

Medsafe is seeking comments on:

The changes proposed to CMN Form B.

1. Proposed changes by Medsafe:

- Change of category name from 'Bulk Active methods of manufacture' to 'Active Ingredient methods of manufacture -Grade 1'."
- "Addition of 'Grade 2' to the existing category 'Active ingredient method of manufacture.'"

2. Proposed changes by Medsafe:

Test methods and specifications

Option 1)

Test methods and specifications - Grade 5

- extension of retest period or expiry period for a reference standard if the protocol used for this extension has not been previously approved.

Option 2)

Test methods and specifications - Grade 6

- Extension of reference standard expiry or retest period, if the protocol used for extension of the expiry or retest period has been previously approved for use in a SACN

Option 3)

Stability and packaging

Shelf life/storage conditions - Reference standard used for potency/assay

- revised shelf life and/or storage conditions with no other changes

1. Proposed revision by Amgen:

The "revised category name" has been introduced on two locations. The term "bulk active" is still used on 7 other locations throughout the document. To avoid confusion, it would be preferable to be consistent in terminology, using either "active ingredient" or "bulk active".

2. Proposed revision by Amgen:

There are three options to update the shelf life/expiry of reference standards (see above). It is unclear when option 3 should be used to revise the expiry rather than using option 1 (when no extension protocol has previously been approved) or option 2 (when extension protocol has been approved). To avoid confusion, Amgen suggests providing additional information on when option 3 is appropriate eg reduce shelf life and/or revise storage conditions with no other changes.

Additional Comments

Amgen would like to thank Medsafe for the opportunity to provide feedback. Amgen supports the other changes made by Medsafe in the proposed CMN Form B, which reflects issues identified by industry during use of the form. We anticipate these changes will bring about clarity and efficiencies for both sponsors and Medsafe.

Please include additional pages if necessary.