Association of Pharmacy Technicians UK (APTUK)
The Professional Leadership Body for Pharmacy Technicians

Rebalancing Medicines Legislation and Pharmacy Regulation

New Dispensing Errors Legislation Update for Branches
May 2018

www.aptuk.org @APTUK1

"Leading pharmacy technicians to deliver professional excellence for patient centred care"

WELCOME

Dear Branches,

As you are aware from news on our website, our journal and other media, the new defence concerning inadvertent dispensing errors came into force on the 16th April 2018. It provides a new criminal defence for unintended dispensing errors made by pharmacists and pharmacy technicians in registered pharmacies.

To inform our members of the new requirements I have put this presentation together for you to share or present at your Branch meetings.

The presentation outlines the key requirements and emphasises the importance of learning and sharing from 'near misses' and errors and providing a more open culture. It also provides some useful resources that you can use to support your learning and to take this forwards, embedding a safety culture in our pharmacy practice. Pharmacy Technicians have a crucial role to play in keeping patients safe from medication harm.

Tess Fenn

APTUK President

May 2018

BRANCH PRESENTATION

Aim: To provide an update on the commencement of 'The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018'

Learning Outcomes:

By the end of this session attendees will be able to:

- Discuss the key principles and requirements of the legislation change
- Contribute to discussions on legislation change and how this will affect pharmacy professionals
- Explore the wider context of reporting, sharing and learning from errors
- Identify any personal training needs linked to new order

REBALANCING MEDICINES LEGISLATION AND PHARMACY REGULATION

Rebalancing

a review of the balance between medicines legislation and statutory professional regulation in pharmacy to keep safe those who use pharmacy services,

while

reducing barriers to the responsible development of practice, innovation and a systematic approach to quality in pharmacy

Programme Board

The board advises ministers on the development of policy

Chair: Ken Jarrod

Pharmacy Technicians on the Board

APTUK President: Tess Fenn

New member: Community

Julie Mathieson : Hospital

Underpinned by work on regulation, professionalism, patient safety, quality systems & culture in pharmacy

WHAT DOES IT INVOLVE?

Board was set up by DH to look at the components:

1. Review of dispensing errors legislation
2. Enabling registered pharmacy standards and related matters
3. Review of pharmacy owner, superintendent and responsible pharmacist arrangements
4. Review of hospital pharmacy regulation, in respect to dispensing errors
5. Review of pharmacist supervision

Components: Different timescales
Phase 1: Dispensing Errors & Pharmacy Standards
Pharmacy Owners, Superintendent Pharmacists & Responsible Pharmacists

BERWICK REPORT: *A PROMISE TO LEARN – A COMMITMENT TO ACT: IMPROVING THE SAFETY OF PATIENTS IN ENGLAND* (AUGUST 2013)

“Recommendation 10:

We support responsive regulation of organisations, with a hierarchy of responses. Recourse to criminal sanctions should be extremely rare, and should function primarily as a deterrent to wilful or reckless neglect or mistreatment.”

“ ……. unintended errors must be handled very differently from severe misconduct.”

DISPENSING ERRORS

What is a dispensing error?

What happens when a dispensing error is made?

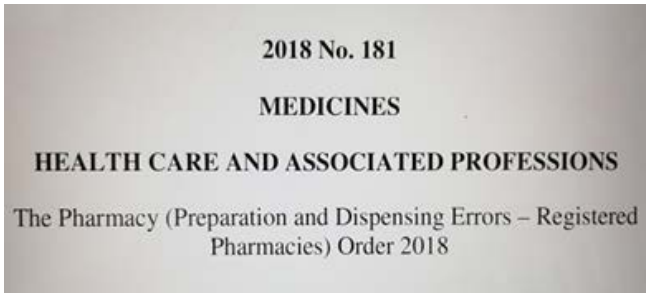
Triple Jeopardy

- Professional regulation
- Medicine legislation criminal sanctions
- General criminal law

Why did this need to change?

- Fear of prosecution impacts willingness to record and report dispensing errors
- Less reporting means less learning and less opportunity to improve patient safety
- Compare handling of prescribing errors

THE PHARMACY (PREPARATION AND DISPENSING ERRORS – REGISTERED PHARMACIES) ORDER 2018


2018 No. 181

MEDICINES

HEALTH CARE AND ASSOCIATED PROFESSIONS

The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018

Extends to England, Wales, Scotland and Northern Ireland

Will be reviewed in 5 years

Background

- Developed on a UK wide basis
- Been debated and approved in both Houses of Parliament and by the Privy Council.
- Following approval by the Queen 'The Pharmacy (Preparation and Dispensing Errors – Retail Pharmacies) Order 2018 (Commencement) Order of Council 2018' was made by the Privy Council on 21st March 2018
- Enacted on 16th April 2018

https://www.legislation.gov.uk/ukdsi/2018/9780111161524

DISPENSING ERRORS - LEGISLATION AMENDED

Medicines Act 1968 - sections 63 and 64

Section 64 - *"No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser."*

Section 64 also applies to dispensing private or NHS prescriptions and sales, but not supplies pursuant of directions

Section 63 concerns the adulteration of a medicinal product in course of preparation, where an ingredient is omitted or added

Section 63 applies to sales and supplies against a prescription or directions

Written directions to supply (in hospitals) allows a hospital to sell & supply POMs against a patient specific 'written direction' from an appropriate practitioner on a patient's bed chart or notes instead of a prescription.

DISPENSING ERRORS

New defence

- For pharmacists & pharmacy technicians, in respect to the criminal offences in sections 63 and 64, for inadvertent dispensing errors, providing certain conditions are met
- Also apply to unregistered pharmacy staff and pharmacy owners

Conditions

- Medicine sold or supplied by a registered pharmacist/pharmacy technician from registered pharmacy premises
- Sale or supply in pursuance of a prescription/directions
- Registered pharmacist/technician acting in course of their profession
- Patient promptly notified of the error, unless considered unnecessary

DISPENSING ERRORS

Notification when an error has occurred

- An ***appropriate person*** on becoming aware of an error must ensure all reasonable steps were taken to promptly inform the patient
- Unless the view is reasonably formed that it was not necessary or appropriate to do so in the circumstances, for example
  - In the overwhelming majority of cases it is the patient or carer who will discover the error
  - In light of pharmacy regulator guidance or discussion with legal representative
  - More appropriate to inform someone else, e.g. parent of young child

- **Appropriate person** = pharmacist or pharmacy technician who dispensed the product, the supervising pharmacist, the pharmacy owner, a person acting for the pharmacy owner

DISPENSING ERRORS

Unregistered pharmacy staff, e.g. PTPT, dispenser, assistant, delivery driver

- Defence applies provided conditions met and the wrong medicine was not deliberately sold or supplied by the unregistered staff member, who would remain liable for prosecution

Burden of Proof: Not acting in course of their profession

- Used professional skills for an improper purpose
- Deliberately failed to have due regard for patient safety
- Not following a standard operating procedure of itself does not count

DISPENSING ERRORS – HOSPITAL PHARMACY PROFESSIONALS

"Ensuring hospital pharmacy professionals have the same right of protection against criminal prosecution for inadvertent dispensing errors is a priority for the Board" **Ken Jarrold CBE, Chair, 16 February 2015**

Unlike community pharmacies the governance/regulation of hospital pharmacies differs across the four home countries

Supplies pursuant of directions, that are not also a sale, are not covered by section 64 – so a large proportion of hospital pharmacy medicine transactions are not subject to that criminal offence

However, section 63, concerning adulteration, applies to all transactions – dispensing, supply against directions and sales

A separate Order providing defences to section 63 and section 64 of the Medicines Act 1968, for errors made by a registered pharmacy professional in a hospital or other pharmacy service (e.g. in care homes and prisons) is needed

There are plans to consult on draft proposals shortly

DISPENSING ERRORS

Dispensing errors fortunately only occur in a small proportion of cases.

- There are over a billion prescription items dispensed by community pharmacies every year and it is testament to the professionalism of pharmacy staff that the error rate is so low.

Pharmacy professionals have listed multiple explanations for the occurrence of dispensing errors, including;

- Similar medicine names and the same branding on packaging for different products
- Poorly written prescriptions
- Workload, interruptions and distractions
- Physical environment, e.g. lighting.

IMPROVING PATIENT SAFETY

Government, regulatory and professional bodies expect **pharmacy teams** to be pro-active and engaged in improving patient safety.

To encourage and foster a culture of learning and improvement in registered pharmacies, the regulatory and professional pharmacy bodies across the UK have:

1. Published professional standards to support increased reporting, learning, changing practice and sharing learning from dispensing errors and near misses
2. Run patient safety and quality roadshows and medicines safety conferences to promote the standards and engage the professions.
3. Published a range of tools and resources to support the further improvement to systems and procedures

PROFESSIONAL STANDARDS

WHAT THIS IS FOR

Describe good practice & good systems of care for reporting, learning, sharing, taking action and review as part of a patient safety culture.

Provide guidance & information support the implementation of the standards.

WHO THIS IS FOR

These professional standards are for pharmacists, ***pharmacy technicians*** and the wider pharmacy team across the United Kingdom.

May also be of interest to the public, to people who use pharmacy & healthcare services, healthcare professionals working with pharmacy teams, regulators & commissioners of pharmacy services.

http://www.aptuk.org/aptuk-news/2016/12/5/professional-standards-reporting-learning-sharing-/

QUALITY SYSTEMS

To promote learning about quality healthcare and the systems that are needed to support this.
It aims to encourage the use of improvement science and provides a platform to share pharmacy improvement stories.

Our mission is to link pharmacy to quality and the pursuit of improvement.

Making sure that our systems are quality systems is beneficial to patients, pharmacy teams, organisations providing care and the pharmacy profession

http://www.pharmacyqs.com/

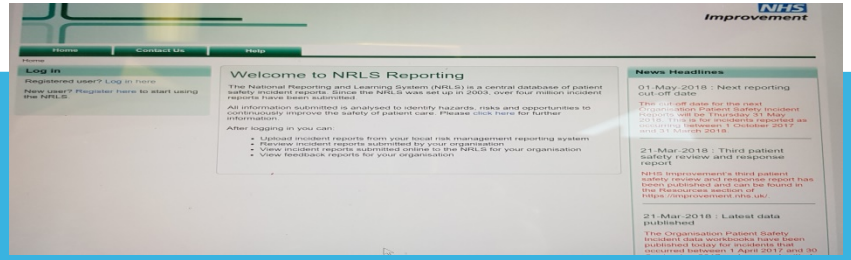
CONTINUING SAFETY IMPROVEMENTS

September 2014, NHS England (now NHS Improvement) & MHRA issued a Stage Three Directive recommending all large community pharmacy organisations (as well as NHS Trusts, homecare companies and independent providers) to identify a named Medication Safety Officer (MSO) to review medication incidents & oversee safety improvement within their organisation.

UK wide - number of system wide initiatives to support learning and improvement at a local, regional and national level and help to better identify and address system errors.

For example, in England there has been the introduction of medication safety officers and improvement of reporting systems (the National Reporting and Learning System – also in Wales).

https://report.nrls.nhs.uk/nrlsreporting/



https://report.nrls.nhs.uk/nrlsreporting

COMMUNITY PHARMACY PATIENT SAFETY GROUP (CPPSG)

Community Pharmacy Patient Safety Group
Our priorities for 2018

Continue to drive incident reporting culture and practice across the community pharmacy sector, promoting the Report, Learn, Share, Act, Review principles

Share learning from serious or recurrent patient safety incidents at regular CP PSG meetings so that warnings and recommendations can be cascaded throughout the network

Rise to the World Health Organization's global Medication without Harm challenge, and support Government ambitions to reduce prescribing and medication errors across the NHS, including through the Pharmacy Quality Collaborative

Work with NHS Improvement to inform the development of the new Patient Safety Incident Management System (PSIMS) and ensure the current National Reporting and Learning System (NRLS) is fit for purpose

Investigate practice issues or processes impacting on patient safety using programmes of audit and data capture and support implementation of recommended best practice

www.pharmacysafety.org

Work with key stakeholders and policy makers, including on the Rebalancing Board, to drive for changes in legislation relating to inadvertent dispensing errors, and other policy changes that will enhance patient safety culture

Arrange mental health training for Medication Safety Officers to empower them to champion mental health and wellbeing within their organisations, on behalf of both their patients and their pharmacy teams

Use external speaking opportunities, social media, videos, blogs and a second Patient Safety Forum event to champion the vital role that community pharmacy teams play in keeping people safe

Issue another patient safety CPD module, update our safeguarding resources, and work with the Centre for Pharmacy Postgraduate Education (CPPE) to inform their patient safety and safeguarding learning programmes

Work with Schools of Pharmacy to ensure patient safety is embedded throughout the MPharm curriculum

Engage with, and potentially partner with, organisations or charities that represent people who use community pharmacy services to help improve the quality of our work

@PharmacySafety

MSOs in community pharmacy organisations are the Superintendent Pharmacist, or a senior member of their team

2015 Pharmacy Voice Patient Safety Group

https://pharmacysafety.org/

GOVERNMENT : JEREMEY HUNT

February 2018

Patient Safety Movement Foundation Summit, Secretary of State for Health and Social Care outlined the results of a recent evidence base review that indicated the prevalence, scale and economic burden of medication errors in the NHS.

New research estimates that some 237 million medication errors occur in England per annum.

Hunt set out a number of areas where we could do better to tackle *prescribing and medication errors*:

- from improving how we use technology, such as electronic prescribing & medicines administration system,

- to understanding how best to educate & inform patients about their medicines.

Professor Sir Norman Williams is currently undertaking a review of healthcare professionals and gross negligence manslaughter which is due to report at the end of spring 2018.

Hunt to crack down on NHS drug errors linked to up to 22,000 deaths

Health secretary says mistakes in dispensing medicines cause 'totally avoidable harm and death'

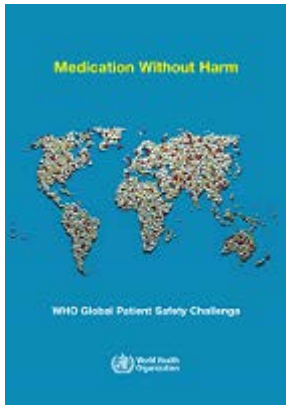
The Patient Safety Movement Foundation believes reaching ZERO preventable deaths in hospitals by 2020 is not only the right goal, but an attainable one with the right people, ideas, and technology

WORLD HEALTH ORGANISATION

WHO's Third Global Patient Safety Challenge: Medication Without Harm

WHO report that 'Unsafe medication practices and medication errors are a leading cause of injury and avoidable harm in health care systems across the world'

The global challenge aims to reduce severe avoidable medication-related harm by 50%, globally in the next 5 years.



Download the Brochure
http://www.who.int/patientsafety/medication-safety/medication-without-harm-brochure/en/

Real-life stories

There is also collection of stories on the website from patients, families and health care providers shows how they have been affected by medication errors and harm, as well as other stories on what they have done to prevent such errors and harm from reoccurring

http://www.who.int/patientsafety/medication-safety/en/

APTUK PATIENT SAFETY - GOING FORWARDS

Annual Professional Conference 2018

PTJ- regular column

MHRA alerts

Branches

CPPE: Patient Safety Learning Campaign 2018