Overview of the rules
- Promotion Code

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PURPOSE OF THE OVERVIEW

The purpose is to provide a quick overview of the most used provisions in the Promotion Code.

The information in this overview cannot stand alone. To gain full knowledge of the rules, please refer to ENLI's "Promotion Code" and "the guidance to the Promotion Code".

PURPOSE – ART. 1

Remember Article 1 (purpose provision) regardless of the activity

FIELD OF APPLICATION – ART. 2

The Promotion Code applies to pharmaceutical companies' activities relating to advertising and communication of medicines, if:

- All or part of the activity is aimed at Danish healthcare professionals
- The activity is held in Denmark

The Promotion Code does NOT apply to activities that:

- Relate exclusively to non-medicinal products, e.g. medical devices, skin care products etc.
- Not aimed at healthcare professionals
- Conditions covered in sec. 2 i of the Executive Order on Advertising of medicinal products: labelling, package leaflets, safety information, price lists, press releases, SPC etc.
- Clinical research. However, Sec. 13.3 – 13.10, applies for meetings and art. 15 & 16 for remuneration

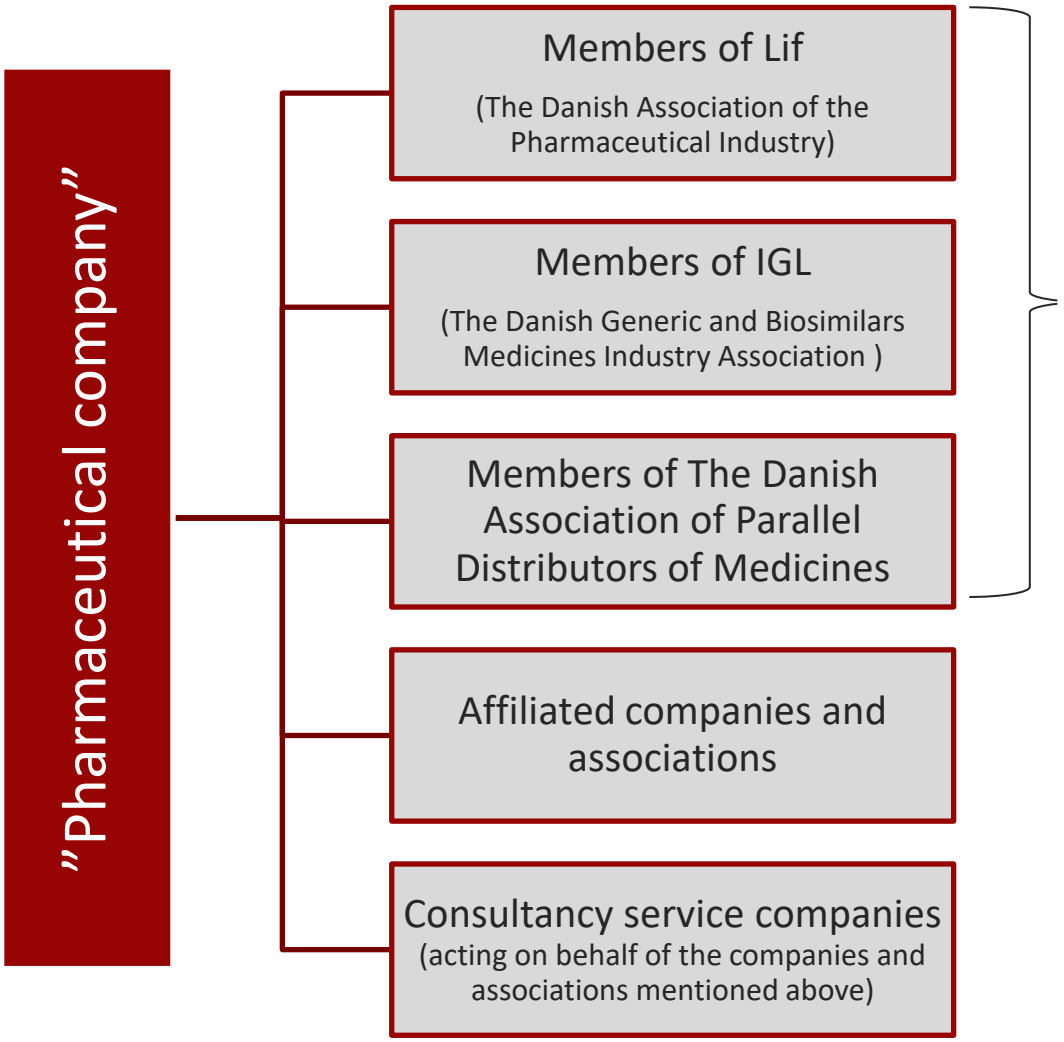
DEFINITIONS – ART. 3

”Healthcare professionals”

Doctors, dentists, pharmacists, nurses, veterinary nurses, pharmaconomists, midwives, bioanalysts, clinical dieticians, radiographers, social and health assistants and students of these disciplines..

The general public = Everyone who is not defined as healthcare professionals

DEFINITIONS – ART. 3



MARKETING AUTHORIZATION – ART. 4

Advertising for medicine requires:

- Marketing authorization
- Notify the price of the medicine to the Danish Medicines Agency at: Medicinpriser.dk (only a requirement for pharmacy-only medicinal products)

Advertising is NOT allowed for:

- Medicinal products that cannot be lawfully treated or supplied in Denmark
- Magistral products, medicinal products with a special authorization in accordance with the Danish Medicines Agency, etc.

REQUIREMENT OF OBJECTIVITY – ART. 4

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An advertisement for a medicinal product must be:

- Adequate
- Objective
- Not misleading
- Not exaggerate the properties of the medicine
- In accordance with SPC

COMPULSORY INFORMATION – ART. 5

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An advertisement for a medicinal product must include the information below:

1. The invented name and the generic name of the medicinal product
2. Name and adress
3. Therapeutic indication
4. Contraindications
5. Adverse reactions and risks
6. Dosage
7. Pharmaceutical forms
8. Pack sizes
9. Reference to the current price on medicinpriser.dk
10. Dispensing group
11. Reimbursement status
12. The date on which the promotion material was generated or last revised

Article 5, section 1

REQUIREMENT FOR COMPULSORY INFORMATION – ART. 5

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Requirement for compulsory information

- The compulsory text must correlate with the advertisement
- The compulsory text must clearly be stated in the advertisement

Article 5, section 1 and 2

REMINDERS – ART. 6

A reminder is an advertisement that is directed only at healthcare professionals and is limited solely to the trade and common name of the medicinal product

- Company name and logo can be used if they do not indicate/refer to the therapeutic indication/use of the medicinal product
- Not a requirement for enclosed compulsory text (Sec. 5.1) in a reminder

INFORMATION MATERIAL & DOCUMENTATION – ART. 7

An advertisement for a medicinal product:

↓

- Must not exaggerate the properties of the medicinal product (Sec. 7.1)
- May not have laudatory claims, unless the claims can be documented (Sec. 7.1)
- Must contain the compulsory information in Sec. 5.1 (Sec. 7.2)
- Must be adequate, objective, accurate, relevant and verifiable (Sec. 7.3)

Article 7, section 1, 2 and 3

TABLES & ILLUSTRATIONS – ART. 7

Quotations, tables and illustrations

- Must be faithfully reproduced in relation to the source material
- The exact source must be disclosed and referred to
- Non-marketed dosages and medications must be removed
- Laudatory and emphasizing adjustments are not allowed
- Allowed to create other figures, even if a figure already exists in the original reference*
- Allowed to remove information from a figure/table if the information is irrelevant to the advertisement *
- Allowed to make figures, etc. based on text in a reference - there is no requirement for fixed method *

* It must be stated that the graph/ figure/table is made by the company. The changes are only allowed if they are loyal to the reference and are not misleading

Article 7, section 4

DOCUMENTATION – ART. 7

Sources that can be used as documentation for **factual** information in an advertisement

- Guidelines from medical societies (both Danish and foreign)
- Danish Medicines Council (Medicines Council)
- IRF, RADS og KRIS
- Medicin.dk, Sundhed.dk or the like
- Health economic analyzes

Article 7, section 5: for further information, please referer to ENLI´s Documentation guide

DOCUMENTATION – ART. 7

Sources that can be used as documentation for information on the **medicine's properties** in a medicine advertisement

- SPC (The approved product summary)
- Scientific studies
- Systematic overview articles with meta-analysis

In order for scientific studies to be used as documentation, it is required that:

- The research must have been published in established and independent professional journals
- The research must have been subject to an independent assessment (peer review)

Article 7, section 5: for further information, please referer to ENLI´s Documentation guide

DOCUMENTATION – ART. 7

Other sources that can be used as documentation in a medicine advertisement. Additional information is needed in the advertisement to ensure that the information meets the documentation requirement in Sec. 7.3

- Registry studies, observational studies, cohort studies, real world evidence/data and the like
- Non-clinical studies
- Post hoc analyzes

Article 7, section 5: for further information, please referer to ENLI´s Documentation guide

DOCUMENTATION – ART. 7

Sources that **cannot** be used as documentation in a medcine advertisement

- Expert opinions and the like
- Casuistics
- Abstracts og Posters
- Data on file
- Ongoing clincal trials
- Foreign recommendations
- EPAR (European Public Assessment Reports)
- PSUR (Product Safety Update Report)
- Decisions from courts of justice
- Market research

Article 7, section 5: for further information, please referer to ENLI´s Documentation guide

COMPARATIVE ADVERTISING - ART. 8

If a promotion material includes a comparison between several medicinal products, the following requirements must be met

- It must clearly appear which medicinal products the comparison includes
- The comparison must only include medicinal products, which are relevant to compare from an objective point of view (i.e. medicinal products with the same field of application)
- Comparative advertising must be based on the information in the SPC of the medicinal products
- Comparisons between different medicinal products must not be misleading or disparaging
- The comparison must be accurate, relevant, loyal
    - Objective, serious, adequate – cf. Art. 4
    - Sufficient and adequate information – cf. Art. 7

PROHIBITION AGAINST FINANCIAL BENEFITS AND GIFTS – ART. 12

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It is not allowed to supply, offer or promise healthcare professionals gifts or financial benefits, either in the form of cash, cash equivalents, personal services or benefits, except as listed in Art. 13 - 15

Art. 13 (exception to Art. 12)	**Art. 14** (exception to Art. 12)	**Art. 15** (exception to Art. 12)
Professional events, sponsorships and hospitality - Program (Sec. 1) - Invitation (Sec. 2 - Venue (Secs. 3 & 10) - Events abroad (Secs. 4 & 13) - Hospitality (incl. transportation and accommodation: Secs. 5, 6 & 7) - Catering (Sec. 8) - Entertainment (Sec. 9) • Obligation to report to ENLI	**Information and educational material** (Sec. 1) **Medical equipment** (Sec. 2) • No requirement to report to ENLI	**Consultant** • No requirement to report to ENLI

All exceptions are interpreted restrictively, as the starting point is a prohibition

PROFESSIONAL EVENTS - ART. 13

Organizer

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A pharmaceutical company is considered an **organizer** when:
- You choose who to invite as participants
- You prepare the program and choose the speakers
- You choose the venue
- You choose the catering at the meeting
- You send out the invitation to the meeting

If the pharmaceutical company helps to determine just one of the above, the company will be considered a co-organizer.

The same rules apply, whether you are an organizer or a co-organizer.

Sponsorship to external organizer

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A pharmaceutical company provides a sponsorship to an **external organizer** when:

- A pharmaceutical company gives money to an external party, for example to a medical society or an organizer of a congress
- The company has no influence on any of the following:
  - Program
  - Speakers
  - Venue
  - Catering
  - Sends out the invitation

For example, if a company gives a sponsorship of DKK 100,000 to a medical society to conduct their annual meeting (sponsorship only for the professional part of the meeting.)

Sponsorship for participation

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A pharmaceutical company provides a **sponsorship to a participant** when:

- A healthcare professional asks a pharmaceutical company if they will cover the healthcare professional's expenses related to a professional activity or

- A pharmaceutical company contacts a healthcare professional to invite her/him to an external professional event, e.g. to a congress

- The company has no influence on any of the following:
  - Program
  - Speakers
  - Venue
  - Sends out the invitation for the congress

For example, if the company pays for the healthcare professional's expenses for registration fees, flights, hospitality in conjunction with a congress or similar.

REQUIREMENT FOR PROFESSIONALISM - ART. 13

An event must have a special professional healthcare content and be intended as continuity training for healthcare professionals, e.g. medical presentations on disease, areas of disease, medicines and methods of treatment, cf. Sec. 13.1

- No support may be granted to non-healthcare related courses, such as those also offered to other professional groups, such as financial control, organizational development, leadership, computer and collaboration courses, planning meetings, coaching, practice management, communication, teacher training, etc.
- The extent of professionalism is assessed differently depending on whether the company organizes an event or give a sponsorship to an external organizer or for participation of a healthcare professional:

Organizer/ co-organizer → The ENTIRE program must be professional

Sponsorship → The program must be PREDOMINANTLY professional

Article 13, section 1

INVITATION & EVENTS ABROAD – ART 13

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Invitation require-ments Sec. 13.2

- The organizer and purpose of the event must appear from the invitation
- The invitation must always state, whether the event has been sponsored by one or more pharmaceutical companies

Events abroad Sec 13.4

General rule:	No events/sponsorships abroad
Exception:	- If most of the invitees come from abroad - If the location of the relevant resource or expertise makes significantly more logistical sense to hold the event in another country.

REMEMBER the company´s obligation to inform the healthcare professionals about the association rules and the duty for HCP's to notify the Danish Medicines Agency when they participate in professional activities abroad supported by the company (Sec. 13.13)

HOSPITALITY – ART. 13

Hospitality can be offered at a "reasonable" level and must be strictly limited to the main purpose of the event – Sec. 13.7

Hospitality is limited to travel, meals, accommodation and genuine registration fees.

- Only expenditure actually incurred is covered (against receipt)

Hospitality may only be offered when relevant in connection to the professional event

- Balance between the offered hospitality in relation to the purpose and content of the event

Accommodation:

- Only hotel, if the duration of the (professional) event makes it necessary
  - events that last over 6 hours and have professional activities on both the day before and after the accommodation

Transportation:

- Rail travel – allowed regardless of the choice of class
- Air travel to professional events (to which the healthcare professional has been invited):
  - Europe -> Economy class
  - Overseas destinations -> Economy or Economy Plus
  - Business Class is acceptable at all travels, if the traveller is in a wheelchair, etc.

Article 13, sections 5, 6 and 7

CATERING – ART. 13

Price-cap in Denmark

- For professional meetings up to 2 hours: DKK 100
- For other meeting activities: Lunch: DKK. 450, dinner: DKK. 850, all day event: DKK. 1.400

Price-cap outside Denmark

- EFPIA countries – the national limit for each country (refer to ENLI's EFPIA map - www.enli.dk)
- Outside EFPIA countries - the Danish price-caps applies, however, with adjustment if significant price difference/standard of living

Article 13, section 8

VENUE – ART. 13

Suitable venue
Sec. 13.3

- The venue must be suitable for the main purpose of activity
- The venue must have meeting facilities
- The venue must not be an attraction in itself

Prohibition on using venues, which are known for their entertainment facilities or are extravagant and/or luxurious – Sec. 13.10

Extravagant/luxurious means no meetings at:

- Five-star hotels, gourmet restaurants
- Castles, manor houses, mansions, estates, golfing, skiing and beach hotels (in season)

The deciding factor is whether the planned venue, in the general public, is "known" for its entertainment facilities, is extravagant and/or luxurious

Exception: 3 situations where a venue is accepted even if it is "known" for entertainment:

- The venue is not an attraction in itself
- It is obvious that attendance at a professional event at the venue is at a time when there is no general access to entertainment, or that no kind of entertainment is taking place
- The venue is similarly known for its meeting facilities, which to the public is considered separate from entertainment facilities

ENTERTAINMENT – ART. 13

PROHIBITION OF SPONSORING OR ORGANIZING ENTERTAINMENT EVENTS

Remember the difference between:
Company events - total prohibition
Sponsored third party events:
- ”Primary” (prohibited unless self-payment)
- ”Secondary” (allowed)

”Primary” entertainment:
- Stand-alone performance
- Damaging to the industry's credibility and image
- Celebrities
  - Only allowed by attendees self-payment or if the sponsorship comes from a non-pharmaceutical company

“Secondary” entertainment:
- Activities not consisting of a special event
- Limited in its extent and/or reputation
- Does not have any entertainment value of significance
- Not damaging to the industry's credibility and image

Art. 13, section 9

INFORMATION MATERIAL – ART. 14

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Payment of information and educational material and medical equipment is permitted if the requirements of Art. 14 are met:

Information and educational material (sec. 1)

Requirements:

1. Inexpensive
2. Directly relevant to the practice of medicine or pharmacy business
3. Directly beneficial to the care of patients

Medical equipment (sec. 2)

Requirements:

1. Inexpensive
2. Aimed directly at the education of healthcare professionals and patient care
3. Do not replace the usual equipment required in the recipient's medical or pharmacy business

Inexpensive (sec. 3)

Existing official Danish practice: must not exceed DKK 300 in a calendar year pr. HCP

Branding (sec. 4)

- The name of the pharmaceutical company is allowed on the material/equipment
- Trade or common name of the medicinal product is not allowed:
  - unless the name of the product is essential for the correct use of the material or item.

No obligation to report to ENLI

CONSULTANTS – ART. 15

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It is permitted to contract healthcare professionals as consultants and advisors for a fee

Requirements:

- A written contract/agreement must be concluded prior of the commencement of the services, specifying the nature of the services
- The association of doctors, dentists and pharmacists with a pharmaceutical company requires prior notification to/or the permission of the Danish Medicines Agency
- Pharmaceutical companies must inform the healthcare professionals of this notification as well as inform the Danish Medicines Agency of the doctors, dentist and pharmacists who are associated with the company
- Anonymous market surveys does not need to be notified or authorized
- Remember that if a healthcare professional attends an event in a consultant or advisory capacity, the relevant provisions of Art. 13 applies

No obligation to report to ENLI

EXHIBITION – ART. 18

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It is permitted to promote medicinal products at professional events

Requirements:

- Promotion of medicinal products must be conducted **separate** from the rest of the event's professional content
  - No exhibitions are permitted in the training rooms, but for example in the foyer
- Requirement for **professionalism**, cf. Section 13.1
  - The same assessment of professionalism as when given a sponsorship -> the program must be predominantly professional, cf. Section 13.1
- **Price**, including VAT and administration fee, must reflect the market price
  - As a rule of thumb, it can be reckoned that a square metre price of DKK 2,000 for a whole-day event in a rented, external location with about 50-80 delegates is acceptable
  - A higher square metre price would only be acceptable if so indicated by the market price, due to the possibility of exposure or the like, cf. above
- Exhibition vs. Sponsorship
  - If the price of the exhibition stand exceeds the normal market price, the purchase will become a sponsorship, which means that the entire Article 13 applies

MEDICAL SAMPLES – ART. 19

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It is permitted to supply a sample of a medicinal product

Requirements:

- Samples must not be supplied for more than two years after the date of introduction
  - 1 sample a year for a maximum of two years
- The date of introduction for a new medicinal product shall be the date at which it is placed on the market for the first time, i.e. listed in Medicine Prices for the first time after grant of a marketing authorization

Other rules, cf. Executive Order on supplying medical samples, controlled by the Danish Medicines Agency (excerpt)

- Only for doctors, dentists and veterinarians
- Only to the extent that the person concerned is entitled to prescribe the medicinal product
- Only one sample per healthcare professional per year (of each form and dosage)
- No larger than the smallest package marketed
- Must be labeled "free medical sample" and "not for sale"
- Only at the request of the recipient

PERSONNEL IN PHARMACEUTICAL COMPANIES - ART. 20

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Requirements for pharmaceutical companies' sales representatives

- Ensure they know the rules well, are appropriately trained, and have sufficient knowledge of the medicine in question
- The sales representatives must give the persons visited a summary of the product characteristics for each medicinal product they present, accompanied by information on reimbursement and reference to medicinpriser.dk, if needed
- Performing their duties responsibly and ethically
- Visits must not cause inconvenience for the healthcare professionals
- Visits to hospitals and the subject of the visit must be agreed upon in advance, ie. prohibition on unannounced visits
- Must immediately disclose all information to the company received from HCP regarding the use of the medicine, including adverse reactions

The same applies to contracted third parties who contact healthcare professionals in connec-tion with the promotion of medicinal products

REPORTING REQUIREMENT - ART. 21

Pharmaceutical companies are obligated to report the following activities to ENLI

Sec. 21 (1) (a) **Organizer of own event**	**Sec. 21 (1) (b)** **Sponsorships** - sponsorship to external organizer or - sponsorship for participation	**Sec. 21 (1) (c)** **Exhibition**	**Sec. 21 (3)** **Promotional materials**
Must be submitted within 10 working days prior to the opening day of the event	Must be submitted within 10 working days prior to the opening day of the event	Must be submitted within 10 working days prior to the opening day of the event	Must be filed at least on the same day as the printed promotion material is distributed

No notification requirement for:

- Activities where an HCP is providing a service in return by way of their expert knowledge, ex. consultants
- ”Save the date” – without possibility of registration
- Visits by medical representatives not accompanied by a speaker