



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 March 2018  
EMA/CHMP/171323/2018

## CHMP List of questions

To be addressed by the applicants and marketing authorisation holders for omega-3 acid ethyl esters – containing medicinal products for oral in use in prevention after myocardial infarction

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1464

Active substance: omega-3 acid ethyl esters



## Questions

The applicant and marketing authorisation holders MAH(s) are requested to address the following questions:

### Question 1

Concerning your omega-3 acid ethyl esters – containing medicinal products for oral use in cardiovascular (CV) disease prevention after myocardial infarction please provide in the annexed table information on type of marketing authorisation, marketing and legal status and an overview of the approved indication(s). Please clearly indicate for which country a specifically dedicated presentation has been granted in a particular indication. Please also provide figures on sales by product, member state.

### Question 2

Please provide scientific evidence related to the therapeutic efficacy of omega-3-acid-ethyl esters-containing medicinal products for oral use in cardiovascular disease prevention after myocardial infarction in adults.

New scientific evidence deriving from published studies and meta-analysis<sup>1-4</sup> which raise concerns with regard to the efficacy of these products in cardiovascular disease prevention should be discussed. In addition, discussions on recent European Guidelines shall also be provided.

If you are the sponsor of ongoing clinical trials, please provide information on the expected date for availability of data from these trials.

### Question 3

Provide a full benefit-risk assessment of omega-3-acid-ethyl esters-containing medicinal product(s) for oral use in prevention of CV disease after myocardial infarction. This should include an assessment of the impact of the results of the above mentioned published studies and meta-analysis<sup>1-4</sup> on the benefit-risk balance in prevention after myocardial infarction indication(s).

### References

1. Rizos EC, Ntzani EE, Bika E, Kostapanos MS, Elisaf MS. Association between omega-3 fatty acid supplementation and risk of major cardiovascular disease events: a systematic review and meta-analysis. *JAMA*. 2012;308(10):1024-1033.
2. Kotwall et al. Omega 3 Fatty Acids and Cardiovascular Outcomes Systematic Review and Meta-Analysis, *Circ Cardiovasc Qual Outcomes* 2012;5:808-818.
3. Kwak et al. Efficacy of omega-3 fatty acid supplements (eicosapentaenoic acid and docosahexaenoic acid) in the secondary prevention of cardiovascular disease: a meta-analysis of randomized, double-blind, placebo-controlled trials. *Arch Intern Med*. 2012 May 14;172(9):686-694.
4. Aung et al. Omega-3 Fatty Acid Supplement Use With Cardiovascular Disease Risks Meta-analysis of 10 Trials Involving 77 917 Individuals. *JAMA Cardiol*. Published online January 31, 2018.

## Annex

### Question 1

<b>INN</b>	<b>Product name</b>	<b>Type of marketing authorisation</b>	<b>Marketing and legal status</b>	<b>Indications<sup>1</sup></b>	<b>Pharmaceutical forms and strengths</b>	<b>Sales figures</b>

<sup>1</sup> MAH should clearly indicate for which country a specifically dedicated presentation has been granted for a particular indication