Medicines Safety Matters

Sharing Learning Across Community Pharmacy In Northern Ireland

Vol 1 Issue 1 Jan 2012

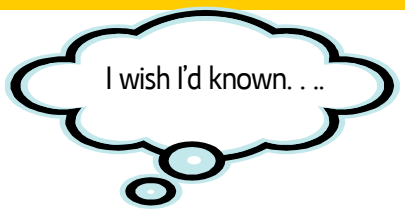
This newsletter is sent to all Community Pharmacies in NI.

Please share with your colleagues.

It is also available on the HSCB website, see link on the back page

Inside this issue:

Sharing learning from incidents and near misses



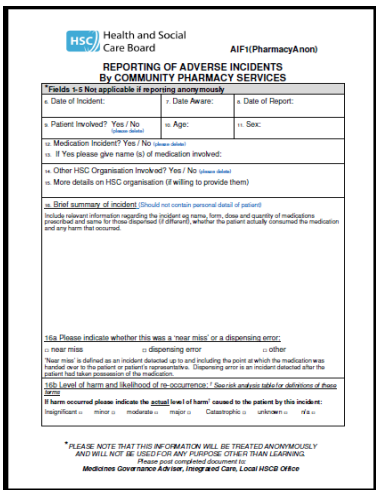
Based on information from a study conducted in 35 Community Pharmacies in Manchester [1] it is estimated that there could be over 94,000 dispensing incidents occurring in NI per year.
If details on dispensing incidents could be captured and any learning from them disseminated, there would be a huge potential to prevent similar incidents from happening in the future.
The Board has developed a process to allow such reporting to take place anonymously using the HSCB Adverse Incident Reporting Form. A series of nine evening training events were held across NI to raise awareness on how pharmacists can make practice safer and 236 pharmacists, mostly working in community, attended the training. Following this, all community pharmacies received a pad of 50 Adverse Incident Reporting Forms.

There are no hidden identifiers on the form and it will be treated anonymously, without HSCB follow-up. The purpose of the forms is to determine what the error involved, why it happened and what measures can been taken to help reduce re-occurrence of similar incidents.

We encourage reporting of all incidents and would ask that you consider putting in place a process for staff to complete and submit these forms as and when either a dispensing error or 'near miss' occurs.

Data from the submitted forms is being used to analyse trends and produce the articles for this newsletter, which is sent to all community pharmacies across Northern Ireland for the purpose of highlighting any learning points.
Completed forms should be posted to the Medicines Governance Pharmacist at your local HSCB office.
If you have any queries please contact us (see back page for details).

1. Ashcroft D et al. Pharmacoepidemiology and Drug Safety 2005; 14: 327-32.


Health and Social Care Board

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REPORTING OF ADVERSE INCIDENTS
By COMMUNITY PHARMACY SERVICES

*Fields 1-5 Not applicable if reporting anonymously

1. Date of Incident:
2. Date Aware:
3. Date of Report:
4. Patient Involved? Yes / No (please delete)
10. Age:
11. Sex:
12. Medication Incident? Yes / No (please delete)
13. If Yes please give name (s) of medication involved:
14. Other HSC Organisation Involved? Yes / No (please delete)
15. More details on HSC organisation (if willing to provide them)
16. Brief summary of incident (Should not contain personal detail of patient)
Include relevant information regarding the incident eg name, form, dose and quantity of medications prescribed and same for those dispensed (if different), whether the patient actually consumed the medication and any harm that occurred.
16a Please indicate whether this was a 'near miss' or a dispensing error:
near miss
dispensing error
other
'Near miss' is defined as an incident detected up to and including the point at which the medication was handed over to the patient or patient's representative. Dispensing error is an incident detected after the patient had taken possession of the medication.
16b Level of harm and likelihood of re-occurrence: * See risk analysis table for definitions of these terms
If harm occurred please indicate the actual level of harm' caused to the patient by this incident:
Insignificant
minor
moderate
major
Catastrophic
unknown
n/a
*PLEASE NOTE THAT THIS INFORMATION WILL BE TREATED ANONYMOUSLY AND WILL NOT BE USED FOR ANY PURPOSE OTHER THAN LEARNING.
Please post completed document to:
Medicines Governance Adviser, Integrated Care, Local HSCB Office

Initial reports received from Community Pharmacists

We are pleased to feed back that anonymous incident reports are already being received from community pharmacists. Most incidents relate to an incorrect dose or strength of medication being dispensed, followed by the wrong medication being dispensed, as summarised in the table below:

Type of error	% occurrence
Dose or strength was wrong or unclear	53
Wrong/unclear drug/medicine	19
Mismatch between patient and medicine	12
Formulation of medication was wrong	7
Wrong quantity	4
Wrong/transposed/omitted medicine label	3
Omitted/delayed medicine or dose	2

Featured Anonymous Incident - Pramipexole

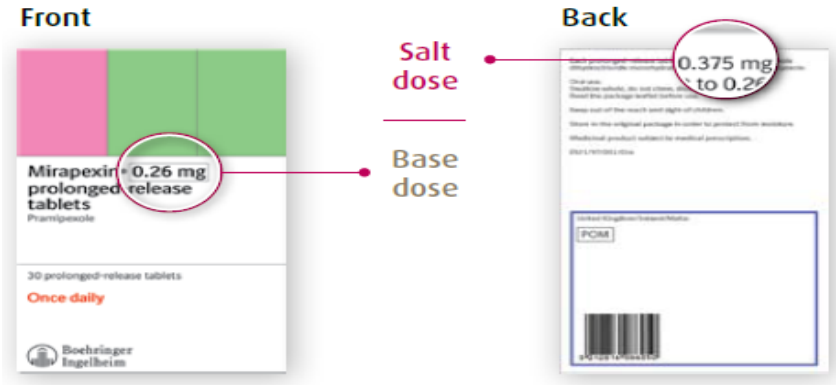
It can be very confusing when drug manufacturers express the strength of their medication in two different forms. This is the case with pramipexole (Mirapexin®) which is licensed to treat Parkinson's disease and moderate to severe restless leg syndrome. The strength of pramipexole can be expressed as either:

- Base = pramipexole **or**
- Salt = pramipexole dihydrochloride monohydrate

Why is the strength expressed in two different ways?
In 1998 when Mirapexin® was first licensed, the European Licensing Authority had just changed its policy from licensing a product expressed as salt to licensing a product expressed as base. However the drug company's published studies and promotional material had already expressed the strength in terms of the salt.

- BNF doses and strengths are stated in terms of the BASE
- GP clinical systems and prescriptions may present the strength as either base, salt or both
- Tablet strengths or doses may be stated in milligrams OR micrograms.

Dose equivalents for the base and the salt are shown in the table on page 3.



Reported Incident

A Community Pharmacist has reported the following incident:
The patient was prescribed **pramipexole m/r 2.1mg base (3mg salt)** but due to confusion about strengths, was dispensed **pramipexole m/r 3.15mg base (4.5mg salt)**. The patient returned the medication before it had been taken. The pharmacist took the following measures to prevent re-occurrence of the incident:

- All pharmacy staff were briefed about the incident
- 'Caution with dose' warning labels were placed on the medicine boxes and the different strengths separated well on the shelves
- All patients taking this medication have had the following warning placed on the Patients' Medication Records 'check BNF for dose at time of dispensing'
- Get second check from another pharmacist if possible.

Advice:

- Be aware that prescriptions for pramipexole (Mirapexin®) may have:
  - The strength expressed as the salt or the base, in most cases, both will be stated
  - The strength/dose expressed in either milligrams or micrograms
- Double check medication packages of pramipexole (Mirapexin®) for the strength, as both salt and base and ensure this matches the strength on the prescription.

Pramiprexole Base & Salt Dose Equivalents

Pramipexole base	Pramipexole dihydrochloride monohydrate salt
Pramipexole (Mirapexin®)	
88 micrograms base	125 micrograms salt
180 micrograms base	250 micrograms salt
350 micrograms base	500 micrograms salt
700 micrograms base	1mg salt
Pramipexole (Mirapexin®) prolonged release	
260 micrograms base	375 micrograms salt
520 micrograms base	750 micrograms salt
1.05 mg base	1.5 mg salt
1.57 mg base	2.25 mg salt
2.1 mg base	3 mg salt
2.62 mg base	3.75mg salt
3.15 mg base	4.5 mg salt

Medication Out Of Stock - Patient Hospitalized

An adverse incident has been reported involving a patient with schizophrenia. His condition had been well controlled on trifluoperazine (Stelazine®) and he attended the same local pharmacy for his prescriptions. However, over the summer there had been problems with supply, the pharmacy was unable to source the medication and the patient did not have his prescription dispensed.
However, the GP was not made aware that this patient was not receiving his antipsychotic medication. Two months later, the patient's mental health had deteriorated to an extent that he was sectioned and hospitalised.

When you have difficulty sourcing a medication, would you inform the patient's GP?

Advice:

- When medications are not available from your usual wholesaler, consider all potential supply routes, e.g. an alternative wholesaler, the drug company
- Consider the risk to the patient of not receiving the medication. For some conditions the risk may be low. However, for patients being treated for more acute/serious conditions (such as severe mental health problems e.g. schizophrenia or bipolar disorder), the risk may be high.
- For high risk patients, it is good practice to inform the GP that the medications could not be dispensed. This will allow GPs to follow up vulnerable patients or recommend alternative treatment if appropriate.

Double Dose Taken

An incident occurred recently where a patient was prescribed diclofenac m/r 75mg BD for a sports injury. The medicine was dispensed using stock from two different manufacturers. The patient did not realize that the two generic products were the same medicine and as a result, took double the maximum recommended dose for 2 weeks.

Advice:

- If possible, avoid using stock from more than one manufacturer when dispensing a prescription for a generic medicine
- Remember to inform patients if you have to dispense stock from different manufacturers or have changed your regular supplier.

Gabapentin/Pregabalin Mix ups–Patients Hospitalized

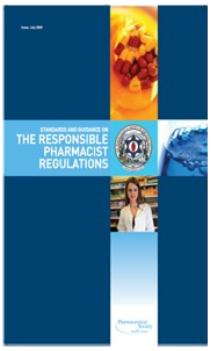
There have been two very similar incidents reported recently where **pregabalin 300mg** was dispensed in two different community pharmacies when the prescriptions were for **gabapentin 300mg**. Both patients ended up being admitted to hospital. In both cases, the medication was labelled as 'gabapentin 300mg Take two three times a day'. The maximum dose of pregabalin is 600mg per day, so this was above the recommended dose. In the first case, the patient was admitted to hospital after having fallen. The patient reported feeling dizzy before the fall and suffered a laceration to the head and fractured ribs. In the second instance, the patient was admitted to hospital with paraesthesia and numbness. In both cases the dispensing error may have been a contributory factor in the hospital admission.
Advice: Please be aware of the potential for confusion between these two medicines.

Time for Review?

A number of community pharmacy adverse incidents have been reported in recent months where a contributing factor involved the pharmacy's Standard Operating Procedures (SOPs). In particular,

- SOPs were not in place
- SOPs lacked detail
- SOPs were not followed

The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 require:



- Community pharmacies to have adequate and up-to-date SOPs, covering all stages of the 'prescription journey' to ensure the safe and effective running of the pharmacy
- Pharmacy procedures to be regularly reviewed to ensure they are fit for purpose and reflect the day to day running of the specific pharmacy premises
- Pharmacy procedures to be reviewed every two years as a minimum or at any time that an incident occurs which may potentially have led to a compromise of patient safety
- All relevant staff to be trained on the SOPs and a record of training to be maintained.

Some of the areas that SOPs must cover include how medicines are:

1. Ordered
2. Stored
3. Prepared
4. Sold by retail
5. Supplied in circumstances corresponding to retail sale
6. Delivered outside the pharmacy
7. Disposed of.

Resources

PSNI
See PSNI website for full requirements of the regulations and details on all the areas that SOPs must cover:
http://www.psni.org.uk

NPA
To assist with the development and update of SOPs, members of the National Pharmacy Association (NPA) can download a "Guide to Writing SOPs – Step by Step, for Community Pharmacists"
Template SOPs are also available from their website:
http://www.npa.co.uk.

Advice:

- Review your pharmacy SOPs to ensure they meet the requirements of the Responsible Pharmacist Regulations as outlined above
- Ensure all relevant staff are trained on the SOPs and adherence to SOPs is monitored.

HSCB Medicines Governance Team Contact Details

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