# GUIDE

## on market research

NB! You can search in the guide by pressing "Ctrl + F" and enter your search word.

## Index

## 1. General

The purpose of this guide is to summarize relevant information for the pharmaceutical companies affiliated with ENLI when preparing market research aimed at healthcare professionals in Denmark.

If you want to know more about the rules that formed the basis for this guide, you can read more in ENLI's Promotion Code, the guide to the Promotion Code and in ENLI's guide on pre-launch.

You can find the rules on ENLI's website: www.enli.dk.

## 2. Scope

Note that, as a rule, the rules in this guide only apply to pharmaceutical companies that have chosen to comply with ENLI's rules. ENLI is a self-regulation body.

The rules of the guide only govern the contact between pharmaceutical companies (and consultant agencies acting on their behalf) and healthcare professionals. The contact that occurs directly with patients or with others who are not healthcare professionals is not covered by this guide.

To see which companies have joined ENLI, you can find an updated list on the front page of www.enli.dk.

The market research guide primarily addresses the general requirements for a market research, including the advertising rules and the use of consulting agencies. In addition, on the basis of the wishes of ENLI's affiliated companies, the guide deals in general with: rules of association, personal data, pharmacovigilance and patient safety.

Please note that the rules of the Marketing Act apply when sending unsolicited advertising, including market research. The rules of the Marketing Act are not addressed in this guide.

## 3. Definition of market research

Pharmaceutical market research studies are characterized by being a structured collection of data that, e.g. can be used to investigate the market in relation to specific medicines, medicines groups, areas of disease, etc.

Market research typically has a commercial purpose and can be used to support commercial and product-specific decisions and strategies. A company can, by means of market research, get the reasons why sales of a medicine are more or less successful.

Market research may include payment for the service provided by the healthcare professional, e.g. in the form of a fee for the service that the healthcare professional provides by participating in the study. Market research aims to investigate market conditions and will typically be used for the company's internal use.

## 4. Advertising rules

Market research can in some cases be considered advertising of a medicine, depending on the questions asked in the study. If a market research study is an advertisement, the general rules for advertising medicines must be observed, cf. Promotion Code Art. 4-8.

### Definition of advertising

Advertising for medicines means "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products". The definition of advertising is the same, regardless of whether you are solely subject to Danish law or also ENLI's rules.

It should be noted that this is a very broad concept of advertising, which means that most of the activities of pharmaceutical companies towards healthcare professionals will be regarded as advertising activities. This means, among other things, that companies should generally stick to what their medicine is approved for and nothing else, otherwise there is a risk that they will get into an illegal advertising situation.

### Requirements for advertising in Denmark

Medicines that have not been approved for the Danish market must not be mentioned or otherwise used in a pharmaceutical advertisement, including market research, to healthcare professionals in Denmark.

In Denmark, there are two requirements that must be met before a medicine can be advertised:

1. There must be an existing marketing authorization (valid in Denmark) and
2. The medicine in question must be price notified to the Danish Medicines Agency[1]

Furthermore, advertising of a medicine must be adequate and factual, and must not be misleading or exaggerate the properties of the medicine. Information in the advertisement must be in accordance with the approved product summary of the medicine, cf. Art. 4 (2) of the Promotion Code.

### Pre-launch, etc.

The assessment of whether mentioning of a potential future specific medicine, before the time of marketing approval, is advertising (pre-launch), is difficult.

ENLI considers, as a starting point, any mentioning, towards healthcare professionals, of scientific studies and data related to **phase I and II** of a clinic development program for potential future medicines, to fall outside the scope of the Promotion Code, as it is not a given that a specific project ends with a mar-

[1] Applies for pharmacy-only medicines.

keting authorization for a specific medicinal product. Such mentioning is considered scientific if the information is presented in a neutral and non-promotional way (i.e. mention of the potentially upcoming medicine may not be laudatory).

When mentioning information from **phase III studies**, one must consider whether it can be advertising, especially if an application for a marketing authorization or publishing of the study is imminent. Mention of results from phase III trial after its publication in a scientific journal (i.e. after e-publishing with DOI number or print in a recognized journal with unbiased review, see. Promotion Code Art. 7 (5)) can therefore, and will, most often, be considered as pre-launch when this is carried out in a specific commercial marketing context, as it must be assumed that from this date, the company is working determinedly on a marketing authorization.

In a medicine's life cycle management, several clinical development programs are typically included which, for example, could intend to examine the medicine's effect on other (sub) populations (e.g. pediatric use) or entirely new indications/uses. In a promotional context, the emphasis of such clinical development programs will, as a basis, be considered as an expansion of indication and thus an unlawful advertisement.

For further guidance, see ENLI's Guide on pre-launch (www.enli.dk).

### Comparative advertising

Comparative advertising is defined as any advertising that directly or indirectly refers to another medicinal product. However, it will always depend on a specific assessment where the content of the advertisement is evaluated in each case.

In principle, comparative advertising will be legal when the advertising is complete, correct, relevant and loyal. The comparison must also be objective and relate to documentable information.

Comparative advertising must be prepared based on the information contained in the summary of product characteristics of the medicinal products included in the comparison[2].

A medicines advertisement containing a comparison between several medicines must clearly state which medicines comprise the comparison. The comparison must only include medicinal products which it is objectively relevant to compare, i.e. medicines with a corresponding scope, cf. Art. 8 (2) of the Promotion Code. Compulsory text must be provided for own medicinal product.

[2] The Guide to the Danish Medicines Agency's Advertising Order section 3.2 states that it applies to the extent that the summary of product characteristics contains information on what is covered by the comparison. If there is a comparison of prices of pharmacy-only medicines, a comparison can be made based on the prices published on medicinpriser.dk..

## 5. General requirements for market research

When a pharmaceutical company wishes to conduct a market research study, a written agreement must be entered between the pharmaceutical company/consulting agency and the healthcare professional, where the benefits and the basis for any payment are stated.

### When is market research considered advertising?

If a market research study does not contain information on medicines, either directly or indirectly, and only mentions **health and illness** at a general level, there will in principle be no advertising.

The fact that medicinal product names are mentioned in a market research does not automatically mean that the market research is regarded as advertising. Whether the market research is considered an advertisement will depend on a specific assessment of, among other things, the setup and wording/content of the questions in the study.

The person who prepares the questions for a market research study must, among other things, be aware of whether the questions are leading, including whether you in the study, e.g. place the company's own medicine in a particularly favorable light.

However, it is noted that it is the form and content of the market research that form the basis for the overall assessment of whether advertisement is involved. If the purpose is to promote the prescription, delivery, sale or consumption of medicines, this will be an advertising activity. If, on the other hand, the purpose is merely to acquire knowledge for, e.g. to support commercial and product-specific decisions and strategies, there will not be the same presumption that this is an advertising activity. A market research may have several purposes.

If a market research is considered an advertisement for a medicine, the rules for medicines advertising must be observed, cf. Art. 4-8 of the Promotion Code. If the market research study is advertising, only medicines that can be legally sold or supplied in Denmark can be advertised.

### Notification

If the market survey is considered an advertisement, it must be **notified to ENLI** cf. Art. 21 (3) of the Promotion Code, no later than the same day that the survey is initially presented to healthcare professionals, cf. Art. 21 (5) of the Promotion Code.

### Compulsory information

If the market survey contains advertising for one or more of the company's medicines, compulsory information must be provided for these medicines (compulsory text).

## 6. Healthcare professionals as consultants/advisors

It is permissible to use healthcare professionals as consultants and advisors when, for example, participating in market research, since participation in a market study is considered counselling.

A written contract or agreement must be concluded prior to commencement of the service specifying the nature of the service and the basis for payment.

### Fees for participation in market research

Payment may only be made in the form of direct payment, and thus not by set-off, transfer of in kind or other indirect means.

In determining a fee, the fee must be proportionate to the service provided by the healthcare professional. General market conditions should be considered, including the market price for similar services and the time consumed.

For it to be transparent what a healthcare professional receives in fees, he or she must not be paid in anything other than money, for example by bank transfer. Payment by set-off, transfer of in kind, e.g. gifts, wine, flowers, gift certificates, etc., or any other indirect way, are thus not allowed, either by a pharmaceutical company or as an agency acting on behalf of the pharmaceutical company.

The detailed rules for the use of consultants can be found in Art. 15 of the Promotion Code and the guidelines for this.

## 7. Consulting/analytics agencies, etc.

The rules in ENLI's Promotion Code apply both to the pharmaceutical companies affiliated to ENLI and to the third parties acting on behalf of these companies, e.g. analytics, advertising and communication agencies, etc., which are hired to carry out work within the scope of the Promotion Code.

If, as a pharmaceutical company, you want to conduct market research and you hire an external consultant agency to carry out the task, the agency will have to comply with the rules, on par with the pharmaceutical company.

It is the pharmaceutical company’s responsibility to ensure that the agency/consultants comply with the rules of the Promotion Code. Thus, the fact that as a pharmaceutical company you "outsource" the task to a third party does not mean that you do not have to comply with the advertising rules, the rules for fees, affiliation, personal data, etc.

## 8. Rules of Association

If a doctor, dentist, nurse, midwife, pharmacist or a clinical pharmacist is associated with a pharmaceutical company, e.g. by participating in a market study, he/she must apply for association with the company at the Danish Medicines Agency prior to participation. The reason for this is that participation in a

market survey is regarded as counseling that requires prior permission from the Danish Medicines Agency.

The pharmaceutical companies have an obligation to provide information to healthcare professionals and must notify the Danish Medicines Agency of which doctors, dentists, nurses, midwives, pharmacists or clinical pharmacists are associated with the company.

You can read more about the rules of association on the Danish Medicines Agency's website.

### Anonymous market research

It is stated in the Danish Medicines Agency's guide to the Association Order that anonymous market research, in which the study is conducted by a third party/external agency, and where the pharmaceutical company and the healthcare professional do not know each other's identity, are not considered an association. It is a requirement that the anonymity between the actual pharmaceutical company and the physician, dentist or pharmacist, respectively, is maintained before, during and after the survey (double blinded studies).[3]

It is ENLI's opinion that the fact that a market study only deals with one medicine, where the healthcare professional may be able to figure out who the sender company is, does not necessarily mean that anonymity is considered broken. In such cases, one will not normally have to apply for permission to participate in an interview. However, it is crucial here that the anonymity between the contributing healthcare professional and the actual pharmaceutical company is maintained both before and after the study has been carried out.

If the market study is considered an advertisement for a medicine, a compulsory text must be enclosed, and this will no longer be an anonymous market study. When a compulsory text is attached (because it is an advertisement), the recipient can figure out that it is the company in question that sent the survey. Advertising requirements demand identification of the sender. Thus, it follows from the advertising rules, that an advertisement must be adequate and of the e-commerce law, that it must be clearly stated who is the sender of an advertisement. Thus, it will not suffice for anonymity to advertise "equally" for all medicines in the study and enclose compulsory information for all medicines.

## 9. Personal data

In the vast majority of market research, personal data will be processed. Therefore, the requirements of the Personal Data Regulation (GDPR – General Data Protection Regulation) must be complied with in the context of market research. Therefore, it is always a good idea when preparing a market survey to

[3] Guidelines on doctors' affiliation with pharmaceutical companies, medical device companies, companies that manufacture, import or distribute products without a medical purpose and speciality stores with medical devices (retsinformation.dk), Guideline no. 9382 of 19 May 2021

discuss the content/questions with the company's own GDPR-officer to ensure that personal data is processed in accordance with the Personal Data Regulation[4] and the Data Protection Act[5].

It should be noted that according to Articles 13 and 14 of the GDPR, a general disclosure obligation rests with the data controller against the data subject. This applies regardless of whether the company itself obtains the personal data of the data subject (Article 13) or whether they obtain it from third parties (Article 14).

In the case of anonymous market surveys where the identity of both parties remains anonymous to each other (double blind), there will be no processing of personal data[6] for the pharmaceutical company.

As a company, one should therefore always be aware of the general principles for processing personal data, especially Art. 5.

### Data processing agreement

If a pharmaceutical company gets an analytics/consulting firm to conduct the market research, a data processor agreement must be drawn up. Reference is made to Articles 28 and 29 of the Personal Data Regulation (GDPR).

## 10. Pharmacovigilance

When conducting a market research, a pharmaceutical company or analytics company must observe the rules of pharmacovigilance.

It may be relevant to deal with information about adverse reactions if a healthcare professional submits information about it in the context of a market study.

It follows from section 53 (1) of the Medicines Act that the marketing authorization holder must use a pharmacovigilance system to monitor the safety of the medicinal product, assess risk minimization opportunities and, if necessary, take appropriate measures. If the marketing authorization holder concerned receives information on the adverse reactions and risks of the medicine in connection with the market survey, the pharmaceutical company must register and process the information. It follows of the pharmaceutical legislation that the marketing authorization holder must register reports of suspected adverse reactions and report suspected adverse reactions seen in Denmark, which are communicated by a healthcare professional, a patient, a relative, or which the marketing authorization holder must

[4] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

[5] Act No 289 0f 8th March 2024 on additional provisions for a regulation on the protection of individuals with regard to the processing of personal data and on the free exchange of such information. (General Data Protection Regulation).

[6] The definition of "personal data" in Article 4 (1) of the Personal Data Regulation (GDPR) includes information on an identified or identifiable natural person.

reasonably be aware of from scientific literature or safety studies, to the Common European Adverse Reaction Database, the EudraVigilance Database, created by the European Medicines Agency (EMA).

Reference is made to the rules on pharmacovigilance in the Medicines Act and the Implementing Regulation on the performance of pharmacovigilance activities.

## 11. Patient Safety

Furthermore, in conducting a market survey, there are certain precautions to be taken regarding a healthcare professional's access to patient records.

It is clear from section 40 of the Health Act that a patient is entitled, as a starting point, for a healthcare professional not to disclose information about patients' health conditions, private matters and similar confidential information.[7]

However, certain exceptions apply, which are stated in sections 41-46 of the Health Act. Thus, it appears, among other things of section 43 of the Health Act, that in certain circumstances information may be disclosed, among other things the patient's health conditions for purposes other than treatment, if the patient has given (written) consent thereto and the consent is entered in the patient record. It is the healthcare professional who holds a confidential information that determines whether the disclosure of the information is justified.

For further information on patient safety, please refer to the Health Act and the Danish Patient Safety Board.

[7] The Danish Health Act, no. 247 of 12th March 2024

# 12. Q & A on market research

## Basics:

1. **Must we have a written agreement prior to the commencement of the market research?**
   ***A***: *Yes, if the survey is an advertisement and there is an association with the HCP, a written agreement must always be entered into, where the basis for the contract and any remuneration is determined. If a pharmaceutical company pays a fee to a healthcare professional for its participation in a market research, there will be an association which must be disclosed.*

2. **When must a market survey be notified to ENLI?**
   ***A***: *If the market survey can be considered an advertising activity, the study must be notified to ENLI at latest by the day it is initially sent to healthcare professionals.*

3. **If a consulting/analytics institute, etc. is involved in carrying out the market survey, can the pharmaceutical company then be held liable for any violations of current legislation, incl. the Advertising Order and ENLI's Promotion Code?**
   ***A:*** *Yes, even if a third party, who will also be responsible, is involved in conducting the study, the pharmaceutical company will also be responsible for the market research.*

## Content of market research:

4. **Is it a requirement that a market survey be blinded so that participants do not know who is behind the survey?**
   ***A:*** *No, a market research is not required to be anonymized. If the market research is not anonymized/blinded between the pharmaceutical company and the interviewed (most often a doctor), the rules on association must be observed for both the pharmaceutical company and the doctor. This means that the doctor must apply to the Danish Medicines Agency for permission to be associated with the pharmaceutical company. (This also applies if the physician does not receive a fee for his services) and the pharmaceutical company must report annually to the Danish Medicines Agency, on doctors, dentists, nurses, midwives, pharmacists and clinical pharmacists in accordance with the rules in the Order on Association.*

   *If, on the other hand, the study is double-blinded by a third party (agency) and the anonymity between the pharmaceutical company and the doctor is maintained, it is not considered as an association with the company, cf. section 4.1 of the Danish Medicines Agency's guide to doctors, dentists and pharmacists regarding association to pharma and MedTech companies. Note that in the case of an advertisement, there can be no double-blind market survey.*

5. **Is there anything that pharmaceutical companies should not ask about in market research?**
   ***A:*** *Yes! Pharmaceutical companies are only allowed to ask questions related to approved conditions set out in the medicine's SPC in the case of an advertisement. Therefore, one should not ask questions about matters not contained in the marketing authorization, e.g. off-label mentioning or pre-launch. See above re. the "pre-launch" section.*

6. **May a pharmaceutical company ask a healthcare professional a question about a competitor's medicine?**
   ***A***: *Yes, one may ask questions about a competitor's medicine. It is assumed that questions about a competitor's medicine do not aim to advertise that medicinal product.*

7. **May I show a doctor two different advertisements for a medicine and hear what he/she prefers?**
   ***A***: *It is stated in section 6.1 of the Danish Medicines Agency's Guide No. 9382 of May 19, 2021*[8] *on physicians' association with pharmaceutical and medical companies that the Danish Medicines Agency will, as a starting point, refuse applications regarding doctors', etc., contribution to the marketing activities of a pharmaceutical or MedTech company.*

8. **Can my company ask a healthcare professional for statements that we can use in our advertisements if references and the compulsory text are included?**
   ***A:*** *It is stated in section 6.1 of the Danish Medicines Agency's Guide No. 9382 of May 19, 2021 on physicians' association with pharmaceutical and medical companies that the Danish Medicines Agency will, as a starting point, refuse applications regarding doctors', etc., contribution to the marketing activities of a pharmaceutical or MedTech company.*

9. **May one show a doctor two pictures of a disease (e.g. tumors or a skin disease) and ask which one of the pictures the doctor thinks best represents the disease?**
   ***A:*** *Yes, you may. It does not seem to have an advertising purpose to ask about illness, including symptoms of illness.*

10. **If, in a market study, one e.g. asks: "When were you last visited by company Y" and you don't list all the companies, but only "company Y" (your own company), will this then mean that market research is considered an advertisement and therefore must be notified to ENLI?**

[8] Guidelines on doctors' affiliation with pharmaceutical companies, medical device companies, companies that manufacture, import or distribute products without a medical purpose and specialty stores with medical devices (retsinformation.dk), Guideline no. 9382 of 19 May 2021,

*A: No, the fact that you only ask about your own company does not mean that it is automatically advertising.*

**Does the same answer apply in the case of double-blinded market research?**
*A: Yes*

11. **May we ask about future medicines in a market survey? These may be questions such as "Which medicines in the pipeline do you know of?", where there is only a free-text box (medicines are not mentioned) or "Would you be interested in using a medicine with the following properties XX?"**
*A: Yes, you may as a starting point. When asked so broadly, it will not be considered advertising.*

12. **If a market survey shows product-lists of all medicines within a given group, and the physician must e.g. tick a box by which he/she knows of, must all generic products and parallel products be mentioned, or is it okay just to mention the original products?**
*A: If this is not an advertisement, no requirements can be set as to how the medicines should appear, including whether all medicines in a given group should be mentioned, since the material/market survey is not covered by the advertising rules. Note, however, that with questions comparing one's own medicine with other medicines and thus comparative advertising, it is a requirement that all medicines within a given group are mentioned.*

**Does the same answer apply in the case of double-blinded market research?**
*A: Yes*

13. **May a pharmaceutical company ask questions in a market survey about medicines that have not yet obtained a marketing authorization valid for sales in Denmark?**
*A: No, you may not. Do not advertise unapproved medicines.*

**Does the same answer apply in the case of double-blinded market research?**
*A: Yes*

14. **May a pharmaceutical company in a market survey ask about therapeutic indications for which the medicine has not yet been approved?**
*A: No, you may not. Pharmaceutical companies may only ask questions related to approved conditions set forth in the medicine's SPC in the case of a medicine advertisement. Therefore, one should not ask questions about matters not included in the marketing authorization, e.g. off-label mentioning or pre-launch. See above re. the "pre-launch" section.*

15. **Can a market survey be considered pre-launch if the company (or an analyst on behalf of the company) asks about a medicine that has not yet been approved; for example, by presenting Phase III data for anonymized 'product X'? (Data is the real data for an upcoming medicine, but is anonymized in the market research)**
*A: It depends on a specific assessment of the questions whether the purpose of the presentation of phase III data is to advertise the medicine.*

**Does the same answer apply in the case of double-blinded market research?**
*A: Yes*

16. **If we know the results of a market research conducted by a consulting firm, without the involvement of a pharmaceutical company, is it then our obligation to ensure that the consulting firm has complied with ENLI's rules, if we wish to buy the data?**
*A: No, the agency has done the market research on its own responsibility. The agency will have to comply with Danish law if the survey may be considered as advertising.*

## Compulsory information:

17. **Should we always include compulsory text when we do a market research?**
*A: No, only in the case of advertising of medicines, must the compulsory text for the medicines being advertised, be enclosed. There is no need to enclose/display compulsory text for other companies' medicines if they are mentioned in the market research.*

**Does the same answer apply in the case of double-blinded market research?**
*A: If it is an advertisement, there must be a compulsory text with information on the marketing authorization holder and therefore this will not be a double-blinded survey in this situation.*

18. **Where should the compulsory text be placed when conducting a market survey?**
*A: The compulsory text may be placed at the back of the material or if it is an electronic advertisement, e.g. as a dynamic link that appears where the compulsory text can be read. As far as references are concerned, these must appear in the survey/advertisement.*

**Does the same answer apply in the case of double-blinded market research?**
*A: When compulsory text with marketing authorization holder information is included, this will not be a double-blinded survey in this situation.*

19. **If you include a compulsory text with a market survey, will this then be considered advertising?**
*A: Yes, if you enclose compulsory text in connection with a market survey, that is otherwise not considered an advertisement, the disclosure of the compulsory text will mean that the survey is now an advertisement.*

**20. Must compulsory texts for all the medicines included in the market survey be enclosed?**
*A: No, only the compulsory text for own medicines that are being advertised must be presented.*

## Fees:

**21. Can a pharmaceutical company give a healthcare professional three bottles of wine as fee for his participation in a market survey?**
*A: No, this is not allowed. Remuneration may only be made in the form of direct payment and thus not by set-off, transfer of in kind or other indirect means.*

**Does the same answer apply in the case of double-blinded market research?**
*A: Yes. However, in the case of a double-blinded market survey, the remuneration must be through an agency so that anonymity is maintained.*

**22. What is reasonable to pay healthcare professionals for participating in a market survey?**
*A: It is not possible to set a ceiling on how much a healthcare professional may receive in order to participate in a market survey. The size of the payment depends on the scope of the assignment, including estimated time spent. Market conditions should be considered, including the market price for a similar service.*

**Does the same answer apply in the case of double-blinded market research?**
*A: Yes*

**23. Our company would like to give a healthcare professional a gift card of DKK 1000 to a supermarket for his/her participation in a market survey. Would that be okay, and does it make any difference whether it is a pharmaceutical company itself or a consulting firm providing the gift card?**
*A: No, a gift card is not allowed. Fees may only be given in the form of direct payment (cash settlement/bank transfer, etc.). This applies regardless of whether it is the pharmaceutical company itself or a consulting firm acting on behalf of the pharmaceutical company.*

**Does the same answer apply in the case of double-blinded market research?**
*A: Yes*

**24. May a research institute/consulting firm give a healthcare professional a fee to participate in a market survey?**

***A:*** *Yes, the institute may do that, regardless of whether the survey is double-blinded or not. If the market survey is conducted anonymously (double blinded), the physician should not apply for association with the company according to the Association Order. If, on the other hand, the survey is conducted openly, where the healthcare professional and the specific pharmaceutical company become aware of each other's identity, permission must be sought from the Danish Medicines Agency in accordance with the rules of the Association Order. A permit must be obtained from the Agency before the healthcare professional can participate in the market survey. Please note that if the survey is an advertisement, it cannot be double-blinded.*

**25. If fees are paid to a healthcare professional who participates in market research, no payment may be made in kind or similar. But does it also apply if an external agency does the research in advance and subsequently sells it to a pharmaceutical company?**

***A:*** *If the survey is not an advertisement and if it is not made on behalf of a pharmaceutical company, the gift rule does not apply regarding prohibition of fees in kind. In the case of advertising, on the other hand, financial benefits must only be offered in the form of cash payment/bank transfer as fees for consulting services.*

## Association:

**26. Should a healthcare professional participating in a market survey request permission from the Danish Medicines Agency?**

***A:*** *Yes, participation in a market survey is regarded as advice and is thus covered by section 10 of the Association Order.*

*If, on the other hand, the study is anonymous, and both the pharmaceutical company and the healthcare professional's identity remain anonymous after the study has been conducted (double blinded), the healthcare professional should not apply for permission to participate in a market survey. Here it is assumed that the market survey does not constitute advertising.*

**27. Is it always a requirement that a healthcare professional who receives a fee for his participation in a market survey must apply for permission from the Danish Medicines Agency in accordance with the rules of the Association Order?**

***A:*** *No. A healthcare professional must only apply for permission from the Danish Medicines Agency if the contributing healthcare professional and the pharmaceutical company are aware of each other's identity. This means that market surveys that are conducted anonymously (double-blinded) are not covered by the rules of the Association Order regarding that healthcare professionals must apply for permission prior to participating in a market survey.*

*If it is an advertisement, there must be a compulsory text with information on the marketing authorization holder, and therefore this will be not be considered a double-blinded/anonymous survey.*

**28. If a compulsory text is presented for all medicines mentioned in a market survey and it is not possible to detect who is the sender of the market survey, then can the advertisement/market survey be regarded as anonymous, thus avoiding the association requirement?**

***A:*** *If the market research is to be regarded as an advertisement, you cannot avoid the association requirement by enclosing all compulsory texts on the medicines that are included in the market survey. In the case of advertising, it must always be stated who the sender is.*

## Patient Safety:

**29. If a pharmaceutical company asks for information on specific patients in connection with a market research, can the physician then pass on information about the patients, even if they are anonymous?**

***A:*** *Although it may be in accordance with the Personal Data Act (GDPR), sections 41-49 of the Health Act prohibit this type of data collection, unless special permits from the Ethical Committee or the Danish Security Authorities, or written consent of the patient are in place. In addition, the legislation prohibits healthcare professionals from accessing patient records unless access is specifically related to the patient's current treatment (section 42a), which is not the case for market research.*

**Does the same answer apply in the case of double-blinded market research?**

***A:*** *Yes*

**30. Can a pharmaceutical company ask the following question in a market survey: "Describe what a typical patient with this disease looks like regarding X parameters"?**

***A:*** *Yes, in principle a company can ask general questions about overall conditions regarding the patients of the interviewed doctor.*

**31. Can a pharmaceutical company ask the following question in a market survey: "Find three typical patient records and note in the schedule regarding X parameters for each patient with this disease"?**

***A:*** *No, no specific questions should be asked regarding individual patients, as there will be a violation of section 42a of the Health Act.*

# 13. Check list on market research

- Market research must comply with the same rules as other medicines advertisements if the research is advertising.
- Medicines that cannot be legally sold or distributed in Denmark must not be advertised. Remember the rules of pre-launch and off-label mentioning.
- If the market survey contains comparative advertising, the rules on this must be complied with.
- The medicines mentioned in a market survey must have a marketing authorization valid in Denmark. For pharmacy-only medicines, these must also be notified to the Danish Medicines Agency regarding price.
- If the advertisement mentions the company's medicine, there is a requirement that a compulsory text must be provided at the end of the market research.
- The association of doctors, dentists, nurses, midwives, pharmacists and clinical pharmacists with a pharmaceutical company (e.g. by participating in a market survey) requires prior permission from the Danish Medicines Agency. However, this does not apply to anonymous (double-blinded) market research. Please note that if the market research is advertising, it is subject to the advertising rules and therefore cannot be anonymous.
- The pharmaceutical company has a duty to provide information to the healthcare professional and has a duty to report to the Danish Medicines Agency on the healthcare professionals who are associated with their company.
- Fees for participation in a market survey must be proportionate to the healthcare professional's performance and may only be given as direct payment - not in kind (e.g. wine, gifts, travel, gift cards).
- Market research must be notified to ENLI if they are considered advertising.

For further information:

ENLI: http://www.enli.dk/

Danish Medicines Agency: https://www.lmst.dk/

Danish Data Protection Agency: https://www.datatilsynet.dk/

Danish Patient Safety Authority: https://stps.dk/

# Annex A

# Market research

An example of a market survey that includes both questions that are considered advertising and questions that are intended to collect information without simultaneously advertising a medicine.

1. What is your primary medical specialty?

| ENLI's assessment is that this question is not to be considered advertising. |
|---|

2. How many patients with "Disease X" have you personally seen or participated in the evaluation/treatment of the past 3 months, regardless of the severity of the disease?

| ENLI's assessment is that this question is basically not to be considered advertising. |
|---|

3. How many patients have you personally monitored or participated in the evaluation/ treatment of per therapeutic indication below, within the past 3 months, regardless of the severity of the disease?
_____ X
_____ Y
_____ Z

| ENLI's assessment is that this question is basically not to be considered advertising. |
|---|

4. Think about the patients with indication X that you have treated within the past 6 months and indicate in the table below what proportion was treated with the different treatment options. (Exclude patients who participated in clinical trials).

| Regime | |
|---|---|
| 1. Product A (generic name)[1] | _____% |
| 2. Product B (generic name)[2] | _____% |
| 3. Product C (generic name)[3] | _____% |
| 4. Product D (generic name)[4] | _____% |

| | |
|---|---|
| 5. Other treatment | _____% |

Product name A [the company's own medicine] is indicated for X.

ENLI's assessment is that the first part of the question is basically not considered advertising. It should be noted that it is subordinate if you mention your own medicine first/last. On the other hand, it is crucial that you emphasize your own medicine in a non-neutral way via text, introductory discussion or otherwise.

In this case, where the therapeutic indication for the pharmaceutical company's medicine (Product A) is also stated, this will basically, solely for that reason, be advertising, as not only information is collected, but here also information about the company's own medicine is planted, without any apparent purpose in relation to the question.

5. What is your view of the various X-inhibitors as treatment of "Disease X" in terms of efficacy, tolerability and overall opinion? State your opinion as one of the following: very negative (1), negative (2), neutral (3), positive (4) and very positive (5). Choose "don't know" if you do not have enough experience with the product to have an opinion.

| | Generic name A[1] (Product name) | Generic name B[2] (Product name) | Generic name C[3] (Product name) | Generic name D[4] (Product name) |
|---|---|---|---|---|
| Efficacy | | | | |
| Tolerability | | | | |

ENLI's assessment is that this question is basically not considered advertising.

6. Which of the available X-inhibitors would you prefer to prescribe to a patient with the therapeutic indication X?

| | Generic name A[1] (Product name) | Generic name B[2] (Product name) | Generic name C[3] (Product name) | Generic name D[4] (Product name) |
|---|---|---|---|---|
| Efficacy | | | | |
| Tolerability | | | | |

ENLI's assessment is that this question is basically not considered advertising.

7. Why would you prefer [answer from question 6] as the first line for a patient with therapeutic indication X?

ENLI's assessment is that this question is basically not considered advertising.

8. What proportion of your patients with disease X also had disease Y at the time of diagnosis?

_____ % of my patients

ENLI's assessment is that this question is basically not considered advertising.

9. Which of the following medicines has data demonstrating efficacy in patients with disease X and Y?

(multiple answer options)

| | |
|---|---|
| Product A (generic name)[1] | ❍ |
| Product B (generic name)[2] | ❍ |
| Product C (generic name)[3] | ❍ |
| Product D (generic name)[4] | ❍ |
| None of the above | ❍ |
| Don't know | ❍ |

ENLI's assessment is that it may be advertising and that the wording of the question may be an attempt to influence the doctor.

The company may be familiar with data, but here you would like the doctor to examine and perhaps find that favorable data is only available regarding the company's medicine.

The fact that you do not mention all or only selected medicines in a medicines group can lead to advertising. This is done, for example, by omitting the competitor's medicine, and/or mentioning only medicines that have a very small market share and thus the company's own medicine appears more favorable. Thus, there may be (unsubstantiated) advertising.

10. In the table below, indicate the extent to which you agree or disagree with the claims:

| | | | | | |
|---|---|---|---|---|---|
| I often think it is most appropriate to use treatment X first, rather than save it as a potential treatment option later in the process. | Totally disagree | Partially disagree | Neither agree or disagree | Partially agree | Totally agree |
| I often think it is most appropriate to save the treatment that has the most significant effect for as long as possible. | | | | | |
| I believe that a convincing X parameter generally indicates that treatment will do Y for patients as well. | | | | | |
| All my patients with disease X receive more than one line of treatment. | | | | | |
| I strictly follow the guidelines that exist regarding the diagnosis and treatment of disease X. | | | | | |

ENLI's assessment is that this question is basically not considered advertising. However, attention should be paid to the wording of the questions. What matters is whether the purpose of the questions is to gather knowledge, or whether the purpose can be, directly or indirectly, to influence the doctor in relation to the company's medicine.

11. Please state the substances under development for the treatment of disease X that you know of which are in clinical trials/in development, but not yet available in Denmark. Please list up to 5 substances under development.

ENLI's assessment is that this question is basically not considered advertising.

12. Please state the medicines you know of that have recently (in the past 12 months) been approved for the treatment of X in Denmark. Please list up to 5 medicines.

ENLI's assessment is that this question is basically not considered advertising. Here, it is likely that the pharmaceutical company will test the doctor's knowledge of the area, e.g. with a view to assessing whether to increase the information going forward.

13. Please state your level of knowledge for each of the following new medicines for X disease.

| | I am not aware that this treatment is marketed | I recognize the name, but I don't know much about the properties of the medicine | I am somewhat familiar with the properties of the medicine | I am familiar with the properties of the medicine | I have a detailed understanding of the properties of the medicine |
|---|---|---|---|---|---|
| Generic name A (Product name A) | 1 | 2 | 3 | 4 | 5 |
| Generic name B (Product name B) | 1 | 2 | 3 | 4 | 5 |

ENLI's assessment is that, in isolation, this question is basically not considered advertising. However, in the assessment of the overall survey, one must consider why you are now only asked for two medicines when you had more choices in the previous questions in the survey. Thus, the fact that one wishes to narrow the focus to one's own medicine can in some situations be regarded as an inducement.

14. Which of the following clinical trials on therapeutic indication X are you aware of?
Possible to choose more than one:

| | |
|---|---|
| 1 | "Study name / agronomic A" (Product name A / generic name) |
| 2 | "Study name / agronomic B" (Product name B / generic name) |
| 3 | "Study name / agronomic C" (Product name C / generic name) |
| 4 | None of the above |

ENLI's assessment is that it is basically not advertising to ask about the knowledge of studies. However, do pay attention to whether, for example, important studies have been omitted or whether there may be circumstances in the selection of the listed studies that may be non-factual and express so-called cherry picking in relation to highlighting the pharmaceutical company's own medicine.

15. Regarding "Study name / agronomic A": What result did the treatment examined show, compared to standard treatment in the study?

| | Examined treatment | Standard treatment | Advantage regarding X for treatment examined | Advantage regarding X versus Y-treatment |
|---|---|---|---|---|
| Study name/ agronomic A | Product name A (generic name A) | Product name B (generic name B) | | |

ENLI's assessment is that the wording of this question is not about collecting information/data, but about advertising, as the company itself knows the results of the study they mention.

This could indicate that the purpose may be to provide the doctor with information about the company's medicine. The question will therefore probably be considered advertising.

The consequence of advertising is that the rules of advertising must be adhered to including the compulsory text. When a compulsory text is enclosed, the market research is no longer anonymous, and the contributing physician must therefore apply for association.

16. Please specify the mechanism of action of Product Name A (generic name) for patients with disease X:

| | |
|---|---|
| 1 | Selective against Z |
| 2 | Binds to Y |
| 3 | Modulates X |
| 4 | I don't know the mechanism of action |

ENLI's assessment is that this question cannot basically be considered advertising, as it may be relevant for the company to know what the doctor's knowledge of their medicine is. The purpose here could be to map the doctor's level of awareness with a view to subsequent information measures.

However, in the context of the other questions, it must be considered why one started broadly asking for more medicines and now focuses only on one's own medicine. Here, the respondent may have the idea that one specific pharmaceutical company is asking. In that case, the double anonymity may disappear.

17. How do you usually do when ordering tests for your patients with disease X?

| | |
|---|---|
| 1 | I usually order tests for X |
| 2 | I usually order tests for Y |
| 3 | I usually order no tests but initiate treatment without testing |

ENLI's assessment is that this question is basically not considered advertising.

18. Which test do you usually order?
Select all answers that are appropriate:

| | |
|---|---|
| 1 | X1 |
| 2 | X2 |
| 3 | X3 |
| 4 | X4 |
| 5 | Other |

ENLI's assessment is that this question is basically not considered advertising.

19. In which order you usually order these tests?

Please rank from first to last test that you order. If you do not order a particular test, then omit the ranking

| | |
|---|---|
| 1 | X1 |
| 2 | X2 |
| 3 | X3 |
| 4 | X4 |
| 5 | Other, what?_____ [only if chosen] |

ENLI's assessment is that this question is basically not considered advertising.

20. To what extent are you, for or against, awaiting the results of the X test before initiating treatment for “Disease Condition”?

| Clearly against | Predominantly against | Neither for nor against | Predominantly for | Clearly for |
|---|---|---|---|---|
| | | | | |

ENLI's assessment is that this question is basically not considered advertising.

21. Do you currently have access to X testing (ie this is something you can ask for/order)?

_____ Yes
_____ No
_____ Don’t know

* X tests are often included as part of a regular test.

ENLI's assessment is that this question is basically not considered advertising.

22. What kind of test material for X do you have the opportunity to analyze in the laboratory you most often use for analysis?

Tissue_____YES/NO
Blood test _____ YES/NO

ENLI's assessment is that this question is basically not considered advertising.

23. Do you currently recommend re-diagnostics for patients with "Disease Condition", such as Y?
_____ Yes
_____ No

ENLI's assessment is that this question basically is not considered advertising. However, it must be considered what the purpose of the question is. The question does not resemble advertising, but if the intention is to get the doctor to think about the company's medicine, or if re-diagnostics are only relevant to the specific pharmaceutical company's medicine, then there most likely would be a case of advertising.

24. Patients treated with X-treatment may develop resistance to these treatments. To test for this, these patients must undergo a new blood test diagnostic.

How large a proportion of your patients with "disease condition" do you offer a re-test (what-ever method) in order to Y? Enter a value between 0-100%

_____ % of patients

ENLI's assessment is that this question is basically not considered advertising.

25. Approximately how much of the re-test showed that the patient had X?

_____ % of patients

ENLI's assessment is that this question is basically not considered advertising.

26. Have you ever prescribed Product Name A (generic name) for patients with disease X?

| | |
|---|---|
| 1 | Yes |
| 2 | No, not yet |
| 3 | Don't know the product |

Product name A is indicated for X.

ENLI's assessment is that the first part of the question is not considered advertising.

In this case, where the indication for the pharmaceutical company's medicine (Product A) is also stated, that will basically, solely for that reason, be advertising, as not only information is collected, but here also information about the company's medicine is planted, without any apparent purpose in relation to the question.

It should be noted that it is the last part of the question (Product name A is indicated for X) that causes the entire question to be considered advertising.

27. For how many patients have you prescribed Product name A (generic name)?

_____ patients

ENLI's assessment is that it is basically not advertising. The anonymity is also not broken, as you do not know whether it is the company itself or whether it is a competitor asking the question.

28. What were your primary reasons for prescribing Product Name A (generic name)?

Please answer as concisely as possible:

_____

ENLI's assessment is that this question basically is not considered advertising.

29. Are you aware that Product Name A (generic name) is now indicated for X-Y?

| | |
|---|---|
| 1 | Yes |
| 2 | No |
| 3 | Don't know |

ENLI's assessment is that this is advertising, since the purpose is not considered to be justified in gathering information, but rather to point out that the medicine is now indicated for a given disease. Thus, it is not a matter of gathering information, but of the fact that the company may intend to plant information with the reader/doctor.

30. Choose the statement that best describes your future intention to prescribe Product Name A (generic name) for indication X-Y for the next 3 months.

Choose a statement:

| | | |
|---|---|---|
| 1 | I expect my prescription of Product Name A to X-Y will decrease | ❍ |
| 2 | I expect my prescription of Product Name A to X-Y to be unchanged | ❍ |
| 3 | I expect my prescription of Product Name A to X-Y to increase | ❍ |
| 4 | I expect to stop prescribing Product Name A to X-Y | ❍ |
| 5 | I'm not sure what my future prescription of Product Name A to X-Y will be | ❍ |

ENLI's assessment is that it is basically not advertising and could be considered as gathering information.

31. In the past 3 months, which of the following medicines have you met with company representatives and received product information for?

| | |
|---|---|
| Product A (generic name) | Yes/No/Don't know |
| Product B (generic name) | Yes/No/Don't know |
| Product C (generic name) | Yes/No/Don't know |
| Product D (generic name) | Yes/No/Don't know |
| My clinic does not allow visits by company representatives | |

ENLI's assessment is that this question basically is not considered advertising.

32. What are the three most important messages you received from the latest product information on Product A?

ENLI's assessment is that this question basically is not considered advertising.

33. We would like to ask you to assess companies working in the field of disease X in terms of their involvement in the field. Choose the top 3 companies in the field and rank from 1 to 3, where 1 = the company you think has the greatest commitment in the field.

| | Rank the top 3 from 1-3 |
|---|---|
| Company1 | ❍ |
| Company2 | ❍ |
| Company3 | ❍ |
| Company4 | ❍ |
| Company5 | ❍ |
| Company6 | ❍ |

ENLI's assessment is that this question basically is not considered advertising.

34. What is your age? _____ years

ENLI's assessment is that this question is not considered advertising.

35. Are you? ❍ Male ❍ Female

ENLI's assessment is that this question is not considered advertising.

Compulsory information/text is enclosed.

If a compulsory text is enclosed, there will be no anonymous market research. If the market research is advertising, there is a requirement that a compulsory text be attached.

# Annex B

# Neutral market research

This is an example of a market research study aimed at gathering information without simultaneously advertising a medicine.

1. What is your age? _____ years

2. Are you?
   ❍ Male ❍ Female

3. What is your primary medical specialty?

4. How many patients with “Disease X” have you personally monitored or participated in the evaluation/treatment of within the past 3 months, regardless of the severity of the disease?

5. How many patients have you personally monitored or participated in the evaluation/treatment of per therapeutic indication below, within the past 3 months, regardless of the severity of the disease?
   _____ Indication X
   _____ Indication Y
   _____ Indication Z

6. Think about the patients with indication X that you have treated within the past 6 months and indicate in the table below what proportion was treated with the different treatment options. (Exclude patients who participated in clinical trials).

| Regime | | |
|---|---|---|
| | **Product A (generic name)[1]** | _____ % |
| | **Product B (generic name)[2]** | _____ % |
| | **Product C (generic name)[3]** | _____ % |
| | **Product D (generic name)[4]** | _____ % |
| | **Other treatment** | _____ % |

7. What is your view of the various X-inhibitors as treatment of "Disease X" in terms of efficacy, tolerability and overall opinion? State your opinion as one of the following: very negative (1), negative (2), neutral (3), positive (4) and very positive (5). Choose "don't know" if you do not have enough experience with the product to have an opinion.

| | **Generic name A[1]**<br><br>**(Product name)** | **Generic name B[2]**<br><br>**(Product name)** | **Generic name C[3]**<br><br>**(Product name)** | **Generic name D[4]**<br><br>**(Product name)** |
|---|---|---|---|---|
| Efficacy | | | | |
| Tolerability | | | | |

8. Which of the available X-inhibitors would you prefer to prescribe to a patient with indication X?

| | **Generic name A[1]**<br><br>**(Product name)** | **Generic name B[2]**<br><br>**(Product name)** | **Generic name C[3]**<br><br>**(Product name)** | **Generic name D[4]**<br><br>**(Product name)** |
|---|---|---|---|---|
| Preferred | | | | |

9. Why would you prefer [answer from question 8] as the first line for a patient with therapeutic indication X?

10. What proportion of your patients with disease X also had disease Y at the time of diagnosis?

    __ % of my patients

11. In the table below, indicate the extent to which you agree or disagree with the claims:

| | | | | | |
|---|---|---|---|---|---|
| I often think it is most appropriate to use treatment X first, rather than save it as a potential treatment option later in the process. | Totally disagree | Partially disagree | Neither agree or disagree | Partially agree | Totally agree |
| I often think it is most appropriate to save the treatment that has the most significant effect for as long as possible. | | | | | |
| I believe that a convincing X parameter generally indicates that treatment will do Y for patients as well. | | | | | |
| All my patients with disease X receive more than one line of treatment. | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| I strictly follow the guidelines that exist regarding the diagnosis and treatment of disease X. | | | | | |

12. Please state the substances under development for the treatment of disease X that you know of which are in clinical trials/in development, but not yet available in Denmark. Please list up to 5 substances under development

13. Do you know of medicines that have recently (in the past 12 months) been approved for the treatment of disease X in Denmark? If so, please state the medicines

14. Please specify the mechanism of action of Product Name A (generic name) for patients with disease X:

| | |
|---|---|
| 1 | Selective against Z |
| 2 | Binds to Y |
| 3 | Modulates X |
| 4 | I don't know the mechanism of action |

15. How do you usually do when ordering tests for your patients with disease X?

| | |
|---|---|
| 1 | I usually order tests for broad spectrum of biomarkers |
| 2 | I usually order tests for one biomarker |
| 3 | I usually order no tests but initiate treatment without testing |

16. Which test do you usually order?

Select all answers that are appropriate

| | |
|---|---|
| 1 | X1 |
| 2 | X2 |
| 3 | X3 |
| 4 | X4 |
| 5 | Other? |

17. In what order do you usually order these tests? Please rank from first to last test that you order. If you do not order a particular test, then omit the ranking

| | |
|---|---|
| 1 | X1 |
| 2 | X2 |
| 3 | X3 |
| 4 | X4 |
| 5 | Other? |

18. To what extent are you, for or against, awaiting the results of the test before you initiate treatment for the condition?

| *Clearly against* | *Predominantly against* | *Neither for nor against* | *Predominantly for* | *Clearly for* |
|---|---|---|---|---|

19. Do you currently have access to X testing (i.e. this is something you can ask for/order)?

_____ Yes
_____ No
_____ Don't know

20. What kind of test material for X do you have the opportunity to analyze in the laboratory you most often use for analysis?

Tissue_____YES/NO

Blood test _____ YES/NO

**Patients treated with X treatment may develop resistance to these treatments. To test for this, these patients must undergo a new diagnostic test (with blood test).**

21. How large a proportion of your patients with "disease condition" do you offer a re-test (what-ever method) in order to Y? Enter a value between 0-100%

____ % of patients

22. Approximately what proportion of the re-test showed that the patient had resistance?
_____ % of patients

23. List the medicines you have prescribed for your patients with disease X:

24. Have you ever prescribed Product Name A (generic name) for your patients with disease X? And what was your reason for this?

25. In the past 3 months, which of the following medicines have you met with company representatives and received product information for?

| | |
|---|---|
| Product A (generic name) | Yes/No/Don't know |
| Product B (generic name) | Yes/No/Don't know |
| Product C (generic name) | Yes/No/Don't know |
| Product D (generic name) | Yes/No/Don't know |
| My clinic does not allow visits by company representatives | |