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# Australian TGA nod for superbug antibiotic

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**Singapore:** An effective new antibiotic designed to specifically treat Clostridium difficile-associated diarrhoea will be available to patients in Australia from 14th May 2013. Specialized Therapeutics (STA), Australia, received Therapeutic Goods Administration (TGA) approval to market the drug Dificid (fidaxomicin) in Australia. Until now, it has only been available in Australia under the Special Access Scheme. STA licenses Dificid for the Australian market from US-based Optimer Pharmaceuticals.

The macrocyclic antibiotic therapy, taken in tablet form, is regarded as a breakthrough treatment to help fight serious CDI, which typically develops in patients following broad-spectrum antibiotic use. CDI targets the large intestine, causing diarrhea, which can range from moderate and debilitating-to-severe and life-threatening. It is extremely common in hospitals and aged care facilities as older patients are particularly vulnerable, and can be fatal. A recent media report indicated that 14 Victoria residents died from the infection during a 15-month period in 2010 and 2011.

STA CEO, Mr Carlo Montagner, said that, "Dificid is a potentially life saving drug for this extremely serious infection plaguing public hospitals and the wider community. Unfortunately, it is estimated that almost 30% of patients can have a recurring infection. DIFICID is the only approved drug on the market which studies have shown will lower the risk of that infection returning."

Dificid is the first in a new class of antibiotics that are minimally absorbed by the bloodstream and have been shown to fight CDI while leaving healthy gut flora untouched. Hypervirulent strains of C. difficile, including the PCR ribotype 027 strain recently identified in Australia, have been associated with epidemic spread and high rates of severe disease and death.

Risk factors for CDI include exposure to antimicrobial drugs, gastric acid-suppressive therapy, advanced age, prolonged hospitalisation, cancer chemotherapy, co-morbidity and immuno- suppression. Although most cases have been in hospital inpatients, increasing numbers of community-associated cases are now being reported.