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Supporting prescribing excellence - informing colleagues in primary and secondary care

Editorial Team

Fiona Benzies
(Specialist Pharmacist)

Helen Christie-Thom
(MMT Administrator)

Fiona Cleat
(Pharmacist)

Anne Gilchrist
(Lead Pharmacist, MMT) (Chair)

Alison Mackie
(Lead Pharmacist Medical Education)

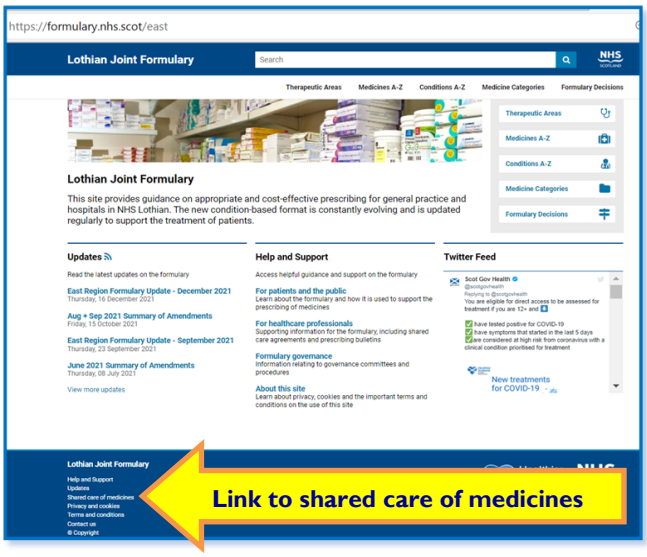
Dr Alison MacRae
(General Practitioner)

Alison McCulloch
(Specialist Clinical Pharmacist)

Stewart McNair
(Integrated Care Pharmacist)

Sharing the care: what you need to know...

Shared Care Agreements (SCAs) aim to facilitate the seamless transfer of care of individual patients between secondary care and general practice. SCAs are used when medicines, often prescribed for potentially serious conditions and complex in nature, are initiated in secondary care, and prescribing is then continued by GPs and other primary care prescribers. SCAs provide important information to ensure the medicine is initiated and continued safely. All SCAs can be found in the Shared Care of Medicines section of the Formulary website.



The General Practice Prescribing Committee (GPPC) recently agreed that the following statement would be added to all SCAs: *The presence of this SCA does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.*

The NHS Lothian procedure for shared care of medicines[1] revised in 2021, defines circumstances for which medicines are considered appropriate for shared care. It also seeks to ensure patients have equitable access to medicines across secondary and primary care and that information is communicated effectively.

The range of healthcare professionals now authorised to prescribe medicines has broadened and continues to expand. The updated procedure therefore reflects this and relates to all those professionals with responsibility for prescribing.

SCAs are currently reviewed every three years unless extensive changes are required earlier. Reviews are coordinated by a group of primary care pharmacists who liaise closely with hospital colleagues. Revision of the existing agreement is considered and developed by specialist teams and submitted to the GPPC for approval. The document may be shared with the Lothian Local Medical Committee (LMC) for any potential workforce implications. Finally, the approved SCA is added to the formulary website. If an SCA is no longer required by the specialist team, a proposal to withdraw the document must be submitted to the GPPC for approval.

Thanks to the shared care pharmacists for their contribution.

Reference

1. NHS Lothian Procedure for the shared care of medicines. https://policy-online.nhslothian.scot/Policies/Procedures/Shared%20Care%20of%20Medicines.pdf

Thanks to Professor Simon Maxwell, Medical Director, YCC Scotland and Consultant Physician for this contribution.

Pharmacovigilance during the COVID-19 pandemic and beyond

Pharmacovigilance and adverse drug reactions

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. Although all medicines are required to undergo rigorous testing for safety and efficacy through clinical trials before they receive a marketing authorisation (licence), the full extent of their potential adverse effects cannot be known at that point. The clinical trials process generally involves a relatively small number of selected participants, studied over a relatively short period of time. Some rarer adverse drug reactions (ADRs, sometimes referred to as 'side-effects') may only emerge after medicines are used more widely among tens of thousands of people, who are less carefully selected and monitored, have other diseases, take potentially interacting drugs, and are exposed to the new medicine over a longer period.

The COVID-19 pandemic and vaccine development

The COVID-19 pandemic has forced us all to confront these issues head on. The impact of infection has put significant pressures on healthcare services by causing illness, hospitalisation and deaths. Over 150,000 people across the UK have died within 28 days of a positive test for COVID-19. Part of the response has been a major effort to develop and deploy effective COVID-19 vaccines around the world.

In the UK, a national immunisation campaign has been underway since early December 2020. Three COVID-19 vaccines (Pfizer/BioNTech, Oxford/AstraZeneca and Moderna) are currently used in the UK. All have been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) following a thorough review of safety, quality and efficacy information from clinical trials. However, this was done under emergency or temporary authorisation (Regulation 174), after a much shorter than usual development and clinical programme.

In those pre-authorisation clinical trials, the vaccines showed high levels of protection against symptomatic infections with COVID-19. Subsequent 'real world' data confirmed the efficacy of the vaccines in preventing serious illness and hospitalisation during 2021. But what of safety?

Reviewing suspected adverse effects

Following emergency approval, it was recognised that an intensive pharmacovigilance process would be necessary. The pre-authorisation clinical trials in around 44,000, 23,000 and 30,000 volunteers respectively had demonstrated that some predictable vaccine side-effects were very common (injection site pain, fatigue, headache, muscle pains, chills, joint pains, and fever). The key question was, would anything else emerge? Healthcare professionals and the public were urged to report adverse events suspected to be related to vaccination through a dedicated reporting portal. To date, around 48 million Pfizer/BioNTech, 46 million AstraZeneca and 3 million Moderna first or second vaccine doses have been administered. In addition around 36 million booster vaccinations have been administered. As of 12 January 2022, 158,933 Yellow Card reports have been reported for the Pfizer/BioNTech vaccine, 242,148 for the AstraZeneca vaccine and 33,630 for the Moderna vaccine (around 3.5 Yellow Cards per 1,000 doses administered). These data, including the nature of the adverse event, number of reports made and number of deaths have been continuously available and regularly updated on a dedicated MHRA website, openly available to scrutiny by all.

The data have been widely cited, debated and also misused. However, these discussions have provided us with the opportunity to disseminate some very important messages relevant to pharmacovigilance:

- The safety profile of any new medicine (not just those approved under emergency authorisations) is never fully known at the point it is launched onto the market

- Although the scientists and manufacturers have primary responsibility for the safety of medicinal products, everyone (including members of the public) has a role to play in that process by reporting suspected ADRs
- It can be hard to distinguish adverse events occurring in association with medical treatment from spontaneous events that happen frequently in the population; a causal association only becomes clearer as more Yellow Cards reports are made ('signal generation').

The future

The profile of the MHRA as a body has been greatly increased during the pandemic, even if the comments have not always been supportive. Although the administration of nearly 136 million vaccine doses is impressive, it is important to remember that there are around a billion prescriptions issued every year in the UK for thousands of other medicines. These collectively result in around 30,000 reports annually.

The pandemic now offers a golden opportunity for those of us involved in the process of pharmacovigilance to harness the awareness of and enthusiasm for reporting suspected ADRs in the coming years. The value of the Yellow Card scheme reporting has been demonstrated on many occasions and has led to regulatory changes that enhance safety for patients.

If you read this and are inspired to contribute to the pharmacovigilance process, please consider reporting any suspected adverse drug reactions at yellowcard.mhra.gov.uk or contact us at yccscotland.scot.nhs.uk.

Key messages

- Pharmacovigilance is the science relating to the detection and prevention of adverse drug reactions
- The safety profile of any new medicine is never fully known at the point it is launched onto the market
- We all have an important role as healthcare professionals to participate in the pharmacovigilance process and encourage others to do so
- The Centre for Adverse Reactions to Drugs (CARDS)/YCCScotland is based in Edinburgh and is always happy to be contacted on questions about adverse reactions.

Formulary update - doing it together

The development of an East Region Formulary is now well underway. Adult sections for gastro-intestinal, infections and skin have been reviewed by the newly established Clinical Expert Working Groups, with representation from all three NHS boards – Borders, Fife and Lothian. The formulary pathways have been updated and approved and are now visible on the East Region Formulary website platform at formulary.nhs.scot/east/.

Key changes include:

Gastro-intestinal

- Constipation pathways now include palliative care and hepatic encephalopathy.
- Treatment of eosinophilic oesophagitis is now included.
- New pathways added for biliary cirrhosis.

Infections

- New pathways for acute necrotising ulcerative gingivitis (Vincent's infection) and for treatment of MRSA UTIs, non-bullous impetigo and MRSA soft tissue infections (moderate/severe).
- Staphylococcal carriage treatment clarified as two pathways, eradication and prevention.
- Treatment of epididymo-orchitis clarified as two pathways, STI cause suspected and UTI cause suspected.
- New information on eye drops added on administration and microbial contamination.

Skin

- The recommended medicines in the acne pathways now align with new NICE Acne guidelines.
- Actinic keratosis pathways are defined as small, large and specialist management.
- Additional guidance provided on emollients and corticosteroids in dermatitis and eczema.
- New pathway for oral treatment of pruritis.
- Psoriasis pathways now include biologic treatment in secondary care and specialist dermatology management for secondary care is now included.

Biologics, biosimilars and the formulary

Biological medicinal products are fundamentally different from chemically derived medicines in terms of their production, complexity of chemical structure, purity and immunogenicity.[1] Biosimilars are biological medicines which have been shown not to have any clinically meaningful differences from the originator medicine in terms of quality, safety and efficacy.[2] Once the patent for an original biologic has expired, other manufacturers can produce biosimilars. Although the active ingredients are similar to that of the original biologic, they are not identical and cannot be considered generic treatments.[2] The production of new biosimilars can potentially provide the NHS with cost savings of hundreds of millions of pounds.[2]

Biologic and biosimilar medicines are becoming increasingly more common in both primary and secondary care, and are recommended in the formulary for a range of conditions. Unless already established on a different brand of biological treatment, patients should be prescribed the branded product as recommended in the formulary. It is important to note that the recommended biosimilar may vary depending on the clinical condition.

It is highly recommended to prescribe the same brand that the patient has been established on because there are slight variations in molecular make up of the biosimilar products, despite in theory having the same clinical efficacy. Prescribing another product may impact upon control of the disease or result in possible adverse effects.

As part of the development and review of the East Region Formulary, biologic and biosimilar medicines are now fully incorporated into treatment pathways. These include pathways of the completed reviews of gastro-intestinal and skin sections.

One example is the **adult pathway for severe ulcerative colitis** formulary.nhs.scot/east/gastro-intestinal-system/inflammatory-bowel-disorders/ulcerative-colitis-inflammatory-bowel-disease/ and are for use in patients who have not responded to conventional therapy or who are intolerant of or have contraindications to conventional therapy. As indicated above, the branded products as recommended in the formulary should be prescribed. The first choice product and brand for Borders, Fife and Lothian is decided at health board level, and are all specialist use only, tagged in the formulary as:

SUO

The branded products are shown by clicking on the drop down tab to the right of the medicine.

References

1. Biosimilar medicines. A national prescribing framework. Updated March 2018. www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/programme_resources/lar_medicines_framework.aspx

2. Biosimilar medicines. SMC. May 2015. www.scottishmedicines.org.uk/media/2836/biosimilar-medicines.pdf

28-day supply of medicines in care homes - it's good practice!

The Royal Pharmaceutical Society in Scotland advocates 28-day prescribing in care homes,[1] dosette/instalment dispensing and Medicines Administration Recording (MAR) charts. This is to manage the risks with regards to medicines changes, and helps minimise waste. This is supported by the General Practice Prescribing Committee.

In reality there is a mixture of 28- and 56- day scripts in a few practices throughout Lothian. This may also occur on individual patient records.

Synchronising all care home prescribing to 28 days for this group of patients will simplify the workload of Community Pharmacists, Care Home, and Care at Home staff to enable more efficient and safer prescription management, therefore minimising risk.

Reference

1. RPS Scotland Improving Pharmaceutical Care in Care Homes. March 2012.

www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Policy%20statements/pharmacists-improving-care-in-care-homes-scot.pdf?ver=2016-10-12-142628-923

Thanks to Karen Reid, Lead Pharmacist Primary Care.