What you should know

as a healthcare professional when collaborating with a company

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This pamphlet brings together most information about your obligation as a healthcare professional to notify and apply when collaborating with a pharmaceutical or medical device company.

The healthcare industry and healthcare professionals share a responsibility for ensuring transparency and rules to increase confidence in the collaboration. The law reform that was passed by the Danish Parliament in 2014, i.a., results in publication of individual information regarding healthcare professionals' collaboration with companies on the website of the Danish Medicines Agency.

To whom do the notification and authorization rules apply?

- If you are a doctor, dentist or pharmacist collaborating with a pharmaceutical or a medical device company, you must either notify the Danish Medicines Agency or apply to obtain permission from the Agency.
  As a doctor or a dentist, the rules apply if you either work with or assist in patient treatment in Denmark.
- If you are a nurse and collaborates with a medical device company, you must either notify the Danish Medicines Agency of the collaboration or apply to obtain permission from the Authority. The rules apply if you either work with or assist in patient treatment in Denmark.
- For sponsorships of professional events abroad, the rules apply to a much wider range of persons, ref. "Sponsorships of professionals events abroad".

Do you have to notify or apply for authorization?

The new rules provide two different schemes:

1. Notification scheme

For the types of association falling under the notification scheme, you must notify the Danish Nation. After notifying the Agency, you can start the collaboration right away.

2. Authorization scheme

For the types of association falling under the authorization scheme, you must apply to obtain permission from the Danish Medicines Agency. The Agency will either authorize or reject the collaboration according to an individual assessment. Permission must be granted by the Agency before you can start the collaboration.

What types of association fall under the new rules?

Agreements of collaboration regarding training, research, consultancy support etc.

1. Training and research

For these two types of collaboration, you must *notify* the Danish Medicines Agency.

Training assignments: e.g., when giving presentations or lectures etc. on research results or therapies.

Research assignments: e.g., when your work involves clinical trials or investigations, non-interventional studies or various development tests within the area of medical devices.

Note! Only personal fees should be reported

Your notification must only include information on fees that you, as a healthcare professional, receive *personally* from a pharmaceutical or medical device company, either directly or indirectly through a hospital administered research account.
In connection with a clinical trial or clinical investigation conducted by a hospital department, a person will have been appointed by the company to be responsible for preparing a list of the healthcare professionals working with the trial or investigation. The person responsible may be a primary investigator or another person responsible for the project, and the list can be prepared from the GCP-list, the ISO-standard log or other list.
As a doctor, dentist or pharmacist included in the list, you must notify the Danish Medicines Agency of your association with the pharmaceutical company that the trial concerns.
As a doctor, dentist, pharmacist or nurse included in the list, you must notify the Danish Medicines Agency of your association with the medical device company that the investigation concerns.
In both cases, you must report your association without stating any amount as a fee, provided, of course, that the research funds have been allocated to the hospital and deposited into the hospital account.

2. Consultancy support and positions of trust

This type of collaboration falls under the authorization rules.

Consultancy support: e.g., when participating in advisory boards or other type of professional consultancy support including professional communication via the company mailbox or blog, or in connection with pamphlets, reports etc.

Positions of trust: e.g., when being a member of a company's board of directors.

Note! Before starting the association, you must obtain permission from the Danish Medicines Agency, based on your application.

Note! If participating in a questionnaire or a market analysis, you must only apply for permission if you know which pharmaceutical or medical device company is behind it, i.e., if the survey has not been anonymised.

3. Ownership of pharmaceutical or medical device companies

If you are the owner of shares or other securities in a pharmaceutical or medical device company up to a value of DKK 200,000 (at the time of purchase), you must notify the Danish Medicines Agency.
If you own shares or other securities with a value of more than DKK 200,000 (at the time of purchase), you must apply to obtain permission by the Agency.

Sponsorships of professional events abroad

If you receive financial support from a pharmaceutical or medical device company to participate in a professionally relevant activity abroad, you must notify the Danish Medicines Agency.
The activity could be e.g., a scientific congress, symposium or conference.

The sponsorship must be reported if you are a doctor, dentist, veterinarian, pharmacist, nurse, veterinary nurse, pharmacy assistant, midwife, bioanalyst, clinical dietitian, radiographer, social and healthcare assistant, or a student in these disciplines.
If you are a veterinarian, a veterinary nurse or a student in these disciplines, you are not required to notify the Agency if the financial support is granted by a medical device company.
With regard to sponsorships, medical device companies are defined as all medical device companies and not just companies manufacturing products in class IIa, IIb or III, to which the rules on association otherwise apply.
Certain types of professionals are also subject to the notification rules (see the chart on the last page).

Note! Only professional events held *abroad* are subject to the new rules. If you receive a sponsorship from a company for a professional activity in Denmark, this should *not* be reported.

Note! Sponsorships must be reported to the Danish Medicines Agency at the time you receive the financial support or when you are reimbursed for expenses in connection with your participation in the professional activity abroad.

How and what must you report to meet the requirement for notification or application?

On the website of the Danish Medicines Agency, you must complete a standard form for either association or sponsorship (financial support) by providing different types of information, depending on whether the nature of your collaboration requires notification or authorization.

- For collaboration regarding research, training, consultancy support or positions of trust etc., you must provide details about yourself, your primary workplace, the company name, the nature of your work (type of association), duration of the association, and payment. *Note!* You must submit a notification/application to the Agency, whether you receive a fee for your work or not.
- In case of ownership, you must supplement the above information with details about your owner ship, e.g., number of shares, the acquisition date, the value on the day of the acquisition and, if relevant, if you have obtained ownership by inheritance.
- For sponsorship of a professional event abroad, you must provide information about yourself, the company name of the sponsor, the organizer of the professional event (if the organizer is not the sponsoring company itself), details about the professional activity and the date that the activity ends. Concrete sponsorships (amounts) should not be reported.

Remember to update in case of changes

If the information previously submitted by you to the Danish Medicines Agency change, you must remember to update accordingly, e.g., if the form or content of the collaboration changes or the actual amount paid to you differs from the previously reported amount. Also, it could be that the scope or content of a professional activity abroad changes or the activity abroad is cancelled. The update must be made by completing and submitting a form for change. You will find the form on the website of the Agency. A request for change is always evaluated by the Danish Medicines Agency.

Where do you notify or apply for permission?

All notifications and applications are submitted via the website of the Danish Medicines Agency, www.laegemiddelstyrelsen.dk/en.

Where and when is the collaboration published?

After you have notified the Danish Medicines Agency or received permission from the Agency, your collaboration with the company will be published on the website of the Agency.

Individual information, including the total fee, if any, received by you annually from a company, will be published and made available for two years after the collaboration has ended. The list of the Agency is available on the website, Laegemiddelstyrelsen.dk/en.

What are the obligations of the pharmaceutical and medical device companies?

Pharmaceutical and medical device companies must inform healthcare professionals of their duty to notify and seek permission as healthcare professionals when the parties enter into collaboration with each other, or when a company grants a sponsorship for a professional event abroad. With regard to ownership, companies have no obligation to inform healthcare professionals.

Once a year, pharmaceutical and medical device companies will submit information to the Danish Medicines Agency about the doctors, dentists and pharmacists with whom they have collaborated. Medical device companies will also submit information about their collaboration with nurses.
When submitting the data to the Agency, the companies must advise the individual healthcare professional about the contents of the submitted data.

The information that the pharmaceutical and medical device companies submit is:

- The name and legal registration number of their company
- The name, primary workplace, private address and social security number of the healthcare professional
- The duration of the association

Control and consequences?

According to the Danish Health Act, the Danish Medicines Agency is authorized to check if healthcare professionals comply with their obligation to notify and apply for permission when being associated with a pharmaceutical or medical device company. For this purpose, the Agency may request that the individual healthcare professional submit additional information.

The Agency may also request companies to submit additional data. If the request is not complied with, this is punishable by fine.

Note! Your association with a pharmaceutical or medical device company may disqualify you from participating in certain national advisory councils or committees. Read more on the website of the Agency, www.laegemiddelstyrelsen.dk/en.

Companies subject to the new rules

On Laegemiddelstyrelsen.dk/en. you will find three lists of companies that are subject to the rules, i.e. one list of pharmaceutical companies, one of medical device companies and one of speciality stores dealing in medical devices.
The medical device companies that are subject to the association rules are companies with products in high risk classes, i.e. class IIa, IIb and III as well as in vitro-diagnostic and active implants. However, a company could still be listed if its products are both I-products and products in higher risk classes. If your association involves a class-I product or a class-1 product area, e.g., diapers or ostomy pouches, then you are not obligated to do anything. This association does not fall under the legislation. This both applies if the association involves training, research assignments and consultancy support. However, if you purchase or inherit securities in a medical device company which is included in the lists of the Danish Medicines Agency, you must either notify or seek permission, ref. item 3.

Note! All medical device and pharmaceutical companies are subject to the notification requirement in connection with sponsorships of professional events abroad.

Where to read more?

Go to the website of the Danish Medicines Agency, www.laegemiddelstyrelsen.dk/en, to obtain more specific guidance on what information you need to report and how to do it. Here you can also learn about the applicable transition rules.

Professional and financial association

1 ASSOCIATION WITH WHOM?

Pharmaceutical company
Doctors, dentists and pharmacists are obligated to register their collaboration with medical device companies. Other professions are not.

Medical device company
Nurses, doctors, dentists and pharmacists are obligated to register their collaboration with medical device companies. Other professions are not.

2 WHAT TYPE OF ASSOCIATION?

NOTIFICATION SCHEME
Training or research Ownership of up to DKK 200,000

AUTHORIZATION SCHEME
Consultancy support
Ownership of more than DKK 200,000

3 WHAT TO DO?

Apply for permission or notify the Danish Medicines Agency

www.laegemiddelstyrelsen.dk

Sponsorships of professional activities abroad

WHO IS SPONSORING YOU?

Pharmaceutical company
Doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, pharmacy assistants, midwives, bio-analysts, clinical dietitians, radiographers, social and healthcare assistants, or students in these disciplines as well as owners of or senior executives in stores which have been approved to sell non-pharmacy-only, over-the-counter medicines or medicines for production animals including consultants and purchasers of medicines outside pharmacies must report sponsorships.

Medical device company
Doctors, dentists, pharmacists, nurses, pharmacy assistants, midwives, bioanalysts, clinical dietitians, radiographers, social and healthcare assistants or students in these disciplines as well as owners and senior executives in stores selling medical devices as well as medical technicians must report sponsorships.

WHERE DOES THE PROFESSIONAL ACTIVITY TAKE PLACE?

Abroad → **Notify the Danish Medicines Agency**

www.laegemiddelstyrelsen.dk

In Denmark → **Do NOT notify**

Further information about the publishing organizations:

Dansk Sygeplejeråd: **www.dsr.dk**

Industriforeningen for Generiske Lægemidler: **www.lgldk.dk**

Lægemiddelindustriforeningen: **www.lif.dk**

Medicoindustrien: **www.medicoindustrien.dk**

Tandlægeforeningen: **www.tandlaegeforeningen.dk**

Lægeforeningen: **www.laeger.dk**

Apotekerforeningen: **www.apotekerforeningen.dk**

Lægevidenskabelige Selskaber: **www.selskaberne.dk**

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