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**Rechtsanwalt *Dr. Peter Dieners* on the prohibition of cost assumption for doctors attending continued training events in Lower Saxony**

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Since 1 February 2013, the State Medical Chamber of Lower Saxony (ÄKN) has declared that costs in connection with the passive participation of doctors in Lower Saxony in continued training events may no longer be assumed by companies from the pharmaceutical and medical devices industry. It bases its new position on an amendment to the Professional Code of Conduct of the State Medical Chamber of Lower Saxony (*Berufsordnung der Ärztekammer Niedersachsen – NBO*) adopted on 24 November 2012.

#### **Substance of changes**

The provision in section 32 (2) of the (Sample) Code of Conduct for Doctors Practising Medicine in Germany (*Berufsordnung für die in Deutschland tätigen Ärztinnen und Ärzte – MBO-Ä*) (version from 2011) provides that financial sponsoring of doctors in connection with their passive participation in continued training events (such as assumption of their travel and accommodation expenses) is allowed.

However, this provision was not taken over by the State Medical Chamber of Lower Saxony into its Professional Code of Conduct for Lower Saxony which alone is binding on doctors in that federal state. As a result, such financial support must be evaluated solely on the basis of the general prohibition of special benefits of section 32 (1) of the Code of Professional Conduct of the State Medical Chamber of Lower Saxony (NBO), according to which all forms of unilateral benefits granted by third parties are impermissible *if these give rise to the impression* that the independence of medical decisions is being influenced thereby.

#### **Interpretation by the State Medical Chamber of Lower Saxony**

According to the interpretation applied by the State Medical Chamber of Lower Saxony (published in its medical journal, *niedersächsisches Ärzteblatt* 1/2013, p. 35), this amendment has the following meaning:

*“Doctors are not permitted to accept any benefits (assumption of hotel and travel expenses, conference fees) from the pharmaceutical industry that enable or sponsor their participation*

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*in a continued training event. A pharmaceutical company is of course permitted to assume, in addition to a medical speaker's fee, also that speaker's travel expenses."*

The State Medical Chamber of Lower Saxony, which is also responsible for imposing sanctions against physicians under professional law for violations of the Professional Code of Conduct, thus wanted to make clear that in future it considers sponsoring of doctors in Lower Saxony in connection with their passive participation in continued training events to be prohibited. It is true that section 32 (1) of the NBO provides for a legal qualification and prohibits only such benefits giving rise to the impression that the independence of medical decisions is influenced thereby. However, in its assessment this qualification is disregarded by the State Medical Chamber of Lower which apparently proceeds on the assumption that such impression normally arises in the case of any special benefits granted in connection with the participation in continued training events.

Whether such categorical classification is actually reasonable and can stand up to the scrutiny of the courts remains to be seen. That is because this question will probably depend decisively on the respective individual case. In any case, such question up to now was answered in the negative if for the sponsoring benefits granted in connection with the passive participation in continued training events the relevant provisions of the (Sample) Professional Code of Conduct (section 32 (2)) and the industry codes were complied with. One consequence of the new professional-law assessment by the State Medical Chamber of Lower Saxony would be that doctors practising in Lower Saxony in future will no longer be permitted to accept sponsoring benefits for participation in continued training events if and to the extent such events are capable of giving rise to doubts about the independence of medical decisions.

This applies in particular to:

- registration fees,
- travel expenses, and
- hotel/accommodation expenses.

By contrast, in the assessment of the State Medical Chamber of Lower Saxony, remunerating doctors for their active participation (e.g. as speakers) in a continued training event is still to be permitted as before. Thus, companies may also continue to pay doctors reasonable remuneration for such services. Moreover, companies are still allowed to issue invitations to free internal informational events, but in this connection may not pay any travel expenses, hotel costs or other sponsoring benefits for the participants. Doctors who therefore accept such benefits, in the assessment of the State Medical Chamber of Lower Saxony, violate the Professional Code of Conduct and face the professional law

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consequences defined in Part 4 of the State Act for Healthcare Professions in Lower Saxony (*Kammergesetz für Heilberufe Niedersachsen – HKG*) (i.e. sanctioning by the Chamber or even professional law proceedings).

But for companies as well, the new provision is of significance, even though they are not directly addressed by the Code of Conduct of the Medical Profession. As a result of the amendment to the Professional Code of Conduct, the risk for companies from the pharmaceutical and medical devices industry is that competitors might take action against them for “inducing doctors to engage in professional misconduct” based on the German Unfair Competition Act (*Gesetz gegen den unlauteren Wettbewerb – UWG*) in the event that the State Medical Chamber of Lower Saxony should succeed with its very broad interpretation.

**Companies need to act**

For this reason, the compliance systems and processes of companies should take account of the new legal environment and find out exactly in what federal state the doctor concerned practises before extending an invitation.

***The view of the State Medical Chamber of Lower Saxony caused quite a stir and criticism and also raised numerous questions on the part of the doctors and companies concerned. The specific questions on the Code of Professional Conduct of the State Medical Chamber of Lower Saxony (NBO) are answered below.***

**What specific scope does the Code of Professional Conduct of Lower Saxony have?**

**Answer:** Sponsoring benefits to doctors for their passive participation in continued training events (for example assumption of travel and accommodation expenses) are to be evaluated solely on the basis of general prohibition of special benefits of section 32 (1) of the NBO. according to which all forms of unilateral benefits granted by third parties are impermissible *if these give rise to the impression that the independence of medical decisions is being influenced thereby.*

**Is the sponsoring of passive participation therefore generally prohibited?**

**Answer:** The NBO does not contain any express prohibition of sponsoring for passive participation in continued training events. Nevertheless, the State Medical Chamber of Lower Saxony would interpret section 32 (1) of the NBO such that henceforth “doctors are not permitted to accept any benefits (assumption of hotel and travel expenses, conference fees)

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*from the pharmaceutical industry that enable or sponsor their participation in a continued training event.”*

However, for the **legal assessment** the decisive question is whether the assumption of travel and accommodation expenses as well as any registration fees by the industry actually gives rise to the impression of a causal influence being exerted over doctors. This cannot be answered in general but instead always based on the individual case. The still prevailing opinion assumes that the impression of a causal influence being exerted over doctors as a general rule does not exist if the event as well as the sponsoring benefits granted satisfy the stringent requirements of the national (Sample) Code of Conduct for the Medical Profession ((*Muster-*) *Berufsordnung der Ärzte* – MBO-Ä) as well as the relevant industry codes. It is only when qualifying circumstances come into play suggesting the impression of a causal influence being exerted that the sponsoring benefits, according to the prevailing view, are impermissible both under the industry codes and the respective codes of conduct of the medical profession.

Both the MBO-Ä and the industry codes, e.g. the FSA Code for Healthcare Professionals (FSA-Kodex Fachkreise), the AKG Code for Pharmaceuticals and Cooperation in the Healthcare Sector (AKG-Kodex) and the "Medical Devices" Code as well as the "Common Position on the evaluation of co-operation between industry, medical facilities and their staff in terms of criminal law" (*Gemeinsame Standpunkt der Verbände zur strafrechtlichen Bewertung der Zusammenarbeit zwischen Industrie, medizinischen Einrichtungen und deren Mitarbeitern*) in this connection provide that sponsoring doctors for passive participation in continued training events by assuming for example accommodation costs as well as travel expenses and registration fees is definitely permissible under the following conditions:

- The attended continued training event has a **scientific-informative aim** with reference to the indication and research fields of the sponsoring company.
- No** expenses are assumed for **general and entertainment programmes**.
- No** expenses are assumed for **accompanying persons**.
- The **accommodation expenses** are **necessary** and **reasonable** (accommodation in customary business and conference hotels, no assumption of costs for “luxury hotels”, no financing of “extra days”).
- The **travel expenses** are **reasonable** (train tickets, car journey costs equal to the flat rates per kilometre allowed for tax purposes, other travel expenses (public transport, taxis), no assumption of costs for first-class flights).

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These specific requirements to be met ensure that the abstract risk of independence being influenced is adequately counteracted. Despite that, the State Medical Chamber of Lower Saxony now apparently assumes that sponsoring benefits already in an abstract respect satisfy the elements of creating the impression of influence being exerted, without however wishing to examine this specifically in the individual case. With its interpretation of the general prohibition of special benefits it thus departs from the general understanding of the German Federal Medical Association, the other State Medical Chambers, the industry and the national legislator (cf. section 7 (2) of the German Act on the Advertising of Medicinal Products (*Heilmittelwerbegesetz* – HWG), which likewise favours the sponsoring of participation in continued training events). Ultimately, this turns the specific strict liability tort (*konkretes Gefährungsdelikt*) of section 32 of the NBO into an abstract strict liability tort (*abstraktes Gefährungsdelikt*) in a way that is contrary to the system.

It therefore comes as no surprise that the stance taken by the State Medical Chamber of Lower Saxony has led to a very intense and in some instances heated debate within the medical profession and to uncertainties on the part of the industry. It is because of such uncertainties that numerous companies from the pharmaceutical and medical devices industry have (for the time being) discontinued their sponsoring. Other companies continue to grant sponsoring benefits while drawing the attention of the invited doctors to the different view taken by the State Medical Chamber of Lower Saxony and recommending them, as a precaution, to contact the Medical Chamber, specifying and clarifying the costs to determine whether the invitation may be accepted. Such notices are now also being included in letters of approval of university administrations in Lower Saxony for acceptance of such sponsoring benefits by hospital doctors.

**What is advisable for companies?**

**Answer:** If companies in future wish to continue, in keeping with the view prevailing to date, to enable doctors in Lower Saxony to participate in continued training events pursuant to the criteria set out above by granting reasonable sponsoring benefits, it is absolutely necessary to ensure that the event in question satisfies all requirements of the industry codes (e.g. section 20 of the FSA-Kodex Fachkreise), the MBO-Ä (section 32 (2) of the MBO-Ä) and section 7 (2) of the HWG and is thus consistent with the generally accepted standards of conduct in the healthcare field.

At the same time, it should be pointed out to doctors in Lower Saxony that, notwithstanding the foregoing, it is possible that acceptance of sponsoring benefits might be considered by the State Medical Chamber of Lower Saxony as a violation of the Code of Conduct of the

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Medical Profession in Lower Saxony. In this connection they should be recommended to contact the State Medical Chamber of Lower Saxony to have it reviewed in the individual case whether, even when the relevant codes are complied with, a violation of professional regulations has to be assumed.

**Does the NBO apply to community-based doctors and hospital doctors in Lower Saxony?**

**Answer:** The State Medical Chamber of Lower Saxony is the self-governing organisation of the some 36,000 doctors in Lower Saxony, i.e. both community-based doctors and hospital doctors. Each doctor is a compulsory member of the State Medical Chamber within the territory of which he practices medicine. The NBO governs professional obligations for all doctors who are members of the State Medical Chamber of Lower Saxony. In this context, no distinction is made between community-based doctors and hospital doctors. The NBO and the obligations as well as prohibitions set out therein are therefore applicable to all doctors in Lower Saxony.

**Does the NBO apply to doctors only or to other professional groups as well?**

**Answer:** The NBO governs the professional law for licensed doctors in Lower Saxony. For other professional groups (e.g. nurses, pharmacists, audiologists, etc.) working in the healthcare sector, this Professional Code of Conduct does not apply. These professional groups are therefore exclusively subject to the general regulations and legal provisions governing their respective professional groups. If the conditions described above for sponsoring (scientific continued training event, reasonable travel and accommodation expenses, etc.) are complied with for these other professional groups, the granting of such benefits for passive participation continues to be permissible and satisfies the requirements as set out in the industry codes and section 7 (2) of the HWG.

However, the State Medical Chamber of Lower Saxony reportedly took the view that section 32 (1) of the NBO also applied to employees of medical practices. A cost assumption for internal and external continued training measures also had to be regarded, within the meaning of section 32 (1) of the NBO, as an impermissible special benefit granted to the doctor with whom the staff is employed since such doctor in this regard realises savings of own expenditures. This view, too, as explained above, cannot apply in cases in which the (Sample) Code of Conduct as well as the industry codes are observed.

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**Does the NBO also apply to doctors from other federal states attending continued training events in Lower Saxony?**

**Answer:** The NBO applies only to compulsory members of the State Medical Chamber of Lower Saxony, not to doctors in other federal states. These doctors are not subject to the provisions of the NBO, even if they participate in continued training events in Lower Saxony.

**Are there likely to be similar debates with other state medical chambers?**

**Answer:** The fundamental exemption provided for in section 32 (2) of the (Sample) Code of Conduct for the Medical Profession from the general prohibition of granting special benefits in the form of sponsoring benefits for the passive participation of doctors in continued training events has already been adopted in identical content by 13 of the 17 state medical chambers. The state medical chambers of Berlin, Hesse and Saarland have not made any such amendments to their codes of professional conduct since the (Sample) Code of Conduct for the Medical Profession was revised. However, these three codes of professional conduct contain the previous provision from the old version of the (Sample) Code of Professional Conduct prior to 2011 that set out the same exemption in section 33 (4) of the MBO-Ä. It remains to be seen whether these three state medical chambers will likewise adopt the identical provision of section 32 (2) of the MBO-Ä when amending their codes of professional conduct. So far there have been no indications that any deviations from the MBO-Ä are being planned in federal states other than Lower Saxony.

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