

〔一般論文〕

Generic Submissions in Japan from a Global Generic Player's Perspective

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Summary : Japan, with the highest life expectancy in the world, is an aging society and its health insurance system is increasingly burdened by this demographic development. As the Japanese government seeks to maintain a healthy economic outlook, it must also adopt policies that continue to restrict overall health expenditures. One approach is to increase the use of low cost generics.

The Japanese government, indeed, is committed to increase generics volume share to over 30% by 2012, and is implementing a number of pro-generic measures. As the result, its generic market, expected to grow significantly in the following years, is becoming a major focus for global players. However, despite the fact that Japan is a member of the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) it has restricted this harmonization process towards new and innovative drugs and has excluded generics to a very great extent.

In contrast, the other two ICH regions, USA and the European Union, are successfully applying current international standards to generics. Manufacturers from these countries struggle with a different regulatory system when they try to get their products approved for the Japanese market.

The following review summarizes major issues concerning the application files necessary to receive generic drug approval, and outlines the differences between the three major pharmaceutical markets in this respect.

Keywords : Generics, Drug Approval, Registration Dossiers, Stability, Analytics, Bioequivalence, Pharmacovigilance, Good Manufacturing Practice (GMP)

Introduction:

The Japanese pharmaceutical market is the second largest individual market after the USA and with sales of more than 60 billion USD per year constitutes approximately 10% of the world market.

Japan's society is growing old; according to the United Nations Populations Division the proportion

of elderly people aged at least 65 years was 19.9% in 2005 and is expected to rise to 36.0% by 2050, — thanks to an average lifespan of 82 years, the highest in the world. This demographic development is putting pressure on Japan's healthcare system, and price cuts are one approach of the Japanese government to trim ballooning healthcare expenditures. Another very recent approach is the implementation of policies to push the use of low cost generics, including generics substitution promoted at pharmacies and flat-fee payment system (DPC-Diagnosis Procedure Combination) promoted at acute hospitals.

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