Asian cooperation and Initiatives of PMDA

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Outline

1. What is the importance of China-Japan Cooperation ?

2. PMDA initiatives on Global clinical trials

3. Future directions of PMDA
   - Improvement of “Regulatory Science”
   - Building of collaborative relations among International community

4. Conclusion

1. What is the importance of China-Japan Cooperation ?

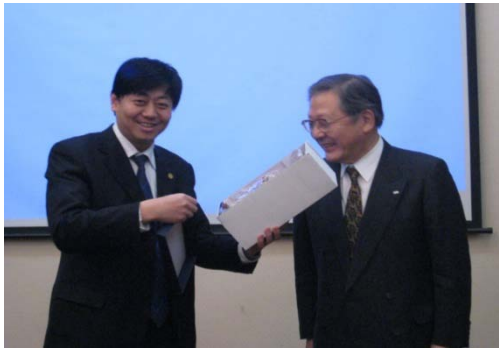
China- Japan Bilateral Relationship

MOU concluded in January 2009

- Cooperation on Drugs, Devices and Cosmetics
- Information Exchange (not confidential)
- Dialogue on Important Issues on Laws, Regulations and Related Issues
- Compare and assess their differences in regulatory or legal approaches, to explore possibilities for co-operation in the field of dissemination of standard

Bilateral Meeting in April & December 2009

- Acceptance of trainees
- Future Cooperation



Objective of China-Japan Cooperation

- Share each other's dynamism

~ tremendous benefits ~
for the region
for the international community

- Build an East Asian community to send

~ the latest innovative drugs/Medical Devices from Asia to the world ~

Join forces among Asian countries

Seek an opportunity to share experiences and ideas

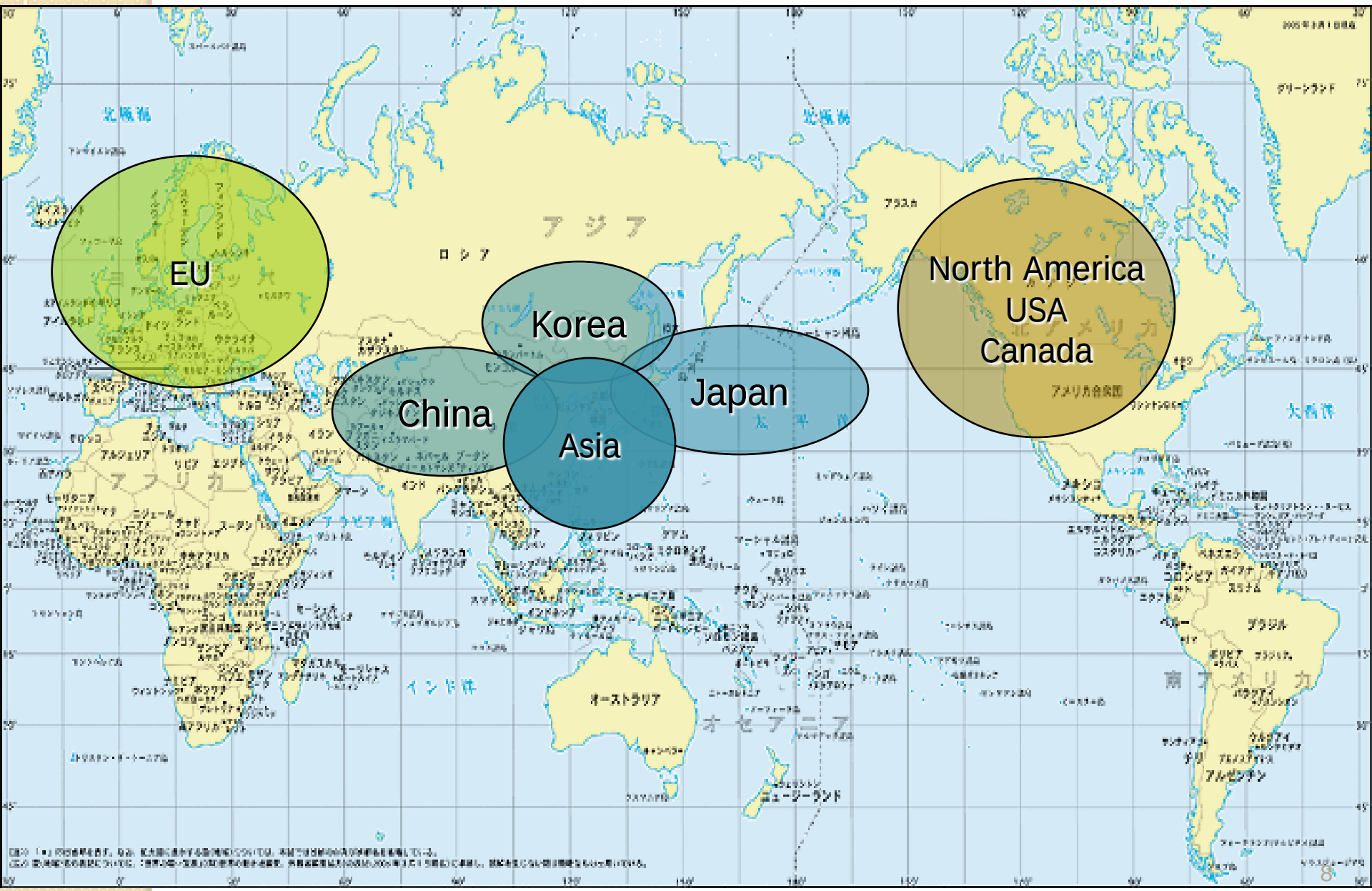
More experiences & Scientific researches
Net-working & collaborations in Asian region
Develop best fit drugs for Asian populations

Globalization : starting point for working together

Our view for multiregional drug development

- Clinical Drug Developments in Asia are rapidly growing
- Timely Discussion between Industry and Regulatory Agency is important to maximize efficiency of drug developments
- Inclusion of Asia in multiregional drug development is encouraged
- Regulatory Harmonization and more collaborations among regulatory agencies are necessary

Innovative Drugs from Asia to the world



2. PMDA initiatives on Global Clinical Trials

Basic principles on Global Clinical Trials

Japanese version

薬食審査発第0928010号
平成１９年９月２８日

各都道府県衛生主管部（局）長　殿

厚生労働省医薬食品局審査管理課長

国際共同治験に関する基本的考え方について

従来、我が国においては、ＩＣＨ－Ｅ５ガイドラインに基づく「外国臨床データを受け入れる際に考慮すべき民族的要因について（平成10年8月11日医薬審第762号 厚生省医薬安全局審査管理課長通知）」により、いわゆる「ブリッジング」による海外臨床試験成績を承認申請資料として活用することを認めており、また、欧米諸国における市販後調査等の結果についても必要に応じ承認審査に際して活用しているところである。

http://www.pmda.go.jp/operations/notice/2007/file/0928010.pdf

English version

September 28, 2007
Notification No.0928010

Attention to:
Commissioner of Prefectural Health Supervising Department

From Director of Evalution and Licecing Division,
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

Basic principles on Global Clinical Trials*

Up to the present according to "Ethnic Factors in the Acceptability of Foreign Clinical Data" based on ICH-E5 guideline (Notification No. 762, Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health and Welfare, dated August 11, 1998), utilizing foreign clinical trial data in a new drug application what is called "Bridging" has been accepted in Japan, and post-marketing data in USA and EU have been taken into consideration in a review for regulatory approval where necessary.

http://www.pmda.go.jp/operations/notice/2007/file/0928010-e.pdf

Published on September 28th, 2007 for helping to make a strategy and clinical trial designs for Global Drug Development

Points to Be Considered by the Review Staff Involved in the Evaluation Process of New Drug

Points to Be Considered by the Review Staff
Involved in the Evaluation Process of New Drug
(FINAL)*

April 17, 2008
Pharmaceuticals & Medical Devices Agency

1. Purpose

The purpose of this document is to promote an understanding among the review staff involved in the evaluation of new drugs, of the basic principles and major points that need to be considered in being involved in the drug evaluation process at the Pharmaceuticals and Medical Devices Agency (PMDA).

2. Scope

This document summarizes the points that need to be considered during the actual evaluation process of drugs after an new drug application has been submitted, covering all new drugs which are reviewed by teams at the PMDA.

However, the points covered in this document are limited to basic points generally considered, and it should be kept in mind that there may be many other points that need to be judged on a case-by-case basis.

Especially, for drugs in the field of orphan diseases or serious diseases for which existing therapies have not yet been established, final decisions should not be based exclusively on the points covered in this document, but should also take into consideration other points such as clinical significance of the drug. Even for such drugs, however, the scientific evaluation using appropriate data should be based on a full understanding of the purpose and principle of this document.

Published on April 17th, 2008 at PMDA Homepage

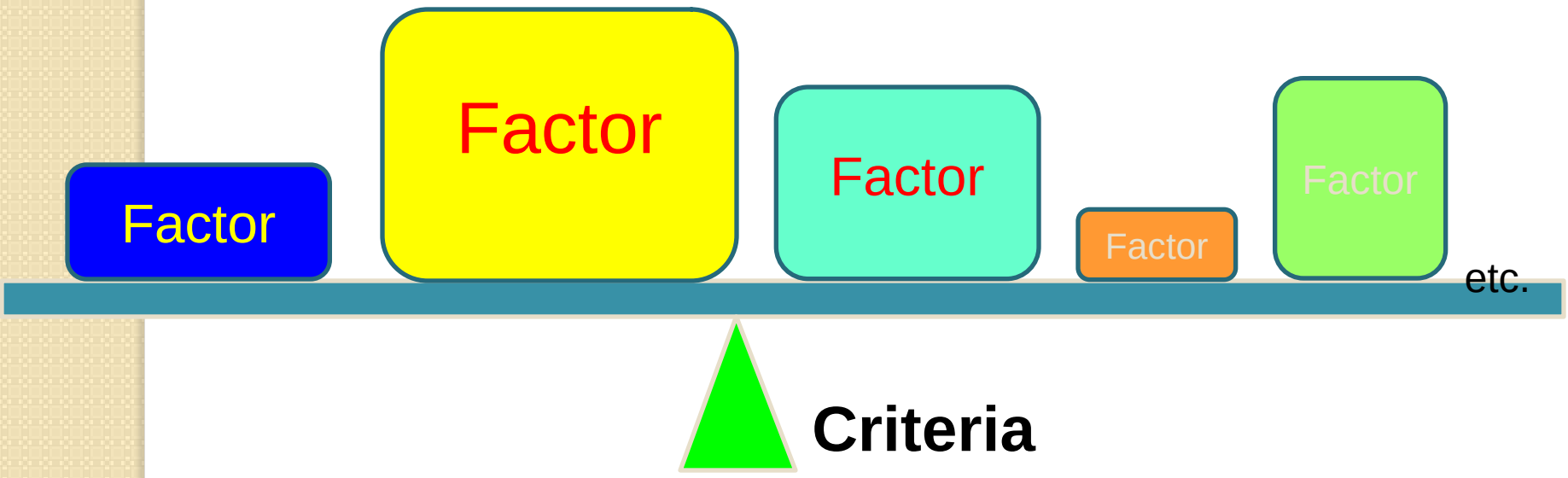
Japanese: http://www.pmda.go.jp/topics/h200417kohyo.html
English: http://www.pmda.go.jp/english/service/pdf/points.pdf

3. Future directions of PMDA

- Improvement of “Regulatory Science”

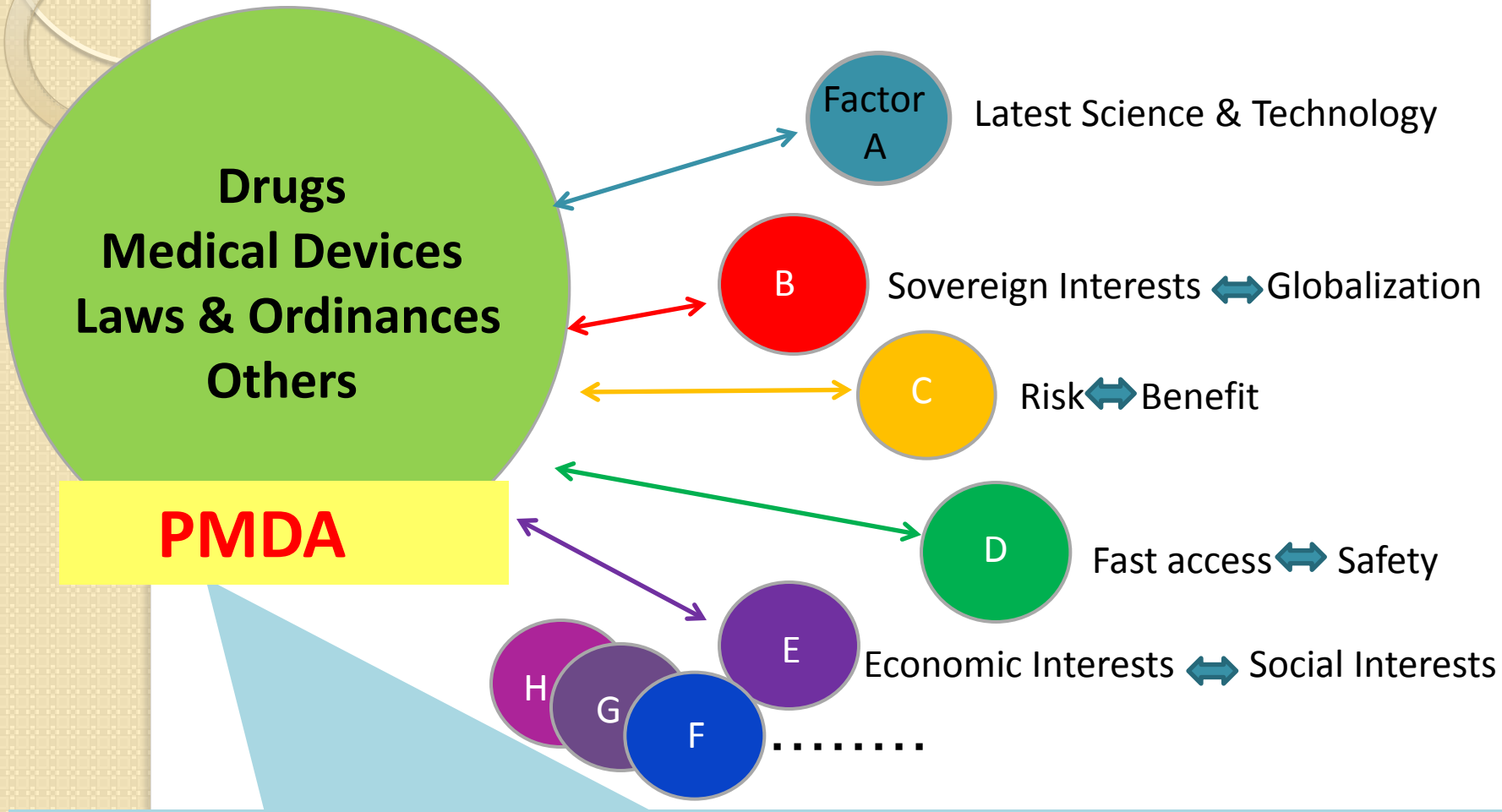
Challenge (1)

Develop comprehensive & robust disciplines in the field of "Regulatory Science"



In response to social demands,
we take balanced judgments ⇒ toward a more desirable form of society

Regulatory Science:



We must conclude Scientific Judgment that meets many complicated factors

Regulatory Science ~for pharmaceuticals~

Evaluate the scientific data to determine whether an drug is “safe and effective for its intended use “

【drugs 】

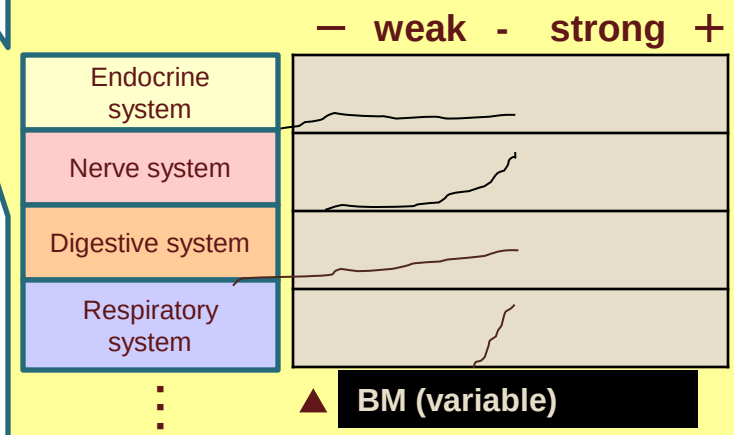
- Therapeutic area and effect-efficacy
- Dosing period
- Used as the sole regimen / co-prescribing of several drugs
- GLP, GCP, GMP

【medical user of drugs（Doctors, hospital）】

- Highly specialized hospital（w or w/o medical specialist ）
- Special hospital（ w or w/o medical specialist ）
- General hospital
- Specialized clinic （ w or w/o medical specialist ）
- General clinic

【patients】

- Individual deference in Genome
- Diagnosis （single / multiple）
- severity
- Dosage ／administration route／duration of administration etc.

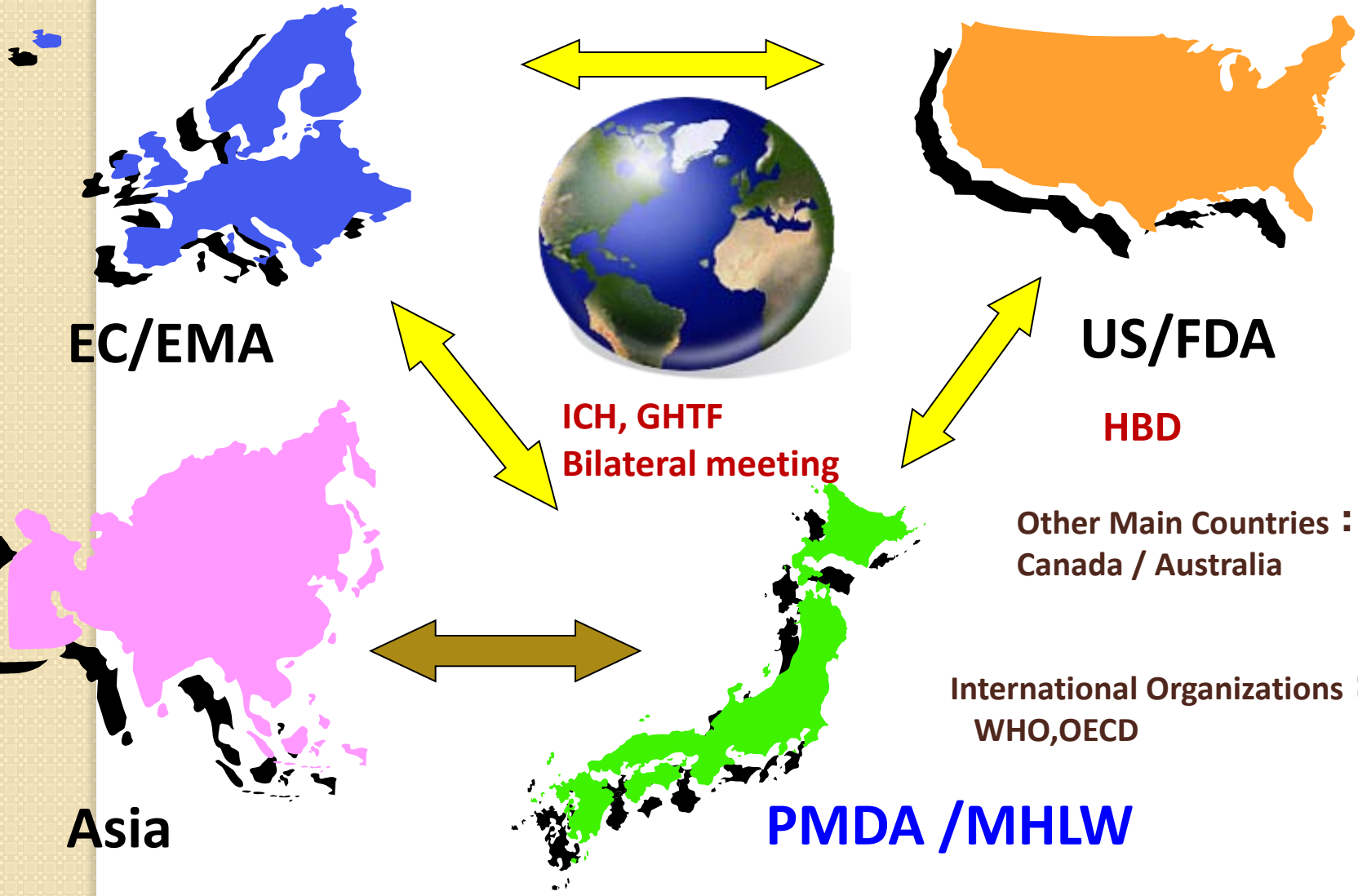


Therapeutic benefit vs Adverse events

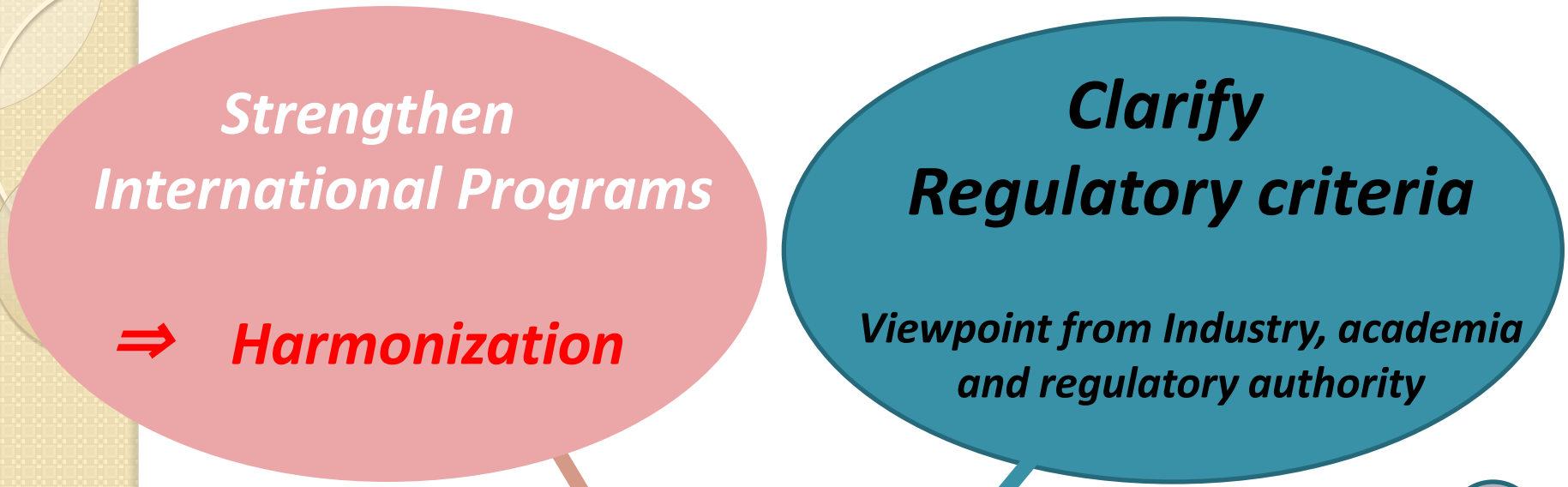
3. Future directions of PMDA

- Building of collaborative relations among International community

Challenge (2) :
Building of collaborative relations



As the Chief Executive of PMDA,

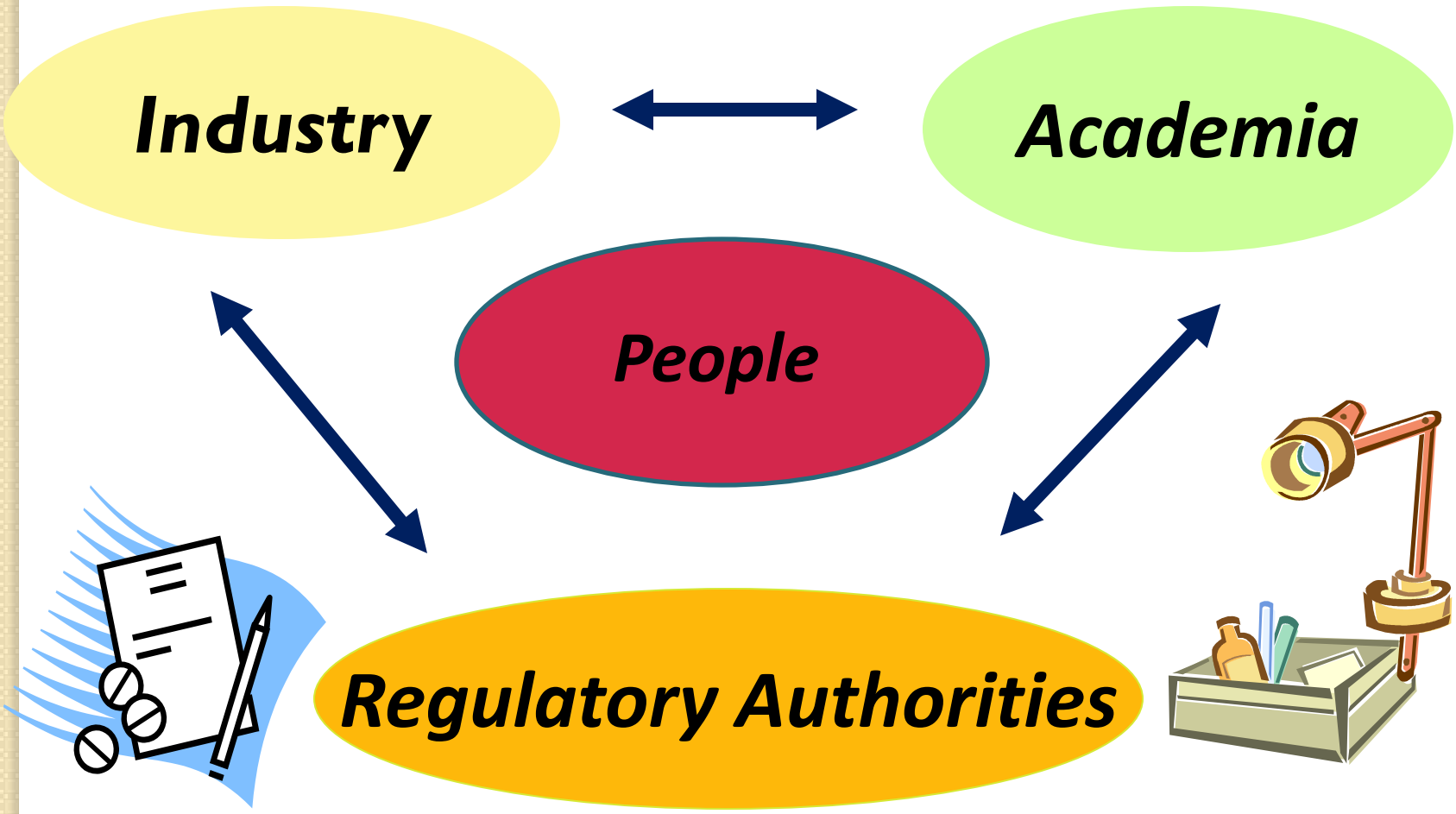


As the Chief Executive of PMDA

Build sophisticated, high level Japanese criteria

International criteria

Work together in a responsible manner based on "Regulatory Science"



Future Asian Collaborations
will deliver effective and safe drugs quickly
to all patients in ASIA and the world.

Thank you for your great cooperation !

謝謝

Pharmaceuticals and Medical Devices Agency