

Recent Development of Mutual Cooperation between Japan and India in Medical Products Regulation



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Today's Agenda

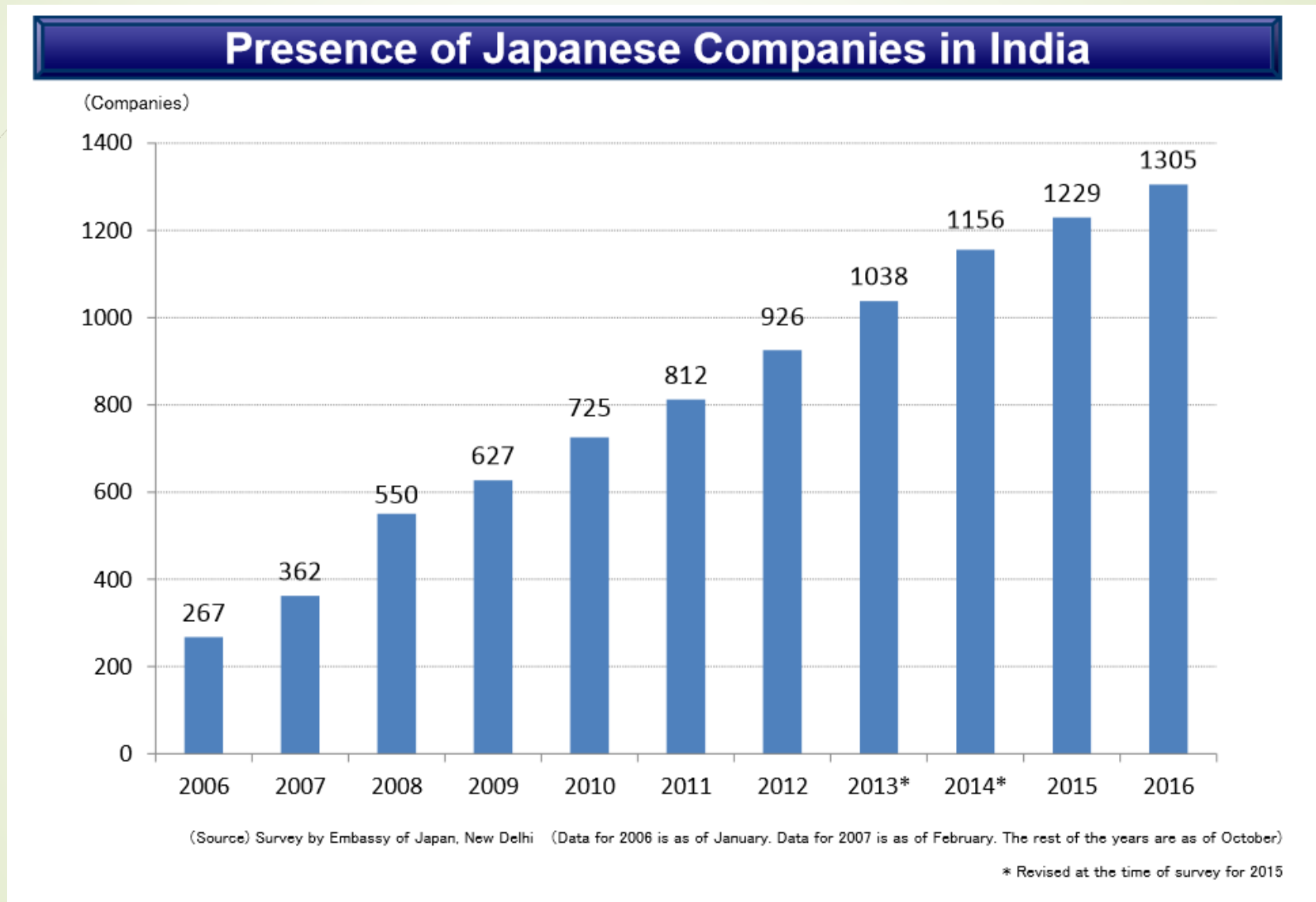
- I . Increased Importance of India for Japan**
- II . Huge potential of Cooperation in Healthcare**
- III . Review of the recent development of the bilateral cooperation with my experience in India**
- IV . Message for officials and business leaders**

I Increased Importance of India for Japan

1. Politics (Summit Meetings)

- Prime Minister Yoshiro Mori's visit to India in August 2000 provided the momentum to strengthen the Japan-India relationship. Mr. Mori and Prime Minister Atal Bihari Vajpayee decided the establishment of "Global Partnership between Japan and India".
- Since Prime Minister Junichiro Koizumi's visit to India in April 2005, Japan-India annual summit meetings have been held in respective capitals.
- In January 2014, Prime Minister Shinzo Abe paid an official visit to India and had a Summit with Prime Minister Manmohan Singh and was the Chief Guest at the Republic Day parade in New Delhi."
- In September 2014, Prime Minister Narendra Modi paid an official visit to Japan and had a summit meeting with Prime Minister Shinzo Abe. PM Abe pledged to realize public and private investments worth JPY 3.5 trillion and doubling of the number of Japanese companies in India over the next five years.
- In December 2015, Prime Minister Abe paid an official visit to India and had a summit meeting with Prime Minister Narendra Modi. 16 Agreements/MoUs/ MoCs/ Lols were signed/exchanged during the visit.
- In November 2016, Prime Minister Modi paid an official visit to Japan and had a summit meeting with Prime Minister Abe. 10 Agreements/MoUs/ MoCs were signed/exchanged during the visit.

2. Economy (Japanese Companies)



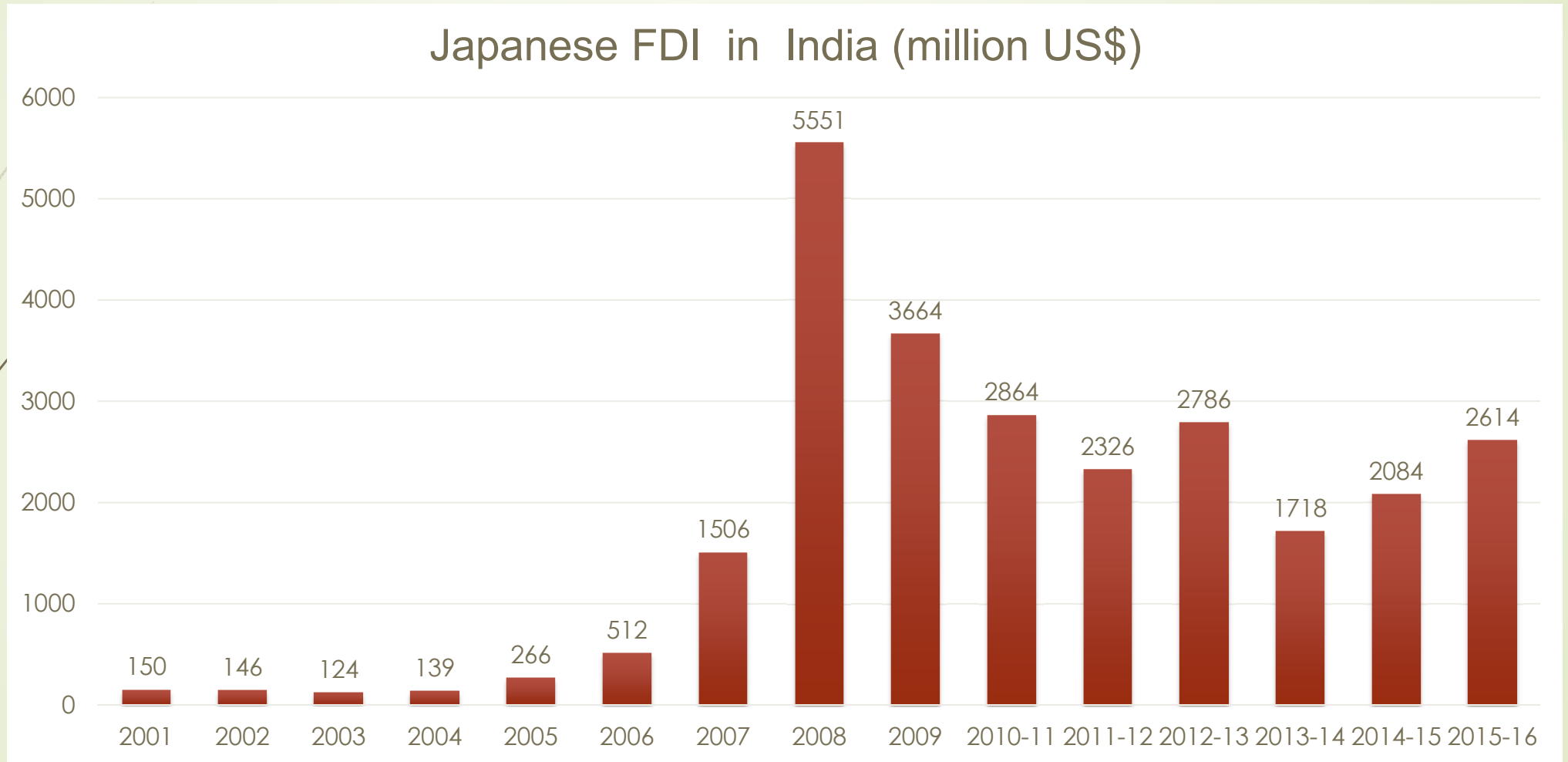
3. Economy (Trade)

(Dollar billion)

Year	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16
India's export to Japan	3.86	3.02	3.63	5.09	6.33	6.09	6.81	5.38	4.66
India's Total Export	163.13	185.29	178.75	251.13	305.96	300.27	314.4	310.33	262.29
% Share	2.37	1.63	2.03	2.07	2.07	2.03	2.17	1.73	1.77
India's import from Japan	6.32	7.89	6.73	8.63	12.1	12.51	9.48	10.13	9.85
India's Total Import	251.65	303.69	288.37	369.77	489.32	491.94	450.2	448.03	381
% Share	2.52	2.6	2.34	2.33	2.47	2.54	2.11	2.26	2.58
India-Japan bilateral trade	10.18	10.91	10.36	13.72	18.43	18.61	16.39	15.51	14.51
Percentage Change	36.5	7.2	-5.04	32.4	34.3	1	-11.9	(-) 5.36	(-) 6.4

Source: Embassy of India in Japan

4. Economy (Japanese FDI)

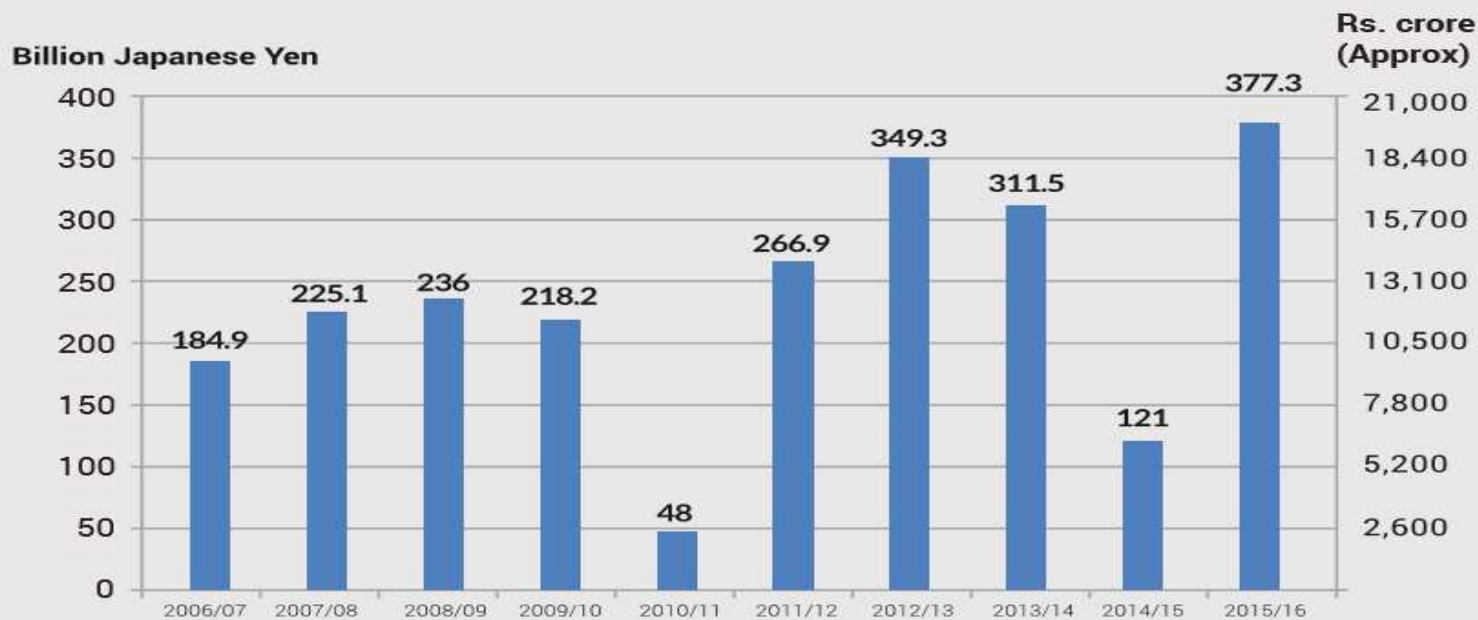


Source: Embassy of India in Japan

5. Economy (Japanese ODA)

- For India, Japan is the largest donor of official assistance.
- For Japan, India is the largest recipient of ODA Loan support.

Trends in ODA Loan Commitment for the Past 10 Years (FY 2006/07 - 2015/16)



*The great East Japan Earthquake occurred in FY2010/11

*Prime Minister Modi's new administration in FY2014/15

II Huge potential of Cooperation in Healthcare

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1. Contrast of Features of both countries

	Japan	India
Economy	<ul style="list-style-type: none">- Developed- Stable	<ul style="list-style-type: none">- Emerging- Rapid growth
Population	<ul style="list-style-type: none">- Aging & Declining	<ul style="list-style-type: none">- Young & Growing
Healthcare Access	<ul style="list-style-type: none">- UHC with Public Insurance for all- Fiscal sustainability is the issue	<ul style="list-style-type: none">- Being Improved- but still limited
Pharma Industry	<ul style="list-style-type: none">- Matured- High Quality & Innovative- Reduce cost & Look at new market	<ul style="list-style-type: none">- Huge & Growing- Cost Effective & Generic- Expand export & Look at new drugs
MD Industry	<ul style="list-style-type: none">- Matured- High Quality & Innovative- Need to reduce the cost- Need to look at new market	<ul style="list-style-type: none">- Relying on import, but emerging- Cost Effectiveness- Need Technology for manufacturing to deliver affordable MD for Indians
Manpower	<ul style="list-style-type: none">- Skilled, but need to globalize	<ul style="list-style-type: none">- Young stars, global

Japan and India can complement each other and be the **best partners**.

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2. What were the challenges to overcome?

Many experts pointed out differences between two countries in...

Regulations, Qualities of Products required by Markets, IPR System, Price, Distribution, Business Practices, Way of Communication, Time Management, Language Ability, etc.

So, big collaboration didn't happen before, but I learned...

I learned from my experience in India that we also have similarity in personal character.

We both:

- think that personal connection is sometimes more important than interest
- try to support someone in trouble (expression is different though)

It is, however, not so easy for us to find out such a similarity unless we deeply work together because working culture and way of communication are different.

The real issue was limited mutual understanding caused by the following:

- Lack of Communication and Interaction
- Lack of People who work in their partner country
- Lack of Government Officials & Business Leaders who know both countries

III Review of the Recent Development of the Bilateral Cooperation with my Experience in India

- In 2012, I had a sudden call from personnel division of MHLW. Senior official told me...
- In 2013, I started working for Embassy of Japan in New Delhi as a first Health Attaché.
- What was my mission? No connection with MHFW, CDSCO, Japanese industry and Indian industry
- In January 2014, we visited Dr. A. K. Panda, then JS (drug), MHFW and Dr. G. N. Singh, DCGI.
- In June 2014, [JCCII \(Japanese Chamber of Commerce and Industry in India\) formed Healthcare Group](#).
- In September 2014, [MoC in healthcare \(comprehensive one\) was signed](#) during PM Modi's visit to Tokyo.
- In December 2014, Mr. Nakashima, MHLW (Japan) visited MHFW (India) and had the first meeting with Mr. K. L. Sharma, JS (Drugs), MHFW and Dr. G. N. Singh, DCGI.
- In May 2015, [the first meeting between two regulators](#) for exchanging information was held in India.
- In December 2015, [MoC in medical product regulation](#) was signed during PM Abe's visit to Delhi. Both-sides agreed to continue cooperation including exchanging information, holding symposium, training, etc.
- In May 2016, both regulators hold the [1st India-Japan Medical Product Regulation Symposium](#) at IHC in New Delhi with the presence and support of both industries.
- In July 2016, CDSCO had a meeting with JCCII for the explanation of new regulation for medical devices.
- In September 2016, Indian Delegation including DCGI visited Japan.



We had many meetings in a cooperative manner and industry was involved.

- No industries' support, No patient safety
- Credible Relationship between regulators can also enhance business collaborations.
- So, **Gathering 4 parties (G & B of Japan & India) was imperative.** In fact, 4 parties always supported me.

1st India-Japan Medical Product Regulation Symposium

New Delhi, May 2016

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Bridge gaps between both countries through sharing information and experiences among regulators and industries

IV Message for Officials and Business Leaders

- Both regulators have already been enjoying their good relationships, and actual cooperative projects including capacity building are ready.

Relationship is here.

- Business meetings between industries of both countries also became more active.

More officials and business leaders became familiar with the other country.

I hope ...

- Of course, mutual understanding should be enhanced more and more, but time has past.
- Now is the good timing to step into the actual cooperative projects. We witnessed some achievement in business sectors. We are expecting more outcome of the ambitious projects including exporting Indian product, both APIs & formulation, to Japanese market, introducing Japanese products with medical technic to India and exchanging and training of medical professionals in both way.
- Bring back useful knowledge, information and personal connection with someone who you met today and find a seed of an idea of collaboration.



2nd Japan - India Medical Products Regulation Symposium

Latest trend of pharmaceutical and medical device regulation in Japan

**Dr. Nobumasa Nakashima,
Director for International Regulatory Affairs
Ministry of Health, Labour and Welfare (MHLW)**

April 24th, 2017



Summit and ICMRA 2017 in Kyoto

Japan will host the 12th Summit of Heads of Medicines Regulatory Agencies, ICMRA (International Coalition of Medicines Regulatory Authorities) and “Summit Symposium” in Oct. 23-27 2017 in Kyoto.

Summit of the Heads of Medicines Regulatory Agencies: started in 2006; consists of the heads of 23 regulatory agencies; chaired by a host country; and discusses the future vision of regulation (Regenerative Medical Products, Novel Information Databases, AMR, SSFFC .etc).

ICMRA (International Coalition of Medicines Regulatory Authorities): started in 2012; consists of 22 regulatory agencies; chaired by MHRA (UK) at present; and discusses strategically important areas (Crisis Management, Pharmacovigilance, and Supply Chain Integrity .etc).



“Innovation” will be the key theme through the Summit and ICMRA 2017.

Symposium of the Summit of Heads of Medicines Regulatory Agencies

▶ Date: Oct. 27, 2017 (Fri) *Keep the date!*

▶ Venue: Kyoto International
Conference Center (KICC) – Main
Hall

▶ Hosts: MHLW, PMDA, Kyoto
Prefecture, DIA Japan

▶ Supports: JPMA, JFMDA

▶ Contents:

1. *“For innovative technology and its practical use”*

Speech by: Prof. [Shinya Yamanaka](#), key Regulatory and Industry
Representatives

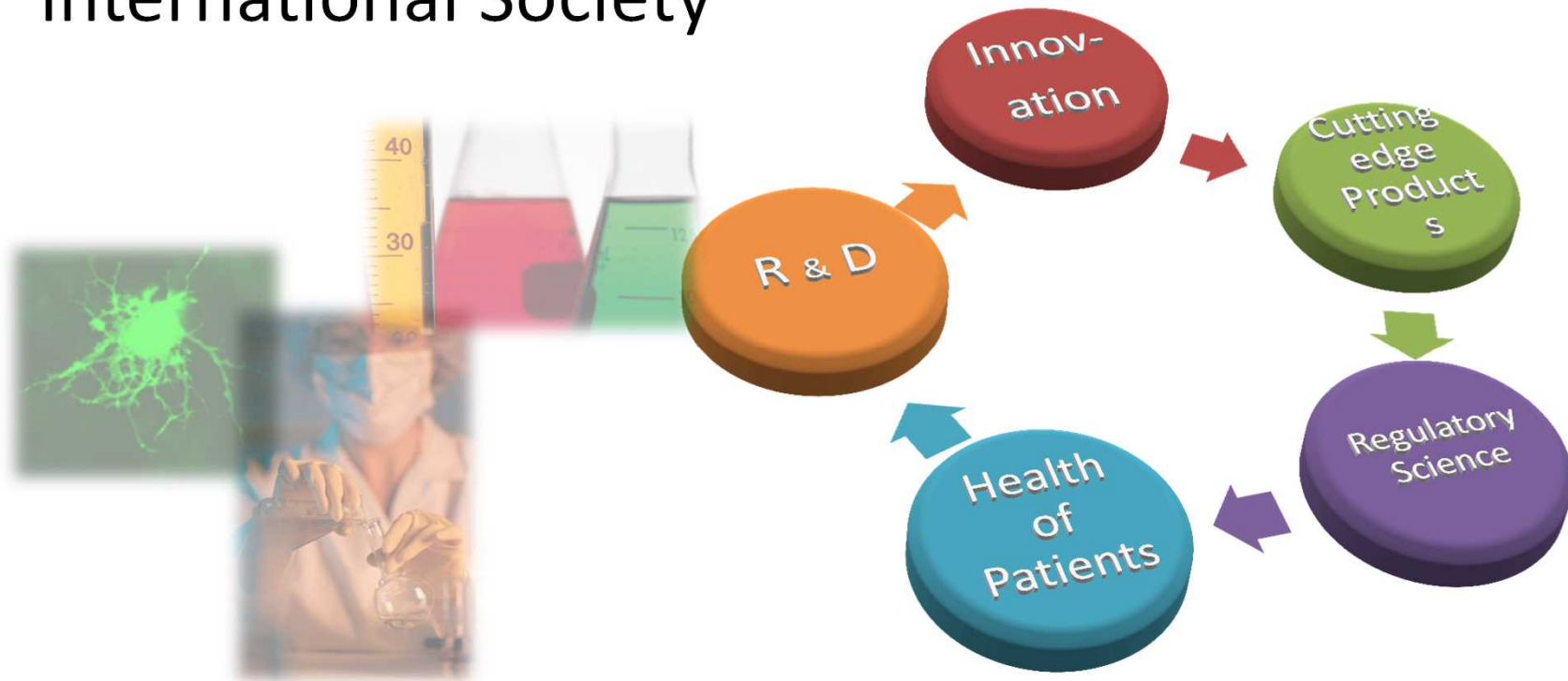
2. *“Actions and challenges by Regulatory Agencies ~From
the results of 12th Summit and ICMRA~”*

Speech and discussion by: [Core members of Summit and ICMRA](#)



Contents

1. Organizational Updates of MHLW/PMDA
2. Regulatory measures to promote innovation
3. Regulatory Cooperation with India and International Society



Regulatory Authorities in JAPAN

MHLW – PSHE Bureau

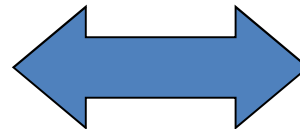
Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health Labour and Welfare

- Final Authorization of applications
- Publishing Guidelines
- Advisory committee
- Supervising PMDA Activities

PMDA

Pharmaceuticals and Medical Devices Agency

- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Consultation on Clinical Trials etc.



Reform of Pharmaceutical Safety and Environmental Health Bureau

Minister of Health, Labour and Welfare

<Pre>

Pharmaceutical and Food Safety Bureau

Department of Food Safety

General Affairs Division

Evaluation and Licensing Division

Medical Device and
Regenerative Medicine
Product Evaluation Division

Safety Division

Compliance and Narcotics Division

Blood and Blood products Division



(1) As of
Oct. 2015

<Post>

Pharmaceutical Safety and
Environmental Health Bureau

Department of Environmental
Health and Food Safety

General Affairs Division

Office of International
Regulatory Affairs

Pharmaceutical Evaluation Division

Medical Device Evaluation Division

Safety Division

Compliance and Narcotics Division

Blood and Blood products Division ⁶

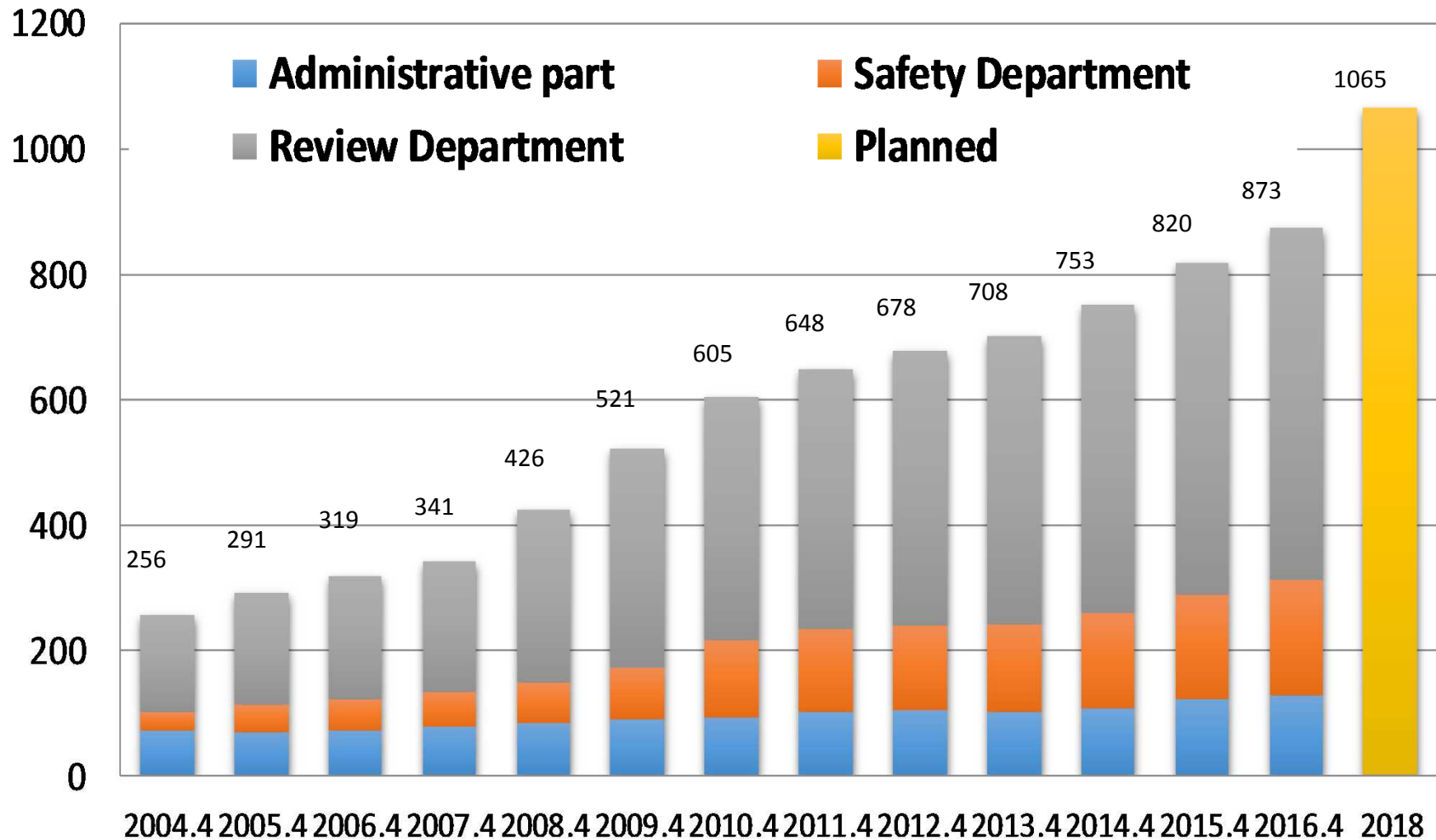


(2) As of
Apr. 2016

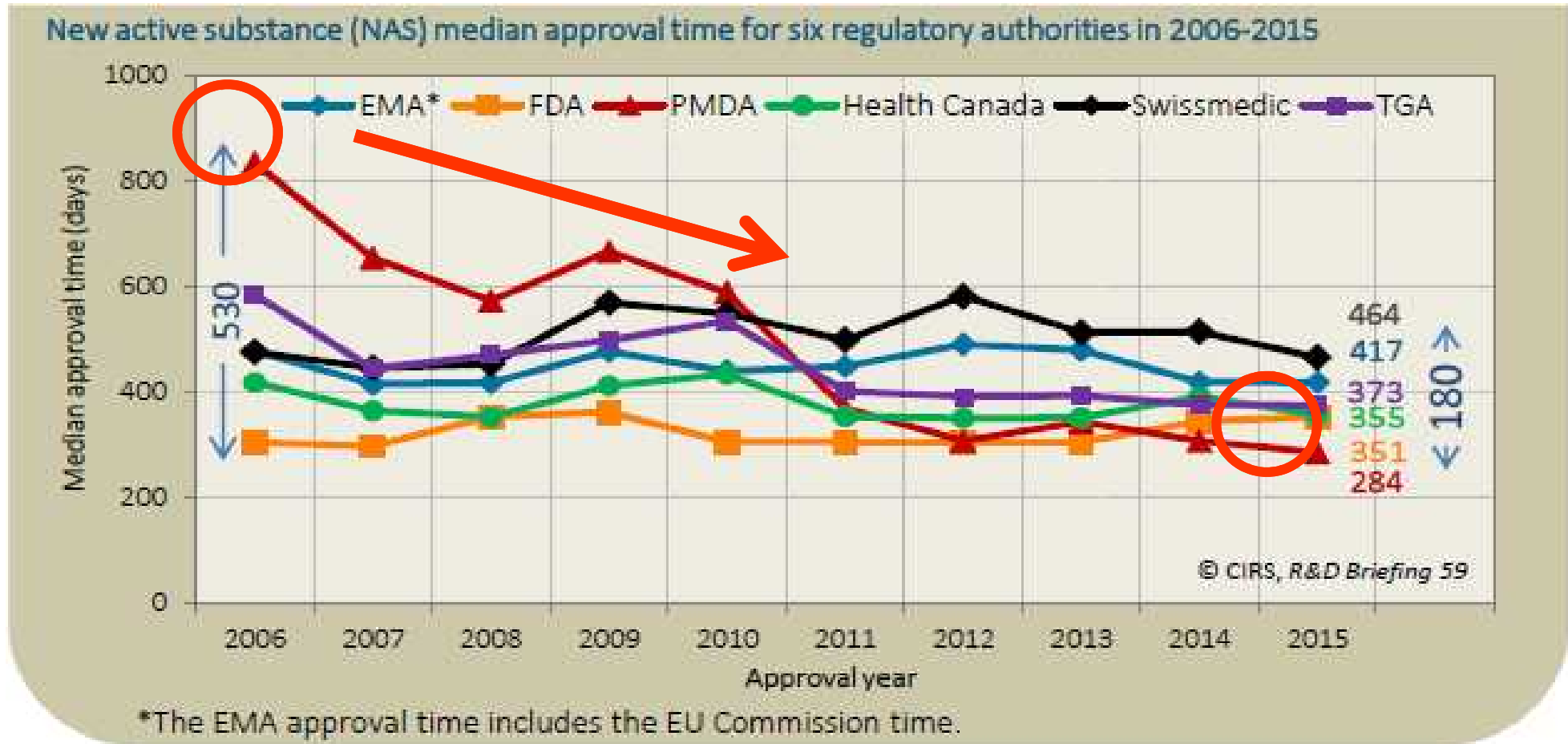


(3) As of
Jun. 2016

PMDA Staff Size



High performance at review speed



http://www.cirsci.org/wp-content/uploads/2016/05/CIRS_RD_-Briefing_59_23052016.pdf

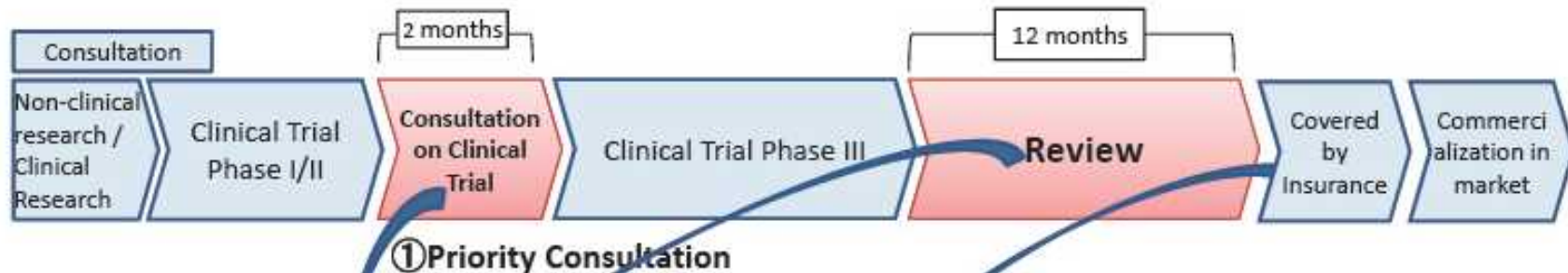
2. Regulatory measures to promote innovation

- ▶ 2nd Round of Sakigake Designation
- ▶ Conditional Early Approval System
- ▶ Projects for the use of Real World Data

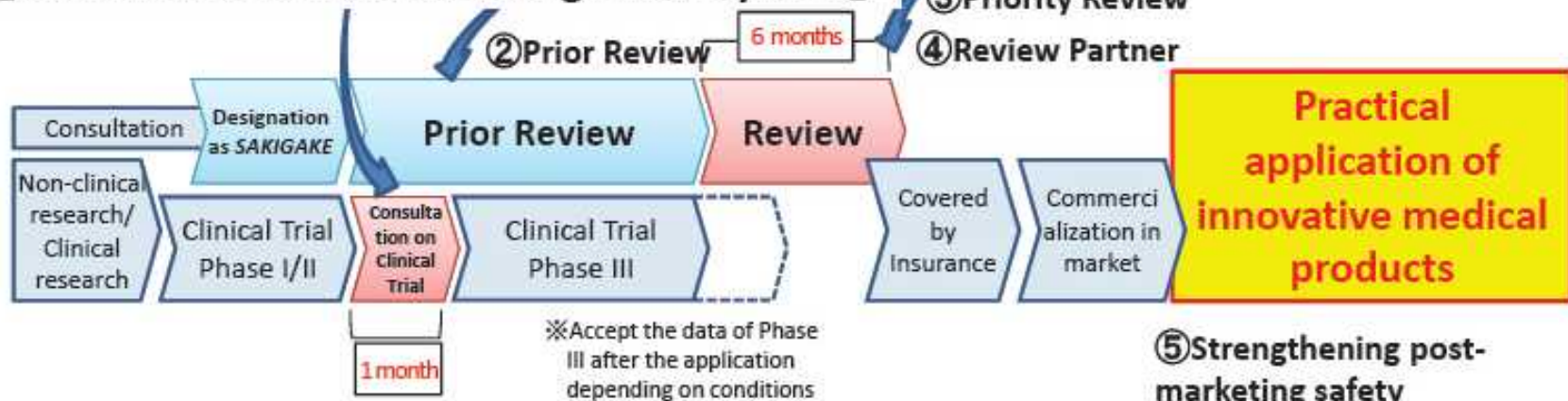


SAKIGAKE Designation – 2nd Round

【Ordinal Review】



【Review under SAKIGAKE Designation System】



Designated in 1st round pilot (Oct. 2015)

6 Pharmaceuticals, 2 Medical Devices, 3 Regenerative Products

Designated in 2nd round pilot (Feb & April. 2017)

5 Pharmaceuticals, 3 Medical Devices, 1 In-Vitro Diagnostic, 3 Regenerative Products

⑤ Strengthening post-marketing safety measures (re-evaluation period)

2nd Round of SAKIGAKE Pharmaceuticals (Apr 2017)

| Name of product | Planned indications | Name of applicant |
|--|---|------------------------------|
| Olipudase Alfa
(Genetical Recombination) | Acid Sphingomyelinase Deficiency | Sanofi KK |
| aducanumab | Suppression of Alzheimer's disease progression | Biogen Japan Ltd. |
| DS-5141b | Duchenne muscular dystrophy (DMD) | Daiichi Sankyo Co., Ltd. |
| SPM-011 ※ | <ul style="list-style-type: none"> - Recurrent malignant glioma - Unresectable locally recurrent head and neck cancer and locally advanced head and neck cancer (non-squamous cell carcinoma) | Stella Pharma Corporation |
| Nivolumab
(Genetical Recombination) | Biliary tract cancer | Ono Pharmaceutical Co., Ltd. |

2nd Round of *SAKIGAKE* Designated Products - Regenerative Medical Products and *In-Vitro* Diagnostic-

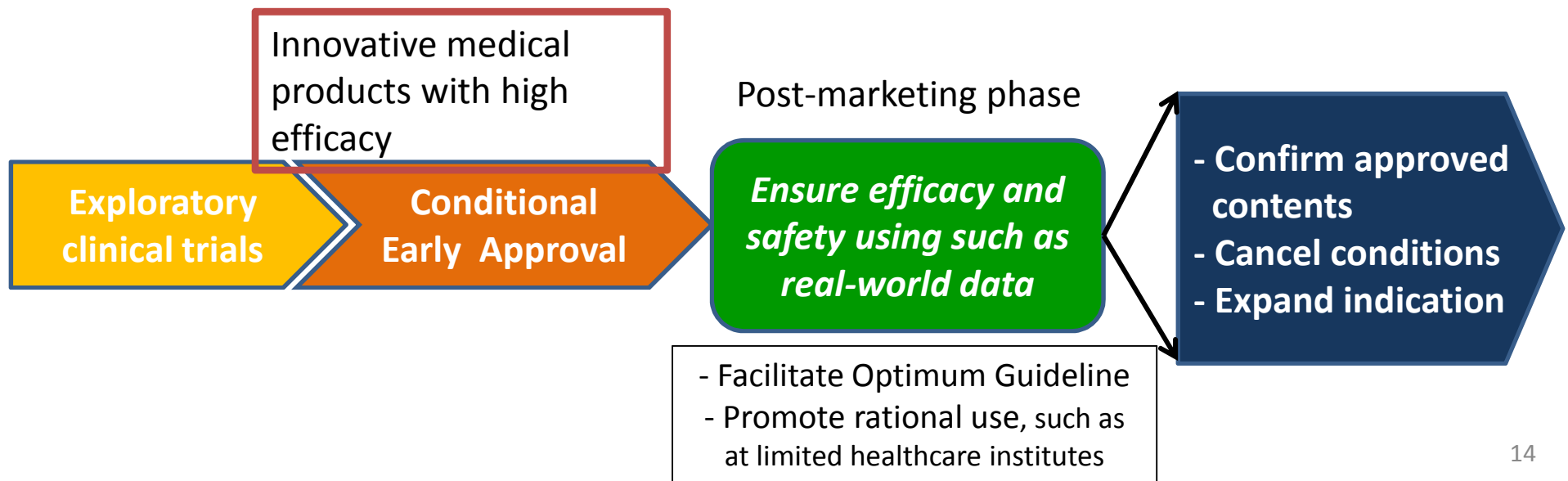
| Name of product | Summary of product | Name of applicant |
|--|--|--|
| <p>CLS2702C/D
(Oral mucosa-derived esophageal cell sheet)</p> | <p>Shorter re-epithelialization period after extensive endoscopic submucosa dissection (ESD) in esophageal cancer.</p> | <p>CellSeed
(Seeds: Tokyo Women's Medical University Hospital)</p> |
| <p>Dopamine neural precursor cell derived from non-autologous iPS cell (Therapeutic stem cell for Parkinson's disease)</p> | <p>Novel therapy by inducing dopamine discharge to mitigate neural symptoms of patients with Parkinson's disease.</p> | <p>Sumitomo Dainippon Pharma Co., Ltd.
(Seeds: Center for iPS Cell Research and Application, Kyoto University)</p> |
| <p>Pluripotent progenitor cell derived from human (allogeneic) adult bone marrow (Stem cell suspension derived from adult marrow)</p> | <p>Novel therapy for improving functional impairment caused by acute brain infarction.</p> | <p>Healios K.K. in Japan
Athersys (US company) outside of Japan</p> |
| <p>Cancer-related gene panel examination system
(Diagnostic system for DNA sequencer)</p> | <p>Collective examination of cancer-related genes to aid decisions on cancer treatment strategies</p> | <p>Sysmex Corporation
(Seeds: National Cancer Center)</p> |

2nd Round of *SAKIGAKE* Designated Products - Medical Devices -

| Name of product | Summary of product | Name of applicant |
|---|---|---|
| <p>Artificial tracheal
(made of polypropylene mesh and collagen sponge)</p> | <p>Aiding reconstruction of tracheal while maintaining intratracheal structure after partial removal.</p> | <p>Daiichi Medical
(Seeds: Kyoto University, etc.)</p> |
| <p>Boron neutron capture therapy (BNCT) system
(Neutron irradiation system for BNCT)</p> | <p>Selective destruction of tumor cells marked by boron agents, without damaging normal cells.</p> | <p>Stella Pharma Corporation
Sumitomo Heavy Industries, Ltd.
(Seeds: Kyoto University, etc.)</p> |
| <p>UT-Heart
(Software program to aid prediction of effectiveness of cardiac resynchronization therapy)</p> | <p>Higher accuracy of prediction of effectiveness of cardiac resynchronization therapy for patients with serious heart failure.</p> | <p>Fujifilm Corporation
UT-Heart Inc.
(A venture company by The University of Tokyo)</p> |

Conditional Early Approval System (for pharmaceuticals)

- Efficacy and safety will be ensured by using the rational and scientific post-marketing data (including the Real-World Data[※]). Regulations will be modified to confirm the approved content and expand indications.
- [※] Real-world data includes MID-NET and registry data of Clinical Innovation Network.
- Promote “Optimal use Guideline” based on regulatory science as well.
- Details of “Conditional Early Approval” will be finalized by summer of 2017.



Accelerated approval Scheme for Innovative Medical Devices (Draft)

“There are cases where innovative MDs created by medical venture enterprises are expected to have extremely effective and safe profile, however, these MDs target extremely few patients. In such cases, the development might be stagnated because of difficulties in collecting patients for clinical trial.

Considering such a situation and our mission to introduce innovative MDs to the public, **the government should construct the scheme which accelerate the approval of the innovative MDs by minimising the burden regarding clinical trials and enhancing the post-market surveillance.**”

From the Report by Conference for promotion of Venture companies driving clinical innovations (July 2016)

Subjects to be solves

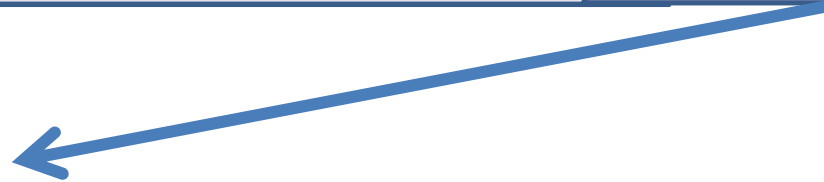
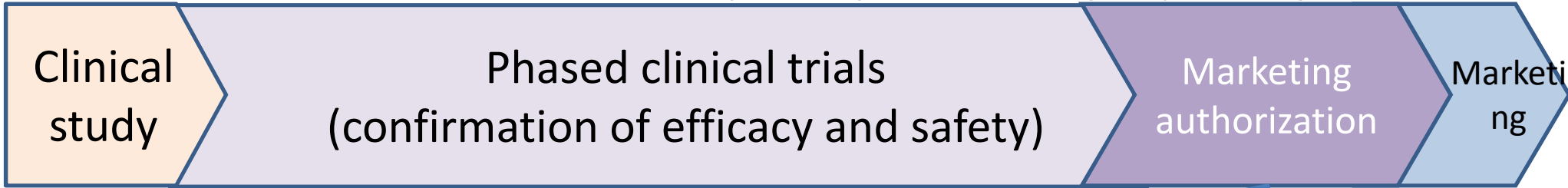
- The scope of the scheme
- The way of **pre-market review with limited number of clinical cases**, overseas data and literature
- **Post-market safety monitoring system** which enables accelerated approval ...etc.

Expedited approval system under PMD Act

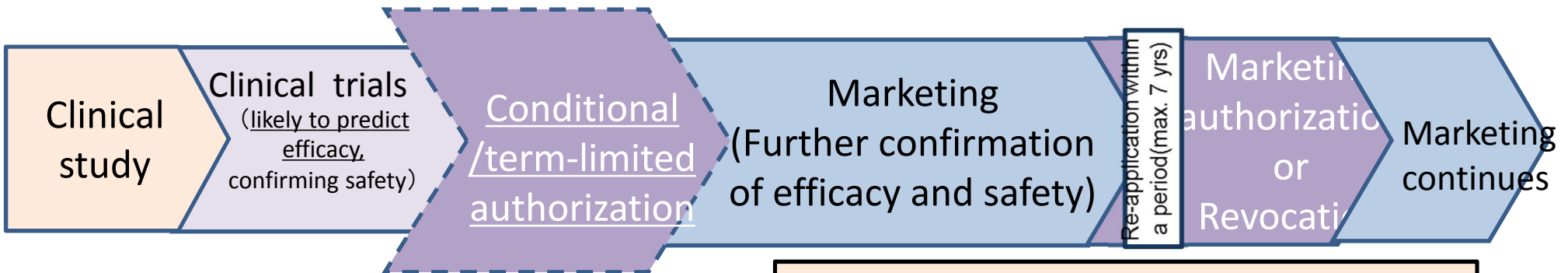
< Drawback of traditional PAL approval system >

Long-term data collection and evaluation in clinical trials, due to the characteristics of cellular/tissue-based products, **such as non-uniform quality** reflecting individual heterogeneity of autologous donor patients

[Traditional approval process]



[New scheme for regenerative medical products]



Post-marketing safety measures must be taken, including prior informed consent of risk to patients

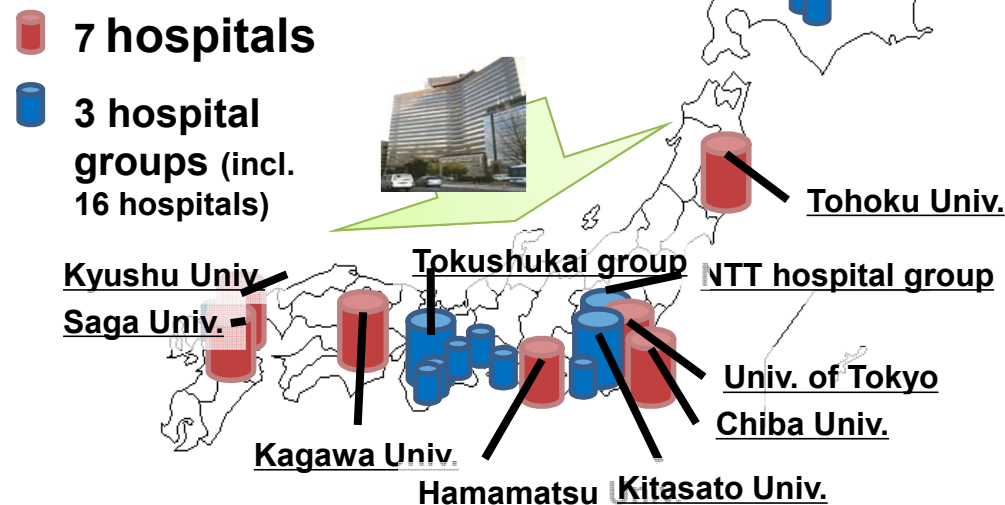
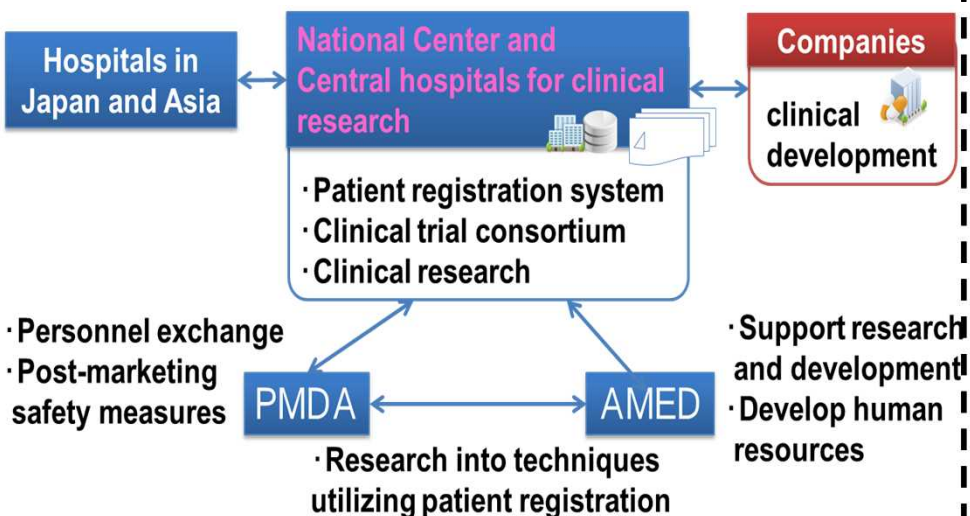
On-going projects for the use of Real World Data

Clinical Innovation Network (CIN)

is an infrastructure to support conducts of efficient clinical trials using patient's registered information.

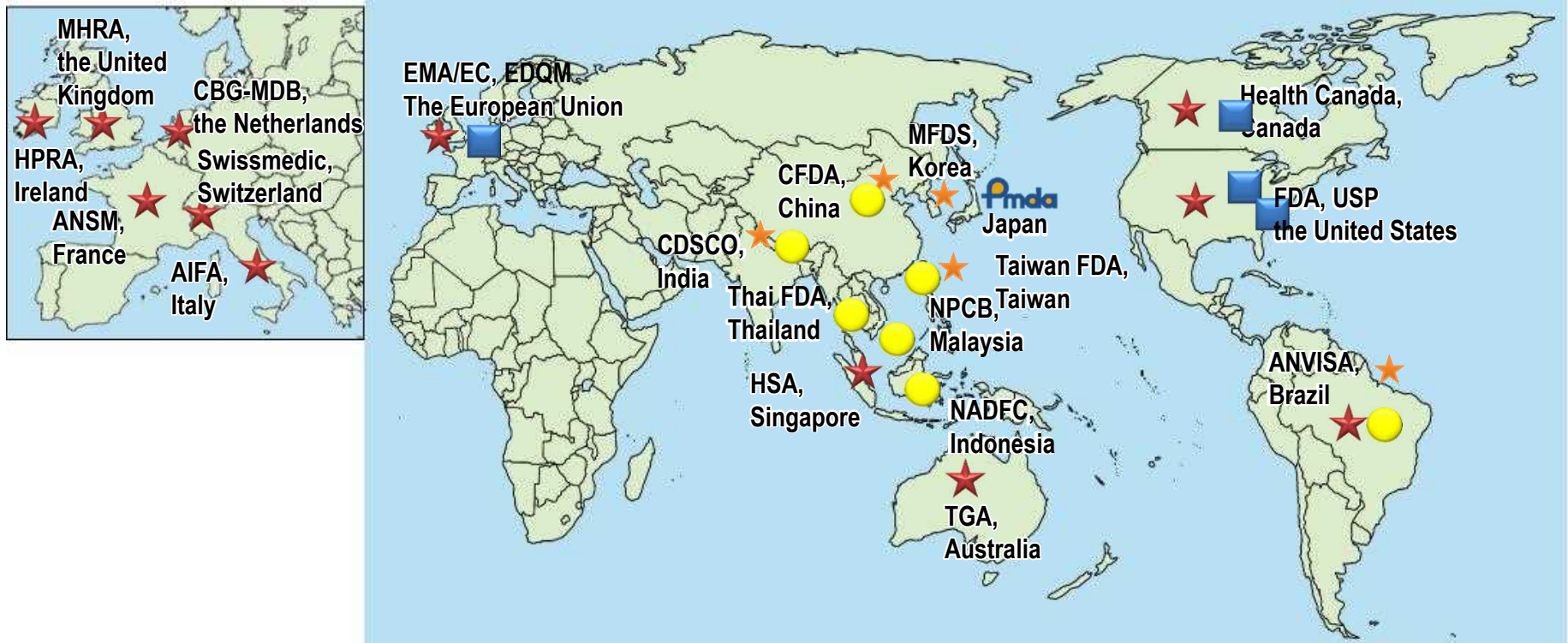
MID-NET (Medical Information Database Network)

is a project to establish the DB network for MIHARI Project to utilize electronic healthcare data for drug safety.




3. Regulatory Cooperation with India and International Society

- ▶ 7th International Meeting of World Pharmacopoeias
- ▶ ICH (International Council for Harmonization)
- ▶ PMDA Asia Training Center



Global Activities

| | | | | | |
|-------------------|------|-------|-------|-------|---|
| Summit | ICH | IMDRF | PIC/S | HBD | ICDRA |
| APEC LSIF
RHSC | OECD | PDG | IDGRP | ICMRA |  |

And so on

| Abbreviation | Official Name |
|-------------------|--|
| Summit | International Summit of Heads of Medicines Regulatory Agencies |
| ICH | International Conference on Harmonization |
| IMDRF | International Medical Device Regulators Forum |
| PIC/S | Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme |
| HBD | Harmonization By Doing |
| ICDRA | International Conference of Drug Regulatory Authorities |
| APEC LSIF
RHSC | APEC Life Science Innovation Forum Regulatory Harmonization Steering Committee |
| OECD MAD | OECD Mutual Acceptance of Data |
| PDG | Pharmacopoeial Discussion Group |
| IGDRP | International Generic Drug Regulators Pilot |
| ICMRA | International Coalition of Medicines Regulatory Authorities |

7th International Meeting of World Pharmacopoeias (Sep 2016, Tokyo)



Good Pharmacopoeial Practices

ICH and its Reform

About ICH *International Council for Harmonization

- International harmonization project of technical requirements involving the Regulators and research-based Industries
- Accomplished through the development and implementation of harmonized Guidelines

ICH Reform (Oct. 2015)

- MHLW/PMDA is one of the founding regulatory members
- **New membership application is now open for regulators and industries in global society**
- Guidelines development will be further activated

Recent Progress of ICH

- **Participation of New Regulatory Members** (in Nov. 2016)
 - ANVISA (Agência Nacional de Vigilância Sanitária, Brazil)
 - MFDS (Ministry of Food and Drug Safety, Korea)
- **Progress in ICH Guideline Development**
 - **E17** (Multi-Regional Clinical Trials): Step 2 in 2016 and Step 4 envisaged in Nov. 2017
 - **M10** (Bioanalytical Method Validation): One of the two Expert WGs established in 2016 with the rapporteur from MHLW/PMDA
- **GCP Renovation** (led by FDA)
 - Comprehensive review of clinical trial design and GCP related guidelines to incorporate the use of Real World Data in the regulation

Membership in the Assembly— Eligibility Criteria for Regulators

Engagement in the ICH Process

- Past regular attendance in ICH meetings
- Past appointment of experts in WGs

Application of ICH Guidelines

- Have implemented at least the following ICH Guidelines (“Tier 1”):
 - Q1: Stability Testing Guidelines
 - Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
 - E6: Good Clinical Practice Guideline



See <http://www.ich.org/products/guidelines.html> for details

規制当局メンバーによるICHガイドラインの実施 (implementation)

| Tier(層) | ICHガイドライン | 実施に関するルール |
|---------|---|---|
| 1 | Q1(安定性試験)
Q7(GMP)
E6(GCP) | ・メンバー参加の条件として、実施 |
| 2 | E2A(治験中の安全性情報)
E2B(個別症例安全性報告のデータ)
E2D(承認後の安全性情報)
M4(CTD)
M1(MedDRA) | ・メンバー参加後に、優先して実施
・5年以内に実施を完了させるための計画書を提出
・管理委員会メンバーになるための推奨要件 |
| 3 | 上記以外の全てのガイドライン | ・メンバー参加後に、できるだけ早期に実施 |

Ref: Articles of Association Article 11, Assembly Rules of Procedure 1.1.3

MHLW/PMDA assigns the largest number of Rapporteurs for WGs

(EWG/IWGs active on Mar. 2017)

“Rapporteur” is the expert who leads the scientific discussion and Guideline development in each ICH Working Group.

| Member | WG with its Rapporteur | |
|------------------|---|----------|
| MHLW/PMDA | E2B, E11, E17, M2*, M8, M10, S3A | 7 |
| FDA | E18, S9, Q3C, Q3D, M2*, M7 | 6 |
| EC/EMA | S5, E9, M2*, M9, Q11 | 5 |
| JPMA | | 0 |
| PhRMA | Q12, S1, S11, E14/S7B | 4 |
| EFPIA | M1 | 1 |
| Health Canada | | 0 |
| Swissmedic | | 0 |
| Total | | 23 |

* “Co-Rapporteurs” are nominated for M2 WG.

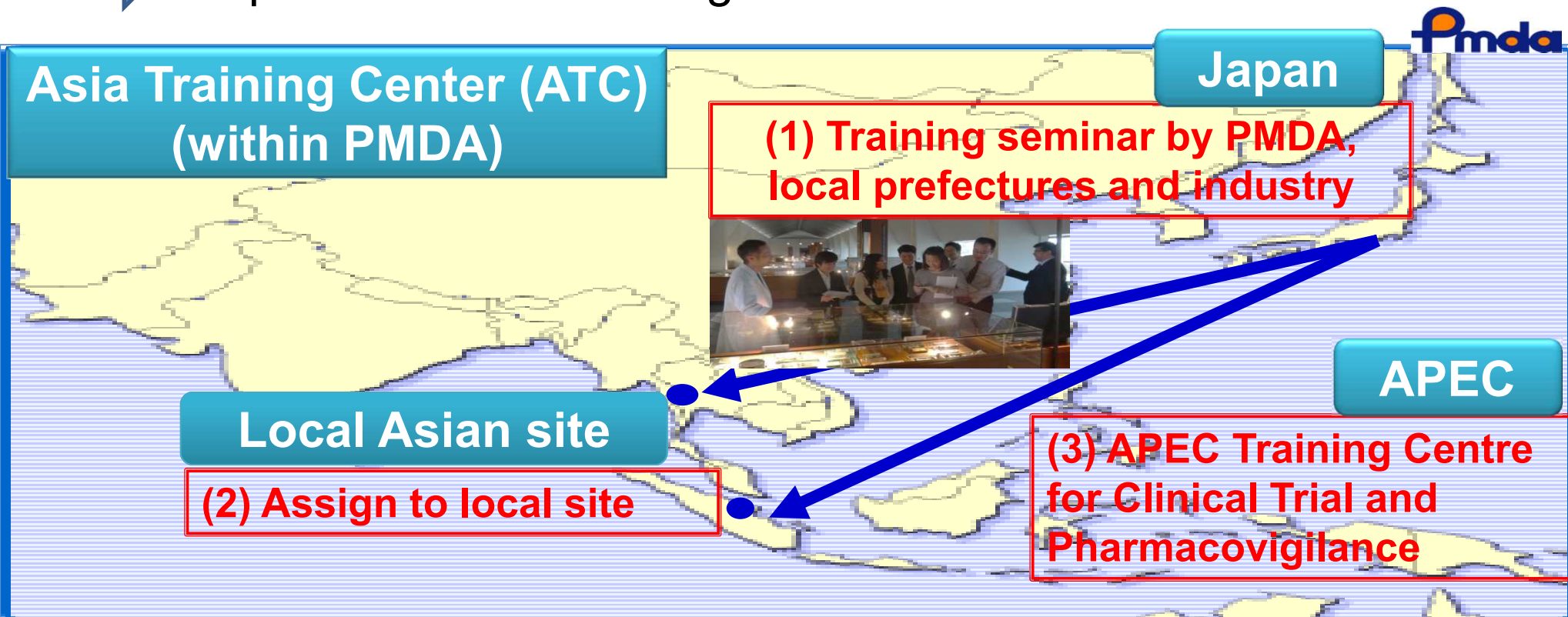
Recent updates of IGDRP

- Created in 2011 to promote collaboration and convergence of generic drug regulators
- Recently the number of participating agencies and organization has steadily increased to 17:
- Main projects are:
 - Quality Working Group
 - Bioequivalence Working Group
 - Information and Work Sharing projects

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (Est. April 2016)

- Plan, design and coordinate training for Asian regulatory authority staff
- Provide training opportunities including on-site training

➔ Help raise the level of regulations in Asia as a whole.



ATC Completed Trainings: FY2016 (April 2016 – March 2017)

| No. | Contents | Date | Location | Number of participants |
|-----|-------------------------------|------------------|--------------------------------|---|
| 1 | Pharmaceuticals Review | July 25-29, 2016 | Tokyo (PMDA) | 13 participants from 7 economies |
| 2 | Pharmaceuticals Review | Sep. 26-29, 2016 | Bangkok | 13 participants from Thailand and Hong Kong |
| 3 | Medical Devices | Nov. 7-11, 2016 | Tokyo (PMDA) | 28 participants from 13 economies |
| 4 | Good Registration Management | Nov. 15-17, 2016 | Taipei | 28 participants from 10 economies |
| 5 | Good Manufacturing Practice | Dec. 5-9, 2016 | Toyama City, Toyama Prefecture | 19 participants from 12 economies |
| 6 | Multi-Regional Clinical Trial | Jan. 23-26, 2017 | Tokyo (PMDA) | 32 participants from 14 economies |
| 7 | Pharmacovigilance | Feb. 6-9, 2017 | Tokyo (PMDA) | 28 participants from 15 economies |

In total 161 Regulators from 27 countries/regions participated.

ATC Planned Trainings: FY2017 (April 2017 – March 2018)

| No. | Contents | Date | Location |
|-----|--------------------------------------|------------------|-----------------------------------|
| 1 | Risk Management Plan (RMP) | May, 2017 (TBD) | Jakarta |
| 2 | Pharmaceuticals Review | June 26-30, 2017 | Tokyo (PMDA) |
| 3 | Good Manufacturing Practice (GMP) | July, 2017 (TBD) | Hikari City, Yamaguchi Prefecture |
| 4 | Anti-infective Drugs | Oct., 2017 (TBD) | Vietnam (TBD) |
| 5 | Medical Devices | Nov., 2017 (TBD) | Tokyo (PMDA) |
| 6 | Good Registration Management (GRM) | Nov., 2017 (TBD) | Taipei |
| 7 | Pharmaceuticals Review | Dec., 2017 (TBD) | Bangkok |
| 8 | Multi-Regional Clinical Trial (MRCT) | Jan., 2018 (TBD) | Tokyo (PMDA) |
| 9 | Pharmacovigilance | Feb., 2018 (TBD) | Tokyo (PMDA) |

All the players in good harmony



Thank you for your attention.
See you again in Kyoto!

Latest trend of Pharmaceutical regulation in India

Dr. G. N.
Singh
DCGI

The Central Drugs Standard Control Organization (CDSCO) is the National Regulatory Authority (NRA) of India for ensuring safe, efficacious and of high quality medical products, imported, manufactured & marketed in India.

The NRA is empowered through the Drugs and Cosmetics Act, 1940 to regulate the import, manufacture, distribution and sale of drugs [and Cosmetics]

As per Constitution of India, this Act is under Concurrent List, i.e., the Federal and State enforcement agencies are responsible for its enforcement.

Functions of CDSCO

Approval of new drugs and clinical trials

Import Registration and Licensing

Licensing of Blood Banks, LVPs, Vaccines, r-DNA products & some Medical Devices

Amendment to D &C Act and Rules

Banning of drugs and cosmetics

Grant of Test License, Personal License, NOCs for Export

Testing of Drugs

Functions of State Authorities

Licensing of Manufacturing Site for Drugs including API and Finished Formulation

Licensing of Establishment for sale or distribution of Drugs

Approval of Drug Testing Laboratories

Monitoring of Quality of Drugs and Cosmetics marketed in the country

Investigation and prosecution in respect of contravention of legal provision

Recall of sub-standard drugs

The Ministry of H & FW has taken various steps in last two and half years to bring ease of drug regulation in India.

- **Risk Based Inspection**
- **Patient safety and compliance**
- **Quality Management System**
- **IT enabled services**
- **Medical Device Rules 2017**
- **Capacity Building & Skill Development**

- **Observer of ICH**
- **Cooperation with regulatory authorities**
 - **PMDA (Japan)**
 - **USFDA (USA)**
 - **MHRA (UK)**
 - **ANVISA (Brazil)**
 - **MCA (Sweden)**
 - **WHO (Geneva)**

Indian NRA is on pathways for bringing ease in drug regulatory functions to foster Drug Discovery and Research through partnership.



Thank you

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