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# PMDA pledges better sponsor and investor communication, speedier approval and electronic submission portal by 2018 – officials

PMDA will increase headcount, boost agency communication with sponsors

Electronic NDA submission portal expected to be running by 2016

Medical database with data from over 10 million patients expected in 2015

Pharmaceuticals and Medical Devices Agency (PMDA) Japan plans to improve communications with international sponsors and financiers, accelerate its approval process and implement an electronic NDA system by 2018, leadership revealed at DIA EuroMeeting in Vienna last week.

The goal is to attract global industry players to develop, finance and market drugs in Japan, they noted.

Japanese pharma and medical device R&D is high in Japan, yet very few products are launched in the region because of a lack of financing and lack of knowledge on local development and regulatory systems, Takao Yamori, director of Center for Product Evaluation, PMDA noted.

To resolve the issue, PMDA launched an R&D strategy consultation service in July 2012 for sponsors and venture companies not familiar with the Japanese market, he noted. Part of the five-year strategy is to grow consultancy capabilities from 750 employees to 1000 by 2018, Tatsuya Kondo, chief executive of PMDA added.

The agency is actively working on translating more information into English, including safety information and pharmacopeia, to become more accessible to foreign pharma and investors, he added.

PMDA also aims to work more closely with other agencies including the FDA and EMA as well as global standardization bodies, the International Conference on Harmonisation (ICH), International Medical Device Regulators Forum and Organization for Economic Co-operation and Development for mutual acceptance of data, Kondo noted.

These measures will hopefully decrease the time between FDA or EMA approval and subsequent regulatory approval in Japan, Yamori said. Kyowa Hakko Kirin's (TYO:4151) targeted monoclonal antibody Poteligeo (mogamulizumab) in adult T-cell leukemia-lymphoma, received approval in Japan in March 2012, he said. The drug is not yet approved elsewhere but is currently in a Phase III trial in cutaneous T cell lymphoma under the FDA and various EU national regulators, expected to finish September 2015, according to ClinicalTrials.Gov.

Another example is Pfizer's (NYSE:PFE) ALK inhibitor Xalkori (crizotinib) for non-small cell lung cancer, first approved through the FDA accelerated approval programme in 2011, followed by approval in Japan one year later, he said. Full FDA approval was granted on 30 November 2013.

Both pathways were originally discovered by universities in Japan, Yamori noted.

R&D consultancy and expedited approvals

Five years ago, a big issue for PMDA was the fact that review times took on average over 20 months, said Kondo. Review times have now been brought down to around 12 months for a standard review and nine months for priority review based on data from applications in 2009 - 2013, he noted.

The aim over the next five years is to complete 80% of all standard approval reviews within 12 months and 80% of priority reviews within nine months, Yamori added. An electronic NDA submission portal is expected to launch in 2016 and PMDA consultancy will be a big driver behind the expedited review timeframes, Yamori added.

PMDA established its pharmaceutical affairs consultancy service in July 2011 and has since assessed over 1200 cases from academia and industry for pharma and medical devices, Kondo said.

The consultation process is split into three parts; free introductory consultation, free pre-consultation to sort out development and regulatory issues, and a fee-based in-person consultation, he said.

Consultation is currently available only for new APIs and combinations, though the agency is planning to extend this to generics applications in the future, Kondo noted.

Cyberdyne (TYO:7779) is one company which opted for a face-to-face consultation to discuss its product Robot Suit Hal (hybrid assistive limb), he said. PMDA approved the robotic exoskeleton, which assists movement in disabled patients, for worldwide distribution from the Japan Quality Assurance Organization (JQA) in February 2013. In August 2013, the robotic device received European CE mark.

Cyberdyne listed on the Tokyo stock exchange on 26 March, and has a current market cap of JPY 77bn (USD 745m).

A new approval system for regenerative medicine has also been introduced, where conditional approval can be granted to gain data for early practical use, Yamori added.

Risk management plans and pharmacovigilance

PMDA is also implementing a risk management plan (RMP) system similar to the EU, which includes pharmacovigilance

**Company**

[Cyberdyne Incorporated](#)  
[Pfizer, Inc.](#)

**Drug(s)**

[POTELIGEO](#)  
[Xalkori](#)

**Topic**

[Generics](#)  
[Medical Devices](#)  
[Other](#)  
[Other](#)  
[Other](#)  
[Regulatory](#)

**Indications**

[Lung Cancer, Non-Small Cell](#)  
[Lymphoma](#)

**Mechanism(s)**

[Anaplastic Lymphoma Kinase \(ALK\) Inhibitor](#)  
[CCR4 Binder](#)  
[C-Met Inhibitor](#)  
[C-Met Inhibitor](#)

**Sub-sectors**

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measures, Hiroshi Yamamoto, chief safety officer, PMDA said. The risk management plan guidance was instated on 1 April 2013, so all RMP discussions for MAs should begin at NDA submission.

The agency is developing a medical information database with data from over 10 million patients to be launched in 2015 to support pharmacovigilance and RMP activity, he said.

Currently, RMPs are not required for biosimilars approval in Japan, though the PMDA will likely implement RMPs in the future for this group, Yamamoto noted in response to an audience question from a Pfizer executive.

There have been some issues in ICH regions, in their approach of biosimilars, Virginia Acha, director, regulatory affairs, Amgen said on the sidelines of the conference. EU is further ahead than other regions in this area, she added.

One reason may be reduced numbers of biosimilars in Japan compared with the EU, as the concept is newer to the region and companies have not submitted as many biosimilar applications to PMDA, compared to EMA, Acha said. However, more biosimilar PMDA submissions are now occurring in Japan, she noted.

This has primarily been due to the regulatory pathway for biosimilars approval in Japan, although the regulatory pathway is now well established and good naming policies are in place, Sundar Ramanan Director global biosimilars R&D policy, Amgen added. WHO naming policy is that a single International Nonproprietary Name (INN) should be selected for each biologic or pharmaceutical - including biosimilars - worldwide for clarity and ease of regulatory management, according to the WHO website.

by Natalie Morrison in London

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