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ASIA EDITION

Sandoz receives regulatory approval from NMPA for Rosuvastatin

09 May 2019 | News | By Kalyani Sharma

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Sandoz has announced that it has received regulatory approval from China's National Medical Products Administration (NMPA) for its generic Rosuvastatin, under the NMPA's Quality Consistency Evaluation (QCE) system.

Sandoz is the first multinational pharmaceutical company to receive such an approval under the recently introduced QCE system, which aims to ensure that all generic medicines marketed (or manufactured) in China meet internationally recognized quality standards.

The QCE regulations are part of a wide-ranging package of healthcare system reforms introduced by the Chinese government over the past few years, which also offer the potential to accelerate national generic registration timelines significantly.

Francesco Balestrieri, ad interim CEO, Sandoz said, "This first-of-a-kind generic approval for a multinational company demonstrates our strategic focus on pioneering access to high-quality medicines in China, which is the world's largest generics market and offers enormous future potential to address unmet needs, particularly in the area of chronic diseases."

He added, "Specifically, this regulatory milestone helps to pave the way for Sandoz to compete in future generic tenders in China, as the evolving tender system increasingly moves to favor QCE-approved molecules. We see great potential to grow long-term in China and have the commitment and capabilities to succeed, including programs to conduct R&D and clinical development in China, specifically for the Chinese market."

Sandoz aims to continue submitting new generics applications in China, with a particular focus on areas of greatest unmet need, with the goal of further expanding access to its existing global portfolio of high-quality generic and biosimilar medicines.

Rosuvastatin belongs to a group of medicines known as statins, which reduce the risk of heart disease and help prevent strokes and heart attacks.