NHS
Kent and Medway

Medicines Optimisation Newsletter [December 24/ Jan 25] (Issue No.66)

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Kent and Medway ICB Updates

Reminder - Registering for MHRA Safety Alerts

In order avoid duplication of emails by the Medicines Optimisation Team and to ensure you receive important MHRA alerts, please register to receive Central Alerting System (CAS) alerts by emailing SafetyAlerts@mhra.gov.uk. They are currently only registering one email address per GP Practice. Please include the following information in your email:

- The email address you would like the alerts to be sent to
- The full name of your practice / organisation and your NHS ODS code if you have one
- The full address of your practice including postcode.

ADHD Medication Supply Disruption Update – November 2024

Summary of Current Situation

Ongoing supply disruptions are affecting the availability of medications used to treat Attention Deficit Hyperactivity Disorder (ADHD). The situation remains fluid, and guidance will be revised as new information becomes available. It is essential that prescribers remain up to date with the latest guidance and ensure that communication with patients is clear and supportive. This summary reflects the most current advice at the time of publication. For live updates, please refer to the **Specialist Pharmacy Service (SPS) Medicines Supply Tool**.

Key Guidance on Methylphenidate Modified-Release (MR) Products

- During the shortage switching between brands may be necessary
- The MHRA advises caution if switching between MR methylphenidate products as it can alter symptom management at different times of the day. This is due to differences in available strengths, ratios of IR to MR methylphenidate, and pharmacokinetics.
- Please ensure to **prescribe methylphenidate MR products by brand**. Alternatively, prescribe using the generic medicine name **and** name of the manufacturer.
- More information can be found on Considerations when prescribing modified-release methylphenidate – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Important Considerations for Primary Care Prescribers

1. **Pharmacy Dispensing Requirements**

   - Community pharmacies are **legally** required to dispense only what is written on the prescription. Therefore, any changes to the drug, dose, or strength will require a new prescription.
   - To avoid unnecessary delays, prescribers are advised to contact local pharmacies to confirm stock availability prior to issuing prescriptions.

2. **Patient Support and Communication**

   - We recognise that these disruptions may cause anxiety for patients and their families. To support patient communication, NHS Kent and Medway has established a **non-clinical helpline**. Patients seeking more information on ADHD medication shortages or for updates and support can call: **01634 335095** (Option 3, then Option 3 for ADHD Medicine Shortages).

For the latest updates, please visit the **SPS Medicines Supply Tool** or contact NHS Kent and Medway's Medicines Optimisation Team by email kmicb.wkmedman@nhs.net for further advice. ADHD Update 20.11.24 v43 KAM.pdf

TARGET webinars

UKHSA are excited to announce the continuation of the TARGET antibiotics and Royal College of General Practitioners (RCGP) webinar series in 2024/2025! All webinars are hosted online for free, and recordings will be published in the toolkit. The next events are:

- Navigating antimicrobial stewardship for new and early career prescribers **(Wednesday 29 January 2025)**
- Managing recurrent UTI and reviewing long-term/repeat antibiotic therapy **(Wednesday 19 March 2025)**

Full details and registration are available here: Sign up - free webinars for 2024/25: How antimicrobial stewardship can help you | RCGP Learning

Varenicline (Champix)

Varenicline (Champix) is NOT approved for prescribing in primary care in Kent and Medway. Our Local Authority colleagues are working on a PGD so that the supply can be completed in conjunction with the smoking cessation services, further details will follow in due course with regards to when this will become available. In the meantime patients can be directed to smoking cessation services for a different treatment options.

National Updates

National Changes to Community Pharmacy Dispensing Regulations: Original Pack Dispensing

Implementation date: 1st January 2025

Purpose of Document:
To brief colleagues with prescribing responsibilities of the upcoming changes and how this may impact supplies of medicines from community pharmacies.

Background:
The Department of Health and Social Care (DHSC) and Medicines Healthcare Regulatory Authority (MHRA) recently held a public consultation around original pack dispensing, which was agreed and is being taken forward as below from 1st January 2025. These changes will **enable** community pharmacies the flexibility to dispense up to **10% more or less** of a medicine compared to the quantity prescribed, to facilitate original pack dispensing.

The aims and benefits of these changes include:

1. Increase patient safety by ensuring medicines are provided with a complete pack including a patient information leaflet which contains information about the safe and effective use of the medicine

2. Improve dispensing efficiency by reducing time splitting boxes, splitting blister packs and repacking medicines to dispense the exact quantity prescribed.

Impact in practice
These changes will apply to NHS electronic prescriptions only, not NHS paper prescriptions.

Note that mandatory original pack dispensing requirements related to medicines containing sodium valproate has been in place since October 2023, and will not be impacted by this change.

For other medicines, a community pharmacy will have the option to supply 10% more or less than the quantity prescribed only if it would result in an original pack being supplied and the supervising pharmacist is satisfied that the patient can still follow the prescriber's intended regimen. This is not mandatory and therefore some pharmacies may choose to continue dispensing exact quantities as per current arrangements, especially whilst digital and IT systems catch up with the changes.

Some medicines will be exempt from these changes, including:

- Schedule 1-4 Controlled Drugs (Schedule 5 will be included)
- Part IX Appliances
- Unlicensed specials
- Special containers
- Products supplied in accordance with Serious Shortage Protocols (SSPs)
- Products supplied in accordance with Patient Group Directions (PGDs)

Pharmacy owners will be reimbursed for the dispensed quantity rather than the prescribed quantity.

Further Information
Please see the below resources for further information:
Explained: the introduction of Original Pack Dispensing - Community Pharmacy England

MHRA Drug Safety Update – November 2024

The latest MHRA Drug Safety Updates can be accessed at Drug Safety Update - GOV.UK (www.gov.uk) . This includes links to alerts, recalls and safety information and to the monthly Drug Safety Update PDF newsletter.

The November Drug Safety Update includes:

MedSafetyWeek November 2024: your Yellow Card report helps prevent future harm to others and improves patient safety - GOV.UK

Letters and medicine recalls sent to healthcare professionals in October 2024 - GOV.UK

****Please follow the link in the titles above for more information and resources.****

NATIONAL CAS ALERTS (National Patient Safety Alerts and CMO Messages):

The MHRA Central Alerting System alerts can be accessed at CAS - Home (mhra.gov.uk)

Influenza season 2024/25: Use of antiviral medicines CMO Message 3.12.24

UKHSA surveillance data indicates that influenza is circulating in the community. While some areas continue to see low levels of influenza activity, surveillance indicators show that activity is increasing in all levels of care and activity is expected to increase further over the coming weeks. The most notable changes have been a significant increase in influenza positivity through laboratory surveillance and an increase in acute respiratory infection outbreaks with a marked increase in those with influenza reported, principally in care homes.

Prescribers working in primary care may now prescribe, and community pharmacists may now supply antiviral medicines (oseltamivir and zanamivir) for the prophylaxis and treatment of influenza at NHS expense. This is in accordance with NICE guidance, and Schedule 2 to the National Health Service (General Medical Services Contracts (Prescription of drugs etc) Regulations 2004), commonly known as the Grey List or Selected List Scheme (SLS).

Antiviral medicines may be prescribed for patients in clinical at-risk groups as well as anyone at risk of severe illness and/or complications from influenza if not treated.

Further information can be found in the download document within the title document link.

NICE News – December 2024

NICE news Dec 24.docx

Shortages

Shortages Summary

From February 2024 onwards, the monthly Medicines Optimisation newsletter will no longer contain the medicines shortages update document, which was compiled each month from the shortages listed on the SPS (Specialist Pharmacy Services) Medicines Supply tool. The information published on the SPS Medicines Supply tool is provided by DHSC and NHSEI Medicines Supply Teams and was not formally reviewed by the NHS Kent and Medway Medicines Optimisation team.

During the time that the shortages update was compiled and included in the Medicines Optimisation newsletter, practices and healthcare professionals were still encouraged to **register for free access to the** SPS website and to **access the SPS Medicines Supply tool directly** in real time, to have access to the most up-to-date and complete information and advice available. Now that the shortages update will no longer be compiled by the Medicines Optimisation team for inclusion in the newsletter, healthcare professionals will be required to access the SPS Medicines Supply tool to access information on the latest shortages. Serious Shortage Protocols (SPPs) can be found on the NHS BSA website here.

Shortage of Quetiapine modified release tablets, Biquelle XL (150mg, 200mg, 300mg, 400mg, 600mg) and Brancico XL (all strengths)

In light of the current supply issues with certain brands of quetiapine modified-release tablets, where patients have insufficient supplies of Biquelle XL (150mg, 200mg ,300mg and 400mg) or Brancico XL (50mg, 150mg, 200mg, 300mg and 400mg) modified-release tablets, clinicians should **consider prescribing quetiapine modified-release tablets generically**, to enable any available brand to be dispensed, where appropriate.

Where patients have insufficient supplies of Biquelle XL 600mg modified-release tablets consider prescribing quetiapine 150mg, 200mg or 300mg modified-release tablets using the largest strength to provide the required dose.

Prescribers should counsel patients on any changes to their prescribed regime and confirm the quantity of tablets to be taken per dose.

Clinicians should consider taking into account patient history and previous hypersensitivity, or adverse reactions if prescribing generically and may prescribe an alternative brand where appropriate. Patient reassurance may be needed when switching between brands of quetiapine modified-release preparations.

Other brands of quetiapine 50mg, 150mg, 200mg, 300mg and 400mg modified-release tablets remain available and are able to support the market.

Please see more information on SPS Shortage of Quetiapine modified release tablets, Biquelle XL (150mg, 200mg, 300mg, 400mg, 600mg) and Brancico XL (all strengths) – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Shortage of Fiasp (insulin aspart) FlexTouch 100units/ml solution for injection 3ml pre-filled pens

The Kent and Medway Medicines Optimisation Team would like to remind colleagues about the **shortage of Fiasp (insulin aspart) FlexTouch 100 units/ml solution for injection pre-filled pens.** A **tier 2 medicines supply notification (MSN)** was issued on 4th of March 2024 and cascaded to practices.

The shortage started on 1st April 2024, and on 26th November 2024 **the anticipated resupply date has been updated to 2nd January 2026**.

The contents of the MSN and how to manage this supply issue can be viewed here on the Medicines Supply Tool. The Tool also details any updates and changes to re-supply dates. To access the Tool you will be required to register (free) with the SPS website.

The national advice includes **not initiating** patients on Fiasp FlexTouch 100units/ml **pre-filled pens** during this time. Fiasp **Penfill** (insulin aspart) 100units/ml solution for injection 3ml **cartridges** remain available and can support increased demand.

Shortage of Tresiba (insulin degludec) FlexTouch 100units/ml solution for injection 3ml pre-filled pens

The Kent and Medway Medicines Optimisation Team would like to remind colleagues about the **shortage of Tresiba (insulin degludec) FlexTouch 100 units/ml solution for injection pre-filled pens.** A **tier 2 medicines supply notification (MSN)** was issued on 24th of May 2023 and cascaded to practices. This has since been deescalated from a tier 3 to a tier 2 in September 2024.

The shortage started on 1st August 2023, and on 2nd December 2024 **the anticipated resupply date has been updated to 2nd January 2026**.

The contents of the MSN and how to manage this supply issue can be viewed here on the Medicines Supply Tool. The Tool also details any updates and changes to re-supply dates. To access the Tool you will be required to register (free) with the SPS website.

The national advice includes **not initiating** patients on Tresiba **FlexTouch** 100units/ml **pre-filled pens** during this time. Tresiba **Penfill** (Insulin degludec) 100units/ml solution for injection 3ml **cartridges** remain available and can support the increased demand.

The Kent and Medway Medicines Optimisation Team would also like to remind colleagues about the **National Patient Safety Alert (NPSA), Potential for inappropriate dosing of insulin when switching insulin degludec (Tresiba) products, was issued on 8th of December 2024.**

- The Medication Safety Officer (MSO) network has highlighted that in response to this shortage, some patients may have been switched to Tresiba® (insulin degludec) FlexTouch® **200units/ml** solution for injection 3ml pre-filled pens. Tresiba® FlexTouch® pen delivery devices **dial up in unit increments rather than volume**.

- However, a small number of patients have been **incorrectly** advised to administer half the number of units. MSOs have highlighted five reports of patients being **incorrectly** advised to reduce the number of units of insulin to be administered. These reports suggest that errors have occurred at the prescribing, dispensing and administration stages of the medicine journey. One case described a patient requiring treatment in hospital for diabetic ketoacidosis because of a reduced insulin dose.
- Please see the link to the NPSA above which provides further background and clinical information and actions for providers.

The Kent and Medway Medicines Optimisation Team would also like to remind colleagues about **the MHRA drug safety update** High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error.

It is important that healthcare professionals understand **the strengths of available insulin products**, the **differences between them** and **how to use them correctly**; to **minimise the risk of medication errors,** such as the wrong insulin dose being administered.

High strength insulins have concentrations greater than 100 units/ml. Examples of insulin products which have high strength preparations available include, for example:

- Toujeo (insulin glargine 300 units/ml).
- Humalog (insulin lispro 200 units/ml).
- Tresiba (insulin degludec 200 units/ml).

The MHRA alert includes information on:

- **Dose conversion when switching between standard and high strength insulin products.**
- The **'dose step'**, which is a term to define how patients dial up the required drug dose on the prefilled pen.

Please also see the MHRA Drug Safety Update on Insulin Degludec (Tresiba): available in additional higher strength.

General prescribing advice for high strength insulins:

- Consult the individual Summary of Product Characteristics (SPC) and educational material before prescribing.
- Prescribe insulin by **brand name**. Include the **strength (units per ml)** and **presentation** (e.g., cartridge or disposable pen). Write the **insulin dose in units** ("units" to be spelled out and in lower case), **timing** and **frequency**.
- **The pen device shows the number of units of insulin to be injected irrespective of strength; therefore, the insulin dose may stay the same.**
- Seek advice on blood glucose monitoring and dose adjustment from the Diabetes Specialist Team if unsure.
- Check the patient has:
  - Received appropriate training on the correct use of the product and understands the dose required and use of the pen device.
  - Read and understands the patient leaflet and any patient education material.

Discontinuations

Discontinuation of Insulatard® (isophane insulin, human) Penfill® 100units/ml suspension for injection 3ml cartridges

The Kent and Medway Medicines Optimisation Team would like to remind colleagues about the **discontinuation** of **Insulatard® (isophane insulin, human) Penfill® 100units/ml suspension for injection 3ml cartridges.** Stock is anticipated to be exhausted **by June 2025**.
A **tier 2 medicines supply notification (MSN)** was issued on 12th of December 2024 and was cascaded to practices via email. Please see the MSN attached below, which should be read in full:

MSN_2024_112
Insulatard insulin isop

The contents of the MSN and how to manage this supply issue can also be viewed here on the Medicines Supply Tool. The Tool also details any updates and changes to re-supply dates. To access the Tool you will be required to register (free) with the SPS website.

Discontinuation of saxagliptin/metformin (Komboglyze) 2.5mg/1000mg tablets

The Kent and Medway Medicines Optimisation Team would like to inform colleagues about the **discontinuation** of **saxagliptin/metformin (Komboglyze) 2.5mg/1000mg tablets** from **30th November 2024**. Stock is anticipated to be **exhausted from late December 2024**. Please note this is the only available strength of this combination product.
Please see here on the **SPS medicines supply tool** (free subscription required) for the information and actions provided by the DHSC and NHS England. In addition to these actions, the Medicines Optimisation Team would like to supplement this information with local advice and actions:
Recommended actions

- Prescribers should **not initiate new patients** onto saxagliptin/metformin (Komboglyze) 2.5mg/1000mg tablets.
- Prescribers should **identify all patients currently on** saxagliptin/metformin (Komboglyze) 2.5mg/1000mg tablets.
- Patients should be **reviewed** against treatment targets (e.g. HbA1c reduction/metabolic benefit), as well as overall diabetes care assessed, to ensure gliptin use is appropriate and to maximise patient outcomes, in line with NG28.
    - NG28 recommends stopping medicines that have had no impact on glycaemic control or weight, unless there is an additional clinical benefit from continued treatment e.g. cardiovascular or renal protection.
    - If targets have not been met, review the gliptin and optimise therapy for the management of the patient/T2DM, considering alternative therapies in line with NG28 and local guidelines where appropriate e.g. if patients meet criteria for SGLT2i.
- Following review, if a gliptin and metformin are indicated to continue, consider prescribing a gliptin and metformin as **separate preparations** in place of the combination product.
- **Generic sitagliptin** is the most cost-effective gliptin. Generic sitagliptin is **first line** for all eligible patients/new initiations in Kent and Medway. Therefore, where ongoing prescribing of a gliptin is indicated following the diabetes review, if appropriate switch the patient to **generic sitagliptin and metformin, prescribed separately.**

- Patients' **renal function** must be known to allow switching to the appropriate doses of generic sitagliptin and metformin. The table below should be used to ensure dosing of generic sitagliptin is appropriate for renal impairment. Renal function should be monitored as part of annual checks required for T2DM.
- **Monitoring:** ensure that patients who are switched have HbA1c rechecked 3 to 6 months after starting separate generic sitagliptin and metformin.
- Linagliptin is the second line gliptin on formulary in Kent and Medway, to be used only after sitagliptin has been tried, or if eGFR <45ml/min/1.73m^2.
- Saxagliptin, and gliptin/metformin combination products, have formulary statuses of "**not recommended**" in Kent and Medway.
- If generic sitagliptin (or linagliptin) is not suitable for a patient, then please **prescribe saxagliptin and metformin separately** as per the national advice in the MSN.

- **Metformin** 1000mg immediate release tablets have a formulary status of "**not recommended**" across Kent and Medway. Metformin 1000mg immediate release tablets cost approximately 35 times more than the equivalent metformin 500mg immediate release tablets. **Please prescribe metformin in multiples of 500mg immediate release (IR) tablets. Do not prescribe the 1000mg (1g) IR tablets.**

  - **Metformin IR** is recommended **first line** as per NICE NG28: "Offer standard-release metformin as first-line drug treatment to adults with type 2 diabetes".
  - In Kent & Medway, **metformin m/r** is **2nd line**. As well as being in line with guidance, metformin **IR 500mg** tablets are more cost-effective than m/r metformin. Consider metformin m/r second line if metformin IR cannot be tolerated or pill burden is a concern.

- Prescribers should **counsel patients** on any changes to their prescribed regime and confirm the quantity of tablets to be taken per dose of each medication.

Safety & Cautions/Contraindications (see SPCs for further information)
- The adverse effects of the gliptins are broadly similar.
- Saxagliptin: use with caution in patients with heart failure and caution in patients at risk of hospitalisation for heart failure. (Sitagliptin has a neutral effect on risk of heart failure).
- The MHRA reported an increased risk of acute pancreatitis for all gliptins.

Renal impairment dose adjustments if changing to generic sitagliptin:

Renal function (eGFR ml/min/1.73m^2)	**Change to generic Sitagliptin (if renal function stable on current gliptin)**
>50ml/min/1.73m^2	100mg OD
45-50ml/min/1.73m^2	100mg OD
30-44ml/min/1.73m^2	50mg OD
15-29ml/min/1.73m^2	25mg OD
ESRD including dialysis (<15ml/min/1.73m^2)	25mg OD

Note: gliptin SPCs use creatinine clearance (CrCl)/GFR rather than eGFR for dosing; eGFR can be used for gliptins.