Regulatory Update from Japan
- New measures to improve access to innovative MDs/IVDs -

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pmda

Topics

1. Implementation of PMD Act; Revision of Pharmaceutical Affairs Law (PAL)
2. PMDA Medical Device Training Seminar
3. New international regulatory harmonization strategies by MHLW and PMDA
4. Official participation in MDSAP Pilot
5. Implementation of Strategy of Sakigake
6. Clinical Innovation Network

1. Implementation of PMD Act; Revision of Pharmaceutical Affairs Law (PAL)

The PMD Act came into force on 25 November 2014 for the purpose of:

1. Strengthening safety measures regarding drugs and medical devices
2. Revising medical device regulations based on its characteristics
3. Introducing cellular and tissue therapeutic product regulations based on its characteristics

According to the revision:

a. Some Class III Medical Devices undergo certification
b. Software as a Medical Device (SaMD) is newly regulated
c. Manufacturer is required to be registered, instead of to be licensed
d. More efficient QMS inspection system is introduced

2. 2nd PMDA Medical Device Training Seminar for regulators in other jurisdictions

The seminar was held on 2 – 6 February, 2015 at PMDA (Tokyo, Japan).
The next seminar is under planning in February 2016 at PMDA.

- Topics such as pre-market review, QMS, PMS and manufacturing site visit were provided in the 2015 seminar.
- The following jurisdictions were participated:
  - ✓ Australia
  - ✓ Brazil
  - ✓ Singapore
  - ✓ Chinese Taipei
  - ✓ Fellow of the Mansfield Foundation (USA)

3. Establishment of new international regulatory harmonization strategies by MHLW and PMDA

International Regulatory Harmonization Strategy by MHLW and *PMDA International Strategic Plan 2015 by PMDA* have been published on 26 June 2015.
Based on the *mutually complementary* strategies, the following measures will be taken:

A) Promotion of Regulatory Science

Guidelines related to medical device regulations in Japan will be prepared and internationally announced.

B) Establishment of Training Center for regulatory matters

PMDA will provide regulators outside Japan with training for capacity building.

C) Active commitment to IMDRF as well as advancement of bilateral collaboration

(Reference) Concept of Training Center for regulatory matters

PDMA is to set up Asia Training Center for Pharmaceuticals and Medical Devices Affairs and *promote understanding of Japan's knowledge of regulatory science and Japan's regulatory system* to mainly Asian regulatory authority staff, which would contribute to advancement of medical deice regulations in Asia as a whole.

Asia Training Center

PMDA establishes professional organization

Liaise with Asian countries to design and coordinate effective training in accordance with their needs and capabilities

In Japan

(1) Provide training seminar attended by regulatory authority staff

(2) Establish central training facility for APEC international collaborative clinical trials

Local Asian site

(2) Visit local site to lecture, carry out a case study, and conduct fieldwork

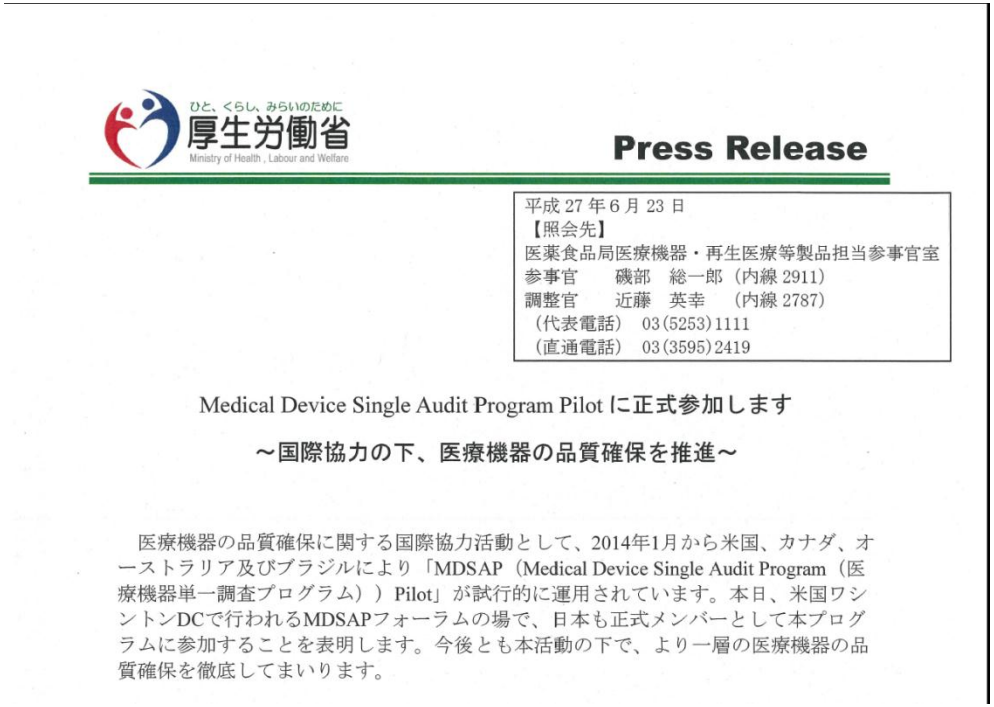
Enables training tailored to local requirements to be offered to more personnel

4. Official Participation in MDSAP

Japan made an announcement on the *official participation in MDSAP Pilot* on 23 June 2015.
Further information will be provided in a timely manner.

Shown at right is the press release on the official participation in MDSAP Pilot in Japan (written in Japanese).

You can find the announcement in English here;
http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm452243.htm



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厚生労働省
Ministry of Health, Labour and Welfare

Press Release

平成 27 年 6 月 23 日
【照会先】
医薬食品局医療機器・再生医療等製品担当参事官室
参事官　磯部　総一郎（内線 2911）
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Medical Device Single Audit Program Pilot に正式参加します

～国際協力の下、医療機器の品質確保を推進～

医療機器の品質確保に関する国際協力活動として、2014年1月から米国、カナダ、オーストラリア及びブラジルにより「MDSAP（Medical Device Single Audit Program（医療機器単一調査プログラム））Pilot」が試行的に運用されています。本日、米国ワシントンDCで行われるMDSAPフォーラムの場で、日本も正式メンバーとして本プログラムに参加することを表明します。今後とも本活動の下で、より一層の医療機器の品質確保を徹底してまいります。

5. Implementation of Strategy of Sakigake

An *innovative MD/IVD for patients in urgent need of innovative therapy* may be designated as a Sakigake Product if;

1) its premarket application will be filed in Japan firstly or simultaneously in some countries including Japan, *AND*
2) prominent effectiveness can be expected.

Once an MD/IVD is designated, its developer can enjoy such benefits as:

A) Prioritized Consultation by PMDA

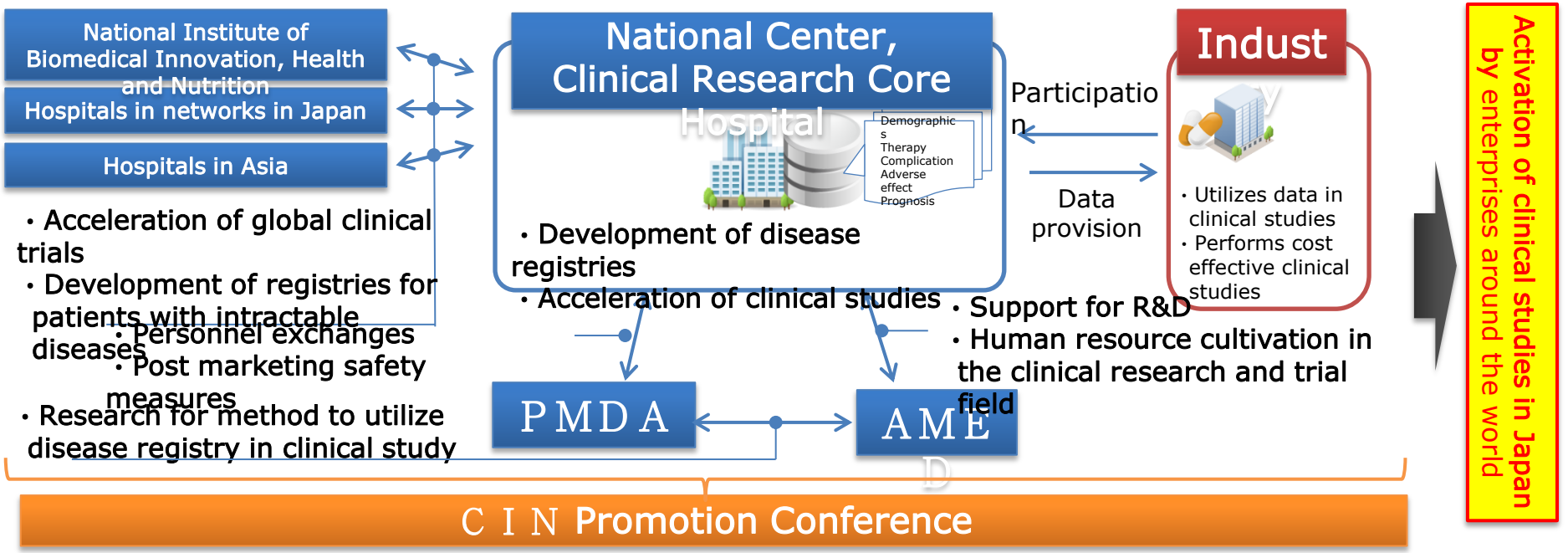
B) Pre-application substantive review

C) Prioritized Review
(12 months → 6 months [MD])

D) Review Concierge assigned by PMDA

6. Clinical Innovation Network (CIN)

The *clinical study infrastructure* in Japan will be improved under the CIN project so that cost effective clinical studies can be performed *with disease registries*, based on Regulatory Science.
The improvement will accelerate clinical studies in Japan by enterprises around the world, which would results in the contribution to extended healthy life expectancy for people.



Thank you

MHLW

PMDA