我が国発のバイオ医薬品
（ホルモン、サイトカイン、酵素類等）の
FDAとEMAでの承認の有無について

森本 和滋　小林 哲　柴田 寛子　石井 明子
国立医薬品食品衛生研究所（NIHS） 生物薬品部

Current FDA or EMA approval status of biopharmaceuticals developed in Japan:
focus on hormones, cytokines, and enzymes

Kazushige Morimoto　Tetsu Kobayashi　Hiroko Shibata　Akiko Ishii-Watabe
Division of Biological Chemistry and Biologicals, National Institute of Health Sciences

Abstract
Objective: To study whether 13 biopharmaceuticals originally developed in Japan, which consisted of 9 hormones and cytokines, and 3 enzymes, were approved by the FDA or EMA.
Methods: A total of 13 biopharmaceuticals first marketed in Japan from 1985 to 2016 were studied. The approval date and label of each medicine were obtained from the databases of the Pharmaceuticals and Medical Devices Agency (PMDA), FDA, and EMA.
Results and Discussion: Mecasermin was approved on Oct 5, 1994 in Japan and on Aug 30, 2005 by the FDA as a treatment of growth failure in children with severe primary IGF-1 deficiency or with growth hormone deletion. Lenograstim was approved in 11 countries, including 6 European countries, as a granulocyte colony-stimulating factor (G-CSF) agent in 1993-1995. We further investigated why the other 11 biopharmaceuticals were not approved by the FDA or EMA. We also discussed the importance of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines in adapting new Good Clinical Practice (GCP) in 1998, and that of the quality of biotechnological/biological products. The establishment of the PMDA in 2004 and history of transparency enhancement in the drug review process were also discussed.

Key words
Japanese new biopharmaceuticals, mecasermin, ICH guidelines, transparency enhancement in the drug review process