Supplementary written evidence submitted by Trixie Foster

REVIEW OF THE THIRD SESSION, THE DEFENCE SELECT COMMITTEE LARIAM INQUIRY, 12 JANUARY 2016

Questions 145-235

On 12 January the Defence Select Committee held the third Meeting for the Lariam Inquiry..

I have stated the conclusions that I have deduced from the Transcript in the introduction. Due to the importance of the JSP (Joint Service Publication) 950 I have referred to it many times. It has been necessary to highlight certain points and to be repetitive with some of the information.

REVIEW

Crucial to the outcome of the evidence given is the fact that when service personnel are deployed medical decisions that are usually directed by the Defence Medical Services, and ultimately the Surgeon General, are superseded by the Chain of Command in the Field. [i] Therefore in this situation i.e. in the theatre of conflict or war it is an administrative issue rather than a medical one and it is this that means service personnel can be put on orders if they refuse to comply with their Commander's directive. This is set out in JSP 950 3-3-1.

The witnesses were the Minister of Defence Personnel & Veterans, Mark Lancaster (referred to as The Minister), the Surgeon General, Rear Admiral Alasdair Walker (referred to as The Surgeon General), Surgeon Captain John Sharpley (referred to as the Surgeon Captain), and Brigadier Timothy Hodgetts (referred to as the Brigadier).

I have included sections of JSP 950 to illustrate where the Defence Medical system is compromised.

Q154

Mrs Moon: Do the other anti-malarials that you are utilising have significant psychiatric side effects as Lariam does?

Surgeon General: ***Some have a degree of psychiatric side effects, although perhaps not as marked as is reported for Lariam'***.

TF: If this is the case that some personnel could be affected by Lariam then the question must be asked why is it still being used?

Q157

Mrs Moon: But there is no geographical area where it is essential that Lariam is used?

Surgeon General: ***There is no geographical area where it is absolutely essential. It is only if people cannot take other drugs, for whatever reason***.

TF: In the Eire Army if a soldier is not able to tolerate Lariam he is not deployed.

Q159

Mrs Moon asks the Surgeon General to supply the Committee with the percentages that each anti malaria drugs are allocated.

TF: It is extremely important for the Committee to receive this information. The HQ for the Military Medical Supplies is now centralised at Donnington Shropshire. See Q166

Q160

TF: The Surgeon General is implying that it is only because Lariam is being discussed in the media and people are being made aware of it that it appears to have more adverse side effects. By default if the media is writing about Lariam surely the other 99% have the opportunity to refute this and state that Malarone and doxycycline have produced equally acute side effects.

Q161

Jim Shannon: Lariam wouldn't be used because it's the cheapest, would it? Is that why it has been used?

TF: The Surgeon General's calculation is not correct. With his calculation based on an eight week supply and MOD prices:

Lariam is £14.53 given weekly.

Doxycycline is £47 given daily.

Malarone is £119.00 given daily

For some reason the Surgeon General when he gave evidence quoted for 12 days and quotes £25.21. I would be very much surprised if cost does not come into it as the Procurement Department of the MOD is always looking at this and **Lariam is 8 times cheaper than Malarone** on their own calculations.

Q162

The Brigadier implies that they adhere to the ACMP Guidelines implicity. As confirmed by Dr Kirkbride in the email to Trixie Foster this is not the case. This was stated at Evidence given to the Committee on 8th December 2015.

Q163

Jim Shannon: ….Can you focus a bit more, not on whether Lariam should be banned worldwide – because no one is suggesting that – but on the question of whether this drug that can be used with the safeguards that its own manufacturers say must be followed if serious adverse consequences are not to follow?

TF: The DMS puts guidelines out which covers themselves to a degree where in theory they say they comply with the Guidelines put in place by the Manufacturers Roche, but it is not possible to adhere to these Guidelines when the DMS in deployment situations come under the command of the Army Commanders. (see JSP 950 3-3-1 Chain of Command -7, 8) [ii]

The side effects listed for Malarone are distinctly less adverse than Lariam

Q164

TF: No individual risk assessment can be thoroughly completed by filling in a computer questionnaire, or taking information from a medical records database where it will not be a comprehensive report and nowhere is direct family history included which the ACMP recommend is taken into account when completing an individual risk assessment.

Q165 (Jim Shannon)

Witness Brigadier: There is no body of evidence to suggest that a non-immune UK civilian traveller is any different to a non-immune UK military traveller in terms of how they will react to individual drugs.

TF: The implication is that due to Malarone and Doxycycline being taken daily a soldier will not comply with manufacturer's instructions and take the drug. Lariam is only taken weekly so they can get a group to take it on a certain day. There are definitive differences between a civilian being given a particular drug and military personnel due to deployment et al. This was referred to in the Meeting 8th December when the MOD had quoted Chapter 3 (Civilians) US CDC 'Yellow Book' 2016 when in fact they should have referred to Chapter 8 US CDC 'Yellow Book' 2016.[iii]

Q166

TF: I have been in contact with the QM Regimental Sgt Major (retired) who was in charge of 84 Medical Supply Squadron, and Medical Logistics & Warehouse Management 1999-2004. He confirmed that Lariam was supplied especially for the Second Iraq War in 2003. When I tried to contact him again he was 'unavailable'. I have his address at his present employment. The HQ Medical Supplies is now at Donnington Shropshire and all records would have been transferred there so information on percentages of each drug supplied should be fairly easy to acquire. The name of the former QM Regimental Sgt Maj could be supplied.

Q167-Q175

TF: The Surgeon General or the Minister cannot categorically say that an individual risk assessment would be carried out as the Directives of the Defence Medical Services would be superseded by the Chain of Command as stated in JS 950.[iv]

JSP 950 3-3-1 Last revised January 2013

CHAIN OF COMMAND

7. 'Whilst the Defence Medical Services acknowledge their ownership of the specialist information that forms the basis of the policy, **they have no executive control over its implementation. That responsibility lies with commanders. It may be inevitable that, in order to achieve the mission, a course of action is chosen that precludes complete compliance with the protection measures outlined in this policy letter'.**

8. The Chain of Command is to identify where compliance cannot be achieved for operational reasons and is to acknowledge the risk that needs to be managed. Under these circumstances it is the responsibility of medical personnel to support the Commander fully by developing appropriate contingencies to minimise the effects of any future malarial outbreak. In the context of force protection, the chain of command is ultimately responsible for the implementation of malarial protection measures but individual compliance is paramount if the policy is to be effective.

It was very apparent from the Surgeon General's response that since 1997 Mefloquine had been singled out as a drug with 'neuropsychiatric reactions, dizziness, bad dreams et cetera' and warnings that personnel who had a history of fits, epilepsy or psychiatric disturbances should not take it.

Q184

Phil Wilson: *This is to the Surgeon General. Does the final responsibility for individual risk assessments rest with you?*

Surgeon General: *At the end of the day, I am the person who signs off the policy and therefore I have the final responsibility.*

This cannot happen when troops are going on deployment and when they will be given anti malaria drugs. REFER to JSP 950. The Surgeon General can be overridden by the Commander in place. See response to Q167-Q175

Q188

Douglas Chapman: *Previous witnesses have highlighted the fact that there are numerous challenges to military physicians being compliant with the prescription of Lariam. Typically, how long do the individual risk assessments take to carry out, and how does the impact on the ability to deploy significant numbers of troops at very short notice?*

TF: Pre-deployment individual risk assessments of a Battalion (600-720 men) would take 300-360 hours. This would simply be 37-45 days (8 hours). As there has to be more than one MO to carry out these assessments and, it would take one about 6 weeks or 6 trained personnel a week to commit themselves. This is <u>not</u> feasible as stated in the US CDC 2016 Yellow Book Chapter 8. The MOD have also quoted the Yellow Book so accept that the Yellow Book is fit for purpose with their professional information.

Brigadier Hodgetts eludes to that an individual assessment is done on the patient notes, which can be abridged or incomplete rather than an individual as such.

Q191

TF: Individual risk assessments CANNOT be guaranteed as commands can be superseded as referred to in JSP 950 (3-3-1 25, c,d Prescribing Group Direction)

Q194

TF: This is a very naïve answer believing that troops do not and did not have access to alcohol. They are very clever at 'hiding' alcohol when deployed. We have actual stories of how this was carried out in the Middle East e.g secured down the barrels of guns on tanks,

hidden in cans of Coca Cola and spirits(whisky etc) sent out by family and friends in parcels in shampoo bottles)

Q198

Ruth Smeeth: *Moving on to the use of Lariam by the military, Dr Nevin, from whom we took evidence and whom many of us have cited, argues that Lariam can 'adversely alter patterns of dreaming and significantly reduce overall sleep duration ….despite broad military acknowledgement of the importance of sleep hygiene'. Do you agree that such side effects are incompatible with deployed servicemen?*

Surgeon Captain: *There is no doubt that Mefloquine has this effect on some people, that the side effects are there and sleep disturbance is one of them, but it is common. I think we have probably all experienced sleep disturbance. I certainly had it last night'.*

TF: I find the response of the Surgeon Captain undiplomatic at best when it is recognised that there are Serving personnel and Veterans who are experiencing daily acute frightening nightmares including Lt Col Andrew Marriott who gave evidence on 8th December 2015. The adverse effects of Lariam should NOT be taken lightly. The Surgeon Captain may consider re-evaluating his observations regarding his routine dreams and the life threatening events these Lariam nightmares can cause.

Chair: *May I interject at that point? Were a soldier to say that he or she did not wish to take Lariam ……would he or she be offered an alternative anti-malaria drug on request?*

Brigadier*: I think the answer to that is yes. If an individual said in the consultation that they did not want to take a particular drug and that they are tolerant of the other available effective drugs of course an alternative can be offered.*

TF: I find that this response cannot be guaranteed as mentioned previously to JSP 950 3-3-1

Q210-214

Chair: *…given the history of controversy of Lariam, if in future it was handed out to serving personnel with some sort of label or warning stating, 'This drug can cause serious side effects for some people. If you do not wish to take it, ask for an alternative'.*

TF: As we are aware we do not read the Patient Information in the box and service personnel would not either. A warning on the front of the box as suggested by the Chairman would be an excellent idea.

Surgeon General: *I am not for prescribing things that people do not want to take. I cannot do that; it is against medical ethics. It is the same for any drugs. If a patient says 'I do not wish to take this', I have to respect this.*

TF: The Surgeon General would not be able to adhere to medical ethics when on deployment according to JSP 950 when he can be overridden by the Chain of Command.

Q217

TF: The Minister's response that he will 'happily engage with them' has not happened in the last two and half years I have been helping the Group. I have requested information from the

previous Minister Anna Soubry and Mark Lancaster and it has always been re-directed to the Surgeon General Secretariat.

Q221

TF: The Brigadier does not mention the CDC recommends the US army to use Malarone as their first choice.

Q228

TF: The Brigadier implies that it is bad publicity, and media coverage that is causing countries to push Mefloquine 'down the batting order' and not clinical issues. It is interesting that no one mentions the other anti-malaria drugs

CONCLUSION

Due to the certainty that no one in an authoritative position such as the Surgeon General or the Minister of Defence Personnel and Veterans can categorically guarantee the safety of Lariam due to the fact that their instructions can be overridden by the Chain of Command in the Field and that individual risk assessments cannot be carried out each time then Lariam should not be used and withdrawn completely from use. One life put at risk is one too many.

- The Surgeon General cannot guarantee that service personnel can refuse to take Lariam and request another drug as he has to comply with the JSP 950 directive[v]
- There is nowhere that it is stated that a MO can override a command. Therefore the Surgeon General cannot guarantee that an MO adheres to his medical ethics.
- Cannot guarantee the Individual will get an individual stringent risk assessment
- Cannot guarantee that Mefloquine is given by someone that is legally permitted to.
- Cannot guarantee that an individual can refuse to take Lariam or any other chemoprophylaxis and request another and not be put on Orders.
- Cannot guarantee that if an individual reports adverse effects that it is reported and the symptoms and condition of the individual is addressed.

The Surgeon General maintains Lariam must be one of the drugs to combat malaria. In fact this is not necessary and the other drugs do not have the acute adverse effects which can affect some personnel that take Lariam.

- Dr Remington Nevin has reiterated (8th December 2015 Inquiry Meeting)that there is nowhere in any Malaria affected regions worldwide that Mefloquine and only Mefloquine has to be taken.

There is/would be a distinct breach of Duty of Care if Lariam is prescribed in the future (as of 12th January 2016) to any service personnel when the Surgeon General Secretariat and the Minister of Defence Personnel & Veterans knowingly disregard the implications and do not instigate the withdrawal of Lariam (Mefloquine) from the Ministry of Defence Pharmaceutical list immediately from being prescribed to personnel where their complete safety from life threatening adverse effects cannot be guaranteed.

ADDENDUM

Ad Hoc Statistical Bulletin submitted by the MOD for the Defence Select Committee, 12 January 2016 – this is very important

This paper was submitted to the Defence Select Committee on the day of the Inquiry and we have just received it. Lt Col Andrew Marriott and Dr Jane Quinn who have already submitted their reviews of the Transcript would like to bring to your notice that the MoD does not follow ACMP advice and it is unable to confirm what prophylaxis has been given to thousands of personnel.

Under the heading 'Deployment' you will see a focus on mefloquine/Lariam use in Afghanistan, an odd theatre on which to focus as Lariam, Doxycycline and Malarone are not ACMP recommended prophylaxes for that region. The mantra that the MoD follows ACMP advice is simply not correct. It seems extraordinary that at least 7,000 were not prescribed the ACMP recommended Chloroquine plus Proguanil. Quite why so many prescriptions appear to be inconsistent with ACMP advice remains to be explained. 7,000 seems to be a rather large figure for those that might be expected to be intolerant to Chloroquine and Proguanil.

Vitally, the MoD is also unable to confirm what drug was given to almost 13,000 individuals in Afghanistan. This exceptionally high figure appears to confirm that anti-malarials were being issued without prescription or appropriate recording. These people may never know if they carry the risk of Lariam toxicity. Presumably the MoD's knowledge of what has been prescribed in high-risk malarial areas such as sub-Saharan Africa may be equally poorly informed.

22 January 2016

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[i] https://www.whatdotheyknow.com/cy/request/169307/response/416124/attach/html/3/JSP%20950%203%203%201%20Preventing%20Malaria%20in%20military%20Populations%20v5%20Jan13%20Final.pdf.html CHAIN OF COMMAND

[ii] https://www.whatdotheyknow.com/cy/request/169307/response/416124/attach/html/3/JSP%20950%203%203%201%20Preventing%20Malaria%20in%20military%20Populations%20v5%20Jan13%20Final.pdf.html

[iii] http://wwwnc.cdc.gov/travel/yellowbook/2016/advising-travelers-with-specific-needs/special-considerations-for-us-military-deployments

[iv] https://www.whatdotheyknow.com/cy/request/169307/response/416124/attach/html/3/JSP%20950%203%203%201%20Preventing%20Malaria%20in%20military%20Populations%20v5%20Jan13%20Final.pdf.html

[v] JSP 950 3-3-1 nos 28,29 COMPLIANCE