A. Preface

The legal rules applying to advertising medicines in Germany resemble a jungle. While a Medical Products Advertising Act (hereafter the Act) has been put in place, which concentrates on rules regarding advertising pharmaceuticals, the Act does not show the entire picture. It is surrounded and complemented by provisions embedded in other sources of law. Moreover, the legal structure of the Act is complex as the distinction between rules on advertising to professional parties and rules on marketing to end consumers is not clear in the face of the structure of the Act. Finally, provisions set out in the Act are of course subject to interpretation by competent courts, including both domestic ones and the European Court of Justice. Recently, courts have increasingly been making decisions which, have a significant impact upon how to construe and apply key rules and legal concepts of the Act. This essay strives to outline the chief categories in the light of pertinent case law, focussing on recent case law and taking both the Act and complementing other sources of law into account – thereby hopefully enlightening “the legal jungle” to some extent.

B. Essay

1. Secondary EC legislation

The central source in EC law is Directive 2001/83/EC, the so-called Community Code Relating to Medicinal Products for Human Use (the Community Code). The Community Code is a sort of “umbrella” directive, consolidating rules pertaining to medicinal products which had been spread amongst various other EC directives previously\(^2\). The Community Code was enacted on November 6\(^{th}\), 2001 and was amended through two subsequent directives\(^3\). It offers – partly in its Title V (Article 62), however more extensively in its Titles VIII and VIIIa – extensive rules regarding advertising of and information on medicinal products.

The Community Code is accompanied by Directive 84/450/EC on misleading advertising. While Art. 87 Community Code provides for rules on misleading advertising, too, it is not lex specialis to Directive 84/450/EC. This clearly follows from Recital 1 and from Art. 128 Community Code which thoroughly lists the directives to be replaced by the Community Code.

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\(^1\) Views expressed in this paper are purely personal and do not necessarily represent those of Celesio or Celesio Group

\(^2\) Cf. the list of directives referred to in Art. 128 Community Code

\(^3\) Directives 2004/24/EC and 2004/27/EC
2. Substantive provisions of the Medicinal Products Advertising Act

2.1 Central definitions

2.1.1 Advertising
The Act does not offer a definition of the term “advertising”. In its sec. 1 para. 3, the Act provides, however, that advertising in terms of the Act also includes announcing adverts. What follows from this is that for the term advertising, a broad scope is intended. In any case, common opinion suggests that the relevant definition of the Community Code can be applied to the Act, too. The Community Code defines advertising medicinal products as “any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products ...”.

2.1.2 Medicinal products
The Act (sec. 1 para. 1 no. 1) refers to the definition in the Pharmaceuticals’ Act which in turn is in line with the pertinent definition in Art. 1 para. 2 Community Code, reading: “Any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.”

2.1.3 Professional Market Parties
Professional Market Party in terms of the Act refers to anybody exercising healthcare professions, institutions devoted to health, and any other person trading or professionally dealing with pharmaceutical products, medical devices or other products and procedures in the context of diagnosing, curing or mitigating diseases (sec. 2).

2.2 Systematic structure of the Act
Some provisions are relevant to advertising to every addressee. In addition, there are provisions which apply to adverts to consumers only, or exclusively to adverts to Professional Market Parties, respectively.

The following provisos pertain to every advertisement regardless of the addressee:
- ban on misleading adverts (sec. 3 and sec. 3a)
- obligation to provide minimum information (sec. 4)
- short list of “black” marketing mechanisms (sec. 6)
- restrictions on rebates and gift items (sec. 7)
- ban on advertising pharmaceuticals by way of tele-shopping (sec. 8)
- ban on adverts printed on package leaflets (sec. 4a),
- ban to promote pharmaceuticals which are not generally approved but only registered according to the Pharmaceuticals’ Act along with relevant medical indications (sec. 3a).

4 Rehmann, Arzneimittelgesetz, 3rd edition, Munich 2008, § 2 ref. 2
5 In the following, all legal quotations which are not explicitly referring to a certain Act or Code refer to the Medicinal Products Advertising Act (Heilmittelwerbegesetz)
When it comes to advertising to consumers, the following concepts apply in addition to the above mentioned general rules:

- ban on campaigning for prescription-only pharmaceuticals, the so-called Rx-products (sec. 10 para. 1)
- Further more, a long list of “black” marketing mechanisms (sec. 11)
- and a concise list of “black” medical indications (sec. 12 and sec. 10 para. 2).
- Finally, adverts towards consumers must be accompanied not only by a warning text standardised by operation of law (sec. 4 para. 3), but also by a short and concise set of minimum information highlighting in particular the medical indication of the relevant product.

When it comes to additional rules for advertising to Professional Market Parties, adverts must be accompanied by a comprehensive set of mandatory information, the scope of which by far and – on the face of it, surprisingly – exceeds the range of information that must be given when advertising to consumers.

2.3 Provisions applying for advertising to every addressee

Amongst the provisions indicated under 2.2 above, the following are key and will be explored in further detail:

2.3.1 Ban on misleading adverts

The Act provides for a general ban on misleading adverts (sec. 3 sentence 1) and sets out a range of typical cases which it specifically qualifies as unlawful. This list includes:

To untruly pretend that pharmaceuticals offer certain therapeutical properties. According to case law, an advert is already then in conflict with this ban where it suggests a certain product to be a cure-all, by stating “wirkt universell” (remedies universally) or the like.

The list also interdicts giving the impression that after treatment with a specific medical product, success is definitely to be expected or that in the course of extended and/or appropriate use of the product, no damages to health are to be taken into account. Examples for the latter would be claims like for instance “unschädlich” (harmless) or “unbedenklich” (inoffensive).

2.3.2 Minimum information

2.3.2.1 Elements

Generally, adverts for medicinal products should be accompanied by the following minimum information (sec. 4):

- Manufacturer’s name, firm and statutory seat;
- If the medicinal product avails itself of one active pharmaceutical ingredient (API) only: Indication of this API after the indication of the name of the medicinal product. However, if the API already forms part of the name of the medicinal product, it can be omitted;
- Name of the medicinal product;
- Therapeutic indications;

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6 Bülow/Ring-Bülow, Heilmittelwerbegesetz, 3rd edition, Cologne 2005, referring to various case law
7 Bülow/Ring-Bülow, cf. footnote 5, § 3 ref. 60
Special precautions for use, insofar it is mandatory to apply them also to the product’s packaging and wrapping;\(^8\)

In the case where the medicinal product is designed to be applied to animals, which in turn are supposed to be used to produce food thereof: indication of the waiting period, i.e. the period between applying the medicinal product to an animal and the point in time as of which it can be expected that the medicinal product will have degraded according to pertinent statutory quantities\(^9\)

Generally, minimum information has in content to match with the designations on the package leaflet (sec. 4 para. 2 and sec. 11f Pharmaceuticals’ Act/ Arzneimittelgesetz).

### 2.3.2.2 Design

As regards to how to arrange minimum information, following rules apply (sec.4 para. 4):

1. Minimum information has to be clearly separated (“abgesetzt”) from advertising messages. Any mix up between advertising messages and minimum information is to be avoided.\(^10\) The legal intention is to enable the addressee to identify the objective minimum information at a glance\(^11\). To securely accomplish this in practice, minimum information preferably should be arranged as a separate text block.

2. Minimum information needs to be clearly outlined (“abgegrenzt”). Again, this is to aid the addressees of the advert to spot the objective minimum information without any effort.\(^12\) Common techniques to accomplish the required outline in practice include putting minimum information into a frame, applying a separating line between minimum information and advertising messages, or simply formatting minimum information in a different typeface\(^13\).

3. Minimum information has to legible. Criteria qualifying this depend on the communication media employed. As a general rule, however, minimum information has to be legible without effort by a person with average eyesight from the relevant reading distance. For adverts in e.g. flyers this means that a 6-dot-typeface on a well-contrasting background generally marks the absolute minimum\(^14\). Adverts on posters or within shop displays on the other hand need to be well readable by an average reader standing on the closest pavement\(^15\).

When it comes to advertisements in audio-visual media, a special rule applies (sec. 4 para. 5): In a nutshell, it is required and suffices when a warning text (as to the wording cf. 2.4.1 below) is faded in and read out at the same time.

### 2.3.2.3 Mitigated regime

Notwithstanding the above rules on minimum information, if an advert is intended solely as a reminder (so-called Erinnerungsverbung), a mitigated regime applies. Concretely, where an advert exclusively consists of the name of the medicinal product and/or the

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\(^8\) See sec. 10 para. 2 Pharmaceuticals’ Act (Arzneimittelgesetz)

\(^9\) See sec. 4 para. 12 Pharmaceuticals’ Act (Arzneimittelgesetz) in connection with Regulation 2377/90/EC

\(^10\) Doepner, Heilmittelwerbegesetz, 2\(^{nd}\) edition, Munich 2000, § 4 ref. 62

\(^11\) OLG (Higher Regional Court) Stuttgart, ES-HWG § 4 IV No. 15; Doepner (see footnote 9), § 4 ref 62

\(^12\) Doepner (see footnote 9), § 4 ref. 62

\(^13\) OLG (Higher Regional Court) Stuttgart, ES-HWG § 4 IV No. 28; Doepner, (see footnote 9), § 4 ref. 62

\(^14\) BGH (Federal Civil Court), NJW 1988, 767, ibid

\(^15\) Doepner (see footnote 9), § 4 ref. 63
name and/or firm and/or trademark of the relevant manufacturer, plus, as the case may be, of the indication of the active pharmaceutical ingredient and/or of further messages which are medically and pharmacologically irrelevant, all minimum information may (at the discretion of the advertising person) be omitted (sec. 4 para. 6). Examples of additional messages without medical or pharmacological relevance would be general statements such as “good quality” or information on the product’s price and quantity.  

2.3.3 Rebates and gift items
Section 7 of the Act provides for a general ban on rebates and gift items with regard to medicinal products. It is unlawful to offer, to announce and to grant rebates and gift items. There is, however, a substantial list of exceptions to this general rule:

2.3.3.1 Items of little value
First of all and practically very important, gift items are lawful if they are of little monetary value (“von geringem Wert”) and if the advertising person or the marketed product are indicated in a permanent and clearly visible manner on the gift item. Gift items are also in order if they qualify as “little somethings” (“geringwertige Kleinigkeiten”) (sec. 7 para. 1 sentence 1 no. 1). There is no clear cut case law on how to determine the relevant value which must not be exceeded. There is a general view, however, that the value is to be determined from the customer’s perspective rather than from the advertiser’s angle. Regarding the applicable threshold, case law suggests that the value of the gift item to the customer should not exceed 1 Euro.

2.3.3.2 Cash benefits and rebates in kind
Secondly and likewise practically very important, a gift item will in following circumstances be lawful:

- if the gift consists of a concrete amount of money or if it can be determined in cash, and if in each case it is not in conflict with the rules of statutory price law under the Pharmaceuticals’ Price Regulation (Arzneimittelpreisverordnung). The Pharmaceuticals’ Price Regulation in turn solely refers to prescription-only pharmaceuticals (Rx-products). Consequently and in a nutshell, cash benefits are in order as long as they do not relate to Rx-products, but exclusively to OTC (over-the-counter) pharmaceuticals or to pharmaceuticals which are freely tradable.
- if the gift consists of a certain quantity of the same medicinal product as in the transaction the gift item relates to – in other words, if the gift item constitutes a rebate in kind. There is, however, one counter-exception: The rebate in kind may not be granted for medicinal products which may be dispensed by pharmacies only. What follows is that rebates are illicit for Rx- and for pharmacy-only-pharmaceuticals, but may well be granted for any other pharmaceuticals.

2.3.3.3 Others
In addition to the above, the following exceptions to the general ban on rebates and gift items with regard to medicinal products exist: conveniences usual in trade, information and advice, and magazines as long as production costs are minor and as long as it becomes clear from the overall design and cover page that the magazine is designed as a marketing tool of the person distributing it.

16 BGH (Federal Civil Court), WRP 1982, 645, 646; Doepner (see footnote 9), § 4 ref. 73
17 BGH (Federal Civil Court), BGHZ 11, 260, 264; Bilow/Ring-Bilow (see footnote 5), § 7 ref. 13
18 Goerke/Koeber, Wettbewerbsrecht für Apotheker, 2nd edition, Bad Homburg 2007, p. 32
2.4 Additional provisions applying when advertising to consumers

2.4.1 Statutory warning text
All advertising to consumers must generally be accompanied by the following warning text as standardised by operation of law (sec. 4 para. 3): “Zu Risiken und Nebenwirkungen lesen Sie die Packungsbeilage und fragen Sie Ihren Arzt oder Apotheker”, stating that the package leaflet plus a medical practitioner or pharmacist should be consulted on any possible risks and side effects associated with the product. Quite like the aforementioned minimum information (cf. 2.3.2.2 above), this standard text has to be clearly separated from advertising messages, has to be outlined and must be well legible. In practice, the warning text tends to be linked with the advert through an asterisk, which is sufficient to fulfil legal requirements.

2.4.2 Ban on promoting prescription-only products
Advertising prescription-only products (Rx-products) to the end consumer is unconditionally prohibited (sec. 10 para. 1). Rx-products may be advertised solely to a certain part of the Professional Market Parties, being medical practitioners, dentists, veterinarians, pharmacists, and people legitimately trading with the products. The rationale behind this restriction is that only this segment of the Professional Market Parties is entitled to prescribe and to sell Rx-products. The prohibition to advertise Rx-products to the end consumer legally intends to avoid a conflict in the mutual trust between doctor and patient which could arise where patients – motivated by adverts for a certain Rx-product – would ask their doctor to prescribe this very Rx-product. Hence, the underlying idea is to protect medical practitioners from being influenced by patients who in turn are influenced by adverts for Rx-products. In practical terms this means on the one hand that Rx-products may not be promoted in business-to-consumer media such as consumer magazines or websites. On the other side it follows for pharmacy, that Rx-product packages may not be visibly displayed but have to be stored in drawers or elsewhere out of consumers’ sight, since displaying an Rx-product would already qualify as an illegal advertising (cf. 2.1.1 above).

2.4.3 “Black” marketing mechanisms
The Act provides for a list of fifteen prohibited marketing mechanisms. These mechanisms have in common that they are suggestive and thereby bear an enlarged risk to influence the addressees in an un-objective way. And where, in turn, the addressee is influenced in an un-objective way, he or she runs the risk to misuse medicinal products – either in terms of consuming the wrong medicinal products or in terms of consuming too many of them. Against the background of this rationale, any prohibition within this section of the Act is to be construed. In the following, the most important prohibitions out of the “black list” will be introduced.

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19 Doepner (see footnote 9), § 4 ref. 61 in the end
20 Gawrich/Parteina/Ziller, Heilmittel und Werberecht, Bonn 1999, § 10 no. 1
21 Bülow/Ring-Ring (see footnote 5), § 10 ref. 1
22 OLG (Higher Regional Court) Karlsruhe, ES-HWG § 11 Nr. 4 No. 15; Doepner (see footnote 9), § 11 ref. 6
23 Erbs/Kohlhaas-Pelchen, Strafrechtliche Nebengesetze, Vol. 2, Munich 2009, § 11 HWG ref. 1
2.4.3.1 Recommendations
Advertising medicinal products through opinions, testimonials, scientific or specialist publications is prohibited (sec. 11 no. 1). The underlying idea is that such statements are bound to influence end consumers particularly intensely, given that consumers will generally be inclined to follow such competent and – allegedly – neutral and objective advice. And the Act goes one step further: Likewise it would be unlawful to advertise a medicinal product indicating that the relevant product was recommended or applied or had been tested by a medical practitioner, a dentist or by any other relevant expert or expert institution (sec. 11 no. 2). Qualify as such relevant expert or expert institution would for instance a biologist, a pharmacists, a midwife or a hospital. Finally, even reference to positive comments by any other person or institution including letters of thanks and letters of recommendation – in short: testimonials – are prohibited in association with advertising medicinal products to end consumers (sec. 11 no. 11). Legal rationale behind is that end consumers would be endangered to take such people for neutral third parties without commercial interest in the relevant product. And end consumers are thought to be likely to be impressed by purportedly positive genuine experiences. However, in its recent Gintec case, the European Court of Justice (ECJ) held that this provision of the Act must be construed in a restrictive way. The ECJ highlighted in the first place that the relevant Directive 83/2001/EC (the Community Code, cf. 1 above) not only creates a minimum standard to be observed by Member States, but at the same time constitutes a final and comprehensive set of rules. In other words, Member States are barred from setting up such provisions within the scope of the Community Code that restrict advertising of medicinal products beyond the scope of the directive itself. Art. 90 c Community Code states that “advertising of medicinal products ... shall not contain any material which: ... suggests that the health of the subject can be enhanced by taking the medicine”. Art 90 j Community Code prohibits advertising medicinal products which “refers, in improper, alarming or misleading terms, to claims of recovery”. For legal practice this means that the prohibition enacted in sec. 11 no. 11 may not be upheld entirely but needs to be interpreted restrictively in light of the Articles of the Community Code as quoted above.

2.4.3.2 Lab coats and other professional clothing
A ban on campaigning for medicinal products by displaying people in lab coats or other professional clothing or in exercising their health profession is introduced by sec. 11 para. 4. Again, the idea is to protect end consumers from the notion of an allegedly neutral, implicit recommendation. Due to this rationale, the ban extends to showing actors or other people dressed in professional medical apparel. Yet, the Federal Civil Court (Bundesgerichtshof) recently held the prohibition in sec. 11 para. 4 to be generally excessive. The court stated that in the wake of recent decisions by the Federal Constitutional Court (Bundesverfassungsgericht), sec. 11 para. 4 needs to be construed restrictively. The court found that a breach thereof could be assumed only where an advertising employing professional clothing had to be regarded capable of influencing laymen addressees in an unobjective way, thereby causing at least indirect danger for the

24 Erbs/Kohlhaas-Pelchen (see footnote 22), § 11 HWG ref 4
25 Gawrich/Parteina/Ziller (see footnote 19), § 11 no. 11
26 ECJ, C-374/05, Gintec International Import-Export GmbH v. Verband Sozialer Wettbewerb e.V.
27 ECJ, C-374-05 (see footnote 25), ref 33 and 37
28 ECJ, C-374-05 (see footnote 25), ref 63
29 Fezer-Meyer/Reinhardt, UWG, Munich 2005, § 4-S4 ref. 458
30 BGH (Federal Civil Court), I ZR 51/04
31 Cf. BVerfG (Federal Constitutional Court), 1 BvR 254/99, NJW 2000, 2736 ff
In practical terms this means that the prohibition laid down in sec. 11 para. 4 still is to be observed. In case of a breach, however, a defence may be raised that no concrete danger for the relevant addressees’ health is perceivable.

2.4.3.3 Triggering angst
An advert for medicinal products which is capable of conjuring severe anxieties with the audience is prohibited (sec. 11 para. 7). Purpose of this norm is to impede irrational medicine consumption triggered by angst created or increased by adverts for medicinal products. However, not any more or less negligible concern evoked by an advert constitutes a breach of this rule. According to the Federal Civil Court (Bundesgerichtshof), smaller anxieties and concerns of daily life are out of scope of this provision which is supposed to exclusively refer to material anxieties induced by impending severe dangers, in particular the danger of alarming restrictions of life or quality of life. To illustrate this, claims like “a quick end to your headache” or “flue is overrunning Berlin” would be permissible, while advertising with phrases such as “millions of people die” would appear as contrary to law.

2.4.3.4 Diagnosis and treatment
Advertising texts instructing the general public how to diagnose certain ailments and how to treat them with specific pharmaceuticals are illicit (sec. 11 para. 10). The purpose of this proviso obviously is to protect medical laymen from improper diagnosis and subsequent improper treatment – or, put another way, to rule out a situation where a layman is kept from seeing his doctor for proper diagnosis and therapy. To qualify as in instruction to diagnose in terms of this provision, the advert needs to enable its addressee to identify a concrete sickness on the basis of the symptoms explained by the advert. Similar to its stance on sec. 11 para. 4 (cf. 2.4.3.2 above), the Federal Civil Court (Bundesgerichtshof) held that sec. 11 para 10 needs to be interpreted in a restrictive way: According to the court, only such adverts are in breach of this norm which at least indirectly endanger the addressees’ health, such indirect danger implying that the advert is suitable to enlarge the risk that the addressee desists from seeing his medical doctor, as would objectively be adequate.

2.4.3.5 Advertising to children
It is prohibited to advertise medicinal products to children under the age of fourteen (sec. 11 para. 12). This prohibition supplements the general prohibition of the Unfair Competition Act (Gesetz gegen den unlauteren Wettbewerb), as amended on the basis of Directive 2005/29/EC (Directive on Unfair Commercial Practices), to advertise to children by directly addressing them. Naturally, the rationale behind is the notion that typically, children can relatively easily be influenced, resulting in a possible medicine misuse by them. Indications that adverts are addressed to children include publishing those in youth magazines, or distributing or placarding them close to schools or playgrounds.

32 BGH (Federal Civil Court), I ZR 51/04, ref 19
33 Doepner (see footnote 9), § 11 Nr. 7, ref. 3
34 BGH (Federal Civil Court), NJW-RR 1987, 163; Bülow/Ring-Ring (see footnote 5), § 11 Abs. 1 Nr. 7 ref. 6
35 Bülow/Ring-Ring (see footnote 5), § 11 Abs. 1 Nr. 7 ref. 14 ff
36 Fezer-Meyer/Reinhardt (see footnote 28), § 4-S4 ref. 469
37 Doepner (see footnote 9), § 11 Nr. 10 ref. 7
38 BGH (Federal Civil Court), PharmR 2004, 327, ibid
39 Cf. sec. 3 para 3 in connection with Appendix no 28
40 Bülow/Ring-Ring (see footnote 5), § 11 Abs. 1 Nr. 12 ref. 2f
2.4.3.6 Sweepstakes and tombolas

It is prohibited to campaign for medicinal products by using sweepstakes, lotteries, or any other mechanism the result of which is subject to hazard (sec. 11 para. 13). An example for such other mechanism would be to promise a medicinal product to the first hundred people submitting an order for another product. The underlying concern is in any case that a person winning a drug as a prize might be inclined to use it carelessly. In its Gintec case of 2007 as introduced above, the European Court of Justice (ECJ) gave an opinion about whether sec. 11 para. 13 was in line with Directive 2001/83/EC (the Community Code, cf. 1 above). German company Gintec International Import-Export GmbH had been announcing monthly tombolas on its website, prize of which supposed to be certain pharmaceutical ginseng products. German courts found this to be in breach of sec. 11 para. 13 but submitted to the ECJ the question whether this provision itself was in line with the Community Code. The ECJ declared an advertising of a medicinal product through a tombola announced on the internet incompatible with Articles 87 para. 3, 88 para 6 and 96 para 1 Community Code. The ECJ thus insofar confirmed the validity of sec. 11 para. 13 from an EC-law perspective.

2.4.3.7 Samples and trials

Promoting a medicinal product through samples and trials of the relevant product is categorically illegal (sec. 11 para. 14). Underlying protection purpose is to prevent end consumers from consuming medicines (at all or in inadequate quantities) out of the simple reason that they were free of charge.

2.4.4 “Black” indications

The legislator found that certain severe indications and maladies should be entirely carved out from any advertising to consumers (sec. 10 para. 2 and sec. 12). The legal rationale behind this is the notion that given their potentially extensive consequences, certain diseases are simply not suited for self-therapy. Concerning human maladies (as opposed to animals’ maladies) the list in sec. 12 refers to: Maladies which need to be reported according to the Infection Protection Act (Infektionsschutzgesetz), covering illnesses like influenza, measles, polio, tuberculosis, or salmonellae infections. The black list further refers to tumour maladies, pathological dependencies (excluding nicotine drug dependency), and pathological complications associated with pregnancy, accouchement and child-bed. As the term “pathological” suggests, pregnancy itself and any ailment associated with an ordinary pregnancy, accouchement and child-bed are out of scope. Medicinal products for such ailments may thus well be promoted. In addition, sec. 10 para. 2 provides a ban on advertising medicinal products designed to remedy insomnia, mental disorders, or to influence mood. It must be noted, however, that the vast majority of relevant products falls within the category of prescription-only medicines, anyway, and may thus generally not be promoted to end consumers (sec. 10 para. 1, cf. above). When it comes to the remainder of the products within this category, a relevant distinction is to be made: Sec. 10 para. 2 solely pertains to hypnotics and narcotics in pharmacological terms and does not prohibit advertising of merely sedative

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41 Gawrich/Parteina/Ziller (see footnote 19), § 11 no. 12
42 ECJ, C-374/05 (see footnote 25), ref. 63
43 Bülow/Ring-Ring (see footnote 5), § 11 Abs. 1 Nr. 14 ref. 2
44 Gawrich/Parteina/Ziller (see footnote 19), § 12 no. 1
45 Doepner (see footnote 9), § 12 ref .76
Prominent examples of merely sedative medicines – advertising of which being perfectly lawful – would be common valerian, melissa and hop products. As to the difference between narcotic and hypnotic products on the one and sedative products on the other hand: while narcotics and hypnotics tend to enforce sleep, sedatives have a calmative impact, only and are, therefore, at the utmost able to provoke sleep indirectly. It has be noted, however, that also sedatives may not be advertised in such a way that associates the merely sedative product with narcotic powers, i.e. with the power to enforce sleep.47

2.5 Additional provisions applying when advertising to Professional Market Parties

2.5.1 Further minimum information
Advertising to Professional Market Parties must be accompanied by following additional points (sec. 4 para. 1): The composition of the medicinal product, contra-indications, side effects, plus, as the case may be, the hint “verschreibungspflichtig” (prescription-only) if the medicinal product qualifies as such prescription-only product.

2.5.2 Expert opinions
Section 6 of the Act provides for a ban on promoting pharmaceuticals by referring to expert opinions if such opinion either stems from a person which is not sufficiently qualified in the relevant area, or if the relevant expert’s name, profession and domicile is not indicated.

2.5.3 Rebates and gift items
Gift items to Professional Market Parties are only legal if intended for being employed in the addressee’s practice of medicine or pharmacy (sec. 7 para. 1 sentence 2). Therefore, the gift item has to somehow facilitate the relevant practice as such; a sheer advantage lacking any intrinsic linkage to the purpose of the relevant practice would not suffice48. To illustrate this, a biro would generally tend to be in order, a balloon possibly within a paediatrician’s practice, whereas a lipstick would by no means be acceptable.49 However, samples of OTC-products (i.e. of non-prescription-only products) are carved out from this prohibition and may well be rendered to doctors, dentists, veterinaries, and to other Professional Market Parties (sec. 7 para. 1 sentence 3; sec. 47 para. 3 Pharmaceuticals’ Act).

3. Sanctions

3.1 Criminal law
A wilful (not only negligent) breach of the ban on misleading advertising (sec. 3, cf. 2.3.1 above) qualifies as a criminal action, sec. 14. Possible legal consequences are prison sentence of up to one year or a fine.

The – wilful or negligent – breach of any other provision of the Act qualifies as an administrative offence and can be sanctioned through an administrative fine, sec. 15.

46 Erbs/Kohlhaas-Pelchen (see footnote 22), § 10 HWG ref. 7
47 Erbs/Kohlhaas-Pelchen (see footnote 22), § 10 HWG ref. 7
48 Bülow/Ring-Bülow (see footnote 5), § 7 ref. 35
49 Bülow/Ring-Bülow (see footnote 5), § 7 ref. 35
3.2 Unfair competition law

The Act does not provide civil law sanctions for a breach of one of its provisions. However, such breach will generally constitute an anticompetitive action in terms of the Unfair Competition Act (Gesetz gegen den unlauteren Wettbewerb), the UCA. In a number of cases, there will be a congruent provision in the UCA so that the breach of the Act would equal a direct breach of the UCA. The UCA, for instance, provides for its own concept of illicit misleading advertising and generally, an advert being misleading in terms of the Act will also be misleading in terms of the UCA. Where the UCA does not provide a clause specifically corresponding with a prohibition laid down in the Act, however, the back-up provision in sec. 4 no. 11 UCA will apply: This clause states that any action being in conflict of a legal provision which is – at least amongst others – designed to protect market behaviour in the interest of other market players qualifies as an anticompetitive action in terms of sec. 3 UCA.

Competitors, certain private law institutions, but also the public law chambers of commerce and chambers of handicrafts are entitled to take legal action against such anticompetitive actions. Usually, as a first step of such enforcement a warning letter tends to be submitted to the person in breach, along with the request to issue a declaration of discontinuance (sec. 12 para. 1 UCA) and to accept a penalty in case of a further breach. If the person in breach refuses to issue a proper declaration of discontinuance and to accept an adequate penalty, interlocutory relief tends to be sought: In summary proceedings according to sec. 936 and sec. 916 ff Code of Civil Procedure (Zivilprozessordnung), an injunction can be obtained in very short term – within hours or at least within days, depending on the severity of the breach.

C. Epilogue

At this point, the expedition into the jungle of German pharmaceutical advertising law is completed. I hope and trust the trip has revealed some orientation, along the aisles cut through the thicket.

Thorsten Witt: 1972: Born near Stuttgart (GER)

1992 - 1997: Studied law at universities of Tübingen (GER) and Leiden (NL)
1998: First German state exam and diploma of laws
1998 - 2000: Legal trainee at law firms, courts and government authorities
2000: Second German state exam
2000: Admitted to the Stuttgart bar as a registered German lawyer (Rechtsanwalt)
2000 – to-date: Corporate Counsel in the central legal department of Celesio AG. Responsible for IP matters
2008: Examination as a certified IP lawyer (Fachanwalt für Gewerblichen Rechtsschutz)

Celesio is a leading international company which covers the spectrum of pharmaceutical trade and pharmaceutical-related services. The group is active in 28 countries and employs around 41,500 people in its three divisions Patient and Consumer Solutions, Pharmacy Solutions and Manufacturer Solutions. Over 2,300 of Celesio’s own pharmacies, as part of Patient and Consumer Solutions, serve over 550,000 customers in seven countries every day. In its wholesale activities, which are part of Pharmacy

50 Bülow/Ring-Bülow (see footnote 5), Einführung ref. 26
51 Hefermehl/Köhler/Bornkamm-Köhler, UWG, 26th edition, Munich 2008, § 4 ref. 11.133 ff
Solutions, around 120 wholesale branches deliver to over 35,000 pharmacies in twelve European countries – day in, day out. In the Manufacturer Solutions division, Celesio offers pharmaceutical manufacturers logistics and distribution solutions and supports them in sales and marketing.