Public Domain

NCHA Position Statement

Clinical governance of unlicensed medicines and off-label use of medicines in Homecare Services

As homecare services are often part of complex treatment pathways prescribing. Where there are local clinical policies that have been agreed that are not aligned with the Summary of Product Characteristics. Sometimes patients may choose not to wait until the registered post administration observation period is over. In all cases, the health care professional administrating the product should be aware of the status of clinical protocols they are following and ensure the episode of treatment is appropriately recorded in patient documentation. There are some areas of clinical practice where unlicensed use of medicines is routine, e.g. paediatric practice.

As homecare services are often part of complex treatment pathways prescribing, dispensing and administration of unlicensed medicines and unlicensed use of licensed medicines should be considered as standard and process should be in place within each homecare organisation to ensure good governance standards are maintained.

Any healthcare professional physically administering the medicines shall follow the SmPC on dosage, precautions for storage, reconstitution and monitoring throughout the administration unless an exception has been reviewed as part of the homecare organisation's governance processes and has been approved by the Chief/Superintendent Pharmacist and the CQC Responsible Manager or other appropriate clinical governance specialist with appropriately delegated authority.

Patient Information

Patients must be fully informed about their treatment pathway including full disclosure of unlicensed medicine use. The primary responsibility for giving patients information rests with the clinical referring centre. However, in line with CQC standards it is best practice to provide information to patients using a layered approach to give patients multiple opportunities to understand and ask questions about their treatment. Where patients, or their carer's express concern about any proposed off license treatment, healthcare professionals should explain, the reasons why medicines are not licensed for the proposed use. If, after further explanation, the patient still has concerns, the treatment should not continue until the patient has received further counselling from their clinical referring centre. Unless otherwise stated in the approved treatment pathway or in the patient's individual care plan, it is best practice for the patient to be given appropriate information each time the unlicensed elements of the homecare service are provided.

Disclaimer

Clinical Governance Processes for use of unlicensed medicines and off-label use

Governance processes for unlicensed medicines and off-label use of medicines in clinical and medicines homecare services are of three distinct types.

Unlicensed Treatment Pathways

Where a treatment pathway does not conform to the requirements of the SmPC, a risk assessment and clinical governance approval process must be followed. This is to ensure regulatory requirements are met and risks to both patient safety and professional conduct standards are minimized. Whilst each healthcare professional involved in the treatment pathway takes responsibility for their own actions, the responsibility for ensuring clinical safety and suitability of the treatment pathway rests predominantly with the clinical referring center and the responsibility for prescribing within that treatment pathway rests with the individual prescriber. Exceptions to the SmPC must be clearly documented including who approved them and when they will be reviewed. Details of SmPC exceptions and their approval must be available to all relevant healthcare professionals delivering the treatment pathway so they can discharge their individual professional duty to ensure their work subject to appropriate clinical governance approval.

Pre-approved Individual Patient exceptions

Where the approved treatment pathway is aligned with the SmPC, but the medicines in the treatment pathway for an individual patient are unlicensed, the rational and approval for such use should be documented in the patient's individual care plan. Records must be kept of when and by whom information was provided to the patient and the patient's agreement[1] to continue their treatment with an unlicensed medicine. The individual patient's care plan should be available to all relevant healthcare professionals to avoid patients being asked repeatedly to detail their understanding of the unlicensed treatment pathway by different healthcare professionals.

Ad hoc Individual Patient exceptions

There may be cases where a patient agrees to proceed in accordance with the SmPC compliant treatment pathway, however, full adherence with the approved treatment pathway requirements is not possible. For example, if the patient or carer asks the health care professional to leave before the post administration observation period is over. In these cases, the patient should be asked to sign a "self-discharge note" or similar showing they understand their actions are not recommended. In any case the healthcare professional should follow the "end of treatment episode" processes, ensuring the patient has information on who to contact if they have concerns about their treatment or feel unwell. It is important that the healthcare professional raises any immediate clinical concerns in accordance with approved clinical escalation processes. The episode of care documentation must include the reasons for failing to complete the expected treatment in accordance with the approved treatment pathway and information given to the patient or carer.

[1] in homecare services consent means GDPR consent to share personal data; common law "consent" to treatment is referred to as patient agreement to treatment

When is Unlicensed and Off Label Medicine Use Appropriate?

When prescribing a medicine for unlicensed or off-label use but the prescriber takes full responsibility for the unlicensed use of the medicine and for overseeing that patient's care including monitoring and any follow up treatment. The prescriber must be satisfied that:

- an alternative, licensed medicine would not meet the patient's needs
- there is sufficient evidence base and/or experience of using the medicine to demonstrate safety and efficacy
- record the medicine prescribed and were common practice is not being followed the rationale.

Medications can be prescribed in an unlicensed way, for example,

- for an unlicensed indication,
- for administration of an unlicensed dose,
- for a patient from an unlicensed cohort of patients.

For novel medicines, initial indications may be limited in the SmPC, whilst further clinical trials are ongoing. It would normally be expected that prescribing outside the SmPC for a novel medicine is initiated as consultant led care within a specialist clinical referring centre. For more established medicines, there may be evidence that patients other than those included in the clinical trials, may benefit from the medicine e.g. small patient cohorts for whom clinical trials are prohibitively costly.

Some medicines are routinely used outside the scope of their license, for example in treating children. Pharmaceutical manufacturers do not always test their medicines on children and as a consequence, cannot apply to license their medicines for use in the treatment of children. The use of medicines that have been licensed for adults, but not for children, is often necessary and appropriate in paediatric practice.

The homecare organisation's governance processes should provide reasonable assurance to health care professionals that they have discharged their professional duty of care for the patient. The health care professional has a duty to raise concerns with their responsible manager and/or the prescriber where the approved local clinical protocol is radically different from SmPC and patient safety is thought to be compromised. In these cases, the health care professional may seek further independent information from the medical information department of the clinical referring centre or medicine manufacturer. If the health care professional feels unable to raise concerns through the homecare organisation's governance processes, they should seek advice from their professional body and/or consider following the organisations "whistleblowing" process.

Background

Every licensed medicinal product in UK has a marketing authorization issued by Medicines and Health Regulatory Agency (MHRA). SmPCs are written and updated by the pharmaceutical companies and are based on their research and product knowledge. During the licensing process, the MHRA review and assess the evidence provided by the manufacturer to support the use of the medicinal product. This review results in publication of a Summary of Product Characteristics (SmPC), approved by

MHRA, for every licensed medicine available in the UK. Updates to SmPC's may be supported by evidence from clinical trials or post marketing surveillance. When a manufacturer wishes to update a SmPC they must gain approval from MHRA. The published SmPC is the primary source of information for health care professionals and explains how to prescribe and use/administer the medicines.

The process of delivering medications to patients is often shared by a number of health care professionals Their roles includes prescribing, administration and monitoring side effects of the medication. Within clinical and medicine homecare services there are increasing numbers of novel and complexity treatment pathways not foreseen in the approved SmPC. In these cases, there is particular benefit in ensuring robust recording and reporting of adverse reactions and clinical outcomes which could support optimisation of medicine use, provide evidence for updates to SmPC and therefore improve overall patient care. Where the clinical and medicines homecare service is funded by the manufacturer or marketing authorisation holder, they have a particular interest in ensuring such robust recording and reporting.
The prevalence of 'off label' and 'unlicensed' or 'out of license' use of licensed medicines requires dispensing staff working in clinical and medicines homecare to be more vigilant than other areas of pharmacy practice. It also requires those homecare staff that administer the medicines to patients to understand and follow the complex treatment pathways following guidance provided in the SmPC and/or in the clinical referring center's clinical protocols where this differs from the SmPC.

Scope:

This document considers the dispensing and administration of medicines in clinical homecare services where the clinical pathway does not follow that envisaged by the manufacturer and regulator as stated in the Summary of Product Characteristics (SmPC). This guidance does not cover clinical trials which are subject to different regulations and controls.

Disclaimer

NCHA does not warrant or represent that the material in this document is accurate, complete or current. Nothing contained in this document should be construed as medical, commercial, legal or other professional advice. Detailed professional advice should be obtained before taking or refraining from any action based on any of the information contained in this document.

History

Version 1 – Final Draft 22 Jan 2020 for approval. Changes after consultation on initial draft: Patient information section updated.
Version 1.1 – Final Version 5 March 2020 – approved by NCHA Board