Registered with the Ministry of Justice of the Russian Federation dated April 4, 2013, No. 27991

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

ORDER
dated December 21, 2012, No. 1353n

ON APPROVAL OF THE PROCEDURE FOR MEDICAL PRODUCT QUALITY, EFFICACY AND SAFETY REVIEW

Pursuant to Article 38, Federal Law dated November 21, 2011, No. 323-FZ, *On Fundamentals of Public Health Protection in the Russian Federation* (Collection of Laws of the Russian Federation, 2011, No. 48, Article 6724; 2012, No. 26, Articles 3442, 3446) and paragraph 5.2.188 of the Regulations on the Ministry of Health of the Russian Federation, as approved by Resolution of the Russian Federation Government dated June 19, 2012, No. 608 (Collection of Laws of the Russian Federation, 2012, No. 26, Article 3526), I order:

To approve:

The Procedure for Medical Product Quality, Efficacy and Safety Review, according to Appendix 1;

The Pro Forma Expert Commission's Opinion on Feasibility (Non-Feasibility) of Medical Product Clinical Trials, according to Appendix 2;

The Pro Forma Expert Commission's Opinion on the Findings of the Medical Product Quality, Efficacy and Safety Review, according to Appendix 3.

Minister
V.I. SKVORTSOVA

Appendix 1
to Order of the Ministry of Health
of the Russian Federation
dated December 21, 2012, No. 1353n

PROCEDURE FOR MEDICAL PRODUCT QUALITY, EFFICACY AND SAFETY REVIEW

I. General Provisions

1. This Procedure determines the rules of arranging for and holding of the medical product quality, efficacy and safety review.

2. The medical product quality, efficacy and safety review shall be based on the principles of legitimacy, observance of human and personal rights and freedoms, rights of a legal entity, expert's independence, objectivity, comprehensiveness and completeness of studies held using the scientific and technical advances, responsibility of the expert institution and experts for holding and findings of the review.

3. The medical product quality, efficacy and safety review shall be carried out by the federal state-owned budgetary institution (hereinafter the 'expert institution') accountable to the Federal Service on Healthcare Surveillance (hereinafter the 'registration authority') based on the registration authority's assignments to hold medical product quality, efficacy and safety reviews.

4. The medical product quality, efficacy and safety review shall be conducted by the expert institution on the stage-by-stage basis:

1) Stage 1: review of the application and documents required to determine feasibility (non-feasibility) of medical product clinical trials;

2) Stage 2: review of comprehensiveness and outcomes of conducted technical trials, toxicological studies, clinical trials as well as tests to establish the metering device type (with respect to the medical products classified as metering devices in state regulation of the uniformity of measurements, the list of which is approved by the Ministry of Health of the Russian Federation <1>) (hereinafter 'review of comprehensiveness and findings of conducted trials and studies').

<1>Part 8, Article 38, Federal Law dated November 21, 2011, No. 323-FZ, *On Fundamentals of Public Health Protection in the Russian Federation* (Collection of Laws of the Russian Federation, 2011, No. 48, Article 6724; 2012, No. 26, Article 3442, Article 3446).

5. The medical product quality, efficacy and safety review shall be carried out by the commission of the expert institution (hereinafter the 'expert commission') comprising three or more experts appointed by its director on the basis of the issued assignment to hold the medical product quality, efficacy and safety review.

6. By resolution of the expert institution Director, persons not employed by the expert institution may be included as experts if their special knowledge is required to carry out the medical product quality, efficacy and safety review and there are no such experts in this expert institution.

Representatives of the companies that have conducted technical tests, toxicological studies and clinical trials of the medical product submitted to the medical product quality, efficacy and safety review, cannot be included into the expert commission.

7. When medical product quality, efficacy and safety review is held, the expert cannot be dependent in any particular way on the authority or the person that has appointed this review, the medical product manufacturer, the medical product manufacturer's authorized representative or other persons interested in the review outcomes.

8. If the expert is aware of any circumstances that prevent his/her engagement in the medical product quality, efficacy and safety review or his/her compliance with the principles of its holding established in Section 2 of this Procedure, the expert shall notify the expert institution Director of these circumstances.

9. Before the medical product quality, efficacy and safety review starts, the expert commission shall conduct the kick-off meeting where experts will:-

(a) elect the expert commission Chairman and its Executive Secretary out of themselves;

(b) determine the operating and decision-making procedure of the expert commission;

(c) approve of the calendar schedule of the expert commission work, proceeding from the review timing;

(d) define other provisions and conditions required for operation of the expert commission and holding of the medical product quality, efficacy and safety review.

If necessary, duties of the Chairman and the Executive Secretary of the expert commission shall be performed by one and the same expert.

The Minutes signed by all members of the expert commission shall be kept at the kick-off meeting of the expert commission.

10. The Chairman and the Executive Secretary of the expert commission shall arrange for its operations, in particular:-

(a) arrange for holding of the expert commission meetings, issue and sign Minutes of these meetings;

(b) control over fulfillment by the experts of the expert commission action plan and, if necessary, jointly make decisions to change it, with allowance for the medical product quality, efficacy and safety review period;

(c) if necessary, draft proposals to the expert institution Director as to change in the composition of its participants, the operating procedure and the decision-making procedure and submit them to the expert commission meetings for approval;

(d) summarize the opinions and conclusions made by the experts and ensure drafting of the opinion on the medical product quality, efficacy and safety review.

11. During the medical product quality, efficacy and safety review the experts shall be obliged to:-

1) promptly conduct a comprehensive study of submitted materials, give a well-substantiated and

unbiased opinion on the medical product quality, efficacy and safety review outcomes;

2) formulate the conclusions responsibly and precisely, to the extent of their competence;

3) refrain from disclosing information that has become known in connection with the medical product quality, efficacy and safety review, as well as the information that constitutes state, commercial or another legally protected secret;

4) comply with the established timing of and procedure for medical product quality, efficacy and safety review;

5) ensure preservation of submitted materials.

12. The experts shall not be entitled to:-

1) conduct the medical product quality, efficacy and safety review upon the applicant's direct application to the expert;

2) independently collect materials for the medical product quality, efficacy and safety review.

13. If necessary, the expert commission shall be free to petition in writing to the expert institution Director to engage other experts in the medical product quality, efficacy and safety review, if their special knowledge is required for the review and there are no such experts in the expert institution.

14. Each expert included in the expert commission charged with the medical product quality, efficacy and safety review shall make conclusions to the extent of his/her special knowledge, independently and on his/her own.

15. The medical product quality, efficacy and safety review findings shall be documented in the expert commission's opinion.

16. The conclusions contained in the expert commission's opinion shall be unambiguous and understandable.

17. The expert commission's opinion shall be signed by the Chairman, the Executive Secretary and other expert commission members indicating their surname and initials. Each page of the expert commission's opinion shall be numbered and certified with a signature of the expert commission Executive Secretary. Amendments to the expert commission's opinion shall be prohibited.

18. In case of any disagreement with the medical product quality, efficacy and safety review conclusions, the expert commission members shall express their opinion in writing and state the reasons for disagreement with the review conclusions.

The document with the opinion of the expert disagreeing with the medical product quality, efficacy and safety review conclusions shall be attached to the opinion and make an integral part thereof.

19. The documents received by the expert institution for the purposes of the medical product quality, efficacy and safety review shall be subject to return to the registration authority, together with the respective review opinion.

II. Procedure for Review of the Application and the Documents to Determine Feasibility/ Unfeasibility of Medical Product Clinical Trials

20. The review of the application and the documents to determine feasibility/ unfeasibility of medical product clinical trials, drafting by the expert commission of the opinion on the feasibility/ unfeasibility of medical product clinical trials and sending this opinion to the registration authority shall be carried out within a period of time not exceeding Twenty business days from receipt by the expert institution of the appropriate registration authority assignment, with attachment of the following documents:-

1) application for the medical product state registration;

2) a copy of the document evidencing powers of the manufacturer's authorized representative;

3) information on the medical product regulatory documents;

4) medical product technical documents;

5) medical product operating documents, including the medical product leaflet/ user manual;

6) photographic image of the medical product overview, together with the accessories required for the medical product application according to its intended purpose (min. size 18 cm x 24 cm);

7) documents evidencing findings of the medical product technical tests;

8) documents evidencing findings of the toxicological studies of the medical product, the use of

which implies contact with a human body;

9) documents evidencing findings of the medical product tests to establish the metering device type (with respect to the medical products classified as metering devices in state regulation of the uniformity of measurements, the list of which is approved by the Ministry of Health of the Russian Federation);

10) list of documents.

21. The expert commission's opinion on the feasibility/ unfeasibility of medical product clinical trials shall be issued in the format according to Appendix 2 hereto.

22. The reasons for making by the expert institution of the opinion on unfeasibility of holding medical product clinical trials shall be absence of the following in the documents listed in Section 20 hereof:-

1) proofs of the medical product conformity to the requirements of regulatory, technical and/or operating documents;

2) proofs of the medical product biological safety.

III. Procedure for Review of Comprehensiveness and Findings of Tests and Studies

23. The review of comprehensiveness and findings of the conducted tests and studies, drafting by the expert commission of the opinion on the medical product quality, efficacy and safety review and sending this opinion to the registration authority shall be carried out within Ten business days from receipt by the expert institution of the registration authority assignment issued in accordance with Section 3 hereof, with attachment of findings of the medical product clinical trials as well as the documents listed in Section 20 hereof.

24. The expert commission opinion on findings of the medical product quality, efficacy and safety review shall be issued in the format included in Appendix 3 hereto.

25. A negative opinion of the expert commission based on the medical product quality, efficacy and safety review findings shall be drafted if one or more of the following reasons exist:-

1) quality and/or efficacy and/or safety of the registered medical product is/are not proven with the received data;

2) risk of causing harm to health of patients and medical professionals as a result of the medical product application exceeds the efficacy of its application.

Appendix 2
to Order of the Ministry of Health
of the Russian Federation
dated December 21, 2012, No. 1353n

_____
(expert institution name)

I APPROVE

_____
(expert institution Director, full name, signature, seal)

_____, 20__

Expert Commission Opinion on Feasibility/ Unfeasibility of the Medical Product Clinical Trials
No. _____ dated _____, 20__

1. Medical product name (with indication of the accessories required for the medical product application according to its intended use)
_____
2. Medical product manufacturer _____
(full and (if any) abbreviated name, legal form of incorporation of
_____
the legal entity, its registered address)
3. Applicant_____
4. Registration authority assignment details _____
5. Information on experts (full name, specialization, degree (title)(if any), place of employment and position)_____
6. I am informed of the responsibility for reliability of the information included into the report:

Expert Commission Chairman _____
(full name) (signature)
Executive Secretary _____
(full name) (signature)
Experts _____
(full name) (signature)

7. Content of the documents submitted for review (to specify the main provisions of the submitted documents): _____
_____
8. Review of the documents submitted, assessment of the scope and comprehensiveness of conducted tests and studies: _____
_____
9. Review findings:
_____
(to specify conclusions of each of the Expert Commission experts)
10. Conclusion:
_____
(to specify if medical product clinical trials are feasible/ unfeasible, to state reasons for unfeasibility of the medical product clinical trials
_____
with confirmation of the medical product type and the class of the potential
_____
risk associated with the medical product application, in accordance with the nomenclature classification)
Expert Commission comprising:
Expert Commission Chairman _____
(full name) (signature)
Executive Secretary _____
(full name) (signature)
Experts _____
(full name) (signature)

Appendix 3
to Order of the Ministry of Health
of the Russian Federation
dated December 21, 2012, No. 1353n

_____
(expert institution name)

I APPROVE

_____
(expert institution Director, full name, signature, seal)

_____, 20__

Expert Commission Opinion on Findings of the Medical Product Quality, Efficacy and Safety Review
No _____ dated _____, 20__

1. Medical product name (with indication of the accessories required for application of the medical product according to its intended use)
_____
2. Medical product manufacturer _____
(full and (if any) abbreviated name
_____
legal form of incorporation of the legal entity, its registered address)
3. Applicant_____
4. Registration authority's assignment details _____
5. Information on experts (full name, specialization, degree (title) (if any), place of employment and position) _____
6. I am informed of the responsibility for reliability of the information included into the report:

Expert Commission Chairman _____
(full name) (signature)
Executive Secretary _____
(full name) (signature)
Experts _____
(full name) (signature)

7. Content of the documents submitted for review (to specify the main provisions of the submitted documents): _____
_____
8. The review of the documents submitted for review, assessment of the scope and comprehensiveness of conducted tests and studies: _____
_____
9. Review findings:
_____
(to specify conclusions of each of the expert commission experts)
10. Conclusion: _____
_____
(to specify the general conclusion, to state reasons, if the opinion is negative)

Expert Commission comprising:
Expert Commission Chairman _____
(full name) (signature)
Executive Secretary _____
(full name) (signature)
Experts _____
(full name) (signature)