## Important Safety Information on the Prescribing of Fluoroquinolone Antibiotics

There is growing evidence of harm from fluoroquinolone antibiotics:

- Ideally avoid fluoroquinolones where possible (MHRA)
- Always supply the MHRA fluoroquinolone patient information leaflet (see below) and encourage yellow card completion
- Explain serious side effects before use and document in the medical notes

There has been a further alert issued by the Medicines and Healthcare products Regulatory Agency (MHRA) on the fluoroquinolone group of antibiotics titled Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate (published 22 January 2024).

The fluoroquinolone antibiotics in common use in the UK include ciprofloxacin, ofloxacin, levofloxacin and moxifloxacin.

Restrictions to the use of fluoroquinolones were introduced in 2019 to minimise the risk of serious, disabling, long-lasting and potentially irreversible adverse reactions. The MHRA has reviewed the effectiveness of these measures in the UK and sought the advice of the Commission on Human Medicines (CHM). As a result of this review a reminder about these risks was published in the <u>August 2023 issue</u> of the MHRA Drug Safety Update.

The MHRA has now taken additional regulatory action to update the indications for all systemic fluoroquinolones to state they should only be used when other commonly recommended antibiotics are inappropriate. Situations where other antibiotics are considered to be inappropriate are where:

- there is resistance to other first-line antibiotics recommended for the infection
- other first-line antibiotics are contraindicated in an individual patient
- other first-line antibiotics have caused side effects in the patient requiring treatment to be stopped
- treatment with other first-line antibiotics has failed

The description of disabling and potentially long-lasting or irreversible side effects in the safety information has also been updated, to include more detail about the range of psychiatric symptoms that may occur as part of these reactions. These may include sleep disorders, anxiety, panic attacks, confusion or depression. While the frequency of disabling and potentially long-lasting or irreversible side effects cannot be estimated precisely using available data, the updated reporting incidence indicates a minimum frequency of between 1 and 10 per 10,000 patients.

Reminders of the potential risks are highlighted on the Optimise Rx system at the point of prescribing any of the affected antibiotics. The MHRA's sheet for patients (regular print or large print) provides further advice and should be given to patients.

For national NICE/UKHSA antimicrobial prescribing guidance on managing common infections click on the <u>link</u>.

Finally, a reminder that broad-spectrum antibiotics increase the risk of resistant infections (including *C.difficile* diarrhoea); avoid their use when narrow-spectrum antibiotics remain effective.

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