

ECHAMP NEWS

EUROPEAN COALITION ON HOMEOPATHIC & ANTHROPOSOPHIC MEDICINAL PRODUCTS

Brussels

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EDITORIAL



The implementation of the review of Directive 2001/83 in the legislation of EU Member States will remain hot news for a while. This time Spain, Portugal, and the UK have done their 'homework'. The UK government has taken the opportunity to create a new National Rules Scheme that allows for the authorisation of homeopathic remedies with indications for minor, self-limiting conditions.

In Switzerland there are also new regulations for a simplified marketing authorisation for complementary and herbal medicinal products. See below for further details.

Although health policy is primarily based on decisions by the Member States, the European Union is in the process of generating and centralising more and more expertise and competence in the Health Agencies: there are seven so far, and the next one, the European Chemicals Agency, is scheduled to be created next year.

The European Agency for the Evaluation of Medicinal Products (EMA) in London is one of these EU-agencies, created in 1995. For the first time, it is organising a workshop on homeopathic medicinal products. This will take place at the end of October this year - we will report in more detail in our next News.

Nand De Herdt
General Secretary

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NEWS FROM SWITZERLAND



New Swiss regulation on the simplified procedure for a marketing authorisation for complementary and herbal medicinal products (Komplementär- und Phytoarzneimittel-Verordnung KPAV)

(MME) New regulations for the registration of complementary and herbal medicinal products will take effect in Switzerland from the 1st October 2006. These regulations were developed by the Swiss agency for therapeutic products, Swissmedic, in collaboration with representatives of different complementary therapies. In a first step the regulation describes the specific requirements for homeopathic (including spagyric), anthroposophic and Asian medicinal products. The chapter for herbal medicinal products is still missing and will be integrated in the first amendment. At the moment herbal medicinal products are still regulated by the Swiss guidelines for herbal medicinal products.

What is new?

1. For the first time, medicinal products of three specific complementary medicinal systems are described in specific chapters and are regulated according to their specific characteristics and risks. There is a chapter on homeopathic and spagyric medicinal products, one on anthroposophic products and for the first time one on Asian medicinal products (Chinese, Ayurvedic and Tibetan medicinal products).
2. The new regulation allows for two kinds of marketing authorisations:



- a) Marketing authorisation for medicinal products with therapeutic indications
- b) Marketing authorisation for medicinal products without therapeutic indications

Group a) will require a complete dossier both now and in the future.

Group b) will be regulated in a more detailed way than it is currently and therefore this group has been subdivided in two new categories:

- b1) Application with a **reduced dossier**
- b2) **Formal notification** for each substance and dosage form without any submission of further documentation, yet linked to master dossiers

3. There are *positive lists* which define which of the new categories applies for medicinal products without therapeutic indications. These cover all traditionally used substances which can be notified or approved with a reduced dossier. The regulation contains two substance lists, one for homeopathic and anthroposophic substances and another one for substances needed for Asian medicinal products.

The first list (List of homeopathic and anthroposophic substances - HAS) has been drawn up on the basis of the Monographs of the German Commission D (Expert Commission of the Medicines Agency for Homeopathic Medicinal Products) and C (Expert Commission of the Medicines Agency for Anthroposophic Medicinal Products), the Monographs of the HAB (GHP, German Homeopathic Pharmacopoeia) and the Ph. F. (Pharmacopoeia Française; Préparations homéopathiques). Further substances were accepted, if associations and companies representing the complementary therapies could supply evidence for their traditional use. For the second list (List for traditional Asian substances - TAS) official defined standard literature in English or specific applications were accepted.

4. The recognised Pharmacopoeia is now the HAB (GHP), also recognised are some specific manufacturing methods of the B.Hom.P. (British Homeopathic Pharmacopoeia), the homeopathic

manufacturing methods of preparations of the Ph. F. 10th edition and in some cases substance monographs of the HPUS.

5. An application has to be submitted for each substance and dosage form by autumn 2008. For sterile dosage forms master dossiers (quality part) are needed by autumn 2007. A master dossier has to be submitted for other topics such as organ preparations (TSE).

6. The fees are new as well. Depending on the new categories of submission the fees will be from 10 (b1) to 500 (b2) Swiss Francs (€6.66-333.33). Additionally the fee for a "Basic Dossier" for the general data of the manufacturer will be 3000.- CHF (€2000) and 1500.- CHF (€1000) for each master dossier e.g. for sterile dosage forms.

Important differences to EU regulations

1. The new Swiss regulation is specific for homeopathic, anthroposophic and Asian medicinal products. In the EU neither anthroposophic nor Asian medicinal products are covered by special regulations.
2. A simplified procedure for Asian medicinal products without indications does not exist in the EU.
3. Safe dilutions can be submitted with reduced dossiers or with formal notifications. The safe dilution for oral and external dosage forms can be below D4; it can even be a mother tincture.
4. With the *positive lists* it is also possible to get a marketing authorisation for sterile dosage forms by a formal notification if a master dossier was submitted previously.

Implications for Swiss companies



1. The new regulation tries to get closer to the requirements for the simplified submission that exist in the EU but has also kept some special regulations for specific complementary medicinal products.
2. High administrative workload which will mean that more personnel are needed.
3. High financial pressure because of the new individualised submission per substance and the new fees (even if Swiss fees are low compared to current fees in the EU). Companies will have to pay approximately 100 times more per year than they do at the moment.
4. Because of disproportionate requirements for a large proportion of traditionally-used medicinal products and because of the new fees, companies will have to analyse their ranges and may have to

take some products off the market. This measure may have an impact on medical doctors prescribing complementary medicinal products and on patients in their freedom of treatment.

Dr. Mónica Mennet-von Eiff is Expert Anthroposophic Pharmacy at SVKH and President of VAEPS (Verband Anthroposophisch Erweiterte Pharmazie in der Schweiz).

Links:

[KPAV \(in German\)](#)

[KPAV \(in French\)](#)

IMPLEMENTATION NEWS - LEGAL UPDATE



(JH) In the last few months a number of changes have been introduced in various Member States with the adoption of new legislation. These legal reforms have mostly been initiated in order to implement Directive 2004/27/EC, which covers amongst others homeopathic

and anthroposophic medicinal products. In particular, both Portugal¹ and Spain² have adopted new rules, and the UK has introduced new legislation³ implementing Article 16(2) of Directive 2001/83/EC on the Community Code on medicinal products for human use.⁴

Spain



Article 50 of the new medicines law lays down the legislative framework for the creation of more specific rules on 'Medicamentos homeopáticos' (homeopathic medicinal products) in Spain. It provides a definition of a homeopathic medicinal product which is very close to the definition provided by Directive 2001/83/EC on the Community Code and mentions that special rules need to be adopted for the authorisation and registration of these products. It also requires the ministry of health and consumer affairs to set up a system of registration codes to facilitate identification. More specific rules will be laid down in a royal decree which still needs to be drafted.

Unique in the EU are the special guidance notes for the Spanish Medicines Agency on the authorisation of 'nosodes'. These appear in the third paragraph of Article 50, and allow the Agency to authorise or register homeopathic medicinal products defined as 'nosodes' only if the applicant can submit sufficient proof of a positive risk-benefit profile. According to the law the following products are 'nosodes': pathological products of human or animal origin,

pathogenic agents or their metabolic products, and products derived from decomposed organs of human or animal origin.

Portugal



The new medicines decree in Portugal is the most recent implementation of Directive 2004/27/EC. It goes much further than the Spanish law,

which simply creates a frame of reference. It basically follows the general lines of Directives 2001/83/EC and 2004/27/EC. A noteworthy feature in the decree is the 2 year-period given to the Portuguese medicines agency to adapt the former system for homeopathic medicinal products to the new regime, which departs from a definition of homeopathic medicinal products that complies with European definition (Article 202(9) Decree 176/2006). Furthermore, it provides the possibility for the minister of health to adopt special rules to implement Article 16(2) of Directive 2001/83/EC (Article 136(4) Decree 176/2006). Such rules were officially available under the former legal regime, but never used in practice. Finally, in accordance with Article 13 of Directive 2001/83/EC, the Decree does not cover products registered or authorised before 1994 (202(8) Decree 176/2006).

United Kingdom



The implementation of Directive 2004/27/EC had already taken place in the United Kingdom in October 2005. With the adoption of the (Homoeopathic Medicinal

Products for Human Use) Amendment Regulations 2006, No. 1952, a new authorisation procedure has been created in line with Article 16(2) of Directive 2001/83/EC on the Community Code (National Rules Scheme). This means that homeopathic medicinal products can now be authorised according to modern standards, alongside the old 'Product Licenses of Right' (based on the pre-1994 regime), and the special simplified registration in conformity with Article 14 of Directive 2001/83/EC. Most importantly it creates new opportunities for OTC homeopathic remedies, because the authorisation procedure allows for the use of indications and information on the treatment and relief of 'minor, self-limiting conditions' with reference to the British homeopathic tradition. The Medicines and Healthcare products Regulatory Agency (MHRA - British medicines agency) expressed the hope that holders of the old 'Product Licenses of Right' will be encouraged by the new scheme to apply for renewals in the form of an authorisation. For more information see:

[Statutory Instrument 2006 No. 1952](#) - (Accessed on 21st September 2006).

(Footnotes)

¹ Ministério da Saúde, Decreto-Lei n.º 176/2006 de 30 de Agosto 2006.

² LEY 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios.

³ No. 1952 Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2006.

⁴ 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 OJ L311/67 [2001].

FOR YOUR REFERENCE: EUROPEAN UNION AGENCIES IN THE FIELD OF HEALTH



(CW/PHS) The principal institutions of the European Union are the Euro-

pean Commission, the European Parliament, the Council of Ministers, the Committee of the Regions and the European Economic and Social Committee. Additionally the EU organises its operational work through agencies. Here is an overview of those organisations which are relevant for health or consumer or environmental issues. All agencies are under the supervision of the "European Court of Auditors". They are financed by public funds of the European Union. The only agency (in the field of health) which is partly self-financing is the EMEA-European Agency for the Evaluation of Medicinal Products, which also raises money through marketing authorisation fees.

Executive Agency for the Public Health Programme

Founded: 1.01.2006 (for a period of six years)

Location: Luxembourg

Main task:

- Realisation and organisation of the public health programme information on public health

Personnel/Budget

Personnel: +/- 32 people

Budget 2006: +/- 5.6 Mio. EUR

Expected Budget: 5.6 Mio. EUR

Info: [Executive Agency](#)

European Centre for Disease Prevention and Control (ECDC)



Founded: Spring 2005

Location: Stockholm, Sweden

Main tasks:

- To strengthen Europe's defence against infectious diseases, such as influenza, SARS and HIV AIDS

- Organise cooperation between national disease control agencies

- Work in partnership with national health protection

bodies across Europe to strengthen and develop continent-wide disease surveillance and early warning systems

- Members: the 25 EU Member States, Iceland, Liechtenstein, Norway

Personnel/Budget:

Personnel 2006: 50 people

Personnel 2007: 90 people

Budget 2006: 16.5 Mio. EUR

Info:

ECDC - Director: Mrs. Zsuzsanna Jakab

Tomtebodvägen 11A, 171 83 - Solna/Sweden

www.ecdc.eu.int

European Environment Agency (EEA)



Founded: 1990

Location: Copenhagen, Denmark

Main tasks:

- To collect, process and provide reliable information on environmental issues

- To co-operate with international environment organisations

- Members: 25 EU-Members + Bulgaria, Iceland, Liechtenstein, Norway, Rumania and Turkey

Personnel/Budget:

Personnel: Network of 3000 national experts

Budget 2006: 32, 973 Mio. EUR

Expected Budget 2007: 34 Mio. EUR

Info:

EEA - Director: Mrs. Jaqueline Mc Glade

Kongens Nytorv 6, 1050 - Copenhagen/Denmark

www.eea.eu.int

European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)



Founded: 1993

Location: Lisbon, Portugal

Main tasks:

- To collect reliable information about drugs and drug addiction in Europe

- To co-operate with e.g. United States International Drug Control

- Programme (UNDCP), WHO (World Health Organisation), Council of Europe's Pompidou Group, World Customs Organisation (WCO), International Criminal Police Organisation (Interpol) and the European Police Office (Europol)

Personnel/Budget:

Personnel: +/- 90 people

Budget 2006: 12.6 Mio. EUR

Info:

EMCDDA - Director: Mr. Wolfgang Götz

Rua da Cruz de Santa Apolonia

23-25, PT-1149-045 - Lisbon/Portugal

www.emcdda.europa.eu

European Agency for the
Evaluation of Medicinal
Products (EMA)



Founded: 1995

Location: London, United Kingdom

Main tasks:

- To protect and promote public and animal health, through the evaluation and supervision of medicines for human and veterinary use
- To co-operate with international organisations
- Members: 42 national competent authorities in 28 EU and EEA-AFTA countries

Personnel/Budget:

Network of 3500 European experts

Staff members 2006: 424

Staff members 2007: 441 people

Budget 2006: 123.515 Mio. EUR

Expected Budget 2007: 144. 073 Mio. EUR

Info:

EMA - Director: Mr. Thomas Lönngren

7 Westferry Circus, Canary Wharf,

London E14 4HB/United Kingdom

www.ema.eu.int

European Agency for Safety and
Health at Work (EU-OSHA)



Founded: 1996

Location: Bilbao, Spain

Main tasks:

- To preserve and protect human and other resources in the workplace
- To collect and analyse relevant information about safety and health

Personnel/Budget:

Staff: 51 people

Budget 2006: 13.522 Mio. EUR

Expected Budget 2007: 14. 349 Mio. EUR

Info:

EU-OSHA-Director: Mr. Jukka Takala
(from September 2006)

Gran Vía 33, E-48009 - Bilbao/ Spain

<http://agency.osha.eu.int>

European Food Safety
Authority (EFSA)



Founded: 28.1.2002

Location: Parma, Italy

Main tasks:

- To provide advice in all matters and topics with a direct or indirect impact on food safety
- To collect and offer information on new developments in science

Personnel/Budget:

Staff: around 350 people

Budget 2006: 46.6 Mio. EUR

Info:

EFSA - Director: Mr. Geoffrey Podger

Director Scientific Committee: Mr. Vittorio Silano

EFSA-Parma: Palazzo Ducale,

Parco Ducale 3, 43100 Parma/ Italy

<http://www.efsa.eu.int>

European Chemicals Agency (ECHA)

Founded: Expected in 2007

Location: Helsinki, Finland

Main tasks:

- To take a central role in the implementation of the regulation concerning Registration, Evaluation and Authorization of Chemicals (REACH)

Personnel/Budget:

Staff: 100 employees in 2007, 400 employees by 2010

Info:

Tilgmann Building - Helsinki, Finland

<http://ec.europa.eu/echa/>

For information about other European Agencies:

http://europa.eu.int/agencies/index_en.htm

ECHAMP Agenda

Oct 11	SG Mutual Recognition	Bensheim
Oct 26	WP Public Relations	ECHAMP Brussels
Oct 27	EMA Workshop	London
	Homeopathy	
Nov 23-24	Board Meeting	ECHAMP Brussels

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