

## **Annex III**

### **Amendments to the summary of product characteristics**

Note:

Note: These amendments are to be incorporated to the valid summary of product characteristics, labelling and package leaflet which are the final versions achieved during the Coordination group procedure.

## **SUMMARY OF PRODUCT CHARACTERISTICS**

[...]

#### **4. CLINICAL PARTICULARS**

[...]

##### **4.2 Posology and method of administration**

[...]

###### **Adults**

[...]

*[The below wording should replace the previous wording]*

Titration on a weekly basis is recommended in case higher doses are required. The mean daily dose in the pivotal study was 20mg/10mg oxycodone hydrochloride/naloxone hydrochloride. Some patients may benefit from higher daily doses up to a maximum of 60 mg/30 mg oxycodone.

[...]