Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Variation under section 42DH of conditions of approval for use of restricted representations by Bayer Australia Pty Ltd

I, Dr Jane Cook, Head, Office of Product Review, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health, approve the following conditions in the use of the references *'Neural tube defects' and 'Spina Bifida'* in consumer advertising of the product ELEVIT film-coated tablet (AUST R 213113), to the effect that advertisements in which the representation is made must include:

- The advisory statement: *"If you have had a baby with a neural tube defect/spina bifida, seek specific medical advice"* must appear in all consumer advertising in which the restricted representations described above are used.

This condition is in substitution for the following conditions imposed on 9 September 2013:

- The advisory statement: *"If you have had a baby with a neural tube defect/spina bifida, seek medical advice"* must appear in all consumer advertising in which the restricted representations described above are used.

Dated this 26 day of May 2014

Jane Cook
Delegate of the Secretary to the Department of Health; and
Head
Office of Product Review