Medicines Safety Newsletter

Issue 1 – October 2017

Let's Talk About Medicines Safety

Welcome to the first edition of Community Pharmacy West Yorkshire's new quarterly Patient 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.

We hope you will feed in to this newsletter by letting us know about any significant medicines related incidents that have occurred in your workplace. By working together and sharing your learning from these incidents we can help prevent the same or similar incidents from happening again which in turn helps to protect our patients from harm.

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, one of the requirements for the Written Patient Safety Report Quality Criterion, (Quality Payments Scheme), is that contractors can demonstrate evidence of sharing learning both locally and nationally. This newsletter provides an opportunity for our local pharmacy teams to share their learning from incidents or near misses that have occurred locally.

So, Please Share and Learn

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 the Community Pharmacy West Yorkshire team. Please DO NOT send patient identifiable details.

Patient Safety Alert

Resources to Support the Safety of Girls and Women Being Treated with Valproate

Community Pharmacy Action Required

The Medicines and Healthcare products Regulatory Agency (MHRA) and NHS Improvement published a patient safety alert in April relating to girls and women who are being treated with valproate (also known as valproic acid – brand names include Epilim and Depakote).

Valproate is associated with serious harm to foetal development. It can cause birth defects and developmental disorders, and should not be taken by women and girls unless no other medication is effective. It is vital where valproate is prescribed to girls and women of childbearing potential that they are made aware of the risks of taking the medication in pregnancy. The need for effective contraception must also be emphasised, along with the requirement for specialist oversight to safely change their medication if planning a pregnancy.

The MHRA has issued a booklet for Healthcare Professionals, a credit sized patient card, a checklist for patients and prescribers and a patient information booklet. These materials highlight the risks of taking valproate whilst pregnant and remind patients to use effective contraception and to see their prescriber urgently should they be planning, or become, pregnant. A full list of resources can be found on the MHRA website here.

The actions in the alert requires community pharmacists who are dispensing valproate to girls or women of childbearing age to ensure that MHRA resources are used to help support patients make a fully informed decision.

Pharmacies should have already received a small number of Valproate Patient Cards and Patient Guides.

Further copies can also be ordered, at no cost, by contacting Sanofi Medical Information on 0845372 7101 or by emailing: uk-medicalinformation@sanofi.com.

They can also be downloaded from the EMC website (see links above).

The Royal Pharmaceutical Society has worked with the MHRA and the Royal College of General Practitioners to produce a short video about the risks of valproate, a medicine prescribed for epilepsy and bipolar disorder. The video is aimed at GPs, pharmacists and other healthcare professionals and gives an overview of the latest MHRA guidance on discussing the medication with patients. See here.

Contractors are reminded that the patient safety report required for the patient safety report quality criterion should include evidence of actions taken in relation to patient safety alerts such as the one above. Therefore, please make sure you document any actions taken.

ACTIONS FOR THE PHARMACIST/PHARMACY TEAM

ENSURE THAT PROCESSES ARE IN PLACE TO ALLOW THESE ACTIONS TO BE MET

- **When dispensing any valproate preparation to female children, female adolescents, women of childbearing potential or pregnant women CHECK that their prescriber has discussed the risks of in utero exposure with them and are aware of these.**
- **If the prescriber HAS NOT DISCUSSED the risk with the patient, contact the prescriber and remind them of their responsibility to do so and ask them to arrange an urgent follow-up appointment with the patient.**
- **PROVIDE a Valproate Patient Card every time you dispense a valproate preparation to females with childbearing potential or pregnant women (unless she confirms she already has one). Encourage patient to read the card and enter name and date to reinforce own accountability that they have considered the information it contains.**
- **ASK if the patient has received a Valproate Patient Guide (booklet), and if not provide a copy.**

Other Patient Safety News

Important Reminder: Serious Interaction Between Miconazole Oral Gel and Warfarin.

Please remember to check that the patient is NOT taking Warfarin when selling or dispensing Miconazole Oral Gel.

The interaction between miconazole oral gel and warfarin is well documented, yet patients continue to be put at significant risk. We have recently received yet another report from the local anticoagulant service of a warfarin patient presenting with an INR >8 after using miconazole oral gel which they had purchased OTC.

Miconazole oral gel is extremely well absorbed from the buccal mucosa, leading to high levels systemically. It is a strong cytochrome P450 (CYP2C9) inhibitor which prevents warfarin from being metabolised, causing high levels of warfarin and leading to a risk of bleeding.

Interactions have also been seen with the vaginal gel and topical miconazole creams.

Practice Points:

- The concurrent use of warfarin should be regarded as a contraindication to the use of miconazole oral gel.
- Miconazole oral gel should NOT be sold to patients taking warfarin.
- If a warfarin patient has been prescribed miconazole oral gel, community pharmacists should alert the prescriber and recommend an alternative.
- Pharmacists should ensure all counter staff are made aware of this serious complication with miconazole's use and ensure relevant queries are referred to the pharmacist for advice.
- If patients on warfarin report using miconazole oral gel, they should be advised to contact their anticoagulant clinic for an urgent INR.
- Any patient taking warfarin who presents with bleeding should be immediately referred to their GP and anticoagulant monitoring clinic.

Insulin Identification Checker

Patient safety incidents involving insulin seem to be a common occurrence and are reported frequently at the local Medicines Safety Group meeting. The NPA have recently launched a new patient safety resource – the insulin identification checker which has been developed to support pharmacy teams in minimising the risk of dispensing errors involving insulin. The resource is intended to help you identify and distinguish between the different types of insulin available.

Fire Risk – Paraffin Based Emollients

Individuals using paraffin-based emollients should be advised to keep away from fire or flames as dressings and clothing soaked with the emollient can be easily ignited.

NHS Improvement and the MHRA have been reminding healthcare professionals of the fire risks that paraffin-based products can cause, following a number of serious incidents and a recent fatality. When patients are being treated with a paraffin-based emollient product that is covered by a dressing or clothing, there is a danger that smoking or using a naked flame could cause the dressings or clothing to catch fire.

Community pharmacy teams have a role to play in advising patients not to smoke; use naked flames (or be near people who are smoking or using naked flames); or go near anything that may cause a fire while emollients are in contact with their medical dressings or clothing. There is of course an important balance to strike when counselling people on these risks, to ensure patients do not stop using the products out of fear (which could worsen their condition).

Useful resources which pharmacy teams can distribute when counselling their patients on the risks include posters, stickers and patient leaflets developed by the NPSA. Teams may wish to record in their PMR system each time these are distributed. Paraffin safety resources can be downloaded here.

PSNC Patient Safety Information

You may find the PSNC patient safety information page a useful reference source when completing your written patient safety report (to meet the Quality Payments Scheme quality criterion) to check that you are aware of all patient safety alerts that have been issued and that you have taken any appropriate action where required.

This page contains a list of:

- Patient safety alerts and recalls which have previously been highlighted as news stories on the PSNC website
- Advice and guidance relating to patient safety which have previously been highlighted as news stories on the PSNC website
- A link to the Medicines and Healthcare products Regulatory Agency (MHRA) monthly drug safety updates

Although pharmacy teams should have responded as appropriate to the above within the required time frames, those that have been highlighted as news stories on the PSNC website have been listed on this page as a quick reference for pharmacy teams to check that they are aware of all of these and have taken appropriate action when required.

If you have any feedback or suggestions about this newsletter, please email info@cpwy.org. Thank you.