

# Therapeutic Class Report Overview - Japan Biosimilars

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## Abstracts

¥200b worth of biologic products is going off patent by 2015 and this value exceeds ~ ¥500b if we include products that will see their patent expiries by 2021 in Japan. There are a number of reasons to believe that follow-on-biologics or biosimilars will not replicate the lethargic growth story of generic – preliminary because the much higher cost of biologic therapy brings significant burden on patients despite relatively low co-pay in Japan – and this will push individuals and DPC Hospitals to use biogeneric products to a greater extent unlike generic drugs. Secondly, the regulatory supports are going to be stringent enough to ensure quality measures and leave ~no room for imported products, thus eliminating the ‘not made in Japan’ factor from prescriber’s and user’s mindsets.

Anticipating this opportunity and favorable macro forces as compared to generics, a number of companies aim to exploit this – Japan has seen a flood like consolidation and partnering activities in biosimilar space. While a dozen+ companies have already laid their road map for biosimilars space, at this time we see Sandoz, JCR, Meiji Seika Pharma, Fuji Film Kyowa Kirin Biologics, Nippon Kayaku, Nichi Iko, Yoshindo etc. to be amongst the key players in biogenerics business in Japan.

In this piece, we attempt to evaluate the future competitive landscape of the biosimilars space in Japan, assess the overall attractiveness of the same, and try to identify the key determinates to succeed in this space.

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JCR Pharmaceuticals

Meiji Seika Pharma  
Fuji Film Kyowa Kirin Biologics  
Nichi-Iko  
Mochida  
NiprPharma  
Yoshindo  
Nippon Kayaku  
Sawai  
Towa  
Daiichi Sankyo  
UMN Pharma  
Kissei  
Kyowa HakkKirin  
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ToyobBiologics

**ANNEXURE-I - CONSOLIDATION ACTIVITIES IN BIOSIMILAR SPACE IN JAPAN**

**ANNEXURE-II - BIOSIMILAR GUIDELINES ADOPTED BY VARIOUS COUNTRIES**

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