

Introduction

This newsletter is intended to support all primary care prescribers with current prescribing initiatives and relevant guidelines. Practices are encouraged to discuss the items in this newsletter at their weekly practice meeting to ensure that these intentions are implemented.

Articles in this month's edition include:

- Local Update
- Prescribing Update
- Drug / MHRA Safety Update

Report Controlled Drugs Incidents & Concerns to www.cdreporting.co.uk

Yellow Card Scheme

Report any suspected adverse reactions with medicines via the national reporting system [here](#)

Medication incidents should continue to be reported to mccg.primarycare.sis@nhs.net

Formulary Website

Medway Policies and Guidelines are available online [here](#)

Local Update

Medicines Optimisation Group

Emollient Guidelines

The Primary Care Emollient Guidelines have been updated and there have been changes to the products available on the formulary. The guidance has been comprised with the input from the Dermatology Consultants, the dermatology nurses (both MCH and MFT) and the medicines optimisation team. This guidance outlines recommended use of emollients in primary care. The guidance and the new dermatology service give us an opportunity to review patients' emollient usage, ensure they are appropriate and refer them for specialist input where appropriate.

Please note:

- The first line products (where there is a diagnosis of Eczema) are AproDerm Emollient Cream or Zerobase Cream.
- Emollients should be reviewed regularly and only continued if they are effectively treating the patient's diagnosed condition.
- Prescribing of bath and shower additives are no longer supported by Medway CCG and patients should be advised to purchase over the counter (OTC) if they wish to continue to use, however they should be advised of the limited clinical value.

Prescribing of Nutritional Supplements Post Bariatric Surgeries

The Medicines Optimisation group have approved the new guidelines on the prescribing of nutritional supplements post bariatric surgeries. Post bariatric surgeries, patients are required to stay on lifelong nutritional supplements in addition to a balanced diet, and have lifelong monitoring of their nutritional status. It is therefore important that blood monitoring should be performed at intervals that are dependent on the type of bariatric surgery performed or as directed by the specialist bariatric service.

Monitoring for the first 2 years is usually undertaken at the Bariatric Centre before discharging care back to the GP, unless otherwise indicated. The centre should provide full details of the patient's nutritional monitoring requirements, and supplements needed.

The guidance gives information on the annual blood monitoring required and the nutritional supplements for the different surgical bariatric procedures. Further information is attached to this email.

Local Update

Medicines-related Electronic Discharge Notification (EDN) queries

Medway NHS Foundation Trust has set up an email address for primary care colleagues (including care homes) to report medicines-related EDN issues - medwayft.medsqueries@nhs.net.

Individual patient issues (such as missing/incorrect information, incomplete EDNs) can be reported via this email address.

The hospital pharmacy department will monitor the inbox and work with relevant departments within the hospital to resolve reported issues.

Prescribing Update

Risk of Hepatotoxicity with Paracetamol

Paracetamol has been used as the first line medicine for acute and chronic pain for more than 60 years. The usual adult dose for oral paracetamol is 0.5 to 1g every 4 to 6 hours up to a maximum of 4g in 24 hours with no dose reductions. However, this should be considered when prescribing.

Risk factors for hepatotoxicity from paracetamol include low body weight, cardiac, pulmonary or renal insufficiency, co-administration of medicines that induce liver enzymes (such as Carbamazepine or St John's Wort) hepatitis and chronic alcohol consumption.

Key messages:

- Review people on long-term paracetamol (> 6 months) or paracetamol containing prescriptions, checking for efficacy.
- Reduce dose or stop where appropriate e.g. if no benefit in terms of pain reduction and improved function.
- Frail elderly and malnourished patients are particularly susceptible to paracetamol toxicity (low body weight <50kg) due to changed pharmacokinetics.
- Do not exceed 1g three times a day in frail, older people (especially Care Home residents). A further dose reduction may be needed if <40kg.
- Use paracetamol suspension for smaller doses and in place of effervescent /soluble paracetamol which contains up to 6g salt (in a 4g/24hours dose), particularly in people with hypertension, cardiac failure & renal failure for example.
- Check whether people are accessing OTC paracetamol or other paracetamol containing products.

Reports of liver failure with therapeutic doses of paracetamol are very rare and widespread use of low doses of paracetamol may result in poorly managed pain and inappropriate escalation to use of NSAID or opioids. However, it is prudent to consider whether a lower dose and/or reduced frequency of administration of paracetamol might be appropriate. As with all analgesics, there should be a regular clinical review of their effectiveness and assessment of adverse effects.

Cannabis-based products for medicinal use

Following the Government's announcement to reschedule certain [cannabis-based products for medicinal use](#), the Royal College of General Practitioners have published [practical advice for GPs](#) which assists practitioners to have informed conversations with patients about medicinal cannabis should the issue arise during consultations. It covers potential indications, legalities of use and what questions patients might ask.

Drug / MHRA Safety Update

Fluoroquinolone antibiotics: new restrictions and precautions for use due to very rare reports of disabling and potentially long-lasting or irreversible side effects. ([Full details available here](#))

Fluoroquinolones are antibiotics authorised for serious, life-threatening bacterial infections. As for all antibiotic medicines, consideration should be given to official guidance on the appropriate use of antibacterial agents used for [managing common infections](#).

Following an EU-wide review of safety, new restricted indications are being introduced for fluoroquinolone antibiotics available in the UK.

- Ciprofloxacin (Ciproxin)
- Levofloxacin
- Moxifloxacin (Avelox)
- Ofloxacin (Tarivid)

Disabling, long-lasting or potentially irreversible adverse reactions affecting musculoskeletal and nervous systems have been reported very rarely with fluoroquinolone antibiotics. Fluoroquinolone treatment should be discontinued at the first signs of a serious adverse reaction, including tendon pain or inflammation.

Advice for healthcare professionals:

- Systemic (by mouth, injection, or inhalation) fluoroquinolones can very rarely cause long-lasting (up to months or years), disabling, and potentially irreversible side effects, sometimes affecting multiple systems, organ classes, and senses.
- **Advise patients to stop treatment** at the first signs of a serious adverse reaction, such as tendinitis (e.g., painful swelling, inflammation), or tendon rupture, muscle pain, muscle weakness, joint pain, joint swelling, peripheral neuropathy, and central nervous system effects, and to contact their doctor immediately for further advice – [useful patient information leaflet](#).
- A useful [patient information sheet](#) has been produced to help healthcare professionals discuss the new measures with patients and the actions patients should take if affected.
- Do not prescribe fluoroquinolones:
 - For non-severe or self-limiting infections, or non-bacterial conditions.
 - For some mild to moderate infections (such as in acute exacerbation of chronic bronchitis and chronic obstructive pulmonary disease; please refer to [revised indications in the Summary of Product Characteristics](#)) unless other antibiotics that are commonly recommended for these infections are considered inappropriate.
- Ciprofloxacin or levofloxacin should no longer be prescribed for uncomplicated cystitis unless other antibiotics that are commonly recommended are considered inappropriate.
- Avoid use in patients who have previously had serious adverse reactions with a quinolone or fluoroquinolone antibiotic.
- Prescribe with special caution for people older than 60 years and for those with renal impairment or solid-organ transplants because they are at a higher risk of tendon injury.
- Avoid use of a corticosteroid with a fluoroquinolone as co-administration could exacerbate fluoroquinolone-induced tendinitis and tendon rupture.
- Report suspected adverse drug reactions to fluoroquinolone antibiotics on the [Yellow Card website](#) or via the Yellow Card app.

Prescribing guidance

Consideration should be given to official guidance on the appropriate use of antibacterial agents. Prescribers should consult NICE and Public Health England's guidance for [managing common infections](#), including upper and lower respiratory and urinary tract infections

The new EU restrictions closely align with existing UK national guidance. The restrictions should not prevent use of a fluoroquinolone for serious or severe infections if this is consistent with UK national guidance or where there are microbiological grounds, and where the benefit is thought to outweigh the risk.

Impending supply issue with Epanutin 50mg Infatabs.

Pfizer, the sole supplier of Epanutin (phenytoin base 50mg) Infatabs have experienced global delays in the manufacturing of this product. As a result, they are anticipating **an imminent** gap in supply until early November 2019.

As you are aware, phenytoin is classified as a Category 1 antiepileptic drug, therefore in the event that you need to prescribe a product from a different manufacturer then this must be carefully managed and increased monitoring of the patient may be required as clinically relevant differences between different manufacturers' products might occur.

Pfizer have been able to secure supplies of a Canadian phenytoin base Infatabs (brand name Dilantin 50mg Infatabs), which will be available when current supplies of Epanutin Infatabs are depleted.

Advice for healthcare professionals:

- Pfizer are confident they have sufficient supplies of Dilantin 50mg Infatabs to meet demand for Epanutin 50mg Infatabs to cover the full out of stock period. **Dilantin will be considered an unlicensed medicine in the UK.**
- The active ingredient in Epanutin 50 mg Infatabs and Dilantin 50 mg Infatabs is the same, however in the absence of bioequivalence data from Pfizer, there may be clinically relevant differences between the two products switching to alternative presentations should be managed under medical supervision and monitoring of phenytoin serum levels are advised to ensure the correct dosage is being given.
- Epanutin 30 mg/5 ml Oral Suspension remains available, however, supplies are only available to meet normal market demand, as such **patients should not be switched to Epanutin Oral Suspension as this may precipitate a shortage of this presentation**
- Alternative formulations of phenytoin continue to remain available including tablets, capsules and injections

Details on prescribing and ordering

- If a clinician chooses to prescribe Dilantin 50mg Infatabs, they should be aware this is an unlicensed medicine in the UK.
- Any decision to prescribe an unlicensed medicine must take into account the relevant GMC guidance and NHS Trust governance procedures. Please see link to GMC guidance: <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines>
- If a prescription for Dilantin 50mg Infatabs is issued Prescribers should ensure that the prescription clearly states that this is a special/unlicensed product. This is to ensure the pharmacies/contractors are reimbursed appropriately.
- Pharmacies/contractors may be unable to dispense Dilantin 50mg Infatabs and/or be reimbursed if the prescription states Epanutin.
- Pharmacies/contractors wishing to order Dilantin should contact Pfizer Customer Contact Centre on 0845 608 8866 directly who will manage the order.

ACTION

Practices should identify all patients currently prescribed Epanutin 50mg Infatabs. Early contact should be made with the patient or the patient's parent/carer to determine if and when switches are likely to be required during this stock out period.

For more information on current medicines supply issues, please see attached document.

Website Update

Disease Modifying Drugs (DMARD) Shared Care Protocol

The DMARD shared care protocol has been updated for use in Rheumatology, Dermatology and Gastroenterology specialities.

Azathioprine, Ciclosporin, Gold (Myocrisin), Hydroxychloroquine, Leflunomide, Methotrexate, Mycophenolate Mofetil, D-Penicillamine and Sulfasalazine have been reviewed and reinstated as **AMBER** medicines. This means that these drugs can be prescribed in primary care following initiation and dose stabilisation by the specialists in secondary care or specialist outpatient clinics for a minimum of 3 months. Following stabilisation, prescriptions and monitoring can be processed in primary care. **The shared care guidance is attached to this email and available [here](#).**

Medicines Optimisation Team

The team would like to welcome Jessica Brooks to the team as the Administrative Assistant to the Medicines Optimisation team.