ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

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The Member States shall agree the final educational material with the Marketing Authorisation Holder (MAH) prior to launch of the multi dose and the single dose product in their territory.

The Member States should ensure that, the MAH provides all physicians, pharmacists and patients expected to prescribe/dispense/use Instanyl with educational material regarding the correct and safe use of the product.

Educational material for the patients should contain the following:

- Instructions for use of the nasal spray device
- Instructions for opening and closing of the child-resistant box (for the multi-dose nasal spray) or blister (for the single-dose nasal spray)
- For the multi-dose nasal spray: information about the dose counting scheme
- Only to use Instanyl nasal spray if they are using other opioid pain medicine on a daily basis.
- Only to use Instanyl nasal spray if they have been experiencing breakthrough cancer pain episodes.
- Not to use Instanyl nasal spray to treat any other short-term pain or pain status.
- Not to use Instanyl nasal spray for treatment of more than four breakthrough cancer pain episodes a day
- Only to use Instanyl nasal spray if they have received the proper information regarding the use of the device and the safety precautions from the prescriber and/or the pharmacist.
- For the multi-dose nasal spray all unused devices or empty containers should be returned systematically according to the local regulation.
- For the single-dose nasal spray all unused devices should be returned systematically according to the local regulation.

Educational material for the physicians should contain the following:

- Instanyl nasal spray should be used only by physicians experienced in the management of opioid therapy in cancer patients.
- Instanyl nasal spray is only indicated for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain.
- Instanyl nasal spray should not be used to treat any other short-term pain or pain status.
- The prescribers of Instanyl nasal spray must critically select the patients and counsel them on:
- Instructions for use of the nasal spray device
- Instructions for opening and closing of the child-resistant box (for the multidose nasal spray) or blister (for the single-dose nasal spray)
- Information about the dose counting scheme included in the labelling and the educational material for the multi-dose nasal spray
- That for the multi-dose nasal spray all unused devices or empty containers should be returned systematically according to the local regulation.
- That for the single-dose nasal spray all unused devices should be returned systematically according to the local regulation.
- The prescriber must make use of the checklist for prescribers

Educational material for the pharmacists should highlight the following:

- Instanyl nasal spray is only indicated for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain.
- Instanyl nasal spray should not be used to treat any other short-term pain or pain status.
- The pharmacist must be familiar with the educational material of Instanyl nasal spray before using it in his/her organisation.
- The Instanyl nasal spray dose strengths cannot be compared with other Fentanyl products.
- Instructions for use of the nasal spray device

- Instructions for opening and closing of the child-resistant box (for the multi-dose nasal spray) or blister (for the single-dose nasal spray)
- Information about dose counting scheme included in the labelling and the educational material for the multi-dose nasal spray
- The pharmacist must inform the patients that in order to prevent theft and misuse of Instanyl nasal spray they have to keep it in a safe place to avoid misuse and diversion.
- For the multi-dose nasal spray all unused devices or empty containers should be returned systematically according to the local regulation.
- For the single-dose nasal spray all unused devices should be returned systematically according to the local regulation.
- The pharmacist must make use of the checklist for pharmacist