



# GUIDE

## **on information material and medical equipment**

**(Art. 14 of the Promotion Code)**

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## 1. Purpose

The purpose of this guide is to summarize relevant information for pharmaceutical companies that wish to supply information material and medical devices to healthcare professionals.

If you want to know more about the rules that have formed the basis for this guide, you can read more about it in Art. 14 of ENLI's Promotion Code and the Guidance to the Promotion Code. You can find the rules and the beforementioned guidance on ENLI's website: [www.enli.dk](http://www.enli.dk).

It should be noted that the rules in this guide only apply to pharmaceutical companies that have chosen to adhere to ENLI's rules. If you want to see which companies are subject to the ethical rules under ENLI's jurisdiction, there is a list on our website: [www.enli.dk](http://www.enli.dk).

## 2. Art. 14 of the Promotion Code

The starting point for the pharmaceutical industry's offer of financial benefits etc. for healthcare professionals is a prohibition, cf. Art. 12 of the Promotion Code, and Art. 14 is an exception that must be interpreted in this light. This means that Art. 14 of the Promotion Code must be interpreted restrictively, and hence it will only be possible to provide information material and medical equipment that can be used in the healthcare professionals' profession, when the provided information material and medical equipment is not necessary for the performance of a healthcare professionals' work. In addition, what is provided under the exemption in section 14 must be of insignificant value and not branded, i.e. it is not allowed to mention either the specific or common name or logo of the medicinal product.

It is also stated in the Guidelines to the Advertising Order that:

*"5.5 Economic advantages for health professionals*

*According to section 22(1) of the Advertising Order, economic advantages must not be offered or given to health professionals for advertising purposes or otherwise to promote the sale of a medicinal product, cf. however subsection (2) and sections 24, 26, 30, 32, 37 and 38.*

*The prohibition in section 22(1) does not extend to gifts of insignificant value when the gift can be used in the recipient's business, cf. section 22(2) of the Advertising Order.*

*The provision makes it legitimate for pharmaceutical companies to offer gifts in kind to health professionals, provided the gift has insignificant value and can be used in the recipient's business. Both conditions must be met to make it legitimate to give or offer a gift.*

*The Advertising Order does not set an upper limit on the value of such gifts, but, if the total value from one giver to an individual health professional does not exceed DKK 300 in a calendar year, such gift(s) can be offered legitimately.*

*The value is not based on what the giver paid for the gift (he may have earned significant discounts through bulk buying), but on what the recipient would have to pay for a corresponding item under normal terms. In other words, it is the market value that determines the value of the gift."*

### 3. Information material and the distribution hereof

Art. 2(2)(c)(5) of the Promotion Code states that information material on health and illness for healthcare professionals is generally not to be considered as advertising, which is why the material is not covered by the rules for advertising material in Sections 4-8 of the Promotion Code. Art. 2(2)(c)(5) of the Promotion Code is an exemption provision and only applies if the material does not directly or indirectly mention specific medicinal products. Although such material is exempt from the rules for promotional material, companies must still comply with the rules for supplying information material and medical equipment to healthcare professionals, cf. Art. 14 of the Promotion Code.

If the information material on health and disease is not considered to be an advertisement, it is a condition that the information material can be provided in accordance with Art. 14 of the Promotion Code.

In connection with this, it should be noted that there must be no overlap between an advertisement and information material that can be provided in accordance with Art. 14(1) of the Promotion Code, as this provision specifically prescribes that the information material must not be an encouragement to prescribe a medicinal product (i.e. an advertisement).

This means that if the purpose of the information material is to praise a medicinal product (both directly and indirectly), it is not information material, but rather an advertisement. Information material about illness and health according to the exemption provision in Art. 2(2)(c)(5) of the Promotion Code shall not focus on treatment, and if treatment is mentioned, information about treatment must be at a general level. Reference is made to the guidance to Art. 2(2)(c)(5) of the Promotion Code for further guidance on the distinction between information material under the exemption provision and (indirect) advertising.

### 4. Information material

A pharmaceutical company can provide information material to healthcare professionals if the following four conditions are met:

1. the material must be of insignificant value (max. DKK 300 per year per healthcare professional)
2. the material must be directly relevant to the practice of medicine or pharmacy
3. the material must be of direct benefit in patient treatment
4. the material must not constitute advertising.

Information material in Art. 14(1) of the Promotion Code means material that promotes education in diseases or treatment, for example:

- Brochures about diseases

- Brochures that the healthcare professional uses to instruct the patient on compliance with treatment regimens, healthy lifestyle choices or the possibility of participating in a patient assistance programme.

## 5. Medical equipment

A pharmaceutical company may supply medical equipment to healthcare professionals if the following three conditions are met:

1. the medical equipment must be of insignificant value (max. DKK 300 per year per healthcare professional)
2. the medical equipment must contribute to the training of healthcare professionals and must be targeted patient treatment
3. the medical equipment must not replace the usual necessary equipment in the recipient's medical or pharmacy business.

In popular terms, it can be said that the company may provide material to the healthcare professional if the material is 'nice to have' for the healthcare professional and not 'need to have'.

Medical equipment in Art. 14(2) of the Promotion Code means professional equipment for use in medical or pharmacy activities as well as medical equipment that improves patient treatment. Please refer to the guidance to Art. 14(2) of the Promotion Code for further information.

## 6. Insignificant value

Pharmaceutical companies can only provide information material and medical equipment that is of insignificant value.

Section 5.5 of the Guidelines to the Advertising Order states that: "*The Advertising Order does not set an upper limit on the value of such gifts, but, if the total value from one giver to an individual health professional does not exceed DKK 300 in a calendar year, such gift(s) can be offered legitimately.*"

It should be noted that expenses for the purchase of course material provided in connection with a continuing education event, are not covered by the annual ceiling of DKK 300, cf. the Guidelines to the Advertising Order, section 5.6.

In the event of a possible case with ENLI, the company must be able to document to ENLI the total value provided by the company to a healthcare professional. Please refer to the Guidance to section 14.3 of the Advertising Code for more detailed information.

## 7. Branding

Information material and medical devices can be labelled with the name of the pharmaceutical company but are not to be labelled with the trade or common name of the medicinal product, unless the name of the medicinal product is essential for the correct use of the material or object.

The provision implements EFPIA's Code of Practice Sec. 17.04.

It should be noted that branding on information material must be interpreted by analogy with Lif's FAQ on branding, according to which:

- Trade and common names are never allowed (unless for patient safety reasons)
- Company name/logo is allowed if it does not appear in an advertising manner
- It is allowed to put your logo on textbooks and write "Supplied by [company name]"

Generally, branding with a product name or logo is not permitted on medical equipment unless the branding serves a relevant informational or patient safety purpose. An example of where it is permitted to place a product name on demonstration devices, such as inhalation devices or injection devices, is situations where the product name is intended to prevent errors by ensuring that the right product can be identified with the device in question. Thus, it is allowed to put a company name and/or logo on such medical equipment if it is not prominently displayed in a promotional manner.

## 8. Q & A's

### Information material for healthcare professionals, cf. Art. 14(1) of the Promotion Code

#### 1. Can a pharmaceutical company provide a reprint to a healthcare professional?

**A:** Yes, a pharmaceutical company can provide professional scientific articles and reprints if:

- it is directly relevant in the exercise of the medical or pharmacy profession,
- directly benefit patients and
- the material provided is of insignificant value (i.e. the total value to the individual healthcare professional does not exceed DKK 300 in a calendar year)

*It is important to distinguish between whether the supply of reprints and professional scientific articles is at the initiative of the company or the healthcare professional in relation to the concept of advertising, cf. section 2.2 of the Guidelines to the Advertising Order.*

*A company's unsolicited supply of scientific articles (reprints) regarding the company's medicinal products is considered an advertising activity, and therefore a compulsory text must be enclosed in connection with the supply, cf. Art. 5 of the Promotion Code. In addition, the pharmaceutical company may only supply the material if the material is in accordance with the summary of product characteristics (SPC).*

*If the material is provided at the request of a healthcare professional, the provision is covered by the rules for "individual correspondence", cf. Art. 2.2(2)(c)(2) of the Promotion Code, and the provision is therefore not considered an advertising activity.*

*Regardless of whether the delivery is on request or unsolicited, a reprint still constitutes a gift, which is why delivery can only take place if the material is of insignificant value (i.e. the total value to the individual healthcare professional does not exceed DKK 300 in a calendar year), cf. Art. 14 (3) of the Promotion Code.*

#### 2. Can a pharmaceutical company supply academic literature to healthcare professionals?

**A:** See the above answer. See also the detailed comments in the guidance to Art. 14(1) of the Promotion Code regarding the difference between a medical textbook and advertising.

#### 3. Can a pharmaceutical company offer a subscription to a professional/scientific journal to healthcare professionals?

**A:** Yes, provided that the journal is professionally relevant, and that the subscription is of insignificant value - i.e. does not constitute a total value of more than DKK 300 per year per healthcare professional.

**4. Can a pharmaceutical company provide information material to a healthcare professional on a USB stick?**

**A:** *Yes, the material can be provided on a USB stick. When dispensing on a USB stick, the capacity of the chosen USB stick must be the least available in relation to the scope of the promotional material in question, so that it reflects a reasonable balance between the needs of the information material and available alternatives (USB sticks etc. with less capacity). It is a condition that the USB stick is of negligible value (max. DKK 300 per year per healthcare professional).*

**5. Can a pharmaceutical company provide information material about a chronic disease to a healthcare professional?**

**A:** *Yes, if the material is of insignificant value (max. DKK 300 per year per healthcare professional) and does not constitute advertising, neither direct nor indirect advertising, cf. Art. 14(1) of the Promotion Code.*

### **Supply of medical equipment to a healthcare professional, cf. Art. 14.2 of the Promotion Code**

**6. Can a pharmaceutical company supply an anatomical model to a healthcare professional?**

**A:** *Yes, a pharmaceutical company can provide an anatomical model: if:*

- *it is directly relevant in the exercise of the medical or pharmacy profession*
- *directly for the benefit of patients and*
- *the provided material is of insignificant value (i.e. the total value to the individual healthcare professional does not exceed DKK 300 in a calendar year).*

**7. Can a pharmaceutical company supply a wall calendar to a general practitioner for use in practice?**

**A:** *No, the supply of a wall calendar can neither be considered as information material nor medical equipment, which is why the supply of a wall calendar does not fall within the scope of application of Art. 14 of the Promotion Code. Supply will therefore be in violation of the gift ban in Art. 12 of the Promotion Code. The Investigator Panel has issued a decision (R-2017-4928) in a similar case. The decision can be found on ENLI's website.*

**8. Can a pharmaceutical company supply a stethoscope to a general practitioner?**

**A:** *No. Notwithstanding the fact that a stethoscope is considered medical equipment, the supply of a stethoscope would be in violation of Art. 14 (2) of the Promotion Code, as a stethoscope is considered to be a usual and necessary equipment for a general practitioner (need to have).*



**9. Can a pharmaceutical company supply an ECG ruler/pain ruler to a general practitioner?**

**A:** *Yes, cf. Art. 14(2) of the Promotion Code, as an ECG ruler/pain ruler is considered as medical equipment that is of benefit to the doctor in connection with patient treatment, however, without the ECG ruler/pain ruler being considered a necessary device in general practice (nice to have). It is a condition that the material is of insignificant value (max. DKK 300 per year per healthcare professional).*

**10. Can a pharmaceutical company provide a needle cushion to a general practitioner for use in teaching patients in connection with training in self-injection?**

**A:** *Yes. See the above answer for further comments.*

**11. Can a pharmaceutical company supply cotton gloves to a general practitioner?**

**A:** *No, the supply of cotton gloves cannot be considered medical equipment (equipment that is suitable for improving the healthcare professional's medical practice and patient treatment, and which has no personal value for the healthcare professional), which is why the supply is not in accordance with Art. 14 of the Promotion Code. The supply will therefore be in violation of the gift ban in Art. 12 of the Promotion Code.*

**12. Can a pharmaceutical company hand out pads and pens without a logo to a general practitioner in connection with a pharmaceutical sales representative visit?**

**A:** *No. A pharmaceutical sales representative visit is not considered as continuing education to such an extent that practical meeting equipment can be provided, cf. the guidance to Art. 12(1) of the Promotion Code.*

**13. Can a pharmaceutical company provide a small calendar (which can be placed in a doctor's coat) to a healthcare professional?**

**A:** *No. See the above-mentioned answer to question 11 for further comments.*

**14. Can a pharmaceutical company supply a device holder (for asthma inhalers) to a general practitioner so that the doctor can keep track of the different inhalers?**

**A:** *No, the supply of a device holder cannot be considered medical devices, as the device does not improve the healthcare professional's medical practice and/or improve patient treatment. The supply therefore does not fall within the scope of the Promotion Code's Art. 14 (2), and the supply would be in violation of the gift ban in Art. 12 of the Promotion Code.*

*It should be noted that the supply of a device holder cannot be supplied to hospital departments under the Donation Code, as a device holder cannot be considered an integral*

*part of either prevention, examination, diagnosis, treatment or medical check-up of the patient, cf. Art. 4 (1) (a) of the Donation Code.*

**15.** Can a pharmaceutical company supply hand sanitizer to doctors, e.g. in small containers of 20-30 ml, so that the bottle can be kept in a coat pocket?

**A:** *No, hand sanitizer is to be considered necessary equipment, which therefore cannot be supplied, cf. section 14(2) of the Promotional Code.*

**16.** May a pharmaceutical company provide a needle box for disposal of used needles to a healthcare professional?

**A:** *No, a needle box is to be considered necessary equipment, which therefore cannot be supplied, cf. Art. 14(2) of the Promotion Code.*