From the Chief Medical Officer
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HSS(MD) 04/2024

Our Ref: HSS(MD) 04/2024
Date: 31 January 2024

BY EMAIL

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Dear Colleague

MHRA Drug Safety Update –

1. **Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate**
2. **Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors**

The Medicines and Healthcare products Regulatory Agency (MHRA) have issued the below Drug Safety Updates.

Healthcare Professionals are asked to note and action the advice for healthcare professionals, advice for healthcare professionals to provide to patients, parents and carers, and recommendations contained within the Drug Safety Updates.

Please find links to the complete **MHRA Drug Safety Updates** included below:

1. **Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate**

Systemic fluoroquinolones must now only be prescribed when other commonly recommended antibiotics are inappropriate. This follows a review by the MHRA which looked at the effectiveness of current measures to reduce

the identified risk of disabling and potentially long-lasting or irreversible side effects.

2. **Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors**

   Systematic reviews and meta-analyses of randomised controlled trials have highlighted a dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors treated with omega-3-acid ethyl ester medicines compared to placebo.

Report suspected reactions on a Yellow Card

Please continue to report suspected adverse drug reactions to the Yellow Card scheme. Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store
- some clinical IT systems for healthcare professionals

When reporting please provide as much information as possible, including information about batch numbers, medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Yours sincerely

Prof Sir Michael McBride
Chief Medical Officer

Professor Cathy Harrison
Chief Pharmaceutical Officer

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