独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Regulatory Updates on Biosimilars in Japan

KISHIOKA Yasuhiro, Ph.D.
Review Director
Office of Cellular and Tissue-based Products
Pharmaceuticals and Medical Devices Agency

The views and opinions expressed in this presentation are those of the presenter and should not necessarily represent the views and opinions of the PMDA.

Copyright © Pharmaceuticals and Medical Devices Agency, All Rights Reserved.

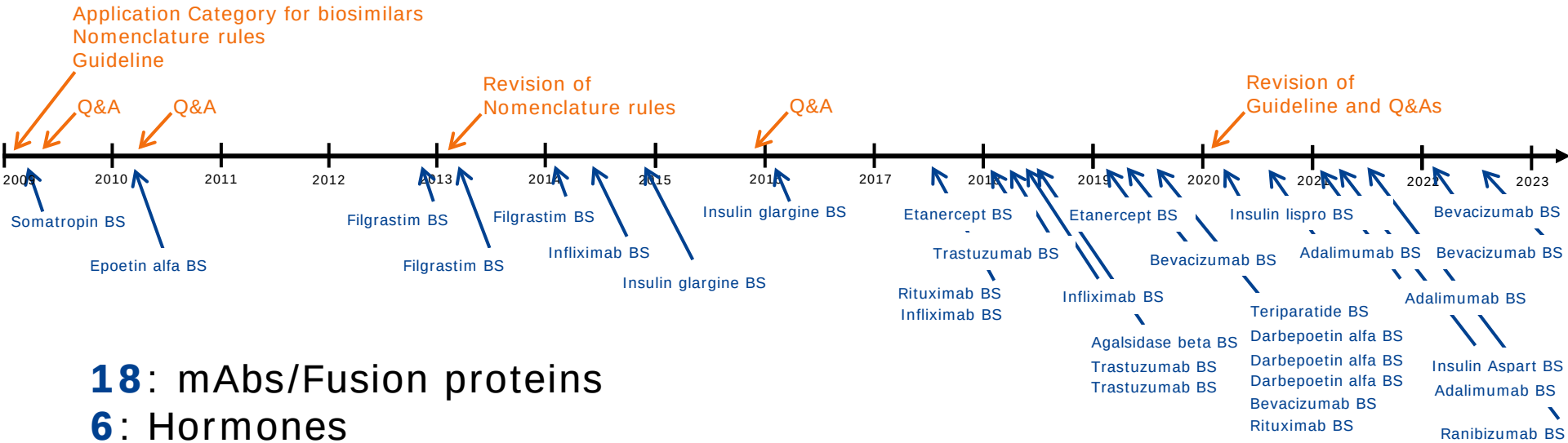
独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Outline

- Regulatory History and Status of Biosimilars
- PMDA International Collaboration
- Future Perspective

Copyright © Pharmaceuticals and Medical Devices Agency, All Rights Reserved.

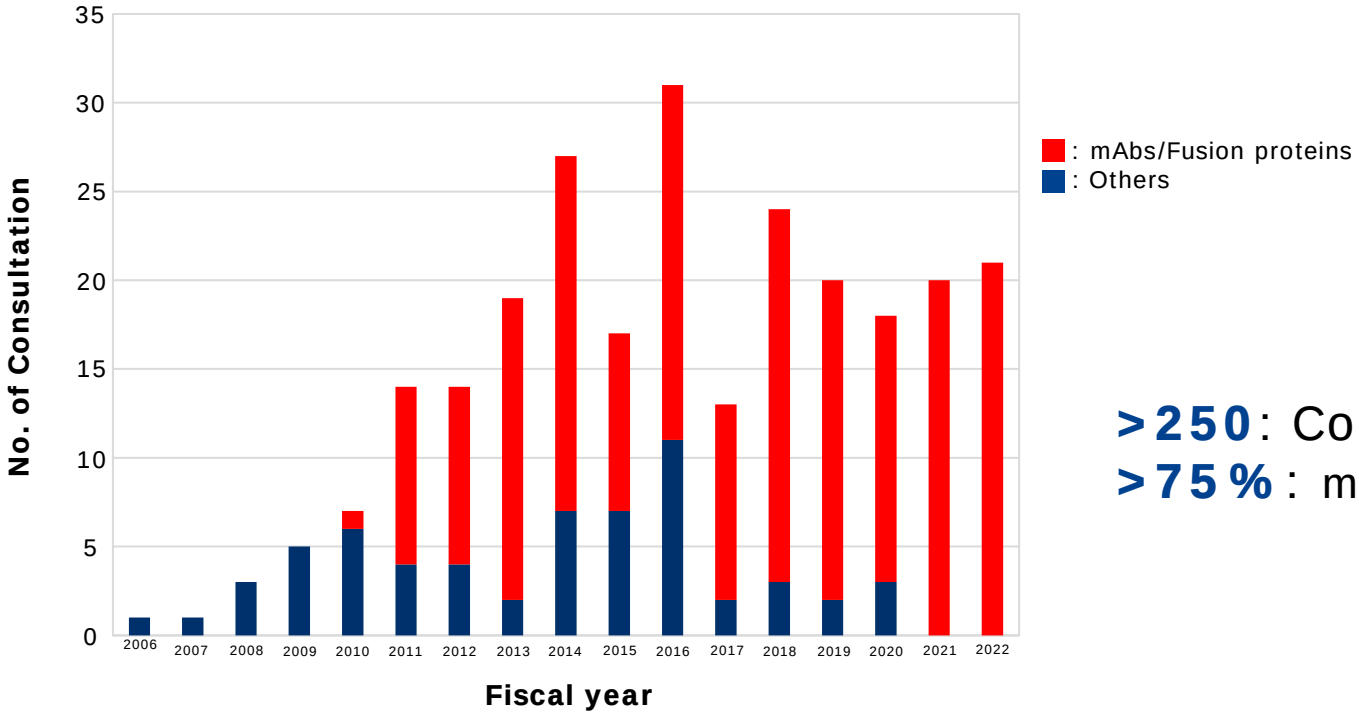
Regulatory History and Status of Biosimilars



18: mAbs/Fusion proteins
6: Hormones
4: EPOs
3: Cytokines
1: Enzymes

Copyright © Pharmaceuticals and Medical Devices Agency, All Rights Reserved.

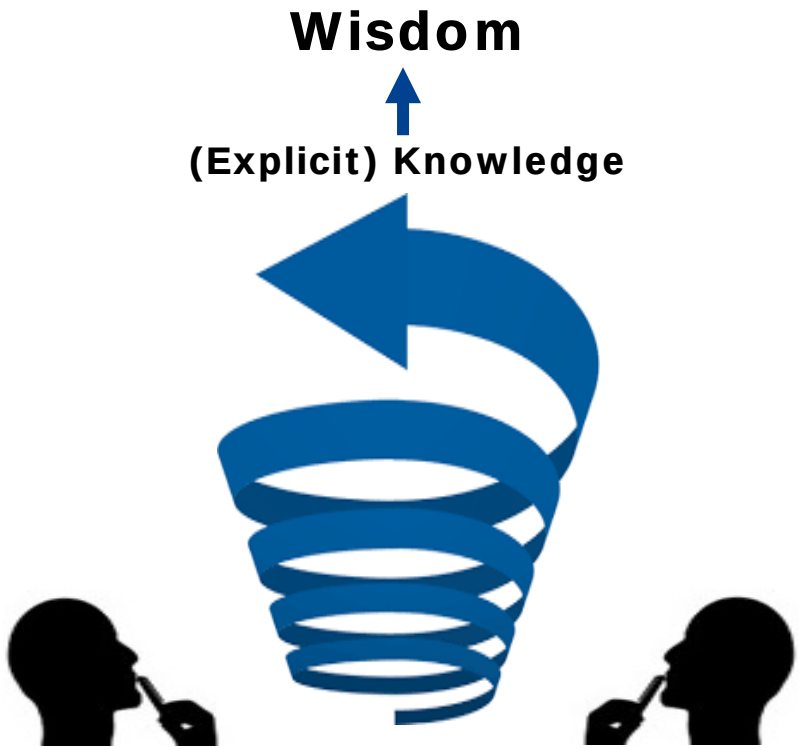
Consultation for Biosimilars



>250: Consultations

>75%: mAbs/Fusion proteins

Copyright © Pharmaceuticals and Medical Devices Agency, All Rights Reserved.



Nonaka & Konno (1998)

Copyright © Pharmaceuticals and Medical Devices Agency, All Rights Reserved.

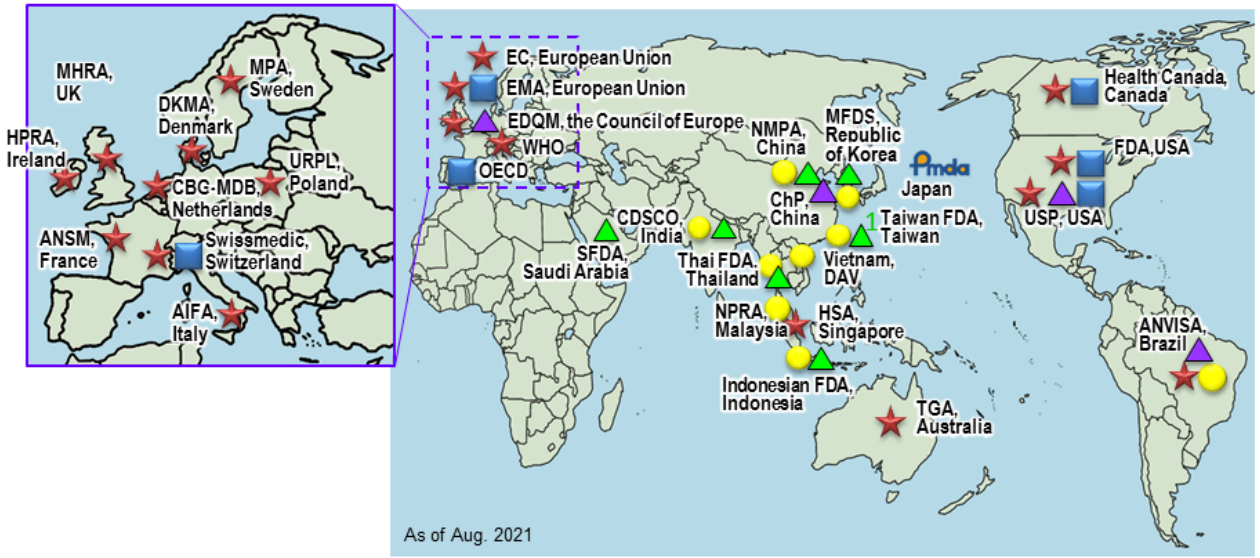
PMDA Multilateral Collaboration

World Health Organization	WHO (1948-) is the directing and coordinating authority on international health within the United Nations' system.
ICMRA	ICMRA (2012-) is a voluntary, executive-level, strategic coordinating, advocacy and leadership entity of regulatory authorities
ICH harmonisation for better health	ICH (1990 renovation 2015-) unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration
IPRP International Pharmaceutical Regulators Programme	IPRP (2018-) for exchange of information and regulatory cooperation for pharmaceuticals
Regulatory Harmonization Steering Committee APEC Life Sciences Innovation Forum	APEC-LSIF-RHSC (2009-) for regulatory convergence by promoting ICH and other international guidelines in the APEC region
PIC/S	PIC/S (1995-) for harmonizing inspection procedures and facilitating communication
GHTF / IMDRF International Medical Device Regulators Forum	GHTF (1992-)/ IMRDF (2012-) for harmonizing medical device regulations

etc.

Copyright © Pharmaceuticals and Medical Devices Agency, All Rights Reserved.

PMDA Bilateral Collaboration



Confidentiality Arrangement signed

Cooperative Arrangement signed

Joint symposium held

Cooperative Arrangement on cooperation of pharmacopoeia signed

PMDA staff stationed at the agency

[1] Cooperative Arrangement signed between the Interchange Association of Japan and East Asia Relations of Taiwan

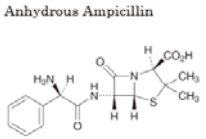
Bilateral Cooperation | Pharmaceuticals and Medical Devices Agency (pmda.go.jp)

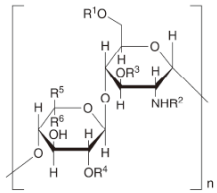
Approach to Development of Follow-on products

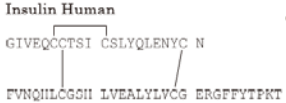
depends on;

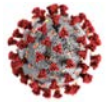
- Analytical techniques
- Understanding of quality attributes relevant to efficacy and safety
- Residual uncertainty
- Experience/Knowledge (Regulatory confidence/relief)

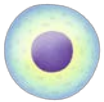
Small molecules | Sugar | Nucleic acid | Peptide | Protein | Virus | Cell | Tissue











small & simple

large & complex

Copyright © Pharmaceuticals and Medical Devices Agency, All Rights Reserved.

With Stakeholders

Y Aoki, et al, YAKUGAKU ZASSHI 142, 547-560 (2022)
Questionnaire Survey on Adoption and Prescription of Biosimilars (Antibody and Its-related Products) by Medical Doctors in Japan

Q4-2. What information do you think is necessary when selecting and adopting biosimilars (mAbs and fusion proteins) in your department/hospital? (two most important answers)

1) Results of comparative studies b/w BS and RP in quality attributes
2) Results of comparative studies b/w BS and RP in non-clinical studies
3) Results of comparative studies b/w BS and RP in clinical PK/PD studies
4) **Results of comparative studies b/w BS and RP in PIII clinical trials**
5) Results of domestic post-marketing surveillance
6) Results of clinical trials on switching from RP to BS
7) Treatment guidelines from relevant academic societies
8) Information on the stable supply of BS
9) Information on national health insurance and delivery price, incl. a comparison of the estimated patient burden for the RP vs. BS, taking into consideration the high cost of medical care (under a high medical cost payment system)
10) Overseas data on BS utilization and studies on efficacy and safety
11) No. of hospitals in Japan that have adopted BSs
12) Others (please specify)
13) Not involvement in biosimilar adoption (or no particular information required)

Thank you for your attention!

KISHIOKA Yasuhiro
Office of Cellular and Tissue-based Products
Pharmaceuticals and Medical Devices Agency