PRESS RELEASE

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Wockhardt Files Marketing Authorisation Application for WCK 5222 with European Medicines Agency

Wockhardt has successfully filed a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA) for its novel antibiotic, WCK 5222, on 5 January 2026.

The EMA is the regulatory authority responsible for the scientific evaluation, of new medicines across the 27 European Union (EU) Member States and three European Economic Area (EEA) countries—Iceland, Liechtenstein, and Norway—covering a total of 30 countries.

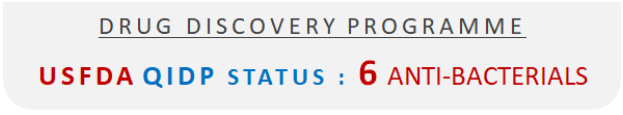
Earlier, the EMA had informed Wockhardt that WCK 5222, a fixed-dose combination of Zidebactam (1 g) and Cefepime (2 g), is eligible for Accelerated Assessment. This pathway allows for an abridged review timeline, reflecting the unmet medical need addressed by the product. The New Drug Application (NDA) on WCK 5222 is already under fast-track review by the US FDA.

Based on the comprehensive clinical and regulatory data included in the application, Wockhardt expects WCK 5222 approval for treatment of resistant Gram negative infections across all countries under the EMA's jurisdiction. The priority review status granted to WCK 5222 underscores the global urgency to make effective treatment options available for patients suffering from life-threatening multi-drug resistant infections.

Notably, WCK 5222 is the first New Chemical Entity (NCE) discovered and developed in India to be submitted for pan-European marketing authorisation.

About Zaynich® (Zidebactam/Cefepime, WCK 5222)
Zaynich® is a novel, proprietary antibiotic developed by Wockhardt, combining Zidebactam and Cefepime to combat multi-drug resistant Gram-negative infections. The drug recently completed a global, pivotal Phase III clinical trial, which will support its marketing authorization across international markets. The New Drug Application (NDA) for Zaynich® has been filed and accepted by the United States Food and Drug Administration (USFDA). The application for Marketing Authorization has also been filed with the Indian regulatory authorities. Prior to this, multiple Phase I clinical pharmacology studies involving the Zidebactam/Cefepime combination were successfully conducted in the United States. Zaynich® has also completed a multi-indication clinical study in India, specifically targeting carbapenem-resistant infections. To date, more than 50 patients in India and the U.S. suffering from highly resistant infections have been treated with Zaynich® under compassionate use programs.

About Wockhardt's Drug Discovery portfolio



For over 27 years, Wockhardt has been at the forefront of antibiotic innovation, focusing its drug discovery efforts on combating multi-drug resistant infections. This commitment has resulted in a strong pipeline of six antibiotics at various stages of clinical development and commercialization—all of which have been granted Qualified Infectious Disease Product (QIDP) designation by the U.S. FDA. Three of these novel antibiotics are already approved for clinical use, while two more are in the final stages of development.

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Wockhardt is employing around ~2900 people and 27 nationalities with presence in UK, Ireland, Switzerland, France, Mexico, Russia and many other countries. It has manufacturing and research facilities in India & UK and a manufacturing facility in Ireland. Wockhardt has a significant presence in Europe and India, with ~77% of its global revenues coming from international businesses.