TaylorWessing

Session #6

Webinar

19 June 2024

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COFFEE BREAK
Life Sciences Start-ups

Consulting Agreements: Dos and Don’ts

19 June 2024 | Dr. Angela Knierim

Agenda

1 What are consulting agreements and which regulations apply?

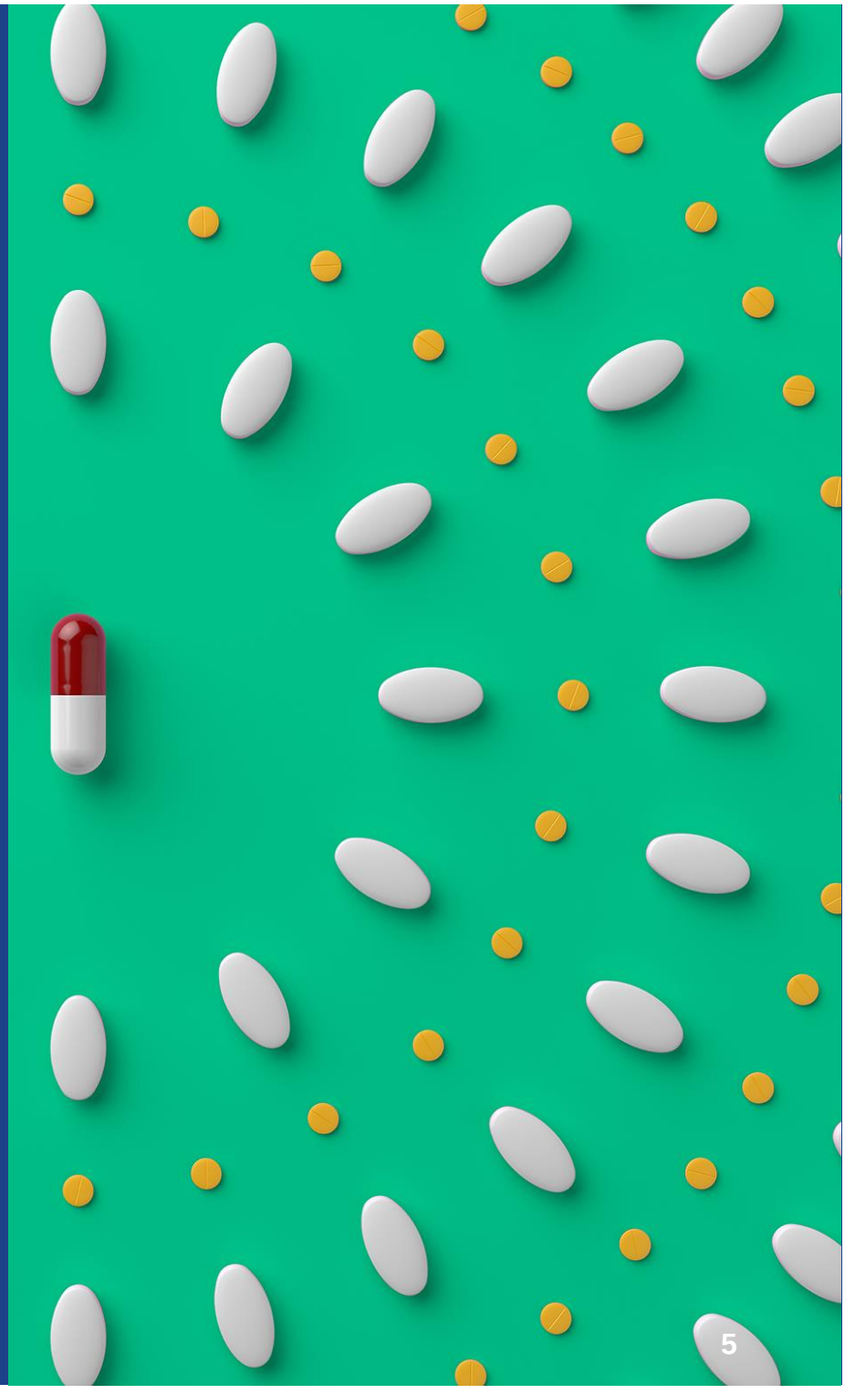
1.1 Consulting agreements

- Possible **consultancy services** provided by healthcare professionals (HCPs) to the industry:
  - Meetings, e. g. “advisory board meetings”
  - Essays
  - Documentation, e. g. of Real World Data (Cave: differentiation from research/clinical trials ➡ specific rules, e. g. consultation of the physician with Ethics Committee)

  The service must be related to an indication of the company’s product(s).

- Possible **consultants**:
  - Clinicians or other employees of medical facilities
  - Medical facilities themselves
  - Physicians in private practice

The principles concerning consulting agreements in the life sciences sector generally do also apply to other types of cooperations with HCPs, for example speaker contracts.



1.2 Legal restrictions

- Consulting agreement ≠ covering unilateral benefits
- The HCP provides the service **in exchange** for remuneration
- Unilateral benefit: when the industry grants benefits without receiving a consideration in return

Why is this differentiation important?

- General prohibition of unilateral benefits, Sec. 7 para. 1 German Therapeutic Products Advertising Act (*Heilmittelwerbegesetz* – “HWG”), with regulated exceptions
- Criminal prohibition of bribery in the healthcare sector (Sec. 299a, 299b German Criminal Code (*Strafgesetzbuch* – StGB) and of corruption in office with regard to physicians in university hospitals (Sec. 331 et seqq. StGB)
- Respective regulations in the professional code of conduct for physicians (Musterberufsordnung-Ärzte – “MBO-Ä” and in codes of conduct (e. g. FSA Code of Conduct on the Interaction with Healthcare Professionals [medicinal products], BVMed Medical Devices Code [medical devices]).
- Service law for public servants

1.3 Rules for practice

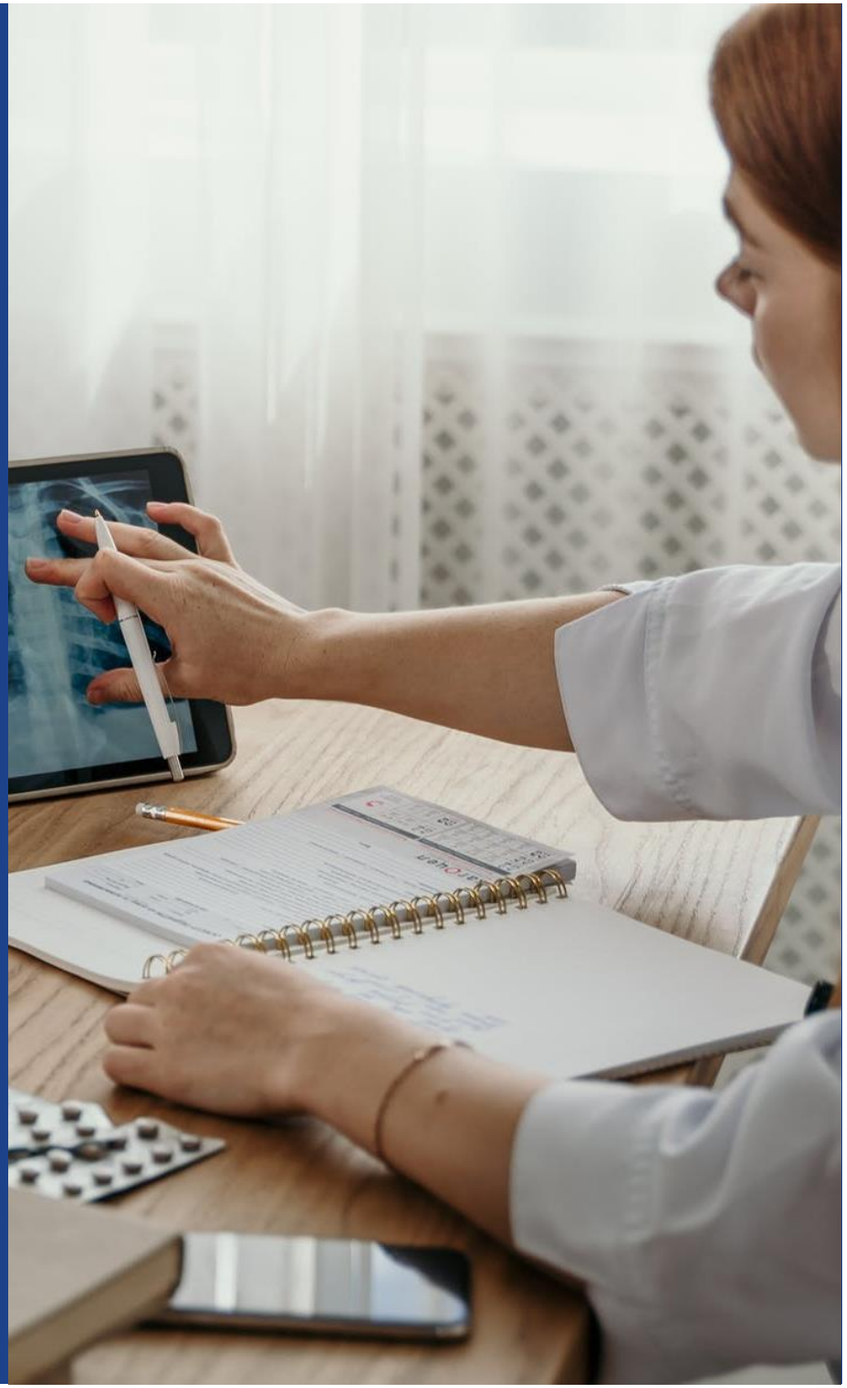
Principle of separation

Principle of transparency

Principle of equivalence

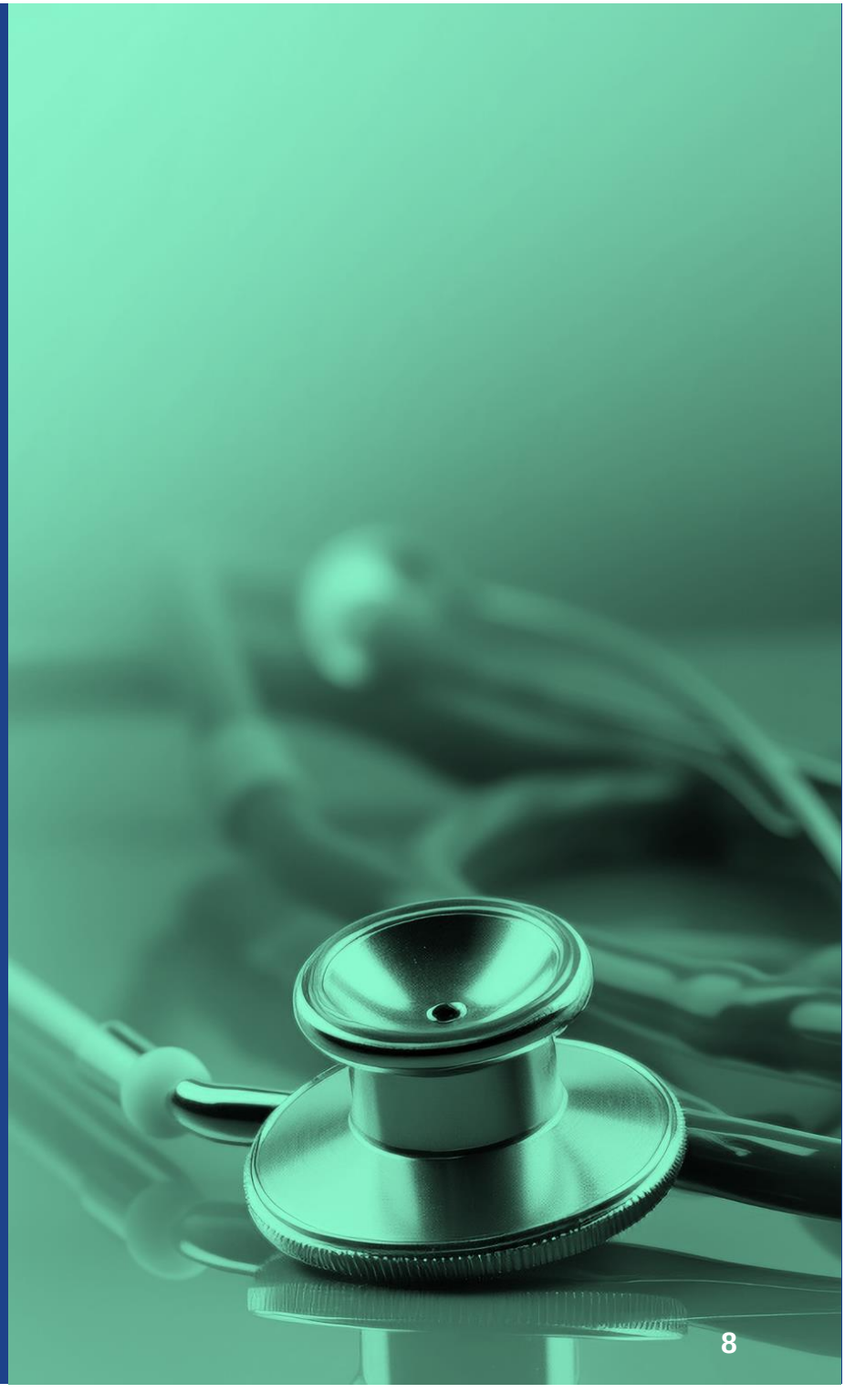
Principle of documentation

- Derived from the legal requirements of criminal law, therapeutic products advertising law, public service law as well as medical professional law
- The four basic principles have found expression in the codes of conduct of various leading associations in the life sciences sector, for example in Sec. 3 BVMed Medical Devices Code



1.3 Rules for practice – Codes of conduct

- FSA Code of Conduct Healthcare Professionals
- FSA Transparency Code
- FSA Code of Conduct Patient Organisations
- BVMed Medical Devices Code
- MedTech Europe Code of Ethical Business Practice



2 The four basic principles of cooperation with HCPs

2.1 Separation

- Payments to healthcare professionals **must not be dependent** on sales transactions or decisions on procurement, prescription or therapy

- It is **impermissible to grant benefits to influence procurement decisions, medical prescriptions or therapy decisions**

2.2 Principle of separation: Dos & Don’ts

- Dos:
  - ✓ If possible, conclude contracts with the medical facility (hospital) and not with individual clinicians or other employees of medical facilities.

- Don’ts:
  - No linking of payments to procurement decisions
  - Do not grant any benefits that serve private purposes, in order to avoid any false impression from the outset
  - Do not grant any benefits to third persons, e. g. relatives or spouses

2.2 Transparency

- Agreements must be concluded **in writing** and, upon request, should be submitted to the competent Medical Association

- Employed physicians require an employer's permit (*Dienstherrengenehmigung*) at the time of the signing of the contract

- In the case of physicians employed in public institutions (e.g. university hospitals**), in addition to the employer's permit**, a secondary employment permit (*Nebentätigkeitsgenehmigung*) must be obtained in accordance with the relevant state law. The university hospitals usually provide their own form for this purpose; in this respect, the contractual obligation to obtain the permit this is sufficient.

2.3 Principle of transparency: Dos & Don’ts

- Dos:
  - ✓ The employer’s permit of employed physicians should be attached to the consulting agreement and signed by the employer
  - ✓ Ask physicians from university hospitals if their university provides for a form for the secondary employment permit
  - ✓ The contract should only become effective subject to the respective approval

- Don’ts:
  - Do not use any services/pay remunerations before the notification of the employer and before the approval has been obtained

2.3 Equivalence [I]

- Consulting service and remuneration must be in reasonable proportion to each other = so-called **fair market value**
- No explicit regulations what “proportionate” is
- Compliance with this principle is intended to ensure that payments made by the industry for services provided by healthcare professionals are solely remuneration for the fulfilment of contracts and not intended to buy procurement, prescription or treatment decisions or any associated goodwill
- For German physicians, the “Fee Structure for Physicians” (*Gebührenordnung für Ärzte* – “GOÄ”) can be used as a reference point

2.3 Equivalence [II]

- Always case-by-case decision

- Criteria for fair market value:
  - ✓ Time required for the contractually owed service
  - ✓ Degree of difficulty of the contractually owed service
  - ✓ Value of the contractually owed service for the company
  - ✓ Documentation effort for the contractually owed service
  - ✓ Special expertise, qualifications and general reputation of the healthcare professional
  - ✓ Standard market remuneration

- Rule of thumb: Taking into account the GOÄ, fees of about **EUR 120,- per hour** might generally be considered reasonable according to the case law on the German Industrial Code “FSA Code of Conduct on the Collaboration with Healthcare Professionals” (which is, however, only legally binding for members).

2.4 Case law of the FSA arbitration board

- **Permissible**:

  - ✓ Remuneration of EUR 200,- for conducting a patient training session with a training time of 1.5 hours and a preparation time of 1 hour
  - ✓ Maximum total remuneration of EUR 456,- per patient as part of an observational study when treating a patient for more than 24 months and carrying out and documenting all visits

- **Impermissible**:

  - – Remuneration of EUR 1000,- for conducting a generic field study if the physician's documentation effort is only a maximum of 1 hour
  - – Remuneration of EUR 150,- for a case report prepared by a doctor based on retrospective data collection, if the preparation time is approximately 30 minutes

2.4 Documentation

- The documentation obligation applies to:
  - ✓ The contract itself
  - ✓ The reasons for and the industry's interest in such a cooperation
  - ✓ The criteria according to which the contractual partner is selected (expertise in the field of XYZ, status as renowned expert, number of publications…)
  - ✓ Detailed list of all services
  - ✓ All remunerations and payments
- Completed services/work results should be documented as well

2.5 Principle of documentation: Dos & Don’ts

- Dos:
  - ✓ Include detailed description of services **and** the amount of time estimated for this in the contract
  - ✓ Include obligation for the physician to document all work results
  - ✓ Archive the contract and the documented work results

- Don’ts:
  - Generic description of services, for example “consultancy services in the indication ‘allergic asthma’”

3 | Cost for travel, accommodation and meals

Regulated in the contract and reasonable?

Travel

- Economy class flight ticket for intra-European flights
- For intercontinental flights, business class tickets are generally possible
- For rail travel, 1st class travel is permitted. For kilometers driven by car, up to 0.30 EURO/km can be charged.

Accomodation

- Over-night stays only if necessary
- Business hotels, no luxury or “holiday” hotels

Meals

- Hotel breakfast if over-night stay is justified
- Other than that, the general rules for catering/hospitality apply

Questions and discussion

Your contact

Angela is a member of the Practice Area Patents Technology & Life Sciences and the Industry Group Life Sciences & Healthcare. She advises national and international pharmaceutical and medical device companies on all aspects of health law, including cooperations with healthcare professionals from a compliance perspective.

One of her main areas of practice is the legal review of marketing materials for both direct-to-consumer and healthcare professional advertising. She supports and optimizes launch strategies including pre-launch activities and advises on disease awareness campaigns. She also supports her clients in the monitoring and legal review of competitors' advertising and develops strategies to challenge advertisements. She has many years of experience with regard to the advertising of both over-the-counter and prescription-only medicinal products as well as medical devices. A further focus of her is the enforcement of and defense against complaints under unfair competition law, in particular in preliminary injunction proceedings.

In addition, she provides regulatory advice with regard to the manufacture, labelling and marketing of medicinal products, medical devices, dietary supplements, cosmetics, biocides and chemicals.

Languages

- German, English

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- Litigation & Dispute Resolution
- Regulatory & Compliance

17 July 2024 – 10 am

Session #7
Clinical trials in the pharmaceutical area: tips and tricks for CTA negotiations

Europa > Mittlerer Osten > Asien

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