NPA MEDICATION SAFETY UPDATE

This is the fourth NPA patient safety and MSO update for 2019.
Our updates are published on a quarterly basis and contain a summary of the most common types of dispensing errors reported to the NPA during the fourth quarter of 2019, and guidance for minimising patient safety incidents and information on current hot topics in patient safety.

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NPA MEDICATION SAFETY UPDATE

OCTOBER – DECEMBER (Q4) 2019

Medication Safety Officer (MSO)

In 2014, **NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA)** issued a national Directive NHS/PSA/D/2014/005 (patient safety alert) to improve medication and error incidents reporting and learning. This Directive established the role of the **Medication Safety Officer (MSO).**

Role of the MSO

- Promoting safe use of medicines
- Supporting pharmacy teams in improving patient safety
- Implementing local and national medication safety initiatives
- Improving reporting, and learning from patient safety incidents
- Sharing learnings from incidents submitted to the NPA with the community pharmacy sector, the Community Pharmacy Patient Safety Group (PSG) and other relevant organisations

Did you know?

The NPA holds the role of Medication Safety officer (MSO) for all independent community pharmacies in England with fewer than 50 branches.

Each of the largest multiples, and the **National Pharmacy Association (NPA) on behalf of independent pharmacies**, has appointed a named person who is committed to making a difference, sharing learning and experiences.

Jasmine Shah, NPA Head of Advice and Support Services, currently holds the role of MSO at the NPA. As part of this role, we are working together with the wider pharmacy sector on the patient safety agenda, and in particular, we look forward to playing our full part in the work of the sector-wide PSG.

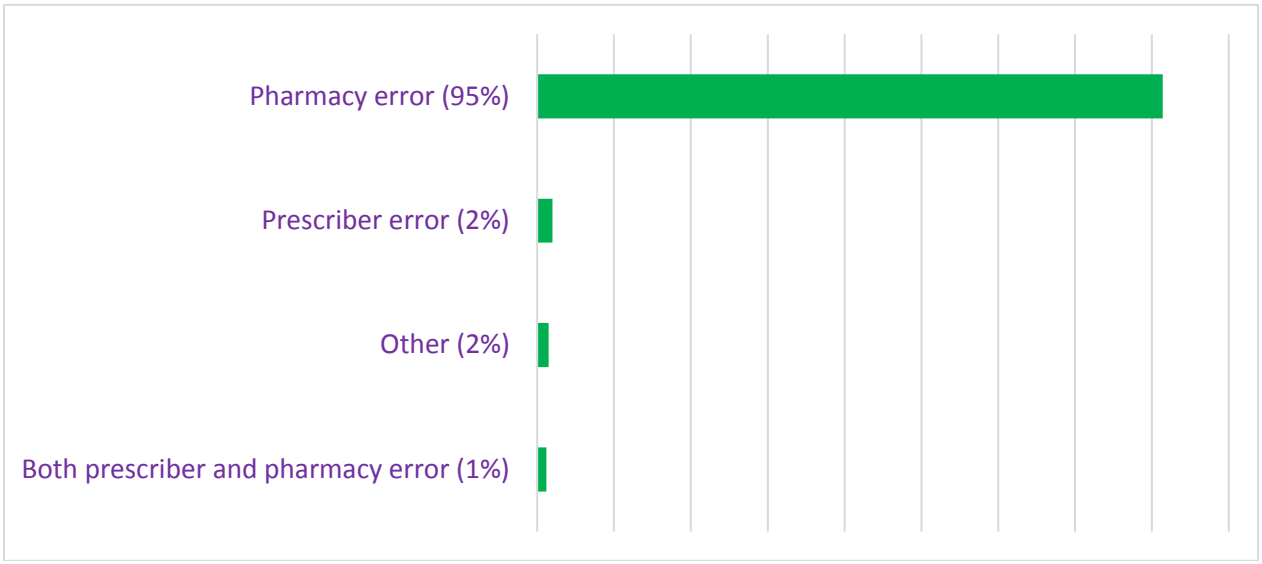
Further information on the work of the PSG is available via the group website: https://pharmacysafety.org/

Analysis of patient safety incidents reported during Q4 2019

Overall, there was a 17% decrease in the number of incidents reported during Q4 2019, compared to Q3 2019. Compared to the same quarter in 2018, there was a 7% increase in the number of incidents reported during Q4 of 2019. Overall, there was a 32% increase in the number of patient safety incidents reported during 2019 compared to 2018. We have shared some of the key findings and statistics from our analyses below.

1) Origin of patient safety incidents during Q4 of 2019

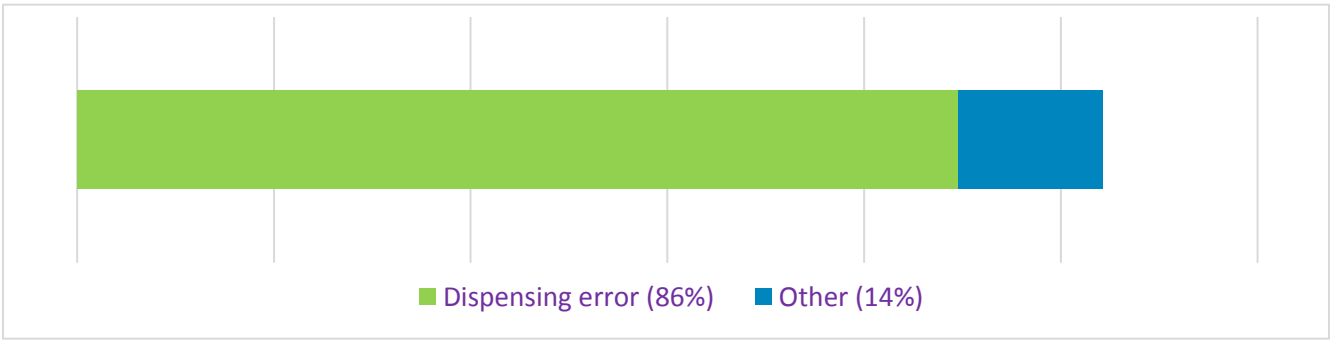
- 95% of incidents reported originated from the pharmacy
- 2% of errors reported were prescribing errors – this is a 3% decrease from Q3 — it is important to report prescribing errors because increased reporting allows identification of trends and increases learning



2) Type of incident reported during Q4 of 2019

The most common type of incident reported during Q4 was 'dispensing error', which accounted for 86% of all reported incidents. Whilst reporting of dispensing errors is encouraged, all types of incidents and near misses in the pharmacy can be reported. These may include, but are not limited to:

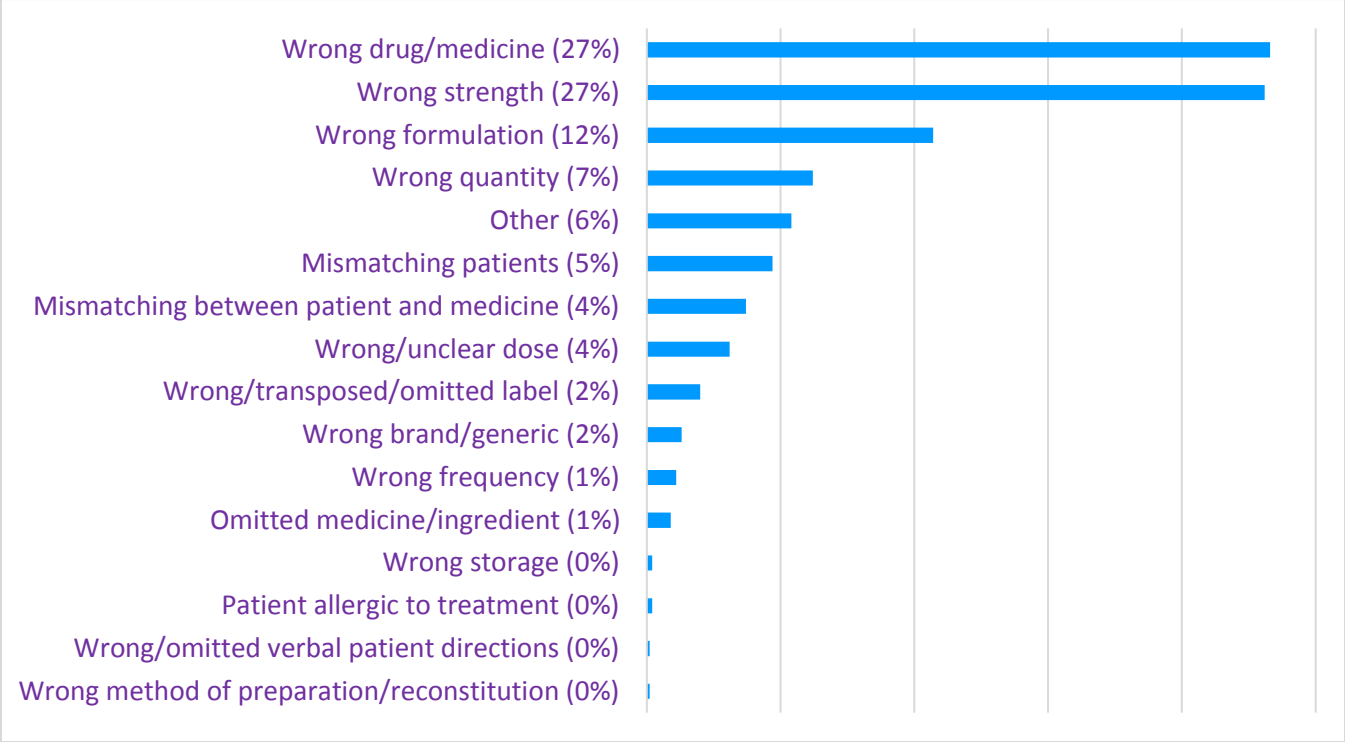
- Counselling errors
- Treatment procedure/administration error
- Patient abuse
- Delivery/collection errors
- Supply of over-the-counter (OTC) medication error



3) Medication error categories and incidents reported during Q4 of 2019

The main categories of errors reported were those involving medication errors such as wrong drug, strength or formulation, these accounted for 66% of errors reported – this is a 4% increase from Q3:

- **'Wrong strength' incidents (27%)**
- **'Wrong drug/medicine' incidents (27%)**
- **'Wrong formulation' incidents (12%)**



Focus on combination products

Errors involving combination products were reported in both the wrong drug/medicine and wrong formulation categories - this was a 3% increase collectively from Q3.

- There have been multiple 'wrong drug/medicine' incidents reported with the correct first active ingredient and the incorrect second ingredient combination ingredient.
- The table below shows examples of combination products prescribed and those dispensed instead in error during Q4 2019

Examples of combination product errors

Combination product 1 - prescribed	Combination product 2 – dispensed in error
Ethinylestradiol/Desogestrel *(Gedarel)*	Ethinylestradiol/Levonorgestrol *(Rigevidon)*
Metformin/Linagliptin *(Jentadueto)*	Metformin/Empagliflozin *(Synjardy)*
Tamsulosin/Solifenacin *(Vesomni)*	Tamsulosin/Dutasteride *(Combodart)*
Budesonide/Formoterol *(Symbicort)*	Beclometasone/Formoterol *(Fostair)*

Key points

- ✓ Pharmacy teams are reminded to take extra care when selecting brands against a generic prescription to ensure all active ingredients are correct
- ✓ Pharmacy teams are recommended to attach warning stickers on shelves near items that commonly feature in error reports; this can remind staff to take care when selecting particular combination products

Focus on mismatching

Mismatching patients or mismatching between patient and medicine accounted for 9% of errors reported. There have been a number of incidents reported where:

- Patient A's medication bag has been handed out or delivered to Patient B instead
- Patient A's medication was bagged up or has fallen into Patient B's bag

Key points

- ✓ Always confirm the patient's identity to ensure that the requested details correspond to those on the prescription; this could be the name, address and/or date of birth
- ✓ Check the bag label against the prescription
- ✓ Before bagging up the medication ensure all items correspond to the patient's name and expected number of items on the prescription
- ✓ Take care when handing out prescriptions for patients with similar or same names/surnames
- ✓ Confirm that the contents of the bag matches the patients expectation
- ! Do not leave prescription bags open once they are ready for collection
- ! Avoid printing additional bag labels

Clarification for handing out medicines under the General Data Protection Regulation (GDPR):

Calling out a patient's name when handing out a dispensed prescription is important to ensure the correct patient/representative receives the dispensed prescription. To ensure a data breach does not occur, the patient/representative should be asked to confirm the address, rather than a member of the pharmacy team stating it – for example, using a phrase similar to "can you please confirm the address?" Seeking confirmation gives the option to the patient/representative to choose whether to confirm the address verbally or to show proof of identification.

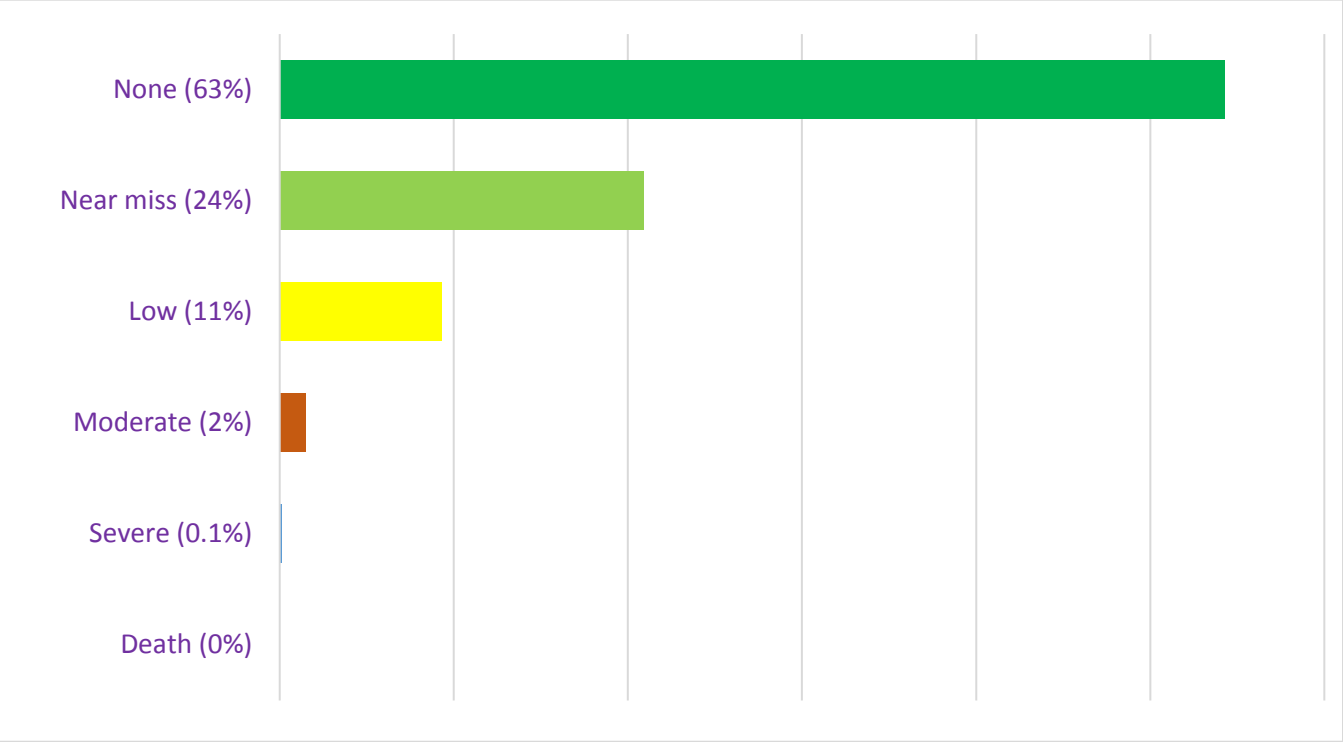
You may also wish to consider displaying a patient notice informing patients of the procedure– this notice can outline that the patient has the option to provide proof of identification instead of verbally confirming their identity. Additionally, the notice can highlight that the process of confirming identity can take place in a consultation room. If a pharmacy organisation chooses to display a patient notice, this process must be highlighted in the pharmacy's standard operating procedure (SOP) and the pharmacy must ensure patient confidentiality is maintained at all times – not just to comply with GDPR, but also to abide by the professional standards set by the GPhC.

NPA support:

- Dedicated GDPR page with a suite of resources, which can be downloaded.
- Template essential SOP including handing out and clinical and legal check.

4. Degree of harm caused to patients by incidents reported during Q4 of 2019

- The degree of harm caused to patients reported as '**none**' (63%) and '**near miss**' (24%) continues to make up the majority of reports.
- The data reported over Q4 highlighted both good and poor reporting. All the reports submitted where the degree of harm was reported as 'severe' and most of the reports that were reported as 'moderate' were incomplete. This meant that no analysis could be undertaken on the root cause of the majority of these incidents or follow up with the pharmacies. Due to the poor quality of reporting, it is not known if these incidents actually caused severe or moderate harm or if reports were completed incorrectly.

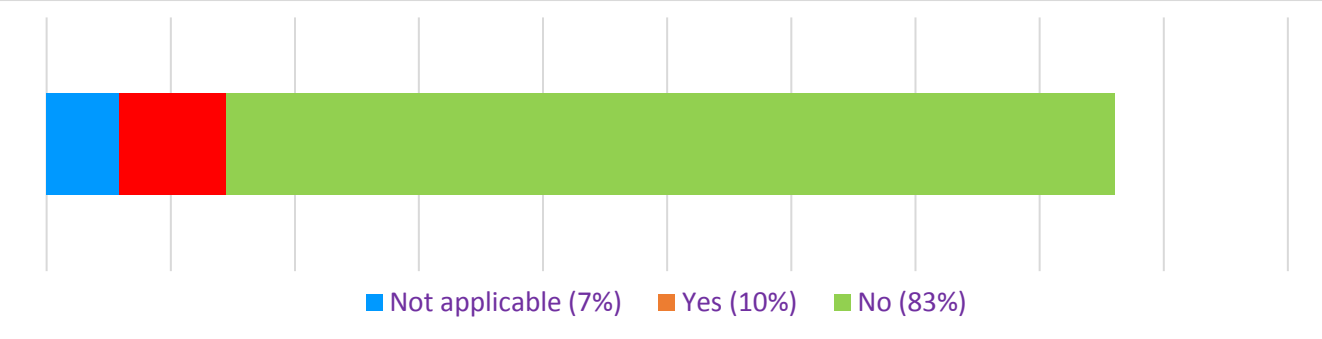


Actions for pharmacy teams when recording degree of harm

- ✓ When documenting the degree of harm caused to patients, the **actual** degree of harm should be documented, not the potential harm that could have arisen.
- ✓ If an incident did lead to moderate or severe harm to the patient a complete detailed outcome is needed for a thorough analysis.
- ✓ Ensure the incident form is fully completed, is accurate and includes sufficient details to allow meaningful analysis of the incident.

5. Self-checking during Q4 of 2019

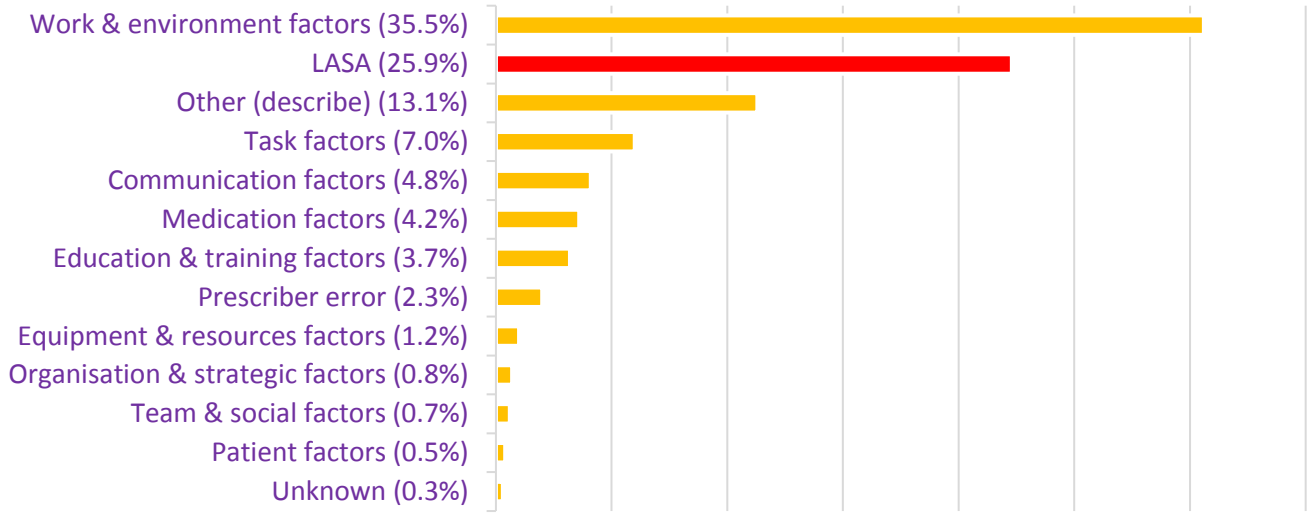
'Self-checking' is defined as a pharmacist carrying out all steps in the dispensing process themselves. It includes the clinical check of the prescription as well as the accuracy check of the assembled items. There was no change in number of errors reported which involved a pharmacist self checking compared with Q3 of 2019.



Refer to the NPA Dispensing process – best practice guidance which includes guidance for self-checking prescriptions.

6. Contributing factors to patient safety incidents during Q4 of 2019

- '**Work and environment factors' (35.5%)** continues to be the main contributing factor reported. This category includes time pressures, understaffing and poorly organised working environments.
- **'LASA' (25.9%)** as a contributing factor was the second largest contributing factor to the errors reported. See more analyses on LASA errors below.



Look-alike sound-alike (LASA) errors

The percentage of each of the top LASA errors (as identified by NHS Improvement) reported in Q4 are listed in the table below:

Top LASA errors as identified by NHS Improvement		Percentage from total number of LASA errors
Amlodipine	Amitryptiline	5%
Atenolol	Allopurinol	3%
Carbamazepine	Carbimazole	0%
Propranolol	Prednisolone	0%
Rosuvastatin	Rivaroxaban	1%

In addition to the LASA errors highlighted as high risk by NHS improvement, 5% of all reported LASA errors involved **gabapentin and pregabalin**. The reclassification of these medicines as schedule 3 controlled drugs may have raised awareness of reporting and may be contributing to the large number of incidents reported where these two medicines have been mixed up.

We would also like to highlight other LASA errors that have been frequently reported in Q4 and throughout 2019:

Frequently reported LASA errors identified by NPA	
Bendroflumethiazide	Bisoprolol
Edoxaban	Etoricoxib
Esomeprazole	Escitalopram
Pantoprazole	Pravastatin
Sildenafil	Sertraline

Reminder on LASA definition - The Centre for Pharmacy Postgraduate Education (CPPE) training providers indicate that a LASA can be due to similar packaging, names or strengths; in fact if a person feels two medicines look or sound similar at all this can be classified as a LASA error.

Actions to take when reporting LASA errors

- ✓ To enable LASAs to be identified as a root cause of the problem, when reporting such errors, the reporter should document that LASA contributed to the error under 'what was the main contributing factor' or 'were there other important factors' depending on how much the LASA contributed to the error.
- ✓ Additionally, the word 'LASA' should be included in the 'Describe What Happened' section of the incident report.

Actions pharmacy teams can take to reduce/prevent LASA errors

- ✓ Discuss the potential for these types of errors with the whole pharmacy team; e.g. at the weekly team huddle, including locums
- ✓ Separate the different strengths of medicines with similar packaging
- ✓ Separate medicines with similar spellings
- ✓ Highlight the medicines using appropriate means such as different coloured stickers
- ✓ Add a note to the PMR to flag up an alert for these medicines
- ✓ Pay particular attention when dispensing in monitored dosage systems (MDS)
- ✓ Barcode scanning / FMD scanning can help reduce LASA errors significantly as a means of accuracy checking
- ✓ Avoid self-checking

Hot topics in patient safety identified during Q4 2019

Influenza

The Community Pharmacy seasonal influenza vaccination Advanced Service and private influenza vaccination service 2019/20 commenced on 1 September 2019 and runs until 31 March 2020.

INCIDENT

- Incidents reported in Q4 2019 have highlighted several reports where the patient has been administered the inappropriate influenza vaccination. This is an increase from those incidents reported in Q4 2018

CONTRIBUTING FACTOR

- Incorrect screening of the patient's record form. Pharmacy teams and pharmacists failed to confirm the patients date of birth which resulted in the incorrect vaccination to be selected and administered

FURTHER INFORMATION

- The Flu Vaccination Advanced Patient Group Direction (PGD) states within the exclusion criteria '*have received a complete dose of the recommended influenza vaccine for the current season',* in this case a recommended influenza vaccine has not been administered and therefore the correct one can be given.
- Where a patient has been given a flu vaccine against a private PGD that is not recommended for their age group, the PGD should be carefully checked to ensure a second dose can be administered. If it is not clear from the PGD, the PGD provider should be contacted for confirmation.

Pharmacists should be aware of the Public Health England (PHE) guidance document *"Inactivated influenza vaccine guidance for healthcare practitioners"* which includes general advice on the steps to follow if a patient has been administered a flu vaccine that is not recommended for their age group.

Out of date vaccines

Pharmacists and pharmacy teams are reminded that the composition of all flu vaccines are changed each season in accordance to the expected circulating flu strain. Vaccines from 2018/19 should not be administered to patients during the 2019/20 season under any circumstance. If a patient has been administered with an expired vaccine, the NHS Flu Vaccination Advanced PGD allows administration of an in date vaccine. The PHE guidance has advised to re-vaccinate the patient with an in date vaccine the same day or as soon as possible.

Pharmacy teams are advised to:

- Inspect the expiry date on each vaccine before administering the dose to the patient
- Appropriately label, segregate and dispose of any expired vaccines
- Document and report such events as a patient safety incident.

Storage of vaccines

- All vaccines should be stored in accordance to the manufacturer's summary of product characteristics (SPC) which forms part of the product license which ensures product stability, efficacy and safety. Any vaccination that is stored outside of the manufacturer's license range would be considered unlicensed.
    - Most of the vaccines recommended for the 2019/20 flu season should be stored in a refrigerator (2°C - 8°C) and then allowed to reach room temperature before administration (except Flucelvax® Tetra (QIVc) where it is not required to reach room temperature before administration).
- In the event of a fridge failure contractors should follow their business continuity plan and SOPs
- PHE have published updated guidance on "*responding to errors in vaccine storage, handling and administration*"

Community Pharmacist Consultation Service (CPCS) - minor illness strand

The NHS Community Pharmacist Consultation Service (CPCS) is a new NHS Advance Service introduced for provision in community pharmacies from 29 October 2019. CPCS is comprised of two strands; low acuity or minor illness and urgent medicines supply.

As part of the low acuity or minor illness strand, pharmacy teams are required to provide patients with self-care advice and support. Pharmacists and pharmacy teams are advised to remain vigilant to identify 'red flag' symptoms and make appropriate referrals to other NHS services and healthcare professionals when required.

The following resources are available to support them in providing this strand of the service:

- The NPA has developed red flag factsheets and sepsis resources that can be used by pharmacists and their teams in identifying 'red flag' symptoms.
- The National Institute for Health and Care Excellence (NICE) Clinical Knowledge Summaries (CKS) provide valuable information on 'red flag' symptoms for all therapeutic conditions.
- The NHS CPCS Toolkit for Pharmacy Staff helps pharmacists to assess any additional individual learning needs.
- Additional training and development materials for minor illness pathways have been produced by the CPPE.
- Enrol for continuing professional development (CPD) sessions - if pharmacists have identified any gaps in their knowledge or confidence they can enrol for CPD, which covers effective consultations, clinical assessments and will focus on identifying red flag symptoms.
    - A limited number of training places are available from CPPE in 2019/20, but the main roll out of the training will be in 2020/21. Further information on availability of local sessions in 2020 will be released in due course.

- Ensure the "Key contact details" form in Annex C of the service specification is completed
    - This completed form allows appropriate referrals to be made if required. The local NHSE&I team will be able to provide these details to you. The details should also be available by searching the Directory of Services (DoS), if you have direct access to this.

Focus on Ranitidine

During Q4 2019, the contaminant, N-nitrosodimethylamine (NMDA), has been identified as a risk factor in the development of certain cancers and has been identified in samples of ranitidine active substance. In response to this the MHRA have issued a number of Class 2 drug recalls for various oral and injectable preparations of ranitidine.

The Department of Health and Social Care (DHSC) have also issued Supply Disruption Alerts (SDA) for all oral and injectable preparations. All UK-manufactured stock has been quarantined whilst the MHRA conducts investigations. The SDA provides further advice for all healthcare professionals who prescribe or supply ranitidine on how to manage affected patients.

The NPA has a dedicated drug alerts, medicines recalls and company-led drug alerts page containing further information on individual alerts.

Fake medication campaign

The #FakeMeds Campaign, run by the MHRA, provides guidance to the public on how to buy medicines and medical devices safely online. The most recent phase of their campaign focused on self-test STI kits, as fake results from these kits can lead to huge impacts on patient's wellbeing. Healthcare professionals including community pharmacists are in an ideal position to raise awareness campaigns. Further information is available on the campaign website.

The MHRA encourages reporting all counterfeit, fake medicines or medical devices and side effects via the Yellow Card Scheme.

Focus on Opioids

Opioids and tricyclic antidepressants

The death of a patient who was taking amitriptyline in combination with oxycodone has highlighted the increased risk of over-sedation and severe respiratory depression that patients using opioid medication and tricyclic antidepressants can experience. When opioids and tricyclic antidepressants are prescribed in combination, pharmacists should take the following steps:

- Counsel patients on the risk of central nervous system depression; this may be experienced as sedation, lethargy and severe shortness of breath.
- Be aware that the respiratory depressant effects are of greater clinical importance in patients who have pre-existing respiratory impairment.
- Remain vigilant and have robust procedures in place to help identify patients to whom this type of interaction may apply, with respect to both prescription and over-the-counter medicines.
- Where appropriate highlight potential issues to the prescriber to ensure that any necessary interventions are made.

OTC sales of codeine and dihydrocodeine: advice for pharmacists

- Ensure your team are aware of the potential for misuse associated with these products.
- Use the sale of medicines protocol and related SOPs.
    - Your team should be vigilant to repeated requests for these products or requests for large quantities and monitor sales on a regular basis.

    - Inform your team that customers trying to obtain these products for illicit use may call in advance and/or be well prepared to give standard answers to avoid suspicion.
- Ensure the pharmacy team are aware of the codeine sale restrictions stipulated by the MHRA.
    - The MHRA has issued guidance that sales of codeine or dihydrocodeine-containing products should not exceed 32 tablets/capsules, and sales should be restricted to one pack; those OTC products that contain codeine or dihydrocodeine are licensed for short-term use only, and customers requiring treatment periods in excess of three days should be referred to their doctor.

Further support is available on the MHRA guidance for "*Over-the-counter painkillers containing codeine or dihydrocodeine*" and the NPA "*Sale of medicines protocol*" guidance and SOP.

Similar packaging - Controlled Drug near miss

Example

A prescription was presented for loperamide capsules 2mg. During the dispensing process phenobarbital, a Schedule 3 Controlled Drug (CD), was selected and dispensed. The pharmacist picked up this incident and the wrong medication did not reach the patient. Upon investigation, it transpired that the phenobarbital was selected from the loperamide shelf in error, where it had been stored away in error as the packaging of both medication was identical. Similar packaging was the primary contributing factor for this near miss.

Although phenobarbital is not subject to safe custody requirements as it falls under a 5,5 disubstituted barbituric acid we would like to highlight additional advice for pharmacy teams:

- Segregate any CDs not subject to safe custody from normal stock lines within the pharmacy.
- Highlight all CDs using appropriate means such as stickers.
- Order from different suppliers to avoid similar looking packaging.
- Ensure stock is put away in the correct place – refer to NPA "*receipt and storage of pharmacy items*" SOP

We would also like to highlight CD safe custody requirements:

- All Schedule 1, 2 and 3 CDs, apart from those exempt (refer to NPA *"CD practical guidance and legal requirements"*), should be kept in a locked safe, cabinet or room, which is so constructed and maintained as to prevent unauthorised access to the drugs.
- Sativex should be kept in a locked refrigerator where possible, but if one is not available, it should be kept in a refrigerator not visible to the public.
- The safe custody requirements do not apply when the CD is under the direct personal supervision of the pharmacist in the pharmacy.
- Further information can be found in The Misuse of Drugs (Safe Custody) Regulations 1973 and NPA *"CD practical guidance and legal requirements".*

Technology as a contributing factor / prescribing error

A prescription was presented for Ofloxacin ear drops 0.3%, an unlicensed preparation. This preparation concerned the pharmacist who contacted the prescribing doctor to discuss the appropriateness of prescribing an unlicensed product. During the conversation, it transpired that the doctor had intended to prescribe Otomize ear spray however had selected the incorrect item from the drop-down-list on the prescribing system.

- There is a growing awareness of errors due to technology, particularly selection of the wrong item on alphabetical drop down lists when both prescribing and dispensing.
- Incidents like these highlight the importance of a thorough screening process and confirming with the patient that what they are expecting is what has been prescribed and dispensed.

- Decisions on prescribing unlicensed medicines should follow the MHRA risk hierarchy for supply of unlicensed medicinal products and pharmacists should contact the prescriber to advise if licensed preparations are available.
- When reporting incidents that arise as a result of technology it is important to mention technology as a contributing factor in the incident.

Yellow Card Reporting

The Yellow Card Scheme is an essential tool that the MHRA uses to monitor the safety of medicines, medical devices and herbal or complimentary medicines. It is crucial to report problems with these products in order to improve patient safety by identifying issues such as side effects, as well as defective and counterfeit medicines or medical devices.

To increase reporting of side effects or issues with healthcare products, the MHRA has released videos to guide patients on reporting suspected side effects of medicines and suspected problems with medicinal devices.

- How to report a side effect from a medicine
- How to report a problem with a medical device

Reporting patient safety incidents

Community pharmacies are required to report all patient safety incidents, as well as analyse and learn from the incidents and share learnings.

NPA Incident reporting platform (IRP)

To support independent community pharmacies, the NPA Incident Reporting Platform (IRP) is available for use by all community pharmacies in England with fewer than 50 branches for reporting patient safety incidents; this applies to NPA members as well as non-members. The NPA IRP can be accessed via this link: https://irp.npa.co.uk/

- Ensure that the form is filled in accurately and includes sufficient details to allow meaningful analysis of the incident.
- **DO NOT** include personal identifiable information in your incident report including staff, patient, carer or relative names or addresses and patient hospital numbers.

In order to use the NPA IRP, you will need to use one of the following supported browsers with Javascript enabled:

- Microsoft Internet Explorer 11
- Microsoft Edge
- Google Chrome
- Mozilla Firefox

NPA patient safety Incident Reporting Platform (IRP) — user information

1. **Details or information that can identify patients or healthcare professionals must not be included when completing the report** — this is especially important since the implementation of the General Data Protection Regulation (GDPR) on 25 May 2018. Use anonymous descriptions such as 'Patient A' or Patient B' instead of patient's name(s), and 'Pharmacist' or 'Pharmacy Technician' instead of their name(s).
2. Where the pharmacy is reporting an error that involves a **Look-alike-sound-alike (LASA) error,** include the word 'LASA' in the 'Describe What Happened' section of the incident report.
3. The incident report receipt is sent via email, helping to reduce administrative time as it can be kept for pharmacy record keeping requirements. Currently there are multiple receipts not reaching the pharmacies who have submitted the report because incorrect email addresses have been submitted; **before submitting the report, check the email address for correspondence submitted is accurate.**
4. When documenting the degree of harm caused to patients, the **actual** degree of harm should be documented, **not** the potential harm that could have arisen.

5. The **NPA IRP can be used to document near misses**. Although it is not a requirement to report near misses, it is a requirement to record them. Reporting near misses is encouraged as learning can occur which can help prevent future events occurring.
6. It is important that a **detailed** description of the patient safety incident in the '*describe what happened*' field is provided (think about the sequence of events and how the error was concluded). Simply writing a brief description, for example, '*wrong strength given'* is not enough as it does not provide sufficient information for us to conduct a full and complete data analysis which is a key part of the NPA's role as the MSO.

Reporting patient safety incidents via NRLS

Community pharmacies can also report incidents via the National Reporting and Learning System (NRLS) e-form: https://www.eforms.nrls.nhs.uk/staffreport/ — select 'Community pharmacy' from the drop-down list under the 'Start reporting here' section, and click on 'Start'

- Ensure that the form is filled in accurately and includes sufficient details to allow meaningful analysis of the incident.
- **DO NOT** include personal identifiable information in your incident report including staff, patient, carer or relative names or addresses and patient hospital numbers.

Relevant links mentioned in this update

- NPA patient safety resources: https://www.npa.co.uk/services-and-support/patientsafety
- NPA incident reporting platform (England): https://irp.npa.co.uk/
- Community Pharmacy Patient Safety Group (PSG): https://pharmacysafety.org/
- NRLS e-form: https://www.eforms.nrls.nhs.uk/staffreport/
- MHRA Yellow Card: https://yellowcard.mhra.gov.uk/
- GPhC: https://www.pharmacyregulation.org/news/principles-good-practice-issued-protect-patients-online-0
- CPPE: https://www.cppe.ac.uk/services/pharmacy-quality-scheme
- SPS: https://www.sps.nhs.uk/articles/which-medicines-should-be-considered-for-brand-name-prescribing-in-primary-care/

Contact your MSO

NPA members

Independent community pharmacies in England, who are **NPA members**, can contact the NPA MSO through the Pharmacy Services Team at the NPA for further information, advice and/or support on any patient safety or pharmacy topic/matter by:

- Tel: 01727 891800 (9am-6pm Mon-Fri, 9am to 1pm Sat)
- Email: pharmacyservices@npa.co.uk (anytime)

Non-members

Independent community pharmacies in England with fewer than 50 branches who are currently not members of the NPA can contact the MSO by:

- Email: pharmacyservices@npa.co.uk
- Include your pharmacy name, ODS code, name of the owner/superintendent pharmacist and their telephone/mobile number, pharmacy's NHSmail email address
- State 'Non-member MSO query' in the subject field

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