



ECHAMP e-News June/July 2010

■ **Editorial : Towards an appropriate regulation for homeopathic and anthroposophic medicinal products**

Can a better understanding of the therapeutic setting for homeopathy and anthroposophic medicine help inform a new legislation for homeopathic and anthroposophic medicinal products that is more appropriate to their specific characteristics? This issue of ECHAMP E-news aims to explore this question. Page 2

■ **Consultation on veterinary pharmaceuticals – hope for homeopathic medicines?**

Perhaps ECHAMP can take heart from the Commission's justification for a review of the legislation for veterinary pharmaceuticals? The Commission identifies the restrictions and the unnecessary burden that this complex legislation places on the veterinary pharmaceutical industry. Christine Marking explains how these arguments could equally well be applied to the legislation for homeopathic medicinal products. Page 3

■ **European Commission work programme – an update on activity** Page 4

■ **The specific characteristics of homeopathic and anthroposophic medicinal products**

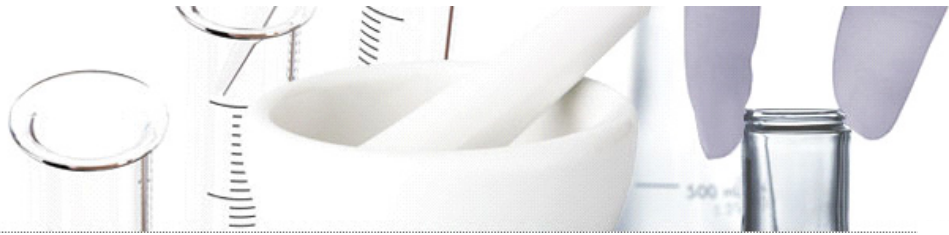
A number of factors differentiate homeopathic and anthroposophic medicinal products from conventional medicines, not least the way in which they are prescribed within a therapeutic or medical setting. Dr Ton Nicolai, President of **European Committee for Homeopathy**, explains the therapeutic context for homeopathic medicinal products in his article **Towards a more suitable regulation of homeopathic medicines**, describing how a new regulation could be better tailored to their specific characteristics. Dr Madeleen Winkler, Vice President of the International Federation of Anthroposophic Medical Associations describes the process of anthroposophic medicinal diagnosis and treatment in her article, **The specific nature of anthroposophic medicine – an integrative medicine**. Page 5

■ **How to catch nature in a bottle? EU pharmaceutical legislation on homeopathic and anthroposophic medicinal products**

Homeopathic medicinal products are used in a medical setting which is fundamentally different from allopathic medicine. Furthermore, the active substances used in homeopathic medicinal products may generally not be compared to the substances used in allopathic medicinal products. Johan Hulshof describes some of the problems encountered in the EU pharmaceutical legislation on homeopathic and anthroposophic medicinal products, and explains why the current legislation is not sufficiently adapted to the specific nature of the products. Page 5

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Karen Chapman, Editor of ECHAMP News, ECHAMP PR and Communications Consultant



Editorial



Towards an appropriate regulation for homeopathic and anthroposophic medicinal products?

Last November ECHAMP's expert seminar concluded that EU legislation for homeopathic and

anthroposophic medicine is not 'fit for purpose'. The current legislation has been tried and tested now for over fifteen years ago, and the experience shows an increasingly complex and inappropriate legal and regulatory environment. Far from bringing harmonisation to the market, it is resulting in limited availability of the medicinal products for the patients who demand them, and the doctors who prescribe them.

There is no doubt that homeopathic and anthroposophic medicinal products do and should continue to reach high standards of quality, safety and effectiveness; however there are a number of factors that differentiate them from conventional medicines, in particular the way in which they are prescribed within a therapeutic setting. In this issue of E-News, we explore whether a better understanding of the therapeutic setting for homeopathy and anthroposophic medicine can help inform a new legislation for homeopathic and anthroposophic medicinal products that is more appropriate to their specific characteristics.

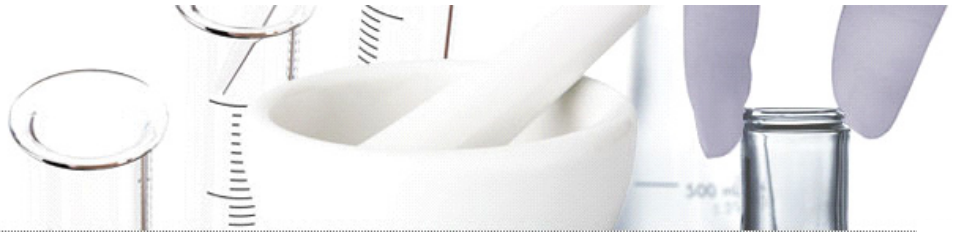
Johan Hulshof describes some of the problems encountered in the registration process, and explains why the current legislation is not sufficiently adapted to the specific nature of the products.

Ton Nicolai looks at the therapeutic context for homeopathic medicinal products and what might be an appropriate regulation for these medicines, taking account of their specific characteristics, while Madeleen Winkler describes the therapeutic process for diagnosis and treatment of anthroposophic medicine.

Clearly a review of this legislation is now well over due. Perhaps ECHAMP can take heart from the Commission's justification for a review of the legislation for veterinary pharmaceuticals? The Commission itself identifies the restrictions and the unnecessary burden that this complex legislation places on the industry. It could be talking about the legislation for homeopathic medicinal products.

ECHAMP hopes that the new start in September will bring better news for our medicinal products. In the meantime, we wish all our readers a happy and refreshing summer break, and a healthy return to work.

Nand De Herdt
President of ECHAMP



Consultation on veterinary pharmaceuticals – hope for homeopathic medicines?



The European Commission has launched an EU wide stakeholder consultation in relation to a review of the veterinary pharmaceutical legislation

(see E-news May 2010). Its declared purpose is to discuss how to put in place a simpler legal framework, safeguarding public and animal health while increasing the competitiveness of companies.

An analysis of the consultation document shows many similarities between the issues listed as shortcomings of the legal veterinary framework and many of the specific issues that ECHAMP identifies as problematic within the current legislative framework for homeopathic medicinal products for human use. This consultation could therefore set a much needed precedent for a detailed review of the existing legislation on pharmaceutical medicinal products for *human* use – in particular in relation to homeopathic medicinal products.

Specifically, the document lists various reasons for the need to review the current legislation for veterinary pharmaceuticals. It argues that it:

- is too complex, given the various procedures, responsibilities and processes in place
- is too cumbersome, time consuming and costly for the industry, which mostly consists of small and medium-sized enterprises (SMEs)
- raises issues over ‘unnecessary regulatory burden’
- leaves too much room for interpretation and different ways of implementation by Member States

- leaves too much room for interpretation and different ways of implementation by Member States
- has not delivered on the availability of and access to products
- has not been successful in creating a harmonised internal market; the mutual recognition and simplified procedures have led to delays in granting marketing authorisations and backlogs in national approval systems.

The same arguments could be just as easily applied to the need for a review of the current legal and regulatory framework for homeopathic medicinal products, specifically in relation to Article 13.1, Article 14.1, Article 16.1, Article 16.2 and the specific national rules, policies and limitations. Like the review of the veterinary pharmaceutical framework, a review of the framework for medicinal products for human should aim to

- increase the availability of homeopathic and anthroposophic products
- decrease the administrative burden for companies
- improve the functioning of the internal market for homeopathic and anthroposophic medicinal products.

ECHAMP has written to Commissioner Dalli, Commissioner for Health and Consumer Policy, underlining that, if the arguments listed call for a review of the veterinary pharmaceuticals legislation, they also call for a review of the human pharmaceuticals legislation. It reiterates its call on the Commission to create a harmonised and workable legal and regulatory environment for homeopathic and anthroposophic medicinal products across the EU in order to comply with the legitimate demand of the citizens, prescribers and patients for these products.



European Commission work programme – an update on activity



The Commission's recently published work programme for 2010 contains several issues of interest to the industry for

homeopathic and anthroposophic medicinal products:

- **Communication on a European Plan for Research and Innovation:** this will propose an indicator to track innovation and specify a policy framework for developing European Research and Innovation Partnerships
- **Reviewed Directive on veterinary medicinal products:** to improve consumer safety and animal health protection and the competitiveness of the veterinary industry
- **Revision of the Directive on the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems:** examine ways to adapt the requirements of the Directive in order to improve the functioning of the internal market for medicines, taking into consideration the development of national pricing and reimbursement policies
- **Proposal for a Competitiveness and Innovation Framework Programme 2014-2020 (CIP II):** to improve competitiveness and sustainable growth, addressing speeding up the adjustment of industry to structural changes, encouraging an environment favourable to initiative and to the development of enterprises (particularly SMEs)

- **Proposal 8th EU Research & Development Framework Programme for the period 2014- 2020:** will contain main orientations and proposals for specific programmes and rules for participation.
- **Communication on smart regulation:** presenting the Commission's priorities for smart regulation covering actions to simplify existing legislation and reduce administrative burdens.

Commission to review the 2004 Clinical Trials Directive

The current EU's Clinical Trials Directive has been severely criticised for resulting in higher costs and a heavier administrative burden while the benefit to patients, researchers or industry are not clear. The Commission has responded to these criticisms, and aims to review the Directive and put in place more effective regulation by October 2011. It has not yet been decided whether some of the more problematic elements in the current Directive will be simplified or whether an entirely new regulation will be put forward.

The Commission has funded a project under the Seventh Framework Programme (FP7), the ICREL project, which aims to obtain a coherent picture of the effect of the Directive on the pharmaceutical industry, academics, research ethics committees and medicines regulators. One of ICREL's findings is that all stakeholders have had to increase their staff and resources in order to cope with the new requirements; moreover, the costs of clinical trials have risen quite substantially.

With Brazil, Russia, India and China rapidly developing their clinical trials infrastructure, it is becoming even more important to attract and keep industry and researchers in Europe. India, for instance, has invested heavily in research and as a consequence,



European Commission work programme – an update on activity

its pharmaceutical sector is growing.

The Commission has published a roadmap outlining its commitment to addressing the shortcomings in the Directive.

Christine Marking
ECHAMP Public Affairs Consultant

Towards a more suitable regulation of homeopathic medicines

Homeopathy has both a systematized theoretical and therapeutic basis. It is a system of natural medicine based on the similarity principle. The similarity principle means that substances capable of causing disorder on any level in healthy subjects can be used as medicines to remedy similar patterns of disorder experienced by people when they are ill. In fact, homeopathy relates individual patterns of responding to environmental influences, infectious agents and potential stressors to specific homeopathic medicines that can remedy these susceptibility patterns. Skilled homeopathic prescribing requires that the state of being that can be elicited by the chosen medicine (in a proving) should be as similar as possible to the disease state of the patient. The more detailed the understanding of the state of the patient, the more accurate the prescription.

Consequently any substance can be used as a homeopathic medicine, which means that a wide variety of homeopathic medicinal products in a large range of potencies are needed by doctors and practitioners in order to undertake successful homeopathic treatment. Any registration system of homeopathic medicines therefore needs to be flexible, simple, practical and inexpensive.

Need for appropriate regulation

Public health must be safeguarded by assessing the quality, safety and efficacy of medicines available to patients in Europe. On the other hand, EU Directives and other regulations must not result in restrictions to the production and the distribution of homeopathic medicinal products. Inappropriate medicine safety requirements and approval costs must not unreasonably impair the availability of homeopathic medicinal products.



Towards a more suitable regulation of homeopathic medicines

Efficacy

Medicines must be able to provide a clinically measurable effect, i.e. be efficacious and preferably also beneficial. For each individual conventional prescription drug, efficacy has to be proven. This requirement is not applicable to homeopathy, because homeopathic medicines are by definition efficacious when they are properly prescribed, i.e. when the medicine pattern is as close as possible to the disease pattern. Homeopathy is a coherent and consistent therapeutic system in itself.

Quality

The quality of homeopathic medicines is influenced both by the quality of the raw material and the quality of the procedure used during their production. The quality of the raw material is defined by the authenticity and the origin of the starting materials according to the homeopathic tradition. In this respect, adherence to information in pharmacopoeias or monographs and to GMP rules is essential. Identification and assay of source materials may not be feasible at high potencies. In such cases the quality should be demonstrated by complete validation of the manufacturing and dilution process.

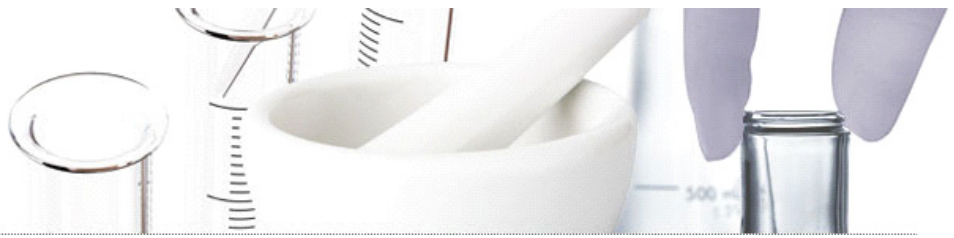
Safety

Understandably there is a need for reasonable and comprehensible requirements for the safety of medicines. Although homeopathic medicines are in general considered to be safe when administered appropriately, toxicological aspects should not be neglected especially when using lower dilutions of unsafe starting material. After all, the raw materials for many homeopathic medicines are known poisons and all materials of animal or human origin are at risk of containing pathogenic agents.

Still, patient safety can be guaranteed if the end product is safe and it is therefore strongly recommended that risk assessment of homeopathic medicinal products should exclusively be related to the end product.

For the simplified registration procedure according to Directive 2001/83/EC a sufficient degree of dilution guarantees the safety of the medicinal product; in particular, the medicinal product may not contain more than one part per 10 000 of the mother tincture. This arbitrary limit is to be replaced by the first safe dilution, individually defined for each substance or for groups of source substances. Above this level the distribution of a homeopathic single medicine and a combination of them is then possible without any further safety concerns.

In the case of raw materials from biological origin there is an additional issue of viral safety. The unproven assumption that even one single prion may cause Creutzfeldt–Jakob disease (CJD) in humans has led to disproportionate and inappropriate requirements to ensure the safety of homeopathic medicinal products from animal and human origin. With regard to homeopathic medicinal potencies above a suitable potency level, however, even in the case of biological raw materials, such requirements are not necessary. A dilution grade ‘safe by dilution alone and per se’, applicable to any homeopathic medicine derived from any raw substance, allows, together with GMP guidelines, to produce safe medicines, without further safety requirements related to the raw substances. The advantage of potentising according to Hahnemann’s method is that it includes fewer imponderables in the calculation of risks than other well-established methods. Different from other methods, Hahnemann’s potentising method allows for a direct calculation of the risk even without providing evidence through experiments. Even in a worst-case scenario and in requiring an additional ‘safety margin’, a dilution of $\log 10^{-23}$ (C12/D23) and above can be counted as safe.



Towards a more suitable regulation of homeopathic medicines

Swiss alternative

A more practical approach in the registration of homeopathic medicinal products is in place in Switzerland. The Swiss medicines agency Swissmedic was in close communication with all groups of stakeholders when it worked out a system that meets the ‘needs for safety, high quality and availability of homeopathic medicinal products in a pragmatic way’. It was laid down in the *Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorisation of complementary and herbal medicinal products* of 22 June 2006. The registration fees are reasonable at 500 Swiss Francs (€375) – in the EU they vary between € 600 and 7,600 – and allow the maintained availability of the large number of medicines that are needed for high quality homeopathic treatment.

Rarely prescribed medicines

Even if the regulation and registration of homeopathic medicinal products are more flexible, simple, practical and inexpensive, and many more registered homeopathic medicines are available on the market, there still may be a need for magistral formula prescription in case of rarely prescribed homeopathic medicines. In several EU Member States specific pharmacies can be authorised to prepare delegated magistral and even officinal preparations. This authorisation should be implemented in legislation throughout the European Community.

Dr. Tom Nicolai

President of European Committee for Homeopathy (ECH)

The specific nature of anthroposophic medicine – an integrative medicine



Anthroposophic medicine integrates conventional medicine with an anthroposophic perception of the human being. It takes a holistic approach to health and is generally considered a form of complementary and alternative medicine (CAM). First developed in 1920, it has been used in both primary and clinical care, and has proved both to be safe and effective and to offer a high degree of patient satisfaction, earning a high level of acceptance within European society. It offers sustainable and cost-effective solutions for public health and considerable added value to the health systems in the EU.

There are many aspects of the anthroposophic medical approach to preventing and curing illness and to promoting health that can be integrated in a conventional medical approach.

Diagnosis

Anthroposophic medicine builds on the well-established facts and methods of diagnosis and treatment of conventional medicine, which it extends with a holistic approach based on the principle of ‘salutogenesis’, a term which describes an approach focusing on factors that support human health and well-being, rather than on factors that cause disease. More specifically, the ‘salutogenic model’ is concerned with the relationship between health, stress and coping. This leads to effective



The specific nature of anthroposophic medicine – an integrative medicine

strategies for treatment programmes but also for disease prevention through education and lifestyle programmes and the development of self-management in the prevention of and coping with disease.

In addition, the anthroposophic medical diagnostic process integrates specific anthroposophic diagnostic skills and modalities into a conventional medical diagnosis, for a holistic treatment of the individual patient. It views a pathological condition as the culmination of a longer process, and so the analysis of the process that leads to a pathological condition is of major importance in assessing the specific situation of the individual patient in his or her biography and for the subsequent diagnosis and therapeutic process. It also assesses the situation of the patient's illness and the patient's relationship with his or her social and natural environment as well as any psychological, mental or spiritual imbalances in the individual patient.

Treatment

This comprehensive individual analysis leads to a highly individualised treatment approach, corresponding to individualised use and application of both anthroposophic and conventional medicinal products and other therapies. The therapeutic approach is seen as a process rather than a switch from a condition of illness to a condition of health. All therapeutic treatments are aimed at stimulating the ability of the patient to self-heal and emphasis is put on an optimal multi-disciplinary approach, adjusting the application of anthroposophic medicinal products and supplementary anthroposophic therapies, according to the actual situation of the patient. These might

include the input and advice of the therapists of physiotherapy and rhythmic massage, dietetics, eurythmy therapy, art therapy, psychotherapy and further anthroposophic therapeutic and lifestyle approaches.

The autonomy of the patient is central to anthroposophic medicine; self-responsibility, patient choice and active participation are all central to the healing process. The treatment approach is agreed in close discussion with the patient.

Research shows that the anthroposophic medical approach is effective, safe and can reduce costs due to a sparing use of antibiotics, painkillers and anti-depressives; a recent survey of 150 000 patients shows a cost reduction of 15 to 25% for the insurance companies and lower mortality rates.

Anthroposophic medicinal products

Anthroposophic medication is individualised and uses both conventional and anthroposophic medicinal products.

Anthroposophic medicinal products are conceived, developed and produced according to anthroposophic pharmaceutical principles, some of which they share with homeopathy and some of which are according to specific non-homeopathic processes. They are produced in a process-oriented way that reflects the inter-relationship between human beings and the realms of nature in minerals, plants and animals, and manufactured in accordance with the Anthroposophic Pharmaceutical Codex (APC). Their quality is GMP standard and controlled by the criteria and parameters of official pharmacopoeia.

25% of total prescriptions of anthroposophic medicinal products are injections, which are of particular importance in acute and severe medical situations such as in emergency clinics in particular in hospitals. In addition,



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anthroposophic treatments for external use include compresses, hydrotherapy, medical washes, medicinal baths (whole body and foot bath), rhythmic massage (with oil or ointment) and inhalations performed with specific anthroposophic medicine techniques.

In conclusion, anthroposophic medicine offers a multidisciplinary approach to the patient concerning his or her body, soul and individuality and stimulates personal development. It concentrates on factors that support human health and well-being rather than on factors that cause disease. It therefore builds up a constructive way of dealing with complaints and illness rather than only fighting illness. Anthroposophic medicine is efficient and cost effective and provides therapies and medicinal products at low risk.

Dr. Madeleen Winkler

Vice -President of International Federation of Anthroposophic Medical Associations (IVAA)

How to catch nature in a bottle? EU pharmaceutical legislation on homeopathic and anthroposophic medicinal products



Directive 2001/83/EC, which lays down harmonised rules on medicinal products in the EU (EU Medicines Directive), includes a specific procedure for the regulation of homeopathic medicinal products. The imposition of special rules on homeopathic medicinal products stems from the idea that homeopathic medicinal products are used in a medical setting which is fundamentally different from allopathic medicine. Furthermore, the active substances used in homeopathic medicinal products may generally not be compared to the substances used in allopathic medicinal products. For anthroposophic medicinal products currently no such special regime exists although the above applies equally to these medicinal products.

Due to these differences between homeopathic and allopathic medicinal products, the European Commission waited a long time before submitting a proposal for the harmonisation of the legal rules and administrative practices on homeopathic medicinal products in Europe. It was not until the early 1990s that homeopathic medicinal products came into the picture, almost 25 years after the introduction of harmonised rules on medicinal products in Europe in 1965 (Directive 65/65/EEC). With its harmonisation proposal for homeopathic medicinal products, the European Commission tried to strike a balance between preservation of



How to catch nature in a bottle? EU pharmaceutical legislation on homeopathic and anthroposophic medicinal products

a special branch of medicine on the one hand, and the protection of the public health in combination with free movement of homeopathic medicinal products in the internal market on the other.

Earlier harmonisation efforts for the regulation of medicinal products in Europe had explicitly excluded homeopathic medicinal products from their scope. Considering the apparent differences between homeopathic and allopathic medicinal products and the fact that homeopathic medicinal products were barely regulated in most Member States, this did not come as a surprise. In fact, it partially explains why most manufacturers and distributors of homeopathic and anthroposophic medicinal products, but also many national medicines' agencies are still struggling today with the legal regimes and administrative practices that apply to these products.

This article provides some examples of the difficulties manufacturers of homeopathic and anthroposophic medicinal products face in relation to the current legal framework. From the experiences drawn out of daily practice, it also points to a number of issues which hamper the effective harmonisation of homeopathic and anthroposophic medicinal products in the EU.

The position of medicines agencies in Europe

Before harmonising measures for homeopathic medicinal products were introduced, homeopathic medicinal products were barely regulated by most Member States. This was largely due to the relatively low market share of these products in combination with a generally shared view among national administrations that these products were not specifically hazardous.

With the rules imposed from 'above', national administrations had to start all of a sudden

regulating a sector of medicinal products of which they had no specific knowledge at all. Furthermore, homeopathy was and still is not much accepted in many national administrations and more specifically medicines agencies. This can be exemplified by the hesitation of the Dutch Medicines Evaluation Board to take up the responsibility for the registration and authorisation of homeopathic medicinal products.

Through the years certain medicines agencies have made a strong effort to build up expertise in the field of homeopathic and anthroposophic medicinal products. However, effective harmonisation of administrative practices in the EU – for example via the Homeopathic Medicinal Products Working Group (HMPWG) of the Heads of Medicines Agencies – is hampered by those medicines agencies which have failed to do so. The foregoing stresses the need for the creation of centres of expertise in the field of homeopathic and anthroposophic medicinal products to rule out paternalism and improve harmonisation.

No special regime for anthroposophic medicinal products

As established in the *Antroposana-case*¹, no specific regime exists for anthroposophic medicinal products. This implies that these products need a marketing authorisation which is based on an evaluation according to the standards for allopathic medicine. Since anthroposophic medicinal products come from a different medical tradition than allopathic medicinal products and the market share of these products is considerably smaller, the imposition of the authorisation rules for allopathic medicinal products effectively rules out these products coming on the market. This is specifically problematic for



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patients who explicitly prefer to make use of a branch of medicine which has been traditionally available in Europe.

Stability-testing and natural active substances

Homeopathic medicinal products are mainly produced from natural substances. This is in contrast to allopathic medicinal products, which are mainly produced from synthetic or chemical substances. Therefore, the stability of the latter group of products can be controlled relatively easily compared to homeopathic medicinal products. The stability of a tincture that has been derived from plant material for example can play serious tricks as a result of a large mixture of active principles, the composition of which tends to change in a manner much less predictable than synthetic substances.

Moreover, a plant substance differs from harvest to harvest. As a result the amounts of active principles in a tincture will vary naturally from year to year. It is difficult to catch nature in a bottle!

As a result there is much discussion on the indication of relevant markers and admitted boundaries for fluctuations of the relevant substances in a tincture. Here one can clearly see the difficulty of applying a regime that is fit for one group of products (in this case allopathic remedies) to a group of products with different characteristics (in this case homeopathic remedies). Such issues need practical solutions. The more know-how that is available at a medicines agency, the greater the likelihood is that such solutions are attained. Local expertise may not be up to standard to meet such challenges, leading to considerable differences in evaluations and therefore inefficient and diverse implementation.

No uniform rules for homeopathic medicinal products

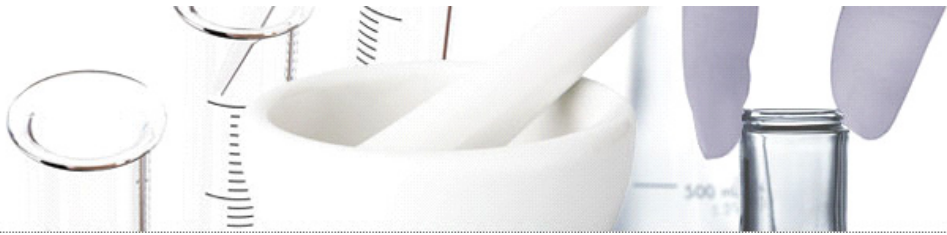
For homeopathic medicinal products there exist two different procedures. On the one hand, the special simplified registration procedure laid down in Articles 14 and 15 of the EU Medicines Directive is compulsory for all Member States. On the other hand, the marketing authorisation procedure laid down in Article 16 is optional. This leads to the awkward situation that Member States are currently free to evaluate certain homeopathic medicinal products either in accordance with the regime for allopathic medicinal products, or in accordance with a regime that takes into account the specificities of homeopathic tradition.

As is the case with anthroposophic medicinal products, the first option factually bars certain homeopathic medicinal products from coming to the market. The main argument used for not applying option two is safety of users. There are however, less stringent possibilities under the EU Medicines Directive to protect the safety of the users. For example, Title VI of the EU Medicines Directive provides the option of making these products subject to a doctor's prescription. Such approach leads to more supervision of the user without effectively ruling out the use of such products.

Considering the above, it is questionable whether the 'safety argument' is proportional in relation to the fact that less stringent options exist. This is even more so since the number of users of these products is relatively low compared to users of allopathic medicinal products. One can therefore question whether this really constitutes a serious public health issue.

MRP and DcP do not work

Finally, a few words on the availability of the



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Mutual Recognition Procedure (MRP) and the Decentralized Procedure (DcP) for homeopathic medicinal products: these were introduced in 2004 with the amendment of the EU Medicines Directive by means of Directive 2004/27/EC. Problematic about these procedures is the lack of the possibility for arbitration that is available for allopathic medicinal products. The EU Medicines Directive remains silent on what should happen if Member States disagree on the safety of a homeopathic medicinal product. This effectively means that MRP and DcP do not lead to a harmonised approach in case medicines agencies disagree.

convictions on the desirability of these forms of medicine should be irrelevant. The needs of the stakeholders involved should be carefully considered in line with the basic principles of the European Union.

Johan Hulshof

Attorney at Law van Benthem ad Keulen

(Footnotes)

¹ Case C-84/06, *Antroposana and Others v The Netherlands* [2007] ECR I-07609

Such an outcome would be economically unsustainable for the applicants for a registration. In addition, it could damage the reputation of the reference Member State. Both applicants and medicines agencies are therefore reluctant to use MRP and DcP for the registration of homeopathic medicinal products. The low number of MRP and DcP registrations in the last six years supports this argument - it is possible to count the initiatives on one hand.

Conclusion

There is clearly a need to improve the harmonised approach EU-wide with respect to homeopathic medicinal products as many problems still exist. Furthermore, there is a need to adopt harmonised rules for anthroposophic medicinal products in Europe, as these are part of a long-standing tradition in European medicine.

The EU Institutions have a responsibility to safeguard safe access for patients to homeopathic and anthroposophic medicinal products, as well as economic sustainability for the European industry that produces medicinal products used in homeopathic and anthroposophic medicine. Personal



Agenda 2010

- ECHAMP Ad-Hoc Injectables Subject Group, Cologne 7 September
- ECHAMP Board of Management meeting, Brussels 22-23 September
- ECHAMP Pharmapolitical Affairs Working Party, Cologne 7 October
- 13th European Health Forum Gastein 2010 6-9 October
- ECHAMP Public Relations Working Party, Brussels 12 October