

Keywords

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Disinfectants for Human Use – Classification as Medicinal Products even following 15th amendment to the AMG

Zusammenfassung

Desinfektionsmittel werden rechtlich verschiedenen Produktkategorien zugeordnet. So sind Flächendesinfektionsmittel Biozid-Produkte. Desinfektionsmittel zur Desinfektion von Medizinprodukten sind Medizinprodukte bzw. Zubehör zu Medizinprodukten. Desinfektionsmittel zur Anwendung am Menschen sind hingegen Arzneimittel. An dieser Einstufung ändert sich auch nichts durch die neue Arzneimitteldefinition im deutschen Arzneimittelgesetz. Mit der 15. AMG-Novelle will der Gesetzgeber die deutsche Arzneimitteldefinition der europäischen anpassen. Damit hat der Gesetzgeber aber nur nachvollzogen, was die Rechtsprechung seit Jahren bereits vorgegeben hat. Der Beitrag zeigt auf, warum sich an der Einstufung von Desinfektionsmitteln zur Anwendung am Menschen als Arzneimittel nichts ändert und was die Konsequenzen für die Praxis sind.

Hyg Med 2009; 34 [6]: 240–247

Introduction

To date, disinfectants for human use have been correctly classified in Germany as pharmaceuticals or medicinal products. These disinfectants include products for hygienic or surgical hand disinfection, products to prepare the patient's skin prior to injections or operations as well as disinfectants for mucous membrane and wound antiseptics.

For users in a clinic or practice, the issue regarding the status as a medicinal product is interesting firstly because re-filling such disinfectants constitutes manufacture of medicinal products¹. A manufacturing step of this kind means that the user is responsible for the product. In this case, he would be responsible for the absence of microbial contamination, absence of spores and the shelf life of the product.

Secondly, however, the user can rely on the fact that, in the case of a medicinal product, the efficacy, safety and quality of every single product has been tested by a competent licensing body. In addition to the proof of efficacy in humans, evidence must be furnished during the marketing authorisation procedure for the medicinal product, that, in view of the benefits of the product, potential risks, such as, e.g. the potential to cause skin irritation, are reasonable. Lastly, the manufacture of medicinal products is subject to constant official supervision, starting from the manufacture or import of active substances through to the release of the final product. This ensures that the manufacture of medicinal products complies with the strict requirements of the GMP guidelines². Furthermore, for medicinal products a pharmacovigilance system is prescribed, which governs the details of product supervision and the duty to inform buyers

Summary

Disinfectants are assigned to various regulatory categories. Public health area disinfectants are biocidal products; disinfectants specifically intended for use with medical devices (e.g. endoscopes) are classified as medical devices or accessories; disinfectant products applied directly to the human skin are classified as medicinal products. This classification will remain unaltered following the implementation of the 15th Amendment of the German Pharmaceuticals Act. This amendment will enact a new definition of the term "medicinal product". In so doing, the legislator is merely following the interpretation of the term by the German courts. This article will explain why there will be no change in the classification of disinfectants and will highlight the impact of the amendment in practice.

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of post-sale risks, as well as communication with the competent authorities³. This is far from the case with some other regulatory categories.

With the 15th amendment to the German Pharmaceuticals Act (Arzneimittelgesetz, AMG)⁴, the definition of medicinal product is to be brought into line with that in European law. What is of interest for the users of disinfectants for human use is whether the status of these products as medicinal products will change. This article will show that the 15th amendment to the AMG will not lead to any change in the regulatory status of disinfectants for human use, nor is the aim of the amendment to effect such change.

Current Status of Disinfectants for Human Use (Medicinal Products)

According to the current legal situation, disinfectants for human use are classified as medicinal products (Box 1).

The (former) German definition of medicinal products, in force until 22.07.2009, differentiates between medicinal products⁵, products considered to be medicinal products⁶ and non-medicinal products⁷.

Box 1: Definition of Medicinal Product according to Sect. 2(1) German Pharmaceuticals Act (old version).

Pursuant to Section 2 (1) AMG (old version) the following are medicinal products:

"[...] substances and preparations made from substances which, by application on or in the human or animal body, are intended

1. to cure, alleviate, prevent or diagnose diseases, suffering, bodily injury or symptoms of disease,
2. to diagnose the nature, the state or the functions of the body or mental health conditions,
3. to substitute active substances or body fluids produced in the human or animal body,
4. to ward off pathogens, parasites or substances alien to the body or to destroy them or render them harmless
5. to influence either the nature, the state or the functions of the body or mental health conditions."

Disinfectants for human use on the one hand fall under Section 2 (1) No. 1 AMG, since they are substances or preparations made from substances which, by application on or in the human body, are intended to prevent disease. This prevention of disease relates in the first instance to the patient, to whom the product is applied. Killing germs on the skin prior to injections, operations etc. prevents disease, specifically infections such as abscesses caused by injections or infection of the wound. In addition, through hygienic disinfecting of hands, disinfectants prevent

the transfer of germs from physician or nursing staff to other people. This breaks chains of infection, which also constitutes prevention of disease.

A disinfectant for human use is also a medicinal product within the meaning of Section 2 (1) No. 4 AMG. After all, it is intended specifically to ward off or render pathogens harmless.

The classification of disinfectants for human use as medicinal products under German Pharmaceuticals Law is largely undisputed, both in the literature and the case law on the subject⁸.

Background of the discussion surrounding the status of disinfectants

Within the European Union, the classification of disinfectants is not uniform⁹. The reason for this is, inter alia, the European Biocidal Products Directive, which entered into force in 1998¹⁰.

Biocidal products are substances or preparations intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means¹¹.

As early as at the beginning of the 1990s, the Council of the European Union had expressed doubts regarding the lack of community regulations on biocidal products. At that time, these products were described as "pesticides not used in agriculture". Initially, the Biocidal Products Directive was intended only as "a small offshoot of the plant protection

¹ Pursuant to Section 4 (14) AMG, re-filling or decanting also constitutes manufacture of medicinal products.

² Good Manufacturing Practice (GMP): Provisions based on European law and now legally binding regarding the manufacture and quality control of medicinal products; see Section 3 (2) Ordinance on the Manufacture of Pharmaceuticals and APIs (Arzneimittel- und Wirkstoffherstellungsverordnung, AMWHV) in conjunction with the EC-GMP Guidelines.

³ According to the WHO definition, pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. The EU has passed comprehensive guidelines on this matter: Vol. 9A of the Rules Governing Medicinal Products in the European Union – Guidelines on Pharmacovigilance for Medicinal Products for Human Use; http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol9_en.htm, as per: September 2008.

⁴ 15th AMG Amendment Act of 17.07.2009, Federal Official Journal (Bundesgesetzblatt) Part I, p. 1990 ff. See also: Government draft of 16.03.2009, BT-Drs. 16/12256; Counterstatement of 22.04.2009, BT-Drs. 16/12677, Final referral to the Health Committee of the Bundestag on 17.06.2009.

⁵ Section 2 (1) AMG, version before 15th amendment.

⁶ Section 2 (2) AMG, version before 15th amendment.

⁷ Section 2 (3) AMG, version before 15th amendment.

⁸ Kloesel/Cyran, Arzneimittelrecht, as per: April 2008, Section 2 AMG, Note 63; Bales/Baummann/Schnitzler, Infektionsschutzgesetz, Section 18, margin note 6; Higher Regional Court (OLG) Stuttgart, judgement of 24.04.2008, APR 2008, 118; followed by the Administrative Court (VG) Cologne, judgement of 31.07.2007, Juris.

⁹ In the United States of America and in Canada disinfectants for hygienic or surgical hand disinfection are pharmaceuticals; in Australia "hospital grade disinfectants" are pharmaceuticals "when claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides".

¹⁰ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998, OJ L 123 24.4.1998, p. 1.

¹¹ Art. 2(1) a) Directive 98/8/EC, respectively Section 3b (1) No. 1 and 2 ChemG.

¹² E. g. household insecticides, wood protectants, rat poison or antifoulings.

Box 2: Definition of Medicinal Product according to Art. 1 No. 2 Directive 2001/83/EC.

Pursuant to Art. 1 No. 2 Directive 2001/83/EC, a medicinal product is:

- „a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.“

Box 3: Changes to the definition of Medicinal Product in Germany (15th AMG amendment).

With the 15th amendment to the AMG the legislator is seeking to bring the German medicinal product definition into line with the European, Section 2 (1) AMG:

“Medicinal products are substances or combinations of substances,

1. intended for use in or administration to humans or animals with properties for treating or preventing diseases or pathological complaints, or
2. which can be used in or administered to humans or animals, in order either
 - a) to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action or
 - b) to make a medical diagnosis.“

Section 2 (2) and (4) AMG are to remain unaltered.

products directive” and was intended to govern only a few products similar to plant protection products¹² that were not covered by the Plant Protection Products Directive¹³. In the course of the legislative process, the sphere of application was then extended to cover 23 very diverse types of products¹⁴.

According to the recitals of the Biocidal Products Directive, biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manu-

factured products. However, due to their intrinsic properties and associated use patterns, they can pose risks to humans, animals and the environment in a variety of ways. The regulatory framework provided by the Biocidal Products Directive was thus intended on the one hand to harmonise European law and on the other to secure a high level of protection for humans, animals and the environment in all member states. A procedure is provided for the implementation, which first consists of a risk assessment for the substances in each case (substance

procedure). On the basis of the outcome of that assessment, there will be a positive list of substances¹⁵ that may be used in biocidal products. This is followed by a product authorisation procedure. For existing products there are transitional provisions¹⁶. The Biocidal Products Directive expressly does not apply to a number of regulatory categories, such as e.g. medicinal products, medical devices or cosmetics.

Annex V of the Biocidal Products Directive contains an exhaustive list of 23 types of product with examples descriptions within each type of product. The introduction of the Biocidal Products Directive prompted the EU Member States to categorise disinfectants – in some cases without any further distinction – as Biocidal Products. However, the classification of disinfectants for human use as biocidal products contradicts both the wording of the Biocidal Products Directive¹⁷ and the purpose of the provisions on biocidal products and on medicinal products and the legislative history (see below: d).

Changes to the definition of medicinal product in Europe and Germany (15th AMG amendment)

The European definition of a medicinal product can be found in the so-called Community code relating to medicinal products for human use (Directive 2001/83/EC). This Directive was amended in 2004¹⁸.

Insofar as there were divergences between German and European definitions of medicinal products, the case law in Germany has switched to using only the European definition. The reasoning given for this was the complete harmonisation of the definition of medicinal product through Directive 2004/27/EC¹⁹.

The provisions on non-medicinal products are supplemented with a provision that applies in the case of doubt, which, in terms of the contents, is the same as the European provision in the case of doubt, Section 2 (3a) AMG. According to this, products that both fall fully within the definition of a medicinal product and the definition of a non-medicinal product – such as medical devices or cosmetics – are treated as medicinal products. “Biocidal products as

¹³ Gärtner/Lahl, StoffR 2007, 257, 259.

¹⁴ E. g. masonry preservatives, slimicides or embalming fluids (products used for the disinfection and preservation of human or animal corpses, or parts thereof).

¹⁵ Annexes I (List of substances with requirements agreed at Community level for use in biocidal products) and Ia (List of substances with requirements agreed at Community level for use in low-risk biocidal products).

¹⁶ A detailed description of the complex procedures would go beyond the scope of this essay. For further information see: <http://ec.europa.eu/environment/biocides/> or www.baua.de, as per: 27.01.2009.

¹⁷ Or, as the case may be, the German Act on Chemicals.

¹⁸ Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, OJ L 186 30.4.2004, p. 34.

¹⁹ Supreme Federal Court (Bundesgerichtshof, BGH), judgement of 26.06.2008, PharmR 2008, 430; Supreme Federal Court, judgement of 30.03.2006, PharmR 2006, 329; Supreme Federal Court, judgement of 25.10.2007, PharmR 2008, 254; Supreme Federal Court, judgement of 14.12.2006, PharmR 2007, 211.

defined in Section 3b of the Chemicals Act” are added to the list of non-medicinal products, Section 2 (3) sentence 2 No. 5 AMG.

Effects of the amended medicinal product definition on the classification of disinfectants for human use

The new medicinal product definition in the 15th amendment to the AMG – in the same way as the European definition distinguishes between medicinal products by presentation and medicinal products by function. The two definitions apply alternatively. This means it is sufficient for classification as a medicinal product that a product fulfils one of the two definitions. Thus, if a product is represented as a medicinal product, it falls within the medicinal product definition. The same applies if the product is solely a medicinal product by function.

a) Disinfectant for human use as medicinal products by presentation

According to the definition in the 15th amendment to the AMG, medicinal products by presentation are substances or combinations of substances for use in or administration to humans or animals, presented as having properties for treating or preventing disease or pathological complaints. Insofar as the draft bill uses “described as” instead of “intended for”, this should not be attributed any importance in terms of the interpretation²⁰. This also derives from the fact that the change to the definition through Directive 2004/87/EC changes “described” to “intended” in the German version, while the English text retains “presented”.

Thus, whether or not a product is a medicinal product by presentation is still determined by the intended purpose. Initially, this is allocated to the product by the manufacturer. Since this intended purpose is merely subjective, however, the objective purpose is what is important when classifying the product. According to the case law of the European Court of Justice (ECJ), when classifying a product as a medicinal product by presentation, all aspects of its external appearance and the impression made on the averagely well-informed consumer are decisive²¹. If

an averagely well-informed consumer is given the impression that the product, in view of its appearance, ought to have the characteristics expected of it, then it is a medicinal product by presentation. The reason for this is that where a particular expectation can be triggered in the consumer²², this must be protected by way of the broad interpretation of the term “medicinal product by presentation”²³. Thus, the implicit (consistent) causing of this impression is sufficient. The targeted consumers for disinfectants for human use are – in clinics, surgeries and other health-care facilities in any case – as a rule physicians and medical staff.

Of course, products expressly designated by the manufacturer as having the characteristics of a medicinal product²⁴, are undisputedly medicinal products by presentation. For this it is sufficient that the products in question are intended for use in or administration to humans and are described as substances to prevent human illness. Insofar as the definition set forth in the 15th amendment to the AMG in addition to illnesses also refers to pathological complaints and the alleviation as well as treatment thereof, this is of no consequence for the interpretation. The purpose of this is merely to prevent any discussions as to whether products for preventative treatment, for instance, are medicinal products.

The intended purpose can result from the labelling on the product (bottle, packaging, etc.) or from the product information, package insert, or advertising materials (including websites).

As described above, disinfectants for human use can prevent disease. A designated purpose to this effect must, therefore, always result in such products being medicinal products by presentation. Incidentally, this is precisely what the consumer expects. Users of disinfectants for human use expect a product, the efficacy and safety of which (allergic potential, localised irrita-

tion, etc.) have been officially tested; which has been manufactured according to recognised quality standards (GMP) and for which there is a pharmacovigilance and product recall system.

b) Disinfectants for human use as medicinal products by function

Since a disinfectant for human use is to be seen as a medicinal product by presentation, the classification as a medicinal product by function is not really of any importance. Nevertheless, such disinfectants also fall within the definition of a medicinal product by function. According to the definition set forth in the 15th amendment to the AMG, medicinal products by function are substances or combinations of substances used in or administered to humans or animals in order either

- a) to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action or
- b) to make a medical diagnosis.

The effect of the disinfectant on the skin flora can be seen both as a correction and as a modification of the physiological function.

Insofar as transient skin flora is reduced through disinfection, this also removes pathogens. Since these are not components of normal skin flora, this represents a correction of the physiological function of the resident skin flora, e.g. in surgical hand disinfection or disinfecting the patient’s skin before injections and operations, the number of bacteria normally present on the skin is reduced. The micro-organisms in the resident skin flora belong to the normal state of humans and do not have any clinical significance. On the contrary – the resident skin flora has a protective function for humans. Thus, to this extent what we are dealing with is not a correction of, but an influence on the human physiological functions.

²⁰ See also: Federal Administrative Court, judgement of 25.07.2007, PharmR 2008, 78.

²¹ ECJ, judgement of 15.11.2007, ECR [2007], I-9811 (garlic capsules).

²² In the case of medicinal products, this trust is based on the particularly stringent regulations and monitoring of production and distribution.

²³ ECJ, judgement of 15.01.2009 – Case C-140/07 (Red Rice), intended for publication in ECR.

²⁴ e. g. “to encourage wound healing” or “to protect against Hepatitis B” or “Hepatitis-B prophylactic”, see also – despite the fact that it is not legally binding – Chapter 2.1.2.4. Manual of Decisions for implementation of Directive 98/8/EC concerning the placing on the market of Biocidal Products, as per: 10.07.2008.

Insofar as the definition of a medicinal product by function also demands a pharmacological, immunological or metabolic effect, the pharmacological effect is particularly worthy of discussion. The term “pharmacological effect” is highly disputed. In medicine, pharmacology is the theory concerning the effects of substances produced by the body on the organism, as well as the use of certain substances as medication (= pharmacon)²⁵. The medical definition of pharmacology cannot really be used to define a medicinal product. This is because it requires just such a substance. The use of this definition would result in a (logically impermissible) circular statement. Accordingly, the definition of pharmacology in general speech as the science of the interaction between medication and organism²⁶ is unsuitable, since the definition is contingent on the definition of a medicinal product.

To this extent, definitions from pharmacology textbooks are misleading. There, pharmacology or the pharmacological effects are described with the help of a sequence of actions following application. Following a pharmacokinetic phase, (uptake in organism) and subsequent distribution, comes the pharmacodynamic phase with pharmacon-receptor interaction and the subsequent processes, such as receptor-effector-coupling (signal transduction) and finally the pharmacological effect (efficacy, clinical effect, toxic effect)²⁷.

In a European guideline on the distinction

between medicinal products and medical devices, attempts to introduce a legal definition were made, but this, however, is not suitable for all medicinal products²⁸. The guideline, which is not legally binding, defines pharmacological effect as the interaction between the molecules of the substance in question and a cellular component, usually described as a receptor, which results either in a direct reaction or which blocks the response to another agent. The presence of a dose-response correlation is taken to be an indicator, but not a fully reliable criterion, of the pharmacological effect within this definition.

The definition in this guideline describes the effects of medicinal products that act according to the key/lock principle on receptors in the cell membrane or within the cell²⁹. This attempted definition does not, however, cover all medicinal products. Many antibiotics, for instance, would not be considered to have a pharmacological effect according to this definition³⁰, since they merely kill bacteria and, as a rule, do not act via receptor binding. As most antibiotics do not have an immunological or metabolic effect as stated in the classification guideline, these antibiotics would not be classified as medicinal products. However, it is highly unlikely that anyone would deny that all antibiotics are to be classified as medicinal products³¹. Thus, the definition of the pharmacological effect cannot be restricted to the active principle drug/human receptor³².

Thus, when clarifying the term “pharmacological effect” for the purposes of the medicinal product definition set forth in the 15th revised AMG, it is necessary to go beyond the definition used in the guidelines. Due to its restrictiveness, the definition used in the guideline is referred to in the legal literature as “pharmacological effect in the narrow sense”³³. Moreover, the guideline is not legally binding. This means that the courts – where necessary with help from experts – must determine in each individual case what “pharmacological effect” is to be taken to mean.

As a corrective for the inadequate definition of pharmacological effect in the classification guideline, the literature has developed, among other things, the definition “pharmacological effect in the broad sense”³⁴. This is intended to encompass products that do not display a pharmacological, immunological or metabolic effect in the narrow sense, but which are nevertheless medicinal products. Here, what is crucial is whether the main effect of the substance consists of a beneficial alteration to bodily function. There is unlikely to be any doubt that disinfectants for human use possess pharmacological characteristics in this broad sense.

Accordingly, there is a line of case law pursuant to which pharmacological effect can also be understood as an interaction with germs present on the body³⁵.

Furthermore, when dealing with the issue of pharmacological effect, one must also take into account that, according to the 7th recital of Directive 2004/27/EC, the purpose of the new European medicinal product definition was to cover medicinal products such as gene therapy, radiopharmaceuticals and certain medicinal products for topical application. This means, however, that in the case of products for topical use in particular – such as disinfectants for human use – the restrictive legal definition of pharmacological effect in the classification guideline is not sufficient for determining whether a product is a medicinal product.

Having clarified that the narrow legal definition of pharmacological effect in the classification guideline does not exclude the characteristic of disinfectants for human use as a medicinal product by function, reference is made at this juncture to the relevant case law of the ECJ.

On the basis of the over-narrow definitions of pharmacological, immunologi-

²⁵ Roche Lexikon Medizin, 5th edition 2003, p. 1448; a similarly unsuitable definition of pharmacology for the purposes of defining medicinal products is set forth in Pschyrembel, Klinisches Wörterbuch, 259. edition, p. 1293.

²⁶ Meyers Großes Taschenlexikon in 26 Bänden, 9th edition, Volume 17, p. 5676.

²⁷ See: Mutschler et al., Arzneimittelwirkungen, 9th edition 2008; Dettling, MPR 2006, 53, 54; Anhalt/Lücker/Wimmer, MPR 2006, 77, 78 deal with this, for example.

²⁸ Guidelines relating to the application of: The Council Directive 90/385/EC on Active Implantable Medical Devices; Council Directive 93/42/EEC on Medical Devices, MEDDEV 2.1/3 rev. 2, July 2001 (will be replaced by the version 2.1/3 rev. 3 as of 21 March 2010); MEDDEV 2.1/3 rev. 3, July 2009; Böckmann/Frankenber/Will, Durchführungshilfen zum Medizinprodukterecht, Chapter E 4.2.1.

²⁹ See also: Dettling, PharmR 2006, 58, 64.

³⁰ e.g. Gyrase inhibitors: The inhibited enzymes gyrase and topoisomerase IV do not exist in the human body, but rather only in bacteria. As a result, in the case of gyrase inhibitors there is no pharmacon / receptor action in human cells.

³¹ There are also very broad spectrum antibiotics, which, to this extent, have a similar effect to disinfectants.

³² Even the Guideline MEDDEV 2.1/3 rev. 3 categorises “topical disinfectants (antiseptics) for use on patients” as medicinal products.

³³ See also: Dettling, PharmR 2006, 58, 64.

³⁴ See also: Dettling, Pharmarecht 2006, 58, 65, 66.

³⁵ Specifically: District Court Hamburg, judgement of 10.04.2003 - 315 O 525/02, not published, p. 11 UA; District Court Hamburg, judgement of 26.06.2003 - 315 O 357/02, not published, p. 14 f. UA.

³⁶ See: Anhalt/Lücker, MPJ 2007, 189, 194 with critical comments.

³⁷ ECJ judgement of 15.11.2007, ECR [2007], I-9811.

Box 4: Annex V of the Biocidal Products Directive; Description of Product Types.

The description for product type 1 states:

“Products in this group are biocidal products used for human hygiene purposes.”

In contrast, the description for product type 2 states:

“Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algacides.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in playgrounds).”

cal and metabolic effect, the ECJ interprets the term “medicinal product by function” taking into account the most recent scientific findings (which are constantly changing) and takes a case-by-case approach³⁶.

The ECJ applies the following criteria when determining whether a product is a medicinal product by function³⁷:

- the manner in which the product is used,
- the extent of its distribution,
- awareness of the product among consumers and
- risks which its use may entail.

The need to take these criteria into account has not changed in any way, even after the amendment of the European medicinal product definition through Directive 2004/27/EC. In the view of the ECJ also, nothing in this amended definition indicates any intention to alter the criteria set forth in the case law. In addition to the pharmacological characteristics, only immunological and metabolic characteristics need also be taken into account. This is confirmed by the provision in Art. 2(2) Directive 2001/83/EC new version, pursuant to which a product must be assessed “taking into account all its characteristics”³⁸.

The abovementioned criteria developed in the case law suggest that disinfectants for human use are to be classified as medicinal

products by function. This applies in particular to the criteria of the risk involved in using the product (see below).

The other criteria also support the classification as a medicinal product by function:

For instance, the disinfectants concerned, particularly those for surgical hand disinfection and surgery or injection preparation, are usually distributed in healthcare facilities. The disinfectants referred to are also known among consumers – in this case, healthcare professionals – as substances to prevent disease and are seen as medicinal products.

A decisive argument in support of the classification as medicinal products by function is, however, the risks inherent in the usage. First, the efficacy of the relevant disinfectant for the intended use must be proven. Ineffective products or dosages that are too low can result in considerable damage to the patient (infectious diseases, wound infection, sepsis through to multi-organ failure and resistance). In the case of biocidal products it is mainly the risks for the environment and the consumer that are assessed. In conformity assessment procedures for medical devices in classes IIa (disinfection of medical devices) or IIb (disinfection of contact lenses), the conformity assessment procedure pursuant to Annex II to Directive 93/42/EEC can be carried out. In this case, only the overall quality assurance system, but not the product itself, is tested by an

approved body. Specifically, the structural features, manufacture and performance data of the product are not tested.

With regard to additional aspects of patient risk or risk to nursing staff and doctors, any possible allergic potential, skin irritation, mutagenic potential etc. must be pointed out. A thorough check of these risks occurs on a product-specific basis only in the procedure of an application for marketing authorisation.

The aforementioned risks can be effectively countered only through an official benefit/risk assessment and by means of statutory product monitoring duties and obligations to inform buyers/users of risks.

c) Not a biocidal product

Disinfectants for human use are – in contrast to surfaces disinfectants for example not biocidal products.

According to Section 2(3) sentence 2 No. 5 AMG in the version of the 15th revised AMG, “biocidal products as defined in Section 3b of the Chemicals Act” are not medicinal products. The prerequisite for categorising a product as a biocidal product is, however, pursuant to Section 3b (1) No. 1 Chemicals Act, that the products in question belong to a category of products listed in Annex V to Directive 98/8/EC. In addition, products belonging to one of the exceptional areas listed in Art. 1 (2) of Directive 98/8/EC are not covered by the biocidal products definition. This includes, for example, medicinal products, medical devices, cosmetics or plant protectants. Accordingly, the provision applicable in cases of doubt also specifies that the provisions on medicinal products law take precedence³⁹.

On the basis of the exclusion, disinfectants for human use which, as explained above, are to be categorised as medicinal products by presentation and, in the majority of cases, also as medicinal products by function, are excluded from the scope of the law on biocidal products.

Furthermore, these disinfectants do not belong to a type of product listed in Annex V of Directive 98/8/EC⁴⁰. Annex V describes disinfectants in the main group 1: disinfectants and general biocidal products. At most, the product type 1: “Human hygiene biocidal products” and product type 2: “Private area and public health area disinfectants and other biocidal products” could come into consideration here (Box 4).

³⁸ ECJ, judgement of 15.01.2009 – Case C-140/07 (Red Rice), due for publication in ECR.

³⁹ See below: d.

⁴⁰ For the comparable case of insecticides in dog and cat collars: Kloesel/Cyran, Arzneimittelrecht, as per: April 2008, Section 2 AMG, note 62 with further evidence

⁴¹ See also: Kloesel/Cyran, Arzneimittelrecht, as per: April 2008, Section 2 AMG, note 63.

⁴² Meyers Lexikon Online, article “hygiene”, <http://lexikon.meyers.de>, accessed on 21.01.2009.

Table 1: Overview of the regulatory classification of disinfectants.

Purpose of the disinfectant	Regulatory status in Germany and pursuant to European law
Hand disinfectants (hygienic, surgical)	medicinal product
Skin disinfectants	medicinal product
Disinfectants for instruments	medical device
Surface disinfectants	biocidal product
Products for laundry disinfection purposes	biocidal product

Disinfectants for human use do not fall within product type 2, since only products intended to disinfect non-living surfaces are listed here. Specific reference is made to walls and floors in healthcare institutions and hospital waste. Thus, typical surface disinfectants used in healthcare facilities are biocidal products⁴¹. In this context it should, however, be noted that Directive 98/8/EC does not take sufficient account of the disease-preventing aspect of surface disinfectants. Instead, the purpose of Directive 98/8/EC is the protection against potential environmental risks and aims, to this extent correctly, at achieving the most sparing use possible of biocidal products. It goes without saying that this kind of approach in the healthcare system is counterproductive in terms of the prevention of infection.

However, the classification of disinfectants for human use in product type 1 is also problematic. Surprisingly, in the course of the implementation of Directive 98/8/EC hand disinfectants were sometimes given as an example for product type 1, without this being based on use in the healthcare sector. This is also fairly unlikely.

After all, product type 1 includes: “products for human hygiene purposes”. Here it should be noted that hygiene is not only a branch of medicine, but is also used in general language usage to refer to

protection and encouraging health in general⁴². This refers more to personal hygiene than maintaining health⁴³ or to employees in restaurants or in the catering industry rather than the prevention of specific illnesses⁴⁴.

Secondly, the system structure of main group 1 has to be taken into account: product type 1 comprises, in general “biocidal products for human hygiene purposes”. Product types 2 to 5 include specific products. Thus, product type 2, which governs the area of public healthcare, is a more specific provision than product type 1 and, as such, takes precedence. However, because product type 2 expressly governs only the disinfection of non-living materials in the healthcare sector, such as surfaces, floors and waste, disinfectants with a different intended purpose are not biocidal products⁴⁵.

d) Provision in the case of doubt

However, even if one wanted to allocate disinfectants for human use to product type 1 in Annex V of Directive 98/8/EC, they would still be excluded from the biocidal products definition on the basis of the provision in Section 3b (1) No. 1b) Chemicals Act in conjunction with Art. 1(2) of Directive 98/8/EC. This is because, as explained above, disinfectants for hu-

man use are medicinal products. As such, they fall within the exceptions listed in Article 1(2) of Directive 98/8/EC and are not biocidal products as defined in the Chemicals Act.

Using the provision applicable in the case of doubt reaches the same outcome. The 15th revised AMG introduced a provision applicable in cases of doubt to the German law on medicinal products, Section 2 (3a) AMG:

“Medicinal products are also products that are or contain substances or combinations of substances, which, taking account of all characteristics, fall within one of the definitions in clause 1 and which could, simultaneously, fall within the definition of a product pursuant to clause 3”.

This provision for cases of doubt corresponds to the European model. Here it should be taken into account that this provision is not designed to release the party applying the law from carrying out his/her own legal examination and, if necessary, interpretation. Thus, this provision does not apply if the classification of a product as a medicinal product is supported only on the basis of a certain likelihood⁴⁶.

This is not, however, the case as regards disinfectants for human use. As the discussion has shown, these disinfectants are clearly medicinal products by presentation and in the majority of cases, also medicinal product by function. This positively determines their characteristics as medicinal products. Even if one wanted to allocate these products to another regulatory category (biocidal products, medical devices, cosmetics⁴⁷) they would still unequivocally be governed by the law on medicinal products.

⁴³ e.g. refreshing wipes with disinfectant properties.

⁴⁴ Also expressly stated in: guidance document agreed between the Commission services and the competent authorities of the Member States for the Biocidal Products Directive 98/8/EC and for the Medicinal Products for Human Use Directive 2001/83/EC and the Veterinary Medicinal Products Directive 2001/82/EC: In cases where the intended purpose or existence of a medical effect, the product concerned is a medicinal product.

⁴⁵ Ultimately also: Kloesel/Cyran, *Arzneimittelrecht*, as per: April 2008, Section 2 AMG, Note 70.

⁴⁶ Similarly: ECJ, judgement of 15.01. 2009 – Case C-140/07 (Red Rice), intended for publication in the ECR.

⁴⁷ According to the Guidance document agreed between the Commission services and the competent authorities of Member States for the Biocidal Products Directive 98/8/EC and for the Cosmetic Products Directive 76/768/EEC, the claim “disinfection” or “disinfectant effect” are not permitted for use in cosmetics.

⁴⁸ 15th AMG Amendment Act of 17.07.2009, Federal Official Journal (Bundesgesetzblatt) Part I, p. 1990 ff.

Outlook and conclusion

The 15th revised AMG passed parliamentary procedure and became effective⁴⁸. By amending the definition, the legislator is complying with the requirements of European law and reinforcing what has been legal reality in the courts for some time now.

When applying the new medicinal products definition of the AMG, disinfectants for human use are still classified as medicinal products in Germany. This is to be welcomed in the interests of the patients, the physicians and medical staff.

Conflict of interests

The author provides legal advice to the pharmaceutical and medical device industry, but has no conflict of interests as defined in the Guidelines of the International Committee of Medical Journal Editors.