Provisional Translation (as of November 2025)[1]

PSB/PED Notification No. 1002-2
October 2, 2025

Attention to: Commissioner of Prefectural Health Supervising Department

Director, Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare

Utilization of Prior Assessment Consultation for Drugs (Quality) for Marketing Authorization Applications of Radiopharmaceuticals

Pursuant to the provisions of Article 42, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960, hereinafter referred to as "the Act"), radiopharmaceuticals are designated as pharmaceuticals requiring special attention for public health and hygiene, and their manufacturing methods, properties, quality, and storage conditions are prescribed in the Minimum Requirements for Radiopharmaceuticals (Ministry of Health, Labour and Welfare Notification No. 83 of 2013).

In recent years, the development of radiopharmaceuticals has been accelerating, and it is anticipated that the number of marketing authorization applications submitted by marketing authorization holders with limited experience in radiopharmaceutical approval applications will increase. Since the revision of Minimum Requirements for Radiopharmaceuticals and review of marketing authorization application are conducted in parallel for radiopharmaceuticals, your cooperation is requested in informing relevant medical institution and related organizations under your jurisdiction to pay attention to the following points so that these processes can proceed smoothly.

Remarks

1. When planning to submit a marketing authorization application for a radiopharmaceutical that requires the revision to the Minimum Requirements for Radiopharmaceuticals, it is recommended to request the Prior Assessment Consultation for Drugs (Quality) with Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") to ensure the smooth progress of the Minimum Requirements for Radiopharmaceuticals and the approval review, which are conducted in parallel.

2. If the radiopharmaceutical planned for submission under item 1 qualifies as a priority review drug under Article 14, Paragraph 10 of the Act, it is strongly recommended to apply for the Prior Assessment Consultation for Drugs (Quality) with PMDA to ensure the smooth progress of the approval review process. Please note that if this consultation is not conducted, there is a significant possibility that the standard review timeline for new drug applications may be delayed.

3. When planning to submit a marketing authorization application of a radiopharmaceutical that may fall under items 1 or 2, it is recommended to request a Pre-consultation meeting with PMDA to confirm the contents of the documents to be

[1] This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

submitted for the Prior Assessment Consultation for Drugs (Quality).

4. When technical advice is needed in relation to the marketing authorization application of radiopharmaceuticals, applicants are encouraged to seek appropriate consultations with PMDA as necessary.