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From Carolyn Oddie / Emma Marsh

To **Bronwyn Davis**, Assistant Director, Adjudication Branch, Australian Competition and Consumer Commission

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Dear Ms Davis

Medicines Australia - Application for Authorisation and Interim Authorisation

We refer to your email of 17 January in which you asked whether Medicines Australia (***MA***) has heard from the National Coordinating Committee for Therapeutic Goods (***NCCTG***) in respect of whether or not the NCCTG has endorsed the provisions of the Code relating to starter packs.

1. Background to the issue

As set out in our email of 9 January 2006, MA understands that the NCCTG wishes to consider proposed labelling requirements under the Australia New Zealand Therapeutic Products Authority, which are being drafted by the Joint Expert Committee on Trans Tasman Labelling Requirements for Medicines (***JECTTLRM***). These draft labelling requirements include provisions relating to the labelling of Starter Packs. MA now understands that the NCCTG amended its earlier endorsement of the amended Code provisions in so far as they relate to labelling and agreed to defer endorsement of the Code provisions in this regard until the outcome of considerations of the JECTTLRM regarding stakeholder comments in relation to the draft Label Order are available. The JECTTLRM has now prepared a final draft of the Label Order for the NCCTG's consideration, taking into account stakeholder comments in relation to the original draft.

Having had further discussions to resolve this issue, MA has therefore requested that the NCCTG be asked to review the provisions of the final draft Label Order in relation to Starter Packs out of session so that the position in respect of this aspect of MA's Code can be

resolved. MA understands that this request will be made to NCCTG members early this week.

2. MA's submissions

MA submits that the fact that the NCCTG has not yet finally endorsed the Code provisions in relation to labelling of Starter Packs should not prevent the Commission from granting interim authorisation in respect of Edition 15 of the Code.

The main factors in support of MA's submission in this regard are:

- Labelling is the only element of the Starter Pack provisions of the Code awaiting endorsement of the NCCTG.
- As the Commission is aware, the provisions of Section 5 relating to Starter Packs set an appropriate benchmark for the industry and are much more extensive than the issue of labelling. The provisions relate to matters including:
  - distribution of Starter Packs;
  - who can supply Starter Packs;
  - who can be supplied with Starter Packs;
  - size of Starter Packs;
  - quantity of Starter Packs that can be supplied;
  - quantity of Starter Packs that can be carried;
  - records that must be kept in relation to Starter Packs;
  - transport and storage of Starter Packs;
  - security of Starter Packs; and
  - returns and disposal of Starter Packs.
- As set out in more detail in previous submissions:
  - there is no conflict between the Code provisions relating to labelling of Starter Packs and the existing State and Territory legislative provisions concerning Starter Packs. This means that there is no detriment from the two requirements existing together;
  - the current Label Order (TGO 69) and any new Label Order which supersedes the current Label Order is a legislative instrument and takes precedence over the Code;
  - Section 5.1.8 of Edition 15 of the Code explicitly states that labelling of Starter Packs must comply with the current Therapeutic Goods Order on labelling; and
  - MA has advised all members and non-members to ensure that they are kept informed of any changes in Commonwealth and State laws concerning the supply of Starter Packs, and this statement is included as the Explanatory Note to Section 5 (introductory paragraphs) of the Code.

- Should the outcome of the considerations of the JECTTLRM be such that the Code requires amendment to ensure consistency with the final Label Order, this could be accommodated easily by MA members passing a special resolution.

If you have any queries in relation to the above, please let us know.

Yours sincerely

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