Annex III

Amendments to relevant sections of the Product Information

Note:

These amendments to the relevant sections of the Product Information are the outcome of the referral procedure.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the Reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

A. Summary of Product Characteristics

For omega-3 containing medicinal products, the existing product information shall be amended (deletion of the text as appropriate) as provided below:

Section 4.1: Therapeutic indications

The following indication should be deleted:

Post Myocardial Infarction

Adjuvant treatment in secondary prevention after myocardial infarction, in addition to other standard therapy (e.g. statins, anti-platelet medicinal products, beta-blockers, ACE inhibitors).

Section 4.2: Posology and method of administration

Information related to “secondary prevention after myocardial infarction” indication should be deleted:

Post Myocardial Infarction

One capsule daily.

Section 5.1 Pharmacodynamic properties

Existing relevant text in section 5.1 of the SmPC in relation to “secondary prevention after myocardial infarction” indication should be deleted.

B. Package Leaflet: Information for the patient

For omega-3 containing medicinal products, the existing package leaflet shall be amended (deletion of the text as appropriate) as provided below:

Section 1

Existing relevant information on use after a heart attack should be deleted.

Section 3

The heading and information on dose after a heart attack should be deleted:

Dose after a heart attack

The usual dose is one capsule a day.