



Checklist

for reporting promotion material to ENLI

Checklist for promotion material

The purpose of this document is to help users who are unsure which consideration must be made and which documents must be sent when reporting activities to ENLI.

It is emphasized that the following checklist is not exhaustive, but is only intended as a help, where ENLI has included the most frequently issues ENLI has received. Please remember that it is important that the information in this checklist always is compared with the information in ENLI's Guidance to the Promotion Code.

DOCUMENTS THAT MUST BE UPLOADED TO ENLI

- The promotional material
- Compulsory text
- References to the promotional material
 - If there are many references, the most important references must be submitted, including references that document claims
 - If relevant, the summary of product characteristics (SPC)
 - The references may contain markings in the text, so that it is clear where in the references to find the documentation of the claims.

It is important to ensure that all relevant information and documents are submitted in the report to ENLI, as it is not possible to change the reported information to avoid a sanction, if the material has been selected for a random check, cf. The Promotion Code Sec. 21.4.

For information on how to report activities to ENLI, please refer to ENLI's Guidance on reporting an activity to ENLI available at www.enli.dk/en

In connection with the promotion material, the following should be considered:

- Is there a valid marketing authorisation in Denmark and has the price been notified to medicinpriser.dk (if pharmacy-only medicinal products)?
- Compulsory text – does it meet the requirements of the Promotion Code Art. 5?
- Does the correct and approved indication of the pharmaceutical product appear easy to read and clear directly in the advertising section?
- Is there documentation for all claims made for the medicinal product?
- If references other than SPC are used:
 - Where are references placed in the evidence hierarchy?
 - Do they confirm and/or clarify the information in the SPC?
- Is the reference peer-reviewed and published in an established and independent Danish or foreign publications, professional journals, or the like?
- Is the promotion objective and adequate?
- How are endpoints and study designs used in the promotion materials?
- What is the level of information in the promotion material in relation to the format chosen?
- Are quotes, tables and illustrations faithfully reproduced?
- Does the promotion material include a comparison between several medicinal products?
- How would a competitor evaluate the promotion material?
- Why have the visuals/illustrations been chosen? Are they relevant in the context of the medicinal product? (Do the visuals indicate fear, freedom, vacation or “feel good”?)
- Does the promotion material contain patient-cases?

For further information, please refer to the Guidance to the Promotion Code and the Guide on information material and documentation.