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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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Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the Member States

The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

Prior to launch of Velcade 3.5mg new dual route of administration (subcutaneous and intravenous) package, in each Member State, the Marketing Authorisation Holder (MAH) shall agree the content and format of the educational material with the national competent authority.
The MAH shall ensure that, at launch of Velcade 3.5mg new dual route package and thereafter, all healthcare professionals involved in the prescribing, dispensing, handling or administration of Velcade 3.5mg are provided with educational material.

The educational material shall consist of the following:

- SmPC
- Reconstitution, dosing and administration booklet
- Reconstitution poster
- Dosing Slide Rule

The Reconstitution, dosing and administration booklet shall contain the following key elements:

- Velcade 3.5mg can be administered both intravenously and subcutaneously while Velcade 1mg can be administered only intravenously
- different reconstitution requirements for intravenous (IV) or subcutaneous (SC) use
- dosing instructions and examples: how to calculate the body surface area of a patient and the volume of reconstituted Velcade (both IV and SC use) required for different body surface areas (cross reference to Dosing Slide Rule)
- advice on method of administration for both IV and SC use, including the need to rotate injection sites for SC use
- storage precautions for reconstituted solution
- potential risks of administration errors including overdosing, underdosing and that inadvertent intrathecal administration has resulted in death
- to report any adverse event, or medication error, experienced with the administration of Velcade 3.5mg

The Reconstitution poster shall contain the following key elements:

- different reconstitution requirements for Velcade 3.5mg IV or SC use
- need to handling the medicinal product in sterile setting
- storage precautions for reconstituted solution
- advice on how to reduce the risk of mix-up of IV and SC reconstituted syringes
- that Velcade is to be given only by IV or SC injections; no other route of administration is allowed
- that Velcade 1mg is only for IV use
- to report any adverse event, or medication error, experienced with the administration of Velcade 3.5mg

Dosing Slide Rule shall contain the following key elements:

- a dose-calculation tool that enables prescribers to input a patient's height and weight in order to calculate the body surface area (BSA) and thereby to determine the appropriate VELCADE dose.
- different reconstitution requirements for intravenous (IV) or subcutaneous (SC) use.
- dosing instructions and examples: how to calculate the body surface area of a patient and the volume of reconstituted Velcade (both IV and SC use) required for different body surface areas.