

The Registration and Authorisation of Homeopathic Medicinal Products in the EU and The Netherlands

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1. Introduction

There is a growing demand for complementary and alternative medicine (CAM) in the European Union.¹ The regular use of CAM in the European Member States varies from 20 up to 70 percent of the population.² The net turnover of homeopathic medicinal products in the EU grew from €590 million in 1995 to €775 million in 2001.³ In 1997, 29 percent of the EU citizens used homeopathic medicines.⁴ Although this percentage only reflects 1 to 2 percent of the yearly turnover in the European pharmaceutical industry, it covers 5 percent of the volume of medicine sales in France, Germany and The Netherlands.⁵

The regulation of CAM in the EU diverges considerably on a national level. On the one hand Member States like the United Kingdom and Germany are comparatively open⁶ to alternative medicine and its practitioners.⁷ For example, in Germany – Europe’s largest consumer of herbal medicinal products – St. John’s Wort is the most frequently prescribed antidepressant.⁸ In France and Belgium on the other hand one cannot legally practise as a homeopath if one is not a physician; only qualified physicians may legally prescribe homeopathic medicinal products.⁹ The differences in policy result, amongst others, in an impediment of the free trade in homeopathic medicinal products¹⁰ within the EU.¹¹ The established regime for conventional medicine was considered to be insufficient for the

¹ P. Fischer, *Medicine in Europe: Complementary medicine in Europe*, 309 BMJ 1994, p. 107; S. Maddalena, *The legal status of complementary medicines in Europe*, Stämpfli Ltd. Berne 1999, p. 1.

² W. Jonas, *Alternative Medicine and the Conventional Practitioner*, 279 JAMA 1998, p. 708.

³ European Coalition on Homeopathic and Anthroposophic Medicinal Products (ECHAMP), *Economic Facts & Figures, Homeopathic and Anthroposophic Medicinal Products in Europe*, Brussels 2003, p. 5.

⁴ Homeopathic Medicinal Products, Commission report on the application of Directives 92/73/EEC and 92/74/EEC regarding Homeopathic Pharmaceutical Products, COM(1997)362 final, p. 1.

⁵ Ibid. note 4

⁶ The United Kingdom and Germany both have longstanding traditions with respect to homeopathy. On top of that the regulatory systems in both countries can be qualified as ‘tolerant systems’.

⁷ N. De Bijl, *Legal safeguards against medical practice by not suitably qualified persons: A comparative study in seven EU-countries*, 4 European Journal of Health Law 1997, p.10; S. Maddalena, *The legal status of complementary medicines in Europe*, p. 8.

⁸ E. Brent, *European Community Sheds Light on Tomorrow’s U.S. Herbal Market*, 20 Drug Store News 1998, p. 161.

⁹ These regulatory systems are qualified as ‘monopolistic systems’, Supra note 7; This does however not necessarily mean that a country with a ‘monopolistic system’ does not have a strong homeopathic tradition. See for more information on this topic: *The Legal Situation with Regard to the Practice of Homeopathy in Europe, An ECCH Report (Revised Edition 2002)*, available at: <http://www.homeopathy-ecch.org/ECCH%20Legal%20Report%20Rev.%202002.pdf>, pp. 16-18.

¹⁰ Re-examined proposal for a Council Directive widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and establishing complementary provisions for homeopathic medicines, COM(1992)372 final, p. 3.

¹¹ The free movement of medical practitioners also remains a difficult issue for which harmonisation has not taken place yet. However, this matter falls outside the scope of this paper.

achievement of free movement of homeopathic medicinal products within the Internal Market.¹² Notwithstanding the efforts of the EU to harmonise the legislation on homeopathic products, free trade has not been achieved.¹³ This is mainly due to varying interpretations of the existing EU legislation which keeps the markets divided.

The policy on the licensing system in The Netherlands provides a clear illustration of how restrictive the implementation of the European legislation on the registration and authorisation of homeopathic medicinal products can be. With the introduction of the Dutch policy a high number¹⁴ of homeopathic medicinal products disappeared from the Dutch market.¹⁵ Some of these products had been on the market for decades. Notwithstanding the fact that no exact figures are known, the number of ‘medicinal tourists’ – people buying medicines in other EU-countries when not available in their own country – has also grown considerably,¹⁶ without being limited to The Netherlands.¹⁷

This thesis will discuss the registration and authorisation procedures for homeopathic medicinal products as introduced by Directive 92/73/EEC¹⁸ and incorporated in Directive 2001/83/EC.¹⁹ It will try to answer the question whether the free movement of homeopathic medicinal products will be attained in the near future, or whether the harmonisation effort laid down in Directive 2001/83/EC will largely remain no more than good intentions on paper.

Attention will be given to the development of the homeopathic legislation in the EU and the problems the registration and authorisation regime has provoked. In addition the current regime established in The Netherlands will be considered, since it embodies the most extensive implementation of the European legislation on homeopathic medicinal products.²⁰ Furthermore, the future regime will be assessed in the light of the amendments made in

¹² Supra note 10.

¹³ F. Stebner, *EU und homöopathische Arzneimittel: Noch weit vom einheitlichen Binnenmarkt entfernt*, Pharma Recht 2001, p. 154.

¹⁴ In February 2003, 80 percent of the products that marketed before the introduction of the registration regime had disappeared.

¹⁵ L. Straijer, *Voortgang verkrijgbaarheid van homeopathische geneesmiddelen*, 114(1) Homeopathie 2003, p. 15.

¹⁶ Written Question E-0647/03 by Jules Maaten (ELDR) to the Commission, OJ C 192E/213 [2003].

¹⁷ The Commission even started court proceedings against France for making the registration procedure for homeopathic medicinal products applicable to individuals who imported these products from another Member State for personal use: Action brought on 15 May 2003 by the Commission against France (Case C-212/03), OJ C 158/17 [2003].

¹⁸ Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to medicinal products and laying down additional provisions on homeopathic medicinal products, OJ L 297/8 [1992].

¹⁹ 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].

²⁰ The implementing legislation does not only cover products which were authorised or registered after 31 December 1993, but also products which were already marketed before this date.

Directives 2004/27/EC,²¹ 2004/24/EC,²² and the proposal of new Dutch legislation.²³ Finally, an overall conclusion will be provided.

²¹ 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, OJ L 136/34 [2004]. The Directive will come into force on the 30th October 2005.

²² 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, OJ L 136/85 [2004].

²³ Vaststelling van een nieuwe Geneesmiddelenwet, Kamerstuk 2003-2004, 29359, nrs. 1-2, Tweede Kamer.

2. The licensing of homeopathic medicinal products in the EU

2.1. Introduction (A legislative overview)

Harmonisation of the laws applicable to medicinal products started in the mid-1960s¹ with Directive 65/65/EEC.² Almost three decades later, the Council in cooperation with Parliament adopted Directive 92/73/EEC on homeopathic medicinal products on the basis of Article 100a EEC (now Article 95 EC),³ which came into force on the 31st of December 1993. The primary aim of the Directive was the completion of the internal market. However, the second recital indicates that the regulation of medicinal products essentially seeks to protect public health.⁴

Directive 92/73/EEC is based on the assumption that differences between national provisions in the different Member States are capable of hindering the trade in homeopathic medicinal products. Hence, the harmonisation of the rules regarding manufacture, control and inspection of homeopathic medicinal products is necessary to create a free circulation of qualitatively good and safe products.

The Directive essentially tried to attain these goals by introducing a ‘special simplified registration procedure’ for a number of homeopathic medicinal products, next to the (already existing) authorisation procedure for conventional medicinal products laid down in Directive 65/65/EEC.⁵

¹ H. Hanika, *Europäisches Arzneimittelrecht, Die pharmazeutische Industrie in Europa auf dem Weg zur Vollendung des Binnenmarktes für Arzneimittel*, MedR (2000), p. 63; P. Cassia, *L'autorisation de mise sur le marché des médicaments à usage humain dans l'Union européenne*, 403 *Revue du Marché commun et de l'Union européenne* 1996, p. 749; J. Abraham, *Regulating Medicines in Europe, Competition, expertise and public health*, Routledge London 2000, p. 83.

² Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, OJ L 22/369 [1965].

³ H. Hanika, *supra* note 1, pp. 66-67; *Medicine*, 90(2) *Law Society's Gazette* 1993, p. 46.

⁴ As Article 100a(3) EEC (now Article 95 EC) makes a clear reference to a high level of health and consumer protection, it does not invoke the apparent paradox regarding the division of competences which seemed to underlie the health and environmental legislation based on Article 100 EEC. See for more information on this topic:

E. Vos, *Institutional Frameworks of Community Health and Safety Regulation, Committees, Agencies and Private Bodies*, Hart Publishing Oxford 1999, p. 24. The choice for Article 100 EEC (now Article 95 EC) also complies with the case law of the Court of Justice which creates a considerable platform for health protection within the scope of Article 95 EC. See T. Hervey, *Community and National Competence in Health After Tobacco Advertising*, 38 *CML Rev* 2001, p. 1437; H. Cullen, *Diplomacy by other means: the use of legal basis litigation as a political strategy by the European Parliament and Member States*, 36 *CML Rev* 1999, p. 1255; R. Barents, *The Internal Market Unlimited: Some Observations on the Legal Basis of Community Legislation*, 30 *CML Rev* 1993, p. 101; Case C-491/01, *The Queen v. Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*. [2002] ECR I-11453, paragraph 60-63; and Case C-377/98, *Netherlands v. Parliament and Council* [2001] ECR I-7079, paragraph 27.

⁵ For more information on the differences between the ‘authorisation procedure’, and the ‘special simplified registration procedure’ see paragraphs 2.5 and 2.6.

The 5th recital of the preamble of Directive 92/73/EEC recognises that patients should be allowed access to the medicinal products of their choice, provided that the quality and safety of those products is maintained. In that context, a special simplified registration procedure is applicable to safe homeopathic medicinal products which are placed on the market without therapeutic indications.⁶ For other products the normal rules on the authorisation of medicinal products are applicable.⁷ However, Member States may create or keep in place special rules for evaluating tests and trials related to safety and efficacy, on the condition that these rules are notified to the Commission.⁸

For Parliament the initial proposal for Directive 92/73/EEC did not go far enough; it favoured a more proactive stance in the amendments it sent to the Commission.⁹ The 14th amendment intended to create an obligation for the Commission to integrate homeopathic medicinal products in the European Pharmacopoeia, and to harmonise the requirements for the practise of alternative medicine, the refund by social security, and the official teaching of alternative medicine within five years of the Directive coming into force.¹⁰ The Commission made it however clear in its re-examined proposal that it did not have the competence nor the will to introduce such a complete policy on alternative medicine as suggested by Parliament.¹¹

On the basis of Article 10(3) of Directive 92/73/EEC, the Commission had to present a report on the application of Directive 92/73/EEC before 31 December 1995. On the 14th of July 1997, more than 18 months after the deadline elapsed, the Commission published its Report.¹² Due to the late notification or non-implementation by a number of Member States,¹³ the Commission preferred to postpone the publication of the Report with the purpose of

⁶ According to the 10th recital of the preamble of Directive 92/73/EEC, ‘safe’ means that the pharmaceutical form and/or dosage do not present a risk for the patient.

⁷ Article 9(1) of Directive 92/73/EEC (now Article 16(1) of Directive 2001/83/EC).

⁸ Article 9(2) of Directive 92/73/EEC (now Article 16(2) of Directive 2001/83/EC). This was also emphasized by the Court of First Instance in Case T-463/93, *GUNA Srl v. Council* [1993] ECR II-1205, paragraph 16. See also subparagraph 2.6.2.

⁹ Homeopathic medicinal products Resolution on the Commission Report to the European Parliament and the Council on the application of Directives 92/73/EEC and 92/74/EEC on homeopathic medicinal products, 5 November 1998, OJ C 359/96 [1998].

¹⁰ See the Legislative Resolution (Cooperation procedure: first reading) embodying the opinion of the European Parliament on the Commission proposal for a Council Directive widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of the laws of the Member States on veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products, OJ C 183/322 [1991]. Although the title suggests that the resolution regards veterinary medicinal products, the resolution applies to medicinal products for human use

¹¹ *Supra* note 10, Chapter 1.

¹² *Supra* note 4, Chapter 1.

¹³ The Commission even started court proceedings on the basis of Article 226 EC (ex Article 169 EC) against Belgium (Case C-283/97, *Commission v. Belgium* [1998] ECR I-6081).

assessing the practical experiences of some of the ‘lingering’ Member States. According to the Commission, the Report was based on an in-dept study on the application of Directive 92/73/EEC carried out by independent experts on its behalf.¹⁴ The report does however not excel in transparency as it does not state who performed the study and what criteria have been used. The website of the IVAA (International Federation of Anthroposophical Medical Associations) lends a helpful hand by revealing that the study was conducted by Arbaret & Associés International,¹⁵ which had to give a ‘*description of the market of homeopathic medicinal products at national and European level*’.¹⁶ Strangely enough the Commission Report itself does hardly contain information on the features of the market of homeopathic medicinal products.

In the words of the Commission the Report shows “(...) *a certain degree of disparity in the application of the Directives in Member States and contradictions in the interpretation thereof*”.¹⁷ For this reason, it asked the Council and Parliament to give their opinions on the detected problems and the effect that possible amendments would have on the attainment of the objectives set by the Directives. On top of that, the Commission gave a number of suggestions on how it could amend the existing legislation.¹⁸

In its reaction to the Commission Report Parliament clearly ventilated its discontent with the delayed publication of the Report “*whatever reasons for this delay*”,¹⁹ and called upon the Commission to come with a proposal to amend Directive 92/73/EEC in conformity with the suggestion laid down in the Commission Report.²⁰ Furthermore, it asked the Commission to submit another report within three year after the amendments would come into force. Finally, European Parliament underlined the importance of the research done into

¹⁴ Commission report, supra note 4, Chapter 1, p. 2.

¹⁵ M. Sijmons, *Legal Opinion on Directives 92/73/EEC and 92/74/EEC and Anthroposophic Medicine*, IVAA-Homepage, Section 2.6; available at: <http://www.anthroposmed.com.ua/IVAA/legalopinion.htm#2.6%20Commission%20Report>.

¹⁶ Ibid. note 15.

¹⁷ Supra note 14.

¹⁸ The Commission suggested amongst others to increase the scope of the ‘special simplified registration procedure’, to lay down clear rules for mutual recognition, the possibility to include a fantasy name on the label, and to make Article 9(2) of Directive 92/73/EEC (now Article 16(2) of Directive 2001/83/EC) binding in combination with the demand to involve experts in homeopathic medicine in the creation of the “*specific rules for tests and clinical trials in Member States*”. Commission Report supra note 4, Chapter 1, p. 8.

¹⁹ Resolution on the Commission Report, supra note 9, OJ C 359/96 [1998]. It is also striking to see that Parliament does not seem convinced by the Commission’s reasons. See the Report on the Commission report to the European Parliament and the Council on the application of Directives 92/73/EEC and 92/74/EEC on homeopathic medicinal products, of 28 October 1998 (A4-0378/98). The Committee opinions attached to the report clearly condemn the delay essentially because most Member States had already implemented before the final date. Hence, the Commission could have established most of its findings without the data from the ‘lingering’ Member States.

²⁰ Resolution on the Commission Report, supra note 9, OJ C 359/94 [1998].

the effectiveness of homeopathy and the importance of the Commission reporting on it, as well as stimulating further research.²¹ Conversely, the Council remained silent; it is evident that homeopathy does not have a high priority in the Council.

Despite the findings of the Commission and the clear reaction of the European Parliament, it would take more than three years before new legislation was adopted. On the 28th of June 1999 the Commission presented its first initial proposal for the adoption of Directive 2001/83/EC.²² The proposal was amended after the publication of the opinion of the Economic and Social Committee.²³ Notwithstanding the fact that the Second Commission proposal was not much more than a unification of the existing pharmaceutical legislation in one Directive,²⁴ Parliament approved the proposal without modification in the first reading.²⁵ The changes in the provisions of Directive 92/73/EEC that were incorporated in Directive 2001/83/EC can therefore generally be described as merely cosmetic in nature.

The fact that Directive 2001/83/EC was not intended to introduce substantive changes to the existing legislation, does not fully justify the failure of the European legislator to use the introduction of the new Directive as a platform to provide a number of (intermediate) solutions to the problems identified by the Commission Report two years earlier. This is especially so since it would take an additional three years to enact new legislation in the form of Directive 2004/27/EC. It even takes one and a half year more before the Directive will come into force on 1 November 2005.

As the Commission stated in its report on the application of Directive 92/73/EEC, the introduction of a Directive that harmonises the registration regime of homeopathic medicinal products did not remove the disparities between the national regimes in the Member States.²⁶ Therefore, a single market for homeopathic medicinal products remains unattained and more effective harmonisation efforts are indispensable.

²¹ Resolution on the Commission Report, *supra* note 9, OJ C 359/97-98 [1998].

²² Proposal for a European Parliament and Council Directive on the Community code relating to medicinal products for human use (codified version), COM(1999)315 Final.

²³ Opinion of the Economic and Social Committee on the 'Proposal for a European Parliament and Council Directive on the Community code relating to medicinal products for human use (codified version)', OJ C 368/3 [1999].

²⁴ Amended proposal for a European Parliament and Council Directive on the Community code relating to medicinal products for human use (codified version), COM(2000)830 Final.

²⁵ 1. Medicinal products for human use (codified version) ***I (procedure without report), C5-0763/2000, OJ C 65E/33 [2001]. Fascinatingly the European Parliament which clearly demanded changes in its Resolution on homeopathic medicinal products, did not use its powers under Article 95 EC to propose amendments. Conversely, it approved of the Commission Proposal in the first reading without a single remark. This is even more striking since the power of Parliament has grown considerably compared to the procedure in which Directive 92/73/EEC came about, and parliament had already suggested a more proactive role of the EU in the harmonisation of alternative medicine.

²⁶ *Supra* note 14.

We will now take a closer look at the ‘weak spots’ in the EU legislation that have prevented the realisation of that single market for homeopathic medicinal products. To start with, the definition of homeopathic medicinal product will be analysed. Furthermore, the scope of directive 2001/83/EC will be examined. In addition, the problems related to the level of harmonisation provided by the Directive will be depicted. The difficulties regarding the ‘special simplified registration procedure’ and the ‘authorisation procedure’ will subsequently be scrutinised. And finally, some theoretical pitfalls created by the omission of certain parts of Directive 92/73/EEC in Directive 2001/83/EC will shortly be discussed.

2.2. The definition of homeopathic medicinal product

2.2.1. Ambiguity and Controversy

The first issue under discussion is the definition of homeopathic medicinal product as laid down in Article 1(5) of Directive 2001/83/EC. In general it can be stated that the definition lacks clarity. The ambiguity of the definition is however the product of a larger problem; namely the difficulty to universally describe homeopathic medicine.

At least one of the reasons for this difficulty lies with the absence of a mutual vocabulary among regular and alternative practitioners and researchers.²⁷ It may therefore be very well possible that the gap between the two camps has influenced the current problems with regard to the definition of *homeopathic medicinal product* in the Directive.

Medicinal products presented for self-care use such as *Arnica* or *Echinacea*, provide a good example as they are often qualified and registered as homeopathic medicinal products.²⁸ However, the pharmacological mechanism underlying these products is frequently not homeopathic but phytotherapeutic. Moreover, their use in practice quite regularly fits into the theory of herbal medicine, instead of homeopathy. Hence, these products actually qualify as herbal medicinal products.²⁹

On the basis of the foregoing, and before embarking on the definition of homeopathic medicinal product, this paragraph will give some basic information on the concept of homeopathy. It does not intend to take part in the discussion on its exact definition though.

²⁷ O. Caspi *et al*, *The Tower of Babel: Communication and Medicine*, 160 ARCH INTERN MED 2000, p. 3194.

²⁸ Both products are registered in The Netherlands as homeopathic medicinal products (VSM Arniflor tinctuur: <http://www.cbg-meb.nl/IB-teksten/80033.pdf>; A. Vogel Echinaforce: <http://www.cbg-meb.nl/IB-teksten/85357.pdf>).

²⁹ Much will however depend on the presentation of the product in order to assess its nature. This specific problem will be further analysed in subparagraph 4.3.1.

2.2.2. What is homeopathy?

Homeopathy was introduced by Samuel Christian Friedrich Hahneman (1755-1843) in 1790.³⁰ The word homeopathy is derived from the words *homoios pathos*, which means 'similar suffering' in Old Greek. In essence, Homeopathy is an individualised³¹ form of medicine aimed at stimulating the self restoring ability of the human body on the basis of the law of similars.³² Its remedies consist of potentised³³ substances or principles which are produced in accordance with a Homeopathic Pharmacopoeia.³⁴ Homeopathy mainly differs

³⁰ C. Hammond, *Homeopathy, An Illustrated Encyclopedia of Safe and Effective Remedies*, Element Books Limited Shaftesbury 1995, p. 17; A. Weil, *Health and Healing* (Houghton Mifflin Company, New York, 1998), p.12-25; and D. Ullman, A Modern understanding of Homeopathic Medicine, *Discovery of Homeopathy: Medicine for the 21st Century*, North Atlantic Books 1991, also available at: http://www.homeopathic.com/articles/intro/modern_understanding.php.

³¹ Homeopathy uses a holistic approach. It considers every person individually because every human being has a unique set of physical, mental and emotional characteristics. These features are important for finding the means that can cure the disease or a malfunctioning of the body. A disease is capable of influencing the body in a way that is not directly connected with the main symptoms shown by the patient. A homeopath will not look at each complaint of a person in isolation, but tries to capture every single complaint within one model. Consequently, he will not only ask questions about the particular symptoms of the disease for which the patient seeks treatment – his diagnosis will also involve other (smaller) issues regarding physical, mental and emotional characteristics and complaints of a person. With this information the Homeopath can get a better understanding of the person's condition and his or her sensitivities. The information will lead to the choice of one and sometimes more than one substance that will be administered in order to stimulate the body in restoring its balance.

³² According to Hippocrates (460 BC) empirical research had shown that: "Through the like, disease is produced, and through the application of the like it is cured." that people could be cured from a disease by using a substance that would create symptoms comparable in a healthy person to those of the disease suffered. This is referred to as the 'Law of Similars', or as Hahnemann put it: "Similia similibus curentur"(Let Likes be cured by likes).

³³ Potentisation is a pharmaceutical process, which entails a serial dilution of the active principle or substance. Depending on the dilution technique, one part of the substance will be mixed with a specified number of parts of distilled water, ethyl alcohol or milk sugar. In case of a D (= decimal) solution 9 parts of water are mixed with 1 part of the active principle. The solution will contain 1/10 of the active principle, traditionally referred to as D1. This process can be repeated with the D1 solution creating a D2 (1/100), a D3 (1/1000), and so on. Alternative to a D solution, dilutions characterised with the capital C (= centesimal) contain 99 parts of water, alcohol. The centesimal dilution can alternatively be indicated with the Capital K. The K stands for Korsakow; named after the person who invented this specific form of serial dilution. The difference between C and K lies in the use of new or clean(ed) shakers for every time one makes another dilution (C), or the use of the same shaker during the dilution process without cleaning it (K). The potentisation issue lies at the heart of the controversy about homeopathic medicine. Opponents of homeopathy use the high dilutions as their main argument to rule out the effect homeopathic treatment. It is impossible for science as it stands at the moment to clearly indicate that there is anything left of the active principle in the solution – molecularly speaking that is. On the basis of Avogadro's law molecules will theoretically not be physically left after a dilution of more than 6.02×10^{23} times. More in concrete, every dilution that goes beyond a D24 or a C12 does not contain any active principle in theory. In contrast, proponents base the assumption that homeopathy works on the basis of their own experience and empirical evidence, rather than the static Law of Avogadro which concentrates on molecules only. In this context there is evidence available which claims that molecular existence is not a prerequisite for influencing living creatures or water. See for example: C. Zausner *et al*, *Die Wirkung van homöopathisch zubereitetem Thyroxin auf die Metamorphose von Hochlandamphibien – Ergebnisse einer multizentrischen Kontrollstudie*, 15 *Perfusion* (2002), pp. 268-276; P. Endler *et al*, *The Effect of Highly Diluted Agitated Thyroxine on the Climbing Activity of Frogs*, 36 *Vet Human Toxicol* (1994), pp. 56-59; Louis Rey, *Thermoluminescence of ultra-high dilutions of lithium chloride and sodium chloride*, 323 *Physica A* (2003), pp. 67-74.

³⁴ However, not every product produced in conformity with the homeopathic pharmacopoeia can be qualified as a homeopathic medicinal product. In theory a limited number of mother tinctures can also be qualified as

from conventional medicine, because it does not work symptom repressive and it avails itself of potentised remedies.

There are furthermore two main movements in homeopathy: classical homeopathic medicine and clinical homeopathic medicine. Although the medicinal products utilised are mostly the same for both forms of homeopathy, the manner in which they are used diverges considerably. Clinical homeopathic medicine mainly differs from the classical definition because it works symptom responsive³⁵ and it normally employs lower dilutions than classical homeopathy does.³⁶ Clinical homeopathic remedies are also often used as first aid remedies.³⁷ We will now turn to the definition of homeopathic medicinal product.

2.2.3. The definition of homeopathic medicinal product

Contrary to many state laws in the United States, European legislation does not contain a legal definition on homeopathy.³⁸ As homeopathic medicinal products form the only part of homeopathy that has been regulated on a European level, the Commission has not felt the need to introduce such a definition. Consequently, Directive 2001/83/EC only contains a definition of *homeopathic medicinal product*.

Article 1(5) of Directive 2001/83/EC, which lays down the definition of ‘Homeopathic Medicinal Product’ reads:

‘Homeopathic medicinal product’: Any medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States.

A homeopathic medicinal product may also contain a number of principles.

homeopathic medicinal product; in practice however, these products are rarely used in classical homeopathy. This will be further assessed in subparagraph 2.3.3.

³⁵ This means that it applies a less individualised, or holistic approach. Homeopathic medicinal products with therapeutic indications can therefore only be intended for clinical use, as individualisation has not taken place.

³⁶ See for more information P. van der Veen *et al*, *Het groot homeopathisch gezondheidsboek*, Homeovisie BV Alkmaar 1994, pp. 386-388.

³⁷ C. Hammond, *supra* note 30, p. 240.

³⁸ The State of Washington for example defines homeopathy as: “a system of medicine based on the use of infinitesimal doses of medicines capable of producing symptoms similar to those of the disease treated, as listed in the homeopathic pharmacopeia of the United States”. The laws of Nevada and Arizona on the other hand describe the homeopathic principle as: “a substance which produces symptoms in a healthy person can eliminate those symptoms in an ill person”; See M. Cohen, *Complementary & Alternative Medicine, Legal Boundaries and Regulatory Perspectives*, The Johns Hopkins University Press Baltimore 1998, pp. 42-43.

Considering this definition, Article 1 contains three requirements. Firstly, the product at stake needs to be a medicinal product.³⁹ Secondly, it must be prepared from products, substances, or compositions which qualify as a ‘homeopathic stock’. And thirdly, the preparation must be in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia, or in absence thereof one of the pharmacopoeias used in the Member States. In addition, paragraph 2 explicitly includes homeopathic medicines which are based on more than one active principle.⁴⁰ Even though the definition appears to be neutral, it only partially indicates its exact material scope.⁴¹

The main difficulty lies with the second element, since no clarity on the exact meaning of ‘products’,⁴² ‘compositions’,⁴³ and ‘homeopathic stock’ is provided.⁴⁴ The Commission did, however, give some supplementary guidance on the concept of ‘homeopathic stock’ in its answers to questions that were submitted on this topic by the Belgian Inspectorate General of Pharmacy.⁴⁵ The Commission stated that as long as a product, composition, or substance forms the origin of a homeopathic medicinal product and cannot by itself be qualified as a medicinal product, it must be classified as a homeopathic stock.⁴⁶ Thus, if an ingredient for a homeopathic medicinal product does not fall within the definition of homeopathic medicinal product, it is a homeopathic stock.

³⁹ According to Article 1(2) of Directive 2001/83/EC medicinal product means: *Any substance or combination of substances presented for treating or preventing disease in human beings or animals; and/or any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.* In Case C-227/82, *Criminal proceedings against Leendert van Bennekom*, [1983] ECR 3883, paragraph 16, the ECJ has pointed out that the definition of medicinal product is a Community-based definition. See for more information M. Valette, *Le juge communautaire et l’harmonisation des législations nationales relatives aux médicaments à usage humain*, 32(1) *Revue Trimestrielle de Droit Européen* 1996, pp. 28-31.

⁴⁰ These medicines are often referred to as complex-remedies in homeopathic literature. See P. van der Veen *et al*, *Het groot homeopathisch gezondheidsboek*, p. 387.

⁴¹ According to the Commission however, the member states have accepted an identical interpretation of the definition of homeopathic medicinal product. The Commission therefore concludes that there is no need for Community action in this respect. This conclusion is nonetheless not completely accurate and will be further assessed under the Dutch registration regime.

⁴² According to Black’s Law Dictionary (7th Edition), product means: “*Something that is distributed commercially for use or consumption and that is usually (1) tangible personal property, (2) the result of fabrication or processing, and (3) an item that has passed through a chain of commercial distribution before ultimate use or consumption*”. Yet no definition has been given by the European Legislator.

⁴³ The Cambridge Advanced Learner’s Dictionary defines ‘composition’ as “*the parts, substances, etc. that something is made of*”. Literally interpreted this would mean that ‘compositions’, within the meaning of Article 1, are Homeopathic Stocks consisting of more than one substance. However, the European Legislator remains silent on this point as well.

⁴⁴ The definition of ‘Substance’ is laid down in Article 1(3) of Directive 2001/83/EC as “any matter irrespective of origin which may be: human(...), animal(...), vegetable(...), or chemical(...)”. It does not pose additional problems.

⁴⁵ *Interprétation des Directives 92/73/CE et 92/74/CE*, IP/MA 502/3/2001.

⁴⁶ *Interprétation des Directives 92/73/CE et 92/74/CE*, supra note 45, p. 1.

In practice this negative formulation of homeopathic stock can provoke additional questions in some occasions. Especially on the dividing-line between ingredient and medicinal product the ‘presentation requirement’ and the concept of ‘sufficiently similar to a medicinal product’, introduced by the Court of Justice in *Delattre*,⁴⁷ will be decisive.⁴⁸

Additionally, as mentioned above, the definition homeopathic medicinal product in general may have a certain overlap with the definition of traditional herbal medicinal product when Directive 2004/24/EC on traditional herbal medicines comes into force on the 1st of November 2005.⁴⁹ This issue will be assessed in more detail in paragraph 4.4.

2.3. The scope of Directive 2001/83/EC

2.3.1 Authorisation & Registration

As mentioned in paragraph 2.1., there are two procedures for the licensing of medicinal products. The applications under both procedures are controlled by one or more national agencies depending on the structure chosen by the Member State.⁵⁰ The first procedure, the authorisation procedure for medicinal products, applies in principle to all products that can be qualified as medicinal products. The second procedure, the ‘special simplified registration procedure’, only applies to certain homeopathic medicinal products and is an exception to the abovementioned rule.

The difference between the ‘special simplified registration procedure’ and the authorisation procedure mainly lies with the imposition of different requirements for licensing. The most important feature of the ‘special simplified registration procedure’ in this context is its ability to take account of the special features of homeopathic medicine. Without this special procedure the licensing of a high number of homeopathic medicines would be impossible, since the authorisation procedure has been designed for allopathic medicinal products which do not commonly share the same features as homeopathic medicinal products.⁵¹

Notwithstanding the general obligation in Directive 2001/83/EC to obtain an authorisation or registration for homeopathic medicinal products, the scope of the Directive is both limited formally and materially. In effect these limitations partially undermine the

⁴⁷ Case C-369/88, *Criminal proceedings against Jean-Marie Delattre* [1991] ECR I-01487, paragraph 41.

⁴⁸ See M. Valette, *supra* note 39, p. 30; and subparagraph 3.6.2.

⁴⁹ Article 2(1) of Directive 2004/24/EC.

⁵⁰ See for more information on the Dutch system subparagraph 3.6.1.

⁵¹ The two different procedures will be discussed in more detail in paragraphs 2.5. and 2.6.

harmonising efforts laid down in the Directive. Moreover, as the scope is not always clearly defined, differentiation grows even further. The next two subparagraphs will discuss these issues in more detail starting with the formal scope and subsequently the material scope.

2.3.2. The formal scope

The general obligation to register or authorise homeopathic medicinal products as described in the former subparagraph, is provided for in Article 13 of Directive 2001/83/EC.⁵² Products holding a national authorisation or registration before or on 31 December 1993 are however exempted from the obligation to register; this includes the renewal of such an authorisation or registration.⁵³ The scope of Directive 2001/83/EC is thus limited to products registered or authorised after 1993.

Unfortunately, it is unclear what the terms ‘registration’ and ‘authorisation’ exactly intend to express. Do they refer to authorisations and registrations within the definitions and procedures of Directive 65/65/EEC, or are these terms used in a broader sense to refer to any type of national procedure that qualifies as a form of registration or authorisation? Considering the fact that the European registration or authorisation procedure for homeopathic medicinal products and the term registration did not exist before the introduction of Directive 92/73/EEC, it can be reasonably assumed that the terms refer to national procedures regarding registration or authorisation of homeopathic medicinal products. This is also the interpretation used by most Member States.

In practice the limitation in time has given Member States, which had already registered or authorised homeopathic medicinal products, the opportunity to maintain their standards for those products. Member States which did not register or authorise these products before 1994 had and have to apply the same standard to every product instead.

Moreover, since a large number of homeopathic medicinal products already obtained some kind of marketing authorisation before 1994, the differentiation of national rules with regard to the regulation of homeopathic medicinal products remains unchanged. Of course new products have to be registered in accordance with the Directive, but this is a comparatively small part of the homeopathic medicines available.

⁵² The second paragraph of Article 13 does nonetheless provide for a theoretical opportunity for Member States to refrain from implementing the ‘special simplified procedure’ regulated in Articles 14 and 15. If a Member State chooses not to implement, it has to inform the Commission thereof, and allow the use of homeopathic medicinal products registered or authorised under the ‘special simplified procedure’ in other Member States in its own territory. None of the Member States has made use of this possibility though.

⁵³ Article 13(1) of Directive 2001/83/EC.

As a result of this differentiation between Member States like Germany on the one hand, which has registered and authorised homeopathic medicines since 1976,⁵⁴ or Italy⁵⁵ on the other hand which did not have such special system of authorisation and registration for homeopathic medicinal products, harmonisation of technical standards and administrative or procedural provisions among these Member States has proven to be problematic.⁵⁶ This becomes even more evident with the possibility to renew the original registrations or authorisations.⁵⁷

Considering the foregoing we can conclude that differentiation is created by Article 13(1) by exempting from the scope of the Directive those products which have been registered or authorised before 1994. As these products form a large part of the homeopathic medicinal products on the market, the harmonising effect of Directive 2001/83/EC in respect of the licensing of homeopathic medicinal products is limited.⁵⁸

2.3.3 The material scope

In principle Directive 2001/83/EC applies to all medicinal products. The material scope of Directive 2001/83/EC is however limited by Articles 2 and 3. Although these two Articles are clearly phrased, Article 3 has provoked problems with respect to the need to register or authorise *magistral*⁵⁹ and *officinal*⁶⁰ formulas, and intermediate products.

In Article 3 *magistral* and *officinal* formulas are excluded from the scope of the Directive. Consequently, they do not have to be registered or authorised.⁶¹ The same applies

⁵⁴ K. Keller, *Homeopathic medicinal products in Germany and Europe: Legal requirements for registration and market authorization*, 32 Drug Information Journal 1998, p. 806.

⁵⁵ See: http://www.echamp.org/questions/italy_print.html; See also F. Menniti-Ippolito *et al*, *Use of unconventional medicine in Italy: a nation-wide survey*, 58 Eur J ClinPharmacol 2002, pp. 61-64. Notwithstanding the fact that no previous registration has taken place, homeopathic medicinal products can stay on the Italian market until 2008 without registration on the condition that a fee is paid. As this policy seems to contravene the wording of the Directive, it may well be in breach of community law.

⁵⁶ At this moment all three Member States still apply highly differing regimes.

⁵⁷ Supra note 52.

⁵⁸ For more information on the concept of harmonisation see: M. Dougan, *Minimum harmonization and the Internal Market*, 37 CLM Rev. 2000, pp. 853-856. K. Mortelmans, *The Relationship Between the Treaty Rules and Community Measures for the Establishment and Functioning of the Internal Market -- Towards a Concordance Rule*, 39 CLM Rev. 2002, pp. 1327-1332.

⁵⁹ Article 3(1) of Directive 2001/83/EC: “*Magistral formula: Any medicinal product prepared in a pharmacy in accordance with a prescription for an individual patient*”.

⁶⁰ Article 3(2) of Directive 2001/83/EC: “*Officinal formula: Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question*”.

⁶¹ Although it may be true that the exemption from the requirement for authorisation or registration may lower the amount of control on the safety and quality of these medicinal products, it is felt that beneficial features of the possibility to provide tailor-made medicines outweigh the risks that are created. Moreover, the number of products produced is low and may they only be prepared by licensed pharmacists. Hence *magistral* and *officinal* preparations do not form a real risk for the public health.

to intermediate products⁶² intended for further processing by an authorized manufacturer.⁶³ The value of the *magistral* or *officinal* preparations lies in the creation of a possibility to produce certain medicinal products which are not economically viable to market on a small scale.⁶⁴ Such preparations are normally made from homeopathic stocks or intermediate products. Without this opportunity the number of medicinal products available will be considerably lower. This argument holds even more stake with respect to homeopathic medicinal products which can be characterised by a high batch differentiation.⁶⁵

Unfortunately, Directive 2001/83/EC does not state what constitutes an ‘intermediate product’. The Glossary of the Guidelines on Good Manufacturing Practices 1998 as published by the Commission, defines an ‘intermediate product’ as a “*partly processed material which must undergo further manufacturing steps before it becomes a bulk product*”.⁶⁶ However, a clear distinction between ingredients and ‘intermediate products’ can be hard to make. For example in The Netherlands the status of the mother tincture⁶⁷ differs from other Member States as it is not considered to be a homeopathic stock, but an intermediate product that needs registration in case it is used for *magistral* and *officinal* preparations.⁶⁸

In addition, it is not clear what is exactly meant with an authorised manufacturer. According to Article 2(3) of Directive 2003/94/EC⁶⁹ on Good Manufacturing Practices, pharmacists cannot be considered authorised manufacturers when performing a *magistral* or

⁶² Article 3(4) of Directive 2001/83/EC.

⁶³ The end products produced with the intermediate products need to be registered if they are sold as medicinal products. In effect, the level of control does thus stay the same.

⁶⁴ T. Nicolai, *Noodzaak van de verplichte registratie en de voordelen daarvan*, VHAN congress of 7 February 2003; available at: <http://www.vhan.nl/congres4.htm>.

⁶⁵ ECHAMP, *Injectables for Subcutaneous Administration as used in Homeopathic and Anthroposophic Medicine*, Position Paper 2003/02, p. 15; available at: http://www.echamp.org/upload/Press/group_3/3_Injectables_for_Subcutaneous_Adm._in_Hom._and_Anthr._M_edicine.pdf.

⁶⁶ Guidelines of Good Manufacturing Practices, p. 140, Available at: <http://pharmacos.eudra.org/F2/eudralex/download/volpdf/vol4/vol4en.pdf>.

⁶⁷ The substances used in a homeopathic dilution first need to be processed to make them ‘workable’ ingredients for a dilution. It would be very difficult to dilute for example a piece of raw plant material in water in comparison to salt. In order to solve this problem the raw material has to be changed to a form that can be processed easily. Therefore, a ‘mother tincture’ is derived from most raw ingredients or materials. A Mother Tincture is a concentrated form of the active substance on a strong alcohol base – Normally 65 to 85 volume percent alcohol. Mother tinctures are indicated by the Ø-sign. *Echinacea Purpurea Radix Ø*, for example, means the mother tincture prepared from the root of the Echinacea plant. Not only does a Mother Tincture ease the dilution process, it also makes the active principle easier to preserve. The alcohol in the tincture makes the substance last longer and it guards against external influences, as bacterial infections. See for more information: C. Hammond, *Homeopathy*, supra note 30, pp. 30-33.

⁶⁸ The controversy on the difference between ingredients and intermediate products will be further discussed under subparagraphs 2.3.3. and 3.6.2.

⁶⁹ Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, OJ L 262 /22 [2003].

officinal preparation,⁷⁰ since they are exempted from the authorisation requirement on the basis of Article 40(2) of Directive 2001/83/EC.⁷¹ It is however unclear, whether this definition is general in nature, or if it applies only to Directive 2003/94/EC.

Moreover, Article 3(4) of Directive 2001/83/EC states that only intermediate products for further processing by authorised manufacturers are excluded from its scope. The problem that results from the foregoing is that the status of intermediate products which are delivered to pharmacists, and thus for *magistral* and *officinal* preparations, is unclear, as they are left untouched by the Directive. At the same time, these intermediate products do not qualify as (homeopathic) medicinal products and do therefore not need to be registered or authorised in accordance with Directive 2001/83/EC.

This view is shared by a Study of the AESGP⁷² on herbal medicinal products carried out on behalf of the European Commission.⁷³ The Study states that: “*Intermediate products of herbal origin intended for further processing by an authorised manufacturer or for the preparation of a magisterial or officinal formula do not fall under the definition of a medicinal product according to Council Directive 65/65/EEC [now Directive 2001/83/EC] and are therefore not subject to marketing authorisation as such*”.⁷⁴ Although this study does not directly refer to homeopathic medicinal products, it states the general view related to the status of intermediate products in relation to *magistral* and *officinal* formulas. Hence, since no alternative approach for homeopathic medicines is mentioned by the applicable Directive,⁷⁵ it seems valid to assume that the same reasoning applies to these products.

In sum, the manner in which *magistral* and *officinal* preparations, and intermediate products are exempted from the scope of Directive 2001/83/EC has led to uncertainty with respect to the meaning of intermediate product and authorised manufacturer. Moreover, if the definition of authorised manufacturer in Directive 2003/94/EC is also applicable to Directive 2001/83/EC, the former Directive remains silent on the exact status of intermediate products delivered for further processing to pharmacists.

⁷⁰ Article 2(3) reads: “*manufacturer*” means any person engaged in activities for which the authorisation referred to in Article 40(1) and (3) of Directive 2001/83/EC or the authorisation referred to in Article 13(1) of Directive 2001/20/EC is required.

⁷¹ The second paragraph of Article 40(2) of Directive 2001/83/EC reads: (...) [An authorisation under Article 40(1)] shall not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorized in the Member States to carry out such processes.

⁷² Association Européenne des Spécialités Pharmaceutiques Grand Public (The Association of the European Self-Medication Industry).

⁷³ AESGP, *Herbal medicinal products in the European Union*, 2 Pharmaceuticals Policy and Law 1999, pp. 55-199.

⁷⁴ AESGP, *supra* note 72, p. 127.

2.4. The level of Harmonisation?

A third issue that has provoked problems is the level of harmonisation provided by Directive 2001/83/EC. As in some occasions Member States have imposed higher requirements than the Directive does, it has to be assessed whether this is allowed under the Directive. This will be done in two steps.

The first step in the assessment focuses on the qualification of the form of regulation. A clear distinction in this regard is made by McGee and Weatherill. They distinguish between 'exhaustive regulation' and 'partial regulation'. The first category refers to forms of regulation where no competences are left for the Member States to regulate. The second category does not regulate a full area of law but only certain issues. Except for the issues regulated on a Community level, Member States remain free to adopt their own Legislation.⁷⁶

In terms of harmonisation, 'exhaustive regulation' refers to what is described as full harmonisation. If full harmonisation has taken place, the standard set by the Directive may neither be exceeded by more stringent or higher requirements, nor may it be replaced by alternative standards, since it must be considered a form of exhaustive regulation.⁷⁷ Partial and minimum harmonisation measures both constitute 'partial regulation' as they are not exhaustive in nature. Partial harmonisation on the one hand does not cover a complete area of law. The issues not harmonised on a Community level, therefore remain in the hands of the Member States. Minimum harmonisation on the other hand, can theoretically but not necessarily cover a complete area of law. The distinctive aspect of this type of harmonisation is that only sets minimum standards.⁷⁸ Member States can therefore still adopt more stringent measures in case of minimum harmonisation.

Thus, the question whether there is full harmonisation is of importance, since only if the Directive embodies minimum or partial harmonisation, Member States can impose national measures which go beyond the standards imposed by the Directive, or fill in the gaps

⁷⁵ Articles 2 and 3 of Directive 2001/83/EC do not contain a special regime for homeopathic medicinal products.

⁷⁶ A. McGee and S. Weatherill, *The evolution of the Single Market – Harmonisation or Liberalisation*, 53 *Modern Law Review* 1990, p. 582.

⁷⁷ P. Craig and G. De Búrca, *EU law - Text, cases and materials*, Oxford University Press, Oxford 2003, pp. 1194-1195; see also Case C-322/01, *Deutscher Apothekerverband eV v. 0800 DocMorris NV*, 11 December 2003, not yet reported, paragraph 64; Case C-37/92, *Criminal proceedings against José Vanacker and André Lesage and SA Baudoux combustibles* [1993] ECR I-4947, paragraph 9; and Case C-324/99, *DaimlerChrysler AG v. Land Baden-Württemberg* [2001] ECR I-9897, paragraph 32.

⁷⁸ P. Rott, *Minimum harmonization for the completion of the Internal Market? The example of consumer sales law*, 40 *CLM Rev.* 2003, p. 1110.

it has left open. If a Member State chooses to do so, however, the adopted measures must be in conformity with the EC-Treaty.⁷⁹

Hence, if the Directive in this case constitutes partial or minimum harmonisation, the second step in the assessment has to make sure that the national measures which impose additional or alternative requirements comply with the Treaty, and more specifically Articles 28 EC and 30 EC, or any mandatory requirement with respect to the free movement of goods.⁸⁰ In other words, the national measures installed on top of, or in addition to the harmonising measure may not hamper the free movement of homeopathic medicinal products, unless such obstruction can be justified.

The justification of possible limitations on the free movement of homeopathic medicinal products created by these higher standards will be to a high extent dependent on its conformity with the principle of proportionality, as can be derived from the cases *Schumacher*⁸¹ and *DocMorris*.⁸² In essence the protection of public health or the health of consumers must be a legitimate aim, the measures must be proportionate to the desired objective, and the measures must be the least restrictive ones available.⁸³

In the present case, Directive 2001/83/EC remains silent on the level of harmonisation. The Court of Justice has however held in *DocMorris* that harmonisation of the laws on medicinal products in general cannot be regarded as full harmonisation yet.⁸⁴ However, this does not mean that Member States can simply add extra, or more stringent requirements to every single provision in the Directive. Since the provisions at stake differ largely in respect of formulation and the manner in which they impose obligations, it has to be measured in a case by case approach whether Member States have competences to adopt more stringent measures or add additional rules. For the sake of length, only two distinctive examples will be discussed instead of every provision in the Directive applicable to homeopathic medicinal products.

⁷⁹ P. Craig and G. De Búrca, *supra* note 77, p. 1197.

⁸⁰ Case C-322/01, *DocMorris*, *supra* note 77, paragraph 102; see also P. Craig and G. De Búrca, *supra* note 77, pp. 635-636, and pp. 667-668; and K. Mortelmans, 39 CLM Rev. 2002, pp. 1327-1332; Report from the Commission to the Council, The European Parliament and the Economic and Social Committee, *Second biennial Report on the Application of the Principle of Mutual Recognition in the Single Market*, p. 6, available at: http://europa.eu.int/eur-lex/en/com/rpt/2002/com2002_0419en01.pdf.

⁸¹ Case C-216/87, *Heinz Schumacher v. Hauptzollamt Frankfurt am Main-Ost* [1989] ECR 617, paragraphs 17 and 18.

⁸² Case C-322/01, *DocMorris NV*, *supra* note 77, paragraph 104.

⁸³ See also P. Craig and G. De Búrca, *supra* note 77, pp. 631-634, and pp. 661-666; J. Ueda, *Is the Principle of Proportionality the European Approach?: A Review and Analysis of Trade and Environment Cases before the European Court of Justice*, 14(2) *European Business Law Review* 2003, pp. 561-563.

⁸⁴ Case C-322/01, *DocMorris NV*, *supra* note 77, paragraph 102.

The first example involves the general formulation of Article 16(2).⁸⁵ The optional character of this Article clearly allows Member States to set different standards. This can thus not be regarded as full harmonisation.⁸⁶ Consequently, if a Member State opts into the scheme of Article 16(2), it must also make sure the measures it installs do not impede the free movement of homeopathic medicinal products, except in case this can be justified. This issue will be further elaborated on in subparagraph 3.4.4.

The second example seems to demonstrate the opposite of the first one, since the number of documents required by the French legislation for the ‘special simplified registration procedure’ does not seem allowed under Article 15 – it does not leave discretion for the Member States to demand additional documentation for an application.⁸⁷ Despite the fact that France does require extra documents and the Commission showed its awareness of this in its Report,⁸⁸ it did not start a procedure against France. Probably, it does not consider homeopathic medicinal products a priority. Conversely, Parliament did ask the Commission for a stricter wording of the Directive regarding the content of an application for registration to avoid these diverging implementations.⁸⁹

In conclusion, differentiation between the laws of the Member States can reappear after harmonisation by Directive 2001/83/EC, since it is not always clear whether the imposition of more stringent requirements by Member States is allowed. Moreover, the Commission shows reservation to react to these issues with regard to homeopathic medicinal products which are probably not prioritised.

2.5. The ‘special simplified registration procedure’

2.5.1. Registration & Authorisation continued

As subparagraph 2.4.1. points out, there exist two procedures for the licensing of homeopathic medicinal products. One procedure, the ‘special simplified registration procedure’ is specially designed for the licensing of homeopathic medicines. The other procedure, the authorisation

⁸⁵ See subparagraph 2.6.2.

⁸⁶ M. Dougan, *supra* note 58, p. 854.

⁸⁷ Article 15 of Directive 2001/83/EC prescribes in clear language which documents are needed for applications under the ‘special simplified registration procedure’. France nonetheless, prescribes more documents to be submitted for than the one’s mentioned in Article 15. As a consequence, the ‘special simplified registration procedure’ in France has become more similar to the authorisation procedure. It hardly needs any explanation that such an implementation does not lower the barriers to trade for homeopathic medicinal products between France and the rest of the EU.

⁸⁸ Commission report, *supra* note 4, Chapter 1, p. 6.

⁸⁹ Resolution on the Commission Report, *supra* note 9, OJ C 359/96-97 [1998].

procedure, mainly designed for allopathic medicines, only deals with those homeopathic medicinal products which are not eligible for the ‘special simplified registration procedure’. Because the ‘special simplified registration procedure’ lies at the heart of the licensing of homeopathic medicinal products, the procedure as such and the problems that have been encountered will be discussed first. Paragraph 2.6 will subsequently examine the authorisation procedure in more detail.

2.5.2. The ‘special simplified registration procedure’

The Articles 14 and 15 of Directive 2001/83/EC are the key Articles for the registration of homeopathic medicinal products. Article 14 specifies three conditions that must be satisfied in order to be able to register a product under the ‘special simplified procedure’. The requirements are as follows: the product may only be used orally or externally; the product or any information relating to the product may not contain a therapeutic indication; and the product must be ‘guaranteed safe’.⁹⁰

The procedure is referred to as ‘simplified’ because it lays down fewer requirements for the admission of homeopathic medicinal products than the regular procedure. Consequently, it takes account of the specific characteristics of homeopathic medicine and the difficulty to apply the usual toxicological and pharmacological tests, and clinical trials to homeopathic medicinal products, which is essential for the non-discrimination against the principles and characteristics of homeopathy.⁹¹ In exchange, the products may not bear references of therapeutic efficacy on their labels or accompanying information.⁹² Since the procedure deviates from the ‘regular’ authorisation procedure, it can furthermore be qualified as ‘special’.

Article 15 provides the actual requirements for the ‘special simplified registration procedure’. The main concern of the Article is to ensure pharmaceutical quality and a ‘batch-to-batch’ homogeneity.⁹³ For that reason, it makes the registration conditional upon the submission of a number of documents which constitute the evidence that the abovementioned requirements are met.⁹⁴ The application for a special simplified registration must be submitted

⁹⁰ According to the 21st recital of the preamble of Directive 2001/83/EC, ‘safe’ means that the pharmaceutical form and/or dosage do not present a risk for the patient.

⁹¹ K. Keller, *supra* note 54, p. 803.

⁹² See the 21st recital of the preamble of Directive 2001/83/EC.

⁹³ Article 15 paragraph 1 of Directive 2001/83/EC.

⁹⁴ Article 15 requires the submission of the following documents:

- *scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered,*

by the person responsible for placing the product on the market, and may regard a series of medicinal products which are obtained from the same homeopathic stock or stocks.

Notwithstanding the good intentions expressed by Articles 14 and 15 of Directive 2001/83/EC, the ‘special simplified registration procedure’ suffers from a number of practical drawbacks. Consequently, as the Commission itself concludes, the harmonisation of the requirements for a ‘special simplified registration’ have not been sufficiently attained under the current system of registration.⁹⁵

We will now take a closer look at the main bottlenecks in the current system of registration: the ‘route-of-administration-requirement’ and the ‘guaranteed-safe-requirement’ as laid down in Article 14(1) of Directive 2001/83/EC, and the efficacy of Article 13(1) of Directive 2001/83/EC with regard to the obligation to take due account of registrations of a certain homeopathic medicinal product in other Member States.

2.5.3. The ‘route-of-administration-requirement’

The first requirement prescribed by Article 14(1) of Directive 2001/83/EC is that the route of administration of the homeopathic medicinal product must be oral or external. Other products can only be registered under the authorisation procedure as described by Article 16.⁹⁶ The reason behind this requirement lies in the conviction of the Commission that other routes of administration pose higher risks. However, the Commission has not backed its position with scientific evidence with respect to homeopathic medicinal products.

The difficulties that have arisen under the ‘route-of-administration-requirement’ regard the exclusion of other routes of administration which are not necessarily more dangerous than products for oral or external use. The subcutaneous injections form the largest group of products that has come into trouble.⁹⁷ As these products have great difficulty to comply with the criteria of the regular procedure, a large number disappeared or is likely to

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- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate bibliography,
 - manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation,
 - manufacturing authorization for the medicinal product concerned,
 - copies of any registrations or authorizations obtained for the same medicinal product in other Member State,
 - one or more specimens or mock-ups of the sales presentation of the medicinal products to be registered,
 - data concerning the stability of the medicinal product.

⁹⁵ Commission report, supra note 4, Chapter 1, p. 8.

⁹⁶ See paragraph 2.6.

⁹⁷ The Court of Justice had no opportunity to rule on the matter yet. In the only case brought before the Court, the Court of First Instance denied standing on the basis of Article 230 EC (ex 169 EEC) Case T-463/93, *GUNA Srl v. Council* [1993] ECR II-1205, paragraph 14.

disappear from the market.⁹⁸ A recent study has nevertheless shown, that the subcutaneous injections produce very low health risks.⁹⁹ On top of that a large number of homeopaths that use these injections have stated that they would be seriously hindered in their treatment if subcutaneous injections would no longer be available.¹⁰⁰ Hence, the restrictions via the ‘route-of-administration-requirement’ should be based on a sound scientific evaluation, which draws from empirical evidence on the real risks connected to the use of other routes of administration than oral and external.

Besides the problems created on a Community level by the limitation of the ‘special simplified registration procedure’ to oral and external routes, the different interpretations of the ‘route-of-administration-requirement’ on a national level has also proven to be problematic. The Commission Report observes on the one hand that there are differences regarding the status of transdermal administration patches,¹⁰¹ eye drops¹⁰² and suppositories.¹⁰³ In the United Kingdom on the other hand every route of administration can be registered under the ‘special simplified registration procedure’, with the exception of subcutaneous injections.¹⁰⁴

In general, much depends on the qualification of the product involved. Eye- and eardrops for example are qualified medicines for internal as well as external application. Only in the last situation the ‘special simplified registration procedure’ is available. These types of differences between Member States could be resolved relatively easily with the introduction of a Community wide definition.

Consumers, practitioners, manufacturers,¹⁰⁵ and Parliament¹⁰⁶ are of the opinion that the ‘special simplified registration procedure’ must be available for every route of administration that can be considered safe. Moreover, the manufacturers have put forward that the inclusion of other routes of administration does not lower the standard of protection, since Titles IV (Import and Manufacture) and XI (Supervision and Sanctions) of Directive

⁹⁸ ECHAMP, *Injectables for Subcutaneous Administration*, supra note 65, p. 14.

⁹⁹ Louis Bolk Institute, *Safety of Homeopathic Injectables for Subcutaneous Administration as Used in Homeopathic and Anthroposophic Medicine*, Louis Bolk Instituut voor natuurwetenschappelijk onderzoek 2003, p. 32.

¹⁰⁰ Louis Bolk Institute, supra note 99, p. 33.

¹⁰¹ Italy: Commission report, supra note 4, Chapter 1, p. 4.

¹⁰² Finland: Commission report, supra note 4, Chapter 1, p. 5.

¹⁰³ Ibid. note 102.

¹⁰⁴ ECHAMP, *A Practical guide to the legal situation in the EU, The United Kingdom*; available at: <http://www.echamp.org/guide.php?id=75&group=5>. Subcutaneous injections are also referred to as parenteral dosage forms.

¹⁰⁵ Commission report, supra note 4, Chapter 1, p. 5.

2001/83/EC, and the Directive 2003/94/EC¹⁰⁷ and Guidelines of Good Manufacturing Practices¹⁰⁸ apply to them without restrictions.¹⁰⁹ The Commission has however not thoroughly considered these arguments.

In sum, the ‘route-of-administration-requirement’ has created considerable problems for products which are not administered orally or externally. Therefore, the requirement should be shaped on the basis of sound scientific assessment. Moreover, the implementation of the ‘route-of-administration-requirement’ on a national level diverges considerably, which creates new differentiation. This differentiation can be solved very easily by imposing Community wide definitions.

2.5.4. The ‘guaranteed-safe-requirement’

Article 14(1) names as a second requirement that the homeopathic medicinal product has to be guaranteed safe. According to the 21st recital of the preamble of Directive 2001/83/EC the safety aspects are related to the form and dosage of the products. As a minimum standard the medicinal product may not contain more than 1/10,000th part¹¹⁰ of the mother tincture,¹¹¹ or 1/100th part¹¹² of the smallest dose of active principles utilized in allopathy for which a doctor's prescription is needed when present in an allopathic medicine.¹¹³ This ‘guaranteed-safe-requirement’ has essentially provoked two problems.

Firstly, on Community level, homeopathic medicinal products (not registered or authorised before 1994) in the form of mother tinctures and D1 to D4 dilutions have become less available because of their non-eligibility for the ‘special simplified registration procedure’.¹¹⁴ This non-eligibility entails high research costs to meet the requirements for the regular authorisation procedure which cannot be balanced against the gains, in an industry with a high batch differentiation and a low turnover per batch. As a result, economic considerations diminish the number of products marketed.¹¹⁵

Secondly, on a national level, Member States do not consider the abovementioned standard to be decisive. Instead they set their own standards of what they deem ‘guaranteed

¹⁰⁶ It asked the Commission to investigate whether it is possible to make the rules more flexible if the ‘special simplified registration procedure’ could be used for other routes of administration without provoking risks to health or safety of consumers. (Resolution on the Commission Report, supra note 9, OJ C 359/97-98 [1998])

¹⁰⁷ Supra note 69.

¹⁰⁸ Supra note 66.

¹⁰⁹ Supra note 69.

¹¹⁰ *Id est* a D4 or C2 dilution or higher.

¹¹¹ Supra note 67.

¹¹² *Id est* a D2 or C1 dilution or higher.

¹¹³ Article 14(1), third indent of Directive 2001/83/EC.

¹¹⁴ Commission report, supra note 4, Chapter 1, p. 2.

safe' with respect to the dilution threshold,¹¹⁶ and the type substances. As a result, the differences between the products that are allowed to be registered under the national rules implementing the 'special simplified registration procedure' are considerable.¹¹⁷

Austria for example requires the substances to be mentioned either in the EEA pharmacopoeia, or in a list of substances it has put together.¹¹⁸ This list also specifies the minimal registerable dilution per substance. In other words, there is no general standard but a case to case approach in setting the degree of dilution. Parliament has called upon the Commission in this respect to investigate the possibility of listing degrees of dilution for stocks on a Community level.¹¹⁹

In Germany alternatively no thresholds exist; instead the condition of "an absence of harmful effects" in combination with the requirement that the substance is generally identifiable as a substance used by homeopathic or anthroposophic medicine, is used.¹²⁰ Moreover, the German Law on Medicinal Products (*Arzneimittelgesetz* or *AMG*) does not provide a 'special simplified registration' for homeopathic medicinal products which are not considered 'traditional'.

In this respect, the Administrative Court in Berlin has posed preliminary questions on the legitimacy of the requirement that a homeopathic medicinal product must be "traditional".¹²¹ As the word 'traditional' was removed from the 10th recital of the preamble of Directive 92/73/EEC when incorporated in Directive 2001/83/EC, and the 'special simplified registration procedure' never required medicinal products to be 'traditional', there is a good chance that the Court of Justice will find the requirement of 'traditional' to be too restrictive.¹²²

On the basis of the foregoing we can conclude that the 'guaranteed-safe-requirement' as formulated in the Directive could potentially drive certain lower dilutions out of the

¹¹⁵ Supra note 98.

¹¹⁶ The United Kingdom and Ireland for example have fixed the threshold at 1/10,000th (D4), leaving aside the requirement of 1/100th part (D2) of the lowest dose of substances used in allopathic medicine. The United Kingdom however, does not differentiate between the various routes of administration.

¹¹⁷ Supra note 114.

¹¹⁸ Supra note 114.

¹¹⁹ Resolution on the Commission Report, supra note 9, OJ C 359/97-98 [1998].

¹²⁰ Supra note 114.

¹²¹ Reference for a preliminary ruling by the Verwaltungsgericht Berlin by order of that Court of 28 August 2003 in the case of *meta Fackler KG v. Germany* (Case C-444/03), OJ C 21/12 [2004].

¹²² It will be interesting in this regard how the Court will come to its conclusions. In case it considers the Directive to be full harmonisation, it will probably hold the German interpretation to be outside the scope of the Directive. If considers it to be partial harmonisation, it will be interesting to see if the Court will allow the additional requirement of "traditional".

market. On top of that, the varying implementations of the ‘guaranteed-safe-requirement’ increase the differences between the laws implementing the Directive in the Member States.

2.5.5. Registrations in other Member States

The third problem to be discussed in respect of the ‘special simplified registration procedure’ regards the second sentence of Article 13(1). It reads: “*Each Member State shall take due account of registrations previously granted by another Member State.*” The provision, which was already included in Directive 92/73/EC, aims at facilitating the registration of homeopathic medicinal products that have already been registered under the ‘special simplified registration procedure’ in another Member State. The provision intends to introduce some form of mutual recognition other than the mutual recognition procedure available for regular medicinal products.¹²³ In practice however, this provision has proven to be ineffective since it does not impose an enforceable obligation to use the information on registrations in other Member States.

To different extents, only Denmark, Germany and Sweden have visibly incorporated the abovementioned obligation into their registration procedures.¹²⁴ Among those three states, Denmark is the sole Member State that has implemented a policy that applies the concept of Mutual Recognition to homeopathic medicinal products that have been registered in another Member State.¹²⁵

Manufacturers, consumers and doctors consider the diverging interpretations of this sentence to cause a barrier to the single market of homeopathic medicinal products. As mentioned earlier, the words “*shall take due account of*” do not impose a clearly definable obligation on the Member States.¹²⁶ Hence, legislative action on Community level is necessary to provide an enforceable obligation on the Member States.¹²⁷

Parliament also requested the Commission to investigate the possibility of laying down a system of mutual recognition,¹²⁸ and the possibility of a centralised procedure for the recognition of homeopathic medicinal products. As a short term solution it proposed the

¹²³ The mutual recognition procedure for authorised medicinal products laid down in Articles 28 and 29 of Directive 2001/83/EC.

¹²⁴ Commission report, supra note 4, Chapter 1, p. 3.

¹²⁵ Ibid. note 124.

¹²⁶ The Council agrees that these words do not create a legal obligation (See: Common Position (EC) No 61/2003 of 29 September 2003 adopted by the Council, acting in accordance with the procedure referred to in Article 251 of the Treaty establishing the European Community, with a view to adopting a directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ C 297E/68 [2003]).

¹²⁷ Commission report, supra note 4, Chapter 1, pp. 3-4.;

modification of Article 13 in such a way as to oblige Member States to recognise registrations issued in other Member States.¹²⁹

Unfortunately, the Commission did not take legislative action upon this request. Instead, it did not introduce changes until the adoption of Directive 2004/27/EC. With this newly adopted Directive the mutual recognition procedure for regular medicinal products laid down in Directive 2001/83/EC will be expanded to cover registered homeopathic medicinal products as well.¹³⁰

2.6. The ‘authorisation procedure’

2.6.1. Limited applicability of the authorisation procedure

For the category of homeopathic medicinal products which cannot be registered under the ‘special simplified registration procedure’, Article 16(1) of Directive 2001/83/EC prescribes that the normal rules for the authorisation of medicinal products as laid down in Articles 8 to 12 of Directive 2001/83/EC apply – including the requirement of proof of therapeutic efficacy of these products. In short, if a homeopathic medicinal product cannot be registered, it needs to be authorised in accordance with to the standard procedure for the licensing of medicinal products.

However, as the rule laid down in Article 16(1) of Directive 2001/83/EC is not or not clearly implemented by most Member States, the national laws do not explicitly refer to the obligation to authorise homeopathic medicinal products which cannot be registered. According to the Commission, this is due to the fact that homeopathic medicinal products are already covered by the general rules for the authorisation of medicinal products in most Member States;¹³¹ it has nonetheless not visibly acted to change this situation in order to provide more clarity.

2.6.2. Adjusting the authorisation procedure to the general principles of homeopathy

Notwithstanding the fact that with the authorisation procedure the normal rules for the authorisation of medicinal products are applicable, Article 16(1) is not absolute. According to Article 16(2) Member States have the discretion to maintain or introduce a specific set of

¹²⁸ In respect of mutual recognition Parliament supports the adoption of common safety standards which should have to be assessed by the Member State where the product is first registered.

¹²⁹ Resolution on the Commission Report, *supra* note 9, OJ C 359/96-97 [1998].

¹³⁰ The mutual recognition procedure will be assessed in more detail in subparagraph 4.3.2.

¹³¹ Commission report, *supra* note 4, Chapter 1, p. 7.

rules for the pharmacological and toxicological tests, and clinical trials of homeopathic medicinal products in their territories, provided that the rules are consistent with the homeopathic principles and characteristics present in the Member State concerned, and that they are notified to the Commission. In essence this means that a number of criteria in the standard authorisation procedure can be changed by the Member States individually, with respect to those homeopathic medicinal products which are only eligible to obtain an authorisation. The regular authorisation procedure can therefore theoretically be adjusted in part to the specific features of homeopathic medicine.

The idea behind the exemption of the regular requirements for pharmacological, toxicological tests and clinical trials and the introduction of a reference to the principles and characteristics of homeopathy as practised in the Member States, is that a number of features in the regular authorisation procedure are not able to take account of the specific features of homeopathy and its medicinal products.

For example, a homeopathic medicinal product in low dilution prepared from fluids which are obtained from an inflammation in the leg of a horse, will be considered unsafe by regular medical-pharmacological standards. However, the *similia principle*¹³² identifies the dangerous aspects of these fluids – namely the effects they can bring about in a healthy human body in undiluted form – as the prerequisite for the effectiveness of the homeopathic medicinal product. Hence, where regular values would consider the fluids as dangerous, homeopathy uses the dangerous effects of the fluids to cure.¹³³ Moreover, these fluids are only administered in diluted forms which do not normally pose threats to one's health.¹³⁴ The regular pharmacological, toxicological and clinical data requirements would therefore clash with the principles and characteristics of homeopathy.¹³⁵

In practice, Article 16(2) has not yet proven its effectiveness for two reasons. Firstly, as it is optional, only a hand full of the Member States has used the possibility to apply a specific set of rules for homeopathic medicinal products.¹³⁶ Among these Member States only Germany has clearly defined its rules, by creating monographs and guidelines for the clinical tests.¹³⁷ With respect to the others, the exact requirements for the pharmacological,

¹³² Supra note 31.

¹³³ ECHAMP, *Nosodes in Homeopathy: Significance and Viral Safety*, Position paper 2002/01, p. 2; available at: http://www.echamp.org/upload/Press/group_3/3_Nosodes_Position_Paper.pdf.

¹³⁴ Ibid. note 133.

¹³⁵ See for more information on the status of nosodes (medicines produced from human or animal tissue or fluids) subparagraphs 3.4.3. and 3.5.3.

¹³⁶ Supra note 131.

¹³⁷ Supra note 131.

toxicological, and clinicological data are not clear.¹³⁸ Secondly, the fact that manner in which the rules of the authorisation procedure are changed is at the discretion of Member States, does not have a beneficial effect on the harmonisation of national rules; instead it aids differentiation.

Manufacturers also disapprove of the fact that Article 16(2) is optional; the provision as such does not solve the problem of different authorisation requirements. In addition, the sentence “*specific (...) in accordance with the characteristics of homeopathy*” is perceived to be too vague.¹³⁹ For these reasons, manufacturers believe the attainment of a single market for homeopathic medicines with therapeutic indication is made impossible.¹⁴⁰

Parliament, which agreed with the manufacturers, asked the Commission to make a proposal, in cooperation with experts in homeopathic medicines, for a compulsory adoption of special rules for pharmacological and toxicological tests, and clinical trials regarding homeopathic medicinal products.¹⁴¹ Such a proposal has not been initiated by the Commission until date,¹⁴² and given the fact that the Commission has not acted for more than 5 years, we do not have to expect any short-term change. Probably no majority can be found in the Council on this matter.

To summarise, the homeopathic medicinal products which are not eligible for the ‘special simplified registration procedure’ must obtain a marketing authorisation via the authorisation procedure. Although Article 16(2) creates the possibility to adjust the authorisation procedure partially to the specific features of homeopathic medicine, it has not been beneficial as it is optional and it does not state how the adjustments should be made. Instead, Member States can set their own requirements.

2.7. Theoretical pitfalls introduced by Directive 2001/83/EC

Besides the problems that occurred under the regimes of both Directive 92/73/EEC and Directive 2001/83/EC, the introduction of Directive 2001/83/EC also triggered theoretical issues, since it did not fully incorporate Directive 92/73/EEC. Firstly, the third recital of the preamble of Directive 92/73/EEC, regarding the possibility for patients to access safe and

¹³⁸ Supra note 131.

¹³⁹ Supra note 131.

¹⁴⁰ Supra note 131.

¹⁴¹ Resolution on the Commission Report, supra note 9, OJ C 359/97 [1998].

¹⁴² Supra note 24.

high quality medicinal products of their choice,¹⁴³ has been deleted. Although, recitals 29 and 30 of the preamble of Directive 2001/83/EEC indirectly create almost equal rights of access to medicinal products, their formulation and scope are more restricted.¹⁴⁴

Secondly, the 5th recital of the preamble of Directive 92/73/EEC, which states that certain provisions in Directives 65/65/EEC and 75/319/EEC are not always appropriate for homeopathic medicinal products, has been removed. These Directives have been incorporated in Directive 2001/83/EEC and, conform the situation under the former Directive 92/73/EEC, not every provision of Directive 2001/83/EC has been made applicable to homeopathic medicinal products. The removal of the 5th recital seems thus justified.

However, the mere reference to the particular characteristics of homeopathic medicinal products in the 21st recital of the preamble of Directive 2001/83/EC does not support the general view expressed by Directive 92/73/EEC, that the regular rules for medicinal products can be inappropriate for homeopathic medicinal products.

The omission of the abovementioned provisions in the preamble may be only theoretical in nature; it can make the interpretation of certain Articles in Directive 2001/83/EC less favourable for homeopathic medicinal products. Therefore, although repealed, Directive 92/73/EEC may still have some influence on the interpretation of certain Articles in Directive 2001/83/EC regarding homeopathic medicinal products.

2.8. Conclusion

From the foregoing it has become clear that after the introduction of Directive 92/73/EEC the barriers to trade in homeopathic medicinal products have not been removed. Despite the fact that most of the difficulties arising with implementation of Directive 92/73/EEC have been identified by the Commission,¹⁴⁵ and despite the clear wording of the Resolution of the European Parliament,¹⁴⁶ Directive 2001/83/EC did not bring about the changes asked for by various private parties among whom manufacturers, doctors and patients. The European

¹⁴³ The third recital reads: “*Whereas, despite considerable differences in the status of alternative medicines in the Member States, patients should be allowed access to the medicinal products of their choice, provided all precautions are taken to ensure the quality and safety of the said products;*”

¹⁴⁴ The recognition of the possibility to buy certain medicinal products in another Member State because the products are not available in the Member State of residence does open up the access to medicine, but it brings along practical problems (travel costs, no reimbursement by the social scheme, etcetera) which could be avoided by the recognition of a right for patients to access the medication of their choice, on the condition that the quality and safety of the products are safeguarded.

¹⁴⁵ Commission report, supra note 4, Chapter 1.

¹⁴⁶ Resolution on the Commission Report, supra note 9, OJ C 359/96 [1998]

legislator did thus not use the adoption of Directive 2001/83/EC as an opportunity to reshape the registration procedure for homeopathic medicinal products.

More specifically, it can be concluded that the obligations imposed on the Member States to set up a registration and authorisation regime for homeopathic medicinal products are not phrased narrowly enough to attain a *de facto* approximation of the laws. The limitation of the registration regime in time and the partially optional character of the authorisation procedure only add to the conclusion that factual harmonisation lacks. Furthermore, the reference in the Directive to some form of mutual recognition has not proven to be effective, as its wording does not convene an enforceable obligation.

In addition, the material scope of Directive 2001/83/EC is not clear-cut in respect of the status of intermediate products which are delivered to pharmacists for *magistral* or *officinal* preparations. Moreover, the fact that Directive 2001/83/EC did not fully copy Directive 92/73/EEC can also provoke issues with regard to the exact rights the former Directive generates. As a consequence reference to Directive 92/73/EEC may be needed to exactly indicate the rights and obligations now codified in Directive 2001/83/EC.

3. The licensing of homeopathic medicinal products in The Netherlands

3.1. Introduction

3.1.1. Preliminary remark

Notwithstanding the fact that this chapter focuses on the regulatory policy with regard to the registration and authorisation of homeopathic medicinal products in The Netherlands, it may be generally observed that the national implementations of the Directives on homeopathic medicinal products suffer from a chronic lack of transparency caused by the patchwork structure of pharmaceutical legislation in most Member States.¹ This lack of transparency becomes even more obvious where diffuse interpretations are present among several authorities within one Member State dealing with pharmaceutical regulation and control. Since the re-codification of the Community legislation on medicinal products in Directive 2001/83/EC has not removed the patchwork structure of the national legislation, the lack of transparency remains a EU wide problem.

3.1.2. Why The Netherlands?

As pointed out in Chapter 1, The Netherlands was the first Member State to apply the registration regime laid down in Directives 92/73/EEC and 2001/83/EC to both products authorised on the market before 1 January 1994 and products registered or authorised after that date. As a consequence, about 80 percent of the homeopathic medicinal products formerly on the market had disappeared in February 2003.² Hence it can currently be typecasted as the most stringent regime in the Community. For this reason, it will be further assessed in this chapter.

First, we will have a look at the status of homeopathic medicine in The Netherlands. Second, reference will be made to the laws implementing Directive 2001/83/EC. The next two paragraphs deal with the problematic issues provoked by the implementing legislation, and the practical problems with regard to the applications for authorisation or registration at the Medicine Evaluation Board. Finally, difficulties in respect of the system of control will be discussed.

¹ See for more information: the “*Practical guide to the legal situation in the EU*” of ECHAMP, available at: http://www.echamp.org/eu_guide.php.

² Supra note 15, Chapter 1.

3.2. The status of homeopathic medicine in The Netherlands

In The Netherlands homeopathy does not have the same longstanding tradition which is undeniably present in the United Kingdom, Germany and France.³ Nevertheless, nowadays the Dutch doctors, homeopaths and consumers make comparatively much use of homeopathic medicine.⁴ As homeopathy started to grow as a medical practice at the beginning of the 1870s, a strong polarisation endorsed between proponents and opponents which is still ever present. Typical characteristics of discussions on the desirability and functionality of homeopathy in The Netherlands are the offensive nature and the use of inadequate definitions which regularly lead to incorrect conclusions.⁵

The mixing up of scientific (empirical) evidence on the efficacy of homeopathy in clinical practice on the one hand, and the fundamental scientific research with respect to why and how homeopathy works on the other hand, is exemplary in this regard. Since exact fundamental explanations for the efficacy of homeopathy cannot be provided at this moment, the conclusion of non-effectiveness is drawn from the inability to provide fundamental explanations. In other words, although fundamental scientific research does not touch upon issue of effectiveness of specific homeopathic medicinal products, its results are nevertheless wrongly used to contradict the findings obtained in clinical research based on empirical evidence, obtained by double blind controlled studies.

Another striking aspect of homeopathy in The Netherlands is its rather controversial relationship with the State. A number of civil servants and ministers working in the field of health affairs are not particularly charmed by homeopathic medicine. Most recently for example, Minister Hoogervorst of Health Affairs portrayed homeopathy as a form of medicine of which the therapeutic effect cannot be scientifically proven.⁶ He is however

³ J. Voorhoeve, *Homoeopathie in de praktijk*, La Rivière & Voorhoeve BV Zwolle 16^{de} Druk, pp. 44-49.

⁴ According to the CBS (the Dutch Central Bureau for Statistics) 6 to 7 percent of the Dutch population visited an alternative doctor or practitioner in 2002. On top of that 40 percent of the Dutch regular doctors makes use of homeopathy and 80 percent of the Dutch population is of the opinion that regular and alternative practitioners should work together. See for more information: P. van Dijk, *Geneeswijzen in Nederland, Compendium van alternatieve geneeswijzen*, 9th revised edition, Ankh-Hermes (Deventer 2003), and *Alternatief genezer trekt veel hoogopgeleiden*, NRC Handelsblad 19 February 2004, p. 2.

⁵ *Ga nou eerst op waterdriet*, NRC Handelsblad 3 April 2004, p. 37. See also *Minister Diagnose door arts*, NRC Handelsblad 19 February 2004, p. 2.

⁶ Homeopaten woedend op Hoogervorst, NRC Handelsblad 20 February 2004, p. 2. This is also a good example of blurring the distinction between empirically proven effect of homeopathy and the technical explanation for efficacy.

Moreover, a former Dutch Minister of Health Affairs, Els Borst incorrectly held that there was no legal basis in EC-law which could justify a non-imposition of the Dutch registration or authorisation requirements on all homeopathic medicinal products marketed in The Netherlands. However that is only correct for products which were not registered or authorised before 1994 (Article 13 of Directive 2001/83/EC). Being aware of the large number of difficulties reported in the transitional period between the old Dutch legislation and the new

clearly not the only one.⁷ It is not difficult to understand that this situation is not very beneficial for the relationship between the state institutions and homeopathic interest groups.

Considering the foregoing, the status of homeopathy in The Netherlands can be described as controversial.

3.3. The applicable legislation

In correspondence with the preliminary remark in paragraph 3.1., the manner in which the European homeopathic legislation has been implemented by the Dutch legislator can be characterised as patchwork. The main provisions are laid down in four different pieces of legislation: “*Besluit Homeopathische en Farmaceutische Producten*” (Decree on Homeopathic and Pharmaceutical Products, hereinafter Decree on HPP’s),⁸ “*Regeling Homeopathische Farmaceutische Producten*” (Regulation on Homeopathic and Pharmaceutical Products, hereinafter Regulation on HPP’s),⁹ “*Besluit Registratie Geneesmiddelen*” (Decree on the Registration of Medicines),¹⁰ and “*Wet op de Geneesmiddelenvoorziening*” (Law on the Availability of Medicines).¹¹

Although the regime has been codified in an obscure and diffuse manner, the next paragraphs will try to clarify the applicable Dutch legislation including its practical application with reference to Directive 2001/83/EC. It will furthermore point out the problematic issues caused by the legislation and its application.

3.4. The applicable legislation analysed

3.4.1. Authorisation or registration?

The first issue that has to be needs to be discussed before embarking further on the Dutch system, is the rather misleading Dutch translation of the words ‘authorisation’ and

stringent regime, she effectively denied access to a large number of the homeopathic medicinal products previously on the market (Supra note 15, Chapter 1).

⁷ For example, the Inspector general of the Dutch Health Care Inspectorate, J. Kingma is a prominent member of the Dutch Association against Quackery, which heavily disapproves of homeopathic medicine and other forms of complementary and alternative medicine. Moreover, he did not abdicate from the utterances of Dr Baratz during a meeting of the Association he attended. In this meeting Dr Baratz compared homeopathic practice with medical malpractices in the Nazi-camps during the Second World War. See for more information: http://www.kanker-actueel.nl/ka_me.Kingma.html#2. Mr Kingma’s own utterances on homeopathy are however less profound; according to him homeopathy does not work, but it is not dangerous.

See for more information: <http://www.kwakzalverij.nl/php/display/ap/220/18>.

⁸ Stb. 1992, 48, and lastly amended in Stb. 2000, 467

⁹ Stcrt. 1999, 49.

¹⁰ Stb. 1997, 692, and lastly amended in Stb. 2003, 522.

‘registration’ as found in the English language version of Directive 2001/83/EC. The Dutch language version uses the words ‘Vergunning’ for authorisation and ‘Registratie’ for registration. The Dutch legislation however uses the term ‘*Registratie*’ for both ‘authorisation’ and ‘registration’.

For example, the title of the Decree on the Registration of Medicines misleadingly suggests that every medicinal product has to be registered. The same misleading wording can be found in Article 3 of the Law on the Availability of Medicines, which does not distinguish between the terms ‘authorisation’ and ‘registration’ either. As a result, the distinction between the two procedures is blurred.¹²

Notwithstanding this misleading wording, the two procedures are in effect different from each other. It is thus not true that Dutch legislation requires every medicinal product to be registered in the sense of Article 14 and 15 of Directive 2001/83/EC. Although the wording is misleading, the procedures in principle correspond to the ones laid down in Directive 2001/83/EC. For the sake of clarity, a change in the wording is however advisable. Until such change has been realised, extra caution remains needed when assessing the Dutch legislation.¹³

3.4.2. The ‘special simplified registration procedure’

We will now take a closer look at the legislation implementing the ‘special simplified registration procedure’ in The Netherlands. Subsequently, we will assess the problems it has provoked.

The Decree on HPP’s¹⁴ lies at the heart of the registration procedure for homeopathic medicinal products, because it equals these products with pharmaceutical products, which have to be authorised in accordance with the provisions of the Decree on the Registration of Medicines.¹⁵ Thereby, it extends the scope of the Decree on the Registration of Medicines to homeopathic medicinal products.¹⁶ It furthermore, modifies or exempts the requirements for

¹¹ Stb. 1961, 26; Stb. 1963, 340; Stb. 1964, 162, and lastly amended in Stb. 2001, 337.

¹² See for more information on the differences between ‘authorisation’ and ‘registration’ paragraphs 2.3., 2.5. and 2.6.

¹³ In order to avoid misconceptions, this paper did not follow the Dutch example. Instead it describes the Dutch system making use of the wording of English language version of the Directive.

¹⁴ Supra note 8.

¹⁵ Supra note 10.

¹⁶ Article 1(1) of the Decree on HPP’s *jo.* Articles 3(1) and 26(f) of the Law on the Availability of Medicines.

registration laid down in the Decree on the Registration of Medicines for those products entitled to a registration.¹⁷

In other words, the Decree on HPP's brings all homeopathic medicinal products under the authorisation procedure laid down in the Decree on the Registration of Medicines. Subsequently, it adjusts the procedure for those products entitled to a registration¹⁸ in such a way that it effectively becomes the 'special simplified registration procedure'.¹⁹

The practical result is that Article 2 of the Decree on the Registration of Medicines, which lays down the exact information required for the authorisation of medicinal products, in principle, requires the same information for the authorisation of homeopathic medicinal products. However, if a homeopathic medicinal product complies with the requirements laid down by Article 4(1) of the Decree on HPP's, Article 2 of the Decree on the Registration of Medicines is brought in line with Article 15 of Directive 2001/83/EC.²⁰ This construction factually creates a registration instead of an authorisation.

With respect to the admission requirements for the 'special simplified registration procedure', Article 4(1) of the Decree on HPP's provides the same requirements as the Directive does.²¹ To be more precise, it literally copies Article 14(1), third indent, of the Dutch language version of Directive 2001/83/EC. With reference to paragraph 2.5., homeopathic medicinal products are thus entitled to be registered under the 'special simplified registration procedure' if they are administered externally or orally,²² they do not bear a therapeutic indication,²³ and they are guaranteed safe.²⁴

Having in mind, the system as discussed above, the difficulties provoked by the Dutch 'special simplified registration procedure' will now be analysed. Basically, there are two

¹⁷ Articles 2 to 4, and 6 of the Decree on HPP's.

¹⁸ The Decree on HPP's also changes the authorisation procedure when applicable to homeopathic medicinal products. This will be further discussed in subparagraph 3.4.3.

¹⁹ The wording of the Decree on HPP's does at least give a small hint on the distinction between authorisation and registration. The first group of products, which fall under Article 4 of the Decree on HPP's, is authorised ("*geregistreerd*") according to the wording of Article 4(3) of Decree on HPP's. The Dutch term "*geregistreerd*" refers to the regular procedure being authorisation. The second group of products, which fall under Article 6 of the Decree on HPP's, need to apply for an enrolment in a Register ("*inschrijving (...) in een register*") according to the wording of Article 6(2) of the Decree on HPP's in conjunction with Article 2 of the Decree on the Registration of Medicines. In effect, "*inschrijving (...) in een register*" comes close to the description of a registration in the sense of Articles 14 and 15 of Directive 2001/83/EC.

²⁰ Supra note 17.

²¹ This does however not mean that the interpretation of the wording of Article 4(1) of the Decree on HPP's does not provoke any problems.

²² Article 4(1)(a) of the Decree on HPP's.

²³ Article 4(1)(b) of the Decree on HPP's.

²⁴ Article 4(1)(c) of the Decree on HPP's: The Dilution must at least be 1/10,000 of the mother tincture, or 1/100 of the smallest dose of a substance for which, if used in an allopathic medicine, its presence would oblige the Doctor's prescription.

issues that need to be mentioned: The interpretation of the ‘guaranteed-safe-requirement’; and the accessibility of the ‘special simplified registration procedure’.

A. The ‘guaranteed-safe-requirement’

Besides the general problems provoked by Directive 2001/83/EC,²⁵ and the fact that the Dutch ‘special simplified registration procedure’ is regulated in a diffuse manner, additional problems are created by the Dutch interpretation of the concept of ‘*guaranteed safe*’. For the entitlement to the ‘special simplified registration procedure’, Directive 2001/83/EC stipulates amongst others a minimum degree of dilution and the requirement that the medicinal product must be administered orally or externally. This is the practical outcome of the general the concept of ‘*guaranteed safe*’ laid down in the 21st recital of the preamble of the Directive, which requires that the form and dosage have to be guaranteed safe to make a product eligible for registration. The Dutch legislation goes however further.

According to the Explanatory Memorandum of the Regulation on HPP’s, nosodes²⁶ for oral or external use meeting the minimum degree of dilution, are also excluded from the ‘special simplified registration procedure’ regardless of their exact composition.²⁷ In addition, the Memorandum states that the same applies to every dilution which cannot be considered ‘intrinsically safe’. It does however not provide a definition of what is intrinsically safe.

Although the Directive leaves some space for interpretation, it is questionable whether this is a positive development with regard to legal certainty. Moreover, the interpretation employed in the Memorandum is capable of successfully hindering the harmonising effort laid down in Directive 2001/83/EC.

Firstly, the requirement of intrinsically safe more or less gives state authorities a *carte blanche* to go beyond the minimum degree of dilution prescribed by Article 14 of Directive 2001/83/EC, as no indication is given on the exact meaning of intrinsically safe.

Secondly, the interpretation of the ‘guaranteed-safe-requirement’, as published in the Explanatory Memorandum of the Regulation on HPP’s, has given the Medicine Evaluation Board the opportunity to categorically deny the simplified registration of nosodes.²⁸ As this includes the group of nosodes in the form of dilutions higher than D24 or C12 for oral application, which form a considerable part of the homeopathic medicines commonly

²⁵ See paragraph 2.5.

²⁶ Nosodes are homeopathic medicinal products prepared from human or animal tissue, or body fluids. See for more information: C. Hammond, *supra* note 30, Chapter 2, p. 31.

²⁷ Toelichting, Regeling homeopathische farmaceutische producten, Stcrt. 1999, 49.

prescribed by practitioners in The Netherlands, a significant number of medicines prescribed is no longer available on the Dutch market. Consequently, if nosodes are prescribed in The Netherlands, the patient can only purchase them in another Member State in order to be able to make use of them.

Since these D24 or C12 dilutions do not contain any molecular remnants,²⁹ and they have not provoked serious health risks in the past, it cannot be said that they generally and directly pose high risks to public health, or the health of consumers. It remains therefore unclear why such products are principally excluded from the ‘special simplified registration procedure’ in contrast to other products based on D24 or C12 dilutions, since the last category is considered safe exactly because of its high degree of dilution.

Consequently, the outcome of the interpretation utilised in the Explanatory Memorandum of the Regulation on HPP’s with regard to nosodes, does not seem to strike a fair balance between the aim of public health protection and the free movement of homeopathic medicinal products, as envisaged by Directive 2001/83/EC. This problem will be further assessed under subparagraph 3.5.3.

B. Accessibility of the Dutch legislation

As mentioned above, the actual ‘special simplified registration procedure’ is based on a stripped version of the Dutch authorisation procedure for regular medicines, with some additional modifications. Apart from that, a comparable conclusion can be drawn for the authorisation procedure.

The end result of this indirect construction is that one has to take a look at four different pieces of legislation – The Decree on the Registration of Medicines, The Decree on HPP’s, and the Regulation on HPP’s, and Law on the Availability of Medicines – to be able to indicate the documents required for a registration or authorisation. Hence, it is difficult to pinpoint the exact information necessary for the application for a registration.

In addition, Article 4(3) of the Decree on HPP’s contains an implementation error. At first sight, Article 4(3) of the Decree on HPP’s seems to literally copy the Dutch version of Article 15 of Directive 2001/83/EC. However, the implementation is not fully correct.

To be precise, Article 4(3) states that it is applicable to a series of products derived from the same homeopathic stock; the word ‘stocks’ has been omitted. As a result, contrary to

²⁸ The exact position of the Medicine Evaluation Board in this regard will be further dealt with in subparagraph 3.5.3.

²⁹ Supra note 33, Chapter 2.

Article 15, the registration of a series of products derived from the same combination multiple homeopathic stocks would be excluded from registration in The Netherlands. Subparagraphs a) and b) of Article 4(3) of the Decree on HPP's do however mention the word 'stocks'. It is therefore not likely that this internal inconsistency really leads to a different end result in comparison with Directive 2001/83/EC.

Nonetheless, clarity and accessibility are once again not served. In addition, the vague translation of the terms "authorisation" and "registration", even amplifies this conclusion.

3.4.3. The 'authorisation procedure'

If homeopathic medicinal products are not eligible for the 'special simplified registration procedure' under Article 4(1) of the Decree on HPP's, the regular authorisation procedure as laid down in Article 2 of the Decree on the Registration of Medicines in principle applies. However, as The Netherlands has made use of the possibility in Article 16(2) of Directive 2001/83/EC to partially adjust the authorisation requirements for homeopathic medicinal products, the authorisation procedure is changed on a number of points.

Article 6 of the Decree on HPP's lays down the requirements for the authorisation of homeopathic medicinal products. It exempts homeopathic medicinal products from the requirement to confer data on pharmacological, toxicological tests and clinical trials as laid down in Articles 2(1)(i)(2^o) and 2(1)(i)(3^o) of the Decree on the Registration of Medicines.

In conformity with Article 16(2) of Directive 2001/83/EC, it furthermore provides in Article 6(5) that the Minister of Health Affairs gives special requirements for pharmacological, toxicological tests and clinical trials in accordance with the principles and characteristics of homeopathy as practised in The Netherlands. In accordance with Dutch law this means that the requirements are laid down in the form of a regulation.

A. *The requirements laid down in the Regulation on HPP's*

The Regulation on HPP's³⁰ confers the following requirements. Article 2, paragraph 1 of the Regulation states that, if a homeopathic medicinal product is not administered orally or externally, or if it does not meet the safety requirements laid down in Article 4(1)(c) of Decree on HPP's,³¹ the request must be accompanied by data which gives proof of the pharmacological, toxicological and clinical features of the incorporated elements of the homeopathic medicinal product.

³⁰ Supra note 9.

³¹ Supra note 24.

Article 2(2) of the Regulation on HPP's gives an additional requirement for products which are not orally or externally applied. The data required for these products has to indicate which of the abovementioned features led to an application different from the oral or external route.

The data referred to in Articles 2(1) and 2(2) of the Regulation has to be derived from, or consist of pharmacological, toxicological and clinical data that is considered to be common in medical-pharmaceutical circles, publications in periodicals which count as reliable in medical-pharmaceutical circles, or documents as stipulated by Article 2(1)(i)(2^o) and 2(1)(i)(3^o) of the Decree on the Registration of Medicines.³²

For homeopathic medicinal products which are marketed with therapeutic indication Article 3 of the Regulation on HPP's states that the application for registration must contain data which makes it credible that the product is safe and can be successfully applied. The data must be derived from or consist of clinical documentation as described in part 4 of the appendix of the '*Regeling proeven op farmaceutische producten*' (Regulation on the testing of pharmaceutical products),³³ or bibliographical data which is common in circles of homeopathic and anthroposophic doctors.

Article 4 of the Regulation on HPP's makes the previous rules applicable to homeopathic medicinal products which consist of more than one homeopathic substance. The Regulation finally lays down a number of formal requirements in Article 5 for the monographs in which the data requested by Article 2 to 4 is incorporated.

It is now time to have a look at the problems triggered by the requirements as laid down in the Regulation on HPP's and their conformity with Article 6 of the Decree on HPP's.

B. Problems provoked by the Regulation on HPP's

It is striking to see that the Regulation on HPP's to a large extent fails to comply with Article 6 of the Decree on HPP's and Article 16 of Directive 2001/83/EC. In general it can be observed that the important reference to principles and characteristics of homeopathy in The Netherlands,³⁴ as required by Article 6(5) of the Decree on HPP's, has been left out.

It all starts with the Decree on HPP's, which states in Article 6(2) that the pharmacological, toxicological and clinical data requirements for non-homeopathic medicinal products, as mentioned in Articles 2(1)(i)(2^o) and 2(1)(i)(3^o) of the Decree on the Registration

³² Article 2(3) of the Regulation on HPP's.

³³ Stcrt. 1992, 234 as lastly amended in Stcrt. 2003, 214.

³⁴ See subparagraph 2.6.2.

of Medicines are excluded for homeopathic medicinal products. Instead, according to Article 6(5) of the Decree on HPP's, special requirements must be provided by the Minister of Health Affairs in the form of a regulation. As a *conditio sine qua non*, these special requirements must take account of the principles and characteristics of homeopathy in The Netherlands.³⁵

As a result, the pharmacological, toxicological and clinical data requirements of the authorisation procedure are declared in-applicable to homeopathic medicinal products and must be replaced by special requirements which take account of the principles and characteristics of homeopathy in The Netherlands. The Minister's power to lay down the abovementioned special requirements is moreover limited to requirements which take account of the special features of homeopathic medicine.³⁶

The Regulation on HPP's however stipulates in Article 2(3)(c) that the pharmacological, toxicological and clinical data clearly as excluded by the Decree on HPP's must nonetheless be provided without adding the condition that the tests and trials need to be conducted in conformity with the principles and characteristics of Dutch homeopathy.³⁷

Furthermore, as a second possibility Article 2(3)(c) of the Regulation on HPP's prescribes that pharmacological, toxicological and clinical data may also be derived from or consist of information that is considered common in medical-pharmacological periodicals or circles. However once more, the requirement of conformity with the principles of Dutch homeopathy is not mentioned. The explanatory memorandum of the Regulation on HPP's does not shed a different light on the wording. It only reaffirms that the information must comply with regular medical-pharmacological standards. This undeniably leaves aside some of the universal characteristics and principles of homeopathy that cannot be combined with the regular medical and pharmacological standards.³⁸

Notwithstanding the foregoing, there is one provision in the Regulation on HPP's which partially refers to the principles and characteristics of Dutch homeopathy in The Netherlands. Article 3(2)(b) creates the option to refer to bibliographical data which is common in circles of homeopathic and anthroposophic doctors, in order to support a claim of efficacy on a homeopathic medicinal product bearing a therapeutic indication. This does however not regard the data obtained from pharmacological and toxicological tests.

Article 3(2)(b) of the Regulation on HPP's thus merely stipulates which data can be used to found the credibility of a claim on the successful and safe application of products, if

³⁵ Article 6(5) of the Decree on HPP's.

³⁶ Ibid. note 35.

³⁷ Article 2(3)(c) of the Regulation on HPP's.

‘regular’ clinical proof cannot be provided. The Explanatory Memorandum on the Regulation on HPP’s nevertheless indicates that clinical evidence is preferred.³⁹ If no bibliographical data is available, the applicant does not have a choice and must provide clinical evidence on the therapeutic effect and safety of the product or products.⁴⁰

In conclusion, Article 2(3)(c) of the Regulation on HPP’s is evidently in breach of Articles 6 of the Decree on HPP’s, since it illegally re-establishes the data requirement exempted by Article 6(2) in its original form. Moreover, as the Regulation generally fails to add the obligation to comply with the principles and characteristics of homeopathy in The Netherlands, it does not only contravene Article 6(5) of the Decree on HPP’s, but it also breaches of Article 16(2) of Directive 2001/83/EC.

3.4.4. The level of harmonisation? Continued

In consideration of the problems analysed in subparagraphs 3.4.2. and 3.4.3., the question of full harmonisation as discussed in paragraph 2.4. pops up once again⁴¹ with regard to the conformity of national legislation with EC-law.

With respect to the problems discussed under the ‘special simplified registration procedure’, the conformity of the Dutch implementation and interpretation with Articles 14 and 15 of Directive 2001/83/EC has to be examined. As these two Articles lay down very specific compulsory requirements, and they do not leave much space to deviate,⁴² it seems that the imposition of (more stringent) additional or alternative requirements for registration are not allowed. Hence, although the Directive does not mention it as such, these Articles may constitute full harmonisation. Moreover, it will be interesting to see the ECJ’s views on the categorical denial by the Dutch authorities of the registration of certain homeopathic medicinal products like nosodes which conform to the requirements for registration as laid down in Article 14 of the Directive.

The level of harmonisation regarding the Dutch implementation of the ‘authorisation procedure’ laid down by Article 16 of Directive 2001/83/EC is however a different story, as the Dutch legislator has chosen to make use of Article 16(2). This Article can be deemed to

³⁸ Supra note 2.6.2.

³⁹ Supra note 27.

⁴⁰ Supra note 27.

⁴¹ See paragraph 2.4.

⁴² Article 13(1) of Directive 2001/83/EC creates a theoretical possibility to opt out of implementing the ‘special simplified registration procedure’, however none of the Member States has chosen to apply this option. Moreover, the consequences of opting out are also very clear. Opting out means the imposition of the obligation on a Member State to recognise all homeopathic medicinal products registered in other Member States. In other words, a *de facto* obligation of mutual recognition.

constitute minimum harmonisation, because it is optional in nature and it leaves considerable discretion to the Member States to set out their own policy.⁴³

If a Member State chooses to make use of the optional Article 16(2), it must at least conform to the minimum requirements set out by Article 16(2). This means that the rules must be consistent with the homeopathic principles and characteristics present in the Member State concerned, and that the rules must be notified to the Commission.⁴⁴

Notwithstanding the large discretion to modify the ‘authorisation procedure’ on a national level, the Dutch legislation has failed to comply with the minimum standards laid down in Article 16(2) of Directive 2001/83/EC, since it has not set up a specific set of rules for the authorisation of homeopathic medicinal products which is consistent with the homeopathic principles and characteristics present in The Netherlands. Moreover, it has to a large extent virtually reinstalled the normal requirements for authorisation of medicinal products under the denominator of specific rules for the authorisation of homeopathic medicinal products.⁴⁵

As a consequence of the above, the second step in the assessment of the conformity of the Dutch implementation with the EC-Treaty, as discussed in paragraph 2.4., is not necessary, since the two procedures mentioned above, have failed to comply with the requirements imposed by Directive 2001/83/EC.

After having analysed the Dutch legislation applicable to the registration and authorisation of homeopathic medicinal products, the next two paragraphs will examine the authorities which are involved with the practical application of the Dutch legislation, and the problems their policies or structures have created.

3.5. Application for registration

3.5.1. The Medicine Evaluation Board

In conformity with Law on the Availability of Medicines, the Medicine Evaluation Board (hereinafter MEB) handles the applications for registration of homeopathic medicinal

⁴³ Supra note 41.

⁴⁴ Supra note 34.

⁴⁵ Although there are some extra options available for the authorisation of homeopathic medicinal products in comparison to the normal authorisation procedure, they only refer to pharmacological, toxicological and clinical data that is considered to be common in medical-pharmaceutical circles, or publications in periodicals which count as reliable in medical- pharmaceutical circles [Articles 2(1) and 2(2) of the Regulation on HPP’s], instead of data consistent with the homeopathic principles and characteristics present in The Netherlands.

products.⁴⁶ The Netherlands does not have a separate institution which deals with the registration of homeopathic medicinal products. Instead the MEB has a special section dealing with homeopathic medicine: The ‘Farmaco Therapeutische (FT) Groep IV’. According to the head of the MEB, J. Lekkerkerker, and the process manager of the FT Groep IV, E. van Galen, the MEB aims at guaranteeing the safety of homeopathic medicinal products.⁴⁷

3.5.2. The information provided by the Medicine Evaluation Board

The information provided by the MEB on the practical form in which the registration and authorisation of homeopathic medicinal products takes place can be mainly derived from the website of the MEB. It provides information for applicants in the Dutch and English language.

However, neither language version is kept up very well. The English information on the application of Articles 4 and 6 of the Decree on HPP’s, for example, still refers to Directive 92/73/EC instead of Directive 2001/83/EC.⁴⁸ Furthermore, the English version of the Notice to Applicants has not been fully translated,⁴⁹ leaving that part only available in Dutch.⁵⁰

In addition, it is more difficult for foreign non-Dutch companies and stakeholders to be adequately informed on the developments in The Netherlands regarding the licensing of homeopathic medicinal products as certain documents are only published in Dutch.

For example, unlike the Dutch language version, there is no reference in the English version to the case *VSM v. MEB*,⁵¹ which is of considerable importance for applicants which need an authorisation for a homeopathic medicinal product.⁵² The administrative court held that the disclaimer on the label compulsory imposed by art. 6(6) of the Decree on HPP’s, which states that the evaluation of efficacy of the product by the MEB is not based on scientific criteria, is not in conformity with Directive 2001/83/EC. It is namely not for the Dutch state to impose additional requirements not contemplated by the Directive in this

⁴⁶ Article 3 of the Law on the Availability of Medicines.

⁴⁷ E. van Galen and J.F.F. Lekkerkerker ‘*Registratie van homeopathica is een moeizaam proces, Bewezen veilig, onbewezen effectief*’ 14 Pharmaceutisch Weekblad 2001, pp. 512-515. Also available at the website of the MEB: <http://www.cbg-meb.nl/nl/docs/hpathica/pw-200114.pdf>.

⁴⁸ Conversely, the Dutch version does not contain any reference to European legislation.

⁴⁹ See the heading “dossier requirements”, Part 1B 1 (Summary of Product Characteristics).

⁵⁰ The notice to applicants is available on http://www.cbg-meb.nl/uk/docs/hpathica/homeo_nta.pdf.

⁵¹ *VSM Geneesmiddelen BV tegen het College ter beoordeling van geneesmiddelen*, Rechtbank Alkmaar, 12 November 2003, 02 1297. Available at: http://www.cbg-meb.nl/nl/docs/hpathica/uitspr-vsm_vs_cbg-031112.pdf.

respect. As a result, applicants for an authorisation have to comply with fewer requirements than mentioned in the Dutch legislation.

Since the abovementioned information is more difficult to access for non-Dutch speaking persons, the absence of at least a reference is clearly at the disadvantage of these persons. Moreover, since the MEB pretends to provide information in both Dutch and English, it should try to do so in an equal manner. This is even more evident in a system as vague as the Dutch one.

Notwithstanding the inconsistencies, the website offers a considerable amount of useful information for applicants. Interesting documents are the Notice to Applicants, the application forms, and access to the Medicines Data Bank, which are available in both languages. Furthermore, the section a section news and publications is at least partially available in English. In addition the Dutch language version contains a publicly available version of an evaluation report of a registration.⁵³

3.5.3. Nosodes and the ‘guaranteed-safe-requirement’

As mentioned in subparagraph 3.4.3, after being marketed in Netherlands for decades before the introduction of the current Dutch regime, there are currently no nosodes on the Dutch market. The interpretation of the ‘guaranteed-safe-requirement’ in Article 4(1)(c) of the Decree on HPP’s by the MEB, as laid down in the Explanatory Memorandum of the Regulation on HPP’s,⁵⁴ can be indicated as the main cause of this problem.

Although, the MEB is aware of the fact that the interpretation as published in the Memorandum is not in conformity with Directive 2001/83/EC, it has not yet provided clear and workable criteria which would make the registration of nosodes⁵⁵ possible.⁵⁶ According to the process manager of the Farmaco Therapeutische (FT) Groep IV,⁵⁷ more time is needed to work out the criteria under which the ‘special simplified registration procedure’ can be used for nosodes.⁵⁸ The main reasons given for this delay concern the difficulties with regard to viral safety, quality specifications and denomination.⁵⁹

⁵² The ruling of the section administrative law of the lower court in Alkmaar is also available at: <http://www.rechtspraak.nl/Rechtbank/Alkmaar/>

⁵³ The report regards the registration of *Aconitum D10* by the company A. Vogel, and is available at: <http://www.cbg-meb.nl/nl/docs/hpathica/par-aconitum.pdf>.

⁵⁴ Supra note 27.

⁵⁵ Supra note 26.

⁵⁶ E. van Galen, *Homeopathische geneesmiddelen in 2003 en de innovatie van de homeopathie, resultaten en knelpunten van het registratieproces in Nederland*, 33(2) *Similia Similibus Curentur* 2003, p. 4.

⁵⁷ See subparagraph 3.5.1.

⁵⁸ Supra note 56.

⁵⁹ E. van Galen, supra note 56, pp. 4-6.

However, considering the fact that good standards for the manufacturing of nosodes have been introduced by the French and German⁶⁰ authorities,⁶¹ and the fact that these authorities work together with the MEB and other national agencies to create a more unified approach with respect to the authorisation and registration of homeopathic medicinal products, the inability or unwillingness of the MEB to introduce requirements on a short notice does not seem justified.

It could at least allow nosodes produced in accordance with the French or German system, or it could temporally introduce, for example, the German requirements until it has set up its own set of criteria. This would ensure a high level of quality and safety for those nosodes to be registered, and it would remove the practical ban on nosodes currently in place.

3.5.4. MEB designed for allopathic medicines

The MEB has to be qualified as an independent administrative body created for the evaluation of allopathic medicinal products and devices.⁶² In this capacity it has to evaluate homeopathic medicinal products as well. It is however no secret that the MEB has great difficulty with the evaluation of homeopathic medicinal products, for the reason that homeopathic medicine does not fit into the dogma of allopathic medicine, and the criteria it lays down.

Unfortunately, the former subparagraphs have also shown that the MEB has great difficulty to step out of the dogma of allopathic medicine, and think as homeopaths. The case *VSM v. MEB*,⁶³ and the lax position of the MEB with regard to nosodes are especially illustrative in this respect.

The main cause of this situation probably lies with the under-representation of homeopathic specialists in the MEB, and therefore a lack of knowledge on homeopathy and its vocabulary.⁶⁴ The process manager of the FT Groep IV, as mentioned in subparagraph 3.5.1., is the only identifiable homeopathically qualified specialist working for the MEB. Therefore, the involvement of higher number of homeopathic specialists in the decision making with regard to homeopathic medicinal products within the MEB, would very probably resolve lack of balance with regard to expertise and consequently lead to more understanding. Another solution would be the creation of an independent expert committee specially

⁶⁰ Germany can probably be considered as the most reliable source of reference, as it has a longstanding homeopathic tradition and a high experience and expertise with regard to product quality and safety.

⁶¹ ECHAMP, *Nosodes in Homeopathy*, supra note 133, Chapter 2, p. 3.

⁶² See About MEB, available at: <http://www.cbg-meb.nl/uk/overcbg/index.htm>.

⁶³ Supra note 52.

designed for the authorisation and registration of homeopathic medicinal products, as is the case in Belgium for example.⁶⁵

3.6. System of Control

3.6.1. The Dutch Health Care Inspectorate

If a pharmaceutical product is not registered or authorised in accordance with the Law on the Availability of Medicines, it is not allowed to manufacture, have in stock, or deliver these products,⁶⁶ save for some exceptional circumstances among which *officinal* and *magistral* preparation of medicinal products by an authorised pharmacist.⁶⁷

The Dutch Health Care Inspectorate makes sure that these rules are observed. It has the competence to impose fines, to confiscate the non-complying products, and to suspend or even withdraw a manufacturing authorisation.⁶⁸ Since homeopathic medicinal products also qualify as pharmaceutical products, the Inspectorate controls these products as well.⁶⁹

3.6.2. Mother tinctures for *magistral* and *officinal* preparation

In practice, the competence of the Inspectorate to prevent the use of unregistered or unauthorised pharmaceutical products did not create a significant number of problems, as Inspectorate has no discretion to allow these products on the market on the basis of Community Law.⁷⁰

However, the exemption of *magistral* and *officinal* preparations regarding the obligation to register or authorise medicinal products,⁷¹ has caused problems with respect to the status of mother tinctures. These problems mainly originate from the use of dubious definitions by the Inspectorate for the terms ‘medicinal product’ and ‘intermediate product’ in connection with *magistral* and *officinal formulas*.⁷²

⁶⁴ As homeopathic medicine does not form part of the Dutch curriculum for Medicine, non-homeopathic specialists are not equipped to intrinsically value all elements of homeopathic medicine, including homeopathic medicinal products. See also supra note 27 Chapter 2.

⁶⁵ ECHAMP fact sheet Belgium, available at: <http://www.echamp.be/guide.php?id=125&group=9>.

⁶⁶ Article 3(4)(a) and (b) of the Law on the Availability of Medicines.

⁶⁷ Article 3(6) *jo.* 4(1)(a) of the Law on the Availability of Medicines.

⁶⁸ See Articles 31 and 33 of the Law on the Availability of Medicines.

⁶⁹ Supra note 47.

⁷⁰ According to Article 6 of Directive 2001/83/EC medicinal products may only be marketed in the EU with a marketing authorisation.

⁷¹ See subparagraph 2.3.3.

⁷² ECHAMP, *The status of Homeopathic Starting Materials (Homeopathic Stocks) purchased in order to make magistral preparations in a pharmacy or on request of a pharmacy*, Position Paper 2003/01, p. 2, available at: http://www.echamp.org/upload/Press/group_3/3_Homeopathic_Stocks.pdf

Under the Dutch legislation it is possible for pharmacists to make *magistral* and *official* preparations for customers of a pharmacy; in other words pharmacists may prepare pharmaceutical products for retail supply in their own pharmacy.⁷³ With regard to homeopathic medicines this possibility is however severely restricted, since the Inspectorate only allows pharmacists to buy mother tinctures which are authorised as medicinal products.⁷⁴

It should be noted in this context that mother tinctures are the main stocks for the preparation of homeopathic medicines. If these mother tinctures should not be available to pharmacists, the *magistral* and *official* preparations are merely a theoretical form of preparation.⁷⁵ In effect, the Inspectorate has herewith prohibited the use of the largest number of homeopathic stocks, and pharmacists cannot prepare the *magistral* and *official formulas* which are indispensable.

The reasoning behind the registration requirement for mother tinctures by the Inspectorate is founded on its qualification of the mother tincture. The Inspectorate qualifies mother tinctures which are used for *magistral* and *official* preparations as intermediate products. According to the Inspectorate, these intermediate products do not fall outside the scope of Directive 2001/83/EC, since the mother tinctures are not used for “*further processing by an authorised manufacturer*”,⁷⁶ but for the *magistral* and *official* preparation of medicinal products by a pharmacist which does not qualify as an ‘authorised manufacturer’.⁷⁷ In other words, the Inspectorate is of the opinion that Directive 2001/83/EC applies to mother tinctures which are purchased by pharmacists for the preparation of *magistral* and *official formulas*,⁷⁸ because a pharmacist cannot be qualified as an authorised manufacturer.⁷⁹

In addition, to facilitate the imposition of the registration requirement for starting materials for homeopathic medicinal products, the Inspectorate holds that mother tinctures, which are used by pharmacists for *magistral* and *official* preparations must be registered or authorised as homeopathic medicinal products, since mother tinctures are prepared in accordance with a homeopathic pharmacopoeia, and some of them have been authorised as

⁷³ Supra note 67.

⁷⁴ Inspectie voor de Gezondheidszorg, *Kortschrift, Handhaving Registratie Registratieplicht Homeopathische Geneesmiddelen*, januari 2003, p. 7; available at: <http://www.igz.nl/bestanden/kortschrift%20Verslag%20handhaving%20registratieplicht%20homeopathische%20geneesmiddelen%20II.pdf>

⁷⁵ It is in most cases reasonably impossible for a pharmacist to prepare the mother tinctures from the raw materials in the pharmacy.

⁷⁶ Article 3(4) of Directive 2001/83/EC.

⁷⁷ See subparagraph 2.3.3.

⁷⁸ ECHAMP, *The status of Homeopathic Starting Materials*, supra note 72, Position Paper 2003/01, p. 3.

homeopathic medicinal products.⁸⁰ There is however no basis under EU-law or Dutch law to support this reasoning,⁸¹ as mentioned in subparagraph 2.3.3.

Furthermore, the mother tinctures purchased as starting materials are not physically comparable to those mother tinctures which are presented as homeopathic medicinal products. Normally, the mother tinctures used as stocks need further processing in order to be sold as medicinal products; even if the end-product is presented in the form of a tincture.

Moreover, the inspectorate ignores the fact that these mother tinctures purchased by the pharmacists are not presented as medicinal products.⁸² Consequently, as the presentation requirement forms a cardinal constituent of the definition of medicinal product,⁸³ its disregard is clearly *contra-legem*. That is, intermediate products cannot be registered or authorised as medicinal products.

On top of that, none of the competent authorities in other Member States has followed this line of reasoning,⁸⁴ and the Commission has also ventilated a different approach in its answers to questions submitted by the Belgian Inspectorate,⁸⁵ as discussed in subparagraph 2.2.3.

As a result of the foregoing, Dutch pharmacists are deprived of their right to purchase most of the homeopathic stocks they need for *magistral* and *official* preparations. In fact this deprives patients from purchasing those homeopathic medicinal products for which registration or authorisation is not an economically viable option in The Netherlands.

3.7. Conclusion

In conclusion, The Netherlands can be described as a strongly polarised with regard to homeopathy. Furthermore, homeopathy has a rather controversial relationship with the State.

The applicable legislation is divided over four different pieces of legislation which makes it hard to access. Besides the fact that such a regime can be qualified as in-transparent, it does not make a clear distinction between authorisation and registration. In addition, the

⁷⁹ A comparable reasoning is used for the dilutions which need further potentiation by a pharmacist. For example a pharmacist is not allowed to buy an unregistered D29 dilution for the preparation of a D30, a D200 etcetera.

⁸⁰ ECHAMP, *The status of Homeopathic Starting Materials*, supra note 72, pp. 2-3.

⁸¹ The AESGP-report on Herbal medicinal products in the European Union points out that The Netherlands does not have legislation on 'intermediate products' at its disposal; AESGP, 2 Pharmaceuticals Policy and Law 1999, p. 128.

⁸² Supra note 72.

⁸³ Case C-369/88, *Criminal proceedings against Jean-Marie Delattre*, supra note 47, Chapter 2, paragraph 41.

⁸⁴ Supra note 74.

⁸⁵ Supra note 45, Chapter 2.

expanded interpretation of the “guaranteed-safe-requirement” by the Explanatory Memorandum of the Regulation on HPP’s has pushed a significant number of homeopathic medicinal products from the Dutch market. Furthermore, the Dutch authorisation procedure takes too little account of the principles and characteristics of homeopathy in The Netherlands. In effect, there is very little difference with the normal authorisation procedure for medicinal products.

With respect to the application for an authorisation or registration for homeopathic medicinal products, there is no independent Agency. Instead, the Medicine Evaluation Board which was set up for the evaluation of allopathic medicines handles the registration of homeopathic medicines as well, however not without any problems. The under representation of homeopathic specialists in the MEB, and thus the lack of knowledge, is probably the main cause for these problems. In addition, the MEB is unfortunately lax with regard to the creation of special rules for nosodes. The information provided by the MEB however, although it gives some valuable information for applicants, is not always up-to-date and sometimes only available in Dutch. This is especially to the disadvantage of non-Dutch speaking parties, taking into account the low level of accessibility of the Dutch authorisation and registration system.

Finally, the control on the compliance with the legislation is performed by the Dutch Health Care Inspectorate. This has posed additional problems as a result of a *contra-legem* interpretation of the definition of intermediate product, with regard to mother tinctures used as stocks for *magistral* and *official* preparations.

4. The Legislation Applicable in the Future

4.1. Introduction

On the 31st of March 2004, more than two years after the submission of the initial proposals by the Commission,¹ Directive 2004/27/EC² amending the Community code relating to medicinal products for human use, and Directive 2004/24/EC³ on traditional herbal medicines were adopted. The changes brought about by these Directives will come into force on 1 November 2005 as a part of the Community Code initially laid down by Directive 2001/83/EC.⁴ The Dutch legislator is also preparing new legislation in the form of a proposal to put in place a new law on medicinal products (*Geneesmiddelenwet*).⁵

This chapter will assess the registration and authorisation of homeopathic medicinal products in perspective of the future registration and authorisation regimes. It will first consider whether the changes to the existing European legislation brought about by the new legislation can solve the problems discussed in Chapter two. Second, it will analyse the new concepts introduced into Directive 2001/83/EC by the Directives 2004/24/EC and 2004/27/EC. As a third and final topic, it will evaluate the potential influence of the changes to the system in The Netherlands on the registration and authorisation of homeopathic medicinal products.

4.2. Changes to the existing European legislation

4.2.1. The definition of homeopathic medicinal product

Directive 2004/27/EC lays down a number of amendments in respect of the registration and authorisation procedures for homeopathic medicinal products. The first change in this respect regards the definition of homeopathic medicinal product. The new definition reads as follows:

¹ Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (Submitted by the Commission on 26 November 2001), COM(2001)404 final; Proposal for a Directive of the European Parliament and of the Council amending the Directive 2001/83/EC as regards traditional herbal medicinal products (Submitted by the Commission on 17 January 2002), COM(2002)1 final.

² Supra note 21, Chapter 1.

³ Supra note 22, Chapter 1.

⁴ See Article 2(1) of Directive 2004/24/EC and Article 3, paragraph 1, of Directive 2004/27/EC.

⁵ Supra note 23, Chapter 1.

*“Homeopathic medicinal product: 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

The removal of the words ‘*products*’ and ‘*compositions*’ will change the definition of homeopathic medicinal product considerably.⁷ As a consequence, according to Directive 2004/27/EC, there will remain only one possible qualification for homeopathic stocks in the near future. Homeopathic stocks will fall under the denominator ‘*substances*’. In comparison with the current situation as described in subparagraph 2.2.3., the new definition undeniably provides more clarity as it strikes out those words from the definition which are open to multiple interpretations.⁸

4.2.2. The formal scope

The second important change brought about by Directive 2004/27/EC is the replacement of Article 13 of Directive 2001/83/EC. The changes brought about by the new Article 13 concern the removal of the opportunity to abstain from implementing the ‘special simplified registration procedure’ and the expansion of the mutual recognition procedure for regular medicinal products to include registered homeopathic medicinal products, which will be scrutinized in subparagraph 4.2.4. under A. and subparagraph 4.3.2.

The new Article 13 will nonetheless not bring the homeopathic medicinal products registered or authorised before 1994 within the scope of Directive 2001/83/EC. The differentiation between homeopathic medicinal products marketed before 1 January 1994 and those marketed from this date on will therefore remain a major obstacle for the harmonisation of the laws on the registration and authorisation of homeopathic medicinal products.⁹

4.2.3. The material scope

As mentioned above, the clarification of the definition of homeopathic medicinal product will very likely solve the issues that arose with respect to the qualification of homeopathic stocks.

⁶ Article 1(1)(c) of Directive 2001/27/EC.

⁷ Parliament proposed the removal because Directive 2001/83/EC does not define what ‘*products*’ and ‘*compositions*’ are. Moreover, according to Parliament the term ‘*substances*’ “(...) *sufficiently covers all the sources of homeopathic medicinal products.*”, Report, on the proposal for a European Parliament and Council Directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, A5-0340/2002, p. 104.

⁸ Ibid. note 7.

With the introduction of the new definition of homeopathic medicinal product the material scope will also become easier to define.

With reference to the example of the status of the mother tincture as discussed in subparagraph 2.3.3., a mother tincture cannot be qualified as an ‘intermediate product’ under the future regime, because homeopathic stocks form either the starting materials of homeopathic medicines,¹⁰ or they are presented as homeopathic medicinal products. The ‘presentation requirement’ will probably be decisive in this respect.¹¹

Conversely, products which have already been potentised, but which are presented for further preparation have the properties of an intermediate product.¹² However, if these products are not used for the production of bulk products, it is questionable whether this qualification is correct, since the definition of intermediate product only seems to apply to bulk products.¹³

Unfortunately, Directive 2004/27/EC remains silent on the status of intermediate products used for magistral and officinal preparations. This loophole could however be removed quite easily by adding the words ‘*or a preparation mentioned in paragraphs 1 or 2*’ to Article 3(4) of Directive 2001/83/EC, which would then include the *magistral* and the *officinal* formulas in the exemption. Since, according to Article 2(2) of Directive 2001/83/EC, the Directive only applies to industrially produced medicinal products,¹⁴ this remains the most coherent option for filling up the *hiatus*.

4.2.4. The ‘special simplified registration procedure’

A. *Non-implementation of the ‘special simplified registration procedure’*

In respect of the changes brought about with regard to the ‘special simplified registration procedure’, the replacement of Article 13 of Directive 2001/83/EC must be mentioned in the first place. In effect, this replacement has led to the removal of the possibility not to implement the ‘special simplified registration procedure’ provided in the current version of Article 13(2) of Directive 2001/83/EC. The new Article 13(2) will oblige Member States to

⁹ For more information on the differentiation created by the current Article 13 of Directive 2001/83/EC, see subparagraph 2.3.2.

¹⁰ The DG Public Health Protection: Medicinal Products in Belgium, has published a scheme clearly underlining this conclusion. The scheme is available at:

[http://www.afigp.fgov.be/FR%20home/services/homeo/schema\(lien7\).pdf](http://www.afigp.fgov.be/FR%20home/services/homeo/schema(lien7).pdf).

¹¹ Supra note 47, Chapter 2.

¹² A D29 dilution can clearly not be regarded as a homeopathic stock, however it can neither be qualified as a medicinal product if it is not presented as such to final consumers.

¹³ See the Glossary of the guidelines on Good Manufacturing Practices 1998, supra note 66, Chapter 2, p. 140.

introduce a ‘special simplified registration procedure in accordance with Article 14 of Directive 2001/83/EC.

Since none of the original 15 Member States has refrained from implementing the ‘special simplified registration procedure’,¹⁵ the removal of the possibility to abstain from implementing such a registration procedure seems to be of importance only for the new Member States after the enlargement of the 1st of May 2004. Yet, the Community has not published any official information on the implementations of Directive 2001/83/EC in those Member States, which makes it hard to estimate the exact value of the amendment of Article 13(2).

B. Documentation required for a registration

The second change regarding the ‘special simplified registration procedure’ is a small reformulation of the current Article 15.¹⁶ In order to make the documentation required by Article 15 of Directive 2001/83/EC more adequate, the wording of the second and sixth indents will be slightly changed.

Firstly, Article 1(14)(a) of Directive 2004/27/EC will replace the term ‘nature’ with the word ‘use’. The amendment was enclosed on proposal of Parliament and aims at providing a “*clearer meaning*”.¹⁷ The second change to Article 15 regards the removal of the word ‘specimens’ in the sixth indent.¹⁸

Although it is not clear whether these alterations will lead to changes in national implementations, they will at least provide a more comprehensible reading of the requirements laid down in Article 15.

Moreover, it will normally be easier to prove the use of a certain product than to define its nature. On the one hand, the first requirement in principle only requires factual information. On the other hand, the second requirement prescribes more different types of (scientific) information on the properties of a product which prove its homeopathic nature.

C. Access to the ‘special simplified registration procedure’

Directive 2004/27/EC has also introduced a number of changes to the requirements for access to the ‘special simplified registration procedure’ as laid down in Article 14 of Directive

¹⁴ Medicinal products prepared by a pharmacist cannot be regarded as such.

¹⁵ Commission report on the application of Directives 92/73/EEC and 92/74/EEC regarding Homeopathic Pharmaceutical Products, p. 4.

¹⁶ *Supra* note 94, Chapter 2.

¹⁷ The report on the proposal for a Directive amending Directive 2001/83/EC, *supra* note 7, p. 30.

2001/83/EC. However, the new Directive does not provide a direct solution to the main problems encountered: *i.e.* the limitation of the routes of administration, and the different implementations of the concept of ‘guaranteed safe’ as mentioned in subparagraphs 2.5.3. and 2.5.4.¹⁹

Firstly, the requirements posed with regard to the route of administration have not undergone any change, although repeatedly asked for by Parliament and interest groups.²⁰ The Commission does not believe that other routes of administration are equally safe to oral or external routes.²¹ For that reason, it is not willing to allow more routes of administration under the ‘special simplified registration procedure’, but without basing itself on scientific evidence, or practical experience proving that other routes of administration create higher risks.²² As a result of the foregoing, the difficulties related to the registration of other routes of administration which can be deemed safe remain unresolved. The various approaches with respect to the route of administration will thus continue to exist in the Member States,²³ which leads to legal uncertainty for consumers and businessmen according to the Economic and Social Committee in its Opinion on the proposal for Directive 2004/27/EC.²⁴

Secondly, a comparable conclusion can be drawn for the requirement in the third indent of Article 14(1) that the homeopathic medicinal product needs to be ‘guaranteed safe’. The changes presented for Article 14 do not reckon with the different implementations by Member States in respect of the registerable dilutions. Nevertheless, the addition of the possibility for the Commission to amend the third indent of Article 14(1) by means of a the

¹⁸ Article 1(14)(b) of Directive 2004/27/EC

¹⁹ Additional information on the Dutch interpretation can be found in subparagraph 3.4.2.

²⁰ Resolution on the Commission Report, *supra* note 9, Chapter 2, OJ C 359/97-98 [1998]; Report, on the proposal for a Directive amending Directive 2001/83/EC, p. 28; Recommendation for second reading on the common position adopted by the Council with a view to adopting a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use - Committee on the Environment, Public Health and Consumer Policy, A5-0446/2003, p. 17; ECHAMP, *Homeopathic Injectables Homeopathic Injectables, Importance of the parenteral administration of homeopathic and anthroposophic remedies*, pp. 6-7, available at:

http://www.echamp.org/upload/Press/group_3/3_Homeopathic_Injectables_Risks_and_Benefits.pdf;

ECHAMP, *Injectables for Subcutaneous Administration as used in Homeopathic and Anthroposophic Medicine*, Position paper 2003/02, p.3.

²¹ Amended proposal for a Directive amending Directive 2001/83/EC, COM(2003)163 Final, p. 22.

²² *Ibid.* note 21.

²³ Commission report, *supra* note 4, Chapter 1, p. 5.

²⁴ Opinion of the Economic and Social Committee on: the ‘Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use’, OJ C61/6 [2003].

Regulatory Procedure laid down in Article 5 of Decision 1999/468/EC,²⁵ may have a positive impact in the long run.²⁶

The Commission can accordingly use its discretion to set more thorough standards for the concept of ‘guaranteed safe’ with the assistance Standing Committee on Medicinal Products for Human Use.²⁷ It will also provide a good incentive for the industry and interest groups to actively work together with the Commission to improve the scientific foundation of homeopathic medicines.²⁸ All the same, no direct solution is offered for the differentiation in implementation. Moreover, there is no guarantee that the situation will be altered in due time. Therefore, expectant scepticism remains justifiable in this respect.

Unfortunately, the aforementioned procedure will not be available to amend the first indent of Article 14(1), laying down the requirements for the route of administration. It would have provided a good opportunity to allow other routes of administration under the ‘special simplified registration procedure’ on the basis of scientific evidence.²⁹ Furthermore, it would have led to a more pragmatic approach to risk assessment in this regard, since the procedure enhances the dialog between the Commission and the stakeholders.

4.2.5. The ‘authorisation procedure’

The alterations of authorisation procedure can be considered as purely lay-out related. The only two changes that will be introduced are the renumbering of the Articles mentioned in Article 16(1) of Directive 2001/83/EC, and the substitution of the words ‘*toxicological and pharmacological tests*’ with ‘*pre-clinical tests*’. However, according to Article 1(7)(c)(i) of Directive 2004/27/EC the words ‘pre-clinical tests’ mean exactly the same as the pharmacological and toxicological tests.

The amendments do thus not aid to a more visible implementation of the authorisation procedure for homeopathic medicinal products in the Member States.³⁰ Moreover, Article 16(2) continues to exist as a facultative provision. Therefore, the great diffusion between the

²⁵ Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ L184/23 [1999].

²⁶ According to Article 1(13) of Directive 2004/27/EC the following subparagraph shall be added to the first paragraph Article 14 of Directive 2001/83/EC: “*If new scientific evidence so warrants, the Commission may amend the third indent of the first subparagraph by the procedure referred to in Article 121(2).*” This means that the regulatory procedure as mentioned in Article 5 of Decision 1999/468/EC will be applicable.

²⁷ This effectively brings in Comitology for the assessment of the ‘guaranteed-safe-requirement’. Its functionality will be dependent on the level of expertise on homeopathy made available to the Committee, as well as its political considerations; see E. Vos, *Reforming the European Commission: What Role to Play for EU Agencies?*, 37 CML Rev. 2000, pp. 1130-1133.

²⁸ See e.g. Louis Bolk Institute, *supra* note 99, Chapter 2.

²⁹ *Ibid.* note 28.

³⁰ See subparagraph 2.6.1.

various national regimes with regard to the pharmacological, toxicological and clinical data that is required for homeopathic medicinal products which cannot be registered in accordance with the special simplified registration procedure, as described in subparagraph 2.6.2., will remain unchanged.

4.3. New concepts introduced for Directive 2001/83/EC

4.3.1. ‘Homeopathic medicinal product’ or ‘traditional herbal medicinal product’?

Besides the changes to the existing provisions of Directive 2001/83/EC, there will be other new provisions added to Directive 2001/83/EC. Firstly, next to the new definition of homeopathic medicinal product, Directive 2004/24/EC, introduces the definition of traditional herbal medicinal product from the 1st November 2005 on worth. Therewith it expands the scope of Directive 2001/83/EC to traditional herbal medicinal products.

Article 1(29) of Directive 2001/83/EC will provide that a traditional herbal medicinal product is: “*a herbal medicinal product³¹ that fulfils the conditions laid down in Article 16a(1);*”.³² This definition is capable of covering certain products based on herbal substances or herbal preparations which are currently registered or authorised as homeopathic medicinal products.

For example, without going into detail, *Echinacea* Tincture, or certain medicinal products based on St. John’s Wort (*hypericum*) are now registered as homeopathic medicinal

³¹ The future Article 1(30) of Directive 2001/83/EC describes herbal medicinal product as follows: “*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; Article 1(32) of Directive 2001/83/EC defines herbal preparations as: “preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.”; and Article 1(31) of Directive 2001/83/EC will define herbal substances as: “All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);”.*”

³² In other words, traditional herbal medicinal products are those medicinal products which comply with the following criteria:

“(a) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;
(b) they are exclusively for administration in accordance with a specified strength and posology;
(c) they are an oral, external and/or inhalation preparation;
(d) the period of traditional use as laid down in Article 16c(1)(c) has elapsed;
(e) the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.”

products, but they can be registered as traditional herbal medicinal products as well. As a consequence of the factual overlap of the abovementioned definitions, the registration requirements will depend on the denomination of the medicinal product, instead of the physical characteristics.³³ Hence, the overlap makes it in theory possible to market certain medicinal products with two different labels.³⁴ In a number of occasions their application and the therapeutic indication will even be identical. Arnica tincture would be a good example of this, since it is known as a herbal medicinal product, but it is also used externally as a homeopathic medicine on the basis of the *similia principle*.³⁵

Notwithstanding the above, the registration procedures for these “physically similar”³⁶ products will however differ significantly. For the products marketed with a homeopathic indication the authorisation is based on the ‘regular’ regime laid down in Article 16(1) and (2) of Directive 2001/83/EC has to take place, since low dilutions and mother tinctures which are presented as medicinal products cannot make use of the ‘special simplified registration’ procedure for homeopathic medicines.³⁷ Conversely, products marketed as traditional herbal medicinal products will fall under a new simplified registration procedure – better known as the ‘traditional-use registration’³⁸ – laid down in Articles 16a to 16c of Directive 2001/83/EC.³⁹

In practice this means among others that no results from clinical trials have to be submitted for the registration of a ‘traditional herbal medicinal product’, where this would be required if the product was marketed as a homeopathic medicinal product. Such loopholes in the law can lead to form shopping, as manufacturers will search for the cheapest alternative to market their products.⁴⁰

³³ It is true that the production procedure for homeopathic medicinal products in theory differs from the production procedure used for herbal medicinal products, however this will not always be technically measurable in practice. Especially with regard to low dilutions and mother tinctures, the physical differences between the two end-products will often not be measurable. This makes their physical composition equal from a non-homeopathic perspective. For example in case of risk analysis, it will be hard or maybe even impossible to consider the difference between the two products.

³⁴ Sometimes even three labels are possible if the product can also be marketed as food or a food-supplement.

³⁵ Arnica is used to treat contusions, but it can also create inflammations and swelling in undiluted form when it comes into contact with blood.

³⁶ Supra note 33.

³⁷ Article 14(1), third indent lays prescribes as a minimum standard that homeopathic medicinal products may not contain more than 1/10,000th part of the mother tincture, or 1/100th part of the smallest dose of active principles utilized in allopathy for which a doctor's prescription is needed.

³⁸ Article 1(2) of Directive 2004/24/EC

³⁹ Ibid. note 38.

⁴⁰ In The Netherlands for example, the number of products sold as food or food supplements grew considerably after the introduction of Directive 92/73/EC on homeopathic medicinal products, in order to avoid the more stringent requirements.

4.3.2. Introduction of the mutual recognition procedure

The second important new issue introduced is the addition of the following extra sentence to Article 13(1): “*In case of registrations, Article 28 and 29(1) to (3) shall apply.*”⁴¹ The sentence extends the mutual recognition procedure to homeopathic medicinal products which have been registered. Homeopathic medicinal products which have been authorised remain excluded in accordance with Article 39 of Directive 2001/83/EC.

Regrettably, it is not evident whether the term ‘registrations’ only applies to products registered under the ‘special simplified registration procedure’ in Article 14, or if it also applies to products registered before 1994 in accordance with a national procedure. Since the sentence was included in the final text of Directive 2004/27/EC without being mentioned in the preparatory documents submitted by Commission, Parliament and Council, the reasons for its inclusion and its exact meaning remain vague.

The context and the fact that registration is phrased in plural, however strongly suggest that all types of registration will come under the mutual recognition procedure; not only those under Article 14(1) and 15. Moreover, if this interpretation is not correct, the last sentence of Article 13(1) would be obsolete since the new Article 39 of Directive 2001/83/EC already states that the mutual recognition procedure will apply to homeopathic medicinal products registered under Article 14. If the last sentence of Article 13(1) thus wants to add something, it must also cover registrations issued before 1994.

The logical conclusion would therefore be, that homeopathic medicinal products registered on the basis of national legislation before 1994, or registered after this date on the basis of the ‘special simplified registration procedure’, can be subject to the mutual recognition procedure, regardless of their physical characteristics. Conversely, homeopathic medicinal products which are authorised on the basis of Article 16 of Directive 2001/83/EC, or national legislation before 1994, will not be able to benefit from the mutual recognition procedure as laid down in Articles 28 and 29(1) to (3) of Directive 2001/83/EC.

Whether the mutual recognition procedure will improve the free movement of homeopathic medicinal products is nevertheless questionable. The new Article 28(1) of Directive 2001/83/EC does not mention the requirements of Articles 14 and 16. Although Parliament proposed the inclusion of the requirements of Articles 14 to 16 in Article 28(1) to avoid problems,⁴² the Commission and Council did not accept the proposal.⁴³

⁴¹ Article 1(82) of Directive 2004/27/EC.

⁴² The report on the proposal for a Directive amending Directive 2001/83/EC, *supra* note 7, p. 23.

As a result of this omission, it seems as if the documents required for the ‘regular’ authorisation procedure must be submitted for homeopathic medicinal products under the mutual recognition procedure. In that case, the requirements for homeopathic medicinal products would be much more stringent under the mutual recognition procedure than under the ‘special simplified registration procedure’. The requirements for regular medicinal products would however remain the same in both procedures.⁴⁴

Such a provision would run counter to the idea presented in the 21st recital of the preamble of Directive 2001/83/EC, as it does not provide the requirements for a ‘special simplified registration’ under the mutual recognition procedure. The 21st recital namely states that it is desirable to provide a special simplified registration procedure for those products which comply with Article 14(1) of Directive 2001/83/EC, because the normal criteria for authorisation are not fit for these products.

If the omission of the abovementioned Articles really leads to a differentiation in registration requirements, the mutual recognition procedure would only become a theoretical option, since it is virtually impossible for homeopathic medicinal products, which are eligible for registration, to comply with the regular requirements of the authorisation procedure.⁴⁵

Practice will consequently have to show if the ambiguous formulation of the mutual recognition procedure will really provoke problems. Yet chances are reasonable that the issues described above bring about more than just theoretical difficulties.

⁴³ The Commission regarded the proposal superfluous as Article 39 already lays down the requirements for the use of the mutual recognition procedure for homeopathic medicinal products. However, this argument does not take note of the fact that these requirements are inconsistent with the ‘special simplified registration procedure’ (Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products, COM(2003)163 Final, p. 23). According to the Council the Directive does not impose an obligation for mutual recognition of homeopathic medicinal products. Therefore it rejects the proposal of Parliament. It seems a though the Council did not take proper account of the new Article 39 (Common Position (EC) No 61/2003, OJ C 297E/68 [2003]).

⁴⁴ The Authorisation requirements are the same for regular medicinal products under the Authorisation procedure and the mutual recognition procedure. (See Articles 8 to 12 and 28(1) of Directive 2001/83/EC).

⁴⁵ Pharmacological and toxicological data, for example, cannot be prescribed for products which comply with the requirements of Article 14(1).

4.4. Changes to the system in The Netherlands

4.4.1. The Dutch legislation in preparation

The proposal for a new Law on Medicinal Products in The Netherlands is mainly intended to replace the current Law on the Availability of Medicines.⁴⁶ As the major part of the legislation implementing the registration and authorisation of homeopathic medicinal products is laid down in other provisions like the Decree on HPP's and the Regulation on HPP's,⁴⁷ it will not bring about large changes with respect to the registration and authorisation of homeopathic medicinal products in The Netherlands.

Consequently, the greater part of the difficulties that have occurred under the Dutch legislation will not be resolved by the new proposal. Nevertheless, it suggests an interesting change in respect of the definition of a medicinal product, and it provides some information on the position of the Dutch legislator with respect to the interpretation of the (European) definition of medicinal product.⁴⁸

To start with, a new definition of '*homeopathic medicinal product*' is provided which anticipates on the changes in the definition coming into force on 1 November 2005. The new definition does however not seem congruent with the definition introduced by Directive 2004/27/EC.⁴⁹ First of all, the proposal does not contain the word '*substanties*' (substances) in accordance with the Dutch and English language versions Directive 2004/27/EC. Instead it uses the word '*grondstoffen*', which would translate as '*stocks*'.⁵⁰ As a consequence, the definition in the Dutch proposal is inconsistent with the definition of medicinal product in the Directive. Moreover, the distinction between 'substances' and 'stocks' is blurred, since a homeopathic stock always consists of on one or more substances, but a substance is not necessarily a (homeopathic) stock. Although this deviating formulation does not directly bring about difficulties, it undermines clarity and can lead to problems in defining what a homeopathic stock is.

⁴⁶ See for the applicable Dutch legislation paragraph 3.3.

⁴⁷ Ibid. note 46.

⁴⁸ See for more information on the definition of medicinal product as defined by the ECJ, subparagraph 2.2.3.

⁴⁹ The fraction of the liberals has also noticed this inconsistency and posed questions in this regard. See Vaststelling van een nieuwe Geneesmiddelenwet, Verslag, Kamerstuk 2003-2004, 29359, nr. 5, Tweede Kamer, p. 2.

⁵⁰ Vaststelling van een nieuwe Geneesmiddelenwet, supra note 23, Chapter 1, p. 2.

The second inconsistency is the reference in the Dutch legislation to ‘*homeopathisch-farmacaceutische vakliteratuur*’ (homeopathic-pharmaceutical specialist literature).⁵¹ As this reference is not made by in the European definition, the Dutch definition clearly goes beyond the requirements in Article 1(5) of Directive 2001/83/EC.

Notwithstanding the proposal of an incorrect implementation of the definition of homeopathic medicinal product, the legislator gives an interesting insight on the interpretation of the term ‘medicinal product’.⁵² According to the legislator the European definition must be followed in this respect. A clear reference is also made to the ‘presentation requirement’ as laid down by the Court of Justice in *Delattre*,⁵³ as elaborated on in subparagraphs 2.2.3 and 3.6.2. From the abovementioned it can therefore be derived that the incorrect definition medicinal products in respect of mother tinctures employed by the Inspectorate,⁵⁴ is not only in contravention of EU law, but it also contravenes the interpretation of the Dutch legislator.

Considering the fact that the changes proposed by the new Law on Medicinal Products is only of limited importance for homeopathic medicinal products, the possible changes to the current regime will be dependent on the implementation of the newly adopted legislation under Directive 2004/27/EC.

4.4.2. Common Technical Document

Besides the proposal for a new Law on Medicinal Products, the introduction of a Common Technical Document (CTD) by the national agencies in Europe that deal with the registration of homeopathic medicinal products, will very likely make the applications for registration easier.⁵⁵ Since manufacturers will be able to use the same document for an application regardless of the Member State involved, the registration of homeopathic medicinal products will be easier to access and thus more economic.

4.5. Conclusion

In the light of the current regime, the general conclusion on the newly adopted legislation regarding the registration of homeopathic medicinal products needs to be reserved. It can be acknowledged that quite a number of changes have been put through, yet it is questionable if

⁵¹ Questions were posed in this respect as well by the Green party. See *Vaststelling van een nieuwe Geneesmiddelenwet*, Verslag, p. 7, *Ibid.* note 50.

⁵² *Vaststelling van een nieuwe Geneesmiddelenwet*, memorie van toelichting, Kamerstuk 2003-2004, 29359, nr. 3, Tweede Kamer, pp. 25-26.

⁵³ *Ibid.* note 52. See also *Supra* note 47, Chapter 2.

⁵⁴ See subparagraph 3.6.2.

⁵⁵ E. van Galen, *supra* note 56, Chapter 3, p.6.

these changes will significantly reduce the number of problems encountered by the current regime. Moreover, there is a reasonable risk that new difficulties will come up because of unclear or inconsistent drafting of the new provisions.

More in specific, the new definition of homeopathic medicinal product deserves a warm welcome. Not only will it provide more clarity, but it will also give a better indication of the exact material scope of Directive 2001/83/EC. Consequently, there is a good chance that the problems regarding the status of the mother tincture will belong to the past. However, the new legislation does not clarify the status of ‘intermediate products’ used for magistral and officinal preparations. As a result the material scope of Directive 2001/83/EC will remain at least a little vague.

Furthermore, the ‘special simplified registration procedure’ will no longer be optional. It is not clear whether this will effectively lead to any changes as all ‘original’ Member States had already implemented it, and there is not information available on the implementations in the new Member States. Nonetheless, from the point of view of harmonisation it is a good development.

In addition the procedure creating the possibility to amend the safety requirements for the ‘special simplified registration procedure’ in the third indent of Article 14(1) of Directive 2001/83/EC, and the partial reformulation of Article 15 are in principle favourable towards homeopathic medicinal products, as they clearly react to practical problems encountered under the current version of these Articles. Unfortunately, the abovementioned procedure has not been introduced for the ‘route of administration requirement’, which remains unchanged. Consequently, products that are not applied orally or externally remain excluded from the ‘special simplified registration procedure’ even if it can be proven that they are sufficiently safe.

Notwithstanding the positive changes adopted by Directive 2004/27/EC, there are also a large number of problems which remain unchanged. First of all, the formal scope of Directive 2001/83/EC does not change, which aids to the differentiation between homeopathic medicinal products marketed before 1994, and those marketed afterwards. Subsequently, the authorisation procedure has not been changed which leave the implementations in the several Member States indistinct and the adoption of special authorisation requirements optional. As a result, the authorisation procedure remains not transparently and diffusely implemented.

With regard to the newly introduced provisions, the introduction of the mutual recognition procedure is a step in the right direction. However, just as the possibility to amend the guaranteed-safe-requirement, the amendment does not directly secure the improvement of

the practical situation currently encountered. Moreover, its vague formulation is likely to produce new difficulties. Additional problems can be expected because of the practical overlap of the definitions of homeopathic medicinal product and traditional herbal medicinal product.

The influence of the new Dutch legislation on the current problems has to be qualified as minimal, since the proposal for a new Law on Medicinal Products does barely cover the licensing of homeopathic medicinal products. To the contrary, the adoption of the Common Technical Document (CTD) will clearly aid to a better accessibility and more cost efficiency of applications for authorisation or registration.

In sum, although there have been a number of positive developments in favour of further harmonisation of the laws on the licensing of homeopathic medicinal products, a significant number of the problems observed in the second and third chapter remain unresolved. In addition, potential new problems are created by the introduction of the mutual recognition procedure and the definition of traditional herbal medicinal product.

5. To harmonise or not to harmonise? That's the question

The registration and authorisation of homeopathic medicinal products is a complex procedure, which is undeniably necessary to improve the quality and safety standards for these products. No reasonable person will therefore reject the idea of proper quality and safety control. However, the patients, practitioners and manufacturers should not be the ones to suffer from the practical drawbacks that have come along with the introduction of the registration legislation.

The third recital of the preamble of Directive 92/73/EEC states: “ (...) *patients should be allowed access to the medicinal products of their choice, provided all precautions are taken to ensure the quality and safety of the said products*”. To provide such free access, a reliable risk-benefit analysis should be adhered to. However, the risks and benefits need to be balanced in accordance with the general principles and characteristics of homeopathy in Europe.

In contrast to traditional herbal medicinal products however, homeopathy cannot legally base itself on its longstanding tradition to replace the requirement of proof of therapeutic efficacy, which is at least strange given the fact that a large number of the homeopathic medicines have been used for over 200 years now. No therapy is devoid of risks. Yet the risk benefit analysis applied to homeopathic medicinal products takes too little account of the long and comparatively safe use of homeopathic medicines. On top of that, there is virtually no evidence that homeopathic medicines pose direct significant risks to public health or consumers in general.

The previous chapters have discussed the different aspects of the registration and authorisation of homeopathic medicinal products in the EU and The Netherlands. On the basis of that analysis, the main question underlying this thesis whether the free movement of homeopathic medicinal products will be attained in the near future, needs to be answered.

From the foregoing analysis we may conclude that the Single Market for homeopathic medicinal products is still far from being attained. There are numerous problems that will have to be encountered before we can really speak about the free movement of homeopathic medicinal products. Among these problems the lack of clarity with regard to the material scope, the exemption of products marketed before 1994, the unclear formulation of the ‘guaranteed-safe-requirement’, the limitation to the routes of administration, and the differentiation in pharmacological, toxicological tests and clinical data requirements form the

major barriers to trade. The Dutch approach connected to the status of the mother tincture, the absence of references to the principles and characteristics of homeopathy in The Netherlands, and the practical ban imposed on certain products like nosodes, form practical examples of these problems.

Moreover, the European legislator has not been able to effectively stand up to most of these difficulties in respect of the changes it introduced for the near future. The conclusion of the Commission, already drawn in its Report of 1997 on the application of Directives 92/73/EC and 92/74/EEC, therefore remains valid: “*a certain but not yet satisfying degree of harmonisation has been achieved.*”¹ In other words, the European legislator has failed to produce a piece of legislation that is capable of effectively harmonising the registration of homeopathic medicinal products within the EU.

To overcome the problems encountered, the future legislation should be shaped from the bottom up. The introduction of a Comitology procedure for the potential amendment of the guaranteed-safe-requirement as laid down in Article 14 forms a good start. As a primary goal in this respect, the regulation of homeopathic medicinal products should be brought further in line with the general principles and characteristics of homeopathic medicine in order to resolve the practical problems at issue.

Keller stated that a strong political will is needed to effectively regulate the registration of homeopathic medicinal products.² In contrast to Germany, this political will has not yet displayed itself in the EU. Europe lingers on as it takes too little account of the practical issues at stake. Although it would be incorrect to label the provisions of Directive 2001/83/EC on the registration of homeopathic medicinal products as merely hollow phrases, it does not attain real harmonisation. The implementation and the problems it has provoked in The Netherlands only underline this conclusion.

¹ Commission report, *supra* note 4, Chapter 1, p. 8.

² K. Keller, *supra* note 54, Chapter 2, p. 803.

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