The following is the suggested minimum information to include in a Package Insert for a Health Care Professional (HCP) administered injectable product that requires preparation such as dissolving, suspending, diluting or reconstitution before use. More information about providing instructions for preparation is available in Labelling medicines to comply with TGO 91 and TGO 92.

Sponsors must ensure the content of the package insert is consistent with the approved Product Information.

INSTRUCTIONS FOR PREPARATION PACKAGE INSERT – Trade name (active ingredient(s)) dosage form strength(s)

Note 1: 'Trade name (active ingredient(s))' should be consistent with the title of the approved Product Information. See: Form for providing product information.

Note 2: It is important to specify dosage form and strength in the title, especially where the package insert is specific to one product.

NAME OF THE MEDICINE

- Name of the therapeutically active ingredient(s) included in Section 1 of the Product Information.

Note 3: 'Name of the medicine' in the package insert may be different to 'name of the medicine' defined in the standard for medicine labelling. See Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines.

DOSAGE FORM

- Dosage form as described in Section 3 of the Product Information.

METHOD OF PREPARATION

- Instructions for preparing the medicine before use must reflect information included in Section 4.2 of the approved Product Information This may include:
  - Subheadings. For example, 'Reconstitution', 'Dilution'.
  - Compatible diluents.
  - Dilution volumes.
  - All relevant instructions and diagrams. For example, 'Visually inspect the solution for particles before administration. If particles are observed, discard the medicine solution.'
  - Concentration and appearance of the reconstituted solution.
- Special instructions for handling where relevant, for example, cytotoxic or hazardous medicines.
- Where relevant, include information such as 'For single use on one occasion in one patient only. Discard any residue.'

Note 4: Ensure instructions are specific to the strength of the medicine. Where there are multiple strengths of the medicine available, and you want to include instructions for each in one package insert, ensure instructions are clear and the instructions for each strength is easy to identify.

Note 5: You may only include diagrams or illustrations that are in the approved PI.

STORAGE CONDTIONS AFTER PREPARATION

- A statement of the conditions of storage and the maximum storage time between preparation and use.

Note 6: If multiple preparation steps are involved, for example reconstitution and dilution, specify the storage conditions for the reconstituted and diluted product as described in the approved Product Information.

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VERSION/DATE OF REVISION

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