Current International Cooperation and Strategies

Feb. 8th, 2014

MINISTRY OF
FOOD AND DRUG SAFETY

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❖ Introduction – Launching MFDS

MINISTRY OF FOOD AND DRUG SAFETY

The government's foremost priority: citizen safety

- Launching the Ministry of Food and Drug Safety to have it function as a control tower for safety management of food and drugs
  - ➢ Reflecting the President's government philosophy to ensure the well-being of the nation
- The effort's of the incumbent government to eliminate substandard food products and provide safe food

"I will certainly root out the four major social ills, which are sexual violence, school violence, home-wrecking crimes and substandard food, and will make a nation where law becomes a shield for the socially weak"(Yonhap news agency, Mar. 14, 2013)

❖ Introduction – Drug Safety Mgt.

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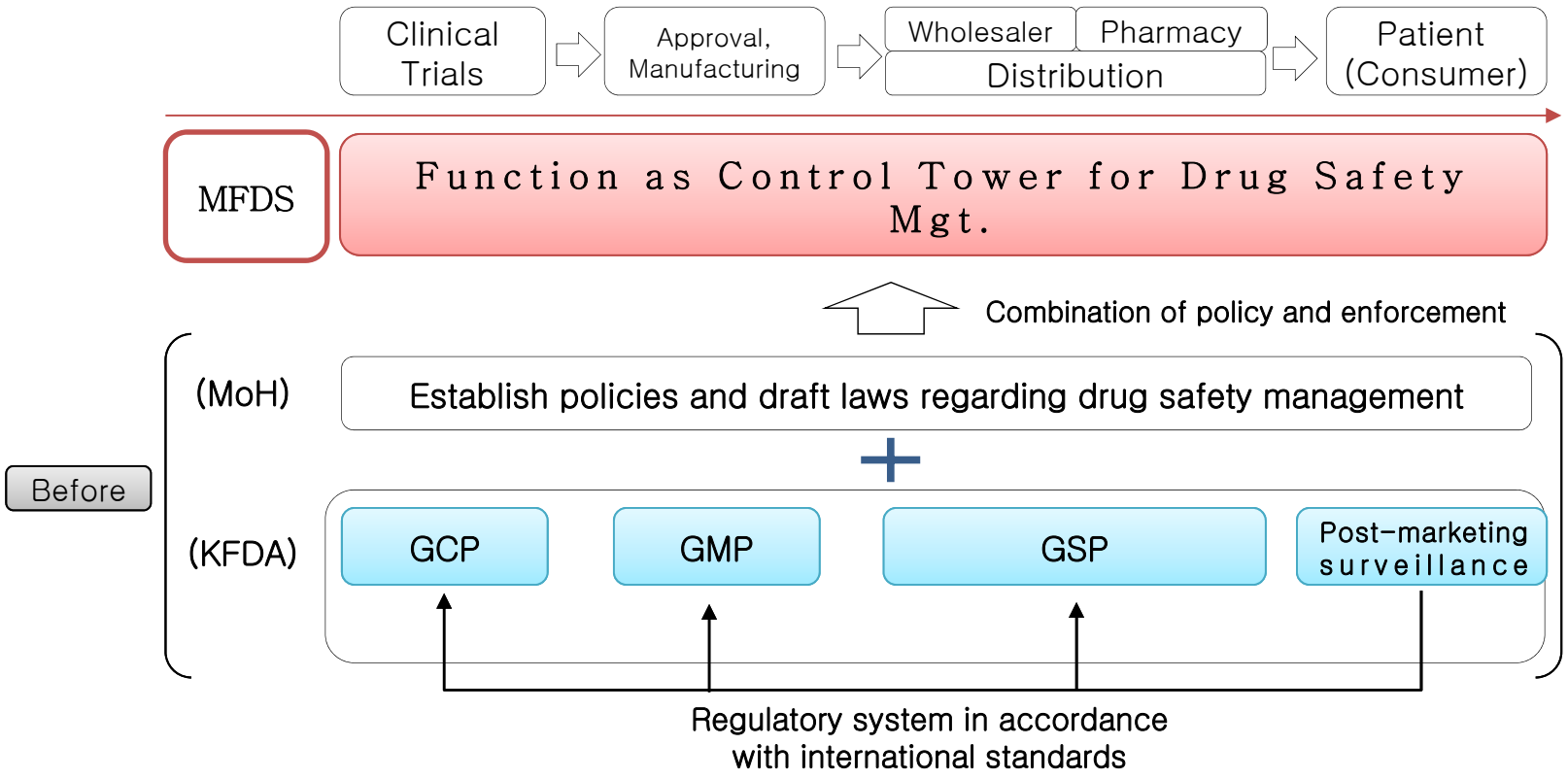
- **Functions as the "Control Tower" of drug safety management by combining enforcement matters regarding clinical trials, drug approval · manufacturing, distribution, post-marketing surveillance etc. with related policy matters such as legislation and system improvement**



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Vision

Safe Food and Drugs, Healthy Nation, Well-being of Society

Purpose

1. Ensuring safety of the people to improve quality of life
2. Consumer-based safety management from Farm to Table
3. Realization of safer and healthier lives of the people
4. Beyond safety, providing assurance to the people

Core Strategies of '14

- Assure food safety from production to consumption
- Guarantee safe and healthy diet for society
- Safety management for medical products · cosmetics
- Enhance capacity through prompt approval and regulatory harmonization
- Develop food and drug R&D projects based on regulatory science

MINISTRY OF FOOD AND DRUG SAFETY

❖ Current International Cooperation and Strategies

1 Why International Cooperation?

2 Current Status of Int'l Cooperation

3 Reflecting on Int'l Cooperation

4 Future Strategies of Int'l Cooperation

5 Cooperation with Japan

Why International Cooperation?

Globalization of Safety Issues

- **Increase in medical product trade with globalization and Free Trade Agreements**
- **Safety issues without borders** ex) heparin contamination

Climate Changes, Increase in Risk factors

- **Climate sensitive diseases spreading with global warming**
- **Discovery of new risk factors caused by climate change**
  * Avian influenza infecting humans, asthma due to increase of allergens in air

Develop New Cutting-edge Technology

- **New cutting-edge technologies present opportunities and challenges to development of new drugs**
- **Collaborative efforts needed to develop regulatory science necessary to evaluate new technology**

Contribution to Global Society

- **First recipient country to become a donor country**
  * Joined OECD Development Assistance Committee (2010)
- **Increased recognition of the need to contribute to global society**

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Multilateral Cooperation

Project Name			Description
1) Official Development Assistance		☞	Providing training for regulators of developing nations
2) WHO	Collaborating Center	☞	Involved in developing vaccine guidelines and providing foreign regulators with training
	Technical Service Agreement	☞	Contract testing lab for vaccines
	Global Learning Opportunity	☞	WHO contracted GMP training for foreign regulators
3) APEC	Regulatory Harmonization Steering Committee	☞	Champion nation of pharmacovigilance, biologics roadmap
	APEC Harmonization Center	☞	Providing training program for APEC regulatory harmonization
4) Int'l Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use		☞	Approval and review guideline development
5) Int'l Pharmaceutical Regulators Forum		☞	Chair of Workgroup for Biosimilar regulatory harmonization
6) Korea China Japan DG level meetings for drugs		☞	Research collaboration on ethnic factors in clinical trials, exchange information
7) Global cooperation for drugs		☞	MOUs with China · Singapore · Indonesia· Germany etc. CAs with Switzerland · France· UK · Denmark · Uganda

Current Status of Int'l Cooperation

1 Providing pharmaceutical affairs ODA

「Pharmaceutical Regulatory Affairs」 training ('12~)

- MFDS' experience sharing in drug safety management to strengthen regulatory capacity of developing countries
  - (General training) Overall course in drug safety management ('12~, 36 regulators from 16 Asian · African countries)
  - (Intensive training) Pharmacovigilance , GMP training ('13~'15, 18 regulators from Vietnam, Philippines, Indonesia, Cambodia)

< Korea's Official Development Assistance > (unit in US dollars)

* Total aid 15.5 million ('12) (Bilateral 11.6 million, Multilateral: 3.89 million)
  - Transportation 17.9%, Education 17.5%, Health 10.4%, Hygiene 10.2%, Public admin. 7.7% etc
  - Asia 54.8%, Africa 22.4%, Central · South America 6.5%, Middle East 3.6% etc

Current Status of Int'l Cooperation

2 Collaborating with WHO

Designated as 5th WHO Collaborating Center for Biological Standardization ('11)

- Involved in developing WHO Guidelines on vaccine stability, adventitious agent etc.
- Provided foreign regulatory authorities with Vaccine Hands-on Training('12~)

Technical Service Agreement with WHO

- Conducts quality testing for vaccines procured by UN (ex Japanese encephalitis vaccines)

WHO Global Learning Opportunity

- Provided GMP training for 77 GMP inspectors from 19 countries ('07~) (Philippines, Thailand, Iran, Turkey etc)

Current Status of Int'l Cooperation

3 Asia-Pacific Economic Cooperation

Proposed at APEC Summit('08.11)/ Established APEC Harmonization Center ('09.6)

- Conduct capacity building training for APEC economy regulators
- 17 international workshops about multi-regional clinical trials, pharmacovigilance, biotherapeutics etc

APEC Regulatory Harmonization Steering Committee

- Designated as champion of pharmacovigilance, biotherapeutics for Strategic Framework Regulatory Convergence for Medical Products by 2020

Current Status of Int'l Cooperation

4 International Conference on Harmonization

Participating in EWG, IWG to develop ICH guidelines

- **Elemental Impurities(Q3D), Good Manufacturing Practice for API (Q7A), Rodent Carcinogenicity Studies(S1), Genotoxic Impurities(M7)**

Participating in IPRF (International Pharmaceutical Regulators Forum)

* Separated from ICH Regulator's Forum('13.6)

- **Participating in regulatory harmonization working group and information exchange network**
  - **Chair of Workgroup for Biosimilar regulatory harmonization**

Current Status of Int'l Cooperation

5 Cooperation with other regulatory authorities

Arrangements with other regulatory authorities

- MOUs to promote mutual understanding and cooperation
  - China SFDA, Singapore HSA, Indonesia NADFC, Germany PEI, Poland URPLWMiPB
- Confidentiality agreements to exchange information on approval, inspections etc. and personnel dispatch
  - United Kingdom, Denmark, France, Germany, Uganda

Korea-Japan-China cooperation for pharmaceuticals

- Cooperation to foster drug development, promote multi-regional clinical trials etc.

Participating in International Coalition of Medicine Regulatory Authorities(ICMRA), Global Coalition for Regulatory Science Research(GCRSR)

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Reflecting on Int'l Cooperation

Bridge between developing countries and developed countries for regulatory harmonization

- Share MFDS's experience and spread regulatory science technology
- Strengthen cooperation with geographically close countries, increase participation in international initiatives

Establish int'l cooperation network to deal with global issues

- Establish int'l cooperation network for drug safety issues
- Promote more confidentiality agreements that enable close cooperation with other authorities

Increase contribution and roles played in global society

- Further engage in official development assistance
- Actively support international cooperative projects

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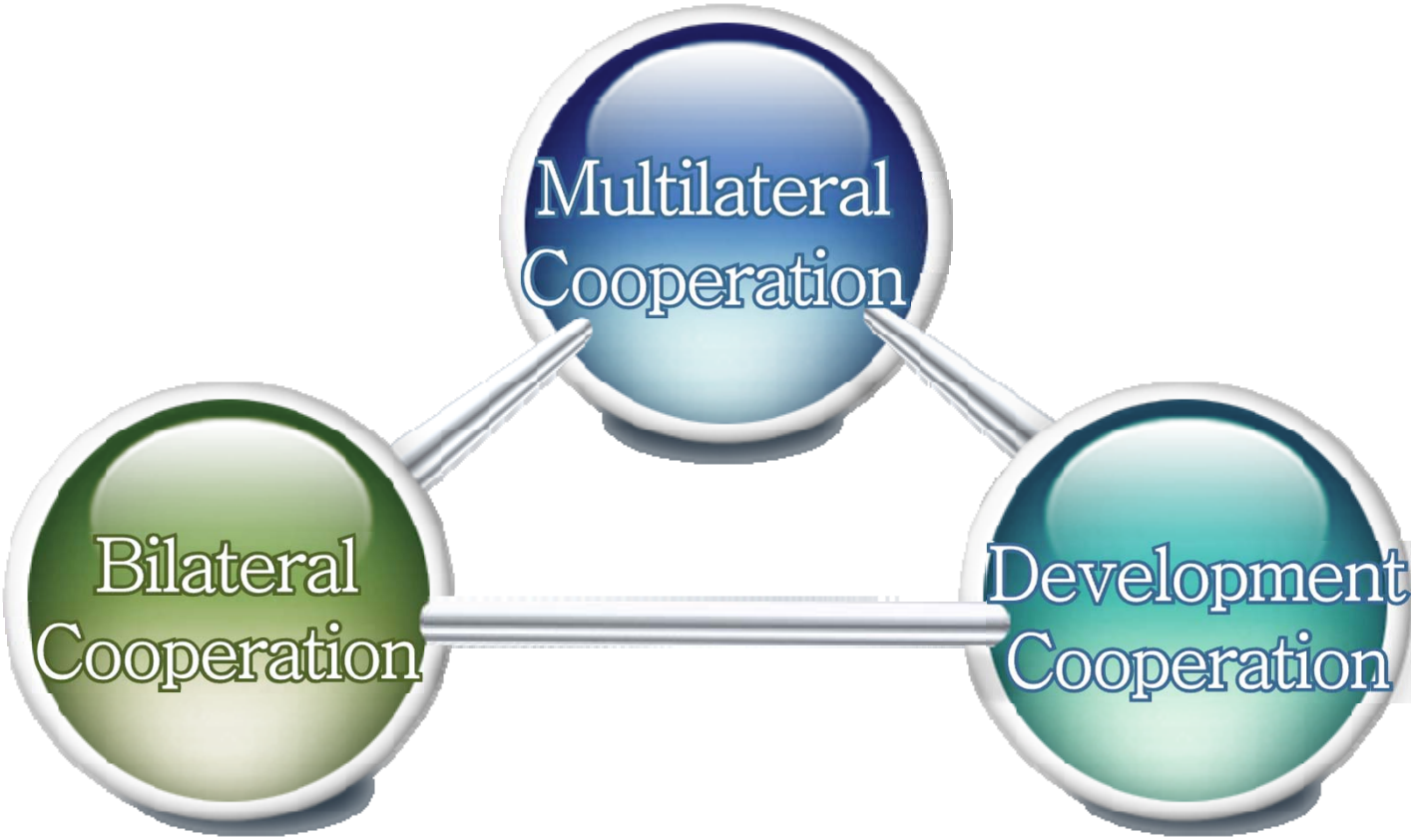
Future Strategies



Future Strategies

1 Further cooperation with int'l initiatives

Increase regulatory cooperation with int'l organization

- Actively participate in WHO's capacity building projects for regulators in developing countries
- Strengthen cooperation with APEC, ICH, and other initiatives through APEC Harmonization Center(AHC)

Strengthen GMP collaboration by joining PIC/S

Research collaboration on regulatory science, exchange of staff

- Joint-research on safety, efficacy, quality control for new therapeutics
- International workshops to strengthen capacity of reviewers
- Cell and Gene Therapeutics reviewer dispatch to US FDA CBER('14.2)

Future Strategies

2 Strengthen G2G* collaboration

* G2G : Government to Government

Establish system for information exchange and work sharing through ICMRA

- MFDS is participating in ‘generic drug initiative’, ‘GMP inspection’, ‘mapping of current int’l cooperation projects’ working groups during ICMRA pilot period

Promote MOUs through bilateral cooperation

- Increase regular meetings, exchanging confidential information, build deeper collaboration for work sharing
  - (MOU) Japan, Ecuador (‘14), (CA) Italy, United States (‘14)
- Increase officer dispatch to overseas Korean embassies to strengthen cooperation between governments
  - United States, China → Japan, Vietnam (‘14)

Future Strategies

3 Increase int'l development cooperation

More development cooperation projects in pharmaceutical affairs

- (Development Experience) pharmaceutical technology development support, improving competitiveness of pharmaceutical industry, capacity strengthening for regulators etc
- (Regulatory Technology) support development of SSFFC monitoring systems, essential medicine supply systems, safety information management systems, pharm IT technologies etc

Increase training support for regulatory authorities

- Increase the number of participants for "the pharmaceutical regulatory affairs management" training program
- Host on-site pharmaceutical regulatory affairs policy workshops

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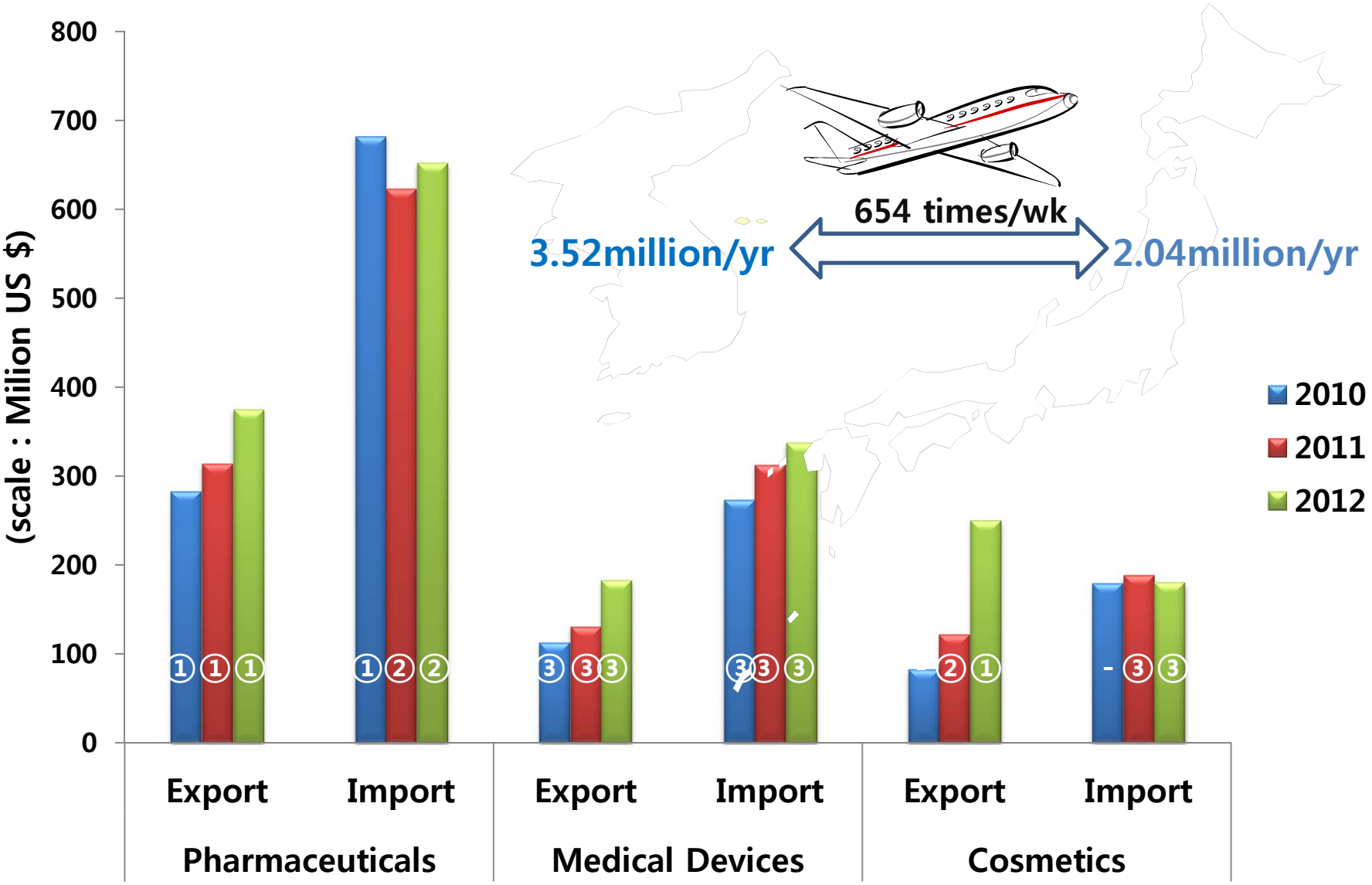
Exchange Between Korea-Japan



Main Cooperation Activities

- **Annual joint-seminar hosted by pharmaceutical manufacturers associations of both nations ('04~)**
  - Establish cooperation network between pharmaceutical industries and improve understanding of both nation's regulations
- **Korea-Japan-China DG meetings for pharmaceuticals ('08~)**
  - Promote new drug development and cooperation in clinical trials
- **Send MFDS officials to PMDA for training ('10.11,'11.11)**
  - Promote understanding of both nation's regulations through exchange of MFDS reviewers
- **Korea-Japan biosimilar review workshop ('12.11)**
  - Lay foundation for sharing biosimilar review information

Future Cooperation

- **Sign MOU for regular meetings to discuss work cooperation**
  - Develop the current relationship which restrictively deals with issues at hand – establish system to contribute to long term cooperation between KOR-JPN
- **Establish administrative basis upon which actual cooperation outcomes may be achieved**
  - Establish legislative basis for regulatory information exchange in order to engage in personnel exchange, mutual collaboration in regulatory affairs
- **Developing bilateral cooperation into regional, global cooperation**
  - Promote and develop collaborative activities and share future vision for the progress of regulatory capacity of KOR-JPN-CHN, Asian Pacific region etc

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Thank you