

EHLERS, EHLERS & PARTNER

RECHTSANWALTSGESELLSCHAFT MBH

Ehlers, Ehlers & Partner • Rechtsanwaltsgesellschaft mbH
Widenmayerstr. 29 • D-80538 München • Germany

KIRM PERPAR law firm, Ltd.
Mr. Andrej Kirm
Attorney at law / managing partner
Poljanski nasip 6
SL-1000 Ljubljana
SLOVENIA

München

Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers^{1,3,6}
Dr. iur. P. Nikolai Ehlers, LL. M.^{1,4}
Karin Gräfin von Strachwitz-Helmstatt^{1,3}
Dr. iur. Christian Rybak¹
Dr. iur. Horst Bitter
Ute Sasse²
Eda Zhuleku
Dr. iur. Anke Erdmann
Sonja Graßl, LL. M.

Berlin

Dr. iur. Melanie Arndt^{1,3,5}
Lars F. Lindemann²
Carsten Gundel-Arndt³
Dr. iur. David Preisner
Tom Karl Soller, M. MEL.

In Kooperation mit

Prof. Dr. iur. K. A. Prinz von Sachsen-Gessaphe

¹ Partner

² Assoziierter Partner

³ Fachanwalt für Medizinrecht

⁴ Attorney at Law, New York

⁵ Fachanwältin für Verwaltungsrecht

⁶ Facharzt für Allgemeinmedizin

By e-mail in advance: andrej.kirm@k-p.si

Ihr Zeichen
Your Reference

Ihr Schreiben vom
Your letter dated

Unser Zeichen
Our Reference
EA/ad/AE

München,
Munich,
17 March 2014

File: Supplemental Ltd. / Advisory
Our reference: **0046/14 - please state in correspondence**
Your contact person(s): Rechtsanwältin Dr. iur. Anke Erdmann

Dear Andrej,

Referring to our e-mails in the end of February 2014, we want to answer your client's questions regarding the introduction of the product "Damiana" in Germany taking into account the several chemical differentiations that are listed in the document "Supplementum Compounds".

According to the list of questions that you provided us with, we want to outline that the import, manufacture, sell and use of a recreational psychoactive product containing any of the listed ingredients made up into a blend for smoking/vaporisation can be prohibited in Germany unless your client applies for a marketing authorization for pharmaceuticals.

We will outline the overall legal framework for such products focussing on the German Narcotics Act (Betäubungsmittelgesetz – BtMG) that regulates how to deal with any of the substances listed in the Annex I to III of the BtMG (See sec. I.). We will then analyze whether the dealing with any of the substance listed in the document "Supplementum Compounds" may be limited according to the German Medicines Act (Arzneimittelgesetz, AMG) (See sec. II to IV.). Lastly, we will estimate the likelihood of any European or German legislation coming into force that will change the current system (See sec. V.).

For Damiana or its supplementum compounds, there does not exist any specific jurisdiction or regional provision for public procurement. Hence, our assumptions and legal analyses are made subject to any authorities' or courts' decision that we cannot foresee with certainty.

.../ 2

München: Widenmayerstr. 29 • D-80538 München • Germany
Telefon: + 49 (0) 89 - 210969-0 • Telefax: + 49 (0) 89 - 210969-99
E-mail: munich@eep-law.de • www.eep-law.de

Berlin: Meinekestr. 13 • D-10719 Berlin • Germany
Telefon: + 49 (0) 30 - 887126-0 • Telefax: + 49 (0) 30 - 88676111
E-mail: berlin@eep-law.de • www.eep-law.de

Geschäftsführung/Managing Director: Marta Pölcz

Partnerschaft eingetragen beim Amtsgericht München PR 146

I.

According to the German Narcotics Act, any illegal cultivation, production, trading, import, export, sale, delivery or bringing into circulation with narcotics can be criminal according to § 29 ff. BtMG.

This penal law (and any other administrative offence regulated in the BtMG) applies in case that the respective substance appears in the Annexes I to III to the BtMG, because § 1 sec. 1 BtMG defines narcotics as the substances listed in these Annexes. In the Narcotics Law, there is no generic clause according to which the basic chemical structures or substance groups can be prohibited. Only the specific chemical compounds listed in the Annexes I to III are relevant for any prohibition.

Annex I lists all those products that are prohibited to provide, to make available and to deal with. The products listed in Annex II are allowed to be dealt with but they are excluded from prescription. Drugs that may be dealt with and that can be prescribed are listed in Annex III; for any of these substances, the manufacturer or the pharmacists need a market authorization according to §§ 3 ff. BtMG.

There is no INN for the chemical substances you enumerated and therefore, a scientifically validated product definition is not possible to refer to. The indicated SGT-/ SDB-codes of the "Supplementum Compounds" are not listed in the Annexes I to III specifically, too. According to the Introduction to the Annexes, the chemical formula then defines whether the substance is excluded from sale and prescription according to the International Union of Pure and Applied Chemistry (IUPAC).

None of the chemical formulations indicated in the list of supplementum compounds shows up in any of the Annexes.

It is thus not prohibited to deal with Damiana and its supplementum compounds according to the Narcotics Act in Germany.

II.

Although Damiana and its supplementum compounds are not prohibited according to the BtMG, they can be classified as medicinal products in the sense of the German Medicines Act (AMG), § 2 sect. 1 AMG with the consequence that the import and sale depends on several prerequisites and can be criminal if the manufacturer does not have a market authorization, §§ 21 ff. In connection with 94 ff. AMG:

1. Medicinal products in the sense of the AMG

According to § 2 sect. 1 No. 1 AMG, medicinal products are substances or preparations of substances that are determined for the use in or on the human or animal body and that have properties for treating or alleviating or preventing human or animal diseases or morbid symptoms (drugs by its presentation). These pharmaceuticals are determined to heal and produced for treating options.

According to § 2 sect. 1 No. 2 AMG, medicinal products can also be substances that are applied to the human or animal body to either restore the physiological functions by exerting a

.../ 3

pharmacological, immunological or a metabolic action or to make a diagnosis (drugs by its function). Preparations are classified as pharmaceuticals if they can have any therapeutic effect, even if they are not determined to.

According to the jurisdiction, any psychoactive substance (sometimes called "Legal-Highs") can be seen as medicinal products because if they have a pharmacological effect in the aforementioned sense, § 2 sect. 1 No. 2 AMG and its intended purpose is a medical one. Thus the classification as a medicinal product might not only depend on the pharmacological effect which might be given for all psychoactive substances. Additionally, the therapeutic or prophylactic purpose might be needed in order to differentiate pharmaceuticals from other substances (EuGH, judgment of 21.3.1991, 3 CS.09; BVerwG, judgment of 26.5.2009). If the purpose only was any food- or smoking purpose, the restrictions of the AMG might not apply.

However, the legal requirement of the "therapeutic purpose" for the application of the AMG is currently disputed in case-law and legal writings. Some classify substances as pharmaceuticals only if there was a therapeutic purpose (see OVG Münster, judgment of 23. 4. 2012 - 13 B 127/12; VG Köln, judgment of 20. 3. 2012 - 7 K 3169/11, Rn. 168 ff.; OVG Magdeburg, Decision of 5. 6. 2012 - 3 M 129/12; Rennert, NVwZ 2008, 1179, 1184; Müller, PharmR 2012, 137, 139; Voit, PharmR 2012, 241, 243 f.; Krumdiek, StRR 2011, 213, 215; Nobis, NStZ 2012, 422, 424 f.; Weidig, Blutalkohol 50/2013, 57, 63 ff.).

Some other courts and authors see it differently and stick to the wording of § 2 sect. 1 AMG that does not require the purpose for drugs by their function but only the pharmacological effect (OVG Saarlouis, judgment of 3. 2. 2006 - 3 R 7/05; VG Potsdam, decision of 9. 6. 2008 - 3 L 115/08, PharmR 2009, 250, 251; *Koyuncu* in: Deutsch/Lippert, AMG, 3. Aufl., § 2 Rn. 18, 21; *Müller* in: Kügel/Müller/Hofmann, AMG, § 2 Rn. 91; *Kloesel/Cyran*, Arzneimittelrecht, 119. Erg.-Lief., § 2 Nr. 69 aE; *Volkmer* in: Körner/Patzak/Volkmer, BtMG, 7. Aufl., Vorbem. AMG Rn. 72; OLG Nürnberg, judgment of 10. 12. 2012 - 1 St OLG Ss 246/12; LG Limburg, judgment of 27. 9. 2012 - 5 KLS 3 Js 14210/11; Diehm/Pütz, Kriminalistik 2009, 131, 135; Patzak/Volkmer, NStZ 2011, 498, 500).

Therefore, the German Federal Supreme Court (Bundesgerichtshof, BGH) has submitted this matter to the European Court of Justice (EuGH) on 28 May 2013 (BGH, Decision ref. 3 StR 437/12). In this order for reference, the BGH puts into question whether a substance that has no therapeutic effect but stimulates a state of intoxication can be seen as medicinal product in the sense of the European Directive 2001/83/EG and thus of the AMG.

Until there will be any clarification by the EuGH, the respective authority might, in the individual case, confirm pharmacological purposes: From what we could gather, *Damiana* has psychoactive effects and therefore it might be classified as medicinal product according to the jurisdiction above: Although the legal situation is unclear at the moment and one needs to await the EuGH decision, the German government commissioner for drugs states clearly that psychoactive substances can be classified as pharmaceuticals and new psychoactive substances were dubious drugs according to § 5 AMG (see below).

The consequences of the application of the AMG also for tobacco products or any other dosage form would be the requirement of the marketing authorization according to §§ 21 ff. AMG or the prohibition to import the substances unless determined for few patients in case there is the therapeutic need, §§ 73 sec. 3 AMG.

2. Dubious drugs

Additionally, some psychoactive products might be classified as dubious drugs (*bedenkliche Arzneimittel*) in the sense of § 5 sect. 2 AMG. The provision reads as follows:

"Pharmaceuticals are dubious, where there are reasonable suspicions according to the state of scientific knowledge, that when used properly, they have harmful effects which go beyond the acceptable according to the findings of the medical science. There is no need for a scientific proof of this dubiousity. It is enough to have scientific assumptions and the respective suspicion."

Dubious pharmaceuticals are prohibited from any sale or putting into circulation, § 5 sect. 1 AMG. Although some legal high substances could be classified as dubious drugs because of scientific proof, we have no occasion for any scientific plausibility (*Rehmann*, Arzneimittelgesetz (AMG), 3. circulation 2008, § 5 Rn. 2). If there are any assessments that you dispose of, let us please know.

Thus it depends on the scientific assessment whether Damiana could be classified as dubious drug – from the theoretical point of view. However, the German government commissioner for drugs states that new psychoactive substances were dubious drugs and therefore, dealing with them was criminal according to § 95 sect. 1 sentence 1 AMG (www.drogenbeauftragte.de).

III.

It is, from a theoretical point of view, uncertain whether the AMG applies and if the sale and import of Damiana and the supplementum compounds are criminal or an administrative offence according to §§ 94 ff. AMG.

In practise, the legality of the import, manufacture, sale and use of any recreational psychoactive product containing Damiana or any of the supplementum compounds will depend on the concerned authority that will get in touch with these substances. Therefore we recommend submitting the list you provided us with to the local authority, the regional government of Upper Bavaria (Regierung von Oberbayern), asking whether these substances currently are free from restrictions and what the current assessment was. Although the different regional authorities may treat your product differently, you will have an official document you will be able to refer to if needed. We are, in fact, in many other cases in contact with the regional government of Upper Bavaria and it usually takes two weeks to receive their opinion.

IV.

Psychoactive products or drugs may be removed from the market very quickly if they are imported: The customs duty may examine any delivery with the substances and is supposed to hand it over to the responsible authority if they entertain suspicion on whether the products may be classified as narcotics or pharmaceuticals. If they are classified as drugs, the regional government will contact the prosecutors' office who will decide on whether to initiate preliminary proceedings.

The police might detect any sales channel in case Damiana is sold to German consumers or intermediaries. Then, the responsible authority or the prosecutors' office might initiate preliminary proceedings. If any substance shall be removed from the market, it may go very quickly and the police may confiscate the products.

V.

We consider the likelihood very high that the European Commission's proposal for new psychoactive substances will pass into law by the European Parliament. The European Commission intends a regulation and no directive so that all these restrictions will come into force in Germany directly. A directive would need to be implemented into German law whereas a regulation is directly applicable in Germany.

As the European Parliament will be elected in the end of May 2014, we might have some delay regarding any legislative initiative. However, there is no legislative discontinuity in the European law so that any legislative initiative can be carried forward just after the elections and a new initiative is not needed. We estimate that the regulation will not be adopted before the parliamentary elections but may be put forward just afterwards.

At the moment, the proposal for the regulation is discussed within the Member States and the German Bundestag and Bundesrat are requested to comment the proposal. The German Bundesrat has made its decision and came to the result to recommending to strengthen the prerequisites for psychoactive substances (decision of 14. March 2014, BR-Drs. 692/13). The German Bundestag has not yet made a decision but will do so in the next weeks, we suppose. We will keep you updated on this.

In fact, the political initiative in Germany aims for a new legal framework for psychoactive substances and German politicians consider tightening the possibilities to deal with psychoactive substances independent of the European initiative. The German government commissioner for drugs intends to complete the German narcotics act and its regulation at very short intervals in order to encompass all chemical variations of psychoactive substance groups; "catch all" clauses aiming to list substance groups in the Annexes I to III of the BtMG are currently discussed and they might be enacted independently of the European regulation.

Hence the incentive to increase hurdles for psychoactive substances is supported a lot by the German government. As a matter of fact, the German national regulations can exceed the European requirements and they often do. We therefore expect the legal framework in Germany to become stricter concerning psychoactive substances. As the current government has only recently been elected, we expect any legal initiative still this year and we therefore consider the legal framework for psychoactive substances to be altered in the near future.

Please let us know whether we should submit your list to the local authority in order to give you some certainty on the current official treatment. We will of course not charge anything, as well as for any further questions or comments in case anything is missing or unclear.

Yours sincerely,



Dr. iur. Anke Erdmann
Lawyer