Decree of the Russian Federation Government dated August 28, 2014 No. 871
On Approval of the Regulations for Preparation of the Lists of Drugs for Medical Use and the Minimum Range of Drugs Required for Rendering Medical Care

In accordance with Articles 55 and 60 of Federal law On Circulation of Drugs, Article 15 of Federal Law On the Fundamentals of Health Protection of Citizens in the Russian Federation and Article 6.2 of Federal Law On State Social Assistance, the Government of the Russian Federation has resolved:

1. To approve the annexed Regulations for Preparation of the Lists of Drugs for Medical Use and the Minimum Range of Drugs Required for Rendering Medical Care.

2. For the Ministry of Health of the Russian Federation to approve the Regulation on the Commission of the Ministry of Health of the Russian Federation for preparation of the lists of drugs for medical use and the minimum range of drugs required for rendering medical care and the composition of the Commission.

3. To determine that in 2014 proposals for preparation of the lists of drugs for medical use and the minimum range of drugs required for rendering medical care shall be sent to the Ministry of Health of the Russian Federation in accordance with the Regulations approved by this Decree until September 15, 2014.

4. Clause 4 of Decree of the Government of the Russian Federation dated October 29, 2010 No. 865 On State Regulation of Prices for the Drugs Included in the List of Vital and Essential Drugs (Legislation Bulletin of the Russian Federation, 2010, No. 45, p. 5851; 2012, No. 37, p. 5002), after the words "by the Ministry of Economic Development of the Russian Federation" add the words ", the Ministry of Labour and Social Protection of the Russian Federation, the Ministry of Regional Development of the Russian Federation, the Federal Antimonopoly Service, the Federal Service for Consumer Rights and Human Welfare Protection, the Federal Agency for Scientific Organizations".

5. For the Ministry of Health of the Russian Federation to provide explanations on the application of the Regulations approved this Decree.

Chairman of the Government
of the Russian Federation — D. Medvedev

Regulations for
Preparation of the Lists of Drugs for Medical Use and the Minimum Range of Drugs Required for Rendering Medical Care
(approved by Decree of the Government of the Russian Federation dated August 28, 2014 No. 871)

1. These Regulations shall govern the procedure for preparation of:

a) the list of vital and essential drugs for medical use (hereinafter referred to as the list of essential drugs);

b) the list of drugs intended for patients with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, haematopoietic and similar tissues, multiple sclerosis and patients after transplantation of organs and/or tissues (hereinafter - the list of expensive drugs);

c) the list of drugs for medical use, including drugs for medical use prescribed by decision of medical commissions of medical organizations (hereinafter - the list of drugs for certain categories of citizens);

d) the minimum range of drugs required for rendering medical care (hereinafter - the minimum range).

2. The list of essential drugs is formed by international generic names of these drugs (in the absence of such names - by modified INN or chemical names), taking into account standards of medical care and clinical recommendations (protocols) relating to rendering medical care, from among drugs for medical use (hereinafter - drugs) which meet the following criteria:

a) a drug is registered in due manner in the Russian Federation;

b) a drug is used for the purpose of diagnostics, prevention, treatment of and rehabilitation after

diseases, syndromes and states, including ones prevailing in the morbidity patterns in the Russian Federation;

c) a drug has an advantage compared to other drugs in the treatment of a particular disease or state;

d) a drug is a medical equivalent to drugs with similar pharmacological effects.

3. The list of expensive drugs is formed by international generic names of these drugs (in the absence of such names - by modified INN or chemical names), taking into account the amount of budget appropriations provided for in the federal budget for the next calendar year and the relevant planning period, from among drugs which meet the following criteria:

a) a drug is registered in due manner in the Russian Federation;

b) a drug is included in the list of essential drugs;

c) a drug has an advantage compared to other drugs in the treatment of patients with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, haematopoietic and similar tissues, multiple sclerosis and patients after transplantation of organs and/or tissues.

4. The list of drugs for certain categories of citizens is formed by international generic names of these drugs (in the absence of such names - by modified INN or chemical names) from among drugs which meet the following criteria:

a) a drug is registered in due manner in the Russian Federation;

b) a drug is included in the list of essential drugs;

c) a drug has an advantage compared to other drugs in the treatment of patients entitled to state social assistance in the form of a set of social services.

5. The minimum range is formed for various types of pharmacy organizations and individual entrepreneurs by international generic names of drugs (in the absence of such names - by modified INN or chemical names) from among drugs for medical use which meet the following criteria:

a) a drug is registered in due manner in the Russian Federation;

b) a drug is included in the list of essential drugs;

c) a drug circulating within the territory of the Russian Federation has at least 2 generic drugs by the relevant international generic name or, in the absence thereof, by the relevant modified INN or chemical name with similar dosage forms and dosages, produced by two or more manufacturers (except for drugs produced by the sole domestic manufacturer);

d) a drug is in demand with the health system and the population during the entire calendar year according to the data on sales in the pharmaceutical market of the Russian Federation.

6. Drugs should be excluded from the list of essential drugs, the list of expensive drugs, the list of drugs for certain categories of citizens (hereinafter - the lists) and the minimum range in the following cases:

a) inclusion of alternative drugs with proven clinical and/or clinical and economic advantages and/or features of the mechanism of action and/or higher safety in diagnostics, prevention, treatment of and rehabilitation after diseases, syndromes and states;

b) obtainment of information on toxicity or high frequency of adverse events during the use of the drug;

c) suspension of application of the drug in the Russian Federation;

d) cancellation of the state registration of the drug;

e) discontinuance of production of the drug or its supplies to the Russian Federation and/or absence of the drug in the civil circulation in the Russian Federation for more than one calendar year;

f) exclusion of the drug from the list of essential drugs - for the list of expensive drugs, the list of drugs for certain categories of citizens and the minimum range.

7. The list of essential drugs shall be prepared on an annual basis. The list of expensive drugs, the list of drugs for certain categories of citizens and the minimum range shall be prepared at least once every 3 years.

8. Amendments to the lists and the minimum range shall be made in accordance with the requirements established by these Regulations.

9. The lists and the minimum range shall be made by the Commission for preparation of the lists

of drugs for medical use and the minimum range established by the Ministry of Health of the Russian Federation (hereinafter referred to as the Commission).

10. Organizational and technical support shall be provided to the Commission by the Ministry of Health of the Russian Federation.

11. The Commission consists of representatives of the Ministry of Health of the Russian Federation, the Ministry of Industry and Trade of the Russian Federation, the Ministry of Finance of the Russian Federation, the Ministry of Labour and Social Protection of the Russian Federation, the Ministry of Regional Development of the Russian Federation, the Federal Service for Supervision in the Sphere of Health Care, the Federal Service for Consumer Rights and Human Welfare Protection, the Federal Antimonopoly Service, the Federal Medical and Biological Agency, Federal Agency for Scientific Organizations, other federal executive authorities, federal state educational institiutions of higher medical and pharmaceutical education, as well as federal state medical and pharmaceutical scientific organizations.

Representatives of other federal executive authorities, as well as non-governmental associations working in the field of health care, drug circulation and protection of the rights of citizens in these respect may be invited to the meetings of the Commission.

12. Meetings of the Commission are broadcast on the official website of the Ministry of Health of the Russian Federation in the information and telecommunication network "Internet" (hereinafter - the official site on the Internet).

13. Pharmaceutical entities and/or non-governmental associations working in the field of health care, drug circulation and protection of the rights of citizens in these respect (hereinafter - applicants) shall send, on an annul basis, to the Ministry of Health of the Russian Federation not later than 31 March, inclusive, on paper medium and in electronic format in accordance with the form established by this Ministry, the following proposals with the relevant documents and information:

a) proposal on the inclusion of a drug into the lists in the form set forth in Appendix 1;

b) proposal on the inclusion of a drug into the minimum range in the form set forth in Appendix 2;

c) proposal on the exclusion of a drug from the lists in the form set forth in Appendix 3;

d) proposal on the exclusion of a drug from the minimum range in the form set forth in Appendix 4.

14. When sending each of the proposals referred to in Clause 13 of these Regulations (hereinafter - proposal) by mail, the date of addressing of the applicant to the Commission shall be the date specified on the postal stamp of the federal postal service at the place of sending this proposal.

15. The Commission shall, within 15 days of the receipt of the proposal, arrange its documentary review.

Documentary review includes check of proper execution of the proposal in accordance with these Regulations, completeness and accuracy of information on drugs, including compliance with information contained in the state register of drugs, based on the results of which the expert report is made in the form set forth in Appendix 5 (hereinafter - the expert report based on the results of documentary review).

16. Further consideration of the proposal shall be refused in the following cases:

a) improper execution of the proposal and documents and information annexed thereto;

b) lack of the proposal and documents and information annexed thereto in electronic format;

c) submission of documents and information not in full;

d) identification of inconsistencies between documents and information submitted in paper medium and in electronic format;

e) submission of false or distorted information.

17. Should further consideration of the proposal be refused, the Commission shall sent to the applicant an expert report based on the results of documentary review within 7 days of its issue, provided that the documents and information submitted to the Ministry of Health of the Russian Federation are not returned to the applicant.

The proposal corrected by the applicant with due regard to the comments specified in the expert report based on the results of documentary review may be resubmitted to the Commission not later than June 1 of the current year.

18. Information on proposals received by the Commission, including proposals having passed documentary review, shall be published on the official website on the Internet.

19. Proposals regarding which a positive opinion was issued upon documentary review shall be subject to further consideration by the Commission in accordance with the procedure established by these Regulations.

20. The Commission shall, within 7 days of the issue of the positive opinion upon documentary review, submit the proposal regarding drugs proposed for inclusion into (exclusion from) the lists for review to the relevant federal state educational institution of higher education (medical and/or pharmaceutical) and/or secondary vocational education which statutory activities include scientific and research activities, or to the medical and/or pharmaceutical scientific organization under the Ministry of Health of the Russian Federation or Federal Agency for Scientific Organizations (hereinafter - the expert organization), with the provision of access to electronic versions of the documents and information submitted by the applicants, including the documents of the registration dossier for the relevant drug, published in due manner on the official website on the Internet.

21. The list of expert organizations shall be approved by the Ministry of Health of the Russian Federation and published on the official website on the Internet.

22. Review of proposals (hereinafter - review) includes clinical, clinical and economic assessment of the drug and shall be carried out by the expert organization within 30 days of the receipt of the proposal from the Commission.

23. For the purpose of review, the expert organization shall establish the Expert Commission from among the specialists with higher medical, pharmaceutical or biological education, provided that the specialists with higher medical and pharmaceutical education prevail.

24. Assessment of the applicant's information on the safety, quality and efficiency of the drug shall be carried out on the basis of integral scales for the drug assessment set forth in Appendix 6.

The clinical and economic assessment of the clinical and economic studies of the drug presented by the applicant and the justification of the clinical and economic characteristics constituting evidence for inclusion of the drug into (exclusion from) the lists shall be carried out based on the calculation of the cost of the course (year) of therapy with the proposed drug compared to the drugs included in the existing lists, proceeding from the estimated price representing the statistical median of prices for the relevant generic drugs registered in due manner (if available).

In the absence of prices for duly registered drugs, the comparison and assessment shall be carried out in respect of estimated prices for purchased drugs according to the electronic platforms, where electronic auctions for the purchase of drugs for state and municipal needs are held. The estimated price for a drug represents a statistical median of prices for actually purchased generic drugs (if available).

During the review, for the purpose of obtaining the necessary additional information and clarifications regarding data presented in the proposal, the expert organization shall search for information on clinical and/or clinical and economic studies of the drug (full-text publications shall be attached to the expert report).

25. Based on the results of review, the expert organization shall make an expert report in the form set forth in Appendix 7 (hereinafter - the expert report based on the results of review) and submit the same to the Commission on paper medium and in electronic format.

26. The expert report based on the results of review with the attached proposal shall, within 7 days of the receipt, be sent by the Commission to the expert (external specialist) of the Ministry of Health of the Russian Federation (hereinafter - chief expert), taking into account the profile of his/her activities, for the preparation of evidence-based recommendations for the inclusion of the drug (exclusion from, refusal to include) into the lists regarding this proposal, with the provision of access to electronic versions of the documents and information, including documents of the registration dossier for the relevant drug, published in due manner on the official website on the Internet.

27. Chief experts shall, within 15 days of the receipt of the expert report based on the results of review, submit to the Commission evidence-based recommendations for the inclusion of the drug (exclusion from, refusal to include) into the lists, on paper medium and in electronic format, prepared on the basis of analysis of the expert report based on the results of review.

When preparing such recommendations, in order to obtain additional information on the safety, quality and efficiency, as well as on the clinical and economic characteristics of the drug, chief experts may send requests to the professional medical and pharmaceutical communities and competent specialists.

28. Should the chief expert disagree in full or in part with the expert report based on the results of review, the chief expert shall prepare a recommendation containing comments with detailed scientific justification and references to the relevant publications regarding clinical studies of the drug and/or its safety monitoring within and/or outside the territory of the Russian Federation, as well as clinical and economic studies and calculations proving the conclusions set forth in the recommendation, with these publications attached.

29. When preparing the minimum range, the Commission shall, within 7 days of the issue of the positive opinion upon documentary review, submit the proposal at least to 2 chief experts, taking into account the profile of their activities, to obtain evidence-based recommendations for the inclusion of the drug (exclusion from, refusal to include) into the minimum range, with the provision of access to electronic versions of the documents and information published in due manner on the official website on the Internet.

30. Chief experts shall, within 15 days of the receipt of the proposal, submit to the Commission evidence-based recommendations specified in Clause 29 of these Regulations, on paper medium and in electronic format.

When preparing such recommendations, the chief experts may send requests to the professional medical and pharmaceutical communities and competent specialists.

31. Decisions on proposals shall be made in the meetings of the Commission considering expert reports based on the results of review, provided that the chief experts shall present in person their evidence-based recommendations specified in Clauses 27 and 29 of these Regulations.

32. Should the chief expert have any remarks regarding the expert report based on the results of review, the expert organization's representatives shall be invited to the meeting of the Commission.

33. Information on the decisions on the proposals made in the meetings of the Commission, the results of reviews and evidence-based recommendations specified in Clauses 27 and 29 of these Regulations shall be published on the official website on the Internet.

34. Should a conflict of interests arise, the relevant members of the Commission shall not participate in the decision-making process for the specific proposal.

Specialists of the expert organization participating in the preparation of the expert report based on the results of review, chief experts and members of the Commission who have submitted false information or failed to submit (submit in due time) to the Commission information on the circumstances which could result in the conflict of interests when considering the proposals, shall be excluded, by decision of the Commission, from further participation in the preparation of the lists and the minimum range, and the decision on the proposal made by the Commission with their participation shall be subject to review.

35. The draft lists and minimum range prepared according to the results of the meetings of the Commission by international generic names of drugs (in the absence of such names - by modified INN or chemical names), with indication of dosage forms, shall be published on the official website on the Internet for a period not less than 15 days.

36. The draft lists and minimum range shall be subject to agreement with the Ministry of Industry and Trade of the Russian Federation, the Ministry of Finance of the Russian Federation, the Ministry of Labour and Social Protection of the Russian Federation, the Ministry of Regional Development of the Russian Federation, the Ministry of Economic Development of the Russian Federation, the Federal Antimonopoly Service, the Federal Service for Consumer Rights and Human Welfare Protection and the Federal Agency for Scientific Organizations.

Appendix 1
to the Regulations for Preparation of
the Lists of Drugs for Medical
Use and the Minimum Range of
Drugs Required for Rendering
Medical Care

(form)

To the Commission of the Ministry of
Health of the Russian Federation
for preparation of the lists of
drugs for medical use and
the minimum range of drugs
required for rendering
medical care

Proposal
on the inclusion of a drug into the list of drugs for medical use*.

1. This proposal refers to the inclusion of a drug into the following lists of drugs:
1.1. the list of vital and essential drugs;
1.2. the list of expensive drugs;
1.3. the list of drugs for certain categories of citizens.
2. Information on the applicant:
2.1. Name of the organization or surname, name, patronymic (if any) of the citizen _____;
2.2. Responsible person, position _____;
2.3. Address (location) or place of residence _____;
Telephone (fax) _____;
Email _____.
3. Information on the drug:
3.1. name of the drug:
3.1.1. international generic name _____;
3.1.2. in the absence of the international generic name - modified INN _____;
3.1.3. in the absence of the international generic name and modified INN - chemical name _____;
3.1.4. in the absence of other names- trade name _____;
3.2. code of the drug in the Anatomical Therapeutic Chemical Classification _____;
3.3. label claims (to be listed)
_____;
3.4. state registration of the drug in the Russian Federation:
date (dd.mm.yyyy) _____;
market authorization number _____;
date of confirmation of the state registration of the drug (if available) (dd/mm/yyyy) _____;
3.5. name and address (location) of the legal entity in whose name the certificate of registration of the drug to be used as a comparator was issued (if available) _____;

manufacturer of the drug to be used as a comparator (if available) _____;

3.6. data on production of the drug in the Russian Federation (if available);

3.7. dosage forms of the registered drug proposed for inclusion (to be listed) _____;

3.8. information on generic drugs (if available) _____;

4. Information and data on the drug proposed for inclusion into the lists of drugs:

4.1. scientific evidence of the necessity and justification of the use of the drug for diagnostics, prevention, treatment of and rehabilitation after diseases, syndromes and states prevailing in the morbidity and mortality patterns in the Russian Federation on the basis of the data of the state statistical monitoring (if any);

4.2. availability of scientific evidence of clinical and pharmacoeconomic advantages of using the drug for treatment of patients with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, haematopoietic and similar tissues, multiple sclerosis and patients after transplantation of organs and/or tissues, compared with drugs already included into the lists of drugs;

4.3. availability of scientific evidence of advantages and/or features of the mechanism of action of the drug in comparison with alternative drugs, including drugs from the lists of drugs for medical use, for diagnostics, prevention, treatment of and rehabilitation after diseases, syndromes and states, taking into account the statistical data on the morbidity and mortality patterns in the Russian Federation;

4.4. demand for (social importance of) the drug in the health care system and among the population, taking into account the presence of the drug in the lists of drugs financed out of the budgets of the constituent entities of the Russian Federation;

4.5. presence of the drug in the list of strategically important drugs production of which must be ensured within the territory of the Russian Federation, approved by Decree of the Government of the Russian Federation dated July 6, 2010 No. 1141-r;

4.6. presence (localization) of production of the drug in the Russian Federation.

5. Justification for the inclusion of the drug into the lists of drugs:

5.1. epidemiological data (if available) - data on morbidity, mortality, disability with respect to the disease, syndrome or state for diagnostics, prevention, treatment of or rehabilitation after which the drug is prescribed (to be provided based on the results of the state statistical monitoring, other official sources and epidemiological studies of the morbidity of the disease);

5.2. clinical data - full-text versions of clinical studies (articles, reports in Russian or translated into Russian, certified by the applicant) (with indication of the authors, title, design of the study, number of enrolled subjects, follow-up period, indication for medical use of the drug which was analyzed in the study, efficiency (safety) assessment criteria, drugs with which the proposed drug was compared (if any), placebo-control or no treatment, findings of the study with quantitative data, expert report, list of references - author, title of the study, imprint. For each clinical study it is required to indicate the level of evidence of the drug efficiency according to Appendix 6 to the Regulations for Preparation of the Lists of Drugs for Medical Use and the Minimum Range of Drugs Required for Rendering Medical Care, approved by Decree of the Government of the Russian Federation dated August 28, 2014 No. 871);

5.3. data on therapeutic equivalence (if applicable) - full-text versions of comparative clinical studies (articles, reports in Russian or articles, reports translated into Russian, certified by the applicant) (with indication of the authors, title, design of the study, number of enrolled subjects, follow-up period, indication for medical use of the drug, findings of the study with quantitative data, expert report, list of references - the author, title of the study, imprint);

5.4. data on clinical and economic (pharmacoeconomic) characteristics of the drug - full-text versions of clinical and economic studies (articles, reports in Russian or articles, reports translated into Russian, certified by the applicant) (with indication of the authors, title of the study, references to the study, design of the study (retrospective, prospective, modelling**), type of analysis, information on drugs which were used for comparison with the proposed drug, costs which were taken into account in the

study with quantitative values in rubles, efficiency of compared drugs (efficiency assessment criteria and quantitative values), findings of the study, list of references - the author, title of the study, imprint)***;

5.5. data on the cost and the price of the drug:

5.5.1. cost of one course of treatment with the drug;

5.5.2. cost of treatment with the drug for one year _____;

5.5.3. date of calculation of the price for the drug _____;

5.5.4. price which the manufacturer intends to register in accordance with the requirements of the law of the Russian Federation _____;

5.6. data on actual sales of the drug in the Russian Federation for the year preceding the submission of the proposal, in terms of dosage forms of registered drugs _____;

5.7. data from drug safety monitoring reports (in the Russian Federation and/or abroad) _____;

5.8. data provided by the applicant on its own initiative _____.

6. Total number of documents submitted _____;
on _____ sheets.

Signature of the applicant _____ /_____ /

Date

_____

* All paragraphs of the proposal are mandatory and must be completed. In the absence of information on the relevant paragraph, it should be marked with "N/A". The documents and materials shall be submitted in the Russian language. In case of publications, documents and articles in foreign languages, they shall be attached with the summary of such materials translated into the Russian language, certified by the applicant.

** Where mathematical modelling is used, all developed models and assumptions for developing of the relevant models and formulas of calculations used in the models shall be provided in electronic format.

*** Subject to Part 6, Article 18 of Federal Law On Circulation of Drugs and Part 3, Article 13 of Federal Law On the Fundamentals of Health Protection of Citizens in the Russian Federation.

Appendix 2
to the Regulations for Preparation of
the Lists of Drugs for Medical
Use and the Minimum Range of
Drugs Required for Rendering
Medical Care

(form)

To the Commission of
the Ministry of Health
of the Russian Federation
for preparation of the lists of
drugs for medical use and
the minimum range of

drugs required
for rendering
medical care

Proposal
on the inclusion of a drug
into the minimum range of drugs required for rendering medical care

1. Information on the applicant:

1.1. Name of the organization or surname, name, patronymic (if any) of the citizen _____;

1.2. Responsible person, position _____;

1.3. Address (location or place of residence) _____;

Telephone (fax) _____;

Email _____.

2. Information on the drug:

2.1. name:

2.1.1. international generic name_____;

2.1.2. in the absence of the international generic name - modified INN _____;

2.1.3. in the absence of the international generic name and modified INN - chemical name _____;

2.1.4. in the absence of other names- trade name _____;

2.2. code of the drug in the Anatomical Therapeutic Chemical Classification _____;

2.3. label claims (to be listed)

_____;

2.4. state registration of the drug in the Russian Federation:

date (dd.mm.yyyy) _____;

market authorization number _____;

date of confirmation of the state registration of the drug (if available) (dd/mm/yyyy) _____;

2.5. data on production of the drug in the Russian Federation (if available) _____;

2.6. dosage forms of the registered drug proposed for inclusion (to be listed) _____;

_____;

2.7 information on generic drugs (if available) _____.

3. Information and data on the drug proposed for inclusion into the minimum range of drugs required for rendering medical care:

3.1. the drug is included into the list of vital and essential drugs;

3.2. the drug according to the labeling may be used for rendering medical care on an outpatient basis for diagnostics, prevention, treatment of and rehabilitation after most common diseases, syndromes and states;

3.3. availability of state registration in the Russian Federation of generic drugs by the relevant international generic name or, in the absence thereof, by the relevant modified INN or chemical name with similar dosage forms and dosages, produced by two or more manufacturers (except for drugs produced by the sole domestic manufacturer);

3.4. demand for the drug in the health care system and among the population according to the executive authorities of the constituent entities of the Russian Federation in the sphere of health

protection and marketing researches on the drug sales in the Russian Federation, when rendering medical care on an outpatient basis in a calendar year (inclusion in the 100 top-selling drugs in the Russian market for a calendar year).

4. Data justifying the inclusion of the drug into the minimum range of drugs required for rendering medical care:

4.1. epidemiological data (if available) - data on morbidity, mortality, disability with respect to the disease, syndrome or state for diagnostics, prevention, treatment of or rehabilitation after which the drug is prescribed (to be provided based on the results of the state statistical monitoring, other official sources and epidemiological studies of the morbidity of the disease);

4.2. data on the cost and the price of the drug:

4.2.1. cost of one course of treatment (one month of treatment with the drug) _____;

4.2.2. date of calculation of the cost of treatment with the drug _____;

4.3. data on actual sales of the drug in the Russian Federation for the year preceding the submission of the proposal, in terms of dosage forms of registered drugs _____;

4.4. data provided by the applicant on its own initiative_____.

5. Total number of documents submitted _____
on _____ sheets.

Signature of the applicant _____ /_____ /

Date

Appendix 3
to the Regulations for Preparation of
the Lists of Drugs for Medical
Use and the Minimum Range of
Drugs Required for Rendering
Medical Care

(form)

To the Commission of
the Ministry of Health
of the Russian Federation
for preparation of the lists of
drugs for medical use and
the minimum range of
drugs required
for rendering
medical care

Proposal
on the exclusion of a drug
from the lists of drugs for medical use

1. This proposal refers to the exclusion of a drug from the following lists of drugs for medical use:

1.1. the list of vital and essential drugs;

1.2. the list of expensive drugs;

1.3. the list of drugs for certain categories of citizens.

2. Information on the applicant:

2.1. Name of the organization or surname, name, patronymic (if any) of the citizen _____;

2.2. Responsible person, position _____;

2.3. Address (location) or place of residence _____;

Telephone/fax_____;

Email _____.

3. Information on the drug:

3.1. name:

3.1.1. international generic name _____;

3.1.2. in the absence of the international generic name - modified INN _____;

3.1.3. in the absence of the international generic name and modified INN - chemical name _____;

3.1.4. in the absence of other names- trade name _____;

3.2. code of the drug in the Anatomical Therapeutic Chemical Classification _____;

3.3. label claims (to be listed) _____;

3.4. state registration of the drug in the Russian Federation:

date (dd.mm.yyyy) _____;

market authorization number _____;

date of confirmation of the state registration of the drug (if available) (dd/mm/yyyy) _____;

3.5. dosage forms of the registered drug proposed for exclusion (to be listed) _____;

3.6. information on generic drugs (if available) _____.

4. Information and data on the drug proposed for exclusion from the lists of drugs for medical use:

4.1. availability of scientific evidence of advantages and/or features of the mechanism of action, higher safety of the alternative drug to be included into the list for diagnostics, prevention, treatment of or rehabilitation after diseases, syndromes and states, taking into account the statistical data on the morbidity and mortality patterns in the Russian Federation;

4.2. new information on the toxicity or high frequency of adverse events during the use of the drug;

4.3. suspension of the application of the drug in the Russian Federation;

4.4. cancellation of the state registration of the drug;

4.5. discontinuance of production of the drug or its supplies to the Russian Federation and/or absence of the drug in the civil circulation in the Russian Federation for more than one calendar year.

5. Justification for the exclusion of the drug from the lists of drugs for medical use:

5.1. clinical data - full-text versions of comparative clinical studies (articles, reports in Russian or articles, reports translated into Russian, certified by the applicant) (with indication of the authors, title, design of the study, number of enrolled subjects, follow-up period, indication for medical use of the drug, findings of the study with quantitative data, expert report, list of references - the author, title of the study, imprint);

5.2. data on clinical and economic (pharmacoeconomic) characteristics of the drug - full-text versions of clinical and economic studies (articles, reports in Russian or articles, reports translated into Russian, certified by the applicant) (with indication of the authors, title of the study, references to the study, design of the study (retrospective, prospective, modelling*), type of analysis, information on drugs which were used for comparison with the proposed drug, costs which were taken into account in the study with quantitative values in rubles, efficiency of compared drugs (efficiency assessment criteria and

quantitative values), findings of the study, list of references - the author, title of the study, imprint)**;

5.3. data on actual sales of the drug in the Russian Federation for the year preceding the submission of the proposal, in terms of dosage forms of registered drugs (if available);

5.4. data and documents confirming the discontinuance of production of the drug or its supplies to the Russian Federation and/or absence of the drug in the civil circulation in the Russian Federation for more than one calendar year. (if available);

5.5. data from drug safety monitoring reports (in the Russian Federation and/or abroad);

5.6. data provided by the applicant on its own initiative.

6. Total number of documents submitted _____
on _____ sheets

Signature of the applicant _____ /_____ /

Date

_____

* Where mathematical modelling is used, all developed models and assumptions for developing of the relevant models and formulas of calculations used in the models shall be provided in electronic format.

** Subject to Part 6, Article 18 of Federal Law On Circulation of Drugs and Part 3, Article 13 of Federal Law On the Fundamentals of Health Protection of Citizens in the Russian Federation.

Appendix 4
to the Regulations for Preparation of
the Lists of Drugs for Medical
Use and the Minimum Range of
Drugs Required for Rendering
Medical Care

(form)

To the Commission of the Ministry of
Health of the Russian Federation
for preparation of the lists of
drugs for medical use and
the minimum range of
drugs required
for rendering
medical care

Proposal
on the exclusion of a drug from the minimum range of drugs required for rendering medical care

1. Information on the applicant:

1.1. Name of the organization or surname, name, patronymic (if any) of the citizen _____;

1.2. Responsible person, position _____;

1.3. Address (location) or place of residence _____;

Telephone (fax) _____;

Email _____.

2. Information on the drug:

2.1. name:

2.1.1. international generic name _____
_____;

2.1.2. in the absence of the international generic name - modified INN _____;

2.1.3. in the absence of the international generic name and modified INN - chemical name _____;

2.1.4. in the absence of other names- trade name _____;

2.2. code of the drug in the Anatomical Therapeutic Chemical Classification _____;

2.3. state registration of the drug in the Russian Federation:

date (dd.mm.yyyy) _____;

market authorization number _____;

date of confirmation of the state registration of the drug (if available) (dd/mm/yyyy) _____;

2.4. data on production of the drug in the Russian Federation (if available) _____;

2.5. dosage forms of the registered drug proposed for exclusion (to be listed)
_____;

2.6. information on generic drugs (if available) _____.

3. Grounds for the exclusion of the drug from the minimum range of drugs required for rendering medical care:

3.1. the drug is not included into the list of vital and essential drugs;

3.2. the application of the drug in the Russian Federation is suspended;

3.3. state registration of the drug in the Russian Federation is canceled;

3.4. civil circulation of the drug in the Russian Federation is discontinued, including its production.

4. Documents and data justifying the exclusion of the drug from the minimum range of drugs required for rendering medical care:

4.1. documents and data confirming the discontinuance of civil circulation of the drug in the Russian Federation, including cessation of production _____;

4.2. data provided by the applicant on its own initiative
_____.

5. Total number of documents submitted _____
on _____ sheets.

Signature of the applicant _____ /_____ /

Date

Appendix 5
to the Regulations for Preparation of
the Lists of Drugs for Medical
Use and the Minimum Range of
Drugs Required for Rendering
Medical Care

(form)

Expert report
based on the results of documentary review of proposals for the inclusion of the drug into (exclusion from) the list of drugs and the minimum range of drugs required for rendering medical care

1. This expert report refers to proposals submitted for:
1.1. the inclusion of a drug into:
1.1.1. the list of vital and essential drugs;
1.1.2. the list of expensive drugs;
1.1.3. the list of drugs for certain categories of citizens;
1.1.4. the minimum range of drugs required for rendering medical care (minimum range);
1.2. the exclusion of a drug:
1.2.1. the list of vital and essential drugs;
1.2.2. the list of expensive drugs;
1.2.3. the list of drugs for certain categories of citizens;
1.2.4. the minimum range.

2. Information on the drug:
2.1. name:
2.1.1. international generic name _____;
2.1.2. in the absence of the international generic name - modified INN _____;
2.1.3. in the absence of the international generic name and modified INN - chemical name _____;
2.1.4. in the absence of other names- trade name _____;
2.2. code of the drug in the Anatomical Therapeutic Chemical Classification _____;
2.3. dosage forms of the registered drug proposed for inclusion (to be listed):
_____;
2.4. dosage forms of the registered drug proposed for exclusion (to be listed):
_____.
3. Time frames for the documentary review:
from _____ to _____.
4. Documentary review of the proposals (in accordance with Appendices 1 and 2 to the Regulations for Preparation of the Lists of Drugs for Medical Use and the Minimum Range of Drugs Required for Rendering Medical Care, approved by Decree of the Government of the Russian Federation dated August 28, 2014 No. 871):

	Required information	Information on the submission by the applicant of the required information
1	2	3
1	Information on the applicant	1.1 is submitted in full 1.2 is not submitted in full (to be listed): 1.3 is not submitted
2	Information on the drug	2.1 is presented in full 2.2 is not submitted in full (to be listed): 2.3 is not submitted
3	Information on the drug proposed for inclusion into (exclusion from)	3.1 is submitted in full 3.2 is not submitted in full (to be listed):

	the lists of drugs and the minimum range	3.3 is not submitted
4	Data justifying the inclusion of the drug into (exclusion from) the list of drugs and the minimum range	4.1 is submitted in full 4.2 is not submitted in full (to be listed): 4.3 is not submitted

5. Comments on the results of the documentary review of proposals (mark whichever applies):

5.1 improper execution of the proposal and documents and information annexed thereto;

5.2 lack of the proposal and documents and information annexed thereto in electronic format;

5.3 submission of documents and information not in full;

5.4 identification of discrepancies between the documents and information submitted in paper medium and electronic format;

5.5 submission of false or distorted information;

5.6 submission of documents and information based on which the Commission made its decision on refusal of inclusion of the drug into (exclusion from) the list of drugs and the minimum range.

Specific comments:

_____

6. Results:

6.1 to submit the proposal for review;

6.2 to submit to the applicant the expert report with comments of non-conformity with the established requirements;

6.3 to submit the proposal to the external specialist of the Ministry of Health of the Russian Federation for preparation of recommendations for the inclusion of the drug into (exclusion from) the minimum range.

Chairman of the Commission of
the Ministry of Health
of the Russian Federation
for preparation of the lists of drugs for
medical use and the minimum range of
drugs required for
rendering medical care

_____ _____/_____
(date) (signature, printed name)

Appendix 6
to the Regulations for Preparation of
the Lists of Drugs for Medical
Use and the Minimum Range of
Drugs Required for Rendering
Medical Care

Integral scales
for clinical, clinical and economic assessment of a drug during review

Scale for assessment
of levels of evidence of the results of clinical
studies of drugs*

Description of studies	Levels of evidence of the results	Scale for assessment (scores)
Systematic reviews and meta-analyses	I	10
Randomized blind clinical studies	II	9
Randomized open-label clinical studies	II	8
Quasi-experimental studies	III	7
Cohort studies	IV	6
Case-control studies	V	5
Description of cases and case series	VI	4
Expert opinion	VII	3

Scale for assessment
of levels of credibility of clinical
studies of drugs**

Level of credibility of evidence	Characteristics of the indicator	Scale for assessment (scores)
A	evidence is credible: there is strong evidence of the proposed statement	3
B	relative credibility of evidence: there is sufficient evidence to recommend the proposed drug for inclusion into (exclusion from) the relevant list of drugs	2
C	lack of sufficient evidence: the evidence is not sufficient to give any recommendations, but recommendations may be given, taking into account other circumstances	1

Integral quantitative assessment of
quality of the clinical study of a drug for medical use

Description of the study	Level of evidence of data	Level of credibility of evidence	Overall assessment of the study (scores)
Systematic review of randomized clinical studies or meta-analysis	I	A	is determined as the product of the level of evidence in scores and the level of credibility of evidence in scores
Large-scale randomized clinical studies with unambiguous results and low probability of errors	II	A	
Large-scale randomized clinical studies with ambiguous results, low or high probability of errors	II	B	
Small-scale randomized clinical studies	II	B	
Quasi-experimental studies with well matched comparison groups	III	B	
Cohort studies with unambiguous results and low probability of errors	IV	B	
Case-control studies with unambiguous results and low probability of errors	V	B	
Description of cases and case series	VI	C	
Expert opinion	VII	C	

Studies of any design of low methodological quality	I	C	
	II	C	
	III	C	
	IV	C	
	V	C	
	VI	C	
	VII	C	
Overall integral quantitative assessment of quality of the clinical study of the drug: at least 18 for issue of the recommendation for inclusion of the drug; at least 12 for issue of the recommendation for inclusion of the orphan drug			

Quantitative assessment
of the efficiency of the drug within the clinical studies

Name of the efficiency assessment criterion	Assessment of the degree of achievement of the target result, taking into account the advantages as compared to the therapy with comparative drugs	Achieving of the target result, taking into account the advantages before the therapy with comparative drugs (in percent)	Scale for assessment (scores)
Criterion as an example: reduction in the arterial blood pressure up to the target value	the target result is fully achieved (high efficiency)	100	10
	the target result is partially achieved (medium efficiency)	90 80 70 60 50 40 30 20 10	9 8 7 6 5 4 3 2 1
	the target result is not achieved (low efficiency or lack of efficiency)	0	0
Total	average score of efficiency (the ratio of the sum of scores for each efficiency assessment criterion to the number of criteria)		

Quantitative assessment
of the safety of the drug within
the clinical studies

Assessment of the level of safety of the drug	Incidence of adverse effects (in percent)	Score points	Weighting coefficient
Absence pf adverse effects	0	0	0
Mild adverse effects	10 20 30	-1 -1 -1	0.25

	40 50 60 70 80 90 100	-2 -2 -3 -3 -3 -4 -4	
Moderate adverse effects	10 20 30 40 50 60 70 80 90 100	-2 -2 -3 -3 -4 -4 -5 -5 -6 -6	0.5
Severe adverse effects - state which result in prolongation of the patient's stay in inpatient facility or causing threat to life	0 20 30 40 50 60 70 80 90 100	-4 -4 -5 -5 -6 -6 -7 -8 -9 -10	1
Total	assessment of the level of safety (the sum of the productions of average scores for each level of safety of the drug and the corresponding weighting coefficient)		

Quantitative assessment
of the additional therapeutic value of the drug

Name of the additional therapeutic value criterion	Result of assessment	Scale for assessment (scores)
1. Dosage frequency	reduction in the dosage frequency	+ 2
	maintenance of the dosage frequency	0
	increase in the dosage frequency	-2
2. New mechanism of action	has significant clinical advantages	+ 2
	has minor clinical advantages	+ 1
	has no clinical advantages	0

Quantitative assessment
of the clinical and economic efficiency of the drug

Assessment criteria	Result of assessment	Deviation in percent	Scale for assessment (scores)
1. The presented cost of	is higher than the cost of	100 and more	-10

the course or the annual treatment with the drug	treatment with the comparative drug	80-100	-8
		60-80	-6
		40-60	-4
		20 - 40	-2
		10-20	-1
	is equal to the cost of treatment with the comparative drug	not more than 10	0
	is lower than the cost of treatment with the comparative drug	10-20	+ 1
		20 - 40	+ 2
		40-60	+ 4
		60-80	+ 6
		80 and more	+ 8
Final score by the scale for assessment of presented costs			
2. Advantages by clinical and economic efficiency of the drug with respect to comparative drugs (for each of the studies presented or found independently)	application of the drug reduces the overall costs (direct and indirect costs to be specified separately)	up to 20	+ 2
		20 - 40	+ 4
		40 - 60	+ 6
		60-80	+ 8
	for rendering medical care under the Programme on State Guarantees to Deliver Free Medical Care (influence on the budget)	more than 80	+ 10
	the use of the drug does not result in increase in overall costs (direct and indirect costs to be specified separately) for rendering medical care under the Programme on State Guarantees to Deliver Free Medical Care (influence on the budget)		0
	the use of the drug results in increase in overall costs (direct and indirect costs to be specified separately) for rendering medical care under the Programme on State Guarantees to Deliver Free Medical Care (influence on the budget)	up to 20	-2
		20 - 40	-4
		40 - 60	-6
		60-80	-8
		more than 80	-10
	assessment of costs and efficiency (the ratio of indicators of the drug and the comparative drug)	reduction in the indicator	+ 1
		increase in the indicator	-1
The final score by the scale for assessments of the advantages of the drug by the clinical and economic efficiency (the ratio of the sum of scores for each study to the number of studies)			

The final score by the clinical and economic efficiency of the drug (the sum of scores by presented costs and the final score by the scale for assessment of advantages of the drug for clinical and economic efficiency)	
The final score of the clinical and economic review of the proposal (not less than + 4) for issue of the recommendation for inclusion of the drug into the lists	

Quantitative assessment
of additional data on the drug

Assessment criteria	Result of assessment	Scale for assessment (scores)
The necessity of the use of the drug for diagnostics, prevention, treatment of and rehabilitation after diseases, syndromes and states prevailing in the morbidity and mortality patterns in the Russian Federation on the basis of the data of the state statistical monitoring	yes	+ 2
	no	0
The feasibility of inclusion of the drug in the standard of care, taking into account the recommended frequency of provision	0.8 and above	+3
	0.6-0.8	+2
	0.4-0.6	+1
	0.2-0.4	+0.5
	below 0.2	0
The feasibility of inclusion in the clinical recommendations (protocols)	yes	+2
	no	0
Presence of generic drugs registered in the Russian Federation	yes	+1
	no	0
The presence of the drug in the list of strategically important drugs production of which must be ensured within the territory of the Russian Federation, approved by Decree of the Government of the Russian Federation dated July 6, 2010, No. 1141-r;	no	0
	yes	+ 1
The presence of the drug in the lists of drugs financed out of the budgets of the constituent entities of the Russian Federation	no	0
	yes	+ 1
The presence of production (localization) of the drug in the Russian Federation.	no	0
	yes	+ 3
The final score of other data on the proposal (not less than + 2) for issue of the recommendation for inclusion		

* Level of evidence of the findings of clinical studies is used for the formal assessment of quality of the clinical study of the drug. Several clinical studies maybe conducted for the same drug, and their levels of evidence according to the design of clinical studies may be different.

** The levels of credibility of the evidence of efficiency of drugs used in assessment of the study population for the same drug. Compilation of data on the levels of evidence of separate studies of different quality shall be carried out, upon which one of 3 levels of credibility shall be assigned.

Appendix 7
to the Regulations for Preparation of
the Lists of Drugs for Medical

Use and the Minimum Range of
Drugs Required for Rendering
Medical Care

(form)

To the Commission of
the Ministry of Health
of the Russian Federation
for preparation of the lists of
drugs for medical use and
the minimum range of drugs
required for rendering
medical care

Expert report
based on the review of proposals for inclusion of the drug into (exclusion from) the list of drugs

1. This expert report refers to proposals submitted for:
1.1. the inclusion of a drug into:
1.1.1. the list of vital and essential drugs;
1.1.2. the list of expensive drugs;
1.1.3. the list of drugs for certain categories of citizens;

1.2. Exclusion of a drug from:
1.2.1. the list of vital and essential drugs;
1.2.2. the list of expensive drugs;
1.2.3. the list of drugs for certain categories of citizens.

2. Information on the Expert Commission:
2.1. name of expert organization _____
_____;
2.2. composition of the Expert Commission (full name, position) _____;
2.3. address (location) of the expert organization _____;
Telephone (fax) _____;
Email _____.

3. Information on the drug:
3.1. name: ;
3.1.1. international generic name _____;
3.1.2.in the absence of the international generic name - modified INN _____;
3.1.3. in the absence of the international generic name and modified INN - chemical name _____;
3.1.4. in the absence of other names- trade name _____;
3.2. code of the drug in the Anatomical Therapeutic Chemical Classification _____;
3.3. dosage forms of the registered drug proposed for inclusion or exclusion (to be listed) _____;
3.4. information on generic drugs (if available):
_____.

4. Date of review:
from _____ to _____.

5. Results of clinical assessment of the proposal (in accordance with Appendix 6 to the Regulations for Preparation of the Lists of Drugs for Medical Use and the Minimum Range of Drugs Required for Rendering Medical Care, approved by Decree of the Government of the Russian Federation dated August 28, 2014 No. 871):

5.1. Results of quality assessment of clinical studies of the drug submitted by the applicant and/or obtained by the Expert Commission independently

	Description of the clinical study	Level of credibility of data	Level of credibility of evidence	Overall assessment of the study in scores
1				
2				
3				
4				
5				
etc.				
Total: average value (the ratio of the sum of scores to their number)				

5.2. Results of quantitative assessment of efficiency of treatment with the drug within the clinical studies submitted by the applicant and/or obtained by the Expert Commission independently

Name of the efficiency assessment criterion	Assessment of the degree of achievement of the target result	Achievement of the target result (in percent)	Assessment in scores
	the target result is fully achieved (high efficiency)		
	the target result is partially achieved (medium efficiency)		
	the target result is not achieved (low efficiency or lack of efficiency)		
Total: average score of efficiency (the ratio of the sum of scores for each efficiency assessment criterion to the number of criteria)			

5.3. Results of quantitative assessment of safety of treatment with the drug within the clinical studies submitted by the applicant and/or obtained by the Expert Commission independently

Assessment of the level of safety of the drug	Incidence of adverse effects (in percent)	Score points
Absence pf adverse effects		
Mild adverse effects		
Moderate adverse effects		
Severe adverse effects		
The final assessment of the level of safety (the sum of the productions of average scores for each level of safety of the drug and the corresponding weighting coefficient)		

5.4. Results of assessment of additional therapeutic value of the drug submitted by the applicant and/or obtained by the Expert Commission independently

Name of the additional therapeutic value criterion	Result of assessment	Score points
1. Dosage frequency		
2. New mechanism of action		

5.5. The final score by the clinical assessment of the proposal (the sum of the totals of Tables 5.1-5.4).

6. Results of the clinical and economic assessment of the proposal:

Assessment criteria	Result of assessment	Deviation in percent	Score points
1. The presented cost of the course or the annual treatment with the drug	is higher than the cost of treatment with the comparative drug		
	is equal to the cost of treatment with the comparative drug		
	is lower than the cost of treatment with the comparative drug		
Final score by the scale for assessment of presented costs			
2. Advantages by the clinical and economic efficiency of the drug with regard to comparative	application of the drug reduces the overall costs (direct and indirect costs		
drugs (for each of the studies presented or found independently)	to be specified separately) for rendering medical care under the Programme on State Guarantees to Deliver Free Medical Care (influence on the budget)		
	the use of the drug does not result in increase in overall costs (direct and indirect costs to be specified separately) for rendering medical care under the Programme on State Guarantees to Deliver Free Medical Care (influence on the budget)		
	the use of the drug results in increase in the overall costs		
	(direct and indirect costs to be specified separately) for rendering medical care under the Programme on State Guarantees to Deliver Free Medical Care (influence on the budget)		
The final score by the scale for assessments of the advantages of the drug by the clinical and economic efficiency (the ratio of the sum of scores for each study to the number of studies)			
The final score by the clinical and economic efficiency of the drug (the sum of scores by presented costs and the final score by the scale for assessment of advantages of the			

drug for clinical and economic efficiency)	

7. The results of review of other data regarding the proposal:

Assessment criteria	Assessment in scores
The necessity of the use of the drug for diagnostics, prevention, treatment of and rehabilitation after diseases, syndromes and states prevailing in the morbidity and mortality patterns in the Russian Federation on the basis of the data of the state statistical monitoring	
The feasibility of inclusion of the drug in the standard of care, taking into account the recommended frequency of provision	
The feasibility of inclusion of the drug in the clinical recommendations (protocols)	
Presence of generic drugs registered in the Russian Federation	
The presence of the drug in the list of strategically important drugs production of which must be ensured within the territory of the Russian Federation, approved by Decree of the Government of the Russian Federation dated July 6, 2010, No. 1141-r;	
The presence of the drug in the lists of drugs financed out of the budgets of the constituent entities of the Russian Federation	
The presence of production (localization) of the drug in the Russian Federation.	
The final score of other data on the proposal (not less than + 2) for issue of the recommendation for inclusion	

8. The final score of the proposal and conclusion of the Expert Commission regarding feasibility or non-feasibility of the inclusion of the drug into (exclusion from) the lists of drugs:

_____

_____

Signature and printed name of experts:

_____

(full name of the head of expert organization (expert)

9. Recommendations of the external specialist of the Ministry of Health of the Russian Federation:

_____

_____

10. Comments of the external specialist of the Ministry of Health of the Russian Federation (if available):

_____

_____

Signature and printed name _____

Date _____