



Office of Hon Dr Jonathan Coleman

Minister of Health
Minister for Sport and Recreation
Member of Parliament for Northcote

14 FEB 2017

Ref: H201604827

Dear [REDACTED]

Response to your request for official information

Thank you for your request of 1 December 2016 under the Official Information Act 1982 (the Act) for

“Further to my FOIA request, I would like to ask for some clarification.

- 1. Could you please elaborate on my FOIA request as to what is meant by “prolonged fatigue-like condition,” whether the term was used in the original reports and what “depersonalisation” means which is also listed as an adverse event.*
- 2. I would also like to request a copy of all adverse reports in CARM’s database, for any medicine submitted to CARM, that specifically included the term “prolonged fatigue-like condition” in the report to CARM.*
- 3. What is the medical or CARM followup, for the adverse events listed in the second attachment and how long are they monitored for? If they do not resolve, what protocol or system is then activated to address this?”*

I will respond to each of your points in turn.

Part 1 The terms prolonged fatigue-like condition and depersonalisation

Reports of suspected adverse reactions to medicines submitted to the Centre for Adverse Reactions Monitoring (CARM) are entered into a database. In order to do this the information in the report is transcribed into data fields. These fields have standard options from which the transcriber can choose. In the case of the reported suspected adverse reaction a standard medical dictionary is used, either WHOART or MedDRA. These dictionaries contain a list of medical terms, they do not include definitions. In some instances published clinical consensus definitions may be used to assist in deciding the appropriateness of a term. The transcriber chooses the closest term in the dictionary to match the information in the report. In some cases the exact term is available and in other cases a similar term has to be used, or a new term introduced and linked to the closest existing term. The use of standard terms allows (similar) cases to be retrieved from the database for detection of possible safety concerns and evaluation of these concerns.

Therefore, there is no exact definition of these terms. The terms are used to group similar reports together for the purposes of review (using the original reports) to detect safety concerns.

Part 2 Request for a copy of all adverse reports in CARMs database with prolonged fatigue-like condition as the adverse reaction

Please find attached a report containing information on cases where the suspected adverse reaction was *coded/assigned* as prolonged fatigue-like condition when entered into the CARM database. This report covers the period 1 April 1965 to 31 December 2016. Please note that '*' denotes the medicine suspected of causing the reaction.

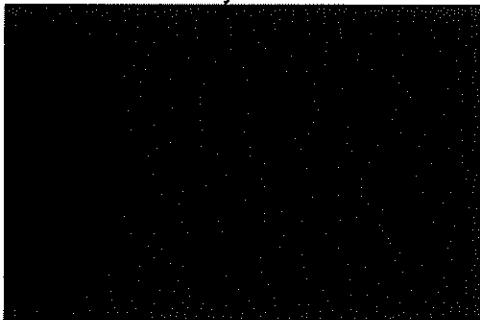
Individual case details have been withheld under section 9(2)(a) of the Act to protect the privacy of natural persons. The withholding of the private details is not outweighed by other considerations which render it desirable, in the public interest, to make this information available.

Part 3 Follow-up of cases reported to CARM

Reporting of suspected adverse reactions to CARM by healthcare professionals and consumers is voluntary. At the time the report is entered into the database further information may be requested to assist in understanding the clinical presentation in relation to the medicine exposure. However, it is up to the reporter whether they respond or not. Similarly if further information on a case becomes available to the reporter it is their decision whether they update CARM. The CARM system is not a clinical study but a method of trying to detect potential problems quickly. The clinical information around these safety concerns such as treatment and recovery are best investigated in clinical studies. The patient-specific clinical support is managed by the clinicians caring for the patient.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely



Prolonged Fatigue-Like Condition

Cases reported to CARM – 01 April 1965 to 31 December 2016

This listing includes all cases, irrespective of causality, where the Adverse Event term Prolonged Fatigue-Like Condition has been assigned.

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
114741	DEC2014	Female	78	* ADALIMUMAB	SJOGRENS SYNDROME PROLONGED FATIGUE-LIKE CONDITION COUGHING URINARY TRACT INFECTION DYSAESTHESIA
117069	JUL2015	Female	12	* HPV-1 VACCINE HPV-2 VACCINE HPV-3 VACCINE	NAUSEA HEADACHE PROLONGED FATIGUE-LIKE CONDITION JOINT PAIN HYPOTENSION ORTHOSTATIC
120504	APR2016	Female	15	* HPV-1 VACCINE * HPV-2 VACCINE	FEVER HEADACHE ARM PAIN PROLONGED FATIGUE-LIKE CONDITION IRRITABLE BOWEL SYNDROME
121222	JUN2016	Female	12	* HPV-3 VACCINE HPV-2 VACCINE HPV-1 VACCINE	FATIGUE DIZZINESS PROLONGED FATIGUE-LIKE CONDITION
073733	OCT2006	Male	3	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION
073734	OCT2006	Male	6	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION
073800	NOV2006	Female	14	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION
073852	NOV2006	Male	12	* MENINGOCOCCAL B	IMMUNOGLOBULINS DECREASED NAUSEA PROLONGED FATIGUE-LIKE CONDITION
073856	NOV2006	Male	14	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION
073887	NOV2006	Male	13	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION
074006	NOV2006	Male	11	* MENINGOCOCCAL B	RENAL FUNCTION ABNORMAL SYNCOPE HEADACHE TIREDNESS PROLONGED FATIGUE-LIKE CONDITION
074108	DEC2006	Male	14	* MENINGOCOCCAL B	SWEATING INCREASED HEADACHE ABDOMINAL PAIN PROLONGED FATIGUE-LIKE CONDITION
074200	DEC2006	Male	15	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION

Prolonged Fatigue-Like Condition – Cases received 1965 - 2016

<u>Report No</u>	<u>Date</u>	<u>Gender</u>	<u>Age</u>	<u>Medicines/Vaccine</u>	<u>Reactions</u>
074279	JAN2007	Female	18	* MENINGOCOCCAL B INSULIN ASPART INSULIN ISOPHANE	PROLONGED FATIGUE-LIKE CONDITION
074322	JAN2007	Female	17	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION
074873	MAR2007	Male	14	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION
074938	APR2007	Female	13	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION
082043	NOV2008	Female	14	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION INJECTION SITE INFLAMMATION
084600	MAY2009	Female	16	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION
086253	SEP2009	Female	917	* MENINGOCOCCAL B	PROLONGED FATIGUE-LIKE CONDITION SERUM IRON DECREASED
109562	JAN2014	Male	14	* MENINGOCOCCAL C CONJUGATE	BLOOD PRESSURE FLUCTUATION MIGRAINE PROLONGED FATIGUE-LIKE CONDITION MENINGOENCEPHALITIS FIBROMYALGIA

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