

## Recommendations:

- **Amendments to the Product Information**

The Portuguese version of the Summary of Product Characteristics (approved in November 2011), which was presented by the MAH as the consolidated version of the SmPC for sufentanil, is not fully aligned with the information in the current CSP. Therefore, sections 4.4, 4.5, 4.6 and 4.8 and the corresponding sections of the PL should be amended/updated as specified below in order to update the safety-related information in all documents.

### SmPC wording

**4.4 Warnings and special precautions for use.** The sentence *“Intravenous use in labour or before clamping of the cord during caesarean section is not recommended due to the possibility of respiratory depression in the newborn infant. This is in contrast to the epidural use in labour, during which sufentanil in doses up to 30 µg does not influence the condition of the mother or the newborn.”* should be deleted from section 4.4 of the SmPC as it is already present in section 4.3 as a contraindication.

**4.5 Interactions with other medicinal products and other forms of interaction.** The sentence *“However, several reports describe the uneventful use of fentanyl, a related opioid, during surgical or anaesthetic procedures in patients on MAO-inhibitors”* should be deleted from the SmPC as this information is not directly applicable to sufentanil and is not present in the CSP.

**4.6. Fertility, pregnancy and lactation.** The sentence *“Controlled clinical studies during labour (...) but intravenous use is not recommended in labour.”* should be amended in section 4.6 of the SmPC to *“Controlled clinical studies during labour (...) but intravenous use is contraindicated in labour.”* as agreed in the last CSP.

**4.8 Undesirable effects.** The following undesirable effects *“Apnoea, Respiratory depression, Pulmonary oedema, Laryngospasm”* should be deleted from SOC Cardiac Disorders in the SmPC.