NPA MEDICATION SAFETY UPDATE

- Analysis of incidents reported during Q2 2020.
- Medication and patient safety information and guidance, including during COVID-19.

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NPA MEDICATION SAFETY UPDATE Q2 2020

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Analysis of patient safety incidents reported during Q2 2020

During the coronavirus (COVID-19) pandemic, since March 2020, there has been a significant decrease in the number of patient safety incidents being reported. We have shared some of the key findings and statistics from our analyses below from the patient safety incidents reported during Q2 2020.

1) Number of patient safety incidents during Q2 of 2020

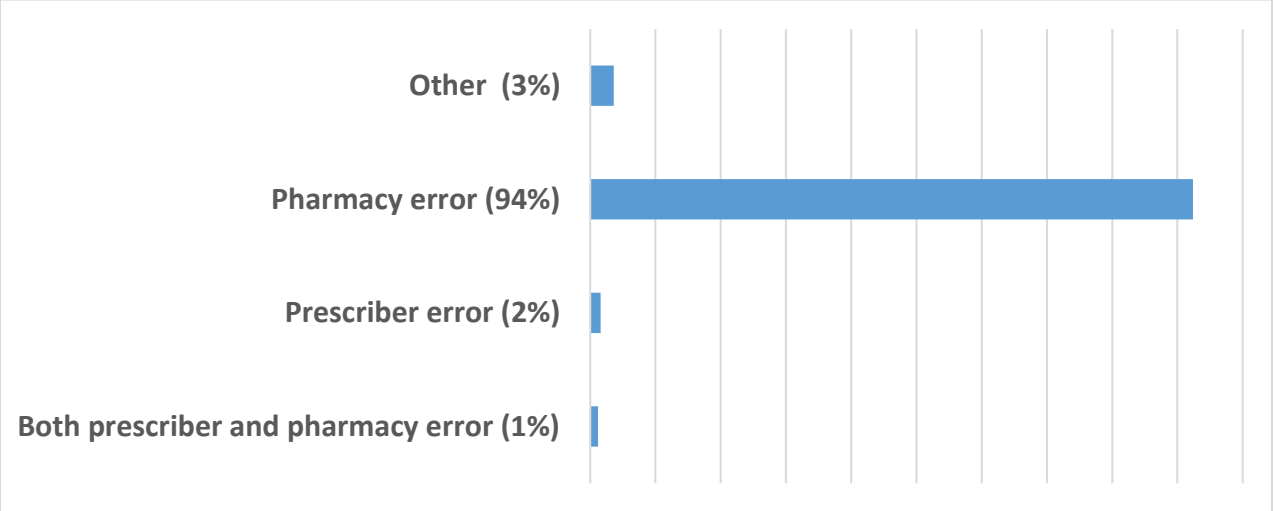
- Overall, there was a 44.5% decrease in the number of incidents reported during Q2 2020, compared to Q1 2020.
- Compared to the same quarter in 2019, there was a 40.6% decrease in the number of incidents reported during Q2 of 2020.

This is a significant reduction in number of incidents being reported. This may be due to the increased workload and pressure on pharmacy teams due to COVID-19 pandemic, whereby pharmacy teams may not be prioritising reporting of patient safety incidents, or due to other, as yet unknown, reasons.

! IMPORTANT REMINDER → Please continue to report, investigate and analyse patient safety incidents, and share learnings from them within your pharmacy teams.

2) Origin of patient safety incidents during Q2 of 2020

- 94% of incidents reported originated from the pharmacy
- 2% of errors reported were prescribing errors – this is a 2% decrease from Q1 2020- it is important to report prescribing errors because increased reporting allows identification of trends and increases learning

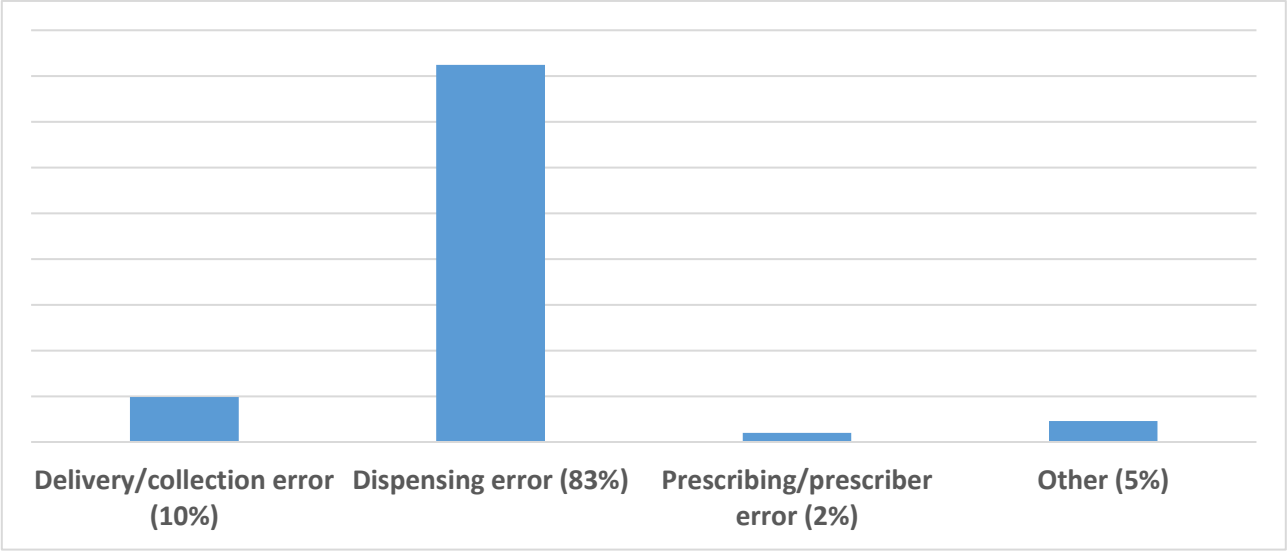


3) Type of incident reported during Q2 of 2020

- The most common type of incident reported during Q2 was 'dispensing error', which accounted for 83% of all reported incidents.
- Delivery/collection errors accounted for 10% of the incidents reported; an increase in 3% since Q1 2020.

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:

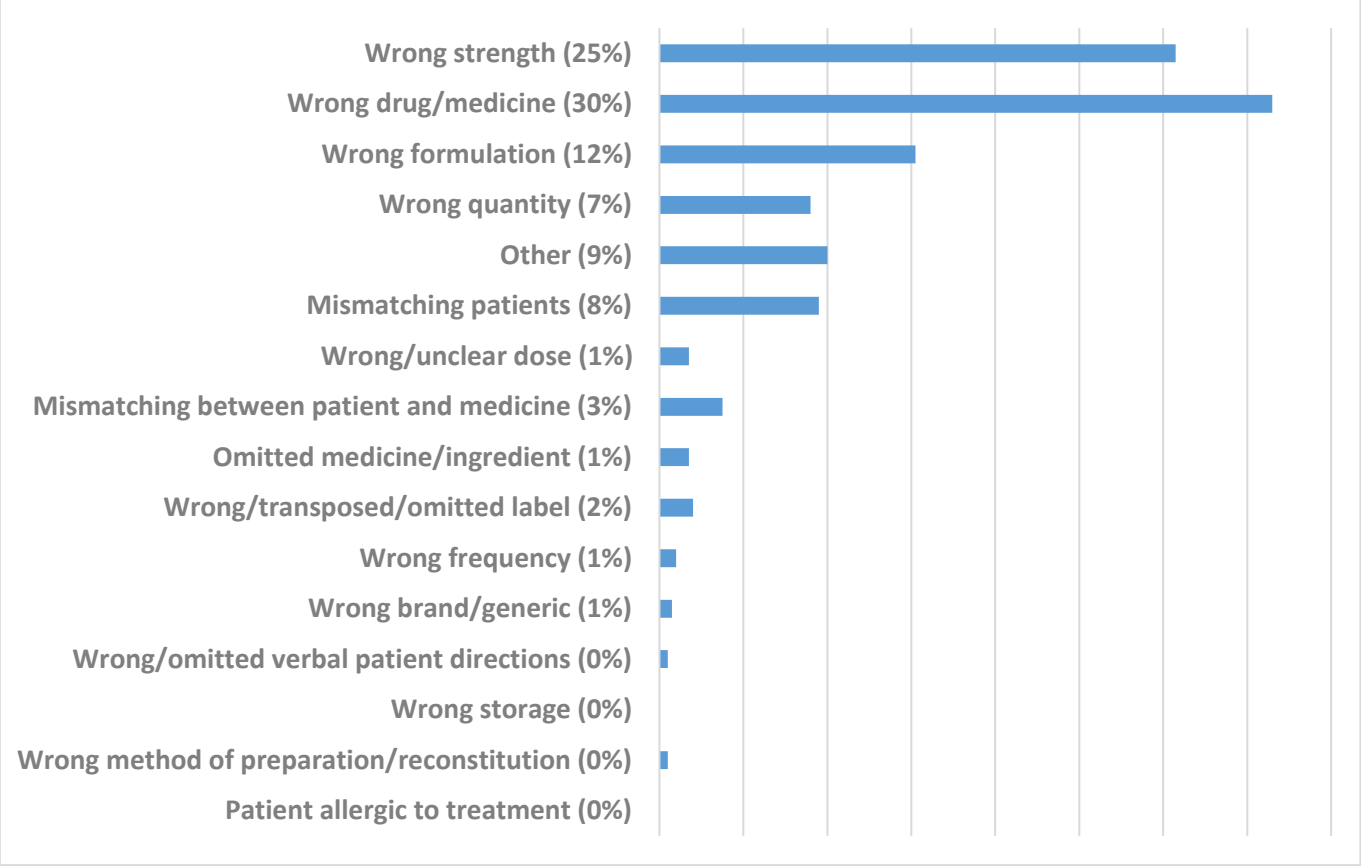
- Counselling errors
- Treatment procedure/administration error
- Patient abuse
- Delivery/collection errors
- Supply of over-the-counter (OTC) medication error



4) Medication error categories and incidents reported during Q2 of 2020

The main categories of errors reported were those involving medication errors such as wrong drug/medicine, strength or formulation, these accounted for 67% of errors reported – this is a 7% increase from Q1 2020:

- **'Wrong strength' incidents (25%)**
- **'Wrong drug/medicine' incidents (30%)**
- **'Wrong formulation' incidents (12%)**

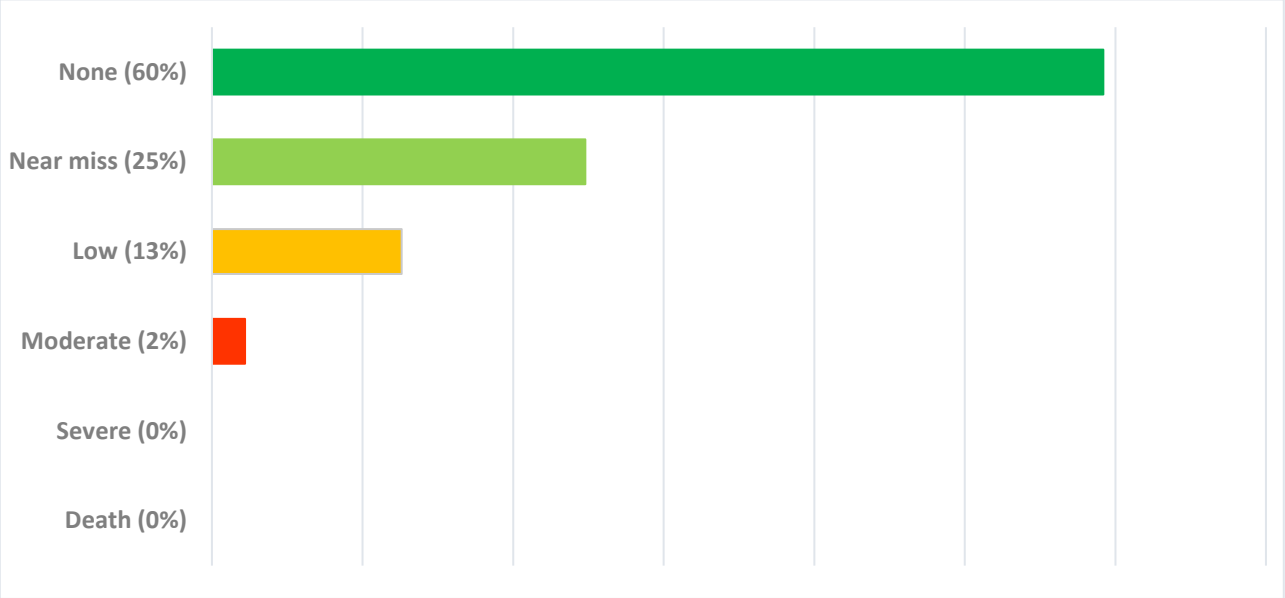


4. Degree of harm caused to patients by incidents reported during Q2 of 2020

- The degree of harm caused to patients reported as '**none**' (60%) and '**near miss**' (25%) continues to make up the majority of reports.
- The data reported over Q2 2020 highlighted both good and poor reporting. There were no reports submitted where the degree of harm was reported as 'severe' or 'death'.

Incident example resulting in moderate harm

A patient in a care home was taken to hospital following a fall due to being dispensed and administered co-codamol tablets 30/500mg in place of the prescribed paracetamol tablets 500mg. Although the patient received no ill lasting effects, the contributing factors to the incident included LASA and self-checking.

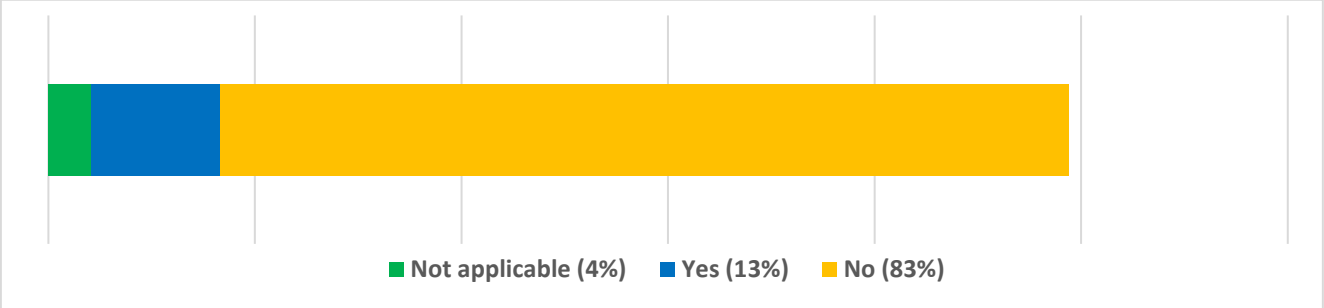


Actions for pharmacy teams when recording degree of harm

- ✓ Please ensure you report the actual degree of harm caused to the patient and not the potential harm that could have happened.
- ✓ Please ensure you complete a detailed outcome if an incident did lead to moderate or severe harm to the patient – this is to allow a thorough analysis to be undertaken by us.
- ✓ Please ensure the incident form is fully completed, is accurate and includes sufficient details to allow meaningful analysis of the incident.

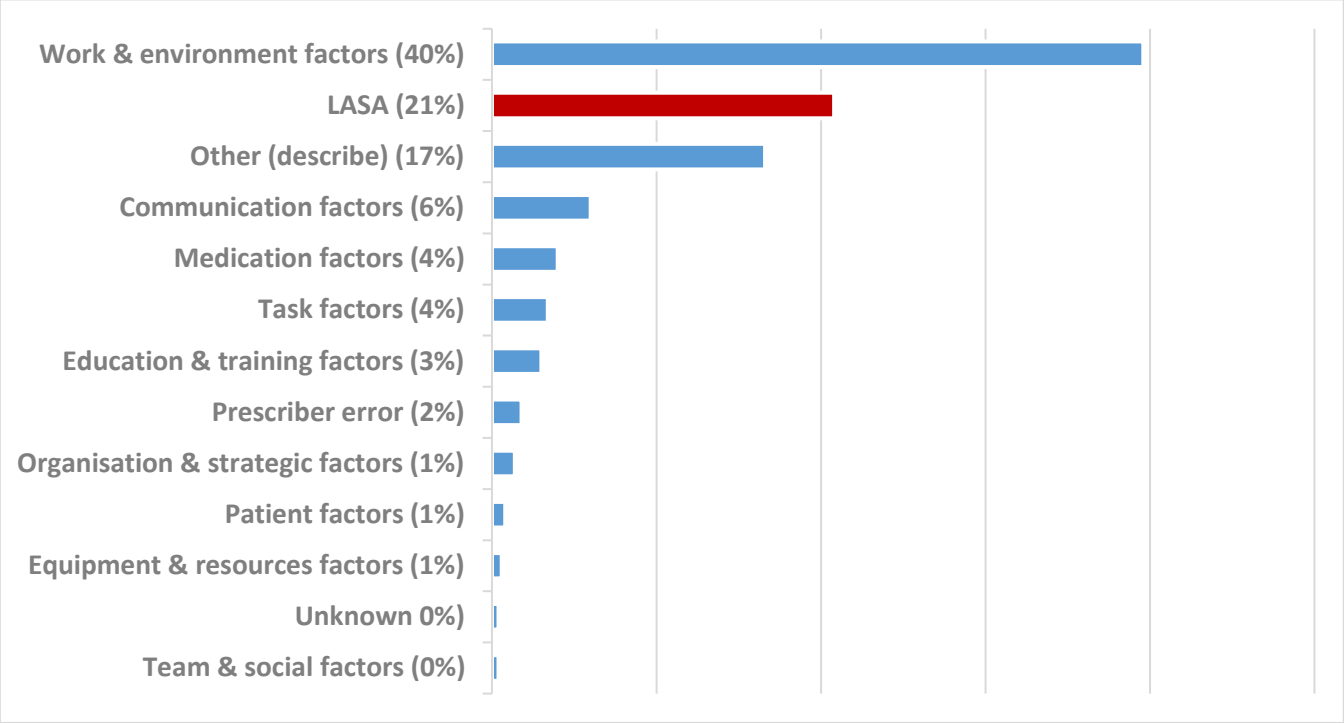
5. Self-checking during Q2 of 2020

'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 a 2% increase in the incidents involving self checking compared to Q1 2020.



6. Contributing factors to patient safety incidents during Q2 of 2020

- **'Work and environment factors' (40%)** continues to be the main contributing factor reported. This category includes time pressures, understaffing and poorly organised working environments.
- **'LASA' (21%)** as a contributing factor was the second largest contributing factor to the errors reported. See more analyses on LASA errors below.
- **COVID-19 –** although the reporting platform does not allow selection of COVID-19 as being a contributing factor, 10.3% of incidents reported included COVID-19 work pressures as other important factors contributing to incidents



Look-alike sound-alike (LASA) errors

The percentage of each of the top LASA errors (as identified by NHS Improvement) reported in Q2 2020 are listed below.

Top LASA errors as identified by NHS Improvement		Percentage from total number of LASA errors
Amlodipine	Amitriptyline	6%
Atenolol	Allopurinol	2%
Carbamazepine	Carbimazole	0%
Propranolol	Prednisolone	0%
Rosuvastatin	Rivaroxaban	4%

Gabapentin and pregabalin

In addition to the LASA errors highlighted as high risk by NHS improvement, 3% of all reported LASA errors involved **gabapentin and pregabalin**. The reclassification of these medicines as Schedule 3 Controlled Drugs (CDs) in April 2019 has raised more awareness of their reporting. However, even in Q2 2020, the trend continues and a significant amount of incidents reported involve these medicines. Both of these Schedule 3 CDs do not need to be kept in a CD cabinet, therefore, it is essential they are separated out in the dispensary with clear reminders for staff to double check the item they pick.

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, please report them under one of the following depending on how much the LASA contributed to the error:
  - 'What was the main contributing factor', or
  - 'Were there other important factors'
- ✓ 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; for example, 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 or note on dispensing shelf/drawer
- ✓ 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 Q2 2020

In this patient safety update, we would like to highlight some key topics and resources available to pharmacy teams to ensure patient safety is maintained during the COVID-19 pandemic.
The NPA has a dedicated COVID-19 page: https://www.npa.co.uk/coronavirus-updates/ which is updated on a regular basis to include the latest news and resources as well as action plans for pharmacy contractors.

Impact of COVID-19 pandemic

There have been a significant number of incidents reported throughout Q2 2020 with COVID-19 pandemic mentioned as an important factor contributing to the incident arising. Below are some example learnings that can be taken away to help pharmacy teams reduce incidents occurring due to the pandemic. This is of particular importance due to the increase in demand in community pharmacies under the current climate.

Example 1

On a biweekly basis, patient A receives a delivery of their CD medicine. Due to a positive COVID-19 test, the regular pharmacist was absent and a locum pharmacist was on duty. Unfortunately, the locum pharmacist was not informed of this delivery and resulted in a missed delivery and patient A was left without their medicine.

Learnings

Due to the COVID-19 pandemic, regular pharmacy team members including Responsible Pharmacists may need to self-isolate. It is therefore essential business contingency planning includes for staff absence. It is key there is good communication between regular pharmacy team members and locum staff to ensure patient safety is not compromised.

Suggestion

- Consider using a communication book and/or diary.

Example 2

A patient's representative presented with an urgent CD prescription. The prescription was dispensed and handed out but due to the increase workload as a result of the COVID-19 pandemic, the prescription was not entered out of the CD register until the next morning. It was only at this point the Responsible Pharmacist established that the CD items supplied were out of date (this was because there was failure to separate the in-date and out-of-date CDS in the CD cabinet).

Learnings

Ensure the pharmacy has a robust process in place for date checking. A Standard Operating Procedure (SOP) should be in place for date checking which must include CDs. If the CD has expired, this should be clearly highlighted and quarantined from other stock and appropriately destroyed.

Suggestion

- Consider using 'expired' stickers to highlight out of date items.

Example 3

Patient B was supplied with an instalment prescription a week in advance in error. Due to the COVID-19 pandemic, a batch of instalment prescriptions arrived for patient B and the instalment interval was changed from weekly to two weekly. The appropriate date on the prescription was not checked appropriately and an advance supply was made.

Learnings

The prescribed item, or first instalment, is required to be supplied within 28 days of the appropriate date on the prescription, as stated in The Misuse of Drugs (Amendment No. 2) Regulations 2006. The appropriate date is the later of the dates on which the prescription was signed (issue date) or the date indicated on the prescription as to when it should be dispensed, as stated in the Human Medicines Regulations 2021.

Suggestion

- Refresh knowledge on instalment dispensing and appropriate dates.

During the pandemic, you may receive requests to alter prescription collection intervals on instalment prescriptions. It is important to remain vigilant of any changes and discuss these with the appropriate prescriber. Verbal requests by the prescriber or patient's key workers do **not** allow the pharmacist to deviate from the legal instructions on the prescription.

- For example, prescribers cannot verbally request that pharmacists dispense a medicine on a day that differs from that stated on the prescription
- Equally, requests from the patient's key worker do not allow pharmacists to deviate from the legal instruction
- The prescription must be amended by the original prescriber
- The only exception to this is prescription information that is not a legal requirement, such as the prescriber giving permission for a dose not to be supervised

Refer to NPA guidance dealing with CDs during the pandemic: https://www.npa.co.uk/information-and-guidance/covid-19-dealing-with-controlled-drugs-during-the-pandemic/

National Patient Safety Alerts

The MHRA will now issue safety-critical alerts for medicines and medical devices, requiring action by healthcare organisations, as National Patient Safety Alerts. This follows agreed criteria and template by the National Patient Safety Alerting Committee (NaPSAC). The new format will (this list is not exhaustive):

- Only be issued for safety-critical issues, which are those with a risk of death or disability, and where healthcare organisations are required to take action
- Ensure the risk is explained clearly and effectively
- Will state the required actions for the relevant healthcare organisations to take that have been assessed for their cost-effectiveness, efficacy, feasibility and safety

Action for pharmacy teams

- To receive the National Patient Safety Alerts, ensure the pharmacy is signed up: https://www.gov.uk/drug-device-alerts/email-signup
- Read full details in the CAS alert: https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103097

Please note:

- Drug alerts and medicines safety communications not meeting the NaPSAC criteria will carry on being issued in the current formats
- Medical devices safety communications not meeting the NaPSAC criteria is also changing and these changes will be communicated soon

Safe use of emollient skin creams

The MHRA has issued guidance, alongside a safe emollients use video, for patients who use emollients to treat dry skin conditions. Emollients can easily be transferred from skin to bandages, bedding and clothing, therefore, making them more flammable- this can result in quick and intense fire burns. The MHRA advises that patients using such emollients should be aware of the risks and to take actions on avoiding them. For details, please read the full guidance: https://www.gov.uk/guidance/safe-use-of-emollient-skin-creams-to-treat-dry-skin-conditions

In 2018, the MHRA issued advice for healthcare professionals, including pharmacy teams when supplying paraffin-based and paraffin-free products. The advice is still relevant and can be found: https://www.gov.uk/drug-safety-update/emollients-new-information-about-risk-of-severe-and-fatal-burns-with-paraffin-containing-and-paraffin-free-emollients

To support pharmacy teams in supplying paraffin-based and paraffin-free products which can cause a risk of fire, the NPA has updated its *"SOP: supplying paraffin-based and paraffin-free skin products"* : https://www.npa.co.uk/news-and-events/news-item/mhra-guidance-on-using-emollient-skin-creams-safely-and-updated-npa-paraffin-sop/ This includes a list of current applicable products, and an information leaflet to give to patients when supplying them with their product.

Direct-acting oral anticoagulants (DOACs) – increased bleeding risk

Direct-acting oral anticoagulants (DOACs) are licensed for various indications related to anticoagulation. DOACs available in the UK are apixaban, edoxaban, rivaroxaban, and dabigatran etexilate.
The MHRA issued a drug safety update which states the use of DOACs increases bleeding risk which can lead to serious, possibly fatal bleeds. Patients with underlying factors are thought to be at increased risk of bleeding. Therefore, caution should be exercised in patients such as the elderly and those with reduced body weight or renal impairment. Regular anticoagulant monitoring is not required for DOACs, therefore, patients at increased risk of bleeding should be made aware of the risk of haemorrhage and be regularly assessed for signs of bleeding or anaemia. Dose adjustment may be necessary for patients with renal impairment due to increased DOAC exposure. Specific reversal agents are available for certain DOACS:

DOAC	Reversal agent
Dabigatran	Praxbind▼, idarucizumab
Apixaban and rivaroxaban	Ondexxya▼, andexanet alfa
Edoxaban	Currently there is no specific authorised reversal agent available for edoxaban.

Key points for pharmacy teams

- Ensure appropriate clinical checks are carried out on prescriptions for patients prescribed DOACs and are at an increased risk of bleeding (for example, elderly patients or those with renal impairment)
- DOACS should not be taken with other anticoagulants and dose adjustments for DOACs may be required when taken with strong inhibitors of P-glycoprotein or CYP3A4
- Regular anticoagulant monitoring is not required, therefore, counsel patients to look out for signs and symptoms of bleeding and urge them to read the patient information leaflet available with their prescribed medicines
- Dose adjustment and regular monitoring required for patients with renal impairment
- DOACs are not recommended in patients with antiphospholipid syndrome; vitamin K antagonists should be considered as an alternative treatment in these patients
- Treatment with DOACs should be discontinued if severe bleeding occurs
- Suspected adverse drug reactions associated with DOACs, including thromboembolic or haemorrhagic events, should be reported via the main MHRA Yellow Card site https://yellowcard.mhra.gov.uk/ .

The full MHRA drug safety update can be accessed here: https://www.gov.uk/drug-safety-update/direct-acting-oral-anticoagulants-doacs-reminder-of-bleeding-risk-including-availability-of-reversal-agents

Medical interventions: sodium valproate, Primidos and pelvic mesh implants

The Independent Medicines and Medical Devices has published its safety review on three medical interventions: sodium valproate, Primidos and pelvic mesh implants. Baroness Julia Cumberlege has chaired the report, which is titled 'First Do No Harm'. Following a two-year review, the report published sets out nine recommendations to support those affected by these interventions and reduce the risk of harm in the future.

The full report including the nine recommendations set can be accessed using the following link: https://www.immdsreview.org.uk/Report.html

Context

The review investigated the following medicines and medical device:

1. Hormone pregnancy tests (HPTs) – such as primidos which were removed from the market in the late 1970's as they were associated with birth defects and miscarriages
2. Sodium valproate - valproate is a highly teratogenic medicine used in the treatment of epilepsy and other conditions
3. Pelvic mesh implants – which are used for the treatment of pelvic organ prolapse or to manage stress urinary incontinence -they have been linked to life changing complications

Valproate

Valproate is known to be highly teratogenic at all strengths. Exposure during pregnancy carries a 10% risk of children being born with congenital malformations and 30-40% risk of neurodevelopmental delays. The MHRA has issued temporary guidance for management of the Valproate Pregnancy Prevention Programme (PPP) during the coronavirus (COVID-19) pandemic to assist specialists in initiating valproate in female patients, undertaking annual reviews, and pregnancy testing procedures during the COVID-19 pandemic. Although the temporary guidance is intended for specialists, pharmacy teams should read the new guidance and be aware of the temporary processes in place due to the pandemic, as well as understand and implement the full MHRA guidance. Pharmacy teams should already be aware and implementing the guidance for pharmacists on dispensing prescriptions for valproate.

The MHRA temporary guidance can be accessed here: https://www.gov.uk/guidance/valproate-pregnancy-prevention-programme-temporary-advice-for-management-during-coronavirus-covid-19

Actions when dispensing valproate:

1. Supply in whole, original packs where possible, with the relevant accompanying patient information leaflet, even if a split pack is given
2. Include a warning sticker if dispensed in a 'white dispensing box' or carton
3. Provide a Patient Card every time valproate is dispensed. Confirm the patient has received a Patient Guide (this does not need to be supplied every time valproate is dispensed) – valproate information materials can be downloaded from the May 2018 Drug Safety Update https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-pregnancy-prevention-programme-materials-online or by contacting Sanofi Medical Information on 0845 372 7101 or email UK-Medicalinformation@sanofi.com
4. Remind patients of the risks in pregnancy and the need for highly effective contraception.
5. If the patient of childbearing potential is not taking a highly effective contraception, and has not been seen by her GP/Specialist in the past year, dispense their medicine and refer them to their GP (including by contacting the GP if necessary).
6. Remind patients of their annual review with the specialist
7. Report any suspected adverse reactions associated with valproate and any adverse pregnancy outcomes via the Yellow Card Scheme: https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/

The MHRA full guidance can be accessed here: https://www.gov.uk/guidance/valproate-use-by-women-and-girls#toolkit

NPA support

The following valproate resources are available from the NPA to support patient safety:

- Valproate standard operating procedure (SOP): https://www.npa.co.uk/information-and-guidance/valproate-sop/
- Medicines in pregnancy and patient safety: https://www.npa.co.uk/information-and-guidance/medicines-in-pregnancy-and-patient-safety/

The GPhC has made a statement on supplying valproate safely to women and girls which explains how inspectors will check compliance with the MHRA's PPP for valproate during inspections of registered pharmacies. The full statement can be accessed here: https://www.pharmacyregulation.org/news/gphc-statement-supplying-valproate-safely-women-and-girls

Steroid Emergency Card

NHS England and NHS Improvement's issued a National Patient Safety Alert in regards to issuing Steroid Emergency Cards to support the early recognition and treatment of adrenal crisis in adults.

All patients with primary adrenal insufficiency are steroid dependent. Some patients who take oral, inhaled or topical steroids for other medical conditions can develop secondary adrenal insufficiency and also become steroid dependent. Adrenal crisis; a medical emergency which left untreated can be life threatening, can occur if steroids are not given to patients with primary or secondary adrenal insufficiency.

The initial Steroid Emergency Card will be issued to eligible patients by their prescriber. Community pharmacies are asked only to issue replacement cards if the patient loses or misplaces their original card. These can be ordered from Primary Care Support England (PCSE) online: https://secure.pcse.england.nhs.uk/_forms/pcsssignin.aspx

The full National Patient Safety Alert can be accessed here: https://www.england.nhs.uk/publication/national-patient-safety-alert-steroid-emergency-card-to-support-early-recognition-and-treatment-of-adrenal-crisis-in-adults/

Isotretinoin – reminder of risks and precautions

Isotretinoin is known to be highly teratogenic and carries a risk for potential psychiatric reactions and sexual dysfunction. Due to these risks, the MHRA have issued an update to highlight that isotretinoin should only be prescribed to treat severe acne by healthcare professionals who have expert knowledge in the use of oral retinoids and the risks associated with therapy including monitoring requirements. Access the full MHRA update: https://www.gov.uk/drug-safety-update/isotretinoin-roaccutane-reminder-of-important-risks-and-precautions

The MHRA has previously issued:

- Temporary guidance for the management of pregnancy testing as part of a pregnancy prevention programme (PPP) during the COVID-19 pandemic; which is essential when prescribing isotretinoin: https://www.gov.uk/guidance/mhra-regulatory-flexibilities-resulting-from-coronavirus-covid-19#pharmacovigilance
- Revised and simplified educational materials for healthcare professionals and women. Although the guidance is intended for specialists, pharmacy teams should read the guidance and be aware of the processes in place. https://www.gov.uk/drug-safety-update/oral-retinoid-medicines-revised-and-simplified-pregnancy-prevention-educational-materials-for-healthcare-professionals-and-women
- Guidance when dispensing prescriptions for isotretinoin. https://www.gov.uk/government/publications/isotretinoin-for-severe-acne-uses-and-effects/isotretinoin-for-severe-acne-uses-and-effects#prescribing-isotretinoin

Advice for pharmacy teams when dispensing isotretinoin

1. Isotretinoin is contraindicated in women of childbearing potential unless all conditions under the PPP are met. When dispensing prescriptions for isotretinoin:
   - The prescription should ideally be limited to 30 days' supply
   - The prescription should be dispensed within a maximum of 7 days
   - Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day
2. There is no restriction for male patients
3. Provide a patient reminder card **each time isotretinoin is dispensed**
4. Pharmacists should use the Isotretinoin Pharmacist Checklist and remind patients of the risks of taking isotretinoin in pregnancy and also what to do if they feel their mental health is affected
5. Report any suspected adverse reactions associated with isotretinoin and any adverse pregnancy outcomes via the Yellow Card Scheme

Alfentanil preparations- risk of 10 times overdose

Alfentanil is a strong opioid used for pain relief in patients. Recent reports to NHS England and NHS Improvement Controlled Drugs Accountable Officers (CDAOs) have shown two administration errors where a 10 times overdose of alfentanil has been administered to patients resulting in severe harm and/or death.

Between June 2018 and June 2020, there have been 38 patient related errors involving the drug reported to the CDAOs. Moreover, in 2017, the London Opioid Safety and Improvement Group (LOSIG) highlighted concerns relating to the safe use of alfentanil injections and safe practice points were included in the Care Quality Commission's Controlled Drugs National Group Sub-Groups Newsletter Number 1 which can be accessed here: https://content.govdelivery.com/accounts/UKCQC/bulletins/1b832ab .

In Q2 2020 data, there was no reports of any alfentanil preparation incidents, however pharmacy teams should be aware of the serious potential risks associated with alfentanil and ensure that the risk of inadvertent overdose have been identified and mitigated.

Supply of Priadel ® (lithium carbonate) modified-release tablets 200mg and 400mg

A Supply Disruption Alert (SDA) was issued in August 2020 for Priadel® (lithium carbonate) modified-release tablets 200mg and 400mg stating their discontinuation with remaining supplies of both strengths are expected to be exhausted by April 2021. However, its **withdrawal has been paused –** on 5 October, the Competition and Markets Authority (CMA) announced it is investigating whether the manufacturer, Essential Pharma, has breached competition law by doing so. This follows a request from the Department of Health and Social Care (DHSC) for 'interim measures' to be put in place by the CMA during the current investigation. Several medical bodies and charities have raised serious concerns on the proposed withdrawal, believing that it will impact on patient health and increased costs to the NHS.

What does this mean for community pharmacies?

Community pharmacies should, for the time-being, not expect a disruption in supply of Priadel® (lithium carbonate) modified-release tablets 200mg and 400mg. this is because Essential Pharma has informed DHSC that they will be continuing to supply the drugs during the CMA investigation. However, it should be noted that until the investigation is complete, the threat of withdrawal remains unless an agreement is reached between the parties involved. For more details, please see: https://www.gov.uk/government/news/cma-to-investigate-the-supply-of-bipolar-drug.

Access the updated Priadel® SDA issued on 8 October 2020:
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103103

Yellow Card Reporting

Case study: how a Yellow Card report enabled the MHRA to make necessary changes to improve patient safety
A pharmacist submitted a Yellow Card report after a patient nearly choked due to inhaling an inhaler capsule through the wrong part of the inhaler. The MHRA conducted a detailed investigation because there was a potential for confusion in the instructions on using the inhaler and medicine. The result was that the manufacturer improved their safety information, to include clearer instructions and pictures on inserting the capsule into the inhaler, and warnings about choking. The MHRA alerted doctors, pharmacists and healthcare professionals across the UK.
For further details, see: https://www.gov.uk/government/news/one-pharmacists-report-helps-safer-use-of-inhalers-in-the-uk

Yellow Card reporting during the COVID-19 response
The MHRA has reported a decrease in Yellow Card reporting especially from healthcare professionals during the COVID-19 pandemic. We encourage pharmacists to use the Yellow Card Scheme as it 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.

Reports should be submitted electronically instead of on paper here: https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals. Further information is available on the NPA website: https://www.npa.co.uk/news-and-events/news-item/yellow-card-reporting-during-the-covid-19-pandemic/ .

COVID-19 Yellow Card reporting site
The MHRA has issued a Central Alerting System (CAS) alert to highlight the launch of a dedicated Yellow Card reporting site for healthcare products that are used in Coronavirus (COVID-19) treatment to be easily reported: https://coronavirus-yellowcard.mhra.gov.uk/.

Healthcare professionals, patients and carers are asked to report all suspected side effects to medicines or medical device adverse incidents related to COVID-19 treatment. This also includes medicines that patients and healthcare professionals are using off-label to treat COVID-19. Reporting for clinical trials should be in line with the trial protocol.

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. We appreciate you are all extremely busy with a massively increased workload currently. However, patient safety incidents may occur in the course of your practice. It is important to continue to manage and report all patient safety incidents in line with you pharmacy process. This includes completing the recording of the incident details carefully and fully.

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 & signposting

- 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/
- PSG COVID-19: https://pharmacysafety.org/corona-virus-covid-19/
- NPA dispensing process – best practice guidance: https://www.npa.co.uk/information-and-guidance/dispensing-process-best-practice/
- NRLS e-form: https://www.eforms.nrls.nhs.uk/staffreport/
- MHRA Yellow Card: https://yellowcard.mhra.gov.uk/
- NPA COVID-19 page: https://www.npa.co.uk/coronavirus-updates/
- NPA COVID-19 CD guidance : https://www.npa.co.uk/information-and-guidance/covid-19-dealing-with-controlled-drugs-during-the-pandemic/
- MHRA safe use of emollients: https://www.gov.uk/guidance/safe-use-of-emollient-skin-creams-to-treat-dry-skin-conditions
- MHRA emollients update: https://www.gov.uk/guidance/safe-use-of-emollient-skin-creams-to-treat-dry-skin-conditions
- NPA supplying paraffin-based products SOP: https://www.npa.co.uk/news-and-events/news-item/mhra-guidance-on-using-emollient-skin-creams-safely-and-updated-npa-paraffin-sop/

- MHRA DAOC: https://www.gov.uk/drug-safety-update/direct-acting-oral-anticoagulants-doacs-reminder-of-bleeding-risk-including-availability-of-reversal-agents
- CQC CD newsletter: https://content.govdelivery.com/accounts/UKCQC/bulletins/1b832ab
- IMMD review: https://www.immdsreview.org.uk/Report.html
- MHRA valproate guidance: https://www.gov.uk/guidance/valproate-pregnancy-prevention-programme-temporary-advice-for-management-during-coronavirus-covid-19
- MHRA valproate alert: https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-pregnancy-prevention-programme-materials-online
- MHRA valproate toolkit: https://www.gov.uk/guidance/valproate-use-by-women-and-girls#toolkit
- NPA valproate SOP: https://www.npa.co.uk/information-and-guidance/valproate-sop/
- NPA medicines in pregnancy and patient safety: https://www.npa.co.uk/information-and-guidance/medicines-in-pregnancy-and-patient-safety/
- GPhC valproate statement: https://www.pharmacyregulation.org/news/gphc-statement-supplying-valproate-safely-women-and-girls
- NHSE&I steroid emergency card: https://www.england.nhs.uk/publication/national-patient-safety-alert-steroid-emergency-card-to-support-early-recognition-and-treatment-of-adrenal-crisis-in-adults/
- PCSE online: https://secure.pcse.england.nhs.uk/_forms/pcsssignin.aspx
- MHRA isotretinoin update: https://www.gov.uk/drug-safety-update/isotretinoin-roaccutane-reminder-of-important-risks-and-precautions
- MHRA oral retinoids revised and simplified PPP materials: https://www.gov.uk/drug-safety-update/oral-retinoid-medicines-revised-and-simplified-pregnancy-prevention-educational-materials-for-healthcare-professionals-and-women
- Care Quality Commission's Controlled Drugs National Group Sub-Groups Newsletter - alfentanil: https://content.govdelivery.com/accounts/UKCQC/bulletins/1b832ab .
- MHRA CAS Priadel®: https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103087
- MHRA yellow card: https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals

Contact your Medication Safety Officer (MSO)

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

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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