Provisional Translation (as of May 30, 2012)[*]

Administrative Notice
March 30, 2012

To: Division of Pharmaceutical Affairs,
Prefectural Health Department (Bureau)

From: Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

On the Standard Review Timeline for New Drug Applications

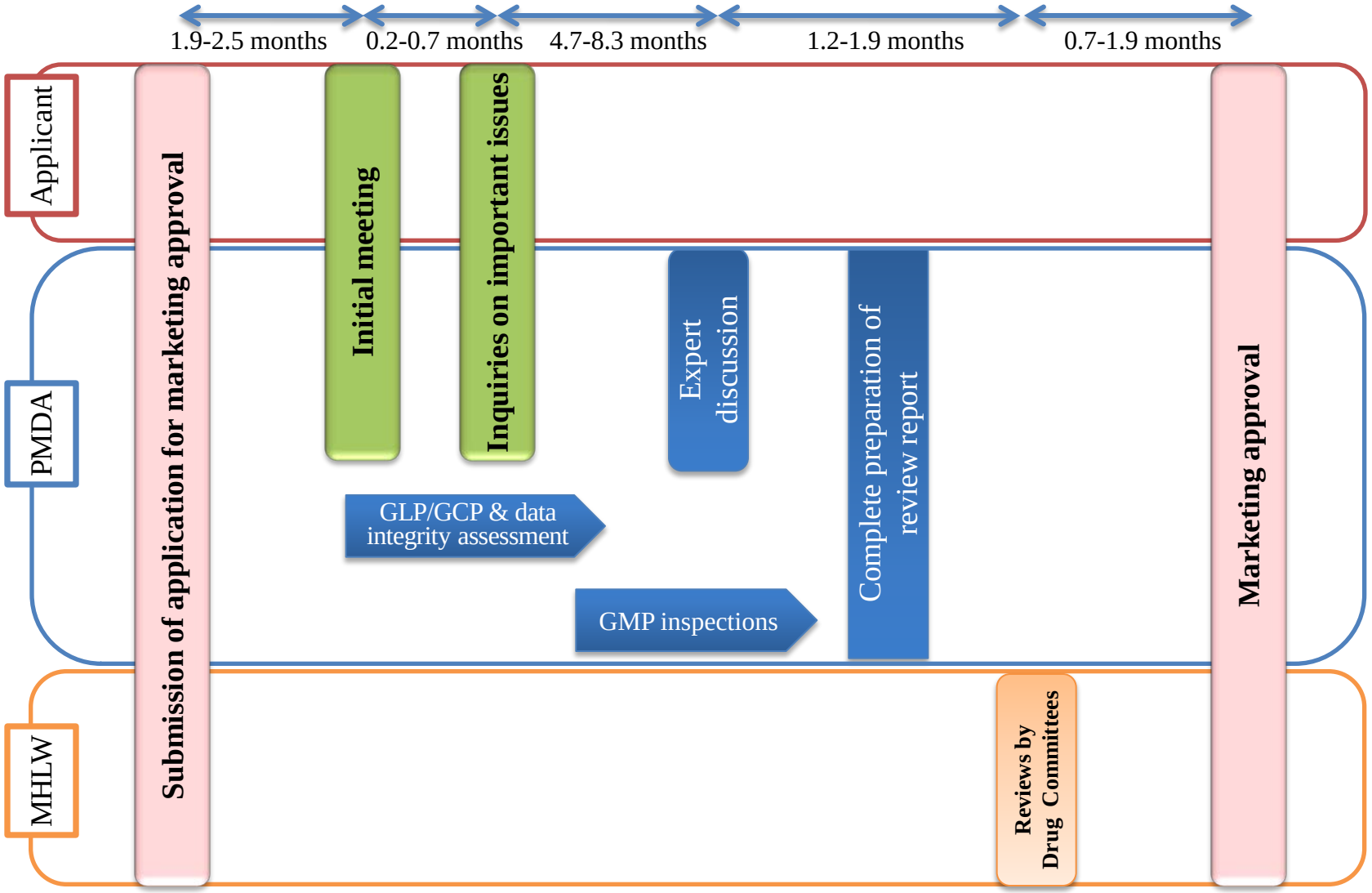
The Mid-term Plan of the Pharmaceuticals and Medical Devices Agency (authorized under MHLW-PFSB No. 0331002 dated March 31, 2009) sets a target for the total review time for new drugs, aiming at a median time of 12 months for standard review products. The target needs to be achieved through efforts by both the regulatory authorities and applicants.

We now wish to seek your recognition of the attached standard review timeline, and request your cooperation in disseminating this information to all related companies and organizations under your jurisdiction.

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

The Standard Review Timeline for New Drug Applications

To achieve the target of 12 months (standard review products) for the total review time (median) from receipt of an application to approval, the standard review timeline indicating the timeframes (the total of the times allowed for the regulatory authorities and the applicant) for each review stage, based on past performance in regulatory review, is shown below. This timeline is applicable when there are no particular concerns in the course of review.



Note: "Inquiries on important issues" means inquiries made by PMDA after the initial meeting.