Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for omega-3-acid-ethyl esters, the scientific conclusions are as follows:

Having reviewed data from spontaneous reports and the literature, regarding hypersensitivity cases in patients allergic to fish, cases of pruritus and urticaria, including in some cases close temporal relationship and in one case a positive dechallenge, the PRAC considered a causal relationship with administration of omega-3-acid-ethyl esters could not be excluded. The PRAC concluded that where not already the case, these adverse reactions should be included in the product information for omega-3-acid-ethyl esters-containing products. In addition the product information should warn to use omega-3-acid-ethyl esters-containing products with caution in patients with known sensitivity or allergy to fish.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for omega-3-acid-ethyl esters the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing omega-3-acid-ethyl esters is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing omega-3-acid-ethyl esters are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.4

[The following warning should appear in this section]

<Invented name> should be used with caution in patients with known sensitivity or allergy to fish.

- Section 4.8

[In products where the following adverse reactions are not already included with a given frequency, they should be included under the SOC Skin and Subcutaneous tissue disorders with a frequency not known]

Pruritus

Urticaria

Package Leaflet

- Section 2

Warnings and precautions

Talk to your doctor or pharmacist before taking <invented name>:

[The following warning should appear in this section]

- If you are allergic to fish.

- Section 4

[In products where the following adverse reactions are not already included with a given frequency, they should be included with a frequency not known]

Other side effects have occurred in a very small number of people but their exact frequency is unknown

Itching

Itchy rash (hives or urticaria)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	October 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	25 November 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	24 January 2018