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EEP-News
Actual Information about Medical and Life Science Law

Corporate INTL Global Awards 2012 Winner
Life Sciences Law Firm of the Year in Germany

2012 ACQUISITION INTERNATIONAL LEGAL AWARDS
GERMAN LIFE SCIENCES LAW FIRM OF THE YEAR

FINANCE MONTHLY LAW AWARDS 2013 SHORTLISTED
Life Sciences law Firm of the year in Germany

CorporateINTL LEGAL AWARDS WINNER 2013
Prof. Dr. Dr. Alexander P. F. Ehlers "Healthcare Law - Lawyer of the Year in Germany"

GLOBAL LAW EXPERTS 2013 PRACTICE AWARDS
Life Sciences law firm of the year in Germany

Dear Ms. Poelcz,

Few months before the elections for the German Parliament, one could think that political activities are solely focused on the election campaigns. The opposite is occurring within the health care sector. The AMNOG-procedure, the first early benefit assessment results of new pharmaceuticals as well as of the existing market, the lawsuit against the latter, the discussion on corruption within the health care sector and lastly the new statutory offense for doctors have heated up discussions. New regulations came into force; the Federal Joint Committee (G-BA) has published the criteria for the early benefit assessment of the existing market and at the same time, six further active substance groups have been published to be appealed in the near future. Curiously, people have been waiting for the decision of the State Social Court Berlin-Brandenburg concerning the early benefit assessment of gliptines that are part of the existing market as there is no document protection to be resorted to. On the “Berlin Floors”, rumor has it that the moratorium for the existing market as well as the prolongation of the mandatory discount may come into force. Future decisions do not only depend on the regulatory will but decisively on the fact whether the early benefit assessment of the existing market exposes as practicable. The obligatory early benefit assessment of new active substances as “learning system” will have to be optimized. However it will persist as an instrument of regulating the pharmaceutical market. Meanwhile other countries are showing interest in the AMNOG-procedure. For example there are discussions in Korea, Japan and especially in the USA. At the BIO International Convention in Chicago in April 2013, at which one of our partners had a speech, Market Access of pharmaceuticals in Europe and thereby the AMNOG-procedure was one of the major subjects. For us who are advising within the health care sector, these encroachments mean a lot of work and a major challenge for the upcoming months. However we should not forget what Arthur Rubinstein depicted felicitously: „If you love life, it loves you, too“. The latter particularly counts these days. We wish you some delightful days of summer and remain sincerely yours,

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EEP News

On May 2nd, 2013, our partner Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers was a guest in the TV broadcast “Scobel” broaching the issue of possible Collapse of the Public Health Care Sector in Germany. Please find the Link hereafter: http://www.3sat.de/mediathek/index.php?display=1&mode=play&obj=36193. Schauen Sie rein!

We congratulate our Associated Partner Lars Lindemann who has been nominated as Chief Executive Officer of the National Confederation of Medical Specialists.

On the occasion of the AMNOG and its obligation to submit a cost-benefit-dossier, Ehlers, Ehlers & Partner have created a team specialized on the review of those dossiers for the pharmaceutical manufacturer. We are on your disposal for any questions.

In April 2013, our partner Prof. Dr. iur. Dr. med. Alexander P. F. Ehlers took part on the BIO International Convention in Chicago. The discussions on the occasion of the Convention showed that also the US authorities are evaluating whether to adopt the AMNOG procedure into the US Health Care System.

We congratulate our Associate Ms Sonja Graßl, LL.M. who recently came to Ehlers, Ehlers & Partner leaving the Examining Section of Doctors in Bavaria. Ms Graßl has finished her master’s extra-occupational in Munster, Germany as head of the class with summa cum laude.

“The law firm Ehlers, Ehlers & Partner is one of Germany’s leading law firms in medical and pharmaceutical law as well as aviation law with distinct international contacts. It enriches the law firms’ scenery significantly”, judged the actual issue of “Kanzleien in Deutschland 2013” – Law Firms in Germany 2013.

The law firm Ehlers, Ehlers & Partner has been awarded with some respectable accolades in the last couple of months:

Acquisition International. Legal Awards 2012. Ehlers, Ehlers & Partner – German Life Sciences law firm of the year.

GlobalLawExperts. 2013 Practice Awards. Ehlers, Ehlers & Partner – Life Sciences law firm of the year in Germany.

FinanceMounthly. Shortlist Law Award 2013. Ehlers, Ehlers & Partner – Life Sciences law form of the year – Germany.

CorporateINTL. Legal Awards. Winner 2013. Prof. Dr. Dr. Alexander P. F. Ehlers – Healthcare Law – Lawyer of the year in Germany.

The International Who`s Who of Life Sciences Lawyers. Alexander P. F. Ehlers – One of the Leading Life Science Practitioners in the world.

Special Publications

We continuously release publications about interesting and actual 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 to you a choice of special publications in order to keep you updated. In this issue of our newsletter, we would like to present you the following releases:

Legal Expertise, in Catheter-Based Cardiovascular Interventions, P. Lanzer (Ed.), Springer-Verlag Berlin Heidelberg, 2013, Ehlers, A., Rybak, C., and Wenke, A.

Relevante Regulierung für Orphan Drugs, in: Seltene Helden, Bertram Häussler, Klaus-Jürgen Preuß (Hrsg.), Verlagsgruppe Handelsblatt Fachverlag, 2013, Ehlers, A., Rybak. C.

Disziplinarrecht für Ärzte und Zahnärzte, Ehlers, A. (Hrsg.), 2. Aufl., C. H. Beck-Verlag, München, 2013.

Kriminologie und Medizinrecht, Festschrift für Gernot Steinhilper, Herbert/Schiller/Michael Tsambikakis (Hrsg.), Negative Konkurrenten-Abwehrklage im Dialysebereich, 2013, Ehlers, A., and Bitter, H.

The International Who’s Who of Life Sciences Lawyers, Roundtable „The International Who`s Who of Life Sciences Lawyers has brought together five of the leading practitioners in the world to discuss key issues facing lawyers today in: Who’s Who Legal Roundtable: Life Sciences – Regulatory 2013.

Ähnlichkeit von Arzneimittelnamen, in: pharmind Nr. 4, 2013, 638-639, Ehlers, A. and Erdmann, A.

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Reference Price group in spite of significant therapeutic improvement for a group of patients?

With regard to the actual German discussion concerning the early benefit assessment according to the AMNOG, other regulatory instruments of the Federal Joint Committee have taken a back seat although the Federal Joint Committee deploys them consistently.
For example the Federal Joint Committee opts for the creation of Reference Price Groups according to section 35 of Book V of the German Social Code, if – according to its opinion – different pharmaceutical products are similar regarding their composition or their mode of action and therefore the price is being adjusted.
Regularly the appropriation to a Reference Price Group causes a reduction of the price that will be reimbursed by the statutory health insurance. Thus the pharmaceutical entrepreneur usually wants to avoid the classification. He therefore needs to prove either the significant therapeutic improvement or the fact that there were no alternative therapy options in case of the Reference Price Group classification.
If the significant therapeutic improvement only shows for a group of patients or indications, the pharmaceutical entrepreneur is in a difficult situation: On the one side, the Reference Price Group System does not allow any exclusion of several patient groups. Therefore the Federal Joint Committee annulled the resolution regarding the creation of a Reference Price Group including insuline and insuline analogues recently. On the other hand, the Federal Joint Committee can exclude the respective drug from prescription for all other patients; it will only be economic for the patient population where there can be confirmed the significant therapeutic benefit. All other patients need to resort to a cheaper alternative.
Hence the better this patient group is encompassed, the more likely the Federal Joint Committee will desist from a Reference Price Group – excluding the respective drug from prescription for all other patients or indications at the same time.
Therefore it will be necessary to additionally check whether alternative therapy options might be expelled. In that case, the Federal Joint Committee cannot exclude the respective drug from prescription. Consequently the pharmaceutical entrepreneur does not need to fear that his pharmaceutical product can only be prescribed for a small number of patients.
What remains to be noted is that the proceedings essentially depend on the early and detailed knowledge of competitors' products. This is the only way to avoid unwanted results as well as to navigate the Federal Joint Committee's choice of regulatory instruments.
For questions or comments please contact: a.ehlers@eep-law.de; a.erdmann@eep-law.de

The early benefit assessment and the existing market after the decision of the Federal Joint Committee dated 18 April 2013

The German pharmaceutical industry was waiting excitedly for the Federal Joint Committee's decision on the concept for the initiation of early benefit assessments for medicinal products that were in the market before AMNOG entered into force on 1 January 2011. When initiating the first procedure, people imputed the G-BA that the decision was not coherent – some say it was arbitrary.
Recently the Federal Joint Committee published that supply-relevant medicinal products have to be screened according to certain criteria. Decisive factors for the supply-relevance were the turnover and the prescription frequency as those two factors were indicating the economic power and the therapeutic relevance of a pharmaceutical product.
On the basis of a publication of the Pharmaceutical Prescriptions Report 2012, the Federal Joint Committee developed an algorithm respecting the revenue of a pharmaceutical product up to 80 % and the prescription forecast up to 20 % - taking into account that the prescription forecast is reflected by the turnover, too.
According to these criteria, the Federal Joint Committee determined several active substance groups which are prescribed most frequently. At the same time, it named the products to be appealed in 2013, the respective pharmaceutical entrepreneurs will have to submit a cost-benefit-dossier.
Essentially the following substance groups, pharmaceutical products and entrepreneurs are affected:

1. Strong, chronic pain (*Tapentadol*, Grünenthal)
2. Osteoporosis (*Denosumab*, Amgen, *Strontiumranelat*, Servier; *Parathyroidhormon* and *Teriparatid*, Lilly);
3. Anticoagulants (*Rivaroxaban*, Bayer; *Dabigatran*, Boehringer Ingelheim);
4. Diabetes mellitus type 2 (*Liraglutid*, Novo Nordisk und *Exenatid*, Lilly);
5. Depression (*Agomelatin*, Servier und *Duloxetin*, Lilly)
6. Rheumatoid arthritis (*Toclizumab*, Hoffmann-La Roche, *Golimumab*, MSD and *Certolizumab,* UCB).

Between the 15 July 2013 and the 1 December 2013, the manufacturers of the aforementioned active substances will be appealed to submit a cost-benefit-dossier three months later.
Thus the Federal Joint Committee has stretched the tight time frame of three months naming the substance groups already. However,

unanswered legal questions remain – especially concerning competition law: As the document protection is ending anyway, some of the manufacturers will be untroubled by the early benefit assessment although their products are supply-relevant, too. Furthermore, the early benefit assessment of the existing marked disposes an encroachment with retroactive effect, although the criteria are published now – *nota bene* after the first initiation. Thus the legal debate about the early benefit assessment of the existing market has good opportunities.
To draw a conclusion, the quality of the dossier to be submitted is of immense importance. Although the decision of the G-BA of 18 April 2013 is not legally binding for the respective manufacturers, the deadlines are set and will expire. Manufacturers should now start preparing their dossiers. Additionally some other active substance groups will follow and the determination of those groups is now possible. We advise you with pleasure.
For questions or comments please contact: a.ehlers@eep-law.de; a.erdmann@eep-law.de

New European Regulation on Clinical Trials

Recently the European Parliament's Committee for Environment, Public Health and Food Safety (ENVI) which is responsible for the Commission proposal for a new Regulation on Clinical Trials adopted the Report on the Amendments to this proposal tabled by ENVI members. Shortly before the vote the most influential political groups of the European Parliament agreed upon several compromise amendments, *inter alia*, concerning the involvement of ethics committees and the transparency of clinical trials data.
Backed by all major political groups the ENVI Committee adopted two Compromise Amendments clarifying that the authorization for a clinical trial shall require prior examination by an ethics committee. The Amendments foresee that the ethics committees shall work in a timely manner, enabling the Member States to comply with the procedural timelines for the assessment. This clarifies that the examination by the ethics committees and will not require additional time or delay the beginning of a clinical trial.
The Committee has furthermore adopted Compromise Amendments on the obligation to submit a summary of the results of the clinical trial to the EU database within one year from the end of a clinical trial or from its early termination. This is in line with the Commission's original proposal whereas the rapporteur Glenis Willmott suggested submitting the entire clinical study report. In this regard, the adopted draft report also specifies the elements of the summary.
However, the ENVI Committee has also added a provision to the original text proposed by the Commission requiring the sponsor to submit the full clinical study report within 30 days after marketing authorization has been granted or if the sponsor has decided not to submit an application for marketing authorization. However it remains unclear how commercially confidential data can be protected in this regard.
The majority of the ENVI committee has rejected an Amendment supported by the Socialist and Green Groups that aimed to clarify that data and information contained in the clinical study report shall not be considered commercially confidential once a marketing authorization has been granted.
The legislative proposal is now awaiting first reading in the European Parliament's plenary. This is scheduled for 8 October 2013. Additionally the ENVI Committee today mandated the Rapporteur Glenis Willmott to start negotiations with the Council as the end of this parliamentary term is approaching.
For questions or comments please contact: a.ehlers@eep-law.de; a.erdmann@eep-law.de

French Transparency Decrees in the Health Care sector: Role Model for other European Member States?

In Germany, enforcement of corruption depicts one of the regulatory objectives and the Government is currently debating about statutory offense for doctors.
The French Government has on Wednesday 22 May 2013 published the Transparency Decree (n° 2013-414), which details the legal requirements of the French Sunshine Act from the Bertrand law n° 2011-2012 dated 29 December 2011. The new article L.1453-1 of the French Public Health Code imposes a general disclosure obligation on any company manufacturing or commercializing health products or services.
Major provisions are the following: The Decree details the information that must be disclosed by life sciences companies with regard to contracts that they sign with healthcare professionals as well as students who are going to become healthcare professionals. Name and address of the parties, signing date of the contract, purpose of the contract, and when the contract is for hospitality, the agenda of the event must be indicated. Contracts must be governed by the French Code of commerce, for the purpose of the purchase of goods or services, are expressly excluded from disclosure. Also, trade or industrial secrets shall not be disclosed and information on signed contracts must be disclosed 15 days after the signing day.
In fact the transparency rules apply to any benefit in cash or in kind, granted directly or indirectly to health care professionals from life sciences companies. Benefits which are beyond the threshold of 10 euro, including VAT, must be disclosed as well as the name and address of the beneficiary and the respective amount of the benefit. Information must be disclosed within six months, either on 1st August or

1st February at the latest.
Furthermore, information must be disclosed, in French, through a public website, which requires the publication of an Order from the Ministry of Health to the professional association of the covered recipient. Before implementation of the National Internet website, information must be disclosed on the website of the professional association of the covered recipient and on the website of the life sciences company, too. The disclosure obligations apply to contracts signed and benefits granted **in the course of 2012**, which is a big problem to deal with. Information is made public on the internet website for a period of **5 years and must be published** at the latest on **1st June 2013**.
The new Transparency Decree will sooner or later come into force in all member states of the European Union although differentiations may be made within the several countries.
For questions or comments please contact: a.ehlers@eep-law.de; a.erdmann@eep-law.de

Recent Amendments of the AMNOG-Procedure

The German Bundestag passed a law on June 5, 2013 containing significant amendments in relation to the early benefit assessment procedure for medicinal products with new active substances.
Background information: Since 2011 pharmaceuticals containing new active ingredients have to be assessed on their additional benefit. This early benefit assessment is carried out by the Federal Joint Committee (*Gemeinsamer Bundesausschuss*) on the basis of a dossier submitted by the manufacturer. This dossier is likely to be required to include information on: Registered indications for use, Medical benefits, the additional medical benefit in comparison to alternative treatments, Numbers of patients/patient groups that profit from a therapeutically significant additional benefit, Expenses of the therapy for the SHI, Request for quality-assured use.
For the first year of market entry the marketing authorisation holder (MAH) is free to price the medicine itself. A possible further procedural process depends on the evaluation's outcome, thus, whether or not the drug provides an additional benefit. Pharmaceuticals without an additional benefit are classified as a *Festbetragsgruppe*, meaning that there is a maximum amount that is subject to reimbursement by the SHI. Therefore, any new product without an ascertained additional benefit is only reimbursed by the SHI at the reference price. In this situation, an existing but not yet verified new use of the medicine is not considered. This also applies if a classification in one reference price group is not possible. The reimbursement is negotiated on the basis of the cost of a one-year therapy with the comparative treatment. One of these amendments eliminates the requirement that the Federal Joint Committee has to conduct its assessment of innovative medicinal products in relation to the cheapest comparator. According to the new bill the additional benefit can be demonstrated in relation to any of the competitive products in case there is more than one appropriate comparator.
Furthermore, the bill clarifies that if an additional benefit can be proven, the arbitration board is fully flexible regarding its decision-making and shall only take into consideration the facts of the individual case. This amendment shall in particular ensure that the board decides on a case-by-case basis and does not apply rigid decision-making algorithms.
The bill also includes a provision stating that there are no legal remedies against the call for the benefit assessment of medicinal products that were already on the market before AMNOG came into force. So far, only the Gliptine were affected by the regulations of this law among the medicinal products that are already marketed before 2011. The lawsuit that was conducted by our law firm on behalf of Novartis has addressed the problem of a lack of legal protection. The concerns expressed in the decision of the Higher Social Court of Berlin-Brandenburg against the wording of the law triggered the clarification of § 35 a SGB V by the Federal Ministry of Health.
However, the inherent constitutional problem remains unresolved by simply changing the legal wording. The intended scheme leads to a constitutionally problematic shortening of effective legal protection. This procedural issue now gained further importance because of the fact that the Federal Joint Committee has announced more evaluations on the pre- AMNOG active substances. It is crucial for a newly introduced system that the legally permissible limits are balanced courts`decisions.
Conclusion: The amendments concerning the choice of comparators are to be considered positive. The possibility to choose between several appropriate options would ensure that all relevant studies may serve as the basis for the GBA´s assessment.
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