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REPORT ON EMEA WORKSHOP ON HOMEOPATHIC MEDICINAL PRODUCTS

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK

Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51

E-mail: mail@emea.europa.eu <http://www.emea.europa.eu>

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1. INTRODUCTION

Further to the 2001 review, the mutual recognition/decentralised procedure is applicable to the registration of homeopathic medicinal products subject to the special simplified registration procedure in accordance with the articles 14 and 15 of Directive 2001/83/EC. The participating European associations stated that the hurdles to industry for the registration of homeopathic medicinal products may threaten a considerable number of them to disappear as it may not be commercially viable to register them. It should be taken into account that the portfolio of homeopathic medicinal products ranges from 3,000 to 4,000 where mainly 200 are used.

The European Medicines Agency (EMA) organised a workshop on homeopathic medicinal products on 27 October 2006 at the request of the European Commission. The aim of the workshop was to provide a forum for discussion among all stakeholders on the current legislative framework for homeopathic medicines. The workshop addressed strengths and weaknesses that have been identified, as well as potential threats and opportunities for improvement with respect to the operation of that framework.

The workshop brought together some 50 experts from industry, healthcare professional and patient associations, as well as regulatory authorities. In particular, ten European associations were invited and nineteen National Competent Authorities (NCAs) were represented along with the chairperson of the Co-ordination Group for Mutual Recognition and Decentralised Procedures (human) (CMD(h)) as well as participants from the European Directorate for the Quality of Medicines (EDQM) and the World Health Organisation (WHO). (See list of participants ANNEX 4.1).

The agenda was prepared based on input from stakeholders and was the basis for discussion of the main regulatory issues and problems within the area of homeopathic medicinal products. The main topics for discussion were:

- Regulatory framework for these medicinal products
- Homeopathic Medicinal Products Working Group (HMPWG) of the Heads of Agencies
- Homeopathy and the European Pharmacopoeia
- Dossier requirements and the Common Technical Document (CTD)

It was discussed that the outcome of the workshop would be presented in a report to the European Commission based on input provided by all parties attending.

2. SUMMARY OF PRESENTATIONS AND DISCUSSION

2.1 Round table for introduction of the European Associations

Thomas Lönngren welcomed the participants and was pleased to have been able to host the workshop and offer all participants the possibility for a good forum for discussion. The Chair invited the participating European associations to start with a brief introduction where their main issues and concerns were presented.

- o *AESGP (Association of the European Self-Medication Industry)*

AESGP was founded in 1964, are located in Brussels and represent the manufacturers of non-prescription medicines in Europe.

Their main concerns are:

- To ensure a pragmatic interpretation of the legislation, where harmonisation is favoured but national traditions and existing products are respected

- To propose a solution to the GMP requirement for active substances ie to consider that the starting material itself is not a homeopathic active substance until having been processed in accordance with a homeopathic manufacturing process.

- ***CIPH (Comité International des Pharmaciens Homeopathes)***

CIPH was founded in 1955 and aims to facilitate patients' and healthcare professionals' access to homeopathic medicinal products.

Their main concerns are:

- The discrepancies between national and mutual recognition procedures.

- ***ECCH (European Council of Classical Homeopathy)***

ECCH was established in 1990 and is based in the UK; they include 27 professional associations in 23 countries. They represent homeopathy practitioners who are not already regulated healthcare professionals.

Their main concerns are:

- Loss of access to necessary homeopathic medicinal products particularly in Germany and The Netherlands (e.g. nosodes¹ and seldom used remedies) where the manufacturers have removed hundreds of products from the market due to lack of commercial interest. This is threatening the freedom of therapy removing choice both for the healthcare professionals and patients.
- Excessive safety requirements with a lack of differentiation between high and low potencies.

- ***ECH (European Committee for Homeopathy)***

ECH was founded in 1991, are located in Brussels and represents 12,000 medical doctors with education and training in homeopathy as a method belonging to 38 associations in 23 European countries.

Their main concerns are:

- Variability in Member States regarding interpretation and implementation of Directive 2001/83/EC as amended, which has caused the disappearance of homeopathic medicines in some Member States while they are still available in others.
- Limited availability of homeopathic medicinal products since many of them have been removed from the market by the manufacturers. Therefore, about 20% of patients seeking homeopathic treatment cannot receive an adequate therapy.
- Disappearance of homeopathic medicinal products whose raw material is of biological origin from the market due to strict safety requirements. Despite the fact that these products are only used in high potencies that are rendered safe by dilution (no molecules, therefore no prions/viruses).

- ***ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products)***

ECHAMP was founded in 1999, are located in Brussels and represents 50 full members, pharmaceutical companies in 14 EU Member States as well as 10 associated members being National manufacturers' associations.

Their main concerns are:

- Harmonisation and free circulation of homeopathic medicinal products with good quality, safety and effectiveness.

¹ According to the draft document '[POINTS TO CONSIDER ON SAFETY OF HOMEOPATHIC MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE FROM BIOLOGICAL ORIGIN](#)', Nosodes are preparations made from products of human or animal disease processes, from pathogens or their metabolic products, from the decomposition products of animal organs, or from cultured micro organisms.

- Proportionality and pragmatism in setting up the regulatory environment for homeopathic medicinal products. For this ECHAMP presented a comprehensive vision on an optimal EU-environment for these medicinal products.
 - The pharmaceutical companies, members of ECHAMP all of them being small and medium enterprises are very interested to be part of the aims and the benefits of the Lisbon Strategy for the European Industry..
 - Need for progress in the regulatory environment, as there are high expectations with respect to the operation of the single market.
- ***ECPM (European council of doctors for plurality in medicine Brussels)***

ECPM is a European Federation of some 45 Medical Doctors' Associations with more than 52,000 members practising Alternative and Complementary Medicines (CAM).

Their main concerns are:

- Need for availability of remedies in order to facilitate a good practise of homeopathy and anthroposophic medicine.
- The different traditions and pharmacopoeias should not shackle the freedom of prescription for doctors and availability of medicines for patients.
- Need for an adequate place for clinical experimentation with homeopathy and anthroposophic medicine within the European Research Programme (FP 7 Framework Programme) funded by the European Commission.

○ ***EFHPA (European Federation of Homeopathic Patients' Associations)***

EFHPA was founded in 2003, are located in Brussels and represents 110 million patients in Europe.

Their main concerns are:

- Availability and affordability of homeopathic medicinal products. The lack of remedies is causing major problems to patients since doctors are not able to prescribe the necessary medicines.
- Manufacturers cannot continue production due to high fees for licensing of these medicinal products.
- Harmonisation of labelling and packaging across the EU.

○ ***EFPAM (European Federation of Patients' Associations for Anthroposophic Medicine)***

EFPAM was founded in 2000, are located in France and represents patients' associations for anthroposophic medicine in 11 EU Member States.

Their main concerns are:

- Equal access and affordability of these medicines.
- Freedom as to the choice of therapy.

○ ***IAAP (International Association of Anthroposophic Pharmacists)***

IAAP was founded in 1940, are located in Switzerland and represents anthroposophic pharmacists internationally and sets standards for national anthroposophic pharmacists' associations.

Their main concerns are:

- Need for proportionality and balance in order to have a pragmatic interpretation of the regulatory requirements.
- Mostly homeopathic and anthroposophic medicinal products do not yield a very high turnover and therefore high registration fees will make it impossible for applicants to register the products in the MRP/DCP or will tend to create a monopoly for a limited number of companies.
- Safety requirements should not be disproportionate for homeopathic medicinal products compared to other medicinal products, considering that a well known homeopathic stock in a concentration of

1:10.000 is present in an amount that is comparable to the allowed range of unidentified impurities in a new drug substance.

- Mandatory implementation of Article 16(2)² of Directive 2001/83/EC as amended.
- Need to establish an appropriate framework for anthroposophic medicinal products.

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

IVAA (International Federation of Anthroposophic Medical Associations)

The IVAA was founded in 1970 (then still as IAV), has its seat in Switzerland and represents approximately 2000 fully qualified medical doctors from anthroposophic medical associations in 18 Member States in Europe.

Their main concerns are:

- Need for an adequate framework for anthroposophic medicinal products and all their pharmaceutical forms, including compound preparations, injectables and eye-drops. Especially injectables and eye-drops are currently a major problem with regards to simplified registration because this is only applicable to products administered orally or externally in accordance with Article 14(1).
- Equal access in all Member States to a full range of anthroposophic medicines.

2.2 Regulatory framework for homeopathic medicinal products – Emiel Van Galen (NL)

Emiel van Galen, Dutch member of HMPWG, gave a very stimulating presentation regarding the regulatory framework for homeopathic medicinal products in the European Union in order to initiate discussions between the Interested Parties.

After a brief history of Homeopathy and Anthroposophic medicine in relation to the development of EU Pharmaceutical Legislation, a review of the national experience in The Netherlands in the last 10 years was provided. The key elements from which are described below.

Due to the particular characteristics of these homeopathic medicinal products, a special simplified registration procedure for those products placed on the market without therapeutic indications is envisaged by Article 14(1) of Directive 2001/83/EC as amended, always with a sufficient guarantee of their quality and safety. Based on 10 years of national experience in one Member State the following conclusions can be drawn so far.

The simplified registration scheme is:

- appears to be applicable to the majority of homeopathic medicinal products
- ensures compliance with pharmaceutical quality standards
- ensures compliance with the safety requirements defined in legislation, taking into account the dilution-process
- ensures safe use by limiting the routes of administration
- applying labelling requirements defined in legislation
- not allowing therapeutic indications, and therefore not requiring proof of efficacy
- exclusively based upon homeopathic justification of its use

For those homeopathic medicinal products placed on the market with therapeutic indications in accordance with Article 16(1) of Directive 2001/83/EC as amended, the usual rules governing the authorisation to market medicinal products should be applied. With the amendment of Directive

² Article 16(2) of Directive 2001/83/EC as amended provides 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 practised in that Member State.

In this case, the Member State concerned shall notify the Commission of the specific rules in force.’

2001/83/EC, recently for the simplified procedure Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP) have been introduced. However in case of disagreement between Member States, referrals to CHMP do not apply to homeopathic medicinal products. Looking to the near future an estimated guess of possible MRP/DCP applications was presented and some scenarios on future development were discussed. An important issue is how to finalise MR procedures when disagreement between Member States arise, both on regulatory and on homeopathic issues.

The above routes of registration and marketing authorisation are also applicable to those anthroposophic medicinal products that are described in an official pharmacopoeia and are prepared by a homeopathic method.

A personal SWOT analysis of the homeopathic regulatory framework was then presented. These are the main highlights:

1. Strengths

Homeopathy relies on a generally recognised broad range of remedies, for which the manufacturing methods are clearly defined. The availability of these remedies is of general interest and in the homeopathic field they are generally accepted principles for use in patients. Apart from scientific controversy, the use of the homeopathic medicines is consistent and based on a European widely used therapeutic system.

2. Weaknesses

The pharmaceutical development of homeopathic remedies traditionally followed two separate main lines, according to the German and the French homeopathic pharmacopoeias together with their traditions. Often solutions for pharmaceutical issues are still influenced by traditional sentiments. In some cases there is a tendency to indifference among stakeholders. ('nothing will change after all'). Quality improvements are not possible without cooperation of suppliers of raw materials as 90% of remedies are based on raw materials with a natural variability. In addition, an enormous amount of different remedies is still used. However, due to the principles of homeopathy, one remedy cannot simply be replaced by an alternative one.

3. Opportunities

Harmonisation is a logical next step to achieve a single European market, also for homeopaths. MRP/DCP are ideal tools to avoid regulatory duplication. of work and recognition of the quality and safety of homeopathic remedies will improve the safe use of these kind of medicinal products. In addition, a range of anthroposophic homeopathic medicinal products can be evaluated under this legislation as well.

4. Threats

Most threatening is the lack of sufficient pharmaceutical and regulatory knowledge in this area within industry as well as National Competent Authorities (NCAs), which could make the homeopathic community reluctant to strive for a fully harmonised EU market. In addition at Member State level regulation of homeopathic products is seldom considered as a priority.

During the discussion several practical points were raised such as the need to develop further guidance for industry and assessors, also, it was highlighted that 5-10% of the homeopathic medicinal products make 90-95% of the turnover and therefore the rest of 90-95% of homeopathic medicinal products represent a big regulatory burden for companies. We must look for 'pragmatic regulatory solutions' in order to keep the whole range of homeopathic products available for the practitioners (ECHAMP). Difficulties have been experienced with regards to MRP and the attempt for harmonisation because of the different national traditions, having raw materials under the same name but with different dilutions and pharmaceutical forms, e.g. sunset clause, timing, etc. (CIPH).

Looking to the way ahead, and taking into account the large amount of homeopathic and anthroposophic products, as well as of assessments to be performed, the concept of Work-sharing should be considered seriously, according to van Galen's personal opinion. During the recent years more cooperation between MS and between companies becomes apparent, so on both sides the concept of work-sharing deserves serious attention. Companies could divide and exchange regulatory

achievements on different registered homeopathic remedies. Regulatory agencies should work together to handle the large quantity of simplified procedures, within clear timeframes.

At this moment MS are assessing 5 to 10 comparable dossiers of different applicants with the same Arnica montana. On the other hand, several homeopathic companies are striving to get hundreds of registrations for nearly the same collection of widely used remedies.

The “Me-Too” principle is also highly applicable to the homeopathic field, which could hinder a firm step forward.

2.3 Homeopathic Medicinal Products Working Group (HMPWG) – Werner Knöss (DE)

Werner Knöss, German member of HMPWG, gave a very interesting and detailed presentation regarding the objectives, achievements and roles and responsibilities of the Homeopathic Medicinal Products Working Party.

The informal meetings of the HMPWG first started in 1999 in Germany (BfArM). The group was formalised by the Heads of Medicines Agencies (HMA) and the first formal meeting was in 2004 in the Netherlands.

The HMPWG mandate (see ANNEX 4.4) as agreed by the Heads of Medicines Agencies in November 2004, identifies the group as being a forum of exchange of regulatory and scientific expertise as well as elaboration and provision of guidance to assessors and applicants and expertise and advice on request regarding procedural, regulatory and scientific issues arising from the MRP/DCP. It was started because there was a clear need for a European solution for the regulation of homeopathic medicinal products due to the particular characteristics of this therapeutic system, such as developing common interpretation of criteria, guidance for the assessment and being a mean for communication and harmonisation in the EU. Before 1999 there were no exchange between Member States, nowadays, Member States work on their differences as some of them have different traditions but others do not have any.

The 4th and 5th formal meeting is due to take place in Germany under its Presidency.

The participants of HMPWG are assessors and regulatory experts from the National Competent Authorities, as well as representatives from the European Commission, European Pharmacopoeia, EMEA and WHO.

In the field of Homeopathy, there is a network of organisations that interacts apart from the already described HMPWG. The NCAs act as RMS or CMS in the MRP/DCP, also give support to HMPWG. EDQM provides quality assurance and develops general and specific homeopathic monographs as well as implementing homeopathic manufacturing methods into the European Pharmacopoeia. WHO provides for an exchange of information among WHO Member States as well as clarifying definitions or elaborating guidelines on quality control for the safety of traditional medicines (homeopathic remedies).

Harmonisation was seen as the key element to be achieved, harmonisation on:

- Scientific assessment
- Common interpretation of requirements
- Non-clinical safety (safe dilution grade)
- Safety of materials of biological origin
- Labelling / Nomenclature requirements
- Interpretation of regulatory issues arising from MRP/DCP
- Technical issues

Subsequent discussions following the presentation emphasised the need of harmonisation in order for MRP/DCP to succeed (CIPH). In addition there was a need for more interaction with healthcare

professionals and patients (ECCH). There was also some concern regarding the rate of publication of guidance in the HoA (Heads of Agencies): all the current published documents still have the status of 'Draft' documents. Question in this respect is the power of the mandate given by the HMA to the HMPWG, the mandate should be revised and strengthened in order to give more impact to the HMPWG and also more flexibility and transparency in the contacts with the Industry (ECHAMP).

The speaker mentioned that the mandate would probably not be revised but that the HMPWG with help from Industry through their applications will be able to make progress. It was also noted that alternative solutions involving legislative initiatives via European Commission/European Parliament could take much longer and that over regulation can be restrictive. The possibility to have hearing between HMPWG and EU Industry and stakeholders was raised and Mr Knöss stated that they would try to arrange this interaction during their presidency.

Another issue raised was regarding viral safety and the need to be more flexible and have more discussions with HMPWG (CIPH).

2.4 Homeopathy and the European Pharmacopoeia – Isabelle Mercier (EDQM)

Isabelle Mercier from the European Directorate for the Quality of Medicines (EDQM) gave a general introduction about EDQM, the membership of which includes 36 European Member States and 20 observers including USA/FDA and WHO. Its role is to harmonise the quality standards for use by healthcare professionals, it is recognised as the only official Pharmacopoeia in Europe to be used for international trade and it is mandatory in European marketing authorisation dossiers in 36 Member States.

The group of experts from the European Pharmacopoeia (Ph Eur) is composed of experts from Member States, proposed by the national authorities and appointed by the Ph Eur Commission. It is chaired by a member of the Ph Eur Commission and the group has a 3-year term of office, renewable once.

It was Directive 92/73/EEC (repealed by 2001/83/EC, as amended) that made reference to European Pharmacopoeia. Its working party on homeopathy was fully established in 1997 and the membership was restricted to national competent authorities. They prepared monographs for European use. The working party was not reappointed in November 2004 but there has been a call for candidates in September 2006 so the work can be restarted in 2007.

It was explained that all general texts and monographs of the Ph Eur that are relevant to homeopathy are applicable, even if not included in a specific section. The chapter on homeopathy contains general monographs and individual monographs on starting materials and stocks, etc

Some of the monographs developed for inorganic, herbal and other substances were described. It was also explained how the harmonisation of different traditions was sometimes hard to achieve with concrete examples such as freshness of the plant or foreign matter. In this case, tests for loss on drying and foreign matter are mentioned in the monographs, however, specifying that are only required upon request of the national competent authority.

A brief description of the achievements from the 2005 Symposium at EDQM was presented. With regards to the general monograph on methods of preparation, only those acceptable for all countries are included at the moment. It was highlighted that the European Pharmacopoeia Commission adopted 9 manufacturing methods of the German Homeopathic Pharmacopoeia and 2 methods from the French Pharmacopoeia in June 2006. During the Symposium there were discussions regarding the work programme of the future working party.

During the discussion industry highly appreciated the progress achieved by EDQM regarding integration of homeopathic preparations into the Ph Eur (ECHAMP). Concerns were raised by ECCH regarding the low priority given to nosodes and stressed that those homeopathic remedies are highly used however they are still controversial and will continue to be until a harmonised view is agreed.

2.5 Dossier requirements and Common Technical Document (CTD)

Due to lack of time this topic was not discussed in.

3. CONCLUSIONS

The workshop provided for an opportunity for a first full level discussion amongst interested parties about the regulatory framework and status of harmonisation in the field of homeopathic medicinal products.

The main concerns highlighted by the participating associations were the difficulties in achieving the needed technical harmonisation for the success in utilisation of Mutual Recognition and Decentralised Procedures together with variability in Member States regarding interpretation and implementation of Directive 2001/83/EC as amended. These difficulties are having an effect on accessibility to necessary homeopathic medicinal products as well as anthroposophic medicinal products, where there is no suitable regulatory framework for existing injectable, eye drops or mixtures of potentised and non-potentised substances; affordability and availability were also raised as concerns. The threat to the freedom of choice of therapy mainly with regards to seldom used remedies (due to excessive paperwork and costs) and nosodes (due to excessive safety requirements) was a major concern to healthcare professionals and patients.

The industry expressed its proposals for the future and the way forward including as well a diagram on an ideal legal and regulatory environment for homeopathic and anthroposophic medicinal products in the Community (See Annex 4.3.5). In addition, the association mentioned the time pressure for doing the whole regulatory work in view of the fact that the allopathic pharmaceutical industry had 27 years (1965 - 1975 – 1992 [see articles 38, 39(2) of Dir. 75/319/EEC]) in order to bring their products in line with regulatory standards. As regulation of homeopathic remedies started rather slowly and, moreover, in many member states the whole system still remains to be initiated; the industry asks to foresee enough time to do the work. In the meantime the member states should look for solutions to harmonise the calendars amongst each other without removing the products from the markets.

Some solutions to these problems were proposed by the participants, including some sort of central coordination to overcome national differences or having a centralised supportive role or playing a role in ensuring that European patients have access to the medicinal products of their choice as originally intended.

With regards to harmonisation, it was emphasised by the Chairman of the CMD(h) that a commitment from the Heads of Medicines Agencies Group to accept CMD(h) decisions is important. She also stated that this is the time to look at the future and make a new start. At CMD(h) there are discussions and once an agreement is reached for a controversial issue, there is no further discussion with the next applications as a precedent has been set. The same principle can be applied to homeopathic medicinal products.

Werner Knöss stated that the process for harmonisation involves all stakeholders and by exchanging information amongst all parties and by providing guidance through HMPWG and with the experience to be gained through the MRP/DCP, harmonisation will be a reality in the very near future. This together with an integration of the different traditions at a European level will enable to develop homeopathy, improve transparency and create a real European market.

The work of HMPWG was much appreciated with regards to the guidance provided and the possibility of interaction with other stakeholders. It was mentioned that more guidance on the content of the dossier was needed. The initiative to host a workshop at the EMEA was also welcomed and the high expectations from industry were highlighted as regards to technical harmonisation and free movement of homeopathic medicinal products.

The level of participation was high and it was greatly appreciated that representatives from users, patients, healthcare professionals, industry and regulators were willing to attend the workshop and have a frank exchange of views concerning current challenges and potential solutions.

This report will be transmitted to the European Commission for consideration of the next steps in the area of homeopathic medicinal products.

4. ANNEXES

4.1 [List of participants](#)

4.2 [Agenda](#)

4.3 Presentations

4.3.1 [AESGP: introduction](#)

4.3.2 [CIPH: Introduction and Viewpoint from Industry](#)

4.3.3 [ECCH: The concerns of the Homeopathy Profession in Relation to Homeopathic Medicines in Europe](#)

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4.4 [HMPWG Mandate](#)