Joint Medical Group Secretariat

Headquarters Joint Medical Group
Coltman House,
Defence Medical Services Whittington,
Tamworth Rd
Lichfield
WS14 9PY

Gavin Roberts

Reference: FOI2020/08641

request-679802-3557e935@whatdotheyknow.com

Date: 20 August 2020

Dear Mr Roberts,

Thank you for your enquiry of 26 July 2020 to the Ministry of Defence (MOD), in which you asked the following:

> *"It is clear from all data available that troops in the Gulf War 1990/91 were not informed that vaccines/ combinations had never been trialled/tested on humans.*
>
> *What is MOD policy today? If a similar situation arises and a decision to use experimental drugs/vaccines and combinations that had never been near a humans immune system (Only animals)*
>
> *Would MOD inform troops of today of this information, to enable for them to give their full legal informed consent?"*

Your enquiry is being treated as a request for information under the Freedom of Information Act (FOIA) 2000. The MOD can confirm that it holds information within the scope of youir enquiry.

There is specific policy on how the MOD gives vaccines. This is Joint Service Publication (JSP) 950 Leaflet 7-1-1 (V3.1 Jul 18): Immunological testing of entitled individuals. The relevant sections are:

> 1. The Armed Forces (AF) has a duty of care to protect Service Personnel (SP) and entitled individuals from preventable diseases. Vaccines are safe and effective medical products available to protect against certain infectious and communicable diseases. This leaflet adds direction to existing national guidance in the context of Defence environment and is to be used in conjunction with the Public Health England and Department of Health Immunisation Against Infectious Disease electronic Green Book1 which is continuously updated.

Consent to vaccination

> 12. Vaccination may only be given with valid consent. Attendance by SP on a parade which they have been ordered to attend does not in itself constitute consent.
>
> 13. For consent to be valid it must be voluntary and informed and the person consenting must have the capacity to make the decision. Detailed guidance is available in the electronic Green Book.

14. Consent is to be sought and recorded at each vaccination visit, ensuring the individual is informed of any new information. There is no requirement for consent to be in writing.

15. Time for gaining consent is to be taken into account when planning vaccination clinics so that personnel have adequate time to study information material and ask questions.

26. It is sometimes necessary to use vaccines beyond the scope of their UK licence, and in some cases to use products which are not licensed for use in the UK. Additional guidance is available on the Service policy on the use of unlicensed preparations and off-label prescribing.

In JSP 950 Part 1 Leaflet 9-3-3 (V1.2 Jan 17), use of unlicensed and off-label medicines within the MOD is covered. There is a specific section outlining the clinician's responsibility.

21. Medical and non-medical prescribers must:

a. Be satisfied that there is sufficient evidence or experience to demonstrate the safety and efficacy of the medicine.

b. Take responsibility for prescribing the medicines and reviewing the patient's care, monitoring and any follow-up.

c. Make a clear and accurate record of any unlicensed medicines prescribed and the reasons for prescribing them.

d. Discuss with the patient or carer the reasons for using an unlicensed medicine including potential side effects. Ensure informed consent is documented.

e. Provide a DMS Unlicensed Medicines Patient Information Leaflet.

f. Review the patient's requirement for an unlicensed product, at least every six months, on change of assignment (particularly overseas or from one overseas location to another), on operational deployment or standby for operational deployment and on transfer of care from the DMS to the NHS or other provider.

g. Articulate accurately the specification of the product required. In conjunction with Pharmacy **staff**, justify why the product is required.

h. Report any adverse events in accordance with paragraph 37 of this policy.

There is also a specific section in JSP 950 about recording any adverse effects.

28. Vaccine associated adverse events are to be recorded in the individual's electronic health record and reported to the Medicines and Healthcare Regulatory Agency via the yellow card system23. Where the adverse event is significant a patient safety incident report is to be raised via the Automated Significant Event Reporting (ASER) system.

Further guidance specific to any new treatment that would be seen as experimental is provided by JSP 536: Governance of Research Involving Human Participants. This sets out the MOD's process for the assessment and approval of research protocols involving human participants. It provides instructions and guidance for all personnel involved in sponsoring, funding, managing, reviewing and utilising research involving human participants that is funded by MOD or involves MOD staff/entitled dependants.

Of particular relevance to your FOIA request is Principle 10 - Choice:

Research participants are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless MOD Research and Ethics Committee agrees otherwise. Where participants' explicit consent is sought, it is voluntary and informed. Where consent is refused or withdrawn, this is done without reprisal.

If you have any queries regarding the content of this letter, please contact this office.

If you wish to complain about the handling of your request, or the content of this response, you can request an independent internal review by contacting the Information Rights Compliance team, Ground Floor, MOD Main Building, Whitehall, SW1A 2HB (e-mail CIO-FOI-IR@mod.uk). Please note that any request for an internal review should be made within 40 working days of the date of this response.

If you remain dissatisfied following an internal review, you may raise your complaint directly to the Information Commissioner under the provisions of Section 50 of the FOIA. Please note that the Information Commissioner will not normally investigate your case until the MOD internal review process has been completed. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF. Further details of the role and powers of the Information Commissioner can be found on the Commissioner's website at https://ico.org.uk/.

Yours sincerely,

Joint Medical Group