EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MHLW / PMDA-EMA Orphan Medicines Collaboration

Japan

The European Medicines Agency and the European Commission have a confidentiality arrangement with the Japanese Ministry of Health, Labour and Welfare (MHLW) and Japanese Pharmaceuticals and Medical Devices Agency (PMDA). The confidentiality arrangements allow exchange of information between the parties as part of their regulatory and scientific processes, both before and after a medicine has been approved.

The types of information covered include:

- advance drafts of legislation and regulatory guidance documents;
- scientific advice on medicine development;
- assessments of applications for marketing authorisations;
- information about the safety of marketed medicines.

The confidentiality arrangements cover human medicines subject to evaluation or authorised under the centralised authorisation procedure, as well as nationally authorised medicines subject to official European Union arbitration and referrals. They build on the previous **mutual recognition agreement** between the European Commission and Japan.

The arrangement was first signed in 2007 and was last extended in 2013 for a further five years.

The European Medicines Agency meets regularly with counterparts at the MHLW and the PMDA. Japan has also seconded a **representative** to the Agency's offices in London since late 2009.

The Agency also works together with these authorities, together with the Japanese National Institute of Biomedical Innovation (NIBIO), on issues related to medicines for rare diseases.

Table of contents

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 July 2012
EMA/488924/2012
Directorate

European Union - Japan orphan medicines cooperation

European Union (European Commission / European Medicines Agency) – Japan (Pharmaceuticals and Medical Devices Agency / Ministry of Health, Labour and Welfare) pilot terms of reference

1. Background

It is indispensable for the patient suffering from orphan diseases to have access to medicinal products for their diseases. However, the limited number of patients of orphan diseases hinders companies from research and development in such area, which creates the situation where active involvements by

Objectives (Aim)

To create an operational framework focused on a series of activities listed below:

- Creation of greater awareness of mutual orphan medicine designations submission process.
- Development of a system of exchange regarding the outcomes of orphan medicine designations in each Agency/Ministry.
- Development of a system of exchange regarding regulatory and licensing stage concerning orphan medicines.
- Development of a system of exchange regarding pharmacovigilance post-licensing activities associated with Orphan medicines.
- Development of a collaboration mechanism regarding small to medium size enterprises (within the range of confidentiality arrangements).

Activities

- ***Bilateral initiative to produce a framework for creating greater awareness of mutual orphan medicine designation submission processes.***
- ***Orphan medicine designation submissions stage:***
- ***Regulatory Licensing stage:***
- ***Post-Licensing/Pharmacovigilance stage:***
- ***Collaboration regarding small to medium sized enterprises:***

Achievements to date

- The EMA and MHLW have work together to increase accessibility and awareness of their mutual orphan designation processes.
- This has been done through quarterly communications where discussions between Agencies have been held to increase understanding of similarities in functioning.
- Improvement of visibility of webpages in Japan and Europe.

Areas of on-going development

- Parallel submissions in Europe and Japan where applicable.
- Parallel consultations regarding Scientific Advice.
- Enhancing mechanisms regarding how orphan conditions are evaluated and endorsed.