NHS Scotland Directors of Pharmacy and Scottish Association of Medical Directors

USE OF UNLICENSED MEDICINES AND OFF-LABEL MEDICINES WHERE A LICENSED MEDICINE IS AVAILABLE

CONSENSUS STATEMENT

This consensus statement is intended as a support for and as a supplement to NHS Scotland Territorial Boards’ own unlicensed medicines policies. These policies will address the full range of issues in relation to safe and effective procurement, supply, prescribing and administration of unlicensed and off-label medicines.

1. CONTEXT

1.1 Marketing Authorisation

Most medicines prescribed within NHS Scotland are covered by a marketing authorisation or product licence which defines a medicine’s terms of use. A licensed medicine has been assessed for efficacy, safety, and quality; has been manufactured to appropriate quality standards; and when placed on the market is accompanied by appropriate product information and labelling (Appendix 1 for definitions).

1.2 Generic Versions of Medicines

It is recognised that, in some cases, the generic versions of a medicine may not have exactly the same indications as those within the marketing authorisation of the original branded medicine, due to patent protection issues e.g. clopidrogel, and pioglitazone. However, with the exception of biosimilars, bioequivalence to the branded medicine must have been demonstrated as part of the generic market authorisation process and therefore, any additional risks of prescribing and dispensing the medicine generically are considered negligible. In addition, for many generic or long established medicines it is common practice to use them for well recognised off label indications e.g. amitriptyline for use in neuropathic pain. These indications are often included in clinical guidelines and their use is well described in the published literature. This consensus statement is not intended to disrupt the
practice of using off label generic or long-established medicines in this way since these will be the subject of local clinical risk assessment.

1.3 **Role of Scottish Medicines Consortium**

The Scottish Medicines Consortium (SMC) led health technology assessment including evaluation of the medicine’s cost effectiveness, is now a core part of an NHS Board’s decision about whether to make a medicine available for its patients. Where a licensed medicine has been deemed not to be cost effective, NHS Boards have begun to consider whether there are occasions when there is justification to use an unlicensed or off-label medicine as an alternative to a licensed medicine.

1.4 **Where a licensed medicine is available, it should normally be prescribed in preference to any unlicensed alternative**. This is particularly applicable to medicines which have been recommended for use by SMC. However, the use of unlicensed or off-label medicines may be required for individual patients and groups of patients and is more common in some areas of medicine such as in paediatrics, psychiatry, oncology and palliative care. The General Medical Council guidance (February 2013) states that doctors should usually prescribe licensed medicines in accordance with the terms of their licence. However, they may prescribe unlicensed or off-label medicines where, on the basis of an assessment of the individual patient, they conclude, that it is necessary to do so to meet the specific needs of the patient.

2. **KEY ISSUES**

2.1 **LIABILITY for Prescribing or Supplying Unlicensed or Off-Label Medicines**

2.1.1 NHS Boards carry a liability for the actions of their employees and may accept liability for the prescription of unlicensed or off-label medicines, where such use has been authorised and agreed, provided that local policies and procedures are adhered to. The NHS Board’s ‘vicarious liability’ does not extend to independent contractors such as General Practitioners and Community Pharmacists. Independent contractors prescribing or supplying unlicensed or off-label medicines have a **personal liability** for their actions that cannot be transferred to the manufacturer or importer of the medicine.

2.1.2 Where it is intended that such prescribing of an unlicensed medicine or off-label medicine will be continued after patient discharge, clear arrangements must be agreed between primary and secondary care regarding clinical and prescribing responsibilities, using appropriate processes such as local shared care arrangements. There may also be some occasions where retention of prescribing responsibility within secondary care may be considered or required.

2.2 **Factors to be considered PRIOR TO PRESCRIBING an unlicensed or off-label medicine for an individual patient by an individual prescriber**

The following criteria should be considered before considering prescribing an unlicensed or off-label medicine for an individual patient:

1. There is no suitably licensed medicine alternative available that will meet the patient’s need, or, there is a suitably licensed medicine available, but it is ‘not recommended’ by SMC and the patient does not fit the criteria for access via an Individual Patient Treatment Request (IPTR), Group Patient Treatment Request(GPTR) or a medicine approved for use through a Peer Approved Clinical System(PACS).
2. There is an acceptable evidence-base to support use and the risk-benefit assessment for the patient is in favour of prescription of the unlicensed medicine. This position should be reviewed at regular intervals to ensure that the evidence base for the decision has not changed.

3. The prescribing decision has multi-professional support and is taken in line with local policy.

4. Patients (or their parents or carers) are given sufficient information on the relative risks and benefits of the unlicensed medicine that is to be prescribed to allow them to make an informed decision. The information provided and the decision should be documented in the patient’s notes.

5. The pharmaceutical quality of the product is confirmed

6. Continuity of supply can be reasonably assured which includes prior agreement with the primary care prescriber of their acceptance of liability associated with the prescribing/dispensing of an unlicensed or off-label medicine.

7. Clinical follow up should be agreed and documented. Adverse drug reactions should be a particular focus of attention, utilising the CHM “Yellow Card” reporting scheme.

2.3 Factors to be considered by an NHS Board PRIOR TO AUTHORISING SUPPLY of an unlicensed or off-label medicine for a group of patients

The following criteria should be considered before an NHS Board authorises supply of an unlicensed or off-label medicine for a group of patients:

In most cases where unlicensed or off-label medicines are being considered for use, the decision is based on clinical need or on occasion, lack of availability of a suitable licensed product. Sometimes, however, a licensed medicine may not be approved for local or national use on the grounds of cost effectiveness. If in these circumstances, the NHS Board is of the view that the unlicensed or off-label medicine is more cost effective then it may be viewed as a treatment option. Consideration of acquisition costs alone must not be used to make such decisions.

1. There is no suitably licensed medicine alternative available that will meet the needs of the group of patients, or, there is a suitably licensed medicine available but it is not recommended by SMC.

2. A NHS board should consider the use of an unlicensed or off-label medicine only on grounds of cost if using the licensed medicine would have a substantial impact on other health services and where there is an acceptable evidence base and a robust risk-benefit assessment indicates that the use of the unlicensed medicine would be as effective as the licensed alternative and result in no additional risk to patients. This position may be strengthened by seeking national opinion and advice from the relevant professional bodies/colleges.

3. A NHS Board making a policy decision to use an unlicensed medicine where a licensed product is available, must fully document their decision and rationale. Decision making should be transparent, agreed at an appropriate level in the organisation and staff fully supported in implementing the decision.

4. Sufficient information on the relative risks and benefits of the unlicensed medicine that is to be prescribed is available for patients (or their parents or carers) to allow them to make an informed decision. The information provided and the decision should be documented in the patient’s notes.
5. The pharmaceutical quality of the product is confirmed. Professional responsibility for the decision will be taken by the pharmacist who procures an unlicensed medicine and who should have the knowledge and experience to make the assessment of pharmaceutical quality.

6. Continuity of supply can be reasonably assured and includes prior agreement with the community pharmacist of their acceptance of the personal liability associated with the procurement and dispensing of an unlicensed or off-label medicine.

3. References


DEFINITIONS

Licensing
The licensing of medicines is covered by Parts One and Two of the Medicines Act 1968, as amended. Additional requirements are enshrined in European Law. A medicine holding a full marketing authorisation will do so after a full evaluation by the Medicines and Healthcare Products Regulatory Agency (MHRA) or European Medicines Agency (EMA) of all data required for the medicine. The marketing authorisation holder is required to ensure that full product information is supplied to both the prescriber and dispenser of the product. The marketing authorisation confers liability upon the Holder for the medicine when used within the terms of the licence.

Unlicensed Medicine
The term ‘unlicensed medicine’ is used to describe a medicine without a marketing authorisation or licence for use in the UK.

“Off-Label” Medicine
The term ‘off-label medicine’ is used to describe a licensed medicine used for a therapeutic indication or circumstances outside the terms of its UK marketing authorisation or licence.