

Newsletter 17 May 2024

Healthcare professional or company?

The Investigator Panel has decided a case concerning a pharmaceutical company's sponsorship of a healthcare professional's IT company.

The healthcare professional had founded a company in which the healthcare professional owned 70% of the company. The company was to develop an app for use in an online community for patients within a given disease area, with the aim of improving their quality of life.

The pharmaceutical company stated that they had mistakenly reported the sponsorship to ENLI, as the CEO of the IT company was a healthcare professional. They therefore did not believe that ENLI had the competence to assess the case, as the pharmaceutical company had not given the sponsorship directly to healthcare professionals.

In its decision, the Investigator Panel emphasized that the healthcare professional owns the IT company with a real ownership share of 70%, and will develop a product to be used in the director's work as a healthcare professional (nurse) in a hospital. The purpose for which the healthcare professional seeks support from the pharmaceutical company, via the healthcare professional's company, is thus directly related to the healthcare professional's work as a healthcare professional, and thus the financial benefit from the pharmaceutical company actually goes to a healthcare professional.

The Appeals Board stated in AN-2014-0917 that when a pharmaceutical company operates within one of the exceptions to the clear main rule prohibiting financial benefits, cf. Sections 13-15 of the Promotion Code, it is incumbent on the pharmaceutical company to carefully ensure that the conditions for deviating from the main rule are met at all times.

The Investigator Panel could not see that the sponsorship of the healthcare professional's business could fall under any of the exceptions in Sections 13-15 of the Promotion Code, and thus the sponsorship was deemed to be a violation of the Promotion Code's Art. 12 (1) on the prohibition against giving healthcare professionals financial benefits.

The case was sanctioned with a fine. The decision can be seen at www.enli.dk.

Reimbursement to HCPs for driving their own car

Throughout 2023, ENLI has received several questions about events that include sponsorship of healthcare professionals' transportation in their own car, where it appears that the transportation is covered at the government's rates. This applies to both healthcare professionals as participants and as speakers.

Only direct transportation costs actually incurred

can be covered. When HCPs travel in their own car, ferry and bridge expenses can be covered on account. As only direct expenses are covered, kilometers driven in your own car cannot be reimbursed at government rates (which are higher than the direct expenses). The pharmaceutical company can only cover the healthcare professional's direct expenses. See further details in the guidance to Art. 13 (7) of the Promotion Code.

For consultants hired by a pharmaceutical company, they may be able to report the kilometers driven to SKAT (Tax authority) in connection with www.skat.dk, employees can get a mileage deduction for transportation if they drive more than 12 km to work (a total of more than 24 km to and from work). This applies to all types of paid work where you pay AM contributions. The rates for mileage deductions can be found at www.skat.dk. There is no right to mileage deduction if the employee's employer pays for transportation or if the employee has a company car available. It also appears from skat.dk that people who receive B-income cannot receive tax-free mileage allowance.

Some pharmaceutical companies have stated that it would be administratively burdensome to have to reimburse transportation by car according to invoice, or based on a calculation of the kilometers driven in relation to the specific type of car and have therefore expressed a desire for a separate tariff.

ENLI has been in dialogue with the Danish Medicines Agency about this, and based on the given considerations that no more than the direct expenses for healthcare professionals may be covered, ENLI has calculated some tariffs for gasoline and diesel cars, as well as hybrid cars and electric cars. These "tariffs" should only be seen as an alternative to a time-by-time calculation or payment by receipt. The calculations make it likely that a healthcare professional will not be reimbursed more than the direct costs per kilometer. If the healthcare professional has higher expenses and the pharmaceutical company wishes to cover these, a specific calculation must be made or receipts presented. If the healthcare professional has lower expenses, the tariffs cannot be used and a specific calculation of the actual expenses will have to be made.

For **gasoline-powered cars**, ENLI has used a mid-range car (Golf), which gets good mileage, and has also used the projected gasoline price that SKAT (tax authority) itself assumes when adjusting the transport contribution. This means that for gasoline-powered vehicles, you will be able to pay **DKK 0.85 per km** for driving in own car.

For **diesel-powered cars**, ENLI has used a mid-range car (Golf), which gets good mileage, and has also used the average diesel price for 2023, with a projection similar to that used by SKAT for gasoline prices. This means that for diesel-powered vehicles, you will be able to pay **DKK 0.54 per km** for driving in own car.

For **electric cars**, it's a slightly more difficult matter, as many people charge at home via a subscription scheme, which may also include reimbursement for self-produced electricity via solar panels. At the same time, the prices of charging stations vary greatly depending on whether it's a fast charger or not. Based on an average calculation of the various schemes (and on the basis that electric cars drive an average of 5 km per kWh), we have arrived at the conclusion that for electric vehicles it will be possible to pay **DKK 0.50 per km** for driving in own car.

For **hybrid cars**, the solution has become a cross between a gasoline-powered car and an electric car, which means that for hybrid cars, you will be able to pay **DKK 0.67 per km** for driving your own car.

The above assumes that a healthcare professional does not request to receive more than the direct costs and that a pharmaceutical company does not incur more than the direct costs.

For example, if the healthcare professional has a subscription scheme that means that they have lower expenses than DKK 0.50 per km for driving an electric car, the tariff cannot be used. In this situation, direct expenses can be incurred upon presentation of documentation for the expenses.

It follows from Section 25 of the Advertising Order that healthcare professionals may not request or receive services that are contrary to Sections 22(1). Section 26 (1)(1) of the Advertising Order covers direct expenses

for travel (transportation) in connection with advertising and professional information about medicinal products.

If you are interested in the calculations behind the above figures, you are welcome to contact ENLI at sekretariat@enli.dk.

Compliance is about more than legislation

At the secretariat, we see from time to time that many questions about compliance with the Promotion Code are about whether something is "legal" or not. This is completely understandable, and of course we can help clarify this. In this context, you also have to consider the signal value and the industry's reputation.

It is stated in the purpose provisions of ENLI's code that pharmaceutical companies must maintain high ethical standards at all times. Companies' activities must never be of such a nature that they bring discredit upon the pharmaceutical industry, reduce confidence in it, or cause offense.

In practice, this means that even if something is legal, you must still consider whether it would be a good idea to carry out the activity in relation to the signal value.

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