Newsletter 1 July 2026

Appeals Board

The Appeals Board has issued a decision in a case concerning the compatibility of a study with the medicinal product's SPC.

A pharmaceutical company had had its application for a preliminary assessment by the Investigator Panel rejected in relation to a presentation based on a post-hoc analysis.

The Investigator Panel found that the study results from the post-hoc analysis deviated from the data set out in the SPC. The summary of product characteristics specified a specific numerical value for the ratio, which differed from the value shown in the post-hoc analysis. The Investigator Panel therefore found that the results of the study neither confirmed nor clarified the information in the summary of product characteristics, and consequently the advertising material was not found to be in compliance with Section 4 (2) of the Promotion Code.

The Appeals Board upheld the Investigator Panel's decision to refuse pre-approval, stating, amongst other things, in its reasoning:
"*As also stated in ENLI's Guide on Information Material and Documentation, section 6.1, the judgment of the Court of Justice of the European Union of 5 May 2011 in Case C-249/09 sets out quite narrow limits on the use of supplementary information in advertisements for medicinal products aimed at healthcare professionals. The judgment establishes, amongst other things, that such information must confirm or clarify the information in the summary of product characteristics and must therefore be consistent with it.*

To date, a relatively strict interpretation of C-249/09 has been applied. This position has most recently been confirmed by the Danish Medicines Agency in its response to ENLI, cf. the Review Panel's consultation response […]. The Agency has stated that where the summary of product characteristics contains a numerical value, subsequent data deviating from this cannot be regarded as confirming or clarifying the information in the medicinal product's summary of product characteristics.

In these circumstances, the Appeals Board finds no grounds for amending the Investigator Panel's decision […]. "

Compatibility of studies with the medicinal product's SPC

In order to use supplementary studies, it is first and foremost necessary that the new information does not conflict with the medicinal product's SPC and is, at the same time, consistent with the information contained therein. If these two conditions are met, it must then be examined whether the information can be said to clarify the information in the SPC (which, for example, is stated in ranges or using imprecise language), or whether it confirms matters already set out in the SPC.

It will not be sufficient for the results of a subsequent study to 'merely' point in the same direction as the results stated in the SPC – there are therefore no de minimis thresholds. If a subsequent study produces results different from those set out in the SPC, the SPC for the medicinal product may (and in some cases must) be updated by means of a variation application. In other words, particular attention should be paid to the following points when using supplementary information:

- *The numerical value is shown in the SPC*:
  - A different numerical value cannot be said to 'confirm or clarify' the informa-

tion in the SPC. There is no de minimis threshold. Information regarding a different numerical value would be inconsistent with the SPC.

- *A range is specified in the SPC*:
  - It is possible to state the results of a follow-up study if those results fall within the range specified in the SPC.
- *The SPC contains an 'imprecise' description*:
  - It is possible to clarify statements from the SPC, for example statements such as 'fast'.

The EU ruling that supplementary studies must be consistent with the SPC is already set out in ENLI's Documentation Guide, and the FAQs, amongst other things, address the issue of confirming or clarifying the SPC. However, ENLI will update the Documentation Guide over the summer to provide further clarification on the use of data from supplementary studies.

Climate claims in pharmaceutical advertising

The Investigator Panel has reached a decision in a case concerning an advert in which climate-related claims were the main focus.

In its response to the consultation, the company argued that the advert did not contain any statements about the climate or the environment in an advertising context, and that the information on propellant gas constituted merely factual information on CO_2 equivalents based on the EMA-approved summary of product characteristics. The company further stated that the information was quantitative, objective and verifiable, that no emotionally charged or normative environmental claims had been used, and that the information related exclusively to the propellant's theoretical global warming potential. In summary, it was the company's view that the advert appeared to be a scientifically dominated pharmaceutical advertisement, in which the information on the propellant was included solely as secondary information.

However, the Investigator Panel found that the assessment depends on the advertisement's overall visual presentation and the general impression that the material is likely to leave on the recipient. In this context, emphasis is placed on which elements, through their placement, size, colour contrast and graphic emphasis, appear most eye-catching.

The Investigator Panel found that the viewer's attention is initially drawn primarily to the central section of the advert and the visual and textual elements placed there. It was thus the information about the new propellant and the associated reduction in CO_2 emissions which, through its prominent placement, size and graphic presentation, appeared to be the advertisement's primary message in the overall impression, whilst information about the medicinal product's efficacy and safety profile did not appear equally prominent and must therefore be regarded as secondary in nature. The information about the new propellant thus appeared to promote the medicinal product.

The decision can be read in full at www.enli.dk. (though only in Danish)

Summer holidays and case processing

During consultations over the summer, it is possible to have the consultation deadline for ENLI extended if this is necessary due to holidays. The secretariat can be contacted by telephone if a postponement of the consultation deadline is required.

In the event of a large number of requests for preassesment, it may be necessary to extend the processing deadline, cf. the ENLI Code of Procedure, section 6 (5), in fine, under which ENLI may, in special cases, extend the case-handling deadline beyond the 10 working days, for example during the summer and Christmas holidays.

The ENLI secretariat will remain open throughout the summer for both telephone enquiries and emails, although staffing levels will be reduced during weeks 28–31.

ENLI wishes everyone a great summer.

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