EHLERS, EHLERS & PARTNER

RECHTSANWALTSGESELLSCHAFT MBB

München · Berlin · Düsseldorf

EEP-News

Current Information on Medical and Life Science Law

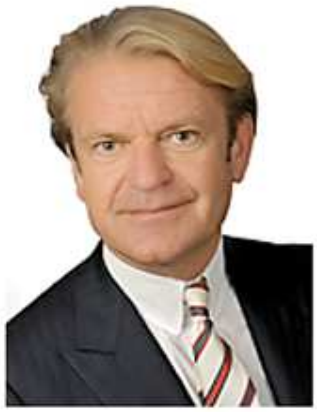
Dear Ladies and Gentlemen,

Some significant legal changes have dominated the last couple of months and we are happy to share some selected topics with you: For example, a new anti-corruption legal framework for the collaboration of healthcare professionals and the industry in Germany will be established in the near future; corruption in the healthcare sector can result in criminal proceedings according to the latest draft bill – however, nothing is fixed yet. As another milestone, the European Court of Justice has decided that data transfer to the U.S. can no longer be justified with the Safe Harbor decision but a Data Privacy Shield is to be established. This has an immense impact on global pharmaceutical companies that carry out clinical trials in the EU.

The broader picture shows further developments of the AMNOG procedure, especially with regard to orphan drugs: The legal privilege to have additional benefit granted by law no longer stands for high prices without proving the additional benefit. In all countries, the market access obstacles especially for orphan drugs are equally observed – will we see harmonization of reimbursement systems in the upcoming decades, maybe starting with an alignment for orphan drugs?

Yours sincerely

Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers
Physician and Lawyer



EHLERS, EHLERS & PARTNER
RECHTSANWALTSGESELLSCHAFT MBB

For queries: newsletter@eep-law.de
www.eep-law.de

EEP News

The new "Getting the Deal Through: Life Sciences 2016" has recently been published. We hope that you can profit from this year's publication for all your projects. You can find further information here: https://gettingthedealthrough.com/area/43/life-sciences-2016.

We may alert you to a very recent **press release:**

http://immunovia.com/immunovia-partners-with-leading-healthcare-consulting-services-firm-to-support-market-access-of-pancreatic-cancer-test-in-germany/

Table of contents

For questions or comments please contact: a.ehlers@eep-law.de

Pharmaceutical Market Facing Changes

Since the introduction of the so-called AMNOG [German Pharmaceutical Market Restructuring Act] in 2011, medicinal products that contain new active substances and are refundable in Germany have been assessed with respect to their benefits. This assessment is carried out based on evidence that is to be provided by the pharmaceutical entrepreneur to the Joint Federal Committee (GBA) no later than at the time of initial market placement, and four weeks after approval of new application areas of the medicinal product in question, along with all clinical trials performed or commissioned. This regulation has in the meantime been established and, given the great number of cases so far completed, a wealth of experience could hereby be gathered. It is still apparent that the availability of data and thus the provision of sufficient evidence for corresponding additional benefit over the respectively suitable comparative therapy remains difficult in individual cases, rendering accurate planning and long preparation – far in advance and during the approval process – a vital requirement. At the same time, experience gathered has also shown that there still is considerable conflict potential and not all legal issues have been satisfactorily resolved. It does hence not come as a surprise that almost all stakeholders have been asked to implement corrections, although the required changes are mostly contrary to the interests of the parties involved. This especially applies to the problem of a lack of additional benefits in a sub-population. Pursuant to the current legal situation, additional benefits are assessed across all sub-populations and, in the context of price negotiations with the Central Association of Statutory Health Insurance Funds, this ultimately results in the so-called mixed price calculation. A standard exclusion of a sub-population from eligibility for reimbursement is not intended in the current process, which is why appropriate legislative changes have been postulated for quite some time now. However, the Joint Federal Committee has in the meantime started to pursue an alternative course of action, irrespective of the pending legal changes with regard to the AMNOG process. For active substances that are currently in the early benefit assessment stage, it has now introduced a commenting procedure regarding a partial exclusion of prescription, which may lead to a possible future omission of eligibility for reimbursement for sub-populations. However, this would also mean that the so-called mixed price problem would disappear. It is therefore apparent that more activities are currently not only to be expected from legislative side, but that considerable influence on medicinal product prices can and will be exerted, in particular applying the existing instruments. We look forward to providing advice on this matter!

For questions or comments please contact: c.rybak@eep-law.de

EU approach on HTA assessment for orphan drugs?

Explaining a non EU pharmaceutical company what the different requirements of the Member States are as regards pricing and reimbursement alerts to the fact that a lot of parallel work needs to be done in order to have access to at least the EU Top 5. For rare diseases, this may mean that only few patients have access to new therapies. Going through the whole HTA procedure in different countries might become uneconomic- despite of regulatory privileges for orphan drugs.

The need for an EU approach is identified by several Members of the EU Parliament and maybe this might lead the way to an overall EU approach to the HTA procedure. At the 2016 EURORDIS Rare diseases Europe - Conference in Brussels, it was made clear that patients will profit enormously from earlier access due to a paneuropean approach. We will monitor the developments carefully.

For questions or comments please contact: a.moroder@eep-law.de

Physiotherapists generally are not allowed to provide osteopathy services anymore

With the decision of 8 September 2015, the Higher Regional Court of Duesseldorf has decided that physiotherapists are only allowed to promote osteopathy services if they are also qualified as physicians or alternative practitioners with a special licence.

Before, many physiotherapists offered osteopathy services if they had completed osteopathy courses in Germany. There are no official standards for these courses. With this decision, osteopathy now is connected to the medical profession or alternative practitioners and will not be allowed to be offered by physiotherapists only. This decision causes consequences for reimbursement of osteopathy services and it is not yet clear what might be paid by the insurances.

For questions or comments please contact: a.moroder@eep-law.de

New anti-corruption rules in Germany

With a new law against corruption in the healthcare business, bribery and corruption of the medical profession will in the future be punished by law.

In this context, the pharmaceutical industry is especially worried about whether co-operation with physicians, workshops, advisory boards and training courses can be carried out in the future. Although basically nothing really changes on the legal framework of physicians working for the industry, a large part of co-operation contracts will have to be reviewed focusing on the criminal legal pursuit.

However, the draft bill is not yet final and criminal legal pursuit may finally not be introduced – we are monitoring current developments carefully.

For questions or comments please contact: a.moroder@eep-law.de

New German provisions on hospice and palliative care

On 8 December 2015, a new law for the improvement of hospice and palliative care came into force in Germany. Seriously ill people should be able to claim intensive care in the last days of their lives epically in rural regions. Hospice financing is improved: 95 % of all costs will generally be reimbursed by the insurances – before, it were only 90%. However, the legislator decided against full cost coverage to avoid commercialization of palliative and hospice care.

Also home palliative care is supported by the new law and costs associated with home care (travel costs etc) are reimbursed now, too. In times of an aging population, better palliative care and better equipment for hospices is one of the latest achievements.

For questions or comments please contact: a.moroder@eep-law.de

What reimbursement system applies if patients leave the hospital but still need their medical devices?

In a recent court's decision of the Social Court of Nuremberg of 19 July 2015, the court has decided about costs for medical devices that social health insured patients have obtained during a hospital treatment but needed also afterwards. In this constellation, the hospital needs to fully pay for these devices i.e. they are included to the DRG-fixed amount. Since all medical services are reimbursed individually in the outpatient sector, hospitals of course are interested in outpatient reimbursement in cases where devices like for example bracers and splints are applied in the hospital but also worn afterwards. This usually costs insurances millions of extra reimbursement. The decision is not yet final.

For questions or comments please contact: h.bitter@eep-law.de

EU – US Privacy Shield

With decision of 6 October 2015 the EuGH had declared Safe Harbor, which regulates the transmission of personal data from the EU into the USA, for inapplicable and therefore data transmission into the USA is now only possible under much more aggravate conditions. The EU

Commission has published the relevant draft documents regarding the successor of the Safe Harbor Agreement ("EU – US Privacy Shield") on 29 February 2016.

According to these documents the Privacy Shield, as well as Safe Harbor, plans a self-certification of the US data recipients; relevant self-certificated enterprises shall have a data protection level equivalent to the EU. However, in relation to Safe Harbor, data protection law requirements for the enterprises shall increase and certificated US enterprises shall be strongly monitored by the US Department of Commerce and the US Federal Trade Commission. Before finalizing, the Privacy Shield shall be checked if the consent given by the US that the access to data is only allowed under explicit conditions and restrictions as well as independent monitoring satisfies the strict requirements of the EuGH.

For questions or comments please contact: e.zhuleku@eep-law.de

Federal High Court of Justice (BGH) defines duties of operators of physician evaluation internet portals

With decision of 1 March 2016 (file number VI ZR 34/15) the Federal High Court of Justice defined the duties of operators of physician evaluation internet portals. According to the decision the operators have to obtain precise information and proof of an asserted treatment from the evaluator and – if permitted – forward it to the affected physician if physicians complain about inadequate anonymous evaluation.

The case dealt with the complaint of a dentist against the physician evaluation internet portal Jameda regarding an extreme bad evaluation from an anonym user who gave the dentist mark 6 in the categories treatment, education and mutual trust. The operator of the portal did not delete the evaluation in question after the dentist demanded to do so.

The Federal High Court of Justice ruled that the operator of the portal is only liable for evaluations its users provide if the operator violated reasonable duties to check. The extent is based on the circumstances of the single case at which the heaviness of the rights violation, the awareness possibilities of the provider as well as the function of the service of the provider is of significant importance. On one side one must not impose the duty to check on the service provider so that his business model is not economically at risk or his activity is unreasonable hindered, on the other side the operator of an evaluation portal with the possibility to post anonym evaluations has a priori a greater risk of violating personal rights in comparison with other portals.

At the present case the defendant portal operator should have sent the complaint of the affected dentist, who disputed from the beginning that the patient in question came to him for treatment, to the evaluator and should have asked him to describe the treatment in question as precise as possible. Furthermore, the operator should have asked the evaluator for documents like bonus

books, prescriptions or other evidence to prove the treatment. The operator then should have forwarded such information and documents to the dentist provided that if would not have violated the data protection law.

Such a high court decision will certainly improve the predictability of legal decisions regarding the rights and duties of all involved parties in connection with much discussed evaluation portals in the future.

For questions or comments please contact: s.grassl@eep-law.de

Special Puplications

We continuously release publications about interesting and current topics in the daily press as well as legal journals. If you are interested in particular issues, please see a list on our homepage (here). However we want to present a choice of special publications in order to keep you updated::

Our milestone publications in recent months have treated the new rules on anti-corruption and anti-bribery in Germany, the ongoing discussions on the pricing of medicinal products and legal challenges with transfer of doctors offices at the occasion of retirement:

Der Nuklearmediziner 2015, 38, 306 – 308, Prof. Dr. Dr. A. P. F. Ehlers and Dr. A. Moroder

pharmind, Nr. 12, 2015, 1760 – 1762, Dr. Christian Rybak

pharmind, Nr. 01, 2016, 86 – 87, Prof. Dr. Dr. A. P. F. Ehlers and Dr. A. Moroder

Medical Tribune, 51. Jahrgang. Nr. 10, März 2016, 34, Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers and Dr. Horst Bitter

DMW - Deutsche Medizinische Wochenschrift, 2016, 141, 474 – 476, Prof. Dr. Dr. A. P. F. Ehlers and Dr. Anke Moroder

pharmind Nr. 3, 2016, 421 – 422, Prof. Dr. Dr. Alexander P. F. Ehlers and Sonja Graßl

Lectures and Moderation

15. April 2016: 15. Bayerisches Gesundheitsforum in Andechs, topic: „Wohnortnahe Versorgung der Bevölkerung - Was heißt das in der Versorgungsrealität?“ Kloster Andechs, „Alte Bibliothek“, moderation Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers

03. Mai 2016: moderation Awarding price for health networker, Berlin-Chemie AG, 11. Kongress für Gesundheitsnetzwerker 3.-4. Mai 2016 Berlin Langenbeck-Virchow-Haus, Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers

11. Mai 2016: 4. Bayerischer Tag der Telemedizin: „Nach vorne schauen“, organizer: Bayerische TelemedAllianz (BTA) in cooperation with the Bavarian Health Ministry, Speeddating with expert Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers. More Information www.telemedizintag.de oder www.eep-law.de.

10. Juni 2016: Kompaktseminar „AMNOG und Market Access – Aktuelle Hintergründe kompakt in zwei Tagen auf hohem Niveau vermittelt“, EBS Business School, Oestrich-Winkel, topic „Juristische Aspekte des AMNOG“, speaker Prof. Dr. iur. Dr. med. Alexandert P. F. Ehlers

11. Juni 2016: „Pneumologie am Main“ 10. – 11.06.2016, Frankfurt am Main, GlaxoSmithKline GmbH & Co. KG, topic: „Antikorruptionsgesetz – was ändert sich?“, speaker Prof. Dr. iur. Dr. med. Alexandert P. F. Ehlers

28./29. Juni 2016: „Wem gehören meine Gesundheitsdaten? – Lösungswege zwischen paternalistischer und partizipativer Datennutzung" –3. Forum Versorgungsforschung von Elsevier Health Analytics and der Gesellschaft für Recht und Politik im Gesundheitswesen (GRPG) e.V., Kaiserin Friedrich-Stiftung in Berlin, moderation Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers

23. Juli 2016: 25. Fortbildungswoche für praktische Dermatologie und Venerologie, 23.-29. Juli 2016, International Congress Center München (ICM), topic „Rechtliche und steuerliche Rahmenbedingungen in der Laser- und Lichttherapie“, speaker Prof. Dr. iur. Dr. med. Alexandert P. F. Ehlers

24. August 2016: „Arztrecht und Haftungsfragen für Ärzte und Pflege“, Medizinische Hochschule Hannover, speaker Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers

06. September 2016: Compliance Symposium Hollister Incorporated, speaker Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers – more information as soon as possible

01. Dezember 2016: MCC 3.0, more information as soon as possible, speaker. Dr. iur. Dr. med. Alexander P. F. Ehlers

Awards and Rankings

Ehlers, Ehlers & Partner has won the Worldwide Financial Advisor Awards Magazine Continental Awards 2016 in the Category Kategorie Health Care Law Firm of the Year – Germany.

Ehlers, Ehlers & Partner has been nominated for the Global Awards for 2016 in the Category Biotech & Pharma.

Ehlers, Ehlers & Partner has won the 2016 Corporate Intl Global Awards in the Category “Healthcare Law - Law Firm of the Year in Germany”.

Prof. Dr. Dr. Ehlers has been shortlisted of the 2016 Dispute Resolution Awards.

Aviation Law Firm of the Year – Germany 2014, 2015

2014, 2015

Life Sience Law Firm Of The Year – 2015

Life Sience Law Firm Of The Year – Germany

Best for Pharmaceuticals Law 2015 & Hospital Law Firm of the Year Germany

The Best Lawyers in Germany 2016 – Litigation

Life Sciences Law Firm of the Year – Germany

Health Care Law Firm of the Year – Germany

Healthcare Law - Law Firm of the Year in Germany

A service of
EHLERS, EHLERS & PARTNER RECHTSANWALTSGESELLSCHAFT MBB

For queries: newsletter@eep-law.de
www.eep-law.de

Contact Location Munich

Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers
+49 89 / 21 09 69 - 12

Karin Gräfin von Strachwitz-Helmstatt
+49 89 / 21 09 69 - 34

Dr. iur. Christian Rybak
+49 89 / 21 09 69 - 81

Dr. iur. Horst Bitter
+49 89 / 21 09 69 - 13

Eda Zhuleku
+49 89 / 21 09 69 - 80

Dr. iur. Anke Moroder (geb. Erdmann)
+49 89 / 21 09 69 - 17

Sonja Graßl
+49 89 / 21 09 69 - 25

Contact Location Berlin

Dr. iur. Melanie Arndt
+49 30 / 88 71 26 - 0

Lars Lindemann
+49 30 / 88 71 26 - 0

Carsten Gundel-Arndt
+49 30 / 88 71 26 - 0

Tom Karl Soller
+49 30 / 88 71 26 - 0

Contact Location Düsseldorf
+49 211 / 583 357-425

Disclaimer

EHLERS, EHLERS & PARTNER
RECHTSANWALTSGESELLSCHAFT MBB
[Law Firm]

Widenmayerstraße 29
80538 München
www.eep-law.de