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11 April 2016

Dear Sir or Madam

Changes to the data sheet process and the Guideline on the Regulation of Therapeutic Products in New Zealand. Part 10: Requirements for information for prescribers and consumers

The Medicines Adverse Reactions Committee (MARC) is in favour of the proposal to adopt the European Summary of Product Characteristics (SPC) format for New Zealand data sheets.

The Committee notes that a consistent format will be useful and additionally the proposed format places information that is frequently used by prescribers early in the document. The Committee notes it is proposed for the clinical study information to be further down the document and considers the inclusion of this information is important for prescribers. The Committee considers that there is value in using bookmarks or hyperlinks to assist accessing the information in the data sheet.

The Committee does not have any comments on the name of New Zealand data sheets however considers 'Undesirable effects' to be a slightly broader term than 'Adverse effects'.

Yours sincerely

Associate Professor David Reith
Chair (Medicines Adverse Reactions Committee)