

Eli Lilly Danmark A/S
Lyskær 3E 2.
2730 Herlev



København, den 15. april 2013

Vedr.: R-2013-1617, Efiend - Afgørelse

Baggrund:

ENLI's granskningsmandspanel udtog til kontrol ovenstående reklame, anmeldt af Eli Lilly Danmark A/S den 19. marts 2013.

Granskningsmandspanelet vurderede på det foreliggende grundlag, at reklamen stred mod ENLI's regelgrundlag, jf. Lægemiddelindustriens kodeks vedrørende reklame mv. for lægemidler rettet mod sundhedspersoner (reklamekodekset). Sagen blev derfor sendt i høring.

Eli Lilly Danmark A/S har svaret i sagen 12. april 2013

Granskningsmandspanelets vurdering:

Regarding § 5 stk. 1 and § 8

In the 2nd response, Eli Lilly comments *"However, we feel that the original PDF still showed that information such as "pligttext" and "sammenligningsskema" was included in the detail aid but that all text was not visible and we apologies to this. However, we question ENLI's belief that we would only show part of these slides when we believe it is quite clear that the images have been suddenly cut."*

As mentioned previously, we at ENLI are aware of the difficulties involving the translation of a given digital format into a pdf-format, which conveys the intended information sufficiently. Hence, we requested that Eli Lilly would send multiple screen shots of the above mentioned "pligttext" and "sammenligningsskema", to aid us in the assessment of the material. ENLI would like to point out, that we do not question your intention with the material despite these have been "cut prematurely". It is necessary for ENLI to assess the validity of the given information; hence the intention itself is not suffice for an assessment of the material.

After reviewing the forwarded material, the investigators at ENLI have concluded, that the information contained within, are in accordance with current regulation; hence the allegations of violation of § 5 stk.1 and § 8 are alleviated.

Regarding § 7 stk. 6

The use of the word “sikkerhed” is prohibited, cf. “vejledning til reklamekodekset” ad § 7 stk.6. Regardless of its intended use, the word can be interpreted as being positively loaded. ENLI’s current practice is very restrictive regarding the use of this word.

We acknowledge your frustration, as to the conflicting rules of § 7 stk. 4 and § 7 stk.6 in the setting of authors using the term “safety” in a given picture/graph. In this particular case, we would encourage the use of an un-altered depiction, as to satisfy the rules of documentation and avoiding infringement of § 7 stk.6. However, it must be noted, that use of the term “sikkerhed” in sentences produced by a given company in a promotional effort is prohibited, despite the presence of an extended wording (as e.g blødningsrisiko), which addresses concerns rather than beneficial aspects.

Furthermore, we would like to emphasize, that we agree with Eli Lilly, that the potential risks of treatment are presented in a balanced way. However, this aspect does not in any way make the wording comply with § 7 stk.6; hence the investigators at ENLI have concluded, that the use of the word “sikkerhed” not associated to an un-altered depiction of a given picture/graph from a publication, is a violation of § 7 stk. 6.

We encourage the use of other wordings, such as “risikoprofil”, “bivirkninger”, “tolerabilitet” etc.

Afgørelse:

Eli Lilly Danmark A/S findes således at have overtrådt reklamekodeksets § 7 stk. 6 og pålægges som følge heraf sanktioner.

Sanktion:

- Pålæg om ikke at benytte reklamen i dens foreliggende form, jf. Sanktions- og gebyrregulativ for ENLI § 1, stk. 1.
- Bøde på kr. 15.000,- for overtrædelse af reklamekodeksets § 7 stk. 6, jf. Sanktions- og gebyrregulativ for ENLI § 4 stk. 1 litra e

Ankevejledning:

Afgørelsen kan ankes til Ankenævnet, jf. Sagsbehandlingsregler for ENLI § 9 stk. 1.

Anke skal ske inden 21 arbejdsdage og sker online via www.enli.dk.

Fristen regnes fra den dag, hvor afgørelsen er afsagt, og den pågældende dag tæller som 1. dag. Weekend- og helligdage medregnes ikke.

Anken skal indeholde en redegørelse for de synspunkter og oplysninger, som anken støttes på.

Bemærk, at såfremt der gives medhold, er anken gebyrfri. Hvis ankesagen derimod tabes, pålægges et gebyr på 50 % af bødens størrelse idømt af Ankenævnet, og hvis bøden nedsættes, pålægges et gebyr på 50 % af det nedsatte beløb, jf. Sanktions- og gebyrregulativ for ENLI § 7.

En anke har som udgangspunkt ikke opsættende virkning.

Kopi af nærværende skrivelse vil blive fremsendt til Sundhedsstyrelsen til orientering.

Med venlig hilsen

Peter Schwarz
Lægefaglig granskningsmand