



COMMONWEALTH OF AUSTRALIA



OFFICE OF THE SECRETARY

GPO Box 9848
Canberra ACT 2601
Telephone: (06) 289 8401
Telex: 61209 Fax: (06) 285 1994

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DEPARTMENT OF
COMMUNITY SERVICES
XXXXX XXXXXXXX

HEALTH, HOUSING AND
COMMUNITY SERVICES

[REDACTED]
Surgeon General
Australian Defence Force
Department of Defence
PO Box E33
Queen Victoria Terrace
CANBERRA ACT 2600

Dear [REDACTED]

ANTHRAX VACCINATION PROGRAM

Thank you for your letter of 26 June 1991 (your reference SG 91-14734 PT 1; SGADF 1102/91).

In accordance with my power under s19(1)(a) of the Therapeutic Goods Act 1989, I approve the importation and use within Australia by the Department of Defence of human anthrax vaccine, for the purpose described in your letter dated 26 June 1991.

Note that no evaluation of the quality, safety or efficacy of the vaccine has been conducted by the Department of Health, Housing and Community Services. My decision has been made on the basis of your information that importation and use of the vaccine is necessary to Australia's involvement in the project you described.

This approval expires three months from the date of signature, and provides for importation of a maximum of 100 doses of the vaccine. Approval is subject to the condition that recipients of the vaccine be informed, before administration of the first dose, that the vaccine has not been evaluated by the Australian Therapeutic Goods Administration.

Yours sincerely

[REDACTED]
June 1991

* Filed on confidential file
relating to this subject.

RECEIVED
28 JUN 1991
90/15764

Secretary

IMPORTATION AND USE OF ANTHRAX VACCINE BY DEFENCE FORCES

See letter from [REDACTED], dated 26 June 1991 (attached).

I have spoken to [REDACTED] about this. It seems that they wish to commence immunisation on 1 July 1991, with a view to participating in a UN-sponsored project. Vaccine would be administered to about 25 people - mostly defence personnel, but including a small number of non-defence Commonwealth officers who would be members of the project team.

I understand a Quarantine clearance has been obtained to cover importation of the vaccine.

TGA knows nothing about this vaccine, and [REDACTED] was not able to tell me today where it was manufactured or by whom. It was being obtained through an arrangement with UK defence authorities.

I explained to [REDACTED] that this was not a situation where approval could be given under the usual IPU criteria. What he was really seeking was an exemption from the usual drug controls, based not on considerations of urgent clinical need or on any assessment of the technical characteristics of the drug, but on the defence authorities' stated need.

I gained the impression that even if no approval was given under the Therapeutic Goods Act 1989, the defence authorities planned to go ahead with importation and use of the vaccine, using a general exemption from regulatory control which they believe is available to them under their legislation. However, they are under instruction to abide by ordinary regulatory controls wherever possible.

I have discussed the request with [REDACTED] and [REDACTED] who agree with me that this ought not be dealt with by your medically-trained delegates, as the question of approval depends entirely on non-medical considerations. It appears that you could give an approval using your power under s 19(1)(a) of the Act (although, strictly, it could be argued that such approval could only be given for specified individual patients). In the next round of amendments to the Therapeutic Goods Regulations, it is proposed that specific power will be given to you or the Minister to give approvals in this sort of situation, and that this amendment will be made retrospective to the commencement of the Act.

If you decide to issue an approval, I suggest it take the form of the attached letter.

[REDACTED]
27/6/91

URGENT

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(Dept of Defence would like
reply by cob 28.6.91)

1.

28/6

If Shat signs the letter, please
let me know & I'll collect
all these papers.

[REDACTED]

27/6/91

Feethy ✓ — Shat — I think the
letter is OK. to sign
by Adams
28/6.

2.

[REDACTED]

will arrange to

have letter despatched after it
has been signed.

Signed,
Feethy

[REDACTED]

[REDACTED]

28/6