Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

[redacted]
[redacted] NSW [redacted]

SAS No: [redacted]
05/04/2013

THERAPEUTIC GOODS ACT 1989, S.19(1) EXEMPTIONS FOR SPECIAL AND EXPERIMENTAL USES APPROVAL TO SUPPLY UNDER THE SPECIAL ACCESS SCHEME

Drug: Adalimumab
Patient: [redacted] **DOB:** [redacted]1984 **Sex:** [redacted]
Dosage Regimen: As per protocol

Duration: Twelve Months

Dose Form: injection

Concerning your application to use the above drug in the treatment of the above patient on the grounds that there is no alternative therapy currently supplied in Australia, I, the medically qualified person named below, hereby provide Notification of Approval. The proposed clinical use of this drug must be regarded both medico-legally and ethically as experimental. No assurance can be given as to the quality, safety and efficacy in the proposed usage. Your co-operation is required concerning sound data management.

Permission is given for the use of the drug in the above patient for the above duration subject to the following conditions:--

1. The doctor and patient, patient's parents or guardian accept responsibility for any adverse consequence of therapy;
2. The product is used within the context of fully informed consent and in accordance with the treatment protocol provided to the TGA with the request.
3. The principles set out in the National Health and Medical Research Council's Statement on Human Experimentation be observed;
4. Details of any suspected adverse drug reactions are to be reported to the Experimental Drugs Section of the Therapeutic Goods Administration ;
5. The Therapeutic Goods Administration be notified of reasons for discontinuation should this occur;
6. Details of patient response to treatment are submitted to the supplier on completion of treatment ensuring compliance with State, Territory and Australian Government privacy legislation.
7. On completion of treatment all remaining supplies of the above product be returned to the supplier or destroyed should no supplier be present in Australia;
8. The person supplying the drug accepts responsibility for any defects in the drug related to the manufacture, distribution or directions for usage including dosage;
9. **Additional Conditions/Comments:** None specified.

This approval must be used within 12 (twelve) months from the date of this letter, or until revoked or until this product is marketed in Australia, whichever occurs first.

[redacted]
Delegate of the Secretary
Office of Medicines Authorisation
05/04/2013

Experimental Products Section, TGA, PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8111 Fax: 02 6232 8112 Email: eds@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CATEGORY B FORM SPECIAL ACCESS SCHEME

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient's initials: [redacted]
DOB: [redacted]/1984
MRN:
SEX: [redacted]

Diagnosis: ULCERATIVE COLITIS

Previous SAS No. (if applicable): [redacted]

Clinical justification for use of product
Include appraisal of seriousness of patient's condition; detail previous treatments and expected benefits from use of the product

Ulcerative Colitis unresponsive to imuran & 5ASA therapy alone so requiring multiple steroid courses. Since receiving compassionate Humira [redacted] symptom control has been excellent, [redacted] has not needed any days off work and is able to walk for an hour a day & has not required steroids.

Product details *Attach efficacy and safety data to support proposed use of the product and details of intended monitoring.*
**Complete for medicines and biologicals only.*

Active* ingredient: Adalimumab
Trade name /Device name: Humira
Company/supplier (State if imported): Abbvie
Dose form*: pen
Route of administration*: sc
Dosage* (dose x frequency): 4omg 2 weekly
Duration of treatment: 12 months
Date of medical device/ biological procedure/use:

Prescribing doctor details

Name: [redacted]
Initial Surname
Hospital: [redacted]
Department: [redacted]

Postal address (hospital or private).
The approval letter will be mailed to this address.

[redacted]
NSW
[redacted] *Postcode*

Phone: [redacted]
Fax number: [redacted]

Signature & date: [redacted] 9/9/13