POSITION STATEMENT FOR THE PRESCRIBING OF VITAMINS, MINERALS, SUPPLEMENTS, HERBAL AND HOMEOPATHIC MEDICINES WITHOUT A PRODUCT LICENCE

The prescribing of Vitamins, Minerals, Supplements, Herbal and Homeopathic medicines without a product licence in the NHS in primary care and secondary care in Lancashire is not recommended unless funding has been agreed for an individual product for a specific indication.

SCOPE

This policy only covers preparations without a product licence. Preparations with a product licence should only be prescribed for its licensed indications.

EXCLUSIONS

Products where funding has been agreed on an individual basis and for a specific indication. One such example maybe vitamin D.

INTRODUCTION

Vitamins, minerals, supplements, herbal and homeopathic medicines without a Product Licence are assigned a

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and are not to be prescribed either in primary or secondary care covered by Lancashire Health Economy unless the product has been individually considered and funding has been agreed for a specific indication.

- Treatments which are judged experimental or not to be of proven effectiveness will not routinely be funded

and

- Funding for individual patients or groups of patients within trials or unstructured 'evaluation' of new treatments will not be supported

KEY PRINCIPLES SUPPORTING THIS STATEMENT

- Commissioning organisations have legal responsibility for NHS healthcare budgets and their primary duty is to stay within the budget allocated to them.
- Commissioners have a responsibility to make rational decisions in determining the way in which they allocate resources and to act fairly between patients.
- Interventions of proven effectiveness should be prioritised above funding research and evaluation.
- The NHS should only invest in treatments which are of proven effectiveness unless it does so in the context of well designed, sufficiently powered and properly conducted clinical trials.
- Because the capacity to meet the needs for R&D and service evaluation is insufficient, research has to be prioritised and therefore not all treatments can be investigated.

EXPERIMENTAL AND UNPROVEN TREATMENTS

Experimental and unproven treatments are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. They may include the following:

- The treatment is still undergoing clinical trials for the indication in question
- The evidence is not available for public scrutiny
- The treatment does not have approval from the relevant government body
- The treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field.
- The treatment is being used in a way other than that previously studied or for which it has been granted approval by the relevant government body.
- The treatment is rarely used, novel, or unknown and there is a lack of evidence of safety and efficacy.
- There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the decision maker does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.

Definitions:
Effectiveness means the degree to which objectives which have been identified in advance are achieved.
C*linical effectiveness* is a measure of the extent to which a treatment achieves the pre-defined clinical outcomes in a target patient population.
A treatment is *efficacious* if it has been shown to have a beneficial effect in a carefully controlled and optimal environment. It not always possible to have confidence that data from clinical trials will translate in clinical practice into the anticipated or any meaningful health gain for the target patient population of interest. This is the difference between disease orientated outcomes and patient orientated outcomes. For example a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy but this relationship might not be borne out in reality.

UNLICENSED OR REGISTERED VITAMINS, MINERALS AND SUPPLEMENTS

Prescribers should NOT prescribe vitamins, minerals and supplements without a Product Licence. They are considered to be low priority treatments and should not be prescribed, or recommended by clinicians.

NHS prescribing of food supplements including various vitamins and minerals (herbal medicines are often included) without a product licence (i.e. a product licensed for a particular indication) is not routinely recommended. Products that do not have a product licence have not undergone the strict criteria laid down by the regulatory authorities to confirm the safety, quality and efficacy of these products. They are often not manufactured to the same high pharmaceutical standards used for licensed medicines to ensure consistency in formulation and potency.

It is felt inappropriate to direct NHS resources towards products that do not have proven efficacy or safety in preference to licensed medicines. Patients may of course purchase these medicines to take as a complementary form of therapy, but should in all cases discuss the use of them with their GP or pharmacist. The latter will try to advise whether they are likely to interact with their usual medication or concurrent disease states, although this information is not always available as these supplements have not undergone the usual tests that conventional medicines are required to go through.

NB: *Products can be prescribed if local funding has been agreed, such as Vitamin D.*
NB: *Vitamins and minerals* ***with a product licence*** *can be prescribed for their* ***licensed indications only.***

UNLICENSED OR REGISTERED TRADITIONAL HERBAL MEDICINES

By their definition, unlicensed and registered traditional herbal medicines would automatically be classified as 'experimental or not to be of proven effectiveness' and not routinely funded. Should there be sufficient evidence of effectiveness, this would have enabled them to have been assessed by the regulator for a full marketing authorisation.

NB: Licensed herbal medicines. *Some herbal medicines in the UK do hold a product licence or marketing authorisation just like any other medicine. These are required to demonstrate safety, quality and efficacy (or effectiveness) and be accompanied by the necessary information for safe usage. These products can be easily identified by a distinctive nine number Product Licence (PL) number on the product container or packaging which is pre-fixed by the letters PL. If in doubt, ask the patient to bring in the packaging to see if the product has a PL number. If the product is not on the area formulary it is advised that a formal New Medicines Request be submitted.*

UNLICENSED OR REGISTERED TRADITIONAL HOMEOPATHIC MEDICINES

The use of all homeopathic preparations are low priority treatments and should not be prescribed, or recommended by clinicians NHS patients should not be referred to homeopaths.

The Commons Science and Technology Committee[1] acknowledges there is no evidence that homeopathy works beyond the placebo effect (where a patient gets better because of their belief in the treatment) and given that prescribing of placebos is not consistent with informed patient choice (which the Government claims is very important) as it means patients do not have all the information needed to make choice meaningful.

The Commons Science and Technology Committee states that the MHRA should not allow homeopathic product labels to make medical claims without evidence of efficacy. As they are not medicines, homeopathic products should no longer be licensed by the MHRA.

The evidence base shows that homeopathy is not efficacious (that is, it does not work beyond the placebo effect) and that explanations for why homeopathy would work are scientifically implausible. Given that the existing scientific literature showed no good evidence of efficacy, further clinical trials of homeopathy would not be justified.

Beyond ethical issues and the integrity of the doctor-patient relationship, prescribing pure placebos is bad medicine. Their effect is unreliable and unpredictable and cannot form the sole basis of any treatment on the NHS.

REFERENCES

1. Commons Science and Technology Committee, Homeopathy report available at: http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/45.pdf

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