

Severn



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10 DOWNING STREET

LONDON SW1A 2AA

From the Private Secretary

20 December

Prime Minister

BW Immunisation

This is the fuller note which
you requested. I think it
answers the main points you
raised. The new point - to me at
least - is that we have been
manufacturing and using the vaccine
since 1963. This puts it in a
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Content?

C. D. P. 20/xii



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28 DecemberPrime MinisterBW Immunisation

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Content?

C. D. P. 28/xii



MINISTRY OF DEFENCE
 MAIN BUILDING WHITEHALL LONDON SW1A 2HB
 Telephone 071- 21 82111/3

MO 6/17/15/1J

27 December 1990

Dear Charles

BW IMMUNISATION

Following Simon Webb's letter of 24th December you asked for some further information about how and by whom Anthrax vaccine is licenced.

I am advised by the Department of Health that the Product Licence awarded by the Licensing Authority (which consists of the Health and Agriculture Ministers of the United Kingdom) indicates that the safety, quality and efficacy of the vaccine have been properly assessed. The Licensing Authority is itself advised by the Medicines Control Agency of the Department of Health, which in turn advised by external experts.

The manufacturer of a Product Licence product has to follow carefully the terms of the Licence, and in the case of biological products such as Anthrax vaccine, has to submit data on each batch produced to the National Institute for Biological Standards and Control (NIBSC), an organisation set up on behalf of the Medicines Control Agency. After the NIBSC have reviewed the data, providing all is in order, they authorise the release of each individual production batch. In the case of Anthrax vaccine, where the Department of Health is the Product Licence holder, independent scrutiny of the production dossier of each batch of vaccine manufactured is also undertaken.

Records immediately to hand in the Department of Health show that the vaccine has been being regularly manufactured since at least 1983, with an average of 3,750 doses made each year. These have been being used principally for vets, abattoir workers, tanners, and others liable to be exposed to the dangers of Anthrax.

I am sending a copy of this letter to the Private Secretaries to members of OPD(G) and the Secretary of State for Health, and to Sonia Phippard (Cabinet Office).

Yours sincerely

J R Binstead
 (MISS J R BINSTEAD)
 Private Secretary

Sir Charles Powell KCMG
 10 Downing Street

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Janet Binstead
 (MISS J R BINSTEAD)
 Private Secretary

Sir Charles Powell KCMG
 10 Downing Street