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Information on Life Science law

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Dear Ladies and Gentleman,

The summer months shall not be calm here in Germany. A law draft has been prepared for the reform of the pharmaceutical market regarding statutory health insurance (AMNOG). Despite expected changes, measures for significant interventions in the pharmaceutical market shall be established.

The predicted deficits of the 2011 statutory health insurance will not be helped by the savings the new law will offer. Even in the second quarter of 2011, a greater number of statutory health insurance funds will have to fear insolvency.

Many of the promises made before the 2010 elections will be broken – not only due to constitutional law reasons.

We were correct when we warned in our September 2009 newsletter, which was published prior to the elections, that promises in connection with the election would be broken.

The basic conditions of our health care system have not been changed by the elections. As a result, future interventions to improve the quality and to reduce costs are expected. This will not only affect innovative pharmaceuticals by quick evaluation, price negotiations and fix price regulations for “innovative pharmaceuticals without additional benefit”. The claim of a member of the European Parliament for standard European prices for pharmaceuticals shows that the “Golden Age” is over.

The politicians will also look at other areas such as the announcement of a pay freeze for physicians at clinical practices and hospitals.

It is possible that all of this will lead to a downward spiral. We refer to a scenario described by Philip Plickert and published in the FAZ: “Griechenlands Krise – Ein Blick zurück aus dem Jahr 2013: Die Alternative” (“The crisis of Greece – A look back from the year 2013: The alternative”).

Nevertheless, we shall not give up hope and remain optimistic.

In this spirit we wish you a pleasant summer.

Yours sincerely,

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Contributions

The G-BA decides exclusion of Glitazone by legal ordinance

Despite vehement debate and extensive petitions in the procedure of positions, the combined Federal Joint committee (G-BA) decided on 17 June 2010 the amendment of the directive for medicaments supplementing the Annex III (overview of restrictions and exclusions) to a No. 49 “Glitazone for the treatment of diabetes mellitus type II“.

Such exclusion by legal ordinance had been suspected, but there are sound arguments to evaluate the situation differently:

- The effect on a third party of a constitutively administrative decision (approval), i.e. the binding effect of this decision will be disregarded in this procedure.

- The decision is incompatible with the underlying purpose and the objective requirements in accordance with § 92 para 1, sentence 1, sentence 3 SGB V.

- It lacks a sufficiently specific legal basis for the G-BA, because it had not received from the legislature a legal specification task to exclude medicines/pharmaceuticals – as in this case – because of “predominant degree of harmful effects”[1].

- There is a breach of higher-ranking European law as the G-BA undermines the procedural regulations for an authorization to place medicinal products on the market throughout the EU and the relevant competence of the European Commission.

- Conflict with the intended lawful regulation[2] (AMNOG):
  “Restriction or exclusion of a medicament, because of inappropriateness according to paragraph 1, sentence 1 shall not contradict the findings of the approving authority on quality, efficacy and safety of a medicament.”

- The proposed resolution of the G-BA is incorrect since the final report of the study due to IQWiG selection and violations of the principles of evidence-based medicine is incorrect and unlawful.

In our opinion, the most significant argument is that the G-BA exceeded its competence with regard to the authority to decide of EMEA and BfArM.

At this point we will not discuss the specific medical reasons as arguments for the continuance of the Glitazone as a therapeutic option in the treatment of diabetes mellitus type II.

The resolution of the G-BA of 17 June 2010 is available for consideration by the Federal Ministry of Health.

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[1] Holdings, page 4, l.c.
[2] See the Bill of the AMNOG, page 8.

Decision of the Regional Court of Hamburg regarding the Interpretation of “Supply Deficit” of Section 73 (3) No 3 German Medicinal Product Act (“AMG”)

Section 73 (3) No 3 of the German Medicinal Product Act hereafter referred to as "AMG", in its version of the 15 Amendment of the AMG sets out that the import of non-authorized medicines requires an "inter alia", or a supply deficit in Germany, even if the state of origin is a member state of the EU. In a recent court proceeding, a wholesaler claimed that the requirement of a supply deficit, applicable also to unlicensed medicines imported from EU member states, infringes upon the free movement of goods within the EU. On behalf of a pharmaceutical manufacturer, we (Ehlers, Ehlers & Partner) claimed, before the court, that this legal requirement is in accordance with the free movement of goods, as it is justified on the grounds of the protection of health and life of humans. In addition, we stated that the requirement of a “supply deficit” also for non-authorized medicines imported from EU member states, may not infringe the movement of free goods as it is in line with the legislative intention of Article 5 (1) of the Directive 2001/83/EC. Thereafter, a member state may exclude medicines from the requirement to be authorized before being legally placed on the market if, inter alia, a special need must be fulfilled. The wording (“may”) includes that each member state is free to implement this legal exemption into national law, but there has been no legal obligation (i.e., “shall”) created by the European Parliament and the Council of the EU. In consequence, if the German legislator implements Article 5 (1) of Directive 2001/83/EC into national law, it may not infringe the principle of free movement of goods as even no such national exemption would be in line with the legal requirements set out in Directive 2001/83/EC. Please note that the decision of the Regional Court of Hamburg has not yet become final and conclusive. I would be pleased to answer any questions you might have concerning this issue.

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Competition Law: Appellate decision in the Water Dispenser Case

The Higher Regional Court of Munich in its appellate decision of 26.11.2009 (file no.: 6 U 2279/08) overruled the decision of the Regional Court I of Munich regarding the admissibility of a water dispenser given by a pharmaceutical company to a general practitioner at a reduced rental fee. The Higher Regional Court decided that no undue influence according to section 4, subsection 1 of the Law on Unfair Competition can be found in this case, because no influence is exerted on the prescription behaviour of the general practitioner. The physician remains free in his decision on the therapy and the medicine prescribed. Moreover, the Court pointed out that the water dispenser was not free of charge, but given at a reduced rental fee. This does not amount to an undue influence according to section 4 of the Law on Unfair Competition. Therefore, promotional activities with regard to a companies name remain more flexible than product-related advertisement

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Binding effect of the FSA’s code of practice for non-members (Competition law)

As a consequence of the decision of the Higher Regional Court of Munich (decision of 26.11.2009; file no.: 6 U 2279/08) important and more detailed information concerning the legitimacy of promotional activities have been given on the one hand. On the other hand, the question whether the regulation by the code of practice of the FSA (Membership corporation for the Voluntary Self Regulation of the Pharmaceutical Industry – Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V) is generally applicable to those companies which are not member of the FSA has once again become the focal point of interest as well.

As a widespread belief, in particular some lower courts considers the rules by the FSA as applicable for non-members, too, the

decision of the Higher Regional Court of Munich rightly rejects this opinion under reference of the jurisdiction of the Federal Court of Justice (Bundesgerichtshof – BGH). Admittedly, the rules of the code of practice can cause certain indications. However, the applicability of the code to non-members as a basic of principle has to be refused. The ongoing discussion remains to be seen. I would be pleased to answer any questions you might have concerning this issue and will be happy to counsel you.
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Amendment of the FSA Code of Conduct Healthcare Professionals

The FSA Code of Conduct regarding the Collaboration with Healthcare Professionals was amended. Changes were implemented relative to non-interventional studies and job-related training events. According to the novel section 19 of the FSA Code of Conduct, the location, time and the aim and study plan must be disclosed. Moreover, the National Association of Statutory Health Insurance Physicians and the National Confederation of statutory health insurance companies must be informed of the names of the physicians conducting the study.

Changes regarding job-related training events were implemented in section 20 of the FSA Code of Conduct. Pharmaceutical companies are not allowed to support directly or indirectly any entertainment program by paying participation fees for healthcare professionals.
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