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Japan Pharma Outlook 2015: 2015 –Year to Watch Out for Authorized Generics (AGs), Biosimilars and Overseas Strategic Initiatives

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Abstracts

The new pricing system adopted in Japan from April -2014 (Annexure 1) is a game changer initiative. It pains most of the companies - whether generic or innovator. The most of the companies are revalidating their domestic (and thus overseas) strategies to adopt with new regulations. For the innovators – testing Authorized Generics (AGs) phenomenon for protecting their long-listed sales against generic could be one of new choice in Japan. The format and regulations for AG's are still not clear in Japan, however with the largest Japanese product Blopress AG's launched recently and generic companies in queue to compete with their generic versions will make the things lucid for the fate of AG's in Japan.

For most of the generic companies focusing on reducing manufacturing costs, and for many of them to venture in biosimilars space as a new growth avenue would be focus. The trends suggest that Japanese companies may need to set up or alliance with companies overseas for manufacturing. In this note of Outlook-15, we look deeper into these trends to anticipate likely near term changes of Japanese pharma industry.

In innovation space, after Oncology, regenerative medicine and Orphan disease are the areas where Japanese innovator companies are focusing its R & D efforts. While from late stage pipeline/new launch, Edoxaban, Lenvatinib, Entyvio, Brintellix, and Ixazomib are the few important NCEs, uptake of which will decide Japanese Innovator growth in Global market. In this report- We analyzed pipeline, strategies and key growth drivers of 13 major Japanese biopharma companies (Pure play innovators/ Innovators+ Generics/Pure play generics) and detailed our view on these growth drivers along with their interest for inlicensing external innovation from the globe for increasing R&D productivity.

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