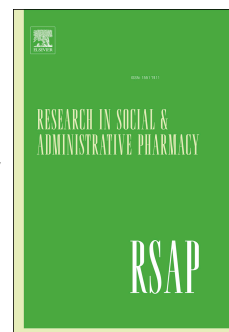


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Michael Heinrich, Sobha K. Sharma, Ursula Suetterle, Sukivinder K. Bhamra



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Herbal Medicine use in the UK and Germany and pharmacy practice - a commentary

Michael HEINRICH^{1,2,*}, Sobha K. SHARMA³, Ursula SUETTERLE⁴, Sukivinder K. BHAMRA^{3,*}

- 1) Research Group 'Pharmacognosy and Phytotherapy', UCL School of Pharmacy, Univ. London, 29 - 39 Brunswick Sq., London WC1N 1AX, UK;
Michael Heinrich m.heinrich@ucl.ac.uk
- 2) Chinese Medicine Research Center, and Department of Pharmaceutical Sciences and Chinese Medicine Resources, College of Chinese Medicine, China Medical University, No. 91, Xueshi Road, North District, Taichung City, Taiwan
- 3) Division of Natural Sciences. Medway School of Pharmacy | University of Kent, Anson Building, Central Avenue, Chatham, Kent, ME4 4TB, UK
Sobha Kandel ssk27@kent.ac.uk and Sukvinder Bhamra s.k.bhamra@kent.ac.uk
- 4) Schneckental Apotheke, Schwabenmatten 3, 79292 Pfaffenweiler, Germany
"Ursula Sütterle" Ursula@suetterle.com

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Abstract

Using two case studies from Europe, this paper illustrates that there is a need to understand the role of pharmacists' professional practice relating to traditional and complementary medicine. Especially in countries, where there is a strong ongoing tradition of using most notably herbal medicines and at the same time a limited focus on pharmacy practice research, there is a need for further studies. Comparing the role of community pharmacists in the context of herbal medicines and their use, two contrasting approaches emerge, and we exemplify this using a case study approach with two countries, which show the different approaches in the context of healthcare and specifically community pharmacy. In Germany (as in many other European countries) herbal medicines have remained a core element of community pharmacy, and are an important healthcare resource, while in the UK, these products are no longer primarily sourced through community pharmacies. This case study also highlights different regulatory approaches and classification in these countries to identical healthcare / medical products. Pharmacy practice research should endeavour to systematically compare the regulatory framework of this class of products and their importance in community settings.

1. Introduction

Many terms are used to describe treatments, which do not strictly follow conventional medicinal practice and they are often referred to as alternative, complementary or traditional medicine. In many regions of the world 'traditional medicine' is an essential element of healthcare¹, for example in many Asian countries (including China, Thailand, India, Malaysia, Indonesia, Japan, and of course China / Taiwan) as well as in many (esp. Central) European countries (including Poland, Hungary, Austria, Germany, Italy and Switzerland).

In this commentary we distinguish between herbal medicinal products (HMPs) and herbal medicines (HMs). HMPs are made from plant materials and in this commentary the use of this term is restricted to *products which have been regulated as medicines* (both traditional and licensed medicines). HMs on the other hand cover the entire range of preparations derived from medicinal plants used and sold with a medicinal claim or bought with the expectation that they have a medical effect. Many different types of HMs are employed in the practice of healthcare systems like Ayurveda, Kampo, Traditional Chinese Medicine (TCM) and Western herbal medicine. Specifically for Germany the concept of 'rational phytotherapy' is important², a concept which emphasizes a healthcare practice combining the scientific evaluation of HMPs in combination with empirical (medical) evidence

(empirical medicine). HMs is a broad umbrella term, which – in regulatory terms includes a wide range of products and it also refers to the general use of plants as medicines. Unlike modern medicines derived from medicinal plants, such as digoxin, where the medicine contains a single active compound, HMs contain a complex mixture of chemicals that are present in the plant material being used³. In this commentary we use the term ‘herbal medical product’ or briefly ‘herbal medicines’ for any medicinal product, ‘exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations⁴.’ However, in other regulatory systems such products may be classed differently, like for example as natural health care products (Canada), listed medicines (Australia) or AYUSH (AYUSH is the acronym of the medical systems that are being practiced in India such as Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy).⁵ Traditional forms of medicine are widely practiced in all global regions of the WHO.⁶ The Astana Declaration of Primary Healthcare (2019) calls for applying scientific, as well as traditional knowledge, to strengthen Primary Health Care (PHC), to improve health outcomes and ensure access for all people to the right care at the right time and at the most appropriate level, respecting their rights, needs, dignity and autonomy.⁷ In the context of technologies to be included in PHC, the declaration states that it supports extending access to a range of healthcare services which are of high quality, safe, effective, and affordable including traditional medicine as well as other technologies. (Astana Declaration 2018).⁸

In this commentary we showcase the diversity of how HMPs are used in healthcare in two countries of the WHO’s [World Health Organization’s] European region (UK & Germany) in order to understand the different approaches to the use of HMPs in community pharmacy. We also showcase some of the challenges associated with poorly regulated products available and the potential roles of community pharmacists. The two countries were selected since they are both important economies in the region and represent two contrasting frameworks for the use of herbal medical products.

2. Approach and Methods

Based on the experience of two community pharmacists in Germany and the UK (US and SSK), who are co-authors of this paper, we used a case study approach describing and comparing the framework on the use of herbal medical products in the two countries. The two countries represent two important economies of the WHO’s European region and show the spectrum of approaches to HMs and HMPs within this region. Therefore, the commentary includes an overview on the wider regulatory and policy background in Germany and the UK. Based on a series of regular (virtual) meetings over a period of four months, we developed the framework for the role of HMs and specifically HMPs in the two countries and for an analysis of the challenges faced within community pharmacy.

3. A comparison - UK and Germany

3.1. The healthcare systems

The National Health Service (NHS) was founded in 1946 as a government sponsored universal healthcare system, in the United Kingdom (UK). The NHS provides public healthcare to all permanent residents, which is free at the point of need and is paid for by general taxation. The UK also has a growing private healthcare sector that is still much smaller than the public sector. The medications available under the NHS are selected based

on both clinical and pharmacoeconomic criteria. A defined list of prescribable medicines form the basis of healthcare professionals' choices.⁹

The National Institute for Health and Care Excellence (NICE) provides guidance to the NHS on effective treatments that are value for money. Treatments options are assessed and endorsed by NICE and listed in the British National Formulary (BNF) as well as some additional formularies (e.g., for children).¹⁰

All NHS healthcare professionals are advised strongly to refer to the NICE guidelines in accordance with evidence-based practice. Even though in the UK, citizens are entitled to free healthcare under the NHS system, they have the option to buy private health insurance as well. Healthcare in the UK is a devolved matter, meaning England, Northern Ireland, Scotland, and Wales each have their own systems of private and publicly funded healthcare, as well as access to integrative, alternative, holistic and complementary treatments.¹¹

The German system is an insurance-based system with circa 85% of the German citizens being a member of a mandatory health insurance (*gesetzliche Krankenversicherung - GKV*) and the rest of the population covered through private health insurance providers. The largest mandatory ones are the *Allgemeine Ortskrankenkassen* (AOKs - general regional insurance companies which are corporations under public law - *Körperschaften öffentlichen Rechts*), but there are also around a hundred other insurance companies (*Ersatzkassen*). Financial contributions to the health care insurance are paid equally from both, the employee, and the employer. There is some competition between these companies based on the rate they charge and some variation in add-on insurance options / services. About 10 % of the citizens are members of private insurance companies, which offer a large range of additional benefits. People receiving social security payments are insured via the state social service (*Sozialamt*). Practically everybody is covered by a healthcare insurance (99.7%). In both countries, laws that ensure that practitioners are properly qualified and adhere to certain standards or codes of practice (statutory professional regulation) regulate the practice of conventional medicine. Different bodies oversee supervising these regulations. For medicines and medical devices, the BPharM (Germany) and the MHRA (UK) are the relevant authorities and for the pharmacy profession it is the State Board of Pharmacists of each federal state (*Landesapothekerkammer*, Germany) and the General Pharmaceutical Council (UK).

3.2 The role of herbal medicine

One of the most telling differences is the size of the HMP market in the two countries. Germany has the largest herbal medicine market in Europe for products with a medical claim and ones mostly dispensed in pharmacies. Based on manufacturers prices in Germany the market has an annual cost of €1.33 Billion (MAT – Moving Annual Total) equivalent to 20.7.% of the total European market. The UK is a much smaller market (€ 66 Million, ca 1%) coming 16th among 27 countries included in the analysis (IQVIA, pers. Comm. 2022)¹². Other major countries in terms of sales of herbal medicines include Italy (17.1), France (13.0), Russia (9.2%), Poland (7.2%) and Spain (6.3%)¹² (Figure 1). At the same time, this statistic may underestimate the importance of such herbal medicines since the survey does not cover non-pharmacy channels as systematically as it covers the pharmacy sector. In several surveys, one fifth to half of the UK's population claimed to regularly use herbal medicine as well as a range of other non-standard therapies alone or in addition to

biomedical (or conventional) medicine and treatments.²⁴ This usage is particularly frequent amongst those who are over-the-counter medicines-users.¹³ The use of these HMPs is often not endorsed or prescribed via the NHS.¹⁴ (cf. Table 1). The availability of HMPs and more generally CAMs on the NHS is therefore limited, and in most cases the NHS will not offer such treatments (Tables 1 & 2). NICE has recommended the use of HMPs in a limited number of circumstances including honey for cough, ginger for reducing morning sickness.¹⁵ Until April 2018 the Royal London Hospital for Integrated Medicine (formerly the Royal London Homoeopathic Hospital) offered NHS-funded HMPs but this was stopped due to lack of scientific evidence. Furthermore, while not HMPs, homeopathic remedies which were rarely prescribed on the NHS were also stopped.¹⁶

The use of HMPs is in essence based on the consultation with non-NHS healthcare practitioners including herbalists trained in European or one of the Asian therapeutic traditions and on patients' self-selection of Over The Counter (OTC) products and it may not only include the use of regulated HMPs. The MHRA regulates OTC HMPs under the Traditional Herbal Medicines Regulation (THMR) scheme, which is a part of UK law. In this scheme, HMP's are required to meet specific standards of safety and quality, agree upon indications for use based on their traditional use and provide information in a leaflet to promote safe use of the product by the purchaser³. Importantly, there is no statutory professional regulation of herbal medicine practitioners.

There are concerns on the safety of most HMPs, which may be further compromised by a lack of suitable quality control, inadequate labelling, and the absence of appropriate patient information.¹⁷

Any adverse effects must be reported to the Commission on Human Medicine via the Yellow Card Scheme but does not cover non-medical products (i.e., supplements and HMs without registration).¹⁸ The use of dangerous substances like mercury, lead, and arsenic in unlicensed Ayurvedic and traditional Chinese medicines is highlighted on the relevant NHS websites.¹⁹

In Germany HMPs are commonly prescribed or recommended by GPs and dispensed in community pharmacies. Many (fully) licensed products exist. A product with a full market authorisation in Germany may well be available in the UK under the THMR scheme or as a food supplement (Table 2). There is a very large range of medications available listed in the list of all medicines, medical devices and products commonly sold in pharmacies (the 'Lauer Taxe' - LT) which also provides basic data on uses, formulation, regulatory status, dosage forms, and price. In essence, doctors are free to select from the LT. However, the best practice guidelines (Arzneimittel-Richtlinie -AM-RL) define which medications are covered by the mandatory health insurance system. Specifically, the following groups are excluded: OTC preparations not restricted to pharmacies; pharmacy-only medicines, which do not require a prescription; medicines for treating minor ailments and lifestyle medicines.

Pharmacies remain a major point of contact for the advice on and the dispensing of HMPs and there clearly is a competition with stores selling health care products (Drogeriemärkte and Reformhäuser as well as mainstream supermarkets) and online supplies. Some community and hospital pharmacies specialize in herbal products, for example, HMPs from China and India, and are licensed to sell those, which are considered safe to use. As in other countries, unregulated products are sold without pharmacists' advice and knowledge, and with a large segment of the internet market not being under medical regulation, there is limited knowledge about the impact of such products at a community level.

For children below the age of twelve, HMPs can be prescribed and are reimbursable via the health insurance system. For adolescents and adults, the costs either have to be covered by the patient or through a supplementary element of the health insurance (aside from two products, which still are reimbursable).

Alternative practitioners use a wide range of interventions including, for example, ones from non-European medical traditions (est. Traditional Chinese medicine), European phytotherapy, and homeopathy.

As in the UK, adverse events with HMP (not listed and registered) are recorded, and if these are new serious events, they have to be reported with priority to the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM). The health care professionals are encouraged to report unusual events and those with products only introduced in the last five years (e.g. www.akdae.de).

3.3. Herbal medicines in community pharmacies

In the UK, HMPs are more widely found in many health food shops and supermarkets and not limited to be only sold in pharmacies. Therefore, there are no pharmacy-only HMPs as such (Table 2). Also, unlike Germany, pharmacies in the UK do not make extemporaneous preparations in the dispensary. This was triggered by a fatal incident in the year 2000. In the “Peppermint water” case an infant formulation of the medicine had a 20-fold excess of chloroform due to human error resulting in a tragic death.²⁰

In contrast, in Germany there is a well-defined group of HMPs, which are only available in pharmacies²¹. Some higher dose products are prescription only and in general all licensed products are pharmacy only (Table 2). Aside from prescription medicines, this includes products of a higher strength and any product considered to require pharmaceutical advice (cf. Table 1). In general, it is seen as essential that pharmacists provide advice on the use and any potential risks of herbal medicine making them products (HMPs) exclusively available through pharmacies. HMPs are commonly prescribed or recommended by healthcare professionals and then bought in a pharmacy (so-called OTX products – prescribed over the counter medicines)²² (Bundesverband der Arzneimittel-Hersteller e.V, 2021).

Alternative practitioners (Heilpraktiker) are a regulated profession; regularly prescribe specific herbal products and a range of alternative interventions.

OTC products registered under the EU scheme of Traditional Herbal Medicinal product (THMP) regulation are also widely available in healthcare stores (Drogeriemärkte, a group of highstreet and now online shops selling general household goods, toiletries, beauty products, health foods, foods for special groups like infants and children). Larger chains of pharmacies are not permitted in Germany. A pharmacist may own up to four pharmacies (one principal pharmacy with up to three subsidiaries). This ownership structure allows pharmacy to develop ‘unique portfolios’ and expertise, and it is common that pharmacies specialize, for example, in herbal medicines (including products which may not be HMPs).

OTC products including HMPs are commonly advertised in the shop windows of a pharmacy with a regular turn-over during the year, covering specific healthcare needs during the seasons.

Phytopharmaceuticals and 'Gesundheitsmittel' (medial health care products) are mostly sold through pharmacies. In terms of total value 71% of the total sales value is through pharmacies (1146 Million € out of 1622), 20 % online (333) and 9 other outlets outside of pharmacy (143). With respect to units sold the picture is somewhat different but the majority is still sold via the pharmacy channel (59% - 93 million packaging unites), with 14% (21.8) going through online channels and 27% (42.6) through other outlets outside of pharmacy (BAH 2021, p 37). This excludes products sold without a medical claim, i.e. supplements and general health care products.²²

There is a list of approved exempt standard formulations (Standardzulassungen) which are produced on site, including, for example, one for a valerian tincture or specific tea preparations for certain indications. Many but not all these formulations are based on herbal preparation, and all botanical drugs approved for medical use are covered by such a standard formulation. Each of these has a product licence or a registration number.²² The extemporaneous preparation of medicines containing herbal substances is still possible but is mostly done for an individual patient and often on an individual medical prescription. Therefore, extemporaneous preparation of HMP is also an important aspect of a Pharmacy in Germany.

Comparing these two countries highlights that the same product can be classified in different categories, namely registered medicinal product including prescription only medicine, traditional HMPs, well established HMPs or food supplement, or medical device, or homoeopathic/anthroposophical medical product, cosmetic in different countries. A product with a full license may well be a THR product in the UK or without a medical license e.g., for a major condition (vide *Ginkgo*) (see Table 2).

3.4. Impact of unregulated products on pharmacy practice

In both countries pharmacies sell products which are not under a pharmaceutical and medical regulation. In this chapter we focus on products which are used with a medical claim. Until relatively recently, most HMPs available in the UK were not regulated. Since the introduction of the Traditional Herbal Medicine Registration Scheme (THMRS) which took full effect in the UK in 2011.³ The UK has been at the forefront of the new licensing arrangements. Within the THMRS, traditional use means the HMPs has been in medicinal use for a period of 30 years, including at least 15 years within the European Community.³ HMPs can be authorised through the THMRS and are also available to the public as food supplements or cosmetics, the decision about whether a HMPs is a food, cosmetic or a medicine is made by the Borderline unit at the MHRA.²³

THMRS ensures the quality, safety, and efficacy of HMPs available for self-selection by patients. The RPS recommends that if a patient requests advice on a suitable manufactured herbal product, only authorised preparations [those bearing a Traditional Herbal Registration (THR) or Product Licence (PL) number] should be recommended.³ Since HMPs are generally not recommended by the NHS or prescribed, patients take them without telling their healthcare provider including community pharmacists or GPs.²⁴ Therefore, if patients do not disclose to community pharmacists that they are taking herbal remedies, it is difficult to advise them appropriately.

There is limited regulation of herbal practitioners or the HMPs that they supply to patients following a one-to-one consultation. Unlicensed remedies can be made up and supplied by an herbal practitioner to meet the needs of an individual patient following a one-to-one consultation.²⁵ Examples of actual and potential risks to public safety relevant to the use of HMPs by vulnerable groups are well documented.¹⁴ This is a result of poor herbal practitioner practice such as little sharing of information between herbal practitioners and GPs, for example, resulting in possible under-reporting of adverse incidents; some source products being potentially toxic; lack of control over actual contents of products; herb/medicine interactions; and adulteration of products.²⁶

The concern of the profession is mostly about low strength products available widely and the specific risks associated with unregulated products are poorly known. Online suppliers increasingly play a role, but in terms of public health impact, their importance is poorly understood. There can be no doubt that questions about poorly regulated products are also a concern expressed by community pharmacists in Germany, it will be essential to better understand the relative importance of this by, for example, comparing the two countries.

3.5. The role of education in the two countries

Providers of medicines, such as physicians, nurses, and pharmacists, often have little training in and understanding of how herbal medicines affect the health of their patients.²⁷ While pharmacists learn about conventional medications extensively during pharmacy school, courses focusing on herbal medicines are often lacking. However, the education of healthcare professionals is vital for the prevention of potentially serious risks from misuse of herbal medicines.²⁷

In pharmacy courses in the UK only very few lectures / practicals if any are dedicated to HMPs or HMs. The role of Complementary and Alternative Medicine is included in the competency catalogue of the indicative syllabus, but again it remains limited, and training is non-specific.²⁸ The General Medical Council (GMC) and General Pharmaceutical Council (GPhC) have set very broad statements, which teaching institutes must include in their syllabi (GMC, 2009; GPhC, 2011), unlike the General Dental Council (GDC) which does not have any requirements for undergraduate dentistry students to learn about complementary therapies (GDC, 2015).²⁷ Pharmacognosy was formerly taught in schools of pharmacy but while it may still be present in various forms (e.g. drug discovery), it is usually lacking in curricula as a stand-alone course.²⁸

Although some regulatory bodies do state HCPs should have an awareness of CAM including HMs, the extent to which this knowledge is taught to undergraduate HCPs remains to be discovered. In the UK, healthcare professionals identified their lack of knowledge on herbal

medicines (including HMPs) and their insufficient training as an important gap in their knowledge, which made them unable to advise patients on the safe use of herbal medicines.²⁷

There is currently no NHS accredited postgraduate education provision on HMPs for the healthcare professionals in the UK. There used to be a postgraduate module for pharmacists via CPPE (Centre for Pharmacy Postgraduate Education) and Health education England (HEE) on complementary medicine and therapies (which included HMPs) as well as an E-lecture guide however it has been discontinued.^{29,30}

In Germany, the education in pharmacy is broadly divided into five major fields, Pharmaceutical Biology, Pharmaceutical Chemistry, Pharmaceutics and Pharmaceutical Technology, Pharmacology and Clinical Pharmacy. This is defined in a national curriculum the 'Approbationsordnung für Apotheker' where the content and structure of the curriculum is defined in considerable detail. This includes a definition of how many hours are to be spent on certain topics and the type of didactic approaches to be used (lectures, seminars, practicals, excursions).³¹ The course is split into three consecutive sections, with the first two (overall four years) under the responsibility of a university and the final year being dedicated to the practical training normally in a community pharmacy, with six months potentially being spent in a hospital, a pharmaceutical company (incl. producers of HMPs) a university or another accredited institution.

Pharmaceutical Biology covers a wide range of subjects relevant in modern pharmaceutical sciences and practice – including biotechnology, (basic) immunology, microbiology, phytopharmaceutical analysis and HMs/HMPs. The development of this field of pharmaceutical biology within pharmacy is somewhat unique to Germany and has only been implemented in a similar way in some other Central European countries like Poland. It offers a focus on the (albeit diverse) biological aspects of pharmacy and clearly defines expected teaching and learning outcomes.³²

The 'Approbationsordnung' also covers specific main thematic areas to be taught, in the context of HMs, this includes fundamentals of biology and human biology, 'biogenic medicines', pharmaceutical analysis, dosage forms and others. Knowledge of medicinal plants, how to recognize them, their use and the pharmacology of their major effective metabolites (pharmaceutical biology) is a part of the academic pharmacy studies and about 15 % of the entire academic curriculum is dedicated to this.³² This is mostly covered in 'pharmaceutical biology, but also addressed for example in pharmaceutics in the context of dosage forms or in pharmacology within specific therapeutic areas. It also includes basic aspects of quality control of HMPs and botanical drugs as well as the formulation of typical extemporaneous products like creams and gels. However, the training remains focused on the drug substances and their preparation with little focus on pharmacy practice. There are opportunities to specialise in herbal medicine with a postgraduate diploma in Germany for Pharmacists & Doctors.³³

4. Conclusion

This commentary has identified major gaps in our understanding of the role of HM (incl. HMPs) in Germany and UK. A concerted effort is needed for a strong engagement of the professional bodies with this topic as HMPs play such an important role in self-directed patient care. It is also essential that community pharmacists have a strong knowledge of HMPs and how to advise patients on them. It is therefore highlighted that further research is needed on the role of HMPs in community pharmacy settings as well as the training and education needed for community pharmacists to be able to competently advise on HMPs. A CPD module or a postgraduate certificate like the German model seems to be a potential solution for the UK to upskill pharmacists so that they can be more confident in consultations with patients who ask for advice on HMPs. In the future this training can be incorporated into pharmacy undergraduate degrees too.

This commentary is a strong reminder that HMPs play an important role in any healthcare system based on patient choice and autonomy. Germany and UK are only two examples of differing perspectives; however, internationally it is an important and contentious topic. In conclusion, HMs and HMPs are an important element of any healthcare system and community pharmacists as trusted healthcare professionals are well placed to advise on HMPs. Indeed, most of the advice on HMPs is sought and delivered via community pharmacies in many countries therefore pharmacy practice research should endeavour to systematically compare the importance of HMPs in community pharmacy settings embedded in different regulatory frameworks. It also highlights that pharmacists need to be (as they are in case of Germany) or become (UK) a primary point of contact for advice on the safe use of HMPs. Overall, we call for a transnational effort to better understand the role of HMPs and to ascertain that pharmacists are well-trained to respond to patients' needs and demands.

Table 1- Comparison of herbal medical products in Germany and the UK

Important themes surrounding HMPs	Germany	UK
Regulatory status of herbal medicines	A large number of licensed medicines (mostly not re-imbursable via the health insurance system for patients above the age of 12 years, as any other not prescription only medicines), as well as THRs and supplements are available	Mostly THRs and many food supplements, very few licensed products.
Main groups of indications of 'TC&Ms' which are commonly asked for	Cold, cough and hoarseness Cystitis Stress relievers and sedatives Stimulants of the immune system	Bruising Constipation / Digestive problems Immunity Insomnia Stress relief & sedatives Teething
Prescription only (PO)/ Prescribable	PO: High dose St. Johns wort (900 mg) (PO) with an indication also for moderate depression and Cannabis preparations.	PO: THC – based Cannabis preparations. Prescribable: HMPs dispensed on the NHS include senna tablets, Ispaghula husk, Menthol & eucalyptus containing products, peppermint oil capsules, capsaicin containing creams

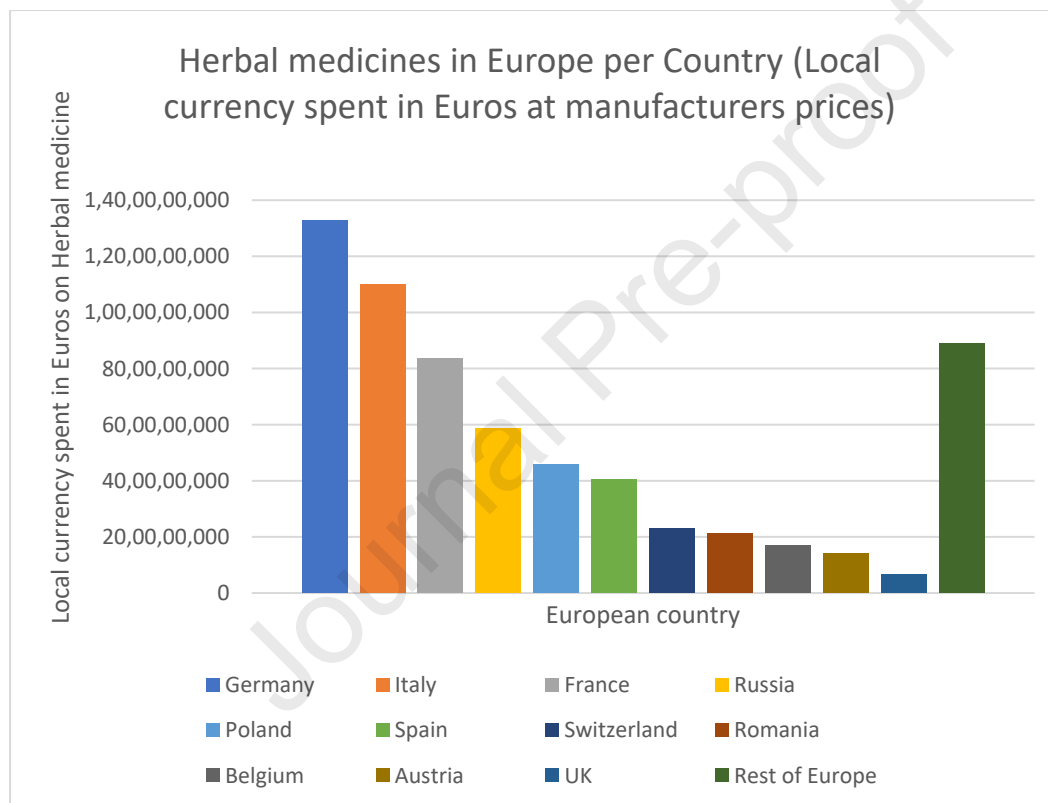
HMPs which are available	Prescribable: In essence all licensed and listed herbal preparations are prescribable, but not necessarily re-imbursable. HMPs for use in children maintain their status as medicines to be prescribed and paid for by the health insurance system. Manuka honey is classed as a medical device / cosmetic agent (cf. UK)	& cannabis extract preparations, dressings containing Manuka honey.
Pharmacy only products	Based on the regulatory authority (BfArM) depends on the indication, kind and amount of the active ingredients, the dosage and type of application	None aside of the THC-based Cannabis
What type of advice do patients commonly seek in the context of TC&Ms?	Patients are looking for safe and well suitable medicines, especially for the children, but also for adults. They like to have something natural, in contrast to medicine with chemical components, which are considered more harmful for the organism. They want to know the dosage, sometimes the taste, the compatibility with other medicaments and probable side effects. How long it takes for the requested effect, how long it can be ingested.	<p>People seek advice as they want to try a “natural” and “safer” option first.</p> <p>The advice that patients seek includes how to use the herbal medicines (incl. many unregulated products), efficacy, side effects, also herb-drug interactions, caution/contraindications with medical conditions.</p> <p>Cheaper alternatives to buying over the counter or prescription medicines.</p>

Table 2: Examples of different regulatory classifications of herbal medicines available both in Germany and the UK –

We can see here that in different European countries the legal positions of the HMPs are varied and that the same product is classified in different categories.³⁴

Botanical Drug and formulation	Germany		UK	
	Regulatory status and daily dose/ composition.	Indication (if applicable) /use.	Regulatory status and daily dose/ composition.	Indication (if applicable) / use
Ginkgo (<i>Ginkgo biloba</i> L. leaf) tablet and tincture	Pharmacy only (PO) licensed medicine: Special extract with 120 mg EGB 761 quantified [flavonoid glycosides (24–26%) and terpene lactones (6– 8%)]. THR and licensed medicines: Lower strength product both as and licensed medicines (pharmacy only)	As a supportive therapy in case of cognitive decline due changes in the brain (dementia, including primary, degenerative and vascular dementia including hybrid forms) including problems to concentrate and memory problems; for chronic and acute tinnitus; depressive disorders, dizziness, headache vascular insufficiencies esp.in the arms and legs	THR (OTC - GSL) Dry extract 120 mg per tablet & oral drops (tincture) 1 ml (20 drops) contains: 40 mg of extract (as dry extract) from <i>Ginkgo biloba</i> L. leaf (35– 67:1) Extraction solvent: Acetone 60% v/v. ³⁵ THR and lower strength preparations available OTC-GSL.	To relieve the symptoms of Raynaud's syndrome and tinnitus, based on traditional use only.
Lavender (<i>Lavandula officinalis</i> L. essential oil) soft gel capsules	Pharmacy only (PO) licensed medicine 80mg of oil from flowering tops of lavender)	Anxiety restlessness	THR (OTC –GSL): Capsule based on 80mg of oil from flowering tops of lavender, identical to the German product. ³⁵ THR & Lower strength preparations available OTC-GSL	For the temporary relief of the symptoms of mild anxiety such as stress and nervousness. Based on traditional use only.
St John's wort (<i>Hypericum perforatum</i> L. aerial parts) tablets	Prescription only (PO) licensed medicines: 900 mg. dry extract 3-6:1 THR: Lower strength product both as and licensed medicines (pharmacy only)	Mild and moderate depressions	THR (OTC -GSL): Tablet containing 66 mg of extract (as dry extract) Extraction solvent: Ethanol 68% V/V. ³⁵ THR & Lower strength preparations available OTC-GSL	For the relief of symptoms of slightly low mood and mild anxiety, based on traditional use only.
Valerian (<i>Valeriana officinalis</i> L., root coated tablets	Pharmacy only (PO) licensed medicine: 441,35 mg dry extract 6- 7,4:1	Nervous disorders, difficulties to fall asleep	THR (OTC - GSL): tablet 150mg of dried root extract. ³⁵ THR & Lower strength preparations available OTC-GSL	For the temporary relief of sleep disturbances due to symptoms of mild anxiety, based on traditional use only.

Figure 1: The top ten countries and the UK in terms of expenditure on herbal medicines in Europe. The UK's share makes it the 16th country out of 23 included (IQVA pers comm). Included are all products containing at least one herbal substance and the preparation is used with a medical claim.



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