Medicines Safety Newsletter

Issue 3 – June 2018

Welcome to our Summer Edition

Welcome to our third edition of the Community Pharmacy West Yorkshire Medicines Safety Newsletter. Our aim is to promote and support safer practice by highlighting to pharmacy teams medication incidents that have occurred both locally and nationally and sharing the lessons that have been learnt to help prevent these from happening again.

Establishing a safety culture is essential to help protect our patients from harm. All humans are fallible and even the most capable pharmacist, technician or pharmacy team member can make a potentially harmful mistake. Having robust systems in place to both detect errors quickly and prevent them from occurring again is key to a safer working environment.

We hope that you find this newsletter both engaging and informative and encourage you to continue to feed in by letting us know about any significant medicines related incidents that have occurred in your workplace. Please feel free to contact us at Community Pharmacy West Yorkshire (see contact details at the end) if you have any comments or would like us to help you in any way.

We hope you all have a fantastic summer and thank you again for your continued support.

Share and Learn

You will already be reporting patient safety incidents nationally, (to the NRLS), and/or via your local reporting system. **Please continue to follow your company's SOP for incident reporting.**

However, it would be fantastic if you could also help us to support all our West Yorkshire pharmacy teams by "sharing the learning". If you have come across or been involved in a dispensing error (or other medicines related incident) it is likely that this may not be a "one off". The chances are that this may have already happened at the pharmacy over the road and may yet happen at the pharmacy in the next town. By reporting incidents and sharing the learning you can prevent this from happening and potentially save a patient from harm.

Report it – for everyone's sake!

If you wish to share any medicines safety incidents, (with your learning), with other West Yorkshire pharmacies via this newsletter please complete the Report, Learn, Share, Act, Review template (click here) and return to info@cpwy.org.

All reports will be treated completely anonymously and no details of who submitted the report will be shared outside of the Community Pharmacy West Yorkshire team. Please remember to NOT send any patient identifiable details.

MHRA DRUG SAFETY UPDATE VALPROATE LICENCE CHANGE: IMPORTANT INFORMATION FOR PHARMACY TEAMS

The Medicines and Healthcare products Regulatory Agency (MHRA) has changed the licence for valproate medicines (Epilim, Depakote and generic brands) so it must no longer be prescribed to women or girls of childbearing potential unless they are on the Pregnancy Prevention Programme (PPP).

This is because valproate is associated with a significant risk of birth defects and developmental disorders in children born to women who take valproate during pregnancy. The change in licencing is to make sure patients are fully aware of the risks and the need to avoid becoming pregnant. These new regulatory measures also include a ban on the use of valproate for migraine or bipolar disorder during pregnancy, and a ban on the use of valproate to treat epilepsy during pregnancy unless there is no other effective treatment available. Healthcare professionals who seek to prescribe valproate to their female patients must make sure they are enrolled in the PPP which includes completion of a signed risk acknowledgement form when their treatment is reviewed by a specialist, at least annually. All women and girls who are prescribed valproate should contact their GP and arrange to have their treatment reviewed. No woman or girl should stop taking valproate without medical advice.

The April Drug Safety Alert includes actions for all healthcare professionals. GPs are asked to identify and recall all women and girls of childbearing potential, provide the Patient Guide and check they have been reviewed by a specialist in the last year and are on highly effective contraception. Action for community pharmacists include:

ACTIONS FOR COMMUNITY PHARMACY TEAMS

- To ensure valproate medicines are dispensed in whole packs whenever possible — all packs dispensed to women and girls of childbearing potential should have a warning label either on the carton or via a sticker (see below for more about warnings added to packs).

- Pharmacists should give a patient card (see below) to female patients when dispensing valproate. Packs of valproate medicines will start to be available with a detachable patient card from December 2018.
- To discuss risks in pregnancy with female patients each time valproate is dispensed and ensure patient guide has been given and patient has seen their GP or specialist to discuss treatment and the need for contraception.
- If a woman or girl of childbearing potential reports that she is not taking effective contraception, pharmacists should advise her to contact her GP for an urgent follow-up.

The MHRA valproate guidance page provides all the background information to the changes and includes some useful resources for pharmacy teams. This includes the patient card which should be given by pharmacists to all female patients who are dispensed valproate medicines to inform them of the risks.

Hard copies of these materials will be sent to healthcare professionals shortly including stickers with warning symbols for pharmacists to add to the packaging of valproate medicines (see below).

To support these materials the MHRA has also produced a patient information sheet (including a large print version) which may be useful when discussing these new measures with patients.

Warnings added to the packaging of valproate medicines

A visual warning symbol will be added to the carton of valproate medicines by September 2018. This symbol will show a pregnant woman in a red circle with a line through it, with warning text about the risks and information about the new measures.

Pharmacists should therefore dispense in whole packs whenever possible to ensure that patients always see the warning symbol and receive the statutory information. If you must split a pack, or if the carton does not have a symbol on it, warning labels should be added to the box. These will be sent out in the post with the educational materials discussed above.

MHRA DRUG SAFETY UPDATE: DRUG-NAME CONFUSION: REMINDER TO BE VIGILANT FOR POTENTIAL ERRORS

Since the last Drug Safety Update on drug-name confusion in 2013 (see here) there have been a number of recent cases, some with fatal outcomes, where patients have received the wrong medicine due to confusion between similarly named or sounding brand or generic names, and Yellow Card reports of harm have been received following confusion between the drugs listed in the table below:

Clobazam (benzodiazepine)	Clonazepam (antiepileptic drug)
Atenolol (beta blocker)	Amlodipine (calcium channel blocker)
Propranolol (beta blocker)	Prednisolone (corticosteroid)
Risperidone (antipsychotic)	Ropinirole (dopamine agonist)
Sulfadiazine (antibiotic)	Sulfasalazine (disease-modifying anti-rheumatic drug)
Amlodipine (indicated for hypertension and angina)	Nimodipine (indicated for the prevention of ischaemic neurological deficits following aneurysmal subarachnoid haemorrhage)

See the Drug Safety Update in April 2013 for more examples.

Advice for healthcare professionals includes:

- To be extra vigilant when prescribing and dispensing medicines with commonly confused drug names to ensure that the intended medicine is supplied.
- If there is any doubt about which medicine is intended, community pharmacists should contact the prescriber before dispensing the drug.
- To follow local and professional guidance in relation to checking the right medicine has been dispensed to a patient.

Double checking when prescribing or administering any medicines is important to avoid any medication errors. This should include:

✓ **Right medicine**
✓ **Right patient**
✓ **Right dose**
✓ **Right route**
✓ **Right time**

Community pharmacy teams are asked to report any look-alike, sound-alike errors to the MHRA via patient.information@mhra.gov.uk.

INCIDENT SHARING

The following are summaries of some of the medicines safety incidents which have been reported from our local pharmacy teams. THANK YOU to everyone that has shared details of their incidents with us. This will hopefully benefit other local pharmacies by helping to avoid the same errors happening again, and thus potentially helping to avert patient harm.

Wrong drug/medicine – following on nicely from the MHRA article above, a report was received about a patient who was dispensed Fibrazate XL 400mg tablets INSTEAD of Flomaxtra XL 400mg tablets. Following a review of the incident the pharmacy have now placed warning labels in front of stock and added notes to the PMR to try and prevent this from happening again.

Wrong drug/medicine – Gabapentin was dispensed instead of Pregabalin. The patient had been taking the Gabapentin 1.5g (instead of the prescribed 1.5g Pregabalin) for approximately 6 weeks before the error was identified. The pharmacy reviewed the incident and identified a number of contributory factors including staffing, (there were a number of trainees working that day and the dispenser was a newly recruited pharmacy student), and that the two medicines have similar strengths, (both the 300mg & 100mg strengths were dispensed incorrectly). A team huddle was held for the whole dispensary team to discuss the incident and generate an improvement plan. This helped the team to identify several changes as a result of the incident including placing "select with care" stickers on both shelves where Gabapentin and Pregabalin is stored.

Community Pharmacy West Yorkshire Comment – Please exercise caution when dispensing any medicines with similar names and/or packaging. As the pharmacy that reported this incident has done, it is important that you analyse errors which have occurred in your pharmacy and draw up a list of medicines which have been commonly involved in errors especially those with similar sounding names and similar packaging. Ensure that all members of the pharmacy team, especially pharmacists, are aware of this list and take additional care when dispensing them. Take steps to minimise the risk of further errors with these medicines, for example by separating the products on the dispensary shelves, or by using labels to highlight on the shelf edge.

The two most common error categories in the NPA's patient safety quarterly report for January to March 2018 were dispensing a wrong/unclear dose or strength (31%) and dispensing the wrong drug/medicine (21%). The top look-alike/soundalike medicines reported in the wrong drug medicine category are indicated below. As you can see this also includes pregabalin/gabapentin.

Top Mistaken Medicines (Jan – Mar 2018)	
Amitriptyline	*Amlodipine*
Colchicine	*Cyclizine*
Pantoprazole	*Paroxetine*
Pregabalin	*Gabapentin*

Wrong drug/medicine – Prescription for finasteride 5mg tablets received but methotrexate 2.5mg tablets dispensed. When reviewing the incident the pharmacy team identified that both finasteride and methotrexate are in small boxes which are the same size as each other and are so small that the dispensing label covers the whole of the box. Additionally, although on separate shelves in the dispensary, they are located in the same area (one shelf directly above each other). Actions put in place to try and prevent this incident from happening again have included moving methotrexate to the CD cabinet for safe storage.

Wrong formulation – a prescription was received for "Montelukast 10mg (Teva UK Ltd)". The prescription was dispensed using another brand on 2 separate occasions. The patient became unwell, (they had previously had the Teva brand and were stable on this), and a complaint made to the GPhC. Following a thorough investigation the pharmacy have implemented a number of changes to their procedures:

- Always check with the prescriber when it looks like a generic medicine has been prescribed, (but has a manufacturer specified in brackets), that the specific brand is what is actually required rather than just a selection error by the prescriber.
- A note has been added to the patient's PMR that only the Teva brand should be dispensed for this patient.
- A meeting was held with the GP and practice manager and agreement reached that where a specific brand is clinically necessary the dosage on future prescriptions will carry specific instructions, e.g. "dispense as Teva" to distinguish from when a specific brand is required from when it has been inadvertently selected on the surgery computer.

Community Pharmacy West Yorkshire Comment – where a prescription for a generic medicine specifies the name of a manufacturer or supplier, legally and ethically that manufacturer's product must be dispensed and the pharmacy will be reimbursed based on the manufacturer or suppliers list price. Out of pocket expenses in procuring the product may be claimed where appropriate. Guidance on out of pocket expenses can be found here.

It is recognised that sometimes the product may have been selected unintentionally by the prescriber and that actually a specific manufacturer's brand was not intended. We would therefore suggest that community pharmacists should:

1. *Double check with the patient to ascertain whether that brand is indeed required (ensure you endorse the prescription correctly to reflect what has been dispensed).*
2. *Double check with the prescriber to confirm that the brand prescribed is intended (again ensure you endorse the prescription correctly to reflect what has been dispensed).*

PSNC has received a number of reports of prescribers unintentionally issuing prescriptions in this way because of the way products are listed in the picking-list of their prescribing system.

This practice is not in the interests of patients, the NHS or community pharmacy as for example, this could lead to increased prescribing costs and delays in patients obtaining their medicines. Where contractors identify any issues locally, we would always encourage that this is discussed with the prescriber.

Bitesize News

- **The MESH Service** - a medicines support at home service (MESH) has been funded by NHS Bradford City & District CCGs to give patients in Bradford medicines management support at home.

  It is aimed at people who regularly take 10 or more medicines, or 4-9 but "at risk" from their medicines, are unsure of what their medicines are for, regularly forget to take their medicines, or are not feeling the benefit of taking the medicines they are prescribed. The MESH medication review offers a detailed level 3 medication review in a patient's own home or care home. Patients can be referred into the service by contacting the MESH helpline on 07944 515915 or emailing PSS.MESH@nhs.net

- Legislation introducing new legal defences to prevent the automatic criminalisation of inadvertent dispensing errors came into force on the 16 April 2018. This new defence is expected to reduce fear of prosecution, leading to a professional increase in the reporting of dispensing errors and thus the learnings from these errors to help prevent them from happening again. The Royal Pharmaceutical Society have recently produced professional guidance for members which includes a simple one-page summary document, "Making things right when there's been a dispensing error" which can be downloaded from https://www.rpharms.com/making-things-right#what

- Do not use anti-inflammatory painkillers in chickenpox – pharmacists are reminded that the use of anti-inflammatory painkillers, such as ibuprofen, in adults and children with chickenpox should be avoided. This is due to NSAIDS being associated with an increased risk of severe skin and soft tissue infections particularly in children. If an analgesic is required, paracetamol should be used instead. When supplying over the counter products for use in children with chickenpox pharmacists are strongly advised to follow NICE Clinical Knowledge Summaries on the management of chicken pox. See here.

[1] Thank you to Weldricks Pharmacy for allowing us to share this article with West Yorkshire pharmacies

DO YOU KNOW HOW TO USE A SPOON? [i]

An unusual title admittedly, but a French study from 2016 found that in a sample of 100 caregivers asked to measure a 5ml dosage on a standard 5ml spoon, 56% measured incorrectly, with one of the sources of error being caregivers incorrectly identifying a line on the spoon indicating a 2.5ml dose as the 5ml one.

An alert was sent out previously about a spoon supplied in a particular generic version of amoxicillin. The issue with the spoon appeared to be unique to amoxicillin among the range of liquid medicines the manufacturer supplied, but if measured on a flat surface rather than being held while the liquid was poured out, what appeared to be 5ml of amoxicillin was actually 7.8ml.

These two situations hopefully emphasise that what you probably consider as something simple and not needing to form part of your patient counselling may sometimes need to be included, particularly where a dosing device is included with the product and may have markings that could be misinterpreted. It would be very easy to come across as patronising with this, but a quick reminder of the dose, and mentioning that you've noticed that the spoon has a couple of different measurements on it and to make sure they're measuring to the correct one should suffice.

An incident was recently reported by the NHS England Local Area Team involving an overdose of oramorph due to a medicine spoon not being supplied (they do not come in the box). Community pharmacies are reminded that they should provide a suitable spoon or oral syringe with each medicine that requires one. For products that come with a measuring device these should always be given out rather than substituted or removed. You should always make sure on giving out medicines that patients are familiar with their use and how to dose. Be prepared to explain how to use an oral syringe correctly, or any supplementary device you might be supplying.

TACKLING INAPPROPRIATE SUPPLIES OF CONTROLLED/HIGH RISK DRUGS

A letter was recently sent out by NHS England (see here) which reports a significant increase in incidents where patients have tried to obtain inappropriate additional supplies of controlled/high risk drugs through various service pathways:

"*Patients have frequently presented through the Pharmacy NUMSAS Service; attended OOH GP Care Providers or A & E Departments and successfully managed to obtain supplies at multiple sites across the Yorkshire and Humber region in a very short period of time. Furthermore there has been a report of a patient who consecutively attended five different A&E Departments in our region and managed to obtain supplies of Pethidine".*

All these incidents highlight the potential for patient harm and everyone has a duty of care to identify, manage and reduce this risk within your organisations.

A multidisciplinary approach has been established to tackle the issue including a number of actions for community pharmacies. Please ensure that you have read the letter (see here) and retain a copy for relevant members of your team. Remember, **access to the Summary Care Record is an invaluable tool and should be checked to support decisions for any requests for urgent supply of medicines.**

COMMUNITY PHARMACY ORAL ANTICOAGULANT SAFETY AUDIT

The NHS Community Pharmacy Contractual Framework (CPCF) includes a requirement that community pharmacies undertake two clinical audits each year. NHS England determines the topic of one of the audits and community pharmacy contractors are free to determine the topic of the second audit.

NHS advice on safe anticoagulant therapy is more than 10 years old, and a number of new types of anticoagulant are now in common use. All anticoagulants however are associated with several patient safety hazards. PSNC recommends the Community Pharmacy Oral Anticoagulant Safety Audit created by the NHS Specialist Pharmacy Service. This audit will provide a safety check for patients prescribed anticoagulants and an insight on the current use of alert cards and record books. The audit is available to all contractors to use and is readily available via PharmOutcomes. For more information on this audit see here.

More information and paperwork for other audits can be found on the PSNC website here.

The page has recently been updated with a new valproate medicines safety audit which has been created by the Company Chemists' Association (CCA) to help pharmacy teams to review their support for girls and women taking valproate medicines, reflect on current practice and assess what changes may be required to meet new MHRA requirements (as discussed earlier in the newsletter). The first phase of the audit starts in July 2018 and the second phase starts in November 2018. Please see here for further information.

Drug Safety Updates (MHRA)

Contents of recent Drug Safety Updates are listed below. Where this has particular relevance to community pharmacy this has been highlighted in red and a summary of the advice provided. For further information about any of these updates refer to MHRA Drug Safety Updates in full by clicking here.

January 2018 (click here for January Drug Safety Update)

- Daclizumab (Zinbryta▼) and risk of severe liver injury: new restrictions to use and strengthened liver monitoring.
- Recombinant human erythropoietins: very rare risk of severe cutaneous adverse reactions (SCARs).
- **Drug-name confusion: reminder to be vigilant for potential errors.** This has been covered in more detail in the body of the newsletter - see above.
- **Co-dydramol: prescribe and dispense by strength to minimise risk of medication error.** Previously co-dydramol (dihydrocodeine/paracetamol) was available only as 10/500 mg). Two products are now available with a higher strength of dihydrocodeine (co-dydramol 20/500 mg and 30/500 mg tablets). It is therefore important that co-dydramol products are prescribed and dispensed by strength to minimise dispensing errors and the risk of accidental opioid overdose. Prescribers are asked to clearly indicate tablet strength and dose when writing a prescription for co-dyramol. When dispensing co-dyramol pharmacists are asked to ensure patients receive the prescribed strength of co-dyamol, and, if in doubt, contact the prescriber.
- Herbal medicines: report suspected adverse reactions via the Yellow Card Scheme page.

March 2018 (click here for March Drug Safety Update)

- Daclizumab (Zinbryta▼): suspension and recall for safety reasons; review patients as soon as possible and start alternative therapy.
- Esmya (ulipristal acetate) for uterine fibroids: do not initiate or re-start treatment; monitor liver function in current and recent users.
- **Head lice eradication products: risk of serious burns if treated hair is exposed to open flames or other sources of ignition, e.g. cigarettes**. There have been a number of serious burns associated with Hedrin 4% cutaneous solution which have been reported to the MHRA. The most recent of these was last year when a child undergoing treatment came into contact with a naked flame, resulting in very serious burns. Pharmacists should encourage all patients to read the instructions carefully for all headlice eradication products. The MHRA provides the following advice to pharmacists:
    - Some products for the eradication of head lice infestations are combustible/flammable when on the hair and can ignite and cause serious harm in the presence of an open flame or other source of ignition such as when lighting cigarettes
    - Advise parents, caregivers and the person with head lice, if appropriate, that they should not smoke around treated hair and that it should be kept away from open flames or other sources of ignition, including in the morning after overnight application until hair is washed

- Always advise parents and caregivers and the person with head lice to read the instructions that come with treatments to ensure that they are used safely and correctly

April 2018 (click here for April Drug Safety Update)

- **Valproate medicines (Epilim▼, Depakote▼): contraindicated in women and girls of childbearing potential unless conditions of Pregnancy Prevention Programme are met**. This has been covered in more detail in the body of the newsletter – see above.
- Obeticholic acid (Ocaliva▼): risk of serious liver injury in patients with pre-existing moderate or severe hepatic impairment; reminder to adjust dosing according to liver function monitoring.
- Suspect an adverse reaction? Yellow Card it!

May 2018 (click here for May Drug Safety Update)

- **Valproate medicines (Epilim▼, Depakote▼): Pregnancy Prevention Programme materials online.** This has been covered in more detail in the body of the newsletter – see above.
- **Braltus (tiotropium): risk of inhalation of capsule if placed in the mouthpiece of the inhaler.** The MHRA have received reports of patients who have inhaled a Braltus capsule from the mouthpiece into the back of the throat, resulting in coughing and risking aspiration or airway obstruction. Braltus, (tiotropium), 10 µg per delivered dose inhalation powder is a once-a-day maintenance bronchodilator treatment authorised to relieve symptoms in adults with chronic obstructive pulmonary disease (COPD). The inhalation powder is provided in capsules for inhalation using the Zonda inhaler device. The following advice has been issued for healthcare professionals:
    - Train patients in the correct use of their inhaler. A placebo device is available for training purposes, (from Teva Medical Information. Email medinfo@tevauk.com or call 0207 5407117), and instructions for patients are provided in the patient information leaflet and on the carton.
    - Tell patients to store capsules in the screw-cap bottle provided (never in the inhaler) and to always check the mouthpiece is clear before inhaling.
    - Pharmacists dispensing Braltus capsules should remind patients always to read the instructions for use in the package leaflet and that they must never place a capsule directly into the mouthpiece.

The PSNC's patient safety information page contains a list of patient safety alerts, advice and guidance and MHRA monthly drug safety updates and is useful as a quick reference guide for pharmacy teams to check that they are aware of all these and have taken appropriate action when required.

If you have any feedback, suggestions or wish to include anything in our next newsletter please email info@cpwy.org. Thank you.