HPB/RDD Notification No. 0210-2
PSB/PED Notification No. 0210-2
PSB/MDED Notification No. 0210-2
February 10, 2026

To:
President, Japan Pharmaceutical Manufacturers Association
Chairman, Japan-Based Executive Committee of Pharmaceutical Research and Manufacturers of America
Chair, European Federation of Pharmaceutical Industries and Associations
Chairman, Japan CRO Association
Chairman, Forum for Innovative Regenerative Medicine

Director, Research and Development Policy Division,
Health Policy Bureau, Ministry of Health, Labour and Welfare
(Official seal omitted)
Director, Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare
(Official seal omitted)
Director, Medical Device Evaluation Division,
Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare
(Official seal omitted)

Coordination between the One-Stop Service Platform (OSSP) and PMDA

Changes in the environment surrounding the pharmaceutical industry in recent years have revealed issues such as a decline in drug discovery capabilities and drug lag/loss in Japan, which has emphasized the importance of further improving the clinical trial environment in order to promptly deliver necessary pharmaceuticals to the public. Under such circumstances, with the aim of strengthening the system for conducting international-level clinical trials, the Ministry of Health, Labour and Welfare (MHLW) has decided to promote the strengths of the clinical trial environment in Japan mainly for overseas startup companies and pharmaceutical companies that have no development base in Japan, and establish a one-stop service office which will receive consultations on the conduct of clinical trials in Japan and coordinate the conduct of clinical trials in Japan as well as promote the conduct of clinical trials in Japan (One-Stop Service Platform (OSSP), hereinafter referred to as “ENSEMBLExJ”). It has been decided that ENSEMBLExJ, in liaison with the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”), will give priority to handling consultations, as described below. Please inform the member companies, etc. of your organizations of this notification.

1 Priority Handling of Consultation

(1) Priority consultation will be considered eligible for a product for which ENSEMBLExJ is consulted and which meets all of the requirements (i) to (iii) below, according to “Implementation Guidelines for Formal Consultation and Confirmation of certification, etc., conducted by the Pharmaceuticals and Medical Devices Agency” (PMDA Notification No. 0302070 of the Chief Executive, dated March 2, 2012).

(i) Products considered to have a high medical need by ENSEMBLExJ because there are no effective therapeutic drugs for the target disease available in Japan and no drugs with a similar mechanism of action being developed in Japan.

(ii) Drug products or regenerative medical products

(iii) Products for which a clinical trial is planned to be conducted in Japan

Medical needs will be, in principle, determined individually based on a consultation between ENSEMBLExJ and PMDA according to the principles in “Handling of Priority Reviews etc.” (Joint PSEHB/PED Notification No. 0831-1 issued by Director, Pharmaceutical Evaluation Division and PSEHB/MDED Notification No. 0831-1 issued by the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated August 31, 2020).

(2) Submission of consultation documents written in English to PMDA will be permitted on a case-by-case basis based on consultation between ENSEMBLExJ and PMDA for a product considered eligible for priority consultation as per (1) above, for which consultation with ENSEMBLExJ is highly necessary because its development company is an emerging biopharma company with no Japanese subsidiary (for example, a company with annual global sales of less than 5 hundred million US dollars and annual research and development costs of less than 2 hundred million US dollars) or for other reasons.

(3) It is advisable for those wishing for (1) and (2) above to consult with ENSEMBLExJ in advance.

2 Effective Date

Priority handling as per this notification shall apply to products for which a request for scheduling of a consultation is submitted to PMDA on or after February 10, 2026.