institute shall determine the HRV for the groups of interchangeable medicinal products listed in the positive and the intermediate list of medicinal products with regard to the cheapest medicinal product in view of the reference dose the group of interchangeable medicinal products.
(2) The basis for determining the HRV referred to in the previous paragraph hereunder is the list of interchangeable medicinal products, list of medicinal products and the prices of medicinal products.
(3) The group of interchangeable medicinal products referred to in the first paragraph hereunder shall comprise at least two medicinal products with a proprietary name with regard to the work code and specified by the active substance, ATC code, strength and comparable form of the medicinal product.
(4) The HRV referred to in the first paragraph hereunder is determined by multiplying the lowest price of a reference dose, rounded to four decimal places, with the number of doses of an individual medicinal product, rounded to two decimal places, namely upwards if the third decimal digit is 5 or more, and downwards if it is less.

153.

154. Article 41

155. (Determining the HRV for therapeutic groups of medicinal products)

156.

(1) The HRV is determined by the Institute for each therapeutic group of medicinal products at the level of the price of medicinal product with the most favourable ratio between the costs and effects of treatment so that it covers all doses of at least one medicinal product in the relevant therapeutic group of medicinal products.
(2) The HRV referred to in the previous paragraph hereunder is determined by multiplying the price of a reference dose of the medicinal product with the most favourable ratio between the costs and effects of treatment, rounded to four decimal places, with the number of doses of an individual medicinal product, rounded to two decimal places, namely upwards if the third decimal digit is 5 or more, and downwards if it is less. The HRV is determined on the basis of reference doses for all medicinal products in a therapeutic group of medicinal products accounting for any value added under the fourth paragraph of Article 38 hereof.

157.

158. Article 42

159. (The rule of lower HRV)

160.

If a medicinal product has the HRV determined in accordance with the procedure in accordance with Articles 40 and 41 hereof, the lower of the two HRV shall be set as its HRV.

161.

162. Article 43

163. (Decision on the designation of HRV and marking of the medicinal product)

164.

(1) The HRV in accordance with Articles 40 and 41 hereof and any changes thereof shall be determined, as a rule, once every two months, by a decision of the Institute's Management Board or the Managing Director of the Institute, if authorised by the Management Board of the Institute.
(2) The medicinal products under Articles 40 and 41 hereof shall be assigned the designation C in addition to the list code.

165. IX. AGREEMENT ON THE PRICE OF MEDICINAL PRODUCT

166.

167. Article 44

168. (Agreement on the price of medicinal product)

169.

(1) The agreement on the price of medicinal product may refer to the following method of financing of the medicinal product:
1. The agreed price of the medicinal product;
2. Discount or rebate;
3. The price–sales volume ratio of a medicinal product;
4. Reimbursement of exceeded expenses for a medicinal product;
5. Risk sharing.

(2) The agreement on the price of medicinal product may refer to one or several medicinal products. The entry into agreement on the price of a medicinal product can be proposed by the Institute or a marketing authorisation holder, or a pharmacy if the subject of agreement on the price is a galenic medicinal product. The form Agreement on the price of medicinal product which is attached in Annex 2 herewith, is a constituent part of the agreement on the price of medicinal product. The agreement on the price of medicinal product must be made in writing and in Slovenian in order to be valid. If the agreement on the price of medicinal product was made in Slovenian and in a foreign language, the agreement on the price of medicinal product made in Slovenian shall be used for resolving any disputes.
(3) Authorisation holders or pharmacies if the subject of agreement on the price is a galenic medicinal product shall submit to the Institute an agreement on the price of medicinal product or an annex thereto at least five business days prior to entry into force of the price listed in the form Agreement on the price of medicinal product with the latter also submitted in electronic form, namely as an Excel sheet to the e-mail address zdravila.cene@zzzs.si.

(4) The agreed price of medicinal product is the price of medicinal product agreed by the Institute on the basis of the act regulating on medicinal products.
(5) Discounted price of medicinal product means that the marketing authorisation holder reduces the price of the medicinal product under the conditions agreed in the agreement on the price of medicinal product.
(6) Rebate means financial or quantity discount for a medicinal product granted by the marketing authorisation holder after a specific period of time and under the conditions agreed in the agreement on the price of medicinal product.
(7) Agreement on the price – sales volume ratio of a medicinal product means that the price of a medicinal product is reduced with the increase of the sales volume by the share agreed in the agreement on the price of medicinal product.
(8) The agreement on the reimbursement of exceeded expenses means that the marketing authorisation holder shall reimburse the Institute, after the end of the agreed period, the agreed difference between the actual and the agreed amount for a medicinal product if such amount was exceeded.
(9) The agreement on risk sharing means the sharing of the financing of medicinal product by the marketing authorisation holder and the Institute on the basis of the achievement of clinical criteria stipulated in the agreement on the price of medicinal product.

170. Article 45
171. (Termination of agreed price of medicinal product)
172.

If the MAP of a medicinal product is reduced to or under the agreed price of such medicinal product, the agreement on the price of such medicinal product shall cease to be valid in the part relating to its agreed price unless the marketing authorisation holder and the Institute have previously agreed on a new agreed price of the medicinal product.

173. Article 46
174. (Enforcement of agreed prices of medicinal products)
175.

Marketing authorisation holders or pharmacies, if the subject of the agreement on the price of medicinal product is galenic medicinal products, shall inform legal entities and natural persons with authorisation to perform wholesale trading in medicinal products or with whom they have entered into co-operation agreements of the agreed prices of their medicinal product, immediately after the conclusion of the agreement on the price of medicinal product or no later than within eight days following the date of validity, indicated on the form Agreement on the price of medicinal product or no later than eight days prior to the arrival in the market of the Republic of Slovenia.

176. X. RECORDS ON MEDICINAL PRODUCTS

177.
178. Article 47
179. (Records)
180.

The Institute shall keep the record of reimbursed medicinal products and on the HRV of reimbursed medicinal products and the record on agreed prices of medicinal products.

181.
182. Article 48
183. (Publications)
184.

(1) The Institute shall publish the amendments to the list with validity dates on its website at least 14 days prior to the enforcement. The Institute shall publish on its website the consolidated text of the list of medicinal products.
(2) The Institute shall publish the list of medicinal products with HRV or the amendments to it on its website on the next business day after determining the HRV. The Institute shall also publish on its website the consolidated text of the list of medicinal products with HRV.
(3) The agreed prices of medicinal products shall be published by the Institute on its website, if the marketing authorisation holder or the pharmacy allows such publication, which is marked on the form

Agreement on the price of medicinal products. In the opposite case, the Institute shall only publish the agreed prices of medicinal products for health care providers.
(4) The Institute shall inform the marketing authorisation holders, the health care institutions that address the initiative to the Institute and the health care providers on the listing, relisting, exclusion from the list of medicinal products and changes to the restricted prescription or dispensing and on the HRV via the system of the Institute's system for automatic electronic informing, in which the marketing authorisation holders, the health care institutions that address the initiative to the Institute and the health care providers can register through web application which is publicly available at the address http://www.zzzs.si/egradiva.

185. XI. TRANSITIONAL AND FINAL PROVISIONS

186.

187. Article 49

188. (Applications and initiatives received prior to the enforcement of the Rules)

189.

The applications for listing, relisting, exclusion from the list of medicinal products and changes to the restricted prescription or dispensing which the Institute received prior to the enforcement of the Rules shall be treated under the provisions of the Rules on Reimbursement (Official Gazette of the Republic of Slovenia no. 110/10).

190. Article 50

191. (Termination of validity)

192.

The Rules on Reimbursement (Official Gazette of the Republic of Slovenia, No 110/10). shall cease to be valid.

193. Article 51

194. (Entry into force)

195.

These Rules shall be published in the Official Gazette of the Republic of Slovenia after they have been approved by the minister of health and shall enter into force on the fifteenth day after publication in the Official Gazette of the Republic of Slovenia.
No. 9000-3/2013-DI/11
Ljubljana, 3 April 2013
EVA 2012-2711-0050
President of the General Meeting of the Health Insurance Institute of Slovenia
Vladimir Tkalec
Appendix 1: Contents of the applications
Appendix 2: The form Agreement on the price of medicinal product