IMDRF International Medical Device Regulators Forum

Japan Update

- Progress of measures to improve access to innovative MDs/IVDs -

March, 2016

厚生労働省
Ministry of Health, Labour and Welfare

Pmda

Topics

1. Training center under international regulatory harmonization strategies by MHLW and PMDA

2. Designation of Sakigake products

3. Approval of regenerative medicine products for the first time after the implementation of PMD Act

1. 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 device 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

3nd PMDA Medical Device Training Seminar for regulators in other jurisdictions

The seminar was held in cooperation with Japanese industries on 15 – 19 February, 2016 at PMDA (Tokyo, Japan).

- Topics such as pre-market review, QMS, PMS, training facility visit, collaboration among stakeholders and group works for review were provided in the 2016 seminar.
- 31 officials from the following jurisdictions participated:
  - ✓ Bahrain
  - ✓ Chinese Taipei
  - ✓ Ghana
  - ✓ Hong Kong SAR
  - ✓ India
  - ✓ Indonesia
  - ✓ Iran
  - ✓ Malaysia
  - ✓ Myanmar
  - ✓ Saudi Arabia
  - ✓ Singapore

(Reference) 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

IMDRF has been reaffirmed as one of the most important activities.

2. Designation of Sakigake products

The following 5 products under development have been designated as Sakigake products since 10 February 2016.
If a pre-market application for the products is filed, a priority review is applied.

No.	Product name	Expected performance/effectiveness
MD1	**Titanium Bridge** (Hinge-type plate with titanium)	Adduction-type spasmodic dysphonia
MD2	**Absorbing barrier for adhesion prevention** (Trehalose solution)	Reduction of postoperative adhesion prevention by Intraperitoneal injection
RP1	**STR01** (Autologous bone marrow-derived stem cells)	Improvement of neurological symptoms and functional impairment due to spinal cord injury
RP2	**G47Δ** (Recombinant herpes virus)	Glioma
RP3	**Autologous intracardiac stem cells**	Improvement of heart function in children with congenital heart disease

(Reference) 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

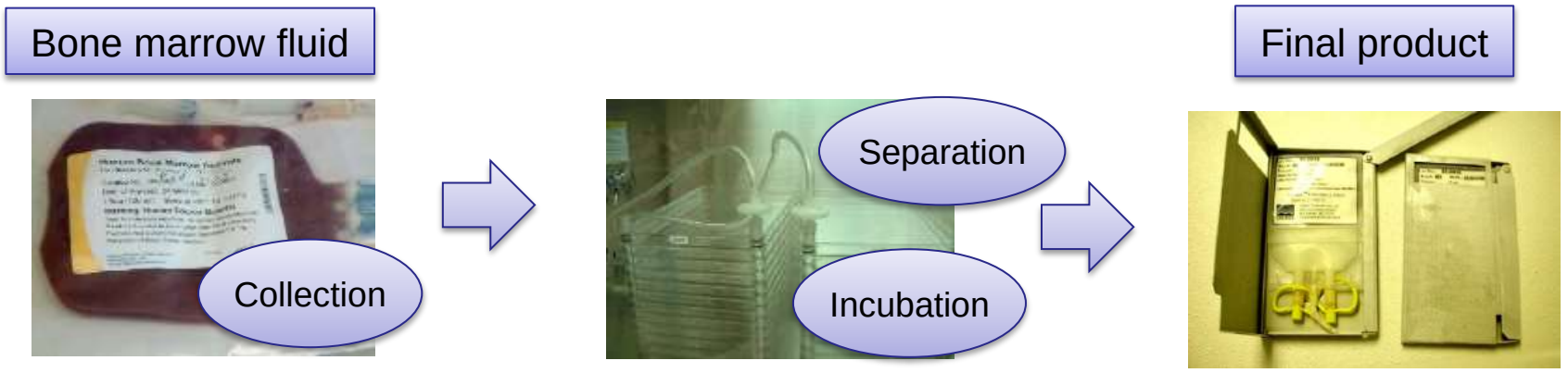
B) Pre-application substantive review

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

D) Review Concierge assigned by PMDA

3. Approval of regenerative medicine product (1/2)

Brand name / General name	TEMCELL® / Human (allogeneic) bone marrow-derived mesenchymal stem cells
Marketing Authorization Holder	JCR Pharmaceuticals Co., Ltd.
Date of approval	18 September 2015
Date of pre-market application	26 September 2014



- The product is administered intravenously to patients that experienced immune response as a side effect after hematopoietic stem cell transplantation.
- Normal approval has been applied.

3. Approval of regenerative medicine product (2/2)

Brand name / General name	HeartSheet / Autologous skeletal myoblast sheets
Marketing Authorization Holder	Terumo Corporation
Date of approval	18 September 2015
Date of pre-market application	30 October 2014

- The product is attached to heart of patients with severe heart failure.
- Conditional and time-limited approval has been applied. The efficacy and safety of the product will be evaluated based on data from approximately 50 patients for 5 years.

Thank you

MHLW

PMDA