RELIANCE EXPERIENCE THROUGH ASEAN JOINT ASSESSMENT - INDONESIA

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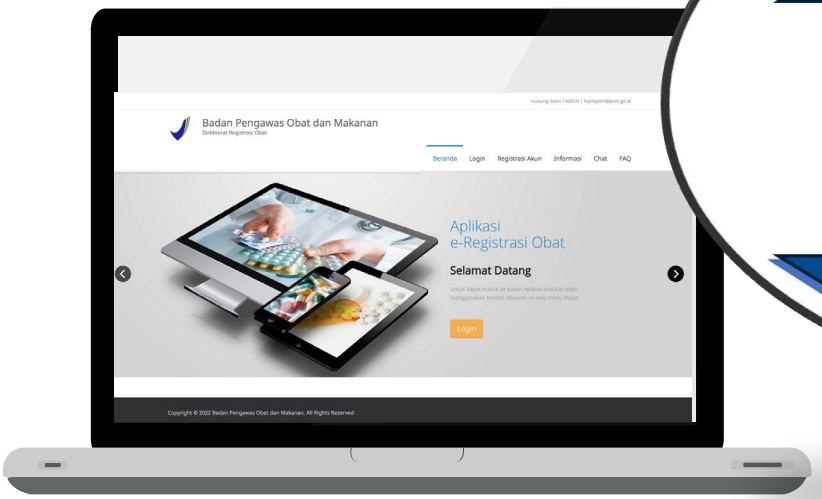
Japan, April 23rd 2024

Drug Registration Process

new-aero.pom.go.id

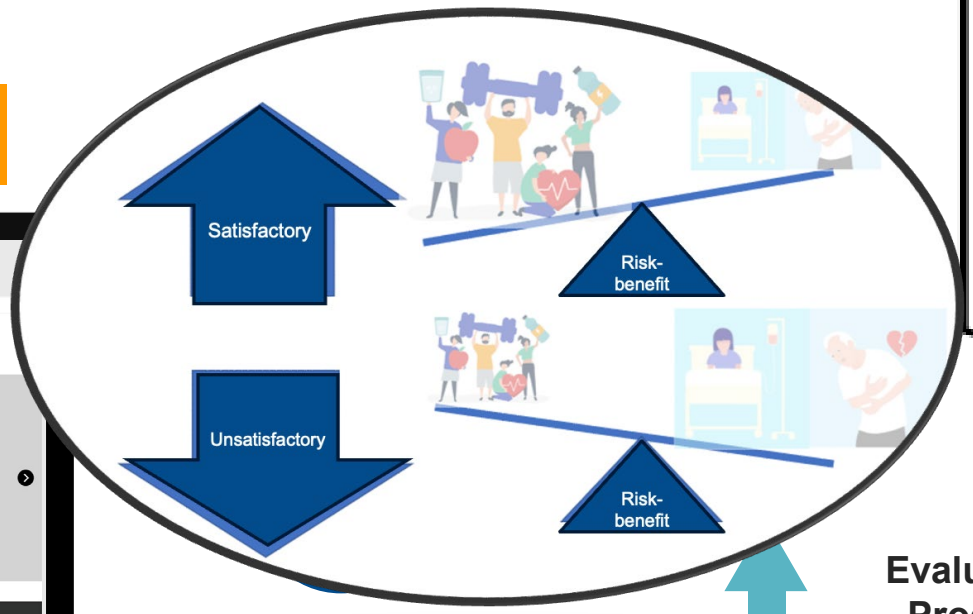


Online submission

Applicant:
Pharmaceutical Industry

Evaluation Process

Safety and Efficacy

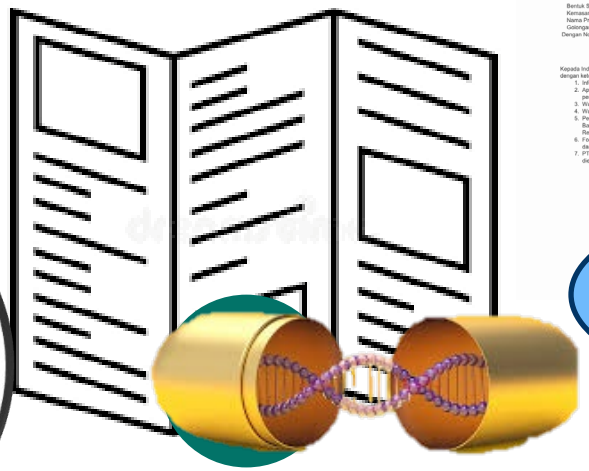


Recommendation

National Committee &
Ad-Hoc Clinician Expert

Evaluation Process

Quality and Labeling



Marketing Authorization

5 YEARS

Regular
300
WD

Reliance
120
WD

RELIANCE MECHANISM IN INDONESIA

INDONESIAN FDA

The evaluation process of 120 WD

- **Medicines are approved at proposed reference country**
- **Applicant provides full assessment report (unredacted) from at least 1 regulatory agency of the reference country with well-established evaluation system**

Sovereignty

USA	European Union	Australia	Canada	United Kingdom	Japan

Regulation of Reliance System in Indonesia

The criteria of reference country :

- Has an established evaluation system.
- Has Public Assessment Report (PAR) in English.
- Has become a reference country to other countries.

U.S Food and Drug Administration

EUROPEAN MEDICINES AGENCY

Australian Government
Department of Health
Therapeutic Goods Administration

Pmda 独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Medicines & Healthcare products Regulatory Agency

Health Canada

Regulation of The Chairperson of The Indonesian FDA Number 24 Year 2017 and its addendum Number 15 Year 2019

Not applicable for drugs that require specific evaluation regarding differences in disease patterns, resistance patterns and/or national program policies

- Unredacted full assessment report from the reference country
- The CMC (chemistry, manufacturing, control) should be the same with that of approved in reference country
- Approval within the last 5 years in the proposed reference country.

Applicable for new drug registration and registration of major variations for new indication/new posology of Biological Products and New Chemical Drugs

Joint Assessment

Joint assessment is a formal procedure in which the same application is simultaneously submitted to all participating National Regulatory Authorities (NRAs).

Assessment is carried out by all participating NRAs and then a joint assessment report is prepared.

At the end of the process, the final decision is then taken by each individual NRA through their regular decision-making process

Joint Assessment Experiences in BPOM

World Health Organization

1. Dengvaxia in 2015
2. nOPV2 in 2020

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1. Qdenga (Indonesian FDA as observer)
2. Perjeta, variation on MCB change, in 2024 (on going)

asean JACG

1. Pyramax in 2018
2. Ocrevus in 2023

ASEAN JACG: Pyramax and Ocrevus

2018

Pilot Project

Evaluation on Malaria Drug (Pyramax, containing artesunate and pyronaridine)

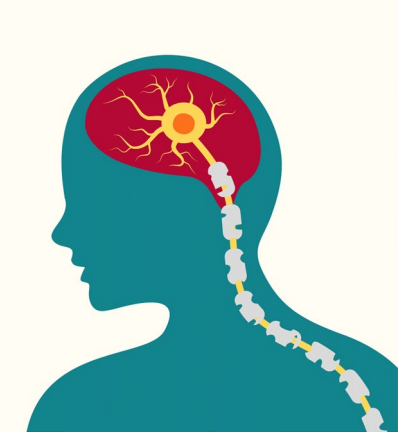
2023

- Evaluation on Ocrevus containing Ocrelizumab.
- Ocrevus was approved by Indonesian FDA on January 22, 2024 (82 working days from required 300 working days)

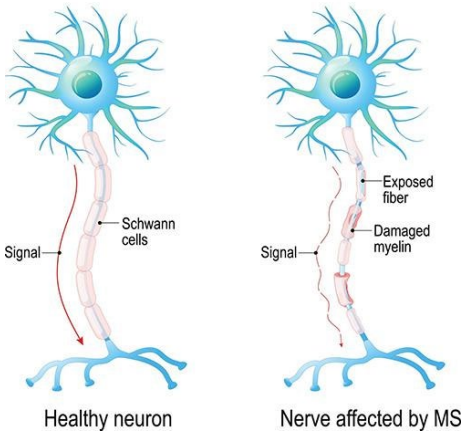
Approved indication by The Indonesian FDA:

Ocrevus is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features (see section 5.1).

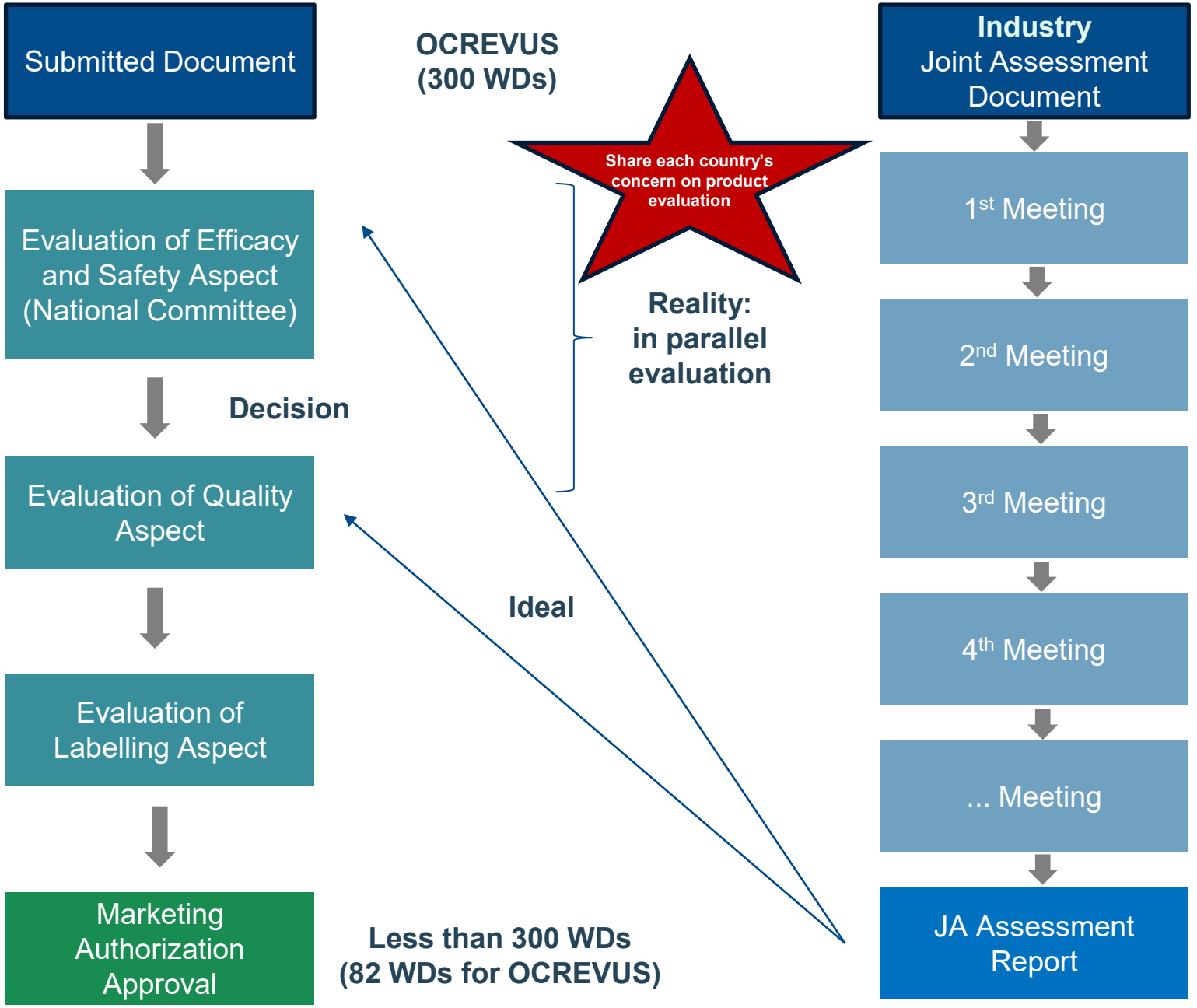
Ocrevus is indicated for the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity (see section 5.1).



Multiple Sclerosis



Our Experience on ASEAN JACG - Ocrevus



BADAN POM

THANK YOU