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# Japan Pharma Outlook 2016: JP Giants leaning in for becoming a Speciality Global Pharma

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## Abstracts

JP Giants leaning in for becoming a Speciality Global Pharma

Sakigake designation – A Push from government to “Innovate”!

“Essential drugs” exemption from Z2 rule- Balancing long listed pricing pressure!

Authorized Generics, Biosimilars, and Patent Litigations - Avenues to grow in JP Generic market!

Increasing decline in long listed products sales, and a few success in R & D in the last decade had put JP giants under pressure to refocus on Innovation with specialty therapy area to strengthen their global presence. Eisai Ajinomoto JV, Teva-Takeda partnership for Speciality Generics is the actions in this direction. Fast track approval based on “Sakigake” designation is the step by PMDA/MHLW to encourage JP Pharmas to research in the area of high unmet medical need/orphan disease where US biotech has taken a successful leap in last decade.

In innovation space, Nivolumab, Alectinib, Dolutegravir global success again demonstrate ability of JP pharma/university research house to contribute Pharma Innovation, while encouraging regulatory environment for “Regenerative Medicine Drug Development” and “Drug Repurposing” will make Japan front runner in this space. From late stage pipeline/new launch, Mirogabalin approval in Neuropathic Pain, Brintellix Cognition label expansion, Edoxaban uptake in EU, Alectinib uptake in US and ACE-910 approval for hemophilia will decide Japanese Innovator growth in Global market. The biennial price cut scheduled in April-2016 will balance Innovation premium with long listed price cut (Z2 rule) to increase R & D productivity.

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In next 3 years, ¥950b drugs will go off patent in Japan- and as happened in 2015, substantial volume growth due to new patent expiry opportunities will help Japanese generic companies to withstand NHI pricing pressure. Consolidation activities like Teva-Takeda JV –will make this growing domestic generic market more competitive and companies with “direct sales model” may fetch upper hand due to less dependence on wholesale distribution channel. Challenging Alimta patent and Evista patent against Lilly in Japan, and Livalo ANDA filing in US by JP Generic companies is indicative of the changing breadth of the JP generic giants from launching generics in Japan to becoming a patent challenger- Intellectual property rights challenging generic company. This is a step towards finding its place against the world generic players in the coming time. Successful launch of Blopress AG, Plavix AG in last few years stamps Authorized Generics as one of the attractive opportunity for Generic players in Japan. Encouraging Uptake of Filgrastim BS and Lantus BS in Japan is indicative of Japan to be the next important market after EU in the next five years for growth of Biosimilar players. In contrast, there is a very slow uptake post launch of Remicade biosimilar (~1% volume share).

In this report- we analyzed therapy focus, changing Strategies, pipeline and key growth drivers of 12 major Japanese biopharma companies (Pure play innovators/Innovators+ Generics/Pure play generics) and detailed our view on their strategic action to withstand in domestic market and expand globally with their interest for inlicensing external innovation from the globe for increasing R&D productivity and priorities on M & A side.

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## LIST OF COMPANIES

Takeda, Chugai, Daiichi Sankyo, Kyowa Hakko Kirin, Meiji Seika, Mitsubishi Tanabe, Shionogi, Symbio, Takeda, Towa, Sawai, Nippon Chemiphar, Nippon Kayaku

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