CAMbrella

A pan-European research network for Complementary and Alternative Medicine

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Herbal and homeopathic medicinal products

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1 Summary

Medicinal products are not defined as a part of health policy, and can therefore be regulated at the EU level. The individual state within the EU/EEA area are therefore no longer free to uphold deviating national regulation of medicinal products in violation of the following three EU directives:

1. *Directive 2001/83/EC of the European Parliament and of the Council, of 6 November 2001* (on the Community code relating to medicinal products for human use).

2. *Directive 2004/24/EC of the European Parliament and of the Council, of 31 March 2004* (amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use 2001/83/EC).

3. Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (amending Directive 2001/83/EC on the Community code relating to medicinal products for human use).

Other amendments on specific topics applicable to all medicinal products have been made in 2003, 2010 and 2011:

* *Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003* **setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components** and amending Directive 2001/83/EC.
* *Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending,* as regards **pharmacovigilance**, Directive 2001/83/EC on the Community code relating to medicinal products for human use.
* *Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending* Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the **prevention of the entry into the legal supply chain of falsified medicinal products.**

Herbal medicinal products marketed without authorization before Directive 2004/24/EC came into force could continue to be marketed until April 30 2011 under transitional measures defined in this directive. After the expiration of this time limit, all previously unauthorized herbal medicinal products must have a registration or marketing authorization according to directive *2001/83/EC - and amended by Directives 2004/27/EC and 2004/24/EC* - before they can be marketed in the EU/EEA states.

Registrations or marketing authorizations for herbal and homeopathic medicinal products are always given at the national level, but a mutual recognition procedure can be used in some cases. Herbal and homeopathic medicinal products are subject to the same requirements as other medicinal products regarding manufacturing procedures, technical quality of the product, and all other requirements with the possible exception of documentation of efficacy. There are five administrative procedures that can be followed to obtain a registration or a marketing authorization for these products: Standard marketing authorization, Well-established use authorization (for herbal medicinal products only), two Simplified registration procedures (one for homeopathic medicinal products and the other for traditional-use registration of herbal medicinal products) and a national registration procedure for homeopathic medicinal products. The simplified registration procedures and the national registration procedure for homeopathic medicinal products allow alternative documentation of efficacy.

Homeopathic medicinal products covered by a registration or authorization granted in accordance with national legislation on or before 31 December 1993 and herbal medicinal products already authorized in accordance with Regulation (EEC) No 2309/93 or supplied in response to a bona fide unsolicited order can be marketed irrespective of the two directives.

These uniform regulations aim to supply citizens with a predictable standard of all medicinal products (including herbal and homeopathic) across Europe. Several stakeholders raised concerns before the rules were implemented. The concerns focused mainly on leaving European citizens without access to beneficial products and the establishment of unnecessary additional regulatory bureaucracy around well-known medicinal products with a long tradition and a well-known safety profile.

In general, the European legal system for herbal and homeopathic medicinal products differs from the legal system surrounding all other aspects of CAM practice. The regulation of clinical practice and practitioners appears to be as diverse as possible in Europe. At the same time the medicinal products these practitioners will be prescribing or recommending are regulated uniformly across the same geographical area. This appears to be inconsistent and European politicians at both the national and EU level need to closely consider whether regional or EU-wide harmonization of CAM practice and its medicinal products could further optimize the healthcare of European citizens. In the frame of free circulation within the EU, calls for these considerations have been articulated in resolutions by both The Council of Europe and the European Parliament.

The present report constitutes the CAMbrella project report number 2 of Deliverable D9, "Legal status and regulations of CAM in Europe". The report describes task 2.2. "Regulation of CAM medicinal products in Europe". The report is provided by Work Package (WP) 2.

2 Aim

To review at EU/EEA level:

- The status of EU/EEA-wide regulation of herbal and homeopathic medicinal products.

To review and describe in all 27 EU member states and 12 associated states:

- The extent of country-specific registration and market authorization of herbal and homeopathic medicinal products according to the EU directives.

3 Methods

As an introduction a comprehensive overview was made of matters that may influence CAM in national and EU legislation. Descriptions of health issues, the legal and CAM terminology and the interaction between conventional medicine and CAM vary both in the European Union bodies and within the 39 countries included in this report. To address CAM-related legislation in the European countries, we included EU legislation that influences the member states' national health legislation.

A search was performed in the web sites/databases *EUROPA* and *EUR-lex* to identify EU official law documents. We searched specifically for information about EU Directives regarding herbal and homeopathic medicinal products, and their EU/EFTA/EEA implications.

In addition a personal visit was made to *the European Union offices* and *NGO bodies* in Brussels to establish firsthand updated information. Meetings were held with:

- *Counselor for health and food safety at the Mission of Norway to the EU.*

At the Mission of Norway to the European Union we received updated information mainly on the EFTA/EEA legal connection to EU legislation and the new Cross-border Healthcare Directive 2011/24/EU.

- *The European Commission Central Library.*

The library assisted in searching for CAM legislation documents.

Meetings with the following NGOs gave important additional CAM information:

- *IVAA (International Federation of Anthroposophic Medical Associations).*

- ICMART *(International Council of Medical Acupuncture and Related Techniques) - EU Liaison Office.*
- *AESGP (The Association of the European Self-Medication Industry).*

We received their information, documents, and viewpoints with regard to the EU regulation of medicinal products.

We have also collected information from *European CAM associations/coalitions* and *other CAMbrella stakeholders* (Listed in Attachment 1).

4 The EU/EFTA legal and regulative system

Report number 1 in the WP2 CAMbrella deliverable 9 gives a detailed overview of how each state covered in these reports are legally tied to the EU(1). Twenty-seven of the states included in the three CAMbrella WP2 reports are full EU members; others are affiliated to the EU through various legislation and agreements. This can potentially determine how EU legislation and regulations influence the states' national legislation on medicinal products. This report will therefore also present a short summary of the general EU regulatory systems and how the European states are linked to those systems.

The European Union Law operates alongside the legal systems of the individual EU member states and consists of Treaties and Laws (Directives, Regulations, Decisions (Court Judgments)). The EU legislation is based on the *EU treaties* and the legislative acts are expressed through *Regulations, Directives* or *Decisions*.

4.1 The EU Treaties

The legislation of interest for this report is mainly based on the 1958 **Treaty of Rome** followed up by the *2007 Treaty of Lisbon(2) with the Four Freedoms* (the requirements that goods, services, capital and persons *are to move freely* within the EEA); article 168 includes common safety concerns and measures setting high quality standards for public health, medicinal products, quality and safety, research and cross-border areas.

The EU Treaties have repeatedly established that health policy is a national responsibility for the member states. Despite this, several EU Directives and Regulations influence how the member states organize their national health policy and services.

Medicinal products are not defined as a part of health policy, and can therefore be regulated at the EU level.

4.2 The Regulations, Directives and Decisions

Directives, Regulations and Decisions have effect within the EU's member states either with local adjustments to national legislation or precedence over national legislation.

EU Regulations are adopted by the Council, cover general measures that are binding for all states, and are to be seen as directly enforceable law in all member states.

EU Directives are addressed to the member states and are intended to align national legislation. How the individual member states implement the Directives in national legislation is left to the member states, but the implementation should conform to the content of the EU Directives.

EU Decisions refer to decisions taken by the European Court of Justice and address individuals. These are automatically binding upon those individuals (individuals and member states) to which they are addressed, but can have a potential influence when creating new EU legislation or modifying existing EU legislation.

EU Parliamentary non-legislative Resolutions are recommendations and political statements only.

4.3 EEA - legislation and procedures

The EEA agreement is based on the EU treaties(2), legislation (EEA relevant Regulations, Directives, Decisions) and on certain non-binding instruments adopted by the EU institutions on an on-going basis(3).

The EU "Treaty of Lisbon" with *"the four freedoms"* is included in the EEA agreement. *"The four freedoms"* aim to enable goods, services, capital and persons *to move freely* within the EEA. Education, training, employment, enterprise and civil protection are among the fields that are handled within EEA. Relevant legislation is incorporated into the EEA agreement by decisions of the *EEA Joint Committee*. The non-EU EEA member states can negotiate adaptations to EU legislation and the documents have to be amended to national legislation. For the EU member states the EU legislation is already binding.

5 EU Directives, Regulations and Decisions of importance for herbal and homeopathic medicinal products

The three directives passed in the European Union with impact on herbal and homeopathic medicinal products cover marketing authorization and registration of herbal and homeopathic medicinal products in the EU.

- *Directive 2001/83/EC of the European Parliament and of the Council, of 6 November 2001* on the Community code relating to medicinal products for human use(4).

This directive states that "No medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State in accordance with this Directive or an authorization has been granted in

accordance with Regulation (EEC) No 2309/93." Directive 2001/83/EC has not significantly been amended for homeopathic medicinal products; For herbal medicinal products substantial amendments have been introduced in 2004 by means of:

- *Directive 2004/24/EC of the European Parliament and of the Council, of 31 March 2004* amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use(5).

And:

- *Directive 2004/27/EC of the European Parliament and of the Council, of 31 March 2004* amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance)(6).

Directive 2001/83/EC with its 2004 amendment for herbal medicinal products has been actively protested from various stakeholders before its implementation(7). The objections have mainly been concentrated around the issues of continued access to well-established medicinal products and on the establishment of unnecessary additional regulatory bureaucracy around safe products. Since both directives are now fully implemented, this report will not describe in detail the pros and cons argued by various stakeholders with regard to the regulation of herbal and homeopathic medicinal products.

5.1 What constitutes a medicinal product?

Directive 2001/83/EC as amended by *Directives 2004/24/EC* and *2004/27/EC* defines a medicinal product as: "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis"(6).

Herbal and homeopathic medicinal products constitute two subsets of medicinal products, and the EU has established special regulations for these. A herbal medicinal product is defined as "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 preparations"(5). A homeopathic medicinal product is defined as "Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles."(6).

It is important to realize that the EU regulation of herbal medicinal products also applies to anthroposophic, traditional Chinese and Ayurvedic medicinal products, as far as they are not homeopathically manufactured, not in form of injection and not containing other ingredients than herbals. There are no separate rules for these medicinal products.

5.2 Limitation

Food supplements are not described in this report. The EU regulation of food supplements can be found in *Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.*

5.3 Relevant institutions regarding herbal medicinal products

Figure 5.1 Relevant institutions regarding herbal medicinal products in the EU.

- *The European Commission* is the EU's executive body. The Commission has the ultimate authority for granting marketing authorizations in the EU.
- The *European Medicines Agency (EMA)* is a decentralized agency of the European Union. The EMA is responsible for the scientific evaluation of medicines in the European Union. Specifically, the EMA is responsible for the centralized procedure and for arbitration in cases where there is a disagreement between Member States in the 'mutual-recognition' and 'decentralized' procedures (see below). Opinions and decisions made by the EMA are transmitted to the European Commission for final approval.
- *Committee on Herbal Medicinal Products (HMPC)* is one of six Scientific Committees of the EMA. The HMPC's activities aim at assisting the harmonization of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrating herbal medicinal products in the European regulatory framework. As part of these objectives, the HMPC provides EU Member States and European institutions its scientific opinion on questions relating to herbal medicinal products. Other core tasks include the establishment of a draft 'Community list of herbal substances, preparations and combinations thereof for use in traditional

herbal medicinal products', as well as the establishment of Community herbal monographs.

5.4 Relevant Institutions regarding homeopathic medicinal products

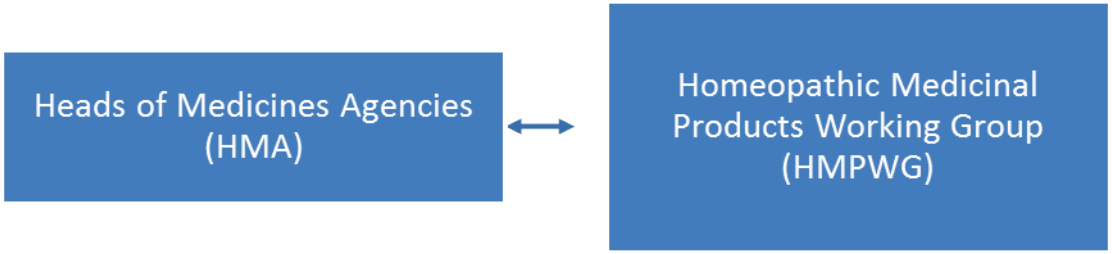

Figure 5.2 Relevant institutions regarding homeopathic medicinal products in the EU.

- The *Heads of Medicines Agencies* (HMA) is a network of the Heads of the National Competent Authorities whose organizations are responsible for the regulation of Medicinal Products for human and veterinary use in the European Economic Area. The Heads of Medicines Agencies is supported by working groups covering specific areas of responsibility and by the Heads of Medicines Agencies Management Group and Permanent Secretariat.
- The *Homeopathic Medicinal Products Working Group* (HMPWG) is a working group of the HMA composed of heads and staff of the regulatory department for Homeopathic Medicinal Products in the national medicines agencies; the aim of the work of this group is to harmonize the assessment of homeopathic products amongst the Member States and to create a network of assessors to facilitate cooperation in National and Mutual Recognition Procedures.

6 Simplified registration and marketing authorization for herbal and homeopathic medicinal products

Figure 6.1 outlines through which procedures herbal and homeopathic medicinal products can acquire an authorization to be on the market.

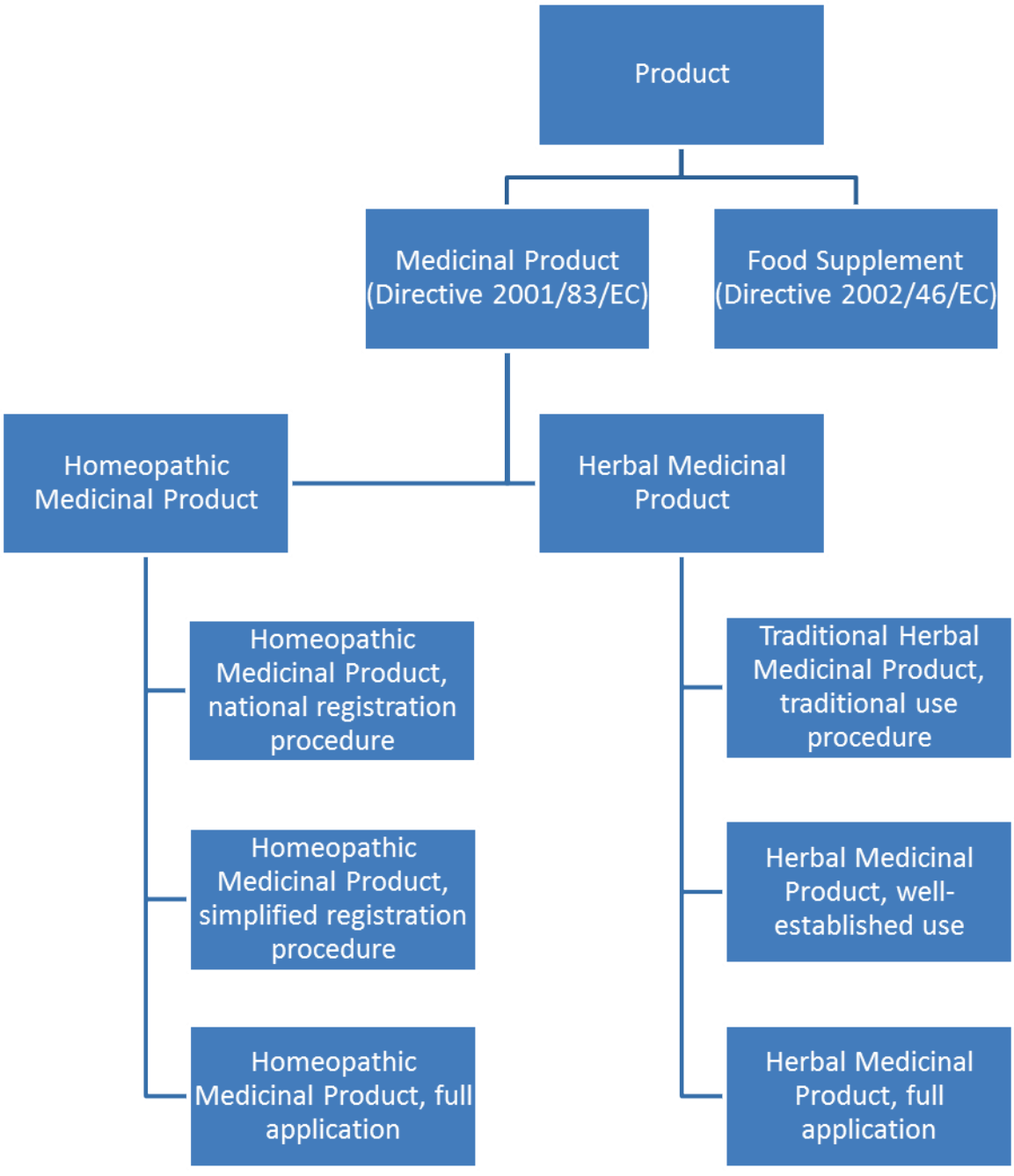

Figure 6.1 Procedures for herbal and homeopathic medicinal products in the EU.

6.1 Regulatory pathways for herbal and homeopathic medicinal products

Herbal and homeopathic medicinal products are subject to the same application procedures (Article 8 in Directive 2001/83/EC)(4) as other medicinal products regarding manufacturing procedures, technical quality of the product, and all other requirements with the possible exception of documentation of efficacy. The well-established use procedure (for herbal medicinal products), a simplified registration procedures (for both, herbal and homeopathic medicinal products), and the national marketing authorization based on special national rules (for homeopathic medicinal products) described below allow alternative documentation of efficacy.

6.1.1 Standard procedure (Full application)

Herbal and homeopathic medicinal products can be given a full marketing authorization through the same pathways as regular medicinal products. All quality and safety documentation has to be submitted, and the efficacy of the product must be demonstrated in clinical trials.

6.1.2 Well-established use procedure for herbal medicinal products

This procedure outlined in Article 10a in Directive 2004/27/EC(6) states that “the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognized efficacy and an acceptable level of safety in terms of the conditions set out in Attachment 1. In that event, the test and trial results shall be replaced by appropriate scientific literature”.

Examples of herbal medicinal products that can be subject to this procedure are: St. Johns wart, Valeriana root and Horseradish seeds.

6.1.3 Simplified registration procedure for traditional-use registration of herbal medicinal products

This is a procedure described in chapter 2a in Title III of Directive 2004/24/EC(5) where bibliographic evidence of safety and efficacy can replace pre-clinical and clinical tests. There must be bibliographic evidence that the product ”has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community”.

The quality requirements of the product are not subject to any “traditional” procedure. It needs to be documented according to article 8(3), in Directive 2001/83/EC(4) amended in Directive 2004/27/EC(6).

6.1.4 Simplified registration procedure for homeopathic medicinal products

A simplified registration procedure is described in Directive 2001/83/EC, Article 14 and 15. Implementation of this procedure is mandatory for the Member States. It is primarily

intended to document that the homeopathic medicinal product is manufactured in a manner that ensures high quality, and thus is safe to use. If this is the case, and the product otherwise meets the three criteria listed below, no further evidence of efficacy is required.

Criteria for this simplified registration procedure:

1. The product is administered orally or externally only.
2. No specific therapeutic indication appears on the labeling of the medicinal product or in any information relating thereto.
3. There is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

6.1.5 National registration procedures for homeopathic medicinal products

Homeopathic medicinal products can, within the framework of specific national rules developed by a Member State, be registered according to article 16.2 in Directive 2001/83/EC(4). This article states that: "A Member State may introduce or retain in its territory specific rules for the pre-clinical tests and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practiced in that Member State." In these cases the requirements for quality and safety of the product are as outlined in the directive, but pre-clinical tests can be country-specific. This can be exemplified by the "National Rules Scheme" in the UK(8). It gives the following requirements for pre-clinical tests of efficacy:

"…the applicant must provide one or more of the following:

- Study reports in relation to the product which is the subject of the application.
- Published scientific literature.
- Homoeopathic provings.

Whatever data is provided, it should be sufficient to demonstrate that UK homeopathic practitioners would accept the efficacy of the product for the indications sought."

6.2 Exceptions from the current general rules for registration or marketing authorization

6.2.1 Homeopathic medicinal products covered by a registration or authorization granted in accordance with national legislation on or before 31 December 1993

Some countries have homeopathic medicinal products registered according to the rule described in a revised article 13 in Directive 2004/27/EC(6). A Member State can exempt these products from any further procedure and leave them on the market.

6.2.2 Medicinal products already authorized in accordance with Regulation (EEC) No 2309/93

This EEC regulation is the previous regulation replaced by Directive 2001/83/EC(4). Herbal medicinal products could, of course, have been authorized in accordance with this regulation if they fulfilled the requirements of the regulation.

6.2.3 Medicinal products supplied in response to a bona fide unsolicited order

Article 5.1 of Directive 2004/27/EC(6) excludes 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 an individual patient under his direct personal responsibility. This makes it possible for authorized health-care professionals to supply individual patients with herbal and homeopathic medicinal products irrespective of the provisions set out in Directive 2001/83/EC and its 2004 amendments.

In the UK the Government is deliberately planning to circumvent the restrictions in the directives(9) by establishing a new category of authorized healthcare personnel, **herbalists**. This new profession will then be able to provide their patients with products without a registration or marketing authorization.

7 Where is a registration or a marketing authorization given?

In the EU/EEA, there are two "main pathways" to the market for medicinal products, national and at the EU level. Health authorities in each member state can provide a registration or marketing authorization valid in the Member State, or the EMA can provide a central marketing authorization that is valid throughout the EU/EEA-area(4).

Homeopathic and herbal medicinal products are only given a registration or marketing authorization at the national level. The procedures described under 6.1.2, 6.1.3 and 6.1.4 in this document are open for a so-called mutual recognition procedure as described in articles 27 to 29.3 of Directive 2001/83/EC (See also paragraph 7.1.1 in this report).

One of the tasks of HMPC is to develop “Community herbal monographs” and “A list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products”(5). These monographs and the published list are to be used as documentation of safety and efficacy when herbal medicinal products are evaluated for traditional-use registration or marketing authorization.

The “Community herbal monographs” are relevant when registration or marketing authorization is sought according to both well-established and traditional use. When Community herbal monographs have been established, the Member States are recommended to take them into account when examining an application(5). This becomes

mandatory if the monograph has been accepted by the European Commission on the herbal medicinal products list.

The list of herbal substances, preparations and combinations thereof is relevant only for registrations and marketing authorizations within the traditional-use category(5). If an herbal substance is included in this list, no further documentation of safety and traditional use is necessary and the relevant national authorities are not permitted to require additional documentation.

The “Community herbal monographs” and the HMPC draft list are published on the EMA website. The official list is published on the website of the European Commission.

7.1 Nationally

The ”competent authority” of a member state can issue a registration or marketing authorization if the requirements outlined in the three directives have been fulfilled(4-6). The competent authority will normally be a Government drug agency.

7.1.1 Multiple states

Registration or marketing authorization can be applied for in several member states simultaneously(6). The applicant shall request one Member State to act as “reference Member State” and to prepare an assessment report on the medicinal product a draft summary of product characteristics and a draft of the labeling and package leaflet. Each Member State in which an application has been submitted shall adopt a decision in conformity with the approved assessment report, the summary of product characteristics and the labeling and package leaflet. This decision is based on a mutual agreement between the states receiving the simultaneous application.

If the medicinal product has already received a prior marketing authorization in one member state at the time of application, this member state will act as the “reference Member state”, and the other concerned Member States shall recognize the marketing authorization granted by this reference Member State.

This is called a decentralized and mutual recognition procedure as described in article 27 to 29(3) of Directive 2001/83/EC(4).

7.2 Central procedure

In some cases, it is also possible to apply directly to the European Medicines Agency EMA, via the central procedure for approval of drugs(10). This applies to medicinal products other than herbal and homeopathic.

8 Herbal and homeopathic medicinal products registered or authorized according to the directive

8.1 Current herbal medicinal products registered or authorized according to the directive

The following table gives an overview as of 30 June 2011 of the uptake and implementation of the provisions of Directive 2004/24/EC in EU Member States with regard to herbal medicinal product registration according to traditional and well-established use.

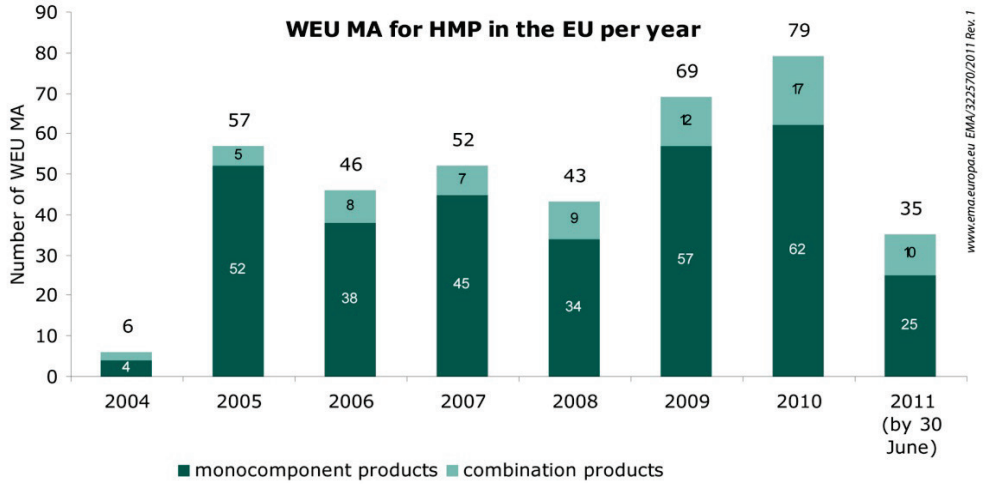

Figure 8.1 Number of well-established use marketing authorizations (WEU MA) for HMP in the EU grouped by year of registration for monocomponent and combination products (11).

8.2 Current homeopathic medicinal products authorized or registered according to the directive

No centralized data are available on homeopathic medicinal product registration and market authorization in EU Member States. A survey of 27 EU member states and two EFTA states in the fall of 2010 made by PricewaterhouseCoopers (PwC) on behalf of ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products) yielded information from 15 countries(12). The number of homeopathic medicinal products reported on the market in these countries varied from “around 31000” in Italy to 0 in Cyprus.

9 The eight countries that are not members of the EU or EFTA

9.1 Albania

Albania’s regulation of “herbal medicinal products for human use” follows with small variations the EU directive/amendment procedures(4-6, 13).

The regulation specifically indicates that these regulations do not include homeopathic medicinal products. We have not found any regulation of homeopathic products in Albania.

9.2 Bosnia & Herzegovina

The regulation of herbal and homeopathic medicinal products in Bosnia&Herzegovina follows with small variations the EU directive/amendment procedures(14).

9.3 Croatia

The regulation of herbal and homeopathic medicinal products in Croatia follows with small variations the EU directive/amendment procedures(15).

9.4 Israel

The regulation of herbal and homeopathic products in Israel follows the following guidelines: "The Pharmacists Regulations (Conditions for Opening and Operating of Pharmacies and Medicine Rooms) 1982 empower the Administration to regulate the marketing of traditional herbal medicinal products and homeopathic products. The regulation of these products focuses on their safety, while their efficacy is neither tested nor guaranteed by the MOH. The Department of Medicinal Herbs and Homeopathy within the Administration maintains a list of medical herbs which, for safety reasons, can only be marketed by a pharmacist, and of other herbs that are generally prohibited for sale. The manufacture and marketing of homeopathic products are regulated by guidelines published by the Administration"(16).

9.5 Montenegro

The regulation of herbal and homeopathic medicinal products in Montenegro is harmonized with the EU directive/amendment procedures(17).

9.6 Serbia

The regulation of herbal and homeopathic medicinal products in Serbia follows with small variations the EU directive/amendment procedures(18).

9.7 The former Yugoslav Republic of Macedonia

The regulation of herbal and homeopathic medicinal products in The former Yugoslav Republic of Macedonia follows with small variations the EU directive/amendment procedures(19).

9.8 Turkey

The regulation of herbal medicinal products in Turkey follows partly the EU directive/amendment procedures. There is no option of registration of a herbal product according to traditional use, and there is no regulation of homeopathic medicinal products(20).

10 Reimbursement of herbal and homeopathic medicinal products

The reimbursement of herbal and homeopathic medicinal products is considered to be an area subject to national healthcare policy, and is therefore not regulated at the EU/EEA

level. This report will not describe in detail the situation in each individual country. The general European situation is, however, that reimbursement of herbal and homeopathic medicinal products in general follows the practice with regard to CAM treatments as described in report 1 of the WP2 deliverable 9(1).

11 Discussion on CAM aspects related to EU/EFTA/EEA legislation and regulation of herbal and homeopathic medicinal products

In this report we have identified and described the European Union directives governing the regulation of herbal and homeopathic medicinal products. This EU legislation i.e. the relevant directives are now all implemented in the national systems of registration or marketing authorization of herbal and homeopathic medicinal products in the 31 EU and EFTA countries. The remaining eight countries have either fully or partially adopted the EU legislation, or have their own similar regulation.

11.1 Consequences of common EU regulation of herbal and homeopathic medicinal products

Having a common set of rules throughout Europe for registration or marketing authorization of herbal and homeopathic products creates a market that is predictable for producers, importers and consumers. Consumers of these medicinal products are thereby ensured safe products with well-established documentation of effect. This common set of rules will, however, not generate a situation where all authorized products are available in all countries. As shown in figure 8.1 (for herbals) or on the national medicines agencies (for homeopathic medicinal products) there is a considerable variety within Europe regarding the number of products registered or authorized according to the rules. This is of course due to the freedom marketers have of choosing to apply for registration or market authorization or not in each country, and the freedom of choosing to market or not, even if a registration or market authorization has been given. The important common factor is, however, that the requirements for registration or marketing authorization are the same throughout the EU/EFTA area.

11.1.1 Exceptions in the established common EU regulation

There are three important exceptions in the general rules for marketing authorization.

The first exception applies to homeopathic medicinal products covered by a registration or authorization granted in accordance with national legislation on or before 31 December 1993(6).This exception only applies to homeopathic medicinal products that have been evaluated by a national medicinal agency in the past. This previous evaluation combined with the low probability of safety concerns attached to homeopathic medicinal products should make this exception of minor concern to the citizens of Europe. It ensures that

previously authorized homeopathic medicinal products are still available to practitioners and their patients.

The second exception is a general exception for all medicinal products(4) and makes it unnecessary to apply for a new marketing authorization for products that have already been legally marketed before Directive 2001/83/EC came into force. This prevents an unnecessary bureaucratic exercise in confirming previous marketing authorizations.

The third exception created to allow authorized health-care professionals to supply medicinal products in response to a bona fide unsolicited order, formulated in accordance with the specifications of and for use by an individual patient under his direct personal responsibility(6) is a necessary provision that gives authorized health-care professionals access to medicinal products currently without a registration or marketing authorization. This provision in the directive was intended to enable authorized healthcare professionals in rare cases, to provide unregistered or unauthorized medicinal products to meet an individual need. This rule of exception applies also to herbal and homeopathic medicinal products irrespective of the provisions set out in Directive 2001/83/EC and its 2004 amendments. If practiced irresponsibly this exception could pose a safety risk to the patient. The intention of this exception was not to deliberately circumvent the general authorization requirements in the directive.

This intention has recently been reaffirmed by the EU Court of Justice in a 29 March 2012 ruling(21). The case had been raised because Poland had been using the "special needs" exception to permit imports of cheap unauthorized medicinal products that contained the same active ingredients, dosage and form as drugs that were currently authorized for sale in the country. Poland had therefore been approving the import and sale of unapproved drugs which were not medically essential for a specific patient, and as a result this constituted failure to obey European law, according to the European Commission. The court added that the "special needs" exception must remain exceptional, so it is used only when completely essential and is based solely on therapeutic considerations which confirm an individual patient's requirement for treatment which is unobtainable on the national market or where there is no authorized equivalent.

It is completely up to the authorized healthcare professional to decide whether their patient has an individual need that necessitates a medicinal product (regular, herbal or homeopathic) outside of the common registration or marketing authorization scheme. The UK Government plan to establish a new category of authorized healthcare personnel, herbalists, is an interesting case. The given intent is explicitly stated as an attempt to circumvent the rules, and it will therefore be an important test case.

12 Conclusions

The EU directives regulating the registration and marketing authorization of herbal and homeopathic products are now permanently established in the EU/EEA area. From both a regulatory and patient perspective, the system aims to provide a predictable scheme of registration or marketing authorization across Europe. Citizens can relate to a uniform standard of medicinal products (including herbal and homeopathic). Several stakeholders raised concerns before the rules were implemented. The concerns focused mainly on leaving European citizens without access to beneficial products and the establishment of unnecessary additional bureaucracy around safe products.

Although uniformly regulated, the market may still appear confusing for the individual consumer due to national varieties in the number of authorized products.

The existing exceptions in the regulation may cause further confusion. The “homeopathic products” exception represents few, if any, safety concerns. While the “bona fide unsolicited order” exception is a necessary scheme to provide individual patients the appropriate therapeutic products, it may also raise safety concerns if practiced irresponsibly. It will be the responsibility of supervisory authorities in the individual country to enforce the legal requirements applicable to every health care professions group to avoid this to happen.

In general, the European legal system for herbal and homeopathic medicinal products is very different from the legal system surrounding all other aspects of CAM practice. The regulation of clinical practice and practitioners appears to be as diverse as possible in Europe. At the same time the medicinal products these practitioners will be prescribing or recommending are regulated uniformly across the same geographical area. This appears to be inconsistent and European politicians at both the national and EU level need to closely consider whether regional or EU-wide harmonization beyond medicinal products could further optimize the healthcare of European citizens. Calls for these considerations have been articulated in resolutions by both The Council of Europe and the European Parliament.

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Attachment 1: European CAM associations

ANME (Association of Natural Medicine in Europe)
CAMDOC Alliance (alliance of the four major European medical CAM umbrella organizations ECH, ECPM, ICMART and IVAA)
ECCH (European Central Council of Homeopaths)
ECH (European Committee for Homeopathy)
ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products E.E.I.G.)
ECPM (European Council of Doctors for Plurality in Medicine)
EFCAM (European Forum for Complementary and Alternative Medicine)
EHTPA (European Herbal and Traditional Medicine Practitioners' Association)
EICCAM (European Information Centre for Complementary and Alternative Medicine)
ELIANT (European Alliance for Applied Anthroposophy)
EPHA (European Public Health Association)
ICMART (International Council of Medical Acupuncture and Related Techniques)
IVAA (International Federation of Anthroposophic Medical Association)
KB (Kneipp-Bund eV)