Orphan Drug Development Guidebook

Building Block J305

This document defines the content of the Building Block created for each identified tool, incentives, initiative or practice introduced by public bodies or used by developers to expedite drug development in Rare Diseases (RDs).

ITEM	DESCRIPTION
Building Block (BB) Title	Consultation on Pharmacogenomics / Biomarkers (As part of PMDA consultations)
References	• PMDA Website: Record of Consultations on Pharmacogenomics / Biomarkers – https://www.pmda.go.jp/english/review-services/consultations/0001.html • PMDA Website: Record of Consultations on Pharmacogenomics / Biomarkers (Japanese) – https://www.pmda.go.jp/review-services/f2f-pre/consultations/0033.html • PMDA Website: User Fees – https://www.pmda.go.jp/review-services/drug-reviews/user-fees/0001.html (Information of consultation fees, Japanese)
Description	Consultation on Pharmacogenomics / Biomarkers is one of the PMDA consultations. The purpose of this consultation is to provide general scientific advice for utilization of pharmacogenomics or biomarkers that are not specified in a certain product.

ITEM	DESCRIPTION
Category	Regulatory Building Block
Geographical scope	Japan
Availability	Similar as for the PMDA consultations BB, this BB is available for developers within Japan for rare and non-rare diseases regardless of the applicant's nature (i.e., public/no-profit/academia, SME, etc)
Scope of use	The purpose of this consultation is to provide general scientific advice for utilization of pharmacogenomics or biomarkers that is not specified in a certain product.
Stakeholders	• Drug/Medical device/Regenerative Medical Product developers • Pharmaceuticals and Medical Devices Agency (PMDA)
Enablers/ Requirements	N/A
Output	Scientific advice with meeting minutes from PMDA
Best time to apply and time window	Anytime during medical product development. It takes approximately 24 weeks from application to receiving minutes.
Expert tips	PROs: Provision from PMDA for appropriate pharmacogenomics or biomarkers utilization in the development of a drug/medical device/regenerative medical product is obtained. CONs: N/A