UPDATE
Clinical
Module 1740

This module covers:

- The UK and European regulation of medicines and where complementary and alternative medicines (CAM) sit
- Nice guidance on when CAM may be used on the NHS
- Regulations around e-cigarettes

March

Clinical: Alternative remedies and interactions month

CAM regulations	March 7*
Alternative therapies	March 14
Common interactions	March 21

Practice: Skill-mix in the pharmacy March 28

**Online-only for Update Plus subscribers*

The regulations on complementary and alternative medicine

Asha Fowells

Not so long ago, complementary health treatments were considered as something only used by people pursuing an alternative lifestyle. Nowadays, they are big business, though the sheer breadth of the term complementary health makes it pretty much impossible to put a figure on uptake or sales.

Although there is no hard and fast definition of complementary and alternative medicine (CAM), it is fair to say that they are generally considered to be treatments that fall outside mainstream healthcare.

This module focuses on products that fall under the CAM heading, because this is the area pharmacists and their teams are most likely to be asked about. Healing therapies, such as reiki and hypnotherapy, are not covered.

Regulation of medicines

In the UK, regulation of medicines falls to the MHRA, which is an executive agency of the Department of Health. Part of this work involves reviewing data in order to ensure any new medicine that is licensed for use in the UK is safe, effective and of good quality.

It is also the MHRA that decides when a recently licensed medicine can lose its black triangle probationary status, and this only happens if the organisation is satisfied that the drug works safely without serious side effects in large numbers of people. The use of a licensed medicine is generally restricted to that detailed on its marketing authorisation, with anything else considered off-licence use.

Nice recommendations enable the suitability of herbal products such as St John's wort to be established

A centralised procedure for marketing authorisation applications also exists, whereby manufacturers submit all the relevant information about a medicine to the European Medicines Agency (EMA). Once the licence is granted, it is valid in all EU member states plus Iceland, Liechtenstein and Norway. This is the process followed for most new medicines.

CAM products generally fall outside these regulations for medicines. The MHRA encourages herbal medicine manufacturers to register products that are mass-produced and sold over the counter via the Traditional Herbal Registration (THR) scheme.

This sets out specific safety and quality standards and also confers a legal obligation ▸

on companies to monitor their products once they are on the market.

The packaging of these medicines bears the letters THR and can include claims for certain minor health conditions for which medical supervision is not required (a list of these is available from the MHRA). However, the manufacturer needs to show evidence that the product has been traditionally used to treat the stated condition for a minimum of 30 years, at least 15 of which must have been in the EU.

The MHRA has two regulatory schemes for homeopathic products:

- **The simplified registration scheme** Manufacturers are required to submit data on the product's quality and demonstrate that it is sufficiently diluted (at least one part of the original substance to 10,000 parts of the dilutant) for safety to be guaranteed. Only oral or external preparations are considered under the simplified scheme, and indications are not allowed.
- **The national rules scheme** This is slightly different in that there is no restriction on the first dilution to be authorised, the pharmaceutical form, or claims being made as long as they are confined to minor symptoms and conditions that do not require medical supervision. Under the national rules scheme, manufacturers must submit data that demonstrates quality, safety and use within the UK homeopathic tradition.

Non-medicinal products

Any product that does not have a marketing authorisation, THR or homeopathic product registration cannot make claims that are considered to be medicinal.

This means that terms such as cure, prevent, fight, heal and clinically proven are very much frowned upon by the MHRA, subject to the context in which they appear. There are a few exceptions:

- Medical devices can make medical claims, though only if the manufacturer can provide supporting evidence. Medical devices – which span a huge breadth of products, from dressings and injection equipment to diagnostic machinery and artificial limbs – generally must carry a CE marking, which means the manufacturer has proved the device is safe and works as intended to an independent certification body. The MHRA is responsible for appointing these bodies and ensuring they work to a consistently high standard.
- Cosmetics, as defined by UK and EU legislation, may have a secondary preventative purpose, but must not claim to be curative.
- Foods, including nutritional and sports supplements and vitamin and mineral products, can only make health claims (eg bone health) that appear on a UK list of nutritional claims (eg low fat) published by the EU and meet the conditions attached to that claim.

Products that could be classified as both a medicinal product and another type of item, eg a food, will generally be considered as a medicinal product by the MHRA and therefore the onus is on the manufacturer to conform to the applicable increased levels of regulation. Similarly, oral products that claim a physical action – for example, a slimming aid that professes to prevent fat being absorbed by the body – could arguably be deemed a medical device, so will be viewed as such by the MHRA if the manufacturer attempts to market the item on such a basis.

It is worth remembering that products that fall outside the scope of medicines from a regulatory point of view may be considered exactly that by patients. Examples where this might be the case include the use of supplements for conditions such as arthritis, and pharmacists have an important roles in providing explanations to customers.

Use of CAM in the NHS

The use of CAM within the NHS varies according to the condition and product being considered for use. A good starting point is to consider what Nice has to say on a particular topic. Some common examples that pharmacists are likely to see include:

- **St John's wort for depression** Nice states that although there is evidence of benefit in mild to moderate cases of depression, St John's wort should not be prescribed or recommended because of uncertainty about appropriate doses, persistence of effect, variation between preparations and the potential for serious side effects and interactions with other drugs including oral contraceptives, anticoagulants and anticonvulsants.
- **Nutraceuticals for osteoarthritis** Nice states glucosamine or chondroitin should not be offered for the management of osteoarthritis.
- **CAM for chronic fatigue syndrome (CFS)/myalgic encephalitis (ME)** Nice does not recommend the use of complementary therapies for CFS/ME due to insufficient evidence, but states that some patients do choose to use them and find them helpful.
- **Herbal and homeopathic products for atopic eczema** Nice states that the effectiveness and safety of such products for the management of atopic eczema has not been adequately assessed, so patients and their carers should be advised of the need for caution and to remember to inform health professionals of any complementary therapies they are using.

Nice has called for more research to be done on CAM. For example, in the organisation's guidance on generalised anxiety disorder (GAD), one of the research recommendations relates to the effectiveness of chamomile and gingko biloba in its treatment. Nice states that the existing evidence base is small, but the results from a placebo-controlled, double-blind randomised trial would be generalisable to a large number of people, which is important for a condition as common as GAD.

Nice also mentions the fact that the two herbal products are relatively inexpensive, widely available and have no known side effects, so could be used at an early stage of GAD as a means of preventing progression to pharmacological treatments.

Another useful resource is the NHS Evidence website, hosted by Nice. This has a search ▸

Reporting issues

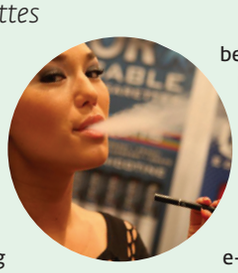
The yellow card scheme is one of the ways in which the MHRA monitors the safety of healthcare products used by patients in the UK.

However, many professionals overlook the fact that it can be used to report issues that may have arisen as a result of someone using a medical device or herbal, homeopathic or other CAM remedy.

It can also be used as a way of logging concerns that an item may be counterfeit or defective, which includes issues with product packaging or patient information leaflet as well as the product itself.

Regulation of electronic cigarettes

The charity Action on Smoking and Health (ASH) estimates that more than 2 million people in the UK now use electronic cigarettes, yet these nicotine-containing devices are unregulated.



This is set to change in May 2016, when any nicotine-containing product (NCP) that makes a medicinal claim (such as helping a smoker to cut down or quit) will require a licence issued by the MHRA.

As arduous as the process is, there are distinct advantages to manufacturers in doing this, not least the chance of their products being prescribed as outlined in Nice's guidance on tobacco harm reduction, which recommends the use of licensed NCPs (though local guidelines will be applicable).

Contrary to popular belief, this does not mean that all unlicensed e-cigarettes will disappear.

Manufacturers choosing not to go down the MHRA route will still have their products subject to control by the EU Tobacco Products Directive, which includes an obligation for packs to feature health warnings and an upper limit for nicotine content that is likely to come into force in 2017.

facility and throws up a huge range of answers to queries pulled from sources including the Cochrane Library, UK Medicines Information, journals, patient organisations and professional bodies. Chances are, if a patient or health professional asks a question, it has probably been asked before, and NHS Evidence provides a way of looking for possible answers from hundreds of accredited and authoritative sources.

Asha Fowells is a pharmacist and freelance health writer

For more information

- The MHRA's *A guide to what is a medicinal product* is a good source of information for anyone who wants to find out more about the regulatory framework outlined in this Update module. Find it at www.gov.uk/government/uploads/system/uploads/attachment_data/file/398998/A_guide_to_what_is_a_medicinal_product.pdf
- The MHRA's portal for marketing authorisation, variations and licensing guidance is at www.gov.uk/medicines-medical-devices-blood/marketing-authorisations-variations-licensing
- Advice on how to apply for THR status for a herbal remedy can be found at www.gov.uk/apply-for-a-traditional-herbal-registration-thr
- For information on the regulations for homeopathic medicines, go to www.gov.uk/register-a-homeopathic-medicine-or-remedy
- Less technical information on herbal medicines is available from NHS Choices at www.nhs.uk/conditions/herbal-medicines/Pages/Introduction.aspx
- For information on health claims that can be made for foodstuffs, go to tna.europarchive.org/20130814101929/http://www.food.gov.uk/scotland/labelling-scotland/claims
- A list of nutrition claims and conditions can be found at ec.europa.eu/food/food/labellingnutrition/claims/community_register/nutrition_claims_en.htm
- Find out more about the Yellow Card Scheme at yellowcard.mhra.gov.uk/the-yellow-card-scheme
- The charity ASH provides information on electronic cigarettes at ash.org.uk/information/facts-and-stats/ash-briefings
- View Nice guidance on tobacco harm reduction at www.nice.org.uk/guidance/ph45
- Other Nice guidance can be accessed at www.nice.org.uk
- The NHS Evidence search facility is at beta.evidence.nhs.uk
- The Royal Pharmaceutical Society has published a quick reference guide on herbal and homeopathic products, available for members at www.rpharms.com/support-resources-a-z/homeopathic-and-herbal-products-quick-reference-guide.asp

5 minute test

■ Sign up to take the 5 Minute Test and get your answers marked online: chemistanddruggist.co.uk/update

Take the 5 Minute Test

1. The regulation of medicines in the UK is carried out by the MHRA.
True/false?

2. A THR licensed medicine can make claims for certain minor health conditions for which medical supervision is not required.
True/false?

3. Under the simplified registration scheme for homeopathic medicines, indications are not allowed.
True/false?

4. Medical devices can make medical claims if the manufacturer can provide supporting evidence.
True/false?

5. Some cosmetics can claim to be curative, but only as defined by UK and EU legislation.
True/false?

6. Foods can only make health claims that appear on a UK list.
True/false?

7. Glucosamine and chondroitin are recommended by Nice for the management of osteoarthritis.
True/false?

8. Nice states that chamomile and gingko biloba should not be offered for managing GAD.
True/false?

9. The yellow card scheme can be used to report issues arising from the use of a medical device or herbal, homeopathic or other CAM remedy.
True/false?

10. From May 2016, any nicotine-containing product that makes a medical claim will require a licence issued by the MHRA.
True/false?

Tips for your CPD entry on the CAM regulations

Reflect **What are the regulations covering complementary and alternative medicine (CAM)? Which CAM products are not recommended by Nice? How will e-cigarettes be regulated from May next year?**

Plan **This article discusses the regulations that govern CAM. It includes information about the general regulation of medicines and the regulation of herbal and homeopathic medicines, non-medicinal products and e-cigarettes as well as the yellow card reporting scheme.**

Act **Read the Update article and the suggested reading (below), then take the 5 Minute Test. Update Plus subscribers can then access answers and a pre-filled CPD logsheet at chemistanddruggist.co.uk/mycpd.**

Find out more about herbal medicines from the NHS Choices website – which is also a useful reference for patients – and from the European Herbal and Traditional Medicine Practitioners Association (EHTMPA)
http://tinyurl.com/camregs1
http://tinyurl.com/camregs2

Read more about homeopathic medicines from the NHS Choices website
http://tinyurl.com/camregs3

Read the information about complementary medicines in the C+D *OTC Guide to Medicines and Diagnostics*, which includes THR medicines.

Find out more about the yellow card scheme from the MHRA website
http://tinyurl.com/camregs4

Update your knowledge of the regulations for e-cigarettes on the Action on Smoking and Health (ASH) website
http://tinyurl.com/camregs5

Evaluate

Are you now confident in your knowledge of the regulations covering CAM products? Could you give advice about these regulations to patients?