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EMA starts review of azithromycin-containing medicines

EMA's human medicines committee (CHMP) has started a review of systemic medicines (given by mouth or by injection) that contain the antibiotic azithromycin. Antimicrobial resistance (AMR) against azithromycin is increasing in the European Union (EU). Therefore, and in view of the broad use of these medicines, a re-evaluation of the benefits and risks of azithromycin in its many authorised uses is considered warranted to optimise its use and minimise the risk of AMR development.

Many azithromycin-containing medicines have been in use for decades and were authorised by national procedures in the EU. This has led to large differences in the product information regarding the indications, treatment dose and duration, and relevant safety information. These differences may conflict with rational use of antibiotics and antibiotic stewardship and may result in further development of antimicrobial resistance to azithromycin.

EMA will now review all available information on the benefits and risks of azithromycin and will consider whether any changes are required to its approved uses across EU Member States.

Use of azithromycin

Azithromycin has been classified by the World Health Organization (WHO) as an antibiotic that carries a higher risk of antimicrobial resistance and is included in WHO's Watch list (AWaRe classification)[1]. It is also included in WHO's list of essential medicines[2,3].

As part of its actions to fight antimicrobial resistance, EMA commissioned a study in 2022 to investigate prescription of antibiotics that are included in WHO's Watch list. This study, performed by DARWIN EU®[4], showed that azithromycin is frequently prescribed in the EU in adults and children. Antibiotic surveillance data[5] from Germany has also shown that azithromycin was increasingly used during the COVID-19 pandemic in the hospital setting.

[1] 2021 AWaRe classification. WHO access, watch, reserve, classification of antibiotics for evaluation and monitoring of use: https://www.who.int/publications/i/item/2021-aware-classification
[2] WHO Model List of Essential Medicines - 23rd list, 2023: https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02
[3] WHO Model List of Essential Medicines for Children - 9th list, 2023: https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.03
[4] https://www.encepp.eu/encepp/viewResource.htm?id=104143
[5] https://avs.rki.de/Content/ReferenceData/HospitalComparisonTime.aspx

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

More about the medicines

Azithromycin is one of a group of antibiotics known as macrolides. It can be given by mouth or by injection to treat infections caused by Gram-positive and Gram-negative bacteria, such as, but not limited to, upper and lower respiratory tract infections and community-acquired pneumonia.

Azithromycin-containing systemic medicines have been authorised nationally in the EU for many years and are marketed under a variety of brand names.

A few azithromycin-containing medicines are approved in the EU for topical use (as eye drops). These medicines are out of scope for this review procedure.

More about the procedure

The review has been initiated at the request of the German Federal Institute for Drugs and Medical Devices under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.