Regulation of herbal medicines

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This Note outlines the historical regulation of herbal medicines in the UK, regulatory changes due to the *EU Directive on Traditional Herbal Medicinal Products,* and proposals to introduce statutory registration of herbal practitioners.

Herbal remedies for human use have for some time been regarded as medicines under UK legislation, in principle subject to the same licensing procedures as pharmaceuticals. In particular, efficacy requirements have been difficult to meet and so most EU Member States developed various pragmatic arrangements to tackle this. In the UK herbal remedies have historically been exempted from licensing.

A review of herbal regulation at EU level was prompted by safety concerns and the need for market harmonisation of various national herbal regulatory regimes.

The *Directive on Traditional Herbal Medicinal Products* (Directive 2004/24/EC) replaces most existing member state regulations and creates a unified licensing system for traditional herbal medicine products (in use for at least 30 years, of which 15 must usually have been in the EU). The Directive came into full effect on 30 April 2011.

The Directive applies to manufactured herbal medicinal products sold over the counter, prohibiting the continued sale of unlicensed products. This note will outline the conditions in which herbal medicines can now be sold in the UK.

The Directive has met with some opposition from suppliers and users of herbal medicines. Objections include perceived disproportionate costs of regulatory compliance and the difficulty some non-European herbal traditions may have in meeting the requirement. There are concerns this will result in threatening the viability of businesses and a reduction in consumer choice.

In February 2011, a statutory regulation scheme for herbal practitioners was proposed which would allow prescribing of unlicensed preparations by registered herbalists under a clause in the 2001 *Medicines Directive*. It was planned that this scheme would come into force in 2012. In July this year, the Under Secretary of State for Health, Dr Daniel Poulter highlighted issues which have made the introduction of the scheme difficult. He announced the setting up of a working group to further consider evidence and options. It will meet for the first time in early 2014.

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1 UK implementation

The *Directive on Traditional Herbal Medicinal Products* (Directive 2004/24/EC) (the 2004 Directive) is implemented in the UK by the *Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005*, which came into full force on 30 April 2011.[1]

Although the 2004 Directive has the potential to have a significant impact on some herbal medicinal products, there are three ways in which herbal medicinal products can continue to be sold in the UK:

- Achieving traditional herbal medicines registration (THR) via an assessment on application to the MHRA. In the UK this is being implemented via the Traditional Herbal Medicines Registration Scheme;
- being licensed as a medicine under a marketing authorisation (limitations of this option include the potentially high costs associated with the requirement in relation to research on safety and effectiveness), [2]or
- being prepared for a specific patient by a practitioner following a one to one consultation;

Despite these modifiers of the impact of the legislation on the availability of herbal medicines, the Directive created new regulatory requirements for many herbal products. The resulting costs to manufacturers, and industry concerns that the registration scheme is not well suited to some types of herbal preparations (such as traditional Chinese medicines), have lead to fears that there will be a loss of some herbal products from the UK market.

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1 http://www.legislation.gov.uk/uksi/2005/2750/contents/made (the explanatory notes include a useful policy background)

2 Directive 2004/24/EC

2. Historical UK regulation of herbal medicines

Historically in the UK herbal medicines were regulated under sections 12(1) and 12(2) of the *Medicines Act 1968,* which provided exemption from regulation for "unlicensed herbal remedies" either made up for individual patients (the "herbalist exemption") or sold over the counter, respectively.

To qualify for these exemptions, preparations must contain only herbal ingredients, cannot make specific medicinal claims, must be sold by herbal name or names rather than brand name, and cannot contain certain herbs which have been prohibited. Where these conditions are not met, products require a formal medicines marketing authorisation, as for any medicinal product. [3]

Prior to the introduction of the Directive, manufactured herbal medicines for human use were subject to licensing provisions under *European Directive 2001/83/EC* (known as the Medicines Directive). This required proof of safety, effectiveness for specified illnesses, and manufacturing quality.

Under the regulations implementing the 2004 Directive, the exemption under Section 12(2) which applied to those products sold over the counter no longer applies and all manufactured herbal medicine products are required to have either a full marketing authorisation or a traditional herbal registration.

Section 12(1) of the *Medicines Act 1968* has been replaced by Regulation 3 of the *Human Medicines Regulations 2012*[4]

The Medicines and Healthcare Products Regulatory Agency (MHRA) advises that those herbal medicines prepared in a one to one consultation are still exempt from the directive[5]:

> Medicines prepared by practitioners themselves for patients in accordance with the exemption described in Regulation 3 of The Human Medicines Regulations 2012 (formally Section 12(1) of the Medicines Act 1968), are largely unaffected by the Directive.

2 The UK Traditional Herbal Medicines Registration Scheme

The Traditional Herbal Medicines Registration Scheme is administered by the MHRA. To achieve Traditional Herbal Registration (THR) for their products, manufacturers or suppliers must demonstrate:

- a history of traditional use for at least 30 years (of which generally 15 years must have been in the EU);
- evidence of safety;
- adherence to appropriate manufacturing standards; and
- provision of appropriate product information to users. [6]

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3 MHRA, Prohibited or restricted herbal ingredients

4 Human Medicines Regulations 2012

5 MHRA, Herbal medicines regulation: Unlicensed herbal medicines supplied by a practitioner following a one-to-one consultation

6 MHRA, Traditional Herbal Medicines Registration Scheme: Key requirements

Granting of a THR does not require any proof that the herbal remedy actually works and the registration gives no assurance about effectiveness. However, the evidence of prolonged use does make efficacy more plausible.

The registration process is simpler than the regulation of conventional medicines- no evidence on efficacy from clinical trials is required. A significant number of mass-market herbal remedies have already been granted THR licences.[7] Herbal medicines that have been awarded a Traditional Herbal Registration include St John's Wort, Black Cohash and Arnica.[8]

However, the large number of possible herbal ingredients and the potential compliance burden for small-scale practitioners or suppliers is identified by some as a potential problem. This is partly addressed within the 2004 Directive through a requirement for publication of an EU list of herbs for which further simplifies the registration process. Companies do not have to produce the evidence of traditional use and safety and can rely on the information provided by the Committee on Herbal Medicinal Products. They still need to provide evidence of quality.

3 EU Community list

As part of the implementation of the 2004 Directive the European Medicines Agency has established the Committee on Herbal Medicinal Products (HMPC). This Committee is developing a 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' based on extensive scientific assessments[9]. It also works on more general areas and provides member states with scientific opinions on herbal medicine issues[10]

If an applicant can demonstrate that a proposed product for registration falls within the parameters set out in the Community list there is no legal requirement to present evidence as to the safety and traditional use of the product. Additionally, whilst not legally binding, the MHRA can take HMPC monographs into account as evidence of safety and traditional use. The applicant does however still need to demonstrate quality.

There are currently ten herbs on the Community list.[11] Alongside this, there is also a list of scientific monographs that can act as recommendations to Member States when considering specific herbs[12].

A list of the current status of the ongoing HMPC assessments, which as of November 2013 covers 165 herbal medicinal products, is published regularly via its website.[13]

4 'Sell through' period for herbal medicines

When the 2004 Directive came into full force in April 2011, the MHRA advised that retailers would be allowed to sell through their stock of herbal medicinal products that were already held. It was anticipated that these products would be sold within 18-24 months as this is the

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7 MHRA, Public Assessment Reports for herbal medicines
8 MHRA, List of products granted a Traditional Herbal Registration (THR)
9 MHRA, How to register your product under the Traditional Herbal Medicines Registration Scheme: The positive list and Committee for Herbal Medicinal Products
10 EMA, Committee on Herbal Medicinal Products (HMPC)
11 European Commission, Herbal Medicinal Products
12 EMA, Community Herbal Monographs
13 Committee on Herbal Medicinal Products, Overview of assessment work - Priority list (status November 2013)

average shelf life of these products. The MHRA advised that this period would allow manufacturers the time to bring their production up to the standards to meet the Directive.

The MHRA launched a consultation[14] in July 2013 to seek views on the proposals to end this concession.[15] At this time they proposed that 31st December 2013 would be the cut off date for the sale of these products.

After considering the responses, the MHRA announced in November 2013 that the 'sell through' period would end on 30 April 2014.[16]

5 Regulation of herbal practitioners

5.1 Proposal for a statutory register for herbal practitioners

Under existing provisions within EU legislation "authorised healthcare professionals" may be able to dispense unregistered simple or manufactured herbal remedies to individual patients:[17]

> A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorized health care professional and for use by his individual patients on his direct personal responsibility.

There is currently no existing statutory regulation system for herbal practitioners in the UK, proposals to introduce such a system have been developed to an advanced stage and a consultation on proposals was undertaken by the former Government in late 2009.[18]

In February 2011 the Secretary of State for Health, Mr Andrew Lansley announced the publication of the analysis report of the 2009 public consultation.[19] He went on to propose that the Health Professions Council (now the Health and Care Professions Council) establish a statutory regulatory scheme for herbal practitioners. It was suggested that this would be the subject of further public consultation[20] and it was planned that this legislation be in place by 2012[21].

There have been numerous parliamentary questions on the subject in 2013. The Under-Secretary of State for Health, Dr Poulter, in response to one such enquiry stated that whilst he acknowledged there had been a delay it was important to work through all the complex issues around this policy:

> **Michael Ellis:** To ask the Secretary of State for Health what progress he has made on implementing a statutory register of herbal medicine practitioners; and when he expects such a register to be in place.

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14 MHRA, Proposal to end the 'sell through' of unlicensed products, Herbal Medicines

15 MHRA, Summary of responses, Herbal Consultation: Sell Through of Herbal Medicinal Products

16 MHRA, Press Release: Medicines watchdog takes further action to protect public from unlicensed herbal medicines, 21 November 2013

17 Article 5.1 of Directive 2001/83/EC

18 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_086359

19 Department of Health, Analysis report on the 2009 consultation on the statutory regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK, 16 February 2011

20 http://www.mhra.gov.uk/NewsCentre/CON108789

21 HC Deb 16 February 2011 c84WS

> **Dr Poulter:** The legislation around this policy is complex and there are a number of issues that have arisen which we need to work through. We appreciate that the delay in going out to consult on this matter is causing concern, however it is important that any new legislation is proportionate and fit for purpose.
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> The Department intends to make an announcement on the progress of this policy shortly.[22]

There was also discussion of the time delays and concerns in the House of Lords.[23] [24]

5.2 Westminster hall debate

On 9 July 2013, Mr David Treddinnick tabled a Westminster hall debate on the subject of statutory regulation for herbal practitioners.[25] A number of members expressed their frustration that the Government had not yet proceeded with their plans to pursue statutory regulation.

In response, Dr Poulter advised that there were a number of issues, including ensuring consumer safety and the robust regulation of herbal medicines to be addressed prior to establishing a regulatory scheme for practitioners.

At this time there was some discussion of a recent European Court of Justice Case in which it was found that Poland had not fulfilled its obligations under a number of EU Directives related to medicinal products. The specifics in this case were related to the selling of unlicensed medicines that were similar but cheaper to those licensed by the European Medicines Agency.[26]

The European case is not related to herbal medicinal products but within his opinion, Advocate General Jääken provided a detailed consideration of Article 5.1 of Directive 2001/83.[27] As discussed above, this article could potentially provide that 'authorised healthcare professionals' can dispense simple or manufactured herbal remedies to individual patients in special circumstances.

The judgement of the Court stated that the article provided some flexibility for Member States to cope with individual circumstances or emergency situations efficiently. It went on to focus on the 'special needs' wording in the article. It agreed with the opinion of the Advocate general that excluding the provisions of the Directive can only be done where it is necessary. Any other approach would conflict with the aim of protecting public health:

> The concept of 'special needs', referred to in Article 5(1) of that directive, applies only to individual situations justified by medical considerations and presupposes that the medicinal product is necessary to meet the needs of the patient.
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> Also, the requirement that medicinal products are supplied in response to a 'bona fide unsolicited order' means that the medicinal product must have been prescribed by the

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22 HC Deb 15 May 2013 c312W
23 HL Deb 16 May 2013 cWA10
24 HL Deb 24 April 2013 cGC443
25 HC Deb 9 July 2013 c2WH
26 Court of Justice of the European Union, Press Release 36/12: Judgement in Case C 185/10 Comission v Republic of Poland, Polish legislation authorising the placing on the market of foreign medicinal products lacking authorisation which are cheaper than, but similar to, those already authorised is contrary to European Union law, 29 March 2012
27 Case C- 185/10, European Commission v Republic of Poland, Opinion of Advocate General Jääken, 29 September 2011

> doctor as a result of an actual examination of his patients and on the basis of purely therapeutic considerations.
>
> It is apparent from the conditions as a whole set out in Article 5(1) of Directive 2001/83, read in the light of the fundamental objectives of that directive, and in particular the objective seeking to safeguard public health, that the derogation provided for in that provision can only concern situations in which the doctor considers that the state of health of his individual patients requires that a medicinal product be administered for which there is no authorised equivalent on the national market or which is unavailable on that market.[28]

The judgement goes on to advise that the article is not concerned with healthcare systems or financial stability but is a provision that must be strictly interpreted. It is applicable in exceptional circumstances and to meet special needs.

Dr Poulter expressed concerns that, whilst the facts of the Polish case were not related to herbal medicines, the judgement and its discussion of the specials regime may impact on UK plans to introduce a statutory register of practitioners:

> Following the EU judgment in the case of the Commission *v.* Poland, which my hon. Friend the Member for Kettering mentioned, we have reassessed the risks. That case actually concerned unlicensed conventional medicines being used because they were cheaper, and although there is a clear distinction between those products and herbal remedies we had to look at what else the judgment said. It looked at the specials regime and, critically, it emphasised how strictly the regime must be applied. The judgment has a knock-on effect for what we propose for the use of herbal medicines manufactured by third parties without a licence, and it therefore needs careful consideration because there is a very high risk that we would be found to be in infraction of the European directive. We therefore need to consider further herbal products manufactured by a third party, and I will return to that point later
>
> The Government would, of course, like to find a way through the issue that supports responsible businesses and ensures public safety. Since the announcement in February 2011, the Department of Health has been working with officials in the devolved Administrations and with the Health and Care Professions Council to establish a statutory register for herbal practitioners. Alongside that, we have been considering a strengthened system for regulating medicinal products, to enable consumers to have access to a greater range of third-party manufactured herbal medicines. The process continues to be complex and lengthy, and it has been further complicated by the judgment in the European Union *v.* Poland case.[29]

He acknowledged that there is widespread support from some groups of herbal practitioners for statutory regulation but said that not all practitioners were in support. It would be irresponsible for the Government to proceed with the setting up the scheme without ensuring that it offered an appropriate form of regulation and addresses the risks to the consumers of these herbal medicines.[30]

Dr Poulter announced the setting up of a working group which will consider views from experts and interested parties from all sides of the debate to gather evidence and consider

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[28] Case C-185/10, European Commission v Republic of Poland, Judgement of the Court, 29 March 2012
[29] HC Deb 9 July 2013 c19WH
[30] HC Deb 9 July 2013 c19WH

options.[31] This working group will be made up of Members of Parliament, and experts in the field of herbal medicines.

6 Public campaigns

6.1 Opposition to the EU Directive

At the time of the introduction of the EU Directive there was opposition from some herbal practitioners, herbal medicine manufacturers, and patients.

Concerns included:

- Costs of regulatory compliance and manufacturing quality requirements would be disproportionate to profits for smaller manufacturers or for low-volume products. In particular, the costs of assays to demonstrate stability and composition are felt to be disproportionate to any risks;
- Exclusion of newer herbs with less than 30 years of use, or less than 15 years of EU use will lead to the withdrawal from sale of useful herbal medicines; and
- More complex herbal preparations, such as those used in Traditional Chinese Medicine (TCM) or Ayurveda, may be more difficult to regulate under the Directive. This is due to them either contain unusual herbs unlikely to be included on the pre-approved list or contain non-herbal components.
- Confusion and inconsistencies across the EU regarding which herbal products should be covered by medicines law and which are covered by food law. Herbal products treated as foods or food supplements currently tend to be regulated more permissively, and there is a trend since the Directive came into force for herbal medicines to be re-marketed as food supplements.

6.2 Industry views on statutory regulation

There is widespread support from herbal medicine and Chinese medicine associations for the introduction of a statutory register of practitioners.[32] [33] There is some concern however about perceived delays in the introduction of the proposed legislation.

The National Institute of Medical Herbalists has an ongoing campaign[34] to urge the government to introduce legislation to regulate herbal medicine practitioners and has recently written a letter to the Under-Secretary of State for Health co-signed by a number of associations representing practitioners and patients. The European Herbal and Traditional Medicine Practitioners Association organised a lobby of parliament on this subject in April 2013.[35]

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31 HC Deb 9 July 2013 c20WH

32 British Herbal Medicine Association, Press releases, February 2011 (accessed 2 June 2013)

33 Register of Chinese Herbal medicine, News, February 2011 (accessed 2 June 2013)

34 The National Institute of Medical Herbalists, Renewed campaign for statutory regulation, 21 May 2013 (accessed 2 June 2013)

35 European Herbal and Traditional Medicine Practitioners Association, Save herbal medicine