Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 21st December 2006 concerning approval to supply Adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient_ , DOB _/1963, URN_)

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of twelve (12) months therapy of the above drug at a dosage as per protocol.

2. This approval is valid for up to eighteen (18) months from the date of this letter or until revoked or until Adalimumab (Humira) is marketed in Australia, whichever is sooner.

3. The approval is for supply for use in the above-mentioned patient only.

4. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

5. The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.

6. The principles set out in the “National Statement on Ethical Conduct in Research Involving Humans” are observed.
7. Details of any suspected adverse drug reactions are reported to the TGA.

8. The TGA is notified of reasons for discontinuation should this occur.

9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister
for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely,

[Name]

[Title]

DELEGATE OF THE SECRETARY
**Patient details**

- **Patient's initials:** 
- **DOB:** 1963
- **MRN:** 
- **SEX:** 

**Diagnosis**

- **Crohn's Disease - Perineal**

**Clinical justification**

- **Patient has responded to infliximab for disabling perineal Crohn's. Now has an allergic reaction to infliximab but has responded to the humanized anti-TNF receptor, adalimumab in open trial. Abbott are prepared to continue this.**

**Product details**

- **Active ingredient:** Adalimumab
- **Trade name / Device name:** Humira
- **Company/supplier (State if imported):** Abbott Australia, NSW
- **Dose form:** Pre-filled Syringe (2 pack)
- **Route of administration:** SC
- **Dosage:** 40 mg
- **Duration of treatment:** 12 months

**Prescribing doctor details**

- **Name:** [Redacted]
- **Hospital:** [Redacted]
- **Postal address (hospital or private):** [Redacted]
- **Postcode:** [Redacted]
- **Date of medical device procedure / use:** Please commence asap
- **Signature & date:** 21/12/06

**Other details**

- **Fax (medicines):** 02 6232 8112
- **Fax (medical devices):** 02 6232 8785
- **Mail:** SAS Officer, TGA, PO Box 100, Woden ACT 2606
Dear [Redacted]

Re: ADALIMUMAB

Thank you for your letter of 2nd November 2006 in response to my request for further information for supply of adalimumab for your patient (Date of Birth: [Redacted]) under the SAS scheme for unregistered medications.

I draw your attention to the review article which accompanied your letter\(^1\). The article notes as follows:

*Currently, ReA is better defined as an immune-mediated synovitis resulting from slow bacterial infections and showing intra-articular persistence of viable nonculturable bacteria and/or immunogenic bacterial antigens synthesized by metabolically active bacteria residing in the joint and/or elsewhere in the body.*

The article also notes a case of reactive arthritis secondary to HIV which resulted in sepsis and death following the use of a TNF-\(\alpha\) antagonist agent.

As you have not discussed the safety of the proposed use in your letter, I request you to please comment on the safety aspect especially in regard to the risk of flare up of serious infection. I'll then submit the information I receive from you to an internal group of senior medical officers for advice before a decision is made.


I thank you and look forward to hearing from you.

Yours sincerely

[Redacted]

Drug Safety & Evaluation Branch

09 November 2006

---

**Patient details**

**Patient details** (initials, ID or URN, DOB, Sex)

- Initials: [ obscured ]
- ID or URN: [ obscured ]
- DOB: 69
- Sex: [ obscured ]

**Diagnosis**

- REACTIVE ARTHRITIS

**Previous SAS No.**

- [ obscured ]

**Clinical justification**

- ACTIVE INFLAMMATION IN MULTIPLE LARGE JOINTS, LEADING TO DAMAGE AND INCREASING LOSS OF FUNCTION

**Product details**

- **Active ingredient**: ADA LINUMAB
- **Trade name/Device name**: HUMIRA
- **Company/supplier**: ABBOTT AUSTRALASIA
- **Dose form**: INJECTION
- **Route of administration**: SC
- **Dosage**: 40mg
- **Duration of treatment**: 6 months (in joint evidence)

**Prescribing doctor details**

- **Name**: [ obscured ]
- **Hospital**: [ obscured ]
- **Department**: [ obscured ]
- **Postal address**: [ obscured ]
- **Signature**: [ obscured ]
- **License number**: [ obscured ]
- **Date**: 27/7/06
Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 15th June 2006 concerning approval to supply Adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient [...]

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of three (3) months' therapy of the above drug at a dosage as per sponsor's protocol.

2. This approval is valid for up to six (6) months from the date of this letter or until revoked or until Adalimumab (Humira) is marketed in Australia, whichever is sooner.

3. The approval is for supply for use in the above-mentioned patient only.

4. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

5. The doctor and patient or patient's guardian accepts responsibility for any adverse consequence of therapy.
6. The principles set out in the "National Statement on Ethical Conduct in Research Involving Humans" are observed.

7. Details of any suspected adverse drug reactions are reported to the TGA.

8. The TGA is notified of reasons for discontinuation should this occur.

9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister
for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

[Signature]

DELEGATE OF THE SECRETARY

14 June 2006
**Diagnosis:** Inflammatory bowel disease

**Previous SAS No.** (if applicable) **A/N/A**

**Clinical justification for use of product**

Inflammatory bowel disease - initial response to infliximab, loss of response over time suggesting development of antibodies to infliximab.

---

**Product details**

**Active ingredient:** ADALIMUMAB

**Trade name/Device name:** HUMIRA

**Company/supplier**

ABBOTT AUSTRALASIA

**Dose form**

40mg/0.8ml

**Route of administration**

Subcutaneous

**Dosage**

80mg then 40mg

**Duration of treatment**

Determined by response

---

**Prescribing doctor details**

**Name:**

**Initial**

**Surname**

**Hospital**

**Department**

**Postal address:** (Hospital or private)

The approval letter will be mailed to this address.

**Signature & date**

**Fax (medicines):** 02 6232 8112

**Fax (medical devices):** 02 6232 8785

Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606

Form no. 2950 (0405)
Dear [Redacted],

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 8th June 2006 concerning approval to supply Adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient [Redacted].

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

- The approval is given for the supply of three (3) months’ therapy of the above drug at a dosage as per sponsor’s protocol.

- This approval is valid for up to six (6) months from the date of this letter or until revoked or until Adalimumab (Humira) is marketed in Australia, whichever is sooner.

- The approval is for supply for use in the above-mentioned patient only.

- The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

- The doctor and patient or patient’s guardian accept responsibility for any adverse consequence of therapy.

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au Telephone: 02 6232 8111 Facsimile: 02 6232 8112 ABN 40 939 406 804
• The principles set out in the "National Statement on Ethical Conduct in Research Involving Humans" are observed.

• Details of any suspected adverse drug reactions are reported to the TGA.

• The TGA is notified of reasons for discontinuation should this occur.

• The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

• The product should be used in accordance with the treatment protocol provided to the TGA with the request.

• This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister
for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

DELEGATE OF THE SECRETARY

9 June 2006
Dear 

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 8th June 2006 concerning approval to supply Adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient [redacted].

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

- The approval is given for the supply of three (3) months' therapy of the above drug at a dosage as per sponsor's protocol.
- This approval is valid for up to six (6) months from the date of this letter or until

[Redacted Information]

[Redacted Information]
**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**

<table>
<thead>
<tr>
<th>Patient details</th>
<th>DOB:</th>
<th>1982</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient's initials:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRN:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEX:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Diagnosis
- Crohn's disease - unresponsive to infliximab.

### Clinical justification
- Patient is unresponsive to infliximab. Has developed infusion reactions presumably due to inactivating antibodies.
- It is possible that [ ] would benefit from an alternative anti-TNF agent.

### Product details
- Attach efficacy and safety data to support proposed use of the product and details of intended monitoring.

#### Active ingredient
- ADALIMU MAB

#### Trade name
- HUMIRA

#### Company/supplier
- ABBOTT AUSTRALASIA

#### Dose form
- 160mg

#### Route of administration
- Subcutaneous injection

#### Dosage
- 160mg/80mg Weekly

#### Duration of treatment
- Depends on response

#### Date of medical device procedure/use
- When approved

### Prescribing doctor details

#### Name
- [Redacted]

#### Hospital
- [Redacted]

#### Department
- [Redacted]

#### Phone
- [Redacted]

#### Fax number
- [Redacted]

#### Signature & date
- [Redacted]

**Fax (medicines): 02 6232 8112**  
**Fax (medical devices): 02 6232 8785**  
**Medical Officer, TGA, PO Box 100, Woden ACT 2606**  
**Form no. 2950 (0405)**
Dear [Redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 30th May 2006 concerning approval to supply Adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient [Redacted] born 1963, [Redacted]

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

- The approval is given for the supply of six (6) months' therapy of the above drug at a dosage as per sponsor's protocol.

- This approval is valid for up to twelve (12) months from the date of this letter or until revoked or until Adalimumab (Humira) is marketed in Australia, whichever is sooner.

- The approval is for supply for use in the above-mentioned patient only.

- The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

- The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.
• The principles set out in the “National Statement on Ethical Conduct in Research Involving Humans” are observed.

• Details of any suspected adverse drug reactions are reported to the TGA.

• The TGA is notified of reasons for discontinuation should this occur.

• The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

• The product should be used in accordance with the treatment protocol provided to the TGA with the request.

• This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister
for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

[Name]

DELEGATE OF THE SECRETARY

31st May 2006
# Category B Form
## Special Access Scheme

**Please use black pen, print clearly and complete all sections.**

### Patient Details

<table>
<thead>
<tr>
<th>Details</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient initials, ID or URN, DOB, Sex</td>
<td>[Redacted] 1962</td>
</tr>
</tbody>
</table>

**Diagnosis:** Crohns disease

**Clinical justification for use of product:**
Severe Crohns disease with enteric fistulas

### Product Details

**Active ingredient:** Adalimumab

**Trade name/Device name:** Humira

**Company/supplier:** Abbott, NSW (02) 93849801

**Dose form:** 40mg/0.8mL

**Route of administration:** SC

**Dosage:** 40mg Q2 weekly

**Duration of treatment:**

### Prescribing Doctor Details

**Name:** [Redacted]

**Hospital:** [Redacted]

**Department:** [Redacted]

**Address:** Brisbane

**Phone:** [Redacted]

**Fax number:** [Redacted]

**Signature:** [Redacted]

**Date:** 25/5/06

---

Form no. 2950 (0105)
Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Dear [Redacted],

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 15th June 2006 concerning approval to supply Adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient [Redacted] (1985, [Redacted]).

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of three (3) months’ therapy of the above drug at a dosage as per sponsor’s protocol.

2. This approval is valid for up to six (6) months from the date of this letter or until revoked or until Adalimumab (Humira) is marketed in Australia, whichever is sooner.

3. The approval is for supply for use in the above-mentioned patient only.

4. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

5. The doctor and patient or patient’s guardian accepts responsibility for any adverse consequence of therapy.

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au
Telephone: 02 6232 8111 Facsimile: 02 6232 8112 ABN 40 939 406 804
6. The principles set out in the "National Statement on Ethical Conduct in Research Involving Humans" are observed.

7. Details of any suspected adverse drug reactions are reported to the TGA.

8. The TGA is notified of reasons for discontinuation should this occur.

9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

[Name Redacted]

DELEGATE OF THE SECRETARY

14 June 2006
<table>
<thead>
<tr>
<th>Patient details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient's initials:</td>
<td></td>
</tr>
<tr>
<td>MRN:</td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Inflammatory bowel disease</td>
</tr>
<tr>
<td>DOB:</td>
<td>1985</td>
</tr>
<tr>
<td>SEX:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical justification for use of product</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Include appraisal of seriousness of patient's condition; detail previous treatments and expected benefits from use of the product</td>
<td>Inflammatory bowel disease with the development of infusion reactions to infliximab therapy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Active ingredient</td>
<td>ADAHMUMAB</td>
</tr>
<tr>
<td>Trade name</td>
<td>HUMIRA</td>
</tr>
<tr>
<td>Company/supplier (State if imported)</td>
<td>ABBOTT AUSTRALASIA</td>
</tr>
<tr>
<td>Dose form*</td>
<td>140mg/0.8mL</td>
</tr>
<tr>
<td>Route of administration*</td>
<td>Subcutaneously</td>
</tr>
<tr>
<td>Dosage*</td>
<td>80mg followed by 40mg each month</td>
</tr>
<tr>
<td>Duration of treatment</td>
<td>Determined by response</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of medical device procedure/use</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Prescribing doctor details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td></td>
</tr>
<tr>
<td>Surname</td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td></td>
</tr>
<tr>
<td>Fax number</td>
<td></td>
</tr>
<tr>
<td>Signature &amp; date</td>
<td>15/06/06</td>
</tr>
</tbody>
</table>

Fax (medicines): 02 6232 8112
Fax (medical devices): 02 6232 8785
Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606
Form no. 2950 (0405)
Dear [Redacted Name],

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 18th April 2006 concerning approval to supply Adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient [Redacted Name] DOB [Redacted Date], URN [Redacted].

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of six (6) months’ therapy of the above drug at a dosage as per sponsor’s protocol.

2. This approval is valid for up to twelve (12) months from the date of this letter or until revoked or until Adalimumab (Humira) is marketed in Australia, whichever is sooner.

3. The approval is for supply for use in the above-mentioned patient only.

4. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

5. The doctor and patient or patient’s guardian accept responsibility for any adverse consequence of therapy.

6. The principles set out in the “National Statement on Ethical Conduct in Research Involving Humans” are observed.

[Address, Website, Telephone, Facsimile]
7. Details of any suspected adverse drug reactions are reported to the TGA.

8. The TGA is notified of reasons for discontinuation should this occur.

9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister  
for Health and Ageing  
Parliament House  
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

[Redacted]

DELEGATE OF THE SECRETARY

19 April 2006
# 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**

<table>
<thead>
<tr>
<th>Patient details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient's Initials:</td>
<td>DOB: 1963</td>
</tr>
<tr>
<td>MRN:</td>
<td>SEX:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Previous SAS No. (If applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crohn's Disease - perineal</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical justification for use of product</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Include appraisal of seriousness of patient's condition; detail previous treatments and expected benefits from use of the product</td>
<td></td>
</tr>
<tr>
<td>Patient has responded to infliximab for disabling perineal Crohn's. Now has an allergic reaction to infliximab but has responded to the humanised anti-TNF α receptor adalimumab in open trial. Abbott are prepared to continue this treatment without charge.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Ingredient</td>
<td>Trade name / Device name</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>Humira</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Company/supplier (State if imported)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Australasia NSW</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dose form</th>
<th>Route of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-filled Syringe (2pods)</td>
<td>SC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dosage</th>
<th>Duration of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>40mg</td>
<td>12 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of medical device procedure/use</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Please commence asap</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prescribing doctor details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name Initial Surname</td>
<td>Hospital</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Postal address (hospital or private). The approval letter will be mailed to this address</td>
<td>Department</td>
</tr>
<tr>
<td></td>
<td>Gastroenterology</td>
</tr>
<tr>
<td></td>
<td>South Australia</td>
</tr>
<tr>
<td>Phone</td>
<td>Fax number</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Signature & date**

---

Fax (medicines): 02 6232 8112  Fax (medical devices): 02 6232 8785  Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606
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 a formal 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 parent or guardian accept responsibility for any adverse consequences of therapy;
2. The principles set out in the National Health and Medical Research Council’s ‘Statement on Human Experimentation’ is observed;
3. Details of any suspected adverse drug reactions are to be reported to the Australia Drug Evaluation Committee;
4. The TGA be notified of reasons for discontinuation should this occur;
5. On completion of the treatment a detailed patient profile, before and after treatment, is to be submitted to the supplier of this product;
6. On completion of the treatment all remaining supplies of the above product be returned to the supplier;
7. The company supplying the drug accepts responsibility for any defects in the drug related to manufacture, distribution or directions for use including dosage.
8. Special Conditions: Nil

Drug Safety and Evaluation Branch
Doctor: Please forward a copy to your Chief Pharmacist
<table>
<thead>
<tr>
<th><strong>SAS Number</strong></th>
<th>[Blank]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug (Active Ingredient)</strong></td>
<td>P.OALIMUMAB</td>
</tr>
<tr>
<td><strong>Drug (Trade Name)</strong></td>
<td>HUMIRA</td>
</tr>
<tr>
<td><strong>Company Name</strong></td>
<td>[Blank]</td>
</tr>
<tr>
<td><strong>Hospital Name</strong></td>
<td>[Blank]</td>
</tr>
<tr>
<td><strong>Section/Department</strong></td>
<td>[Blank]</td>
</tr>
<tr>
<td><strong>Postal Address</strong></td>
<td>[Blank]</td>
</tr>
<tr>
<td><strong>Patient's initials</strong></td>
<td>[Blank]</td>
</tr>
<tr>
<td><strong>Dosage</strong></td>
<td>40mg</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>21-52 x 3 monthly</td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td>Croh's colitis</td>
</tr>
<tr>
<td><strong>Previous/Current Therapy &amp; other Comments</strong></td>
<td>[Blank]</td>
</tr>
<tr>
<td><strong>Monitoring</strong></td>
<td>[Blank]</td>
</tr>
<tr>
<td><strong>Special conditions</strong></td>
<td>[Blank]</td>
</tr>
<tr>
<td><strong>Change details</strong></td>
<td>[Blank]</td>
</tr>
<tr>
<td><strong>Approval</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Delegate's Signature</strong></td>
<td>[Blank]</td>
</tr>
</tbody>
</table>

No issues at present (Relates to SAS No. 74)
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: 1952
MRN: [Redacted] SEX: [Redacted]

Diagnosis: CROHN'S COLITIS

Previous SAS No. (if applicable)

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

- Has intractable CROHN'S COLITIS
- Has failed AZATHIOPRINE therapy and is failing methotrexate therapy. A recent dose of INFliximab was ineffective though did respond originally. Remission is expected. PHOTOTHERAPY is the alternative.

Product details
Attach efficacy and safety data to support proposed use of the product and details of intended monitoring.

*Complete for medicines only.

Active* ingredient: ADA LIM MUMAB
Trade name/Device name: HUMIRA

Company/supplier (State if imported): ABBOTT (AUSTRALIA) P/L.

Dose form*: Ampoule.
Route of administration*: Subcutaneous
Dosage*: 40 mg every other week
Duration of treatment: 3 months (initially)

Date of medical device procedure/use

Prescribing doctor details
Name: [Redacted] [Redacted]
Hospital:
Department:
Postal address (hospital or private):
The approval letter will be mailed to this address.

Victoria

Signature & date: 23/12/05

Fax (medicines): 02 6232 8112 Fax (medical devices): 02 6232 8785 Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606
Dear Dr [redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 23rd December 2005 concerning approval to supply Adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient [redacted] (DOB [redacted]/1952)

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of three (3) months' therapy of the above drug at a dosage of 40mg, every 2 weeks, subcutaneous injection.

2. This approval is valid for up to six (6) months from the date of this letter or until revoked or until Adalimumab (Humira) is marketed in Australia, whichever is sooner.

3. The approval is for supply for use in the above-mentioned patient only.

4. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

5. The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.

6. The principles set out in the “National Statement on Ethical Conduct in Research Involving Humans” are observed.
7. Details of any suspected adverse drug reactions are reported to the TGA.

8. The TGA is notified of reasons for discontinuation should this occur.

9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

[Signature]

DELEGATE OF THE SECRETARY

January 2006
**Australian Government**
**Department of Health and Ageing**

**Therapeutic Goods Administration**

**SPECIAL ACCESS SCHEME**

**PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS**

<table>
<thead>
<tr>
<th><strong>Patient details</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient's initials:</strong></td>
</tr>
<tr>
<td><strong>MRN:</strong></td>
</tr>
<tr>
<td><strong>DOB:</strong></td>
</tr>
<tr>
<td><strong>SEX:</strong></td>
</tr>
</tbody>
</table>

**Diagnosis:** CROHN'S COLITIS

**Previous SAS No.** (if applicable)

**Clinical justification for use of product:**

- has intractable CROHN'S colitis: 
- has failed azathioprine therapy and is failing methotrexate therapy. 
- A recent dose of infliximab was ineffective though [redacted].

**Product details:**

- Active ingredient: ADAлимумаб
- Trade name/Device name: HUMIRA
- Company/supplier: ABBOTT (AUSTRALIA) P/L.
- Dose form: Ampoule
- Route of administration: Subcutaneous
- Dosage: 40 mg every other week
- Duration of treatment: 3 months (initially)

**Prescribing doctor details:**

- **Name:** Initial surname
- **Postal address (hospital or private):**
- **Signature & date:** 23/12/05

**Fax (medicines):** 02 6232 8112  
**Fax (medical devices):** 02 6232 R785  
**Mail:** SAS Office, TGA, PO Box 170, Weden ACT 2606
Dear [Redacted]

Therapeutic Goods Administration

Dr [Redacted]
QLD [Redacted]

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 14th December 2005 concerning approval to supply Adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient [Redacted] (DOB [Redacted]) UR: [Redacted]

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of twelve (12) months’ therapy of the above drug at a dosage of 40mg, every 2 weeks, subcutaneous injection.

2. This approval is valid for up to twelve (12) months from the date of this letter or until revoked or until Adalimumab (Humira) is marketed in Australia, whichever is sooner.

3. The approval is for supply for use in the above-mentioned patient only.

4. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

5. The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.

6. The principles set out in the “National Statement on Ethical Conduct in Research Involving Humans” are observed.
7. Details of any suspected adverse drug reactions are reported to the TGA.

8. The TGA is notified of reasons for discontinuation should this occur.

9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister
for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

[Redacted]

DELEGATE OF THE SECRETARY

December 2005
URGENT + FAX REPLY PLEASE

CATEGORY B FORM
SPECIAL ACCESS SCHEME

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient details (initials, ID or URN, DOB, Sex)

1962

Diagnosis

FISTULIZING CROHN'S DISEASE

Clinical justification for use of product

PREVIOUS RESPONSE TO ADAHIMAB
FAIUIE TO RESPOND TO AZATHIOPRINE
AND OTHER IMMUNOSUPPRESSION

Preceding SAS No. By letter No Number Issued.

NEEDS TO COMPLETE HAVE ONGOING THERAPY.

Product details

Active* ingredient

ADALIMMAB

Trade name / Device name

HUMIRA

Company/supplier

ABBOTT

Dose form*

40mg/10ml syringe

Route of administration*

SC Injection

Dosage*

40mg/wk SC

Duration of treatment

12 months (Total)

Prescribing doctor details

Name

Signature

SOUTH BRISBANE

Hospital

8/12/05

Department

Phone

Fax number

Form No. 2950 (0105)
Dear

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 13th December 2005 concerning approval to supply adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient [DOB: 1/1985] UR: [REDACTED].

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of twelve (12) months' therapy of the above drug at a dosage of 40mg, every 2 weeks, subcutaneous injection.

2. This approval is valid for up to twelve (12) months from the date of this letter or until revoked or until adalimumab (Humira) is marketed in Australia, whichever is sooner.

3. The approval is for supply for use in the above-mentioned patient only.

4. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

5. The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.

6. The principles set out in the "National Statement on Ethical Conduct in Research Involving Humans" are observed.
7. Details of any suspected adverse drug reactions are reported to the TGA.

8. The TGA is notified of reasons for discontinuation should this occur.

9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister
for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

Delegation Secretary

December 2005
**Patient details**

<table>
<thead>
<tr>
<th>Patient details (initials, ID or URN, DOB, Sex)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK: [redacted]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Previous SAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crohn's Disease</td>
<td></td>
</tr>
</tbody>
</table>

**Clinical justification**

Severe active Crohn's disease not responsive to immunosuppressants with terminal ileal, per- and cecal involvement but not fistulizing.

Previous good response to Adalimumab in clinical trials.

**Product details**

- **Active ingredient**: Adalimumab
- **Trade name**: Humira
- **Company/supplier**: Abbott
- **Dose form**: 40mg 10.8ml vial
- **Route of administration**: SC
- **Dosage**: 40mg 2nd weekly SC
- **Duration of treatment**: 12 months

**Prescribing doctor details**

- **Name**: [redacted]
- **Hospital**: South Brisbane
- **Department**: [redacted]
- **Phone**
- **Fax number**: [redacted]
- **Signature**: [redacted]

Form no. 2950 (0105)

Total p. 01
Dear [Name],

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 19th October 2005 concerning approval to supply Adalimumab (Humira) for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab (Humira) for use in the treatment of your patient [DOB] (DOB /1962) UR

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of three (3) months' therapy of the above drug at a dosage of 40mg, every 2 weeks, subcutaneous injection.

2. This approval is valid for up to six (6) months from the date of this letter or until revoked or until Adalimumab (Humira) is marketed in Australia, whichever is sooner.

3. The approval is for supply for use in the above-mentioned patient only.

4. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

5. The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.

6. The principles set out in the "National Statement on Ethical Conduct in Research Involving Humans" are observed.
7. Details of any suspected adverse drug reactions are reported to the TGA.

8. The TGA is notified of reasons for discontinuation should this occur.

9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

DELEGATE OF THE SECRETARY

19 October 2005
**TGA CATEGORY B FORM SPECIAL ACCESS SCHEME**

**PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS**

<table>
<thead>
<tr>
<th>Patient details</th>
<th>Previous SAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(initials, ID or URN, DOB, Sex)</td>
<td></td>
</tr>
</tbody>
</table>

**Diagnosis:** Fistulising Colitis Disease

**Clinical justification for use of product:**

- Multiple enterocutaneous fistulae
- With significant systemic symptoms and previous good clinical response (12 months use as part of clinical trial)

**Product details**

- **Active ingredient:** ADALIMUMAB
- **Trade name:** HUMIRA
- **Company/supplier:** ABBOTT
- **Dose form:** 40 mg oral
- **Route of administration:** Subcutaneous inj
- **Dosage:** 40 mg 2nd weekly
- **Duration of treatment:** 12 months +

<table>
<thead>
<tr>
<th>Prescribing doctor details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong></td>
</tr>
<tr>
<td><strong>Postal address:</strong></td>
</tr>
<tr>
<td><strong>Hospital:</strong></td>
</tr>
<tr>
<td><strong>Department:</strong></td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
</tr>
<tr>
<td><strong>Fax number:</strong></td>
</tr>
<tr>
<td><strong>Signature:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Approval details</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADALIMUMAB/HUMIRA INJECTION</td>
</tr>
<tr>
<td>Dose = 40 mg, every 2 weeks, subcutaneous injection</td>
</tr>
<tr>
<td>3 months' initial trial period</td>
</tr>
</tbody>
</table>

**Form no. 2980 (0105)**

**Oct. 18 2005 04:44PM P2**
Dear Dr. [Redacted],

Hobart [Redacted]

Re: Special Access Scheme Approval – Adalimumab

I refer to your request received 4 August 2004 concerning approval to supply Adalimumab for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab for use in the treatment of your patient [Redacted] (DOB [Redacted]).

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this therapeutic good as defined in the Act, in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, and there may be implications regarding indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of up to six (6) months’ therapy of the above drug at a dosage of 24mg/m^2 BSA subcutaneously every 2 weeks
2. Doses are to be given in a suitably equipped medical facility under the supervision of medical personnel trained in resuscitation, until such time as it is clear that the patient is not at risk of anaphylaxis.
3. This approval is valid for up to twelve (12) months from the date of this letter.
4. The approval is for supply for use in the above-mentioned patient only.
5. The product is used within the context of fully informed consent. The proposed usage is not in accordance with the conditions of registration of Adalimumab and constitutes use as an experimental drug.
6. The doctor and patient or patient’s guardian accepts responsibility for any adverse consequence of therapy.
7. The principles set out in the “National Statement on Ethical Conduct in Research Involving Humans” are observed.

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au
Telephone: 02 6232 8111 Facsimile: 02 6232 8112 ABN 40 939 406 804
8. Details of any suspected adverse drug reactions are reported to the TGA.

9. The TGA is notified of reasons for discontinuation should this occur.

10. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

11. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

DELEGATE OF THE SECRETARY

// August 2004
**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]
- **SEX:** [redacted]
- **MRN:** [redacted]

### Diagnosis

- **Juvenile idiopathic arthritis**
- **Previous SAS No.** (if applicable): [redacted]

### Clinical justification

- **Qualified for Etanercept via HIC criteria - unfortunately had severe exacerbations response to Etanercept.**

### Product details

- **Active ingredient:** Adalimumab
- **Trade name/Device name:** Humira
- **Company/supplier (State if imported):** ABBOTT
- **Dose form:** SC injection
- **Route of administration:** SC
- **Dosage:** 40 mg SC every 2 weeks
- **Duration of treatment:** 12 months

### Prescribing doctor details

- **Name:** [redacted]
- **Hospital:** Hobart
- **Department:** [redacted]
- **Signature & date:** [redacted]
- **Phone:** [redacted]
- **Fax number:** [redacted]

---

**Approved**

- **24 mg/kg/m² BSA every 2 weeks for 6 months:** [redacted]
- **Dosage:** [redacted]
- **Clear that the patient is not allergic to Humira:** [redacted]

---

**Company aware that this is for off-label use so SAS approval is required for them to supply for what they consider to be pediatric pt.**

- **Weight:** 35 kg
- **Plan to use:** 1/2 adult dose (120 mg)
- **Dr F has spoken to medical director of Abbott but he is not sure if it will be approved at this time due to pediatric usage.**
Dear [name]

Re: Adalimumab

I refer to your request received 8 July 2002 concerning approval to supply Adalimumab for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of Adalimumab for use in the treatment of your patient [DOB: 12/1979].

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, in the case of a major company, there may be implications for the company's indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of up to six (6) months' therapy of the above drug at a dosage as per manufacturer's instructions.

2. This approval is valid for up to twelve (12) months from the date of this letter or until revoked or until Adalimumab is marketed in Australia, whichever is sooner.

3. The approval is for supply for use in the above mentioned patient only.

4. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

5. The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.

6. The principles set out in the “National Statement on Ethical Conduct in Research Involving Humans” are observed.
7. Details of any suspected adverse drug reactions are reported to the TGA.

8. The TGA is notified of reasons for discontinuation should this occur.

9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister
for Health and Aged Care
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours

[Signature]

[DELEGATE OF THE SECRETARY]

15 July 2002
**Patient details**

<table>
<thead>
<tr>
<th>Patient details (initials, ID or URN, DOB, Sex)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOB: 179.</td>
</tr>
</tbody>
</table>

**Diagnosis**

- Rheumatoid Arthritis (variant)

**Clinical justification**

Severe, progressive synovitis, uncontrolled using conventional therapies including disease modifying drugs. Note: Patient declines standard treatment.

**Product details**

<table>
<thead>
<tr>
<th>Active ingredient</th>
<th>Trade name/Device name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab (D2E7)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Company/supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>AbbVie</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dose form*</th>
<th>Route of administration*</th>
</tr>
</thead>
<tbody>
<tr>
<td>H01963</td>
<td>Subcutaneous</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dosage*</th>
<th>Duration of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>H01963 S.C.</td>
<td>Indefinite</td>
</tr>
</tbody>
</table>

**Prescribing doctor details**

<table>
<thead>
<tr>
<th>Name</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Postal address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Address**

NEW

<table>
<thead>
<tr>
<th>Phone</th>
<th>Fax number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7110</td>
</tr>
</tbody>
</table>