Regulatory Updates on Biosimilars in Japan

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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.
Outline

• Regulatory History and Status of Biosimilars

• PMDA International Collaboration

• Future Perspective
Regulatory History and Status of Biosimilars

Application Category for biosimilars
Nomenclature rules
Guideline
Q&A

Revision of
Nomenclature rules
Q&A
Revision of
Guideline and Q&As

Somatropin BS
Epoetin alfa BS
Filgrastim BS
Insulin glargine BS
Infliximab BS
Rituximab BS
Insulin lispro BS
Darbepoetin alfa BS
Teriparatide BS
Agalsidase beta BS
Adalimumab BS
Elecsis BS

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

>250: Consultations
>75%: mAbs/Fusion proteins
Wisdom

(Explicit) Knowledge

Nonaka & Konno (1998)
PMDA Multilateral Collaboration

WHO (1948-) is the directing and coordinating authority on international health within the United Nations’ system.

ICMRA (2012-) is a voluntary, executive-level, strategic coordinating, advocacy and leadership entity of regulatory authorities.

ICH (1990 renovation 2015-) unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.

IPRP (2018-) for exchange of information and regulatory cooperation for pharmaceuticals.

APEC-LSIF-RHSC (2009-) for regulatory convergence by promoting ICH and other international guidelines in the APEC region.

PIC/S (1995-) for harmonizing inspection procedures and facilitating communication.

GHTF (1992-)/ IMRDF (2012-) for harmonizing medical device regulations etc.
PMDA Bilateral Collaboration

As of Aug. 2021

- Confidentiality Arrangement signed
- Joint symposium held
- PMDA staff stationed at the agency
- Cooperative Arrangement signed
- Cooperative Arrangement on cooperation of pharmacopoeia signed
- Cooperative Arrangement signed between the Interchange Association of Japan and East Asia Relations of Taiwan
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)
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!

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