The Human Medicines Regulations 2012 No.1916 (14 August 2012)
Summary of the Regulations relevant to herbal practitioners

The Medicines Act 1968 is no longer in use (except for some minor sections), and UK medicines law is now set out in the Human Medicines Regulations 2012. The following three sections summarise the main parts relevant to consultations held by herbal practitioners.

Question 1: What is a herbal medicine?

Regulation 2, Paragraph (1):

In these Regulations "medicinal product" means—

(a) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or
(b) any substance or combination of substances that may be used by or administered to human beings with a view to—
(i) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or
(ii) making a medical diagnosis.

Regulation 8, Paragraph (1):

In these Regulations …

- "herbal medicinal product" means a medicinal product whose only active ingredients are herbal substances or herbal preparations (or both);
- "herbal preparation" means a preparation obtained by subjecting herbal substances to processes such as extraction, distillation, expression, fractionation, purification, concentration or fermentation, and includes a comminuted or powdered herbal substance, a tincture, an extract, an essential oil, an expressed juice or a processed exudate;
- "herbal substance" means a plant or part of a plant, algae, fungi or lichen, or an unprocessed exudate of a plant, defined by the plant part used and the botanical name of the plant, either fresh or dried, but otherwise unprocessed;

These definitions are the same as those used in the Traditional Herbal Medicinal Products Directive (THMPD) and the EHTPA worked with the MHRA to have this definition from the THMPD adopted into these Regulations as this definition gives a clear legal basis for tinctures and extracts.

The THMPD has been transposed into UK legislation, and now forms Part 7 of the Human Medicines Regulations 2012 where,

Regulation 125, Paragraph (1) states that: This Part applies to a herbal medicinal product (a "traditional herbal medicinal product") if the following conditions are met.

(2) Condition A is met if by virtue of its composition and indications the product is appropriate for use without the need for a medical practitioner to—
(a) diagnose the condition to be treated by the product;
(b) prescribe the product; or
(c) monitor the product's use.

All herbal products which are registered under Part 7 of the Human Medicines Regulations 2012 must be on the UK General Sales List, and must be marketed for indications which do not require the advice of a health care professional. These products can carry the THR logo. See
http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicinesregulation/index.htm

There are now almost 600 products registered according to 314 registrations, and the Public Assessment reports for these are available online via the MHRA at http://www.mhra.gov.uk/Publications/PublicAssessmentReports/PublicAssessmentReportsforherbalmedicines/index.htmwebsite. The number of products is greater as some products are marketed under different names but with the same composition.

The relevant aspect of this legislation for herbal practitioners is that if you supply a registered product to a patient for some reason, then you must not remove the packaging and insert. (See Paragraph (10), Chapter 1 of Part 13 of the Human Medicines Regulations).

Note 1: The topic of what is a food supplement, and what is a medicine is extremely complex, and involves the European Food Standards Agency and the European Medicines Evaluation Agency. In some cases, regulators in different countries in the EU have made different determinations about the status of particular herbs which are marketed as food supplements. See http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Borderlineproducts/

Question 2: What has happened to Section 12(1) of the Medicines Act 1968?

The 12(1) exemption now forms Paragraphs (2), (6) and (9) of Regulation 3 of the Human Medicines Regulations 2012, and these are give here:

Regulation 3. Scope of these Regulations: special provisions

(2) Regulations 17(1) (manufacturing of medicinal products: requirement for licence) and 46 (requirement for authorisation) shall not apply in circumstances where paragraph …(6) applies.

(6) This paragraph applies where a herbal medicinal product is manufactured or assembled by a person ("A") if—

(a) the manufacture or assembly takes place on premises occupied by A and from which A can exclude the public;
(b) the product is for administration to a person ("B") and A has been requested by or on behalf of B, and in B's presence, to use A's judgment as to the treatment required;
(c) the product does not contain a substance specified in Part 1 of Schedule 20;
(d) the product does not contain a substance listed in Part 2 of that Schedule, unless the product is sold or supplied—
(i) in or from containers or packages labelled to show a dose not exceeding the maximum dose or maximum daily dose specified in column 2 of that Part, or
(ii) in the case of a product for external use only, with a percentage of the substance in the product that does not exceed the percentage specified in column 3 of that Part; and
(e) the condition in paragraph (9) is met.

9) This condition is that the medicinal product is not manufactured or, as the case may be, assembled—
(a) on a large scale; or
(b) by an industrial process.

This topic is considered on the MHRA website: *Herbal medicines regulation: Unlicensed herbal medicines supplied by a practitioner following a one-to-one consultation.* See http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicinesregulation/Unlicensedherbalmedicinessuppliedbyapractitionerfollowingaonetooneconsultation/index.htm

Question 3: What has happened to herbs listed in Schedule III "Herbal Practitioner only" of the Medicines Act 1968?

Schedule III is now Schedule 20.

Paragraph (6) of Regulation 3 (above) refers to Schedule 20 but otherwise the text appears the same as in the Medicines Act 1968.

Regulation 241 then uses the text of the previous statutory instrument *The Medicines (Retail Sale and Supply of Herbal Remedies) Order 1977* (SI2130) to describe the sections of Schedule 20, as follows:

Regulation 241.—(1) Regulations 220 [Sale and supply of products not subject to general sale] and 221 [[Sale and supply of products subject to general sale] do not apply to the sale or supply, or offer for sale or supply by a person ("A") of a herbal medicinal product if—
(a) the product does not contain a substance listed in Part 1 of Schedule 20;
(b) the product does not contain a substance listed in column 1 of Part 2 of that Schedule, unless the product is sold or supplied—
(i) in the case of a product for which there is a corresponding entry in column 2 of that Part, in or from containers or packages labelled to show a dose not exceeding the maximum dose or maximum daily dose specified in that entry, and
(ii) in the case of a product for which there is a corresponding entry in column 3 of that Part, with the percentage of the substance in the product not exceeding that specified in that entry;
(c) the sale or supply, or offer for sale or supply, takes place on premises occupied by A and from which A can exclude the public; and
(d) the product is for administration to a person ("B") and A has been requested by or on behalf of B and in B's presence to use A's judgment as to the treatment required.

(2) A reference in this regulation to a substance listed in either Part of Schedule 20 is a reference to a substance that is obtained from any botanical source listed in either Part.

Schedule 20 appears to be unchanged from SI2130 (with revisions), and is on page 253 of the Regulations.
Part 1 lists 24 medicinal plants (or parts) that can only be supplied by pharmacists.
Part 2 lists the herbs commonly referred to by practitioners as "Schedule III" with maximum dosages as before.

Part 2: Column 1	Column 2		Column 3
	Maximum dose (MD)	Maximum daily dose (MDD)	
Adonis vernalis	100 mg	300 mg	
Aspidosperma quebrachoblanco	50 mg	150 mg	
Atropa acuminata, A. belladonna	Herb: 50 mg Root: 30 mg	150 mg 90 mg	
Chelidonium majus	2g	6g	
Cinchona spp., bark	250 mg	750 mg	
Colchicum autumnale	100 mg	300 mg	
Convallaria majalis	150 mg	450 mg	
Datura innoxia, D. stramonium	50 mg	150 mg	
Ephedra spp.	600 mg	1800 mg	
Gelsemium sempervirens	25 mg	75 mg	
Hyoscyamus spp.	100 mg	300 mg	
Lobelia inflata	200mg	600 mg	
Aconitum spp.	External only		1.3%
Conium maculatum	External only		7%
Pilocarpus jaborandi	External only		5%
Rhus toxicodendron	External only		10%

Note 2:
Please refer to the complete text online at http://www.legislation.gov.uk/uksi/2012/1916/contents/made