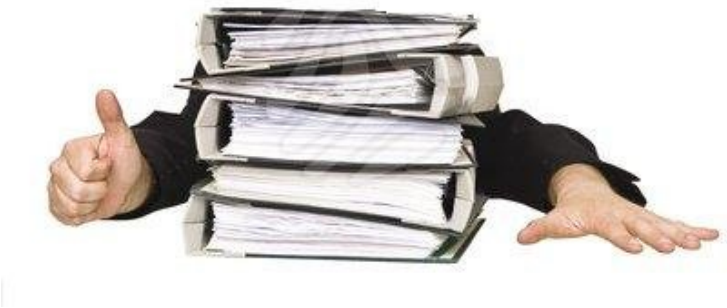
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ASIA EDITION

Marck products get approval in South Africa

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South Africa clears six products from Indian company Marck



Mumbai: Marck Biosciences, an Indian manufacturer and marketer of sterile dosages and Blow-Fill-Seal (BFS) specialist, was granted approval by the South African Medicines Control Council for six products manufactured at its small volume parenterals (SVP) facility at Kheda in the state of Gujarat. The South African market, at around $3.8 billion in 2011, is growing at six percent and is expected to reach $7 billion in 2018, with generics accounting for 60 percent of the volume.

The council's approval will also enable Marck Biosciences to achieve immediate access to key markets including Namibia, Botswana, Zimbabwe, Swaziland, Lesotho, Zambia, Malawi and Madagascar. The approval is expected to result in waiver of inspection by the authorities of these countries and an easier registration of certified products. For Marck Biosciences, the approval carries the opportunity of accessing some of Africa's most stable growth economies.

South Africa's Medicines Control Council is a statutory body that oversees the regulation of medicines in South Africa. Its main purpose is to ensure that all medicines that are sold and used in South Africa are safe, therapeutically effective and consistently meet acceptable standards of quality.

Its certification is also recognized by 43 participating authorities of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP. This may facilitate export by Marck Biosciences of certified SVP to PIC/S participating authorities as well as non-PIC/S authorities who accept GMP certificates from PIC/S participating authorities.

Speaking on the approval, Mr Bhavesh Patel, MD, Marck Biosciences, said: "The MCC-South Africa approval for our Kheda facility will provide further impetus to our current expansion efforts in the African region and PIC/S countries. We would also augment our efforts by our own filing and licensing with new partners in SA. I see strong revenue potential in these under-served markets and we believe that we can make a quantum contribution to healthcare products in these countries."

Six products that have obtained approvals are Sterile Water For Injections BP 5/10 ml; Ciprofloxacin Eye Drops 5/10 ml; Timolol 0.25% Eye Drops 5/10 ml; Timolol 0. 50% Eye Drops 5/10 ml; Lidocaine Injection BP 1% 5/10 ml and Lidocaine Injection BP 2% 5/10 ml.