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# **Anthroposophic Use**

*Rüdiger Zuck*

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## I. What is anthroposophic use about?

### 1. Formulation of the question

#### *a. What does anthroposophic use mean?*

With the concept anthroposophic use, the International Federation of Anthroposophic Medical Associations (IVAA) has expressed anthroposophic medicine's pursuit of legal recognition in analogy with the "homeopathic use" of article 15 phrase 2, 2nd hyphen of Directive 2001/83 EC (Official Gazette L 311, p.67). As shown by the German translation ("homeopathic character"), "anthroposophic use" is meant to describe the characteristics of anthroposophic medicine. At the same time, the analogy with "homeopathic use" highlights the fact that this description is associated with the demand for a degree of legal recognition comparable to that granted to homeopathy in Directive 2001/83 EC, taking into consideration the specific qualities of anthroposophic medicine.

#### *b. Formulation of the question under European Law*

As indicated by the term "anthroposophic use", we are dealing with issues under European law based on Directive 2001/83 EC. The starting point is article 6 paragraphs 1 of Directive 2001/83 EC, according to which a medicinal product may only be placed on the market under the condition that it has been authorised. Chapter 2 of Directive 2001/83 EC (articles 13 ff) contains specific regulations for homeopathic medicinal products. Subject to the fulfilment of certain requirements, homeopathic medicinal products may also be submitted to a specific simplified registration procedure (article 14 paragraph 1 of Directive 2001/83 EC). In the meantime, Directive 2004/24 EC (Official Gazette EC no. L136, 85) amending Directive 2001/83 EC, has introduced a simplified registration procedure as well for traditional herbal medicinal products (chapter 2a, articles 16a ff).

According to recital 22 of Directive 2001/83 EC, anthroposophic medicinal products "described in an official pharmacopoeia<sup>1</sup> and prepared by a homeopathic method are to be treated, as regards registration and marketing authorisation, in the same way as homeopathic medicinal products".

Admittedly, this equality is not to be found in the wording of articles 13 ff of Directive 2001/83 EC. According to settled case law of the ECJ however, the reasons leading to a legally relevant act are to be taken into consideration when it comes to its interpretation.<sup>2</sup> As articles 13 ff of Directive 2001/83 EC, in suggesting a link with the term homeopathic medicinal products, refer to such medicinal products prepared according to a homeopathic

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<sup>1</sup> Under German law, an "official pharmacopoeia" is a collection of recognised pharmaceutical regulations published by the Federal Ministry of Health (§ 55 paragraph 1 German Medicines Act AMG), passed either by the German Pharmacopoeia Commission, the European Pharmacopoeia Commission (§ 35 paragraph 2 phrase 1 AMG) or the German Homeopathic Pharmacopoeia Commission (§ 55 paragraph 6 AMG).

<sup>2</sup> ECJ, judgement of 2000-06-13 – T-204/97 and T-270/97 – EPAC, collection 2000, II-2267, margin number 39; see *Borchardt*, in: Schulze/Zuleeg (eds.), *Europarecht*, 2006, no.15, margin numbers 40 ff, 45. General commentary on the recitals of the TEU preamble *Hilf/Pache*, in: Grabitz/Hilf (eds.), *Das Recht der Europäischen Union*, vol. I, as of 2004, TEU preamble, margin numbers 5 ff.

manufacturing procedure and described in an official pharmacopoeia, the equality is already inherent in Directive 2001/83 EC. Recital 22 therefore does not serve as an (inadmissible) original source of law, but rather as a provision clarifying the contents of articles 13 ff of Directive 2001/83 EC.

Articles 16a ff of Directive 2001/83 EC extends the simplified registration procedure to anthroposophic medicinal products capable of being described as traditional herbal medicinal products.

As a result, however, a loophole in anthroposophic use becomes apparent. Beside the three case groups “registration/authorisation”, “simplified registration according to homeopathic rules” and “simplified registration as a traditional herbal medicinal product”, there is a fourth category comprised of such anthroposophic medicinal products that cannot be allocated to any of these three groups. This fourth group represents the focal issue of anthroposophic use.

## 2. Specific qualities of anthroposophic medicine

### *a. Recognised specific therapeutic approach*

Like homeopathy, anthroposophic medicine as a specific therapeutic approach represents a form of minority medicine, partially ridiculed, partially antagonised and only occasionally taken seriously by conventional (scientific) medicine. Jurists do not have an Archimedean point from which to intervene in the dispute of medical approaches and schools.<sup>3</sup> They can only discuss the legal framework within which this debate must take place as far as legal matters are concerned. In German law, the legal framework is based on the fact that anthroposophic medicine has been expressly recognised (among others) as a specific therapeutic approach by the legislator of SGB (German Social Security Code) V and AMG (German Medicine Law) respectively.<sup>4</sup> This circumstance also impacts the methodological discussion between anthroposophic medicine and conventional medicine.<sup>5</sup> At international level, however, anthroposophic medicine faces the problem that its acceptance – in both factual and legal terms – is widely different in the individual countries.<sup>6</sup> From a European law perspective, it is therefore quite difficult to find a common (possibly the smallest common) denominator.

### *b. Consideration under European law*

A legal approach is always an approach from outside. The inside perspective, capable of being summarised in the (much misunderstood) concept of internal recognition<sup>7</sup>, is superimposed by general, universally binding criteria. The fact that this takes place based on the regulations of European law is not only enforced by the suggested link of anthroposophic use, but above all by the fact that German medicinal product law has come to be largely based on European legal foundations. Though this restricts the possibilities of a legal assessment

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<sup>3</sup> Federal Social Court 81, 54 (69). See *Zuck*, in: *Quaas/Zuck, Medizinrecht 2005*, §11, margin number 116.

<sup>4</sup> See *Zuck*, *Die anerkannten besonderen Therapierichtungen*, *NZS 1999*, 313.

<sup>5</sup> Cf. the articles referring to the focal topic *Pluralism in Medicine – Pluralism of Therapy Evaluation*, in: *ZaefQ 99 (2005)*, 257 ff; *Zuck*, *Der verfassungsrechtliche Rahmen von Evaluation und Pluralismus*, *MedR 2006*, 15. From the methodological perspective of anthroposophic medicine see *Kiene*, *Komplementäre Methodenlehre der klinischen Forschung*, 2001; *Kienle/Kienel/Albonico*, *Anthroposophische Medizin in der klinischen Forschung*, 2006 (English version: *Anthroposophic Medicine*, 2006).

<sup>6</sup> See the comprehensive overviews in *Maddalena*, *Alternative Medicines: On the Way towards Integration? A Comparative legal Analysis in Western Countries*, 2005, 64 ff, 280 ff.

<sup>7</sup> Cf. in detail *Zuck*, in: *Quaas/Zuck, Medizinrecht*, 2005, § 11, margin numbers 118 ff

under German constitutional law<sup>8</sup>, a free and democratic constitutional structure at European level also requires free debate, a marketplace of ideas and hence the acknowledgement of pluralistic structures.<sup>9</sup> The need to harmonise diverging social views and their respective legal frameworks at EU level and the regulation requirements associated with this need, must therefore neither destroy nor endanger the singularities of individual European Union Member States. These singularities must not be overlooked either if the individual (market) citizen's health is concerned.

### 3. The term anthroposophic medicinal product

In the first instance, the following comments take a closer look at the term anthroposophic medicinal product.

## II. What is an anthroposophic medicinal product?

### 1. Definitions

#### a. APC (Anthroposophic Pharmaceutical Codex)

The APC<sup>10</sup> provides the following description:

##### *“1. Definition*

*An anthroposophic medicinal product is conceived, developed and produced in accordance with the anthroposophic knowledge of man, nature and substance.*

*An anthroposophic medicinal product can contain one or more active substances.*

*An anthroposophic medicinal product can fundamentally be employed in every dosage form, including external (topical), internal and parenteral dosage forms.*

*The active substances or dosage forms of anthroposophic medicinal products are produced:*

- in accordance with classical homeopathic or anthroposophic-homeopathic manufacturing methods as described in the Ph. Eur., HAB, Ph. Fr. or*
- in accordance with specific anthroposophic production methods.”*

#### b. Swiss law

Under Swiss law, the anthroposophic medicinal product is understood as a medicinal product conceived, developed and produced in accordance with the anthroposophic knowledge of man, nature and substance.

The regulation of Swiss Medic (Medicines Evaluation Authorities) on the simplified market authorisation of complementary and herbal medicinal products<sup>11</sup> defines anthroposophic medicinal products as follows in article 4 phrases 1 et seq.:

*“Medicinal products, the active substances of which are produced according to a homeopathic manufacturing procedure, an anthroposophic manufacturing method described in HAB or British Hom.P or a specific anthroposophic manufacturing method, and which are*

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<sup>8</sup> Zuck, Homöopathie und Verfassungsrecht, 2004.

<sup>9</sup> Zuck, Das Recht der anthroposophischen Medizin, 2007, preface.

<sup>10</sup> Anthroposophic Pharmaceutical Codex of the International Association of Anthroposophic Pharmacists (IAAP) in the version 7/2005. In respect of anthroposophic medicine in general Burkhard, Anthroposophische Arzneimittel – Eine kritische Betrachtung, 2000; Kohlhasse, Grundlagen Anthroposophischer Pharmazie, in: M. Glöckler, Anthroposophische Arzneitherapie für Ärzte und Apotheker, as of 2005, 2 – 1 ff.; Simon, Methodik der Arzneimittelfindung, in: M. Glöckler, Anthroposophische Arzneitherapie für Ärzte und Apotheker, as of 2005, 3 – 1 ff.; IAAP (ed.), Basic Information on the Working Principles of Anthroposophic Pharmacy, 2nd edition, 2005; Zander, Anthroposophie In Deutschland, vol.2, 2007, 1455 ff.

<sup>11</sup> Ordinance on Complementary and Phyto-Medicinal Products, KPAV (SR 812.212.24) of 2006-06-22.

*composed or developed in accordance with the principles of anthroposophic knowledge of man, animal, substance and nature and designed for use according to these principles.”*

## **2. Content of the definition**

Every definition needs to make a distinction. Recourse to the anthroposophic self-concept does not really achieve this distinction, as the premises of this self-concept themselves are in need of explanation. The various substances and areas of application do not differ from the ones of conventional medicinal products and homeopathic medicinal products. What comes into consideration in the first instance is therefore the specific manufacturing procedure, although there is a significant degree of overlapping with homeopathic medicinal products. A truly differentiating distinction would result from complementing the “definition” under Swiss law by the additional specification that anthroposophic medicinal products are designed for application according to the principles of anthroposophic medicine. In this respect, the specific qualities and the autonomy of anthroposophic medicine constitute the medicinal product as an anthroposophic medicinal product. This however, is associated with a problem that lets one understand why the APC has (hitherto) refrained from this kind of additional specification. For this specification could well be understood in such a way as though use of the anthroposophic medicinal product ought to be limited to treatment in compliance with the rules of anthroposophic medicine. Strictly speaking, this would result in a situation where the medicinal product’s effectiveness depended on the respective method of treatment. The medicinal product would thus be defined no longer by its (identical) content but by its function. The result would be that any use of anthroposophic medicinal products in conventional medicine as well as any prescription of anthroposophic and homeopathic medicinal products outside their respective therapeutic approach would be ruled out – contrary to common practise. The amendment under Swiss law must therefore not be understood as an exclusion criterion. Instead, it refers to the precondition, underlying the production process, that the medicinal product is to be conceived and developed as an anthroposophic medicinal product. This does not imply any statement on its possible use (though it may be an essential element of treatment in the framework of anthroposophic medicine).

## **III. Simplified Registration of Anthroposophic Medicinal Products at European / German Level**

### **1. Legal background**

#### *a. European Law*

In its definition of terms, Directive 2001/83 EC does not mention anthroposophic medicine. Recital 22, however, states that under certain premises, anthroposophic medicinal products are to be treated in the same way as homeopathic medicinal products (see above).

#### *b German Law*

##### *aa. Preliminary Note*

When it comes to homeopathic and anthroposophic medicinal products, German law (AMG) provides the following possibilities:

- Homeopathic medicinal products *without an indication* can be registered according to §§ 38, 39 AMG. Homeopathic medicinal products *with an indication* are authorised according to the general marketing authorisation regulations of §§ 21ff AMG however, the scientific documentation has to be evaluated according to the expertise and experience of the respective specific therapeutic approach (§§ 21ff AMG in connection with section 1 (7) of the evaluation guideline);

– Anthroposophic medicinal products *with or without an indication* that are prepared by a homeopathic method and described in an official pharmacopoeia (HAB, Pharm.Eur.), are treated, as regards registration and marketing authorisation, in the same way as homeopathic medicinal products;

- In addition, anthroposophic medicinal products in case they comply with the requirements of §§ 39a, 39b AMG can be registered as traditional herbal medicinal product with an *officially defined indication*;

Anthroposophic medicinal products, not prepared according to a homeopathic manufacturing procedure, fall under general marketing authorisation regulations of §§ 21ff AMG and are therefore not subject to any particularity in this respect. This applies to around 30 % of all anthroposophic medicinal products, so called “Anthroposophika”.

For anthroposophic medicinal products, the simplified registration procedure therefore comes into consideration only under the restriction of “Description in an official pharmacopoeia / prepared in accordance with a homeopathic manufacturing procedure”. The German Homeopathic Pharmacopoeia (HAB) does not contain an exhaustive description for the preparation of anthroposophic medicinal products. Anthroposophic medicinal products primarily contain natural materials of mineral, herbal or animal origin: they are partially prepared according to a homeopathic manufacturing procedure.<sup>12</sup> In this respect, one distinguishes between anthroposophic medicinal products prepared according to a homeopathic manufacturing procedure and so-called “Anthroposophika”, i.e. such anthroposophic medicinal products that are not prepared according to a homeopathic manufacturing procedure (in the following called “Anthroposophika”).<sup>13</sup>

## bb. Anthroposophic Medicinal Products

If an anthroposophic medicinal product does not meet the requirements of article 1 no. 5 and recital 22 of Directive 2001/83 EC, it cannot be subject to (simplified) registration because §§ 38, 39 AMG only permit registration of medicinal products that are manufactured according to a procedure described in the homeopathic section of the pharmacopoeia<sup>14</sup> (§ 39 paragraph 2 no. 7 AMG). The very reference to the “homeopathic section”, meaning the HAB, therefore rules out a registration of “Anthroposophika”. The Anthroposophic Pharmaceutical Codex (APC) has not been compiled by a commission recognised by the legislator. It therefore does not represent an “official” pharmacopoeia (see footnote 1) and is ruled out as a basis for registration. Given its comprehensive structure, however, it can be considered as a collection of pharmaceutical regulations – recognised by anthroposophic medicine – “concerning quality, examination, storage, distribution and term of medicinal products as well as of materials used in the course of their production” (§55 paragraph 1 phrase 1 AMG). As the HAB already contains sections on anthroposophic medicinal products prepared in accordance with homeopathic manufacturing procedures, it seems appropriate in the future to

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<sup>12</sup> *Kohlhase*, Grundlagen Anthroposophischer Pharmazie, in: M. Glöcker, Anthroposophische Arzneitherapie für Ärzte und Apotheker, as of 2005, 2-10 et seq.

<sup>13</sup> See APC as of 7/2005 (margin number 9).

<sup>14</sup> A pharmacopoeia is a collection of recognised pharmaceutical regulations published by the Federal Ministry of Health (BMG) (§55 paragraph 1 AMG), see footnote 1.

complement the HAB by a section on anthroposophic medicinal products as presented in the APC.

cc. Traditional herbal medicinal products

As far as the anthroposophic medicinal product contains material of herbal origin and, at the same time, complies with the definition of terms for traditional herbal medicinal products (§4 paragraph 29 AMG/§39b paragraph 1 no. 4 AMG), it can be registered pursuant to §§ 39a ff AMG.<sup>15</sup>

## 2. Significance of Directive 2001/83 EC

To find the right criteria for legal assessment under European law, it must be clarified whether or not Directive 2001/83 EC represents an exhaustive regulation. This is of relevance to both European law and national law.

### a. Interpretation Criteria

The provisions of secondary Community legislation may take precedence over provisions of primary legislation (in this case: art. 28, 30 of the Treaty on European Union TEU) provided that secondary legislation harmonises a field of law on an exhaustive basis.<sup>16</sup> In any such case, national legal provisions are also to be assessed on the basis of Directive 2001/83/EC and not on the basis of primary legislation. In both cases it is not ruled out that primary legislation does play a role – on the one hand, if provisions of secondary legislation are to be construed in the light of primary legislation and, on the other hand, in cases where provisions of secondary legislation expressly refer to primary legislation. Finally, it must be noted that even absolutely harmonised secondary legislation has to remain in compliance with the provisions of primary legislation, i.e. must not contradict primary legislation.

### b. Directive 2001/83 EC as an exhaustive harmonisation regulation?

#### aa. Recitals

In actual fact, any assumption of exhaustive harmonisation is ruled out by recital 14 of Directive 2001/83 EC stating:

*“This Directive represents an important step towards achievement of the objective of the free movement of medicinal products. Further measures that may abolish any remaining barriers to the free movement of proprietary medicinal products will be necessary in the light of experience gained, particularly in the abovementioned Committee for Proprietary Medicinal Products.”*

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<sup>15</sup> On the (difficult) differentiation between registration and “Nachzulassung” (authorisation procedure for medicinal products already on the market) cf. *Winnands*, A&R 2006, 159; *Heßhaus*, PharmR 2006, 138; *Krüger*, PharmR, 572. Beside active ingredients of herbal origin, herbal medicinal products may also contain vitamins and/or minerals complementing the effect of herbal active ingredients, provided there is sufficient evidence for their unobjectionability. Medicinal products with purely mineral ingredients or ingredients of animal origin cannot be traditional herbal medicinal products within the meaning of §§ 39a ff AMG.

<sup>16</sup> Final motion of Chief Public Prosecutor Stix-Hackl in legal case C-322/01 – German Pharmacist Association, registered association, vs. DocMorris and others, collection 2003, I-14899, margin numbers 48 ff with reference to ECJ, collection 1989, 3891, margin number 28; collection 1993, I-4947, margin number 9; collection 2001, I-9897, margin number 32; collection 2002, I-9375, margin number 18.

This is confirmed by Directive 2004/24 EC of the European Parliament and of the Council amending, as regards Traditional Herbal Medicinal Products, Directive 2001/83/EC on the Community Code relating to Medicinal Products for Human Use, which states in recitals 6 and 13:

*“(6) The vast majority of medicinal products with a sufficiently long and coherent tradition are based on herbal substances. It therefore seems appropriate to limit the scope of the simplified registration procedure **in a first step** (not underlined in the original) to traditional herbal medicinal products. ...”*

*“(13) The Commission should present a report on the application of the chapter on traditional herbal medicinal products to the European Parliament and to the Council including an assessment on the possible extension of traditional-use registration to other categories of medicinal products.”*

Art. 16i of Directive 2001/83 EC specifies this:

*“Before 30 April 2007, the Commission shall submit a report to the European Parliament and to the Council concerning the application of the provisions of this chapter. The report shall include an assessment on the possible extension of traditional-use registration to other categories of medicinal products.”*

So far, the report exists only as a draft, at the end of which the following is set out:

*“In this regard, the European Commission is of the view that the extension of the simplified registration procedure to other products than herbal substances with a long tradition of safe use could be considered. On the other hand, the key requirements of the simplified registration procedure based on public health considerations, such as the limitation to products with 15 years use in the Community, to certain routes of administration and to products which do not need the supervision of a medical practitioner, should be maintained. For certain of these requirements, more experience is needed before any change to the system could be proposed. In any event, the Commission continues to be dedicated to working towards mutual recognition of authorisations under the existing legal framework.*

*The extension proposed would enable certain anthroposophic, Ayurvedic and traditional Chinese medicinal products, as well as traditional products of a long standing tradition in the European Union such as honey, royal jelly, propolis or fish oils, to be eligible to benefit from a simplified registration procedure with a view to their placing on the market as traditional medicinal products. Many of these products are present in the Community market, and their inclusion under the simplified registration procedure will introduce harmonisation in a sector where differences as regards classification and placing on the market currently exist between the Member States and will increase the protection of public health since the quality, safety and efficacy of the products concerned will be assessed during the simplified registration procedure.”*

#### bb. ECJ legal practise

The circumstance that Directive 2001/83 EC does not represent exhaustive harmonisation regulation is confirmed by ECJ legal practise as outlined below.

In the DocMorris ruling, the ECJ stated that article 30 TEU (Treaty on European Union) continues to apply as long as harmonisation of national rules in this area had not been completed,<sup>18</sup> and added: “In that regard, it should be noted that the sale of medicinal products

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<sup>18</sup> ECJ, C-322/01, collection 2003, I-14951, margin number 102; collection 1989, 617, margin number 15 – Schumacher; collection 1991, I-1487, margin number 48 – Delattre; collection 1991, I-1147, margin number 26 – Eurim-Pharm; collection 1992, I-2575, margin number 10 – Commission/Germany; collection 1994, I-5243, margin number 14 – Ortscheit.

to end consumers has not been subject to full Community harmonisation.”<sup>19</sup>

By contrast, the statement of Advocate General Bot of 2007-05-24 in the ECJ preliminary ruling procedure, legal case C-84/06 – The Netherlands/Antroposana takes the position that Directive 2001/83 EC represents complete harmonisation of existing national regulations and previous European Directives. Somewhat inconsequentially however, the statement then continues:

*“62. Or, nous pensons que l’existence d’une harmonisation complète dans un domaine donné ne signifie pas que celui-ci fait l’objet d’une harmonisation figée, définitive. Autrement dit, le caractère exhaustif de l’harmonisation ne nous paraît pas être incompatible avec le caractère évolutif de cette dernière.*

*63. Dans une matière telle que celle qui nous occupe ici, il est bien évident qu’une évolution de la réglementation communautaire à intervalles réguliers est indispensable et même inévitable compte tenu du progrès scientifique et des enseignements tirés de la mise en œuvre pratique de la norme juridique.”*

The thesis implied in this statement that, as scientific knowledge changes, the corresponding law should be alterable as well (i.e. not considered as completely harmonised), takes up the general aspect of causal rebus sic stantibus. On this basis, exhaustive harmonisation would be ruled out in principle. This, however, cannot be the decisive factor, as the legislator itself understands its measure only as a “first step” (see footnote 17). Consequently, the corresponding legal regulation can only be understood as the beginning of a process, i.e. precisely not as complete harmonisation. This view is shared by the German Federal Government and pointed out in the statement of 2006-05-18 in proceedings C-84/06 under margin numbers 12 ff:

*“The introduction of the simplified procedure took place step by step. The original Council Directive 65/65/EEC of January 26, 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products stipulated:*

*Such approximation can only be achieved progressively; priority must be given to eliminating the disparities liable to have the greatest effect on the functioning of the common market.’*

*Harmonisation was afterwards extended only step by step. Not all medicinal products therefore came under its area of application from the outset.*

*Subsequently, the Second Council Directive 75/319/EEC of May 20, 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products was passed, which among other things included new supervision requirements and provided for the instalment of a Proprietary Medicinal Product Committee. The recitals of this Directive contain the following passage:*

*‘Whereas, moreover, the provisions of this Directive and that of Directive 65/65/EEC which relate to medicinal products, although appropriate, are inadequate for vaccines, toxins and serums, medicinal products based on human blood or blood constituents, medicinal products based on radio-active isotopes and homeopathic medicinal products; whereas the application thereof should consequently not be imposed at the present time in respect of such medicinal products.’*

*Given the particularities of certain medicinal products, comprehensive applicability of the marketing authorisation procedure provided for in the Directive to all types of medicinal products was not envisaged from the outset. For that reason, article 34 stipulated that the Directive shall not apply to these medicinal products. The European legislator has thus taken into consideration beforehand that certain medicinal products, though they do fall under the*

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<sup>19</sup> Collection 2003, I-14951, margin number 102 – DocMorris. This is also confirmed by ECJ, collection 2005, I-5141, margin number 58 – HLH Warenverkehrs GmbH et alia, stating that Member States can no longer take national measures in the framework of article 30 TEU in areas *already harmonised* by Directive 2001/83 EC reaches.

*Directive's definition of medicinal products, should nonetheless not be subject to its regulatory regime. The obvious purpose of this arrangement was that, as the Directive does not sufficiently take the particularities of these medicinal products into account, national marketing authorisation procedures should continue to be applicable.*

*Council Directive 89/342/EEC of May 3, 1989, extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins, serums and allergens, then provided for an additional 'extension of applicability' as implied in the heading of the Directive. According to this concept, the Directive had previously not been applicable to such medicinal products, although the aforementioned products are medicinal products pursuant to the definition of Directive 65/65/EC. In turn, the Directive took the particularities of immunological medicinal products into account and provided specific proof and marketing authorisation criteria for them.*

*This extension also makes clear that the Directive did not have a universal character from the outset, but saw its applicability extended step by step, taking into account the particularities of the respective medicinal products" (see below margin number 26).*

cc. Is there a block on harmonisation?

In consideration of article 152 TEU, it must remain an open question how far harmonisation can reach as a matter of principle. What is certain however, is that complete harmonisation is ruled out. Though article 152 paragraph 4c TEU permits incentive measures designed to protect and improve human health, it expressly forbids harmonisation by stating "excluding any harmonisation of the laws and regulations of the Member States". In addition, article 152 paragraph 4 phrase 1 TEU states: "Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care." However, it is not entirely clear what this subsidiarity block really means. On the one hand, the Commission has noted with respect to the application of Community law in the medicinal product sector: "Functioning of the common market and provision of a high level of public health protection remain the primary and inseparable objectives of this legislation."<sup>20</sup> Directive 2001/83 EC itself however, is based on article 95 TEU. As far as health protection measures also affect fundamental freedoms, i.e. mainly the free movement of goods as far as the medicinal product sector is concerned; ECJ legal practise shows that the complete guarantee of freedom shall take precedence over the Community's limited competence in the field of public health. The harmonisation block of article 152 TEU remains without effect in this sector. This would prove to be of relevance, should incomplete harmonisation in Directive 2001/83 EC turn out to be a deficiency inconsistent with Community law.

dd. Consequences

Consequences from incomplete harmonisation by Directive 2001/83 EC can be drawn in two directions. On the one hand, it remains for the Member States to decide on which legislation they wish to enact in the non-harmonised area. The question of whether there should be a simplified registration and/or marketing authorisation procedure for anthroposophic medicinal products and how such procedures should be worked out is to be decided at a national level and is consequently subject to national legal standards and domestic jurisdiction. As regards European law, however, the question arises whether incomplete harmonisation in respect of

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<sup>20</sup> Commission Proposal KOM (2001) 404 of 2001-11-26; cf. *Bardenhever-Rating/Niggemeier*, in: v. der Groeben/Schwarze (eds.), *Vertrag über die Europäische Union und Vertrag zur Gründung der Europäischen Gemeinschaft*, vol. 3, 6th edition 2003, margin note 31 on article 152 TEU with footnote 81.

anthroposophic medicinal products may well be a continuously desired loophole, and, if that is the case, whether this is compatible with fundamental freedoms and European protection of fundamental rights. In addition, the question arises whether, in the event of a merely temporary loophole, filling of this loophole can be demanded on legal grounds. Both questions play a significant role in the preliminary ruling procedure before ECJ, legal case C-84/06 – The Netherlands/Antroposana. Upon submission by the Hoge Raad de Nederlanden, the ECJ is to answer the following questions:

*“1. Does Directive 2001/83 EC of the European Parliament and the Council of November 6, 2001, on the Community Code relating to Medicinal Products for Human Use, oblige Member States to make anthroposophic medicinal products which are not at the same time homeopathic medicinal products subject to the requirements in respect of authorisation as set out in Chapter 1 of Title III of that Directive?”*

*2. If the answer to question 1 is in the negative: is the Netherlands statutory provision which makes those anthroposophic medicinal products subject to the aforementioned requirements in respect of authorisation an exception to the prohibition under Article 28 EC which is authorised by virtue of article 30 EC?” (also see margin number 24).*

### **3. Legal Assessment**

#### *a. European Law*

##### *aa. Legal policy*

Directive 2001/83 EC provides for three different procedures. According to chapter 1, there is a general marketing authorisation procedure for putting medicinal products on the market. Chapter 2 regulates a specific simplified registration procedure for (homeopathic and anthroposophic) medicinal products prepared according to homeopathic manufacturing procedures. And finally, there is a specific simplified registration procedure for traditional herbal medicinal products in chapter 2a. If anthroposophic medicinal products meet the requirements of chapter 2a, they also fall under this regulation. In consideration of the note in recital 13 of Directive 2004/24/EC in connection with article 16i of Directive 2001/83 EC it is to be assumed that the three procedures described above cannot be understood as exhaustive. Directive 2001/83 EC has not stipulated that anthroposophic medicinal products are to be excluded from a simplified registration procedure, but rather it has not yet decided whether such a procedure should be put in place for them as well. Therefore we are dealing with a loophole on the way towards more far-reaching harmonisation. Whether Directive 2001/83 EC will confine itself to what has been achieved so far in terms of anthroposophic medicinal products and thus turn into an exhaustive regulation in this respect, largely depends on the Commission report requested in article 16i of Directive 2001/83 EC. In this respect, the preconditions of an appropriate *legal policy* are concerned. There are two approaches of considering this issue: first, one may consider it inappropriate that homeopathy and anthroposophic medicine are treated unequally. This approach is most notably nourished by German law, which has recognised both therapeutic approaches (see above) although it does not provide for a simplified registration procedure for anthroposophic medicinal products either as long as they are not prepared according to a homeopathic manufacturing procedure and do not fall under the term traditional herbal medicinal product. This leads to a second consideration. If it is to be a crucial aspect whether medicinal products are on the market on a traditional basis – without adverse effects to health – then this should also apply to anthroposophic medicinal products marketed and used since the 1920s. Unequal treatment as compared to homeopathic medicinal products proves to be the substantially weaker argument in a comparison of these two considerations. The preference given to homeopathic medicinal

products is based on the expressed (article 14 paragraph 1 phrase 1, 3rd indent) or unexpressed idea that, due their high degree of dilution, these medicinal products are practically risk-free. Though the preparation of anthroposophic medicinal products according to anthroposophic manufacturing methods also uses the dilution procedure, this is but one among several pharmaceutical processes.<sup>21</sup> This means that different circumstances are in place, ruling out a comparison with homeopathic medicinal products (on the premises assumed here). Hence the argument with tradition is of more weight. Risks inherent in anthroposophic medicinal products themselves are rare in the almost 100 year's history of their use. Had such risks occurred to a noteworthy extent, recognition of anthroposophic medicine as a specific therapeutic approach by the German legislator would have been ruled out. For after all, no therapeutic approach can be implemented without its methods of examination and treatment.

#### bb. Legal questions

Consequently, there is no reason not to introduce the simplified registration procedure for anthroposophic medicinal products as a matter of principle. In this context, however, the specific characteristics of anthroposophic medicinal products not prepared according to a homeopathic manufacturing procedure would have to be taken into account in an appropriate way. This is not only a consequence capable of being justified in legal policy terms. The necessary amendment of Directive 2001/83 EC by a simplified registration procedure for anthroposophic medicinal products is also a requirement of the legal position in Community law.

##### (1) Free movement of goods

Given that – as stated above – Directive 2001/83 EC has not provided for exhaustive harmonisation in respect of the simplified registration procedure for anthroposophic medicinal products, recourse to the free movement of goods is possible without restriction. The latter implies a ban on discrimination hitherto applied only to national measures.<sup>22</sup> The legal basis of Directive 2001/83 EC is article 95 paragraph 1 TEU, pursuant to which the Council “adopts the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.”<sup>23</sup> However, any such measure must comply with the fundamental freedoms set out in the TEU and the catalogue of fundamental rights developed by the ECJ, for the European Communities and their institutions are also bound by the fundamental freedoms.<sup>24</sup> Even if supervision under Community law has hitherto been exercised by the ECJ only to a minor extent and - therefore – barely been successful so far,<sup>25</sup> this does not change the fact that the legislator of EC Directives cannot exempt itself from the guidelines laid down in the TEU. For its competence does not reach any farther than assigned

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<sup>21</sup> *Kohlhase*, Grundlagen Anthroposophischer Pharmazie, in: M. Glöckler, Anthroposophische Arzneitherapie für Ärzte und Apotheker, as of 2005, 2 – 1 ff; APC Part II General monographs and related specific production methods, 2005, 27 ff.

<sup>22</sup> *Frenz*, Handbuch des Europarechts, vol. 1, 2004, margin numbers 743 ff; *Ehlers*, in: id., Europäische Grundrechte und Grundfreiheiten, 2nd edition 2005, § 7 margin numbers 19 ff.

<sup>23</sup> Cf. *Streinz*, in: Schulze/Zuleeg (eds.), Europarecht 2006, chapter 24 margin number 26.

<sup>24</sup> ECJ, collection 1984, 1229, margin number 18 – REWE; collection 1994, I-3879, margin number 11- Meghui; Schwemer, Die Bindung des Gemeinschaftsgesetzgebers an die Grundfreiheiten, 1995, 45; *Ehlers*, in: id. (ed.), Europäische Grundrechte und Grundfreiheiten, 2nd edition 2005, § 7, margin number 44.

<sup>25</sup> *Ehlers*, in: id. (ed.), Europäische Grundrechte und Grundfreiheiten, 2nd edition 2005, § 7 margin number 7 with further reference.

to it under the treaty.<sup>26</sup> From this it follows that chapter 2 and 2a of Directive 2001/83 EC must be considered as contrary to Community law insofar as they have not introduced a (specific) simplified registration procedure as well for the similarly traditional anthroposophic medicinal products.

## (2) Protection of fundamental rights

With respect to European fundamental rights, one arrives at the same conclusion. The ECJ has acknowledged the general principle of equality as basic Union law.<sup>27</sup> All measures by EC institutions violating fundamental rights are therefore unlawful (null and void).<sup>28</sup> The general principle of equality requires that equal matters must not be treated unequally. If anthroposophic medicinal products are no less traditional medicinal products than herbal medicinal products, it contradicts the principle of equality to deny them simplified registration on the grounds of the incomplete regulations of Directive 2001/83 EC. This can also be considered – with a similar result – from the point of view of medical practitioners, non-medical service providers (freedom of therapy) and patients (patient autonomy), claiming their fundamental rights of free vocational exercise and protection of physical integrity. It cannot be the task of EU Directives to interfere as a mastermind in the dispute between conventional medicine and specific therapeutic approaches. The EU is required to act only as far as the quality of medicinal products and the safety of patients is concerned. Both these issues, however, are guaranteed, and have been recently verified by the HTA report on anthroposophic medicinal products in clinical research<sup>29</sup>.

## b. National Law

As regards Member State law, it must be clarified – assuming that Directive 2001/83 EC is in compliance with Community law in respect of anthroposophic medicinal products – whether renunciation of a simplified registration procedure can be legitimised on the basis of article 30 TEU. The Netherlands have consistently subjected anthroposophic medicinal products to a marketing authorisation procedure and thus, as the applicable authorisation criteria are usually unsuitable for anthroposophic medicinal products, practically excluded them from market access.<sup>30</sup> In the Federal Republic of Germany there is no simplified registration procedure unless anthroposophic medicinal products have been prepared according to a homeopathic manufacturing procedure or are classifiable as traditional herbal medicinal products. Article 30 TEU permits to restrict the free movement of goods, among other cases, if such restrictions are “justified ... to protect the health and life of humans”. This is generally regarded as a supervision opportunity based on the principle of proportionality.<sup>31</sup> In this context, it must be noted that the burden of proof as regards the proportionality of national measures based on article 30 TEU lies with the respective Member State.<sup>32</sup> With regard to German regulations

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<sup>26</sup> If, in this respect, the ECJ only examines in individual cases whether there is an obvious error or whether the EC institution has obviously transgressed the limits of its discretionary scope (cf. collection 1994, I-4973 – Germany/Council; collection 1995, I-6555 – Racke), then these standards fall significantly short of the supervision obligations arising from the principle of proportionality.

<sup>27</sup> *Rossi*, in: Calliess/Ruffert, EGV/EUV, 3rd edition 2007, margin number 2 on article 20 of the European Charter of Fundamental Rights with further reference; *Rengeling/Szczekalla*, Grundrechte in der Europäischen Union, 2004, margin numbers 883 ff.

<sup>28</sup> *Jarass*, Europäische Grundrechte, 2005, § 7, margin number 4 with further reference.

<sup>29</sup> *Kienle/Kienel/Albonico*, Anthroposophische Arzneimittel in der klinischen Forschung, 2006.

<sup>30</sup> This is the subject matter of ECJ procedure C-84/06 – The Netherlands/Antroposana (see above).

<sup>31</sup> *Lux*, in: Lenz/Borchardt (eds.), EU- und EG-Vertrag, 4th edition 2006, margin number 28 on article 30 TEU.

<sup>32</sup> ECJ, C-270/02, collection 2004, I-1559 – Commission/Italy; cf. *Schroeder*, in: Streinz, EUV/EGV, 2003, margin number 57 on article 30 TEU; *Müller-Graff*, in: v.d. Groeben/Schwarze (eds.), Vertrag über die Europäische Union und Vertrag zur Gründung der (Europäischen) Gemeinschaft, vol. 1, 6th edition 2003, margin number 185 on article 30 TEU.

for instance, the Federal Republic of Germany has to demonstrate that the exclusion of anthroposophic medicinal products, not prepared according to a homeopathic manufacturing procedure and not classified as traditional herbal medicinal products, from the simplified registration procedure is “adequate, necessary and appropriate” with regard to proportionality.<sup>33</sup> Accordingly, exclusion of the anthroposophic medicinal products specified above from the simplified registration procedure has been neither demonstrated as necessary nor as an appropriate measure towards manufacturers, service providers and patients. This assessment is justified on the grounds that the quality and safety of anthroposophic medicinal products as methods of treatment within a recognised specific therapeutic approach in the sense of traditional, risk-free use has been proved accordingly.

A simplified registration procedure for anthroposophic medicinal products not prepared according to a homeopathic manufacturing procedure, i.e. anthroposophic use, should take the particularities of anthroposophic medicine and anthroposophic medicinal products (see above) into account at both European and national level.

#### **IV. Summary**

1. The term anthroposophic use is meant to describe a loophole in the recognition of anthroposophic medicinal products, i.e. such anthroposophic medicinal products that are neither registered/authorised nor registered in a simplified procedure according to homeopathic rules or as traditional medicinal products. In this article, the thesis is developed that, in general, anthroposophic medicinal products can be registered in a simplified procedure in accordance with their specific qualities, as soon as the German legislator has created corresponding regulations in the AMG. Directive 2001/83 EC is not opposed to such regulation, as its relevant provisions do not represent absolute harmonisation.

2.a. Following completion of this article, the ECJ took a decision on the discussed legal case Netherlands/Antroposana C-84/06 (ruling of 2007-09-20), holding that exhaustive harmonisation is already in place at European level, thereby ruling out any more liberal national legislation: anthroposophic medicinal products may be marketed only on condition that they have been authorised under one of the procedures referred to in Directive 2001/83 EC. However, only few lines of the decision (margin numbers 40-42) deal with the relevant problem of whether Directive 2001/83 EC really contains exhaustive harmonisation. Essentially, the ECJ contents itself with a reference to the Advocate General’s statements (see above), commenting the statement that Directive 2001/83 EC provides exhaustive harmonisation and is not called into question by the Community legislator’s entitlement to establish new regulations in order to pursue its objectives in a better way (margin number 41). Considering Germany and leaving out article 79 paragraph 3 of the Constitution, any legal norm is amendable. This is a matter of course and – naturally – no argument against assuming “exhaustive” regulation. In its aforementioned statement, however, the ECJ implicates precisely what was in question, namely whether harmonisation in Directive 2001/83 EC is really exhaustive. The opposite opinion, based on the temporariness that Directive 2001/83 EC expressly assigns to itself, is therefore not disproved in any way whatsoever. Consequently, the second consideration on which the ECJ additionally bases its decision, namely that national regulations acting on the assumption of non-exhaustive harmonisation by Directive 2001/83 EC are irrelevant (margin number 42), is up in the air. This consideration would only be compelling if Directive 2001/83 EC had really provided for exhaustive harmonisation. As, however, it is to be assumed that national legislators comply in principle

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<sup>33</sup> *Schroeder*, in: Streinz, EUV/EGV, 2003, margin numbers 49 ff. on article 30 TEU; see also ECJ, C-322/01, collection 2003, I-14951 margin number 104 – DocMorris; ECJ, C-111/02, collection 2004, I-3369 margin number 14 – Kohlpharma.

with Community law, the reference to deviating national law was to be understood merely as a hint that Directive 2001/83 EC has actually not provided for exhaustive harmonisation.

b. The mere fact that reasons are barely given shows that the ECJ's ruling must be considered as political jurisdiction. Considering the fact that European development in the field of traditional medicinal products is currently in progress, the ECJ obviously wanted to prevent this development from being hampered by any unilateral national approach. In this respect, the ECJ's ruling does not really have a blocking effect, as with regard to content it does not have any impact on the development of European law. On the contrary: one can also consider the ECJ's ruling as an indication of how important an update of Directive 2001/83 EC in the field of traditional medicinal products actually is.

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