Notification on Printing and Distributing the Operating Specification of the Expert Consultation Meeting/Public Expert Demonstration Meeting of Center for Medical Device Evaluation

10:00, December 5, 2019

In order to further standardize the expert consulting work of the center, use external expert resources in a reasonable way, and ensure the quality of technical evaluation, our Center has revised the *Operating Specification of the Expert Consultation Meeting/Public Expert Demonstration Meeting of Center for Medical Device Evaluation* in accordance with the existing work functions and the needs of medical device expert consultation, and which is hereby released.

National Medical Products Administration

Center for Medical Device Evaluation

December 5, 2019

Operating Specification of the Expert Consultation Meeting/Public Expert Demonstration Meeting of Center for Medical Device Evaluation

Article 1 In order to further standardize the expert consultation of the Center for Technical Evaluation and ensuring the quality of technical evaluation work, this specification is formulated in accordance with the Administrative Measures of the Expert Consultation Committee for Medical Device Evaluation.

Article 2 The expert consultation meeting as mentioned in this specification refers to the process in which the Center for Medical Device Evaluation, in the process of medical device registration evaluation, invites the consulting experts (hereinafter referred to as “the experts”) to consult the technical problems that need to be consulted and put forward opinions in the form of meeting. The public expert demonstration meeting refers to the process of inviting experts to make discussion and give their opinions in the form of meeting in order to solve major issues about technical disputes existing between the center and the applicant, as well as major and complicated scientific and technical problems.

Article 3 In any of the following circumstances, an expert consultation meeting may be convened after discussed and approval by the sub-technical committees:

(I) Medical devices that have passed the innovation review;

(II) Medical devices that have passed prior approval;

(III) Medical devices that have passed emergency approval;

(IV) The first medical device of the same kind;

(V) Application for clinical trial approval.

The technical problems of other products under evaluation shall be studied and solved by the technical sub-committees on their own. Any dispute may be submitted to the technical committee of the center for discussion. If expert opinions are needed, an application for an expert consultation meeting may be submitted with the consent of the technical committee of the Center.

Article 4 Examination and approval procedures for expert consultation meetings

(I) Application for an expert consultation meeting

1. The circumstances that the clinical department and the review department jointly hold the expert consultation meeting

If the evaluation projects under the responsibility of the clinical department are confirmed to require an expert consultation meeting and meeting the relevant circumstances in Article 3 of this specification, the chief reviewer of the clinical department shall submit an application for an expert consultation meeting and fill in the Application Form for an Expert Consultation Meeting (Attachment 1), draw up the professional direction of the expert panel members (If there are designated specialties and experts, it shall be indicated in the application form), the number of people, specify the required consultation questions, the experts and institutions to be avoided, and whether the applicant needs to attend the meeting, etc. At the same time, after submitting to the sub-technical committee of the department for approval and uploading the minutes of the sub-technical committee meeting, it shall be reported to the department reviewer. The reviewer shall review the application for an expert consultation meeting, and those approved shall be transferred to the review department; for those which are not approved, it is required to explain the reasons and return them to the chief reviewer.

After receiving the application for an expert consultation meeting from the clinical department, the review department shall make a comprehensive evaluation of the project under evaluation and confirm whether to hold an expert consultation meeting together with the clinical department. If it requires to be held together, chief reviewer of the review department shall specify in the application for the expert consultation meeting the professional direction of the added expert group members (If there are designated specialties and experts, it shall be indicated in the application form), the number of people, the required consultation questions, the experts and institutions to be avoided, etc. At the same time, after submitting to the sub-technical committee of the department for approval and uploading the minutes of the sub-technical committee meeting, it shall be reported to the department reviewer. The reviewer shall review the application for an expert consultation meeting, and those approved shall be transferred to the issuer; for those which are not approved, it is required to explain the reasons and return them to the chief reviewer.

2. The circumstances that the clinical department separately holds expert consultation meetings

After the review department receives the application for the expert consultation meeting of the clinical department and confirms that it does not require to hold the expert consultation meeting together with the clinical department, the chief reviewer of the review department shall submit the application for the expert consultation meeting proposed by the clinical department to the reviewers of the department, and the reviewer shall transfer it to the issuer after review.

3. The circumstances that the review department separately holds the expert consultation meeting

After the review department confirms that an expert consultation meeting is required and conforms to relevant circumstances in Article 3, but the clinical department does not need to hold an expert consultation meeting, the chief reviewer shall submit an application for the expert consultation meeting, fill in the Application Form for an Expert Consultation Meeting, draw up the professional direction of the expert panel members (if the specialties and experts require to be designated, it shall be indicated in the application form), the number of people, specify the questions to be consulted, experts and institutions to be avoided, and whether the applicant needs to attend the meeting, etc. At the same time, after submitting to the sub-technical committee of the department for approval and uploading the minutes of the sub-technical committee meeting, it shall be reported to the department reviewer. The reviewer shall review the application for an expert consultation meeting, and those approved shall be transferred to the issuer; for those which are not approved, it is required to explain the reasons and return them to the chief reviewer.

(II) The issuer shall sign the approval opinion. If the application for consultation is approved, the application for consultation shall be transferred to the general business department, and the registered products shall be