



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends authorisation of novel antibiotic agent

First medicine in new class recommended for treatment of *Clostridium difficile* infection

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the authorisation of the first antibiotic in a new class to treat infections with *Clostridium difficile*. Novel antibacterial agents are needed to overcome the harmful consequences of bacterial resistance. The CHMP's opinion therefore represents a major step forward by providing a new medicine to tackle the growing levels of resistance to available antibiotics across the European Union (EU).

Dificlir (fidaxomicin), a first-in-class macrocyclic antibiotic, promises to improve current treatment of the inflammation of the gut and severe diarrhoea caused by *C. difficile*.

Infection with *C. difficile* is one of the leading causes of disease in hospital. It usually causes illness in patients who have been treated with other antibiotics, which upsets the balance of bacteria in the gut and allows *C. difficile* to grow uncontrollably.

Over the past 20 years, the number of cases of *C. difficile* has been increasing, particularly among the elderly. The severity of infections has also been on the increase following the emergence of a new, more virulent strain of the bacterium that has spread to at least 17 European countries. The potential cost of *C. difficile* infection per year in the EU has been estimated to be as high as 3 billion euros.

Currently, few acceptable treatments for *C. difficile* are available, with vancomycin and metronidazole being linked to infection returning after treatment and to significant side effects.

Clinical studies revealed that Dificlir is as effective as vancomycin in curing *C. difficile* infection and that the two medicines have similar rates of side effects, such as feeling sick, low blood potassium levels, headache, vomiting and stomach cramps. Because Dificlir targets *C. difficile* specifically, its effect on other, beneficial bacteria in the gut is minimal. Dificlir's new mode of action also reduces the chances that its activity will be affected by resistance to other antibiotics.

Dr Xavier Luria, Head of Safety and Efficacy at the European Medicines Agency, said, "we welcome this first opinion for a macrocyclic antibiotic for the treatment of infection with *C. difficile*. This is a promising step forward in the Agency's drive for addressing patients' needs in infectious diseases."

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The Committee's opinion will now be forwarded to the European Commission for the adoption of a decision on the marketing authorisation.

Notes

1. This press release, together with all related documents, is available on the Agency's website
2. A summary of the CHMP's opinion on Difliclr is available on the Agency's website.
3. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

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