

BHMA

BRITISH HERBAL MEDICINE ASSOCIATION



**Over 50 Years of
Leadership
in Herbal Medicines**

THE BHMA: AIMS AND OBJECTIVES

For over 50 years the British Herbal Medicine Association has been an advocate and leader of responsible herbal medicine in the United Kingdom. The membership has always encompassed a wide spectrum of interests in the herbal field: manufacturers and suppliers of herbal medicines, herbal practitioners, companies involved in the supply of herbal raw materials and extracts, academics, pharmacists, retailers, students and others with an interest in phytotherapy.

As set out by our founding members, the objectives of the Association continue to be:



- To defend the right of the public to choose herbal medicines and to be able to obtain them freely.
- To promote high standards of quality and safety in herbal medicines.
- To advance the science and practice of herbal medicine by modern techniques.
- To encourage wider knowledge and recognition of the value of herbal medicine.
- To foster research in phytomedicine, exploring the vast potential of medicinal plants.

The Board endeavours to support the membership through a wide range of activities and keeps a close watch on developments affecting herbal medicine, liaising with regulatory authorities, industry forums, academic institutions and the media, providing advice and comment on EU or UK legislation and guidelines, and commenting on specific issues.

The BHMA supports regulatory control of herbal medicinal products and provides support to company members in the process of satisfying stringent EU quality and safety requirements for Traditional Herbal Registrations. It offers a suitable forum for THR holders to develop their mutual interests and ensure the success of herbal medicines in a competitive but fair market.



The BHMA has developed an accreditation process for the Herbal Practitioners Suppliers Section of the industry. Companies who have completed the process are granted the BHMA HerbMark to show that they fully comply with Good Herbal and Manufacturing Standards.



THE BHMA: HISTORICAL PERSPECTIVE

The BHMA was founded in 1964 at a time of increasing regulatory control, when herbal medicine in the United Kingdom faced an uncertain future. The fledgling Association played an important role in convincing the government of the day to include provisions for the herbal industry and profession in the Medicines Act 1968.



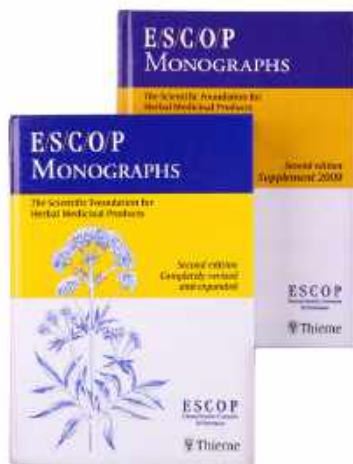
Recognising the need for authoritative monographs on herbal substances, particularly those not featured in or gradually being deleted from official pharmacopoeias, a Scientific Committee was formed in 1965 under the inspired chairmanship of the late Frederick Fletcher-Hyde. With the expertise of leading UK pharmacognosists, pharmacists and herbal practitioners, the Committee produced 232 monographs over a period of 16 years. They were published in stages then consolidated as the British Herbal Pharmacopoeia 1983 - a classic which remains in print to this day.

The BHMA's publishing tradition continued, leading to the British Herbal Pharmacopoeia 1996, its companion, the British Herbal Compendium Volume 1 (1992) and Volume 2 (2006), and A Guide to Traditional Herbal Medicines (2003). BHMA books have an excellent reputation worldwide and have been distributed to well over 50 countries.

Over the years the BHMA Board has developed contacts with a wide range of organisations and individuals with academic, commercial or regulatory involvement in the field of herbal medicine. Countless meetings, seminars and symposia have been organised on important topics of the day and our Annual General Meetings, normally held in June, are traditionally followed by a seminar with guest speakers.

Throughout successive phases in the regulatory control of retail herbal medicines the Board has maintained sound working relationships, albeit at arm's length, with regulatory authorities, primarily the Medicines and Healthcare products Regulatory Agency (MHRA) and its predecessors. The participation of MHRA representatives in BHMA meetings and events, for example in workshops on quality dossiers for herbal medicines, continues to prove helpful to many company members.

In 1989 the BHMA became one of the six founding members of the European Scientific Cooperative on Phytotherapy (ESCOP, www.escop.com) and has been a leading participant in ESCOP's Board and Scientific Committee ever since; the Secretariat is based in the UK. With the subsequent involvement of associations from many other countries ESCOP rapidly developed into a prominent and respected pan-European organisation, perhaps best known for its evidence-based ESCOP Monographs - *The Scientific Foundation for Herbal Medicinal Products*. Regular contact and creative work with our continental cousins is always a rewarding experience.



BHMA BOOKS

Full details of all BHMA books can be found on our website: www.bhma.info



BRITISH HERBAL PHARMACOPOEIA 1983

Widely acknowledged as a classic, the BHP 1983 combines basic quality standards with information on therapeutics in monographs on 232 botanical drugs. The quality standards have been largely superseded, but the originality and conciseness of the Therapeutics sections, based on the experience of many UK herbal practitioners of the time, give this book its enduring value.



BRITISH HERBAL PHARMACOPOEIA 1996

The BHP 1996 is solely a book of specifications; its monographs provide quality standards for 169 herbal substances while Therapeutics sections can be found in its companion, the British Herbal Compendium. Although many texts have been superseded by monographs in the European Pharmacopoeia, the BHP 1996 remains a particularly useful aid to quality assurance for substances not covered in official pharmacopoeias.



BRITISH HERBAL COMPENDIUM

A handbook of scientific information on widely used plant drugs

The British Herbal Compendium, designed as a “companion to the British Herbal Pharmacopoeia”, is extensively based on published research and supported by copious references to scientific literature. The monographs in Volume 1 (1992) and Volume 2 (2006) are listed on the BHMA website and, taken together, they cover almost all the herbal substances in the BHP 1996. Volume 2 includes monographs on most of today's more prominent herbs; a sample monograph (Sage Leaf) can be viewed on our website, www.bhma.info.



A GUIDE TO TRADITIONAL HERBAL MEDICINES

A sourcebook of accepted traditional uses of medicinal plants within Europe

A compilation (2003) of the indications for 263 herbal substances stated in key reference texts published in the UK (British Herbal Pharmacopoeia 1983; Extra Pharmacopoeia - Martindale, 25th edition 1967; British Pharmaceutical Codex 1934), France (Médicaments à base de Plantes) and Germany (Commission E monographs).

BHMA WEBSITE

Redesigned in 2020 and regularly updated, the BHMA website offers a wide range of information about herbal medicines. It is intended to give concise and helpful guidance to everyone, members and non-members, on herbal medicinal products available in the United Kingdom for various ailments, as well as background information on the Association and other topics.

A prominent feature of the website, with a direct link from the home page, is the *Which herbal medicine is right for me?* section, which provides a showcase for herbal medicines marketed by company members of the BHMA under 12 categories:

Coughs, Colds and Flu	Low Mood and Depression	Stress and Anxiety
Sleep Problems and Fatigue	Headache and Migraine	Circulatory
Muscle, Back and Joint Pain	Women's Health	Skin
Digestive Health	Urinary Symptoms	

Each section lists products available in that category and leads to a full page of key information on each product, in many cases with a direct web link to the company's website and online buying facilities or advice on where the product can be purchased.

Other sections of the website cover:

- The BHMA - its history, objectives, members, books and main activities, including participation in ESCOP.
- Information on how to join the BHMA and the benefits of membership.
- Contact details of all company members, with links to their websites.
- Detailed descriptions of the BHMA's currently available publications available to purchase on our website.
- A summary of key legislation relating to herbal medicines.
- A members-only area.
- Information on the Herbal Practitioners Suppliers Section
- Direct links to websites of various organisations involved in the herbal field.



visit us at
www.bhma.info

REGULATION

Manufactured herbal medicines placed on the UK market since April 2011 are required to have either a Traditional Herbal Registration (THR) or a Marketing Authorisation (MA) issued by the Medicines and Healthcare Products Regulatory Agency (MHRA). The agency reviews and approves herbal medicines against stringent criteria, satisfying EU requirements applicable to any medicine: a consistently high standard of quality, regular monitoring of safety, and full information for the user on safe and beneficial use of the product provided by in-pack leaflets.

Product Licences

From the early 1970s a herbal medicine making a medicinal claim on the label required a Product Licence. Acceptable products already on the market were granted Product Licences of Right (PLRs) with minimum formality at the time, but thereby became subject to general regulatory requirements for medicines including, for example, the premises in which they could be manufactured. The European Community Review of Medicines during the 1980s required such products to be reviewed for quality, safety and efficacy by 1990. Those that satisfied the requirements were granted a Product Licence (i.e. a full Marketing Authorisation) and could be identified by a “PL” number on the product pack.



Traditional Herbal Registrations (THR)s

The European Traditional Herbal Medicinal Products Directive or THMPD (Directive 2004/24/EC) established a new regulatory approval process for herbal medicines in the European Union; it was fully implemented in the UK from 30 April 2011.

A herbal medicine meeting EU standards of quality and safety, but not supported by clinical evidence of efficacy considered acceptable for a full Marketing Authorisation (MA), may be granted a Traditional Herbal Registration (THR) provided that bibliographic or expert evidence demonstrates 30 years of traditional use for the required indication, of which at least 15 years must normally have been within the European Union. THR products have traditional use indications and comprehensive information for safe and effective use must be included in each product pack.



A Public Assessment Report on each product granted a THR is published on the MHRA website (www.mhra.gov.uk); it provides substantial information including the Summary of Product Characteristics and images of the label and in-pack leaflet. In retail shops THR products can be readily identified by a THR number and distinctive ‘THR’ logo on the pack.

Since some herbal medicines for which Product Licences with “traditional” indications were granted up to 1990 are more appropriate to the THR category, such products have been transferred from PL to THR status, with upgrading of dossiers where necessary. Consequently, only herbal medicines with medicinal claims supported by clinical data acceptable to the MHRA now have Product Licences (Marketing Authorisations).

Foods and Food Supplements

A number of the more popular 'botanical' ingredients are sold as food supplements in the UK, either as individual herbal products or in combination with vitamins, minerals and other nutrients. These products are manufactured and supplied under food rather than medicines regulations. This means:

- There is less information available to the consumer regarding the botanical materials included in the product.
- No medicinal claims are possible.
- The products have not been assessed for quality, safety or efficacy by a regulatory body.

In addition to finished products, consumers can also purchase dried medicinal herbs through specialist independent retailers in the UK.

The MHRA has faced difficulties in defining which herbal substances and products are categorically medicinal and hence subject to medicines regulations. The status of individual herbal products is therefore assessed on a case-by-case basis. Final Determinations on specific products are published by the MHRA from time to time but they are not extended to provide any general rulings. Since this procedure is slow and laborious, the legal status of numerous herbal products on the market remains to be determined.

Herbal Practitioners

Under section 12.1 of the 1968 Medicines Act, a herbal practitioner was permitted to supply herbal remedies exempt from licensing provided that each remedy was manufactured or assembled on the practitioner's premises and supplied on the basis of a one-to-one consultation with the person receiving it. This is now formally implemented in UK law under Directive 2001/83/EC as SI 2012/1916 (The Human Medicines Regulations 2012), Part 12, Chapter 3, Regulation 241.

The long promised statutory regulation of herbal practitioners has not yet been realised. In February 2011 the Secretary of State for Health announced that statutory regulation of herbal practitioners would be introduced. Regrettably in 2013, following the Walker Report, Her Majesty's Government changed the decision and decided that herbal practitioners would not now be regulated. Following this disappointing U-turn the majority of herbal practitioners continue to be voluntarily regulated by a number of specialist herbal practitioner associations.

PAST AND FUTURE

The past half-century brought enormous and progressive changes in the regulation of retail herbal medicines. At every stage the BHMA was closely involved, liaising with UK and (through ESCOP since 1989) EU regulatory authorities and supporting members in countless ways - including publication of the *British Herbal Pharmacopoeia* and *British Herbal Compendium*. Herbal companies met the challenge of very demanding regulatory standards to achieve the consistently high quality and assured safety of today's herbal medicinal products.

We have confidence in the continued success of THRs and hope that a wider range of herbal medicines with full MAs based on clinical data will gradually become available on the UK market. We hope that in the future the statutory regulation of herbal practitioners will become a reality. No matter what the future holds, the BHMA will be at the forefront, engaging with developments and providing information, guidance and support to its members.

BENEFITS OF BHMA MEMBERSHIP

- An annual BHMA Membership card.
- Up-to-date news and comment on herbal medicine research, safety and regulatory developments as well as information and summaries on other topics via regular membership emails and our newsletter, the BHMA Post.
- Access to the members-only area of the BHMA website: www.bhma.info
- Free entry and lunch at our annual event held in London in June: the Annual General Meeting followed by a Herbal Medicine Seminar - an ideal occasion to meet and network with other members.
- Discounts on the registration fees for a range of informative events held throughout the year, including seminars and workshops organised solely or jointly by the BHMA, and select seminars held by other professional associations.
- A 25% discount on any BHMA book. New members also receive a complimentary copy of *A Guide to Traditional Herbal Medicines (2003)*.
- The services of the voluntary BHMA Board, working on your behalf. Our Directors devote their time to supporting and protecting the interests of members and herbal medicine in general; they liaise and attend meetings with the MHRA and other organisations in order to keep abreast of developments, determine policy and provide members with the most up-to-date information.
- Representation on the Board and Scientific Committee of the European Scientific Cooperative on Phytotherapy (ES COP). **Free access to online viewing of the ESCOP monographs** with discounts on downloads. The ESCOP monographs are uniquely comprehensive and up-to-date reviews of key herbal products as medicines. You can find out more at www.escop.com.
- Access to the BHMA copy clearance service at a reduced price for advertising, websites, social media etc.

ADDITIONAL BENEFITS FOR COMPANY MEMBERS

- A listing of your company, with contact details and logo, and a link to your own website, on the Company Members page of the BHMA website.
- The opportunity to promote herbal medicines with THR licences to the public in the BHMA website's *Which herbal medicine is right for me?* section and to market such products directly online where facilities exist.
- Supporting HPSS members with audits and accreditation necessary for displaying the BHMA HerbMark.
- Participation in meetings arranged from time to time for groups of company members to jointly discuss regulatory topics, to hear from experts or to raise issues directly with MHRA representatives.

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