DEFINITIONS OF TRAFFIC LIGHT CATEGORISATIONS IN DORSET
REDRAFTED MARCH 2014

The "traffic light" system defines where responsibility for prescribing between primary and secondary care should lie through categorising individual drugs as **red**, **amber** or **green**.

The "traffic light" system provides a framework for defining where clinical and therefore prescribing responsibility should lie through categorisation of individual drugs. The "traffic light" system is intended to provide a framework to consider the **clinical responsibility and competency** associated with the prescribing of a medicine and is not based on the cost of a medication.

The list is advisory only (and can be changed by Dorset Medicines Advisory Group (DMAG) on request) but its existence should clarify expectations of prescribing responsibility.

The DMAG recognises that there are some medicines with unresolved 'traffic light status' and others where prescribers may have concerns or disagreements arising from the reclassification of medicines. Please raise these issues with the formulary pharmacists of the employing Trust or the CCG senior pharmacists. The formulary pharmacists and DMAG will aim to resolve the issues in a timely manner.

Following review of clinical data on efficacy, safety and cost-effectiveness by the DMAG and its sub-groups, drug treatments will either be recommended, following which they will receive a "traffic light" category as follows:

- **red** - for secondary or tertiary care initiation and long-term maintenance of prescribing;

- **amber with shared care** – drugs which are appropriate to be initiated and stabilised by a specialist in secondary or tertiary care, once stabilised the drug may be appropriate for responsibility to be transferred from secondary to primary care with the agreement of a GP and a formal 'shared care' agreement.
    - Initiation, prescribing, & monitoring until drug is stabilized is the responsibility of the specialist.
    - Specialist to request GP to take part in ongoing prescribing & associated clinical responsibility according to a 'shared care guideline', this may be prior to or following initiation of therapy
    - GP to respond to the specialist
    - Ongoing communication between primary and secondary care

- **amber without shared care** – drugs which may be initiated within a specialist service, which may be situated in primary, intermediate or secondary care, the drug may require stabilisation in the specialist service before transfer of prescribing to a primary care practitioner **OR** drugs which may be recommended by a specialist following a face-to face assessment or a telephone conversation with the patient's GP and initiated by the GP

- Initiation with 28 day supply (where possible) or recommendation is the responsibility of the specialist. Additional information regarding dosing and monitoring to be supplied by the specialist.
- GP to respond to the specialist (where necessary).
- Ongoing communication between primary and secondary care

- **green** - drugs which may be initiated, stabilised and maintained in a primary, secondary or tertiary care setting

- or, **not recommended**, that is where prescribing is not generally recommended in primary or secondary care. Drugs which are not appropriate for prescribing by primary or secondary care due to a lack of good clinical evidence because of concerns over safety or due to the availability of more suitable cost effective alternatives exist. This list will be reviewed regularly. **Clinicians should not prescribe these drugs**. All new black triangle ▼ drugs which have not been requested or formally assessed should not be prescribed until this has been done

For unlicensed medicines the prescriber, patient and GP should be aware of the unlicensed nature of the drug and reference to the protocol on the use of unlicensed drugs should be made.
Commissioning issues may also need to be considered, for example, the prescribing of unlicensed medications should not generally be transferred to primary care, however off-label use may be suitable for transfer.
Prescribers may wish to access the GMC guidance on prescribing off-label or unlicensed medications:
http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp

Further detail of classifications

Criteria for "Red" classification:
1. Requiring specialist assessment to enable patient selection and initiation and continuation of treatment
2. Requiring long-term, on-going specialist monitoring of efficacy
3. Requiring long-term, on-going specialist monitoring of toxicity (because the side-effect profile necessitates rigorous supervision by the hospital consultant or, the full range of possible side-effects, particularly long-term effects needs to be established (e.g cancer drugs)
4. Specifically designated as 'hospital only' by product licence
(e.g. isotretinoin (Roaccutane®))
5. That are new, or a new indication for an existing drug, that needs evaluation to be undertaken to establish place in therapy, with a recommendation that a formal review process be undertaken.
6. That are hospital indicated clinical trial materials
7. Use restricted by national guidance e.g NICE
8. Unlicensed / Off Label Drugs this includes unlicensed or named patient drugs, unlicensed doses or unlicensed indications for new▼drugs / drugs unfamiliar to primary care.

Criteria for the "Amber with shared care" classification

1. Requiring specialist assessment to enable patient selection and initiation of treatment
2. Requiring specialist monitoring of efficacy, or that responsibility is clearly transferred to primary care
3. Requiring specialist monitoring of toxicity, or that responsibility is clearly transferred to primary care
4. That is rarely used, such that individual GPs are unlikely to see sufficient patients and acquire a working knowledge of the drug
5. NICE guidance
6. Products without a UK product licence would normally be classified as 'red' but may, in exceptional circumstances, be classified as 'amber'.

Shared Care Template

A template for shared care agreements for drugs listed in the Shared care category of the pan-Dorset formulary is available blank shared care template. Shared care category drugs should be prescribed by a secondary care specialist or competent clinician to establish the patient on treatment, i.e. to monitor the patient's response (efficacy, safety and appropriateness), adjust dosage and treat side effects. The patient needs to be stabilised and reviewed before asking the GP to take over clinical and prescribing responsibility. Each 'shared care agreement' will be individualised according to specific requirements of the drug. Shared care guidance should be sent and transfer agreed at least 2 weeks before the GP needs to prescribe the next period of treatment. The GP should consider the competencies required to manage and prescribe for the patient.

Please note that primary care prescribers **should not assume** that drugs listed in the shared care group would attract "Near Patient Testing" payments under GMS Enhanced Services. This decision in relation to individual drugs is subject to local discussion with the CCG.

Criteria for the "Amber without shared care" classification

1. Requiring an assessment by a specialist service, which may be situated in primary, intermediate or secondary care, to enable patient selection and initiation of treatment (this may be face to face or a telephone conversation with the patient's GP)
2. Monitoring of efficacy can be undertaken in primary or secondary care
3. Monitoring of toxicity can be undertaken in primary or secondary care
4. Often used, such that individual GPs are likely to see sufficient patients and acquire a working knowledge of the drug.

Criteria for the "Green" classification

1. Routinely used drugs with a high degree of universal familiarity
2. Initiation may be appropriate in primary, intermediate or secondary care
3. Offers significant benefit over existing treatment and that its use as a first, second or third-line drug has been defined

Criteria for Not Recommended classification

1. Lack of data on effectiveness compared with standard therapy.
2. Lack of data on safety compared with standard therapy.
3. Known increase in risk of adverse events compared with standard therapy.

4. Lack of data on cost-effectiveness compared with standard therapy.
5. Less cost-effective than current standard therapy
6. NICE guidance which does not recommend the use of the drug
7. An interim measure pending review of the drug treatment

It should be noted that there may be occasions where the use of a drug treatment that has been categorised as “not recommended” is considered appropriate. This should be managed by NHS Trusts and the Clinical Commissioning Group on an individual patient basis and with regard to appropriate commissioning arrangements.