Merrell Dow

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OUR REF: TEICO/4

12th March, 1991

The Secretary,
Drug Evaluation Branch,
Department of Community Services and Health,
Alexander Building,
26 Furzer Street,
PHILLIP A.C.T. 2606

Dear Sir,

RE: GENERAL MARKETING APPLICATION
TARGOCID (TEICOPLANIN) INJECTION

Dear Sir,

Please find herewith a General Marketing Application for Targocid (teicoplanin injection).

Teicoplanin is chemically related to the vancomycin-ristocetin group of antibiotics and has activity against aerobic and anaerobic Gram-positive bacteria, including methicillin resistant staphylococci. Teicoplanin acts by inhibition of cell wall synthesis, and thus is bactericidal for most Gram-positive bacteria. To date susceptible bacteria have not developed resistance to the drug.

Unlike most antibiotics teicoplanin is not eliminated from the body but has a very long half life. This distinguishes it from other antibiotics of the glycopepticle class and allows the drug to be administered once a day.

In 1986, Merrell Dow Pharmaceuticals applied to conduct a clinical trial in Australia in MRSA patients (see our CTA application of 22 July, 1986). Chemistry and Pharmacy data (B1), *in vitro* microbiology and animal data (B2), as well as results of an open European multicentre study were submitted on that occasion. The CTA was subsequently approved (see your letter of 7 May 1987 ref. 86/9011), and the trial was started shortly thereafter.

The company is now applying for General Marketing Approval of Targocid, in light of adequate clinical data collected - including results of the multicentre Australian trial. Additionally, six further US pivotal studies are submitted, providing evaluable data on 746 patients for efficacy parameters, and considerably more for safety parameters.

In addition, two other trials are provided as supportive data. All studies include full tabulated individual patient data, and were conducted in accordance with the Declaration of Helsinki requirements for conduct of clinical studies in humans.

This application consists of an updated Section B1 (2 volumes + 1 supplementary volume), a Section B3 (consisting of 98 volumes) and a Section C (consisting of 1 volume).

We thank you for your attention to this matter and look forward to your further correspondence.

Yours faithfully,

[redacted]

PA/jl

Encls.

Sect. B1 2 Vols (x1) 407 P.
Sect. B1 Supp (Bioavailability) 1 Vol (x1) 47 pgs.
Section B3 98 vols (x1) - 18,997 Pages
Section C - 1 Vol (x1) - 168 Pages

(4) boxed PCE
31/5/91 LBP.

ASCSA

1 2 156 29.5.91 .ack letter sent Actioning Officer J Hopman