

File No: 93/16630
formerly (86/9010)
Application No: 91/156/2

FILE NOTE

APPLICATION FOR REGISTRATION

**TEICOPLANIN "TARGOCID" POWDER FOR INJECTION
100, 200 AND 400mg IN COLOURLESS GLASS VIALS PLUS AMPOULES OF
WATER FOR INJECTION
MARION MERRELL DOW AUSTRALIA PTY LTD**

NOMINAL VOLUME OF VIAL FOR 400mg PRESENTATION

There was some confusion as to the exact size of the glass vial for the 400mg presentation. This was realised when the company submitted the DE/GAS form. The Form A completed by the company stated 20mL (see boxed data and f53 of 86/9010).

In addition the draft Product Information (f106 86/9010) and the description of the dosage form (p56 volume 1 boxed data) all supported the 20mL size.

The company has confirmed that **all of the above are in error** (folios 31-29 93/16630) and that the true and correct size is 25mL referring to pp57 and 65 vol.1 of the boxed data.

ACCEPTABLE

NB The attention of the MSA is drawn to the fact that the draft Product Information is incorrect with respect to PRESENTATION (on the last page) and should be ammended to read
400 mg of teicoplanin in 25 mL size rubber stoppered vial.

[REDACTED]

[REDACTED]

Antibiotics Section
TGAL

29 September 1993