STANDING COMMITTEE ON PUBLIC ACCOUNTS

COMITÉ PERMANENT DES COMPTES PUBLICS

EVIDENCE

[*Recorded by Electronic Apparatus*]

Thursday, November 18, 1999

• 1532

[*English*]

The Vice-Chair (Mr. John Richardson (Perth—Middlesex, Lib.)): Could I have your attention, please? The witnesses are here and we have a quorum.

It's my pleasure to welcome the witnesses to the public accounts committee. We will have a series of questions going back and forth according to the side of the government or the opposition. In this case, we will be starting the questioning with an opposition member, Mr. John Cummins.

I would first ask General Auger to introduce the people from DND.

For those from Health Canada, Mr. Michols, would you follow the same suit after General Auger finishes introducing the members from the Department of National Defence?

Brigadier-General Claude Auger (Surgeon General and Commander, Canadian Forces Medical Group, Department of National Defence): Mr. Vice-Chairman, members, I'm General Claude Auger. I'm the surgeon general for the Canadian Forces. With me is Lieutenant-Colonel Greg Cook. He is in our section of medical policy and is our specialist in occupational health.

Mr. Dann M. Michols (Director General, Therapeutic Products Directorate, Health Protection Branch, Department of Health): I'm Dann Michols, the director general of the therapeutics products program within Health Canada. With me is Ian MacKay, who is an officer working within the clinical trials and special access unit of my organization.

The Vice-Chair (Mr. John Richardson): Thank you very much.

We'll begin the meeting with Ms. Maria Barrados leading off with her position.

Ms. Maria Barrados (Assistant Auditor General, Office of the Auditor General of Canada): Thank you, Mr. Chairman. I have Mr. Ronnie Campbell with me from my office today.

Thank you for this opportunity to present the results of the audit note in our April 1999 report. This note deals with procedures concerning the pre-licensing use of an anti-malarial drug, mefloquine, by Health Canada and National Defence.

This issue has been raised in media reports and in the House, as well as in letters to the Auditor General. Our usual practice in response to public and parliamentary concerns is to review them carefully and make some preliminary inquiries. If necessary, we conduct an audit if we feel it is a matter that is significant enough to be brought to Parliament's attention. That was the course we took in this case, resulting in the preparation of an audit observation.

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Mefloquine is recommended by the World Health Organization and others for use against some types of malaria that have become resistant to other drugs. Although licensed in a number of countries since the late 1980s, it was not licensed in Canada until January 1993. Prior to that time, it was available only through special programs.

In 1992, National Defence obtained the unlicensed anti-malarial drug through a clinical trial for use with Canadian Forces personnel being deployed to Somalia.

Health Canada licenses manufacturers to produce and sell drugs that have been demonstrated to be safe and effective. Only licensed drugs can be sold in Canada, except under specific controlled conditions. It was under such a set of conditions—a “clinical trial”—that National Defence obtained mefloquine. The study design and protocol governing this trial must be approved by Health Canada.

[*Translation*]

The study protocol specified the investigators' responsibilities, including keeping accurate records of dispensing information and reporting all adverse drug reactions. It stipulated that informed consent was to be obtained from all participants—soldiers, in this case—and specified that "safety data will be collected and efficiency will be monitored for each subject receiving mefloquin". All data were to be provided regularly to the manufacturer.

Mr. Chairman, let me say that we don't question whether the drug should have been given to the soldiers—they had to be protected from malaria. The problem is that National Defence did not follow the prescribed safety-monitoring study protocol for mefloquin in the fall and winter of 1992-93 when the drug was distributed to about 900 soldiers deployed on a peacekeeping mission. This happened even though the department had followed all the rules in earlier distribution to National Defence travellers.

In concrete terms, not following the protocol means that:

Canadian Forces members were given an oral briefing on malaria, mefloquin and the possible side effects, but did not get the written documentation given to other DND travellers who received the drug;

The Department did not systematically monitor efficacy or adverse reaction for each person receiving the drug;

And although 69,000 doses of the drug had been provided to the Canadian Forces unit in Petawawa, records of their use and adverse reactions or side effects were not reported.

[*English*]

DND officials told us the reason they did not follow the protocol was that they believed they had received authorization from Health Canada to follow a different set of procedures that would not require informed consent. However, this was not the case. No such approval had been sought or obtained by National Defence.

National Defence has since implemented some organizational changes that it believes will minimize the likelihood of this happening again. Mr. Chairman, your committee may want to obtain further information about these organizational changes.

In situations in which unlicensed drugs are being dispensed through clinical trials, Health Canada has the responsibility to review and approve the study design and protocol. It needs to assure itself that conditions of clinical trial protocols are being met, in order to preserve the integrity of the process and to satisfy conditions set out under the food and drugs regulations.

We are concerned about the fact that although Health Canada had approved the protocol for the mefloquine safety monitoring study, it took no steps to ensure that it was followed. In fact the department has no procedure for monitoring these studies. We were told that monitoring was the responsibility of the manufacturer. Mr. Chairman, your committee may wish to ask Health Canada officials how they assure themselves that the protocols for safety and monitoring studies are followed.

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When the use of the drug by Canadian soldiers in Somalia became a media issue in the fall of 1994, Health Canada asked the manufacturer for copies of the records of the 69,000 doses of mefloquine provided to National Defence in 1992. Neither the manufacturer nor DND could provide the information. Nevertheless, Health Canada took no further action.

The failure of Health Canada to monitor the study and the failure of National Defence to provide the manufacturer with the data mean that potentially valuable information about the safety or effectiveness of the drug under “field” conditions was not collected.

Mr. Chairman, there is a need to strengthen measures for ensuring compliance with the approved protocols for clinical trials.

Mr. Chairman, that concludes my opening statement. We would be pleased to answer your committee's questions.

The Vice-Chair (Mr. John Richardson): Thank you very much, Ms. Barrados.

I would now invite the questions to begin, and the lead questioner will be John Cummins, from the Reform Party.

Ms. Beth Phinney (Hamilton Mountain, Lib.): Mr. Chairman, would it be possible to hear all of them before we begin questions?

The Vice-Chair (Mr. John Richardson): Did you want to take that procedure?

An hon. member: Yes.

Ms. Beth Phinney: Yes, that's how we usually proceed.

The Vice-Chair (Mr. John Richardson): Okay, then I gather we will move right to Health Canada and the next speaker, Mr. Michols.

Ms. Beth Phinney: Mr. Chairman, do we have their report?

The Vice-Chair (Mr. John Richardson): Yes.

Ms. Beth Phinney: From Health Canada?

The Vice-Chair (Mr. John Richardson): It's tabled, yes.

Ms. Beth Phinney: I have National Defence, not Health Canada. Is that it?

I don't have it. I was told earlier that it hadn't arrived.

Oh, here it is. Thank you.

The Vice-Chair (Mr. John Richardson): Mr. Michols.

Mr. Dann Michols: Thank you.

Mr. Chairman, I would like to begin by thanking you and the committee for the opportunity to speak on the issues raised by the Auditor General in his audit note,

published in April of this year, concerning the pre-market availability of Lariam, or mefloquine, its generic name.

As I mentioned earlier, I am the director general of the therapeutics products programme. I do not have Ms. Marta Caris with me today—she could not be here for personal reasons—but with me is Ian MacKay, who is responsible for the special access program within my organization.

For your information, the therapeutic products programme is the organization within Health Canada that is responsible for regulating the drugs and medical devices used by Canadians.

As you heard, the Office of the Auditor General conducted an audit of Health Canada's records relating to the Lariam safety monitoring study, as well as the review and approval of Lariam. In addition to their extensive review of our files, representatives from the Auditor General's office had numerous meetings with Health Canada officials to clarify issues related to drug development, the regulatory mandate of the department in the area of clinical trials, and the drug assessment process in general.

As mentioned earlier, Lariam has been and continues to be recognized as the drug of choice for the prevention and treatment of chloroquine-resistant malaria, a form of malaria resistant to most other drugs. It is recommended by the Canadian Committee to Advise on Tropical Medicine and Travel, the American Centers for Disease Control and Prevention, and the World Health Organization. It is noteworthy that the statistics in the open literature estimate that malaria remains one of the world's biggest killers, accounting for over 2 million deaths per year. In Canadian travellers, the malaria-associated morbidity and mortality has increased substantially over the last several years.

In 1990, Health Canada recognized the value of Lariam against malaria and sought to ensure that Canadians had access to this important drug by working with the manufacturer to sponsor a special clinical trial. This trial, which became known as the Lariam safety monitoring study, was a mechanism to provide access to the drug for Canadians travelling to countries where malaria was prevalent. The SMS was approved in 1990, and it closed in the spring of 1993.

When Health Canada issued a notice of compliance for Lariam—a notice of compliance is the marketing authorization in Canada—in January 1993, we received a comprehensive data package that included data from well-designed controlled clinical trials. Furthermore, there were significant international data and case reports of adverse drug reactions from many countries where Lariam been on the market for a number of years, including countries such as the United States and the United Kingdom. This data, when considered together, fully supported the claim that the benefits of Lariam outweighed the risks.

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Mr. Chairman, I now want to turn to some specific points that the Auditor General raises in his audit note on Lariam. To begin with, I believe it might be helpful to take a moment or so to briefly describe Health Canada's role in the area of clinical trials, and also to describe the necessary partnership that must exist with other members of the health care community.

In a general way, drug development relies on an effective partnership between Health Canada as the regulator, the pharmaceutical industry, physicians and other health care professionals, and the institutions within which research is conducted, as well as with the patients themselves. Within this partnership, Health Canada is responsible for ensuring that clinical trials are designed according to national and international scientific and medical standards, and that the patients are not exposed to undue risks.

The actual responsibility for conducting trials rests with the sponsor of the trial—usually the manufacturer, but not always, as it's sometimes a research institution—with physicians, with health care professionals, and with research institutions. To assist researchers and sponsors, Health Canada provides specific guidance on how trials should be conducted and on how to define and report adverse drug reactions.

Turning to the specific issue of the use of Lariam by the Department of National Defence, in 1994, when Health Canada became aware that Lariam may have been used by DND outside of the prescribed auspices of the safety monitoring study, the department took immediate action by requesting that the sponsor confirm that it had provided Health Canada with a complete record of the use of Lariam by the Canadian Forces under the SMS, and also a complete listing of all adverse drug reactions that may have been reported.

Ultimately, after a number of attempts, this information was not provided to us simply because the Department of National Defence did not dispense, use, or gather information on the drug pursuant to the SMS protocol. As noted by the Office of the Auditor General, DND used and obtained Lariam under the mistaken presumption that it had special permission to use the drug outside of the SMS. The Auditor General notes that Health Canada took no further action at that time. This is true, but primarily because there was no further action to be taken.

Clearly, Health Canada was convinced that since the SMS had long since concluded, the prescribing information reflected the worldwide experience with the drug at that time. The weight of evidence available supported the existing risk-benefit profile for Lariam; in other words, we had already approved the drug for the Canadian market.

The Auditor General raises a valid point in that Health Canada needs to assure itself that the conditions of clinical trials are met in order to preserve the integrity of the process and to satisfy conditions set out under the Food and Drugs Act and the Food and Drugs Regulation. In fact, Health Canada does monitor adverse drug reactions submitted by the sponsor of a clinical trial through the course of that clinical trial. Health Canada also has the authority to stop a trial in progress if we feel it is justified and if it is in the interests of public health to do so.

The Auditor General raised another valid point when he stated that the unreported results of the use of Lariam could mean that the drug was approved without knowledge of important real-world data. In fact both the review of Lariam for marketing and the subsequent safety updates contained international post-marketing data. This was real-world data, if you will. It confirmed that the side-effect profile was relatively consistent.

So while you may have the impression that we did not take this kind of data into consideration, the opposite is in fact true. We did take it into account at the time of marketing authorization, and we continue to do so as part of our post-marketing activities.

Mr. Chairman, I also want to say that Health Canada has confidence in the partnership it has with clinical trial sponsors and physicians. Our current practices have ensured that Canadians have timely access to new and promising drugs through clinical trials and, at the same time, that patients are treated by professionals who are trained, who have the experience, and who have the skills to conduct clinical research in accordance with Research Ethics Board standards and national and international guidelines.

We are in the process of considering several reforms to the clinical trial review process, partly as the result of the observations of the Auditor General. These reforms will increase the protection of research subjects participating in clinical trials and will implement more efficient review processes.

The proposed reforms will include development of an audit system of clinical trials with regard to compliance with international guidelines on the conduct of clinical

research. The implementation of an audit system will ensure that research in Canada is conducted in accordance with these high standards and increase the integrity of data generated in support of drug marketing applications.

• 1550

I should say that putting in place an audit system requires regulatory change, and our minister proposes within the next two months to bring forth those changes in regulations that will set up an audit program. So we are very close to having that in place.

I also want to mention that since the events of 1992 to 1994, Health Canada has developed a closer working relationship with the Department of National Defence. This new relationship is characterized by increased and clearer communications relating to the review and approval of clinical trials, as well as special access to new drugs or drugs that are not yet available on the market in Canada.

With respect to Lariam itself, I would like to say to this committee, and through you to all Canadians, that Health Canada is confident that the current prescribing information contained in the product monograph—and the product monograph is the instrument that we approve that contains all information about a particular product being marketed—reflects our current understanding of how Lariam can be used safely. We are confident that when used properly, Lariam is a drug that is safe and effective. While there are risks associated with even the proper use of Lariam, these are far outweighed by the benefits of being protected against a potentially fatal infection.

Mr. Chairman, that was the case in 1993 and 1994, and it is true today.

I wish to close by saying that Health Canada recognizes the need for critical assessment of its mandate and the efforts that we undertake to carry out that mandate in accordance with the expectations of Canadians and their representatives and world standards.

Health Canada wants to maintain its reputation as a world leader in the area of drug and medical-device regulation, and to that end we welcome the comments from the Auditor General and others in that effort.

Mr. Chairman, that concludes my opening remarks. At this point, I will be pleased to answer any questions that may be forthcoming.

The Vice-Chair (Mr. John Richardson): Is there anyone else who has a statement to make before the committee?

General Auger.

BGen Claude Auger: Mr. Vice-Chair, members, I will try in the next few minutes to explain to you why we use mefloquine, how we use it, what the results were, and what we have undertaken since for the future position of non-licensed drugs.

As mentioned before, malaria is a serious parasitic illness spread by mosquitoes. Falciparum malaria is the most dangerous form. As mentioned by Health Canada, there are, worldwide, 200 million to 300 million infected persons a year, and in Africa more than one million deaths a year.

The statistics that we have from 1997 for Canadian travellers show we had 1,036 cases of malaria, with four deaths.

[*Translation*]

When we prepared for the deployment in Somalia, the malarial infection risk was estimated at 2 to 3% per month. The Canadian Forces deployed 1,200 people in Somalia. Based on these statistics and very moderate evaluations, the number of malaria cases, if there was no adequate protection, could be situated at around 20 or more per month, in other words 120 cases over a six-month period. Moreover, there was an estimate of 1 or 2 deaths. It was very clear that protection was needed.

[*English*]

Mefloquine is a very effective drug against chloroquine-resistant falciparum malaria. It is recommended by Health Canada, the World Health Organization, the Centers for Disease Control and Prevention in Atlanta, and Health Canada's Committee to Advise on Tropical Medicine and Travel. In 1992 mefloquine was licensed in 29 countries with an established record of safety and efficacy. Until licensed in Canada on January 22, 1993, mefloquine was available to Canadian Forces members through the Lariam safety monitoring study. DND was enrolled from March 1991 to March 1993.

• 1555

How do we use it? Just before the deployment to Somalia,

[*Translation*]

the Health Protection and Promotion Branch of the Canadian Forces recommended the use of mefloquin to protect the troops during their deployment in Somalia.

Informed consent was not required. The Branch had the impression there had been contacts with Health Canada to obtain the authorization to use mefloquin without going through the control parameters of the study.

Briefing notes were prepared to inform the troops about the risks and the countermeasures in that environment as well as any possible diseases and the advantages and possible secondary effects of the mefloquin.

Briefing notes were distributed to reinforce the use of personal protection measures such as anti-mosquito creams, mosquito netting for beds and anti-mosquito dress. The drugs recommended for malaria were mefloquin and doxycyclin; mefloquin was preferable as it required only a weekly dose while you needed a daily dose of doxycyclin.

The distribution of mefloquin was recommended as well as a register of its use. Medical surveillance operations and accounting were demanded.

[*English*]

How was it monitored in the field? In Somalia, the field medical system included ship and unit medical officers, medical assistants in eight subunits, and a medical holding platoon, which included a surgical team. The unit leaders, medical personnel, and paramedical personnel were informed and vigilant for mefloquine and stress-related psychological side effects. The unit medical officers are normally always informed of significant medical problems or side effects, and they are aware

that NDHQ is to be notified in case of significant illness, injury, medical event, or side effects.

[*Translation*]

As for the efficacity of mefloquin, during the troop deployment in Somalia, the Canadian Forces only had one case of falciparum malaria. After, there were six vivax malaria cases declared after the deployment. The vivax malaria is far less dangerous. The efficacity rate was thus superior to the estimated rate of 95%.

During the deployment in Somalia, over 33,000 mefloquin doses were distributed to the deployed personnel. No significant neuropsychiatric effect due to the use of mefloquin was confirmed. No serious or unexpected effect due to mefloquin was identified. The secondary effects were relatively infrequent. Our documents mention 15 cases where mefloquin was replaced by doxycyclin because of intolerance for the former drug.

Let's summarize the events of the Somalia operation. The main airborne combat group was deployed in Somalia towards the end of December or beginning of January 1993. The mefloquin was approved in Canada on 22 January, 1993. The message from the Health Protection and Promotion Branch of the Canadian Forces was distributed on 24 March, 1993, giving a reminder about the restriction on the use of mefloquin and asking that a register of its use be maintained for six months. The troops redeployed in Canada in June 1993.

[*English*]

What have we done since that time to better control distribution of unlicensed drugs? We have a regulatory affairs position that has been established and serves as a single contact point with Health Canada, and better documentation of discussions with Health Canada. A requirement and procedure for acquisition, distribution, use, and recording of unlicensed medical products has been better confirmed by promulgation of a directive in July 1999. We are in the process of developing detailed drug and vaccine information sheets for the benefit of Canadian Forces health care providers and CF members. We are also in the process of developing an adverse effect monitoring and reporting database.

• 1600

In conclusion, Mr. Vice-Chairman and members, mefloquine was and is a safe and very effective anti-malarial drug. No new mefloquine safety or health concerns were observed during the Somalia deployment. Using mefloquine in our troops according to the standard field medical practices prevented cases of malaria, and neither the health nor the safety of Canadian Forces personnel were compromised.

Mr. Vice-Chairman and members, I will be pleased to answer questions.

The Vice-Chair (Mr. John Richardson): Thank you very much, General Auger.

Just to go over the protocol again, we will have two rounds. In the first round the questioners will have eight minutes, and in the second round they'll have four minutes. I'll begin with Mr. John Cummins from the Reform Party.

Mr. John Cummins (Delta—South Richmond, Ref.): Thank you very much, Mr. Chairman.

I'm going to be directing my questions to the high-priced help from the Department of National Defence. In their statement they said the health and safety of Canadian Forces officials were not compromised by the handling of this drug mefloquine in Somalia.

I challenge them on that issue and on several issues they've raised in their brief. I've been following this issue for close to five years now for three good reasons.

One reason is Private Kyle Brown. The second is Master Corporal Clayton Matchee, his wife, and his daughter. And the third is the late Corporal Scott Smith, and his mother, who was left childless because of the inaction of the Canadian Armed Forces.

I want to remind the gentlemen in green that I have the October 1997 departmental note to the defence minister advising that DND mislead the Somalia inquiry on the status of mefloquine, and advising him to mislead the public as to where DND got the drug. I have that memo.

Your responses have not been accurate. I think smoke and mirrors might be one term to describe them. But I'm going to give you a chance to set the record straight. I have a series of questions that I intend to ask you. They don't require much comment. In fact you can answer them with a yes or a no. We will keep score, and I'll let you know the score at the end.

Is it not true that Canadian soldiers deployed to Somalia were compelled to take an investigational drug, a drug that was under a clinical study approved by the health protection branch and governed by the Food and Drugs Act, that DND by law was obliged to monitor and did not monitor? Yes or no.

Mr. Hec Clouthier (Renfrew—Nipissing—Pembroke, Lib.): I have a point of order. Mr. Chair, I believe Mr. Cummins said that he had a confidential memo. I believe the committee should be able to see this confidential memo. Mr. Cummins is making a statement, and it's basically almost like the Spanish Inquisition with the military, saying, “I demand this, I demand that.” I believe the committee should be apprised of this confidential memo.

Mr. John Cummins: We can make that available, Mr. Chairman.

An hon. member: Before the question is answered.

Mr. John Cummins: Yes.

The Vice-Chair (Mr. John Richardson): Mr. Cummins, do you happen to have copies of it at all?

Mr. John Cummins: I do.

[*Translation*]

Ms. Marlene Jennings (Notre-Dame-de-Grâce—Lachine): In both official languages, please.

[*English*]

Mr. John Cummins: I have it in the language that it was written in.

Ms. Marlene Jennings: I have a point of order.

[*Translation*]

Mr. Chairman, it seems to me the committee had decided on a procedure where no document would be distributed to the members of the committee before it could be handed out in both official languages. As long as I don't have both the French and English versions of this document in hand, I will object to any questions being put concerning them.

[*English*]

The Vice-Chair (Mr. John Richardson): Mrs. Jennings is correct. The document that is being referred to should have been tabled with the research staff, who could then have had it made available to everyone here in both languages. That is a fact that's correct.

At the same time, though, Mr. Cummins does have the right to question witnesses.

Mr. John Cummins: I'll withdraw the comment about that, if you will, at this point. It was just a reference I made. I wasn't questioning him about the document. It was just a reference I made—a caution to the gentlemen from DND and nothing more. The question was not related to the document, as would be obvious to anyone.

• 1605 

Ms. Beth Phinney: I have a point of order, Mr. Chairman. We are here to get some answers, but I think the manner of the questioning is very abrasive. I don't think we can tell anybody in advance how they have to answer a question. We're asking a question, and the person should be able to answer the question the way they want. I think anybody saying you have to answer yes or no is being a little bit rude.

The Vice-Chair (Mr. John Richardson): That anticipates that—

Mr. John Cummins: I suggested, Mr. Chairman, that it was possible to answer that question yes or no. It's not a question that requires a lot of comment—a simple, straight answer.

Ms. Beth Phinney: That's up to them.

Mr. John Cummins: It certainly is up to them, but it's a point that's made all the time in the House. All it takes is a simple yes or no.

The Vice-Chair (Mr. John Richardson): Yes, but it's not often in the House you'll get a yes or no answer. I'll let Mr. Cummins continue on, and if it's seen by the persons they're directed to that they'd like to embellish the answer, that's their desire.

[*Translation*]

Mr. René Laurin (Joliette, BQ): On a point of order, Mr. Chairman. I'm sorry to have to intervene to tell you that as far as I know, there is no written rule, either for this committee or any other, that dictates how we should put our questions. I can very well ask the witnesses to answer with a yes or a no. It's up to them to judge whether they should answer that way or not. I can't be told that I can't put my questions that way. If censorship is going to be imposed on how we ask our questions, there's no more freedom of speech or action.

If we have to have this kind of procedural debate, we'll be cutting down on the time we have to ask witnesses our questions and they won't have time to answer. We will have to have them before us again once we've finished this procedural debate. It would seem that some are trying to protect certain witnesses. I'm sorry, Mr. Chairman, but I don't admit things can be done in this way as it seems very anti-democratic to me and it looks like some Liberal party strategy being used to cut back on the time for questions to witnesses.

[*English*]

The Vice-Chair (Mr. John Richardson): Ms. Phinney, is this on a point of order?

Ms. Beth Phinney: Yes. I didn't have anything against the way he asked the question. He can't demand the way he answers it, that's all I'm saying. I'm not saying anything about the way he asked the question. He can ask any question he wants, but in the same way as we can't tell him what questions to ask, he can't tell him what to answer.

[*Translation*]

Mr. René Laurin: We can ask him what we want.

[*English*]

Ms. Beth Phinney: Okay.

The Vice-Chair (Mr. John Richardson): Look, I think we'll just clear this. Mr. Cummins has the right to place the question. How it's answered is up to the person the question is put to.

Mr. John Cummins: I'll just say, Mr. Chairman, that the questions were designed to elicit a simple yes or no, and if the gentleman wants to fudge the answer, we'll take note of that.

Ms. Beth Phinney: Fudge the answer?

The Vice-Chair (Mr. John Richardson): I think this imputes motives to a witness in this situation, Mr. Cummins. Would you put your question, please.

Mr. John Cummins: I should take that back. Could I get an answer to the first one, Mr. Chairman?

The Vice-Chair (Mr. John Richardson): Would you like the first question repeated?

BGen Claude Auger: Yes, please. I would appreciate that, please.

Mr. John Cummins: Is it not true that Canadian soldiers deployed to Somalia were compelled to take an investigational drug, a drug that was under a clinical

study approved by health protection branch and governed by the Food and Drugs Act, which DND by law was obliged to monitor and did not?

BGen Claude Auger: It is true that the troops deployed in Somalia were required to take mefloquine or the alternative drug to protect them against malaria. DND had obtained medication under the safety monitoring study and was planning, outside the deployment of Somalia, to follow the monitoring study protocol. We were under the impression that we had obtained, through Health Canada, a different agreement to use the medication outside the safety monitoring study through the special access program. At that time that would not have required a consent.

Mr. John Cummins: Just to comment on your effort there, there's no documentation to support your latest contention, and in fact the documentation I'm familiar with might challenge it.

Question two, is it not true that Canadian soldiers were compelled to take an investigational drug that should not have been taken with alcohol, and yet alcohol was provided by DND?

• 1610

BGen Claude Auger: Mefloquine, like most other drugs, is not recommended to be taken with a high level of alcohol. Alcohol is always recommended in moderation dose. Troops deployed in Somalia were directed to use alcohol, when used, with moderation, as in any other circumstances.

Mr. John Cummins: Is it not true that the Canadian Forces compelled soldiers to take an experimental drug that required careful patient selection, without applying the required patient selection criteria?

BGen Claude Auger: Would you clarify your question?

Mr. John Cummins: Is it not true that the Canadian Forces compelled soldiers to take an experimental drug that required careful patient selection, and yet they did not apply the required patient selection criteria?

BGen Claude Auger: Mefloquine was not an experimental drug. It was a not-licensed-yet-in-Canada drug that was licensed in many countries and had a nice safety record. Canadian Forces members were required to take protection against malaria while deployed there.

Mr. John Cummins: In Canada, sir, it was an experimental drug.

The next question: is it not true that Corporal Scott Smith was compelled to take mefloquine while it was unlicensed, that he was not monitored in accordance with Canadian law, was not advised that he stop the drug when he developed neuro-psychiatric side effects, and was not advised that he must never take the drug again?

BGen Claude Auger: I don't think it would be appropriate for me to comment on a specific case, sir, at this time.

Mr. John Cummins: Is it not true that DND failed to properly monitor and manage side effects in our soldiers?

BGen Claude Auger: When the troops were deployed and given mefloquine, they were advised to report significant side effects to the medical personnel in theatre. Significant side effects, when people had to be switched from medication that made it intolerable, were recorded, and we had 15 such cases.

Mr. John Cummins: Is it not true that there's a direct cause-and-effect relationship between the failure of DND to monitor and manage the adverse side effects of mefloquine experienced by Scott Smith in Somalia, his repeat use of mefloquine in Rwanda, and his suicide?

BGen Claude Auger: I don't think I can comment on that, sir.

Mr. John Cummins: It is not true that by not monitoring, DND failed to identify persons who during prophylactic use developed signs of unexplained anxiety, depression, restlessness, or confusion, which may be considered prodromal to a more serious event? In these cases, the drug must be discontinued. Is that not so?

BGen Claude Auger: I think, sir, what you are referring to is that we did not ask questions of every individual given the medication. All those who had significant side effects that were causing them concern were requested to report that to their medical treatment facility, or to the medical assistant. Those were recorded in their medical file as symptoms, but they were not reported, that's true.

Mr. John Cummins: Is it not true that by failing to identify those who must come off the drug, DND equally failed to warn against further and future use, which equally carried the risk of serious neuro-psychiatric effects, including homicide and suicide?

BGen Claude Auger: I think, as I just said, people who reported significant side effects, if they were significant enough, were changed to another drug, doxycycline. There were 15 cases or so, and the corollary is that as far as we know, people who have not very serious side effects quite often have the side effects decrease with time and this will not prevent them from taking it at a future date.

The Vice-Chair (Mr. John Richardson): I'm going to have to move on. We're just a little over the eight-minute mark we've allowed to Mr. Cummins.

The next questioner will be Mr. Laurin of the Bloc Québécois.

• 1615

[*Translation*]

Mr. René Laurin: I'd also like to address the army representatives. In the protocol, there's a list of the responsibilities of the researchers and it was spelled out that you needed the informed consent of all participants, in other words anyone who's getting the medication.

I'm astonished that Health Canada says that it did not inform the army as that department thought the army already knew what was going on. On the other hand, the army says it thought it could dispense with the normal procedures because Health Canada had already stuck its nose into the business. Health Canada also said that it was usually the sponsor who did the clinical trials. Everyone is batting the ball back and forth and during that time the soldiers were taking a drug that could have put them in a situation where the secondary effects could put their lives at risk.

In one of the documents, it says that the drug was not administered to soldiers or people who, in the line of their duties, might find themselves in situations where the drug could have influenced their behaviour. On the other hand, elsewhere in the same document it says that the number of patients was estimated to be 38,000 but that there are registers for only 25,000 people.

How can we be sure, without records, that the drug was not administered to persons who may have been in dangerous situations, as at least 13,000 entries are missing from the records?

We also hear that National Defence attributes this confusion to a lack of communication between two of its directorates. What are these two directorates?

I would like you to explain to me how you can make such contradictory statements. I would like Brigadier-General Auger to answer this question.

Bgen Claude Auger: Sir, regarding your question about the two directorates, they were the Directorate of Preventive Medicine and the Directorate of Military Plans and Operations, which made the recommendations regarding the vaccines or health protection on foreign territory.

Could you be more specific about your second question?

Mr. René Laurin: You stated that the drugs had not been administered to soldiers who could be in hazardous conditions. How can you say that when 13,000 files are missing in the follow-up? Thirteen thousand cases have not been monitored.

Bgen Claude Auger: I am sorry, but I don't follow you. I have some problems with your numbers. You mention 13,000 cases, whereas we deployed 1,250 persons in Somalia. I cannot really speak about 13,000 cases.

Mr. René Laurin: Thirty-five thousand capsules were distributed. On page 28, regarding the final report of the study of the drugs, tabled by 21 researchers, we read:

The reports states:

- that the number of patients was estimated at 38,747, but there are only records for 25,235 persons (65.1%).

There were soldiers among these patients, but we do not know which ones they were. Without knowing this, how can you state that none of them ever the took the drug at times where his behaviour might have been influenced or when he was in hazardous conditions? That is what I want to know. How can you say that any given soldier did not take the drug?

Bgen Claude Auger: I think, sir, that you are alluding to one of the side effects, which is a sudden feeling of faintness, which does not happen often. This is why mefloquine was not distributed to our pilots. However, other armed forces have experimented, administrating mefloquine to their pilots, without noting any side effects.

• 1620

The Canadian military personnel deployed in Somalia were in relatively risky conditions. It was a risky place, but mefloquine was not excluded for people engaged in such operations.

If, on the other hand, you are alluding to the difference found in the results of the study between the number of people included in the beginning and the number dealt with by the report, the members of the Armed Forces can only account for 1,250 of these 13,000 missing persons.

Mr. René Laurin: Brigadier-General, in the statement issued by Health Canada, we read:

... the DND used and obtained LARIUM under the false pretence that it had special authority to use this drug outside the framework of the study.

What was there to justify this pretence which you knew to be false? Under what circumstances did the Department of National Defence declare that it had special authority to use this drug outside the framework of the study while knowing that it did not have that authority? The Department of National Defence should know whether it had the authority or whether it did not have it. How could a member of the Armed Forces have knowingly made such a false statement? And who made it? Who is responsible for this statement?

Bgen Claude Auger: If I understand correctly, your question is addressed to members of the Canadian Armed Forces.

Mr. René Laurin: Yes, that's it.

Bgen Claude Auger: The mefloquine pills had been obtained in 1991 within the framework of the special monitoring study, which was before preparing or envisaging the deployment in Somalia.

Later, during the deployment in Somalia, our directorates were under a false impression, because of a misunderstanding in their mutual communications. Both believed that the other one had informed Health Canada that we intended to use mefloquine outside the framework of the safety monitoring study and that the other one had obtained the authority. That is when we decided to do it.

Mr. René Laurin: When you say that the Department of National Defence believed this, at what level was this opinion held? Surely these were not corporals or sergeants... At what level of the hierarchy were these people, who believed that they had the authority while they did not have it? Where did the power of decision lie in this specific case?

Bgen Claude Auger: I will ask my colleague who is here to answer. In my opinion, these may have been people with the rank of lieutenant-colonel, for instance pharmacists or medical officers from the health protection and promotion directorate and from the health services directorate.

Mr. René Laurin: Thus, these were people who had medical degrees or who were working in the field of medicine.

Bgen Claude Auger: Yes, as a matter of fact. And this information had been transmitted, I believe, by the office of the chief medical officer of the health services directorate.

[*English*]

The Vice-Chair (Mr. John Richardson): I let that go for one full minute because I wanted Mr. Laurin to have a chance to pursue his questioning.

We now go to Mr. Perron for eight minutes. The floor is yours now, Mr. Perron.

I'm sorry, it's over to—

Mr. René Laurin: Mr. Richardson, does it mean that I have finished?

The Vice-Chair (Mr. John Richardson): No, no, you're getting into extraterrestrial territory there with the time.

It's over to Mr. Proud for the first questioning round by the Liberals. The floor is Mr. Proud's now.

• 1625

Mr. George Proud (Hillsborough, Lib.): Thank you, Mr. Chairman.

This seems to be a very scary subject for me. When our people join the military, they join it knowing they are going into dangerous situations. It seems to me we put them in more dangerous situations by things we're talking about today, and I think this is a terrible error on somebody's part, and somebody should be held responsible for it.

My first question will be to Mr. Auger, to ask you the question on this. Whether it's mefloquine or any other drug, what have you done now or since this time to educate the troops about the side effects of this type of drug or any other type of drug?

BGen Claude Auger: If I may, and it has been mentioned by Health Canada, protection of the troops with mefloquine at that time unquestionably was good protection for the troops, and it would have been much more dangerous for them if they had not been protected.

What we have been doing to educate our troops since that time is that we are developing some pamphlets and information sheets that will be given to members of the forces when they are given unlicensed drugs or vaccines that are unlicensed in Canada. Those information sheets will be given to the health care provider and to the Canadian Forces member to make them aware of the benefit and also the risk and the possible side effects of medication and vaccines.

Mr. George Proud: To the Health Canada people, is mefloquine the best drug available for malaria?

Mr. Dann Michols: Most certainly, yes.

Mr. George Proud: Was it the best drug available at the time it was given to our troops?

Mr. Dann Michols: Yes.

Mr. George Proud: Mr. Michols, you mentioned that regulatory changes need to be made by the minister in order for your new audit system to become a reality. What does the new audit system consist of?

Mr. Dann Michols: As was noted in the Auditor General's report, we did not have in place a system whereby once we had approved a clinical trial we would then go back—probably on a random basis—to audit the fact that the clinical trial took place according to the protocol that was approved. So we will now be putting in place the necessary authorities we will need in order to do that. We will have our inspectorate follow up on the approved clinical trials to ensure they were undertaken according to the procedures, if you like, that we approved.

Mr. George Proud: The problem in the process is that DND did not follow Health Canada's guidelines. Now, where was the foul-up in this, what brought this on, or where was the error made in this process?

Mr. Dann Michols: I think it should be understood that while the Department of National Defence believed it was undertaking actions within the approved study, they did follow the protocols. There was this misunderstanding, as has been mentioned, that they were prescribing the drug to the troops in Somalia outside of the monitoring study and consequently didn't follow the procedures of that study. So I think the problem was a misunderstanding in whether or not the drugs were prescribed within the study. They did follow the procedures of the study previous to that.

Mr. George Proud: Can I ask a question to the Auditor General representative, then: have you ever run into a case like this prior to this? Have there ever been other cases like this? Is this an ongoing thing or is this a one-time mistake?

Ms. Maria Barrados: We only report on this particular case. There will be other circumstances in which we will look at the entire process with drugs, but we didn't do it at this time. However, when we raise something like this, we raise it because from our discussions we feel there was something systemic that needed to be done. Both Health Canada and the Department of National Defence have taken action to correct those systemic problems that this one case demonstrates.

Mr. George Proud: Thank you. Thank you, Mr. Chairman.

The Vice-Chair (Mr. John Richardson): Ms. Phinney, please.

Ms. Beth Phinney: I just want to clarify something Mr. Michols was saying a few minutes ago. I didn't understand that paragraph where you explained how the error occurred. In the assistant auditor general's report, she mentions that only licensed drugs are sold in Canada except under specific controlled conditions, and that's a clinical trial.

• 1630

Mr. Dann Michols: It's the clinical trial or the special access program we operate.

Ms. Beth Phinney: Only licensed drugs are sold in Canada, so whatever you're doing with that drug—and Canadians are putting confidence in you—if it's not licensed, it's a clinical trial. If you're saying you have this drug under clinical trial and you can put it under a special condition to give it to the air force, is it no longer under clinical trial and suddenly approved?

Mr. Dann Michols: No.

Ms. Beth Phinney: So the whole time you're handling this, until you give it full approval, it's a clinical trial. Whether you give it to somebody else to use for six months or give it to 900 people, it's still under clinical trial.

Mr. Dann Michols: It is under special circumstances, yes. Sometimes—

Ms. Beth Phinney: But have you approved it yet?

Mr. Dann Michols: We have not approved it.

Ms. Beth Phinney: It's still an unlicensed drug.

Mr. Dann Michols: True.

Ms. Beth Phinney: So no matter what happens to it, it's under your control and you're responsible for it. Canadians understand that you decide what happens to our drugs until they're licensed.

Mr. Dann Michols: We have two responsibilities. We have the responsibility of reviewing a drug and determining whether it can be sold in Canada.

Ms. Beth Phinney: Licensed, you mean?

Mr. Dann Michols: Exactly. Prior to that, we also have the authority to be able to make that drug available in special circumstances. Sometimes those special circumstances are clinical trials; sometimes those special circumstances are on a case-by-case release through our special access program.

Ms. Beth Phinney: What you're saying now is that when you give it to somebody else to use for a special circumstance, you don't have to monitor it at all. You haven't licensed it, but you can just hand it over to somebody to use, without any restrictions or anything.

Mr. Dann Michols: I don't think I'd say that.

Ms. Beth Phinney: That's what you said.

Mr. Dann Michols: In terms of clinical trials, when we are giving the authority to a researcher to use a drug—

Ms. Beth Phinney: Okay, but give me more on this condition. I know what clinical trial means.

Mr. Dann Michols: —it was the military in this case—that we have not approved, we review the situation in which they wish to use the drug, the conditions under which they will use the protocol, and the qualifications of those who will use it. We don't just hand it over; we approve the clinical trial in the first place, or the safety monitoring study that was in place.

Ms. Beth Phinney: It would seem logical that when you handed this drug—in a box or however you shipped it—to somebody to use, you would say, “While you're using this, you must record who you give it to, its results on each person, when you gave it to them, etc.” Isn't that logical?

Mr. Dann Michols: That is exactly what we do.

Ms. Beth Phinney: Okay, so you're now saying you handed that box over, with the instructions on what to do with it and how to report back to you, and somebody else is saying they received the box but not the papers with the instructions.

If you are responsible for it, as far as Canadians are concerned, wouldn't you then send somebody to wherever it was being used and monitor it there, to make sure all that was being done?

Mr. Dann Michols: That is exactly the process we are now putting into place. If I could continue your analogy, we take that box of drugs and, before we hand it over to someone else, we make absolutely certain they have the qualifications to be able to use those drugs properly, they know the conditions under which they will be used, and they know the protocols, etc.

Ms. Beth Phinney: Okay, can I stop you right there? So that means the representatives from the Minister of National Defence's office lied.

Mr. Dann Michols: Not at all.

Ms. Beth Phinney: They said they didn't know they had to do that.

Mr. Dann Michols: I don't think that's the case at all. National Defence set up, with our approval, the safety monitoring study. I think the case being made here is that National Defence thought, when they issued the drugs in Somalia, they were no longer within the confines of that study.

Ms. Beth Phinney: But didn't you tell them that when you passed it to them?

Mr. Dann Michols: Yes.

Ms. Beth Phinney: You said they were, but they didn't think they were.

Mr. Dann Michols: They operated within the confines of that study previously—

Ms. Beth Phinney: Until they gave the shot in the arm and then they—

Mr. Dann Michols: —and there was a misunderstanding with Somalia.

Ms. Beth Phinney: What do you mean, with Somalia? While they were there with the troops, the medical people gave them the drugs.

Mr. Dann Michols: They thought they had sought permission from us to use the drugs outside of the study. They hadn't, and that was the misunderstanding.

• 1635 

Ms. Beth Phinney: Okay. I have one more question, Mr. Chair.

In here you say these data, when considered together, fully supported the claim that the benefits of Lariam outweigh the risks. Could you tell us how you decide in Health Canada what the value is of a risk and how you determine this? Is it done by percentages?

I think it's with aspirin—and I might be wrong, so I have to be careful... I've already said the word now. I know with certain drugs, the company itself will say, well, yes, 200-and-some-odd people might die out of so many million, but that's okay, because the others are helped with their headaches, so we approve these drugs.

What rationale do you use for risk? Maybe I had better stop and just let you answer the question. What is risk? How does it outweigh?

Mr. Dann Michols: The drug review process in Canada is similar to that within all developed countries. We require from someone who wishes to market a drug a significant submission that contains the results of many, many scientific studies—studies for the safety of the drug, but also the clinical trial data. We review it, and the review process takes many months and sometimes longer.

What we are attempting to determine is that the product conveys a benefit of some type and that the risks presented by taking the product are not greater than the benefits.

Ms. Beth Phinney: Okay, so if 51% of the people are affected in a positive way with the drug and 49% in a negative way, that drug is approved?

Mr. Dann Michols: I'm not sure that wouldn't be just a little too close to the—

Ms. Beth Phinney: Well, I'd like to know approximately. What is risk? How do you determine what the risk level is? You said if the risk on this is low enough, it's okay; the good outweighs it. So tell me how you decide that.

Mr. Dann Michols: It would be a case of determining the statistics involved in what the benefit was, what disease was actually prevented or what the consequences of the disease were, against the probability of there being side effects or serious side effects with it.

Each drug is in a different situation. It depends on what good the drug is going to do and what risks it would present, and then it's a scientific evaluation to determine whether or not, in this case, preventing malaria... There would be a statistical calculation of how many cases of malaria might develop within the population. Then we would analyse what the side effects were and what the statistical probability of those side effects was, and we would have to come to—

Ms. Beth Phinney: But you're not willing to give me any figures on what this ratio is? What was it with this drug then?

Mr. Dann Michols: I don't have the data. I don't know if—

Ms. Beth Phinney: It's a big difference.

A voice: It's one in 10,000.

Mr. Dann Michols: We could put together a paper that would lay out, in this particular case, the probability of contracting malaria in a particular situation against the probabilities of the side effects that might arise.

It's confounded, if you like, by whether or not there are other drugs that might be used for similar situations. If there aren't, then the benefit is that much greater and you're prepared to take more risks.

It also depends on what the diseases are. The patients who have contracted HIV are prepared to take a much greater risk in relationship to a benefit that may be delivered than perhaps someone who has a headache and is taking aspirin.

So it's very difficult to answer your question in general, because it depends—

The Vice-Chair (Mr. John Richardson): Mr. Michols, I'm going to have to cut you off. We've gone quite a few minutes over the time.

Ms. Beth Phinney: That's fine.

The Vice-Chair (Mr. John Richardson): Mr. Cummins has to catch a plane that goes to the far west, so I'm going to take the liberty of giving him the chance to make his point, but he doesn't get the eight-minute round here; he only gets the four-minute round.

Mr. John Cummins: Thank you, Mr. Chairman. I have just a couple of points.

With regard to the effect of the drug, members of the committee may or may not be aware, but the day the drug was administered in Somalia was known as Psycho Tuesday or Psycho Wednesday, depending on where it was taken. Widespread effects were felt by the troops who took that drug.

• 1640

The other misconception that's been bandied around today is whether or not DND knew they were participating in the safety monitoring study. You can confirm that in fact DND knew it was participating in the safety monitoring study. If you access their website, the document that proves that is available on their website.

So don't be misled by that statement, “Well, we didn't know.” They knew full well. The signatures are there. It's on that document. If you'd like, I'd be only too happy to provide it to you.

The other point that may be noted is that Australia had the same number of troops as Canada in the area. They used another drug; they used doxycycline. But that's beside the point. I guess it doesn't matter.

I'd like to return, if I could, to the line of questioning I instituted before, mainly because I've recently talked again with Scott Smith's mother, and she's concerned about the fact that her son served in the forces. She just doesn't feel she's been dealt with fairly. That's why I'm doing this.

Is it not true that Scott Smith was compelled to take mefloquine; that the required monitoring was not carried out; that as a result, unexplained anxiety was not identified and the drug was not stopped on that occasion, as was required by Canadian law; and that no warning was given to him to avoid future use?

I'd just point out that the information about Scott Smith is available on your website, so you're not revealing any deep secrets.

BGen Claude Auger: I have to admit I am not aware of the detail of the person or the member you are referring to, so I regret that I cannot make much comment on that.

Mr. John Cummins: Is it not true that Scott Smith was compelled to take mefloquine a second time, on deployment to Rwanda, without being informed that his previous experiences in Somalia signalled a danger in the form of a more serious event, such as suicide? He had had troubles in Somalia and should not have been on the drug, but he went to Rwanda and was compelled to take it. Is that not true?

BGen Claude Auger: As I said earlier, you're getting into the specific issue of a patient and his medical condition or side effects. I don't think that is the mefloquine issue at large, but individual cases.

Mr. John Cummins: Well, to understand the issue at large, we have to understand the individual cases. This was certainly a spectacular case. The young man committed suicide at Christmas.

Is it not true that while taking mefloquine on this second occasion, Scott Smith complained of unexplained anxiety, even in the hours prior to his death by suicide?

BGen Claude Auger: You keep asking me specifics of the case. As I said before, I am not cognizant of that case. I have not reviewed it as such.

Mr. John Cummins: Do you deny a cause-and-effect relationship between DND's failure to monitor and manage the adverse effects on Scott Smith of the mefloquine administered in the Somalia deployment and his repeated use of mefloquine in Rwanda—use that, based on medical knowledge of the effects of this drug, was highly likely to have contributed to his suicide?

The point of that question, if you want to get away from the specifics, is that if you have trouble with it in one theatre, you shouldn't be giving it in another. Yet you did, because you didn't monitor. Is that not true?

BGen Claude Auger: I have to say I am not aware that people who have side effects on one occasion, if the side effects are mild enough, or even severe enough to bring them to medical attention but not to change drugs...

The fact that they take it in a second deployment doesn't have a cumulative effect, and they may not have side effects on other occasions. The side effects being relatively non-specific, they may or may not repeat themselves or be greater or lesser at a second deployment. If they did at that time, members would be informed that if they had side effects they thought were related to medication, they should report to their medical treatment facility, and they would evaluate the effect and may recommend a change of medication. It applies to all members.

The Vice-Chair (Mr. John Richardson): Time does fly. We're over the five-minute mark. I'm going to stop there.

• 1645

Mr. John Cummins: Thank you very much, Mr. Chairman.

The Vice-Chair (Mr. John Richardson): Thank you very much for your contribution, Mr. Cummins.

Mr. Perron, you're in the round now.

[*Translation*]

Mr. Gilles-A. Perron (Rivière-des-Mille-Îles, BQ): To begin, Mr. Auger, I would like to remind you that you are a military man and not a figure skater. Therefore, we should expect clearer answers. This reminds me somewhat of another case, the one of the famous lost documents.

I am intrigued by one thing. How is it that this file is dated 1992-93, the year when the drugs were administered, and that it was only in 1997-98, after several articles had been published in newspapers, after this had become public, that you began to amend your procedures? If these things had not happened in 1997-98, would drugs still be administered without monitoring?

Bgen Claude Auger: There are two parts to your question. First, until 1997, we believed that we had used mefloquine properly because we believed that we had advised Health Canada that it was being done outside the framework of the study.

Then, in 1992, the Canadian Armed Forces began operating on foreign soil, and these operations have become increasingly frequent ever since. We had to use non-authorized drugs and vaccines more and more often and we looked at the matter more closely. Consequently, we took the needed initiatives to get information about the recommended drugs, in order to administer them and keep the required records.

Mr. Gilles Perron: I'll give you a bare passing mark for your answer.

In your original comment, on page 7, you mention infrequent side effects. Just now, as you answer a question, you mention significant side effects. What are these significant side effects? Could you give us an exhaustive list of them? What symptoms could a soldier have after having taken these drugs?

Bgen Claude Auger: Most of the time, the side effects are minor. There are side effects that can be neuropsychiatric and that...

Mr. Gilles Perron: Significant minor side effects?

Bgen Claude Auger: The significant side effects can be indigestion, stomach irritation, diarrhea. A person could suffer clinical depression, go through manic-depressive states, psychotic reactions, encephalopathy as well as convulsions. This may happen in one case out of 10,000.

Mr. Gilles Perron: You also said, in one of your answers, that these drugs should not be taken together with a high level of alcohol. What is a high alcohol level? A glass of beer or a case of beer? What difference will it make in the symptoms? What would be the effect if the drug were taken together with a case of beer or together with a glass of beer?

Bgen Claude Auger: The effects can be different depending on the medication.

Mr. Gilles Perron: The effects of the medication we're speaking about.

Bgen Claude Auger: Mefloquine taken with a moderate quantity of alcohol, one, two or three drinks, doesn't seem to have any synergetic effects. On the other

hand, the—

Mr. Gilles Perron: Is this a recognized fact or is this a conclusion drawn from observations? Are these significant effects clinically recognized by the scientists or drawn from experience?

Bgen Claude Auger: As far as we know, alcohol taken in moderate quantities with mefloquine does not increase the incidence of secondary effects. That hasn't been demonstrated.

Mr. Gilles Perron: I have no more questions.

The Vice-Chairman (Mr. John Richardson): Thank you.

[*English*]

We now go to the Liberal side, to Ms. Jennings, who will have four minutes for questions.

Ms. Marlene Jennings: Thank you.

Is mefloquine now licensed in Canada?

Mr. Dann Michols: It is.

Ms. Marlene Jennings: Since when?

Mr. Dann Michols: Since January 1993.

• 1650

Ms. Marlene Jennings: Okay.

I see in your report, Mr. Michols, that Health Canada is working on a procedure of auditing clinical testing that is done on non-licensed drugs in Canada. Given the fact that the problem of the lack of auditing in Defence's use of mefloquine came up between 1992 and 1994, I find it somewhat disappointing that we're almost on the verge of the third millennium, easily five years after the problem was identified, and Health Canada still has not put into place specific audit procedures to ensure that when it permits the fabrication or the production of an unlicensed drug in Canada and the usage of that through either clinical testing or through your safety monitoring study, that you're actually auditing it.

Are audits going on now by Health Canada? If you don't have a protocol in place, or a directive or guideline, are you actually monitoring drugs that are being used in clinical trials at this point or under the special access program, or whatever you call it? Are you auditing those now? Or am I going to have to worry—and some of the other members here—that two months from now we may hear there was a clinical trial going on and they weren't following the proper procedures?

Mr. Dann Michols: That's an excellent question. I think it raises a number of—

Ms. Marlene Jennings: I think so too.

Mr. Dann Michols: Let us hope the answer is sufficient to it.

Ms. Marlene Jennings: Let's hope it's also excellent.

Mr. Dann Michols: Let me try.

First of all, I think it needs to be understood that while we do not have in place now, and did not have in place then, a system to audit clinical trials as “audit” is understood, that does not mean we were not monitoring the clinical trials. We require all adverse drug reactions that take place within a clinical trial to be reported to us. We analyse those, and if there's a major problem we see developing, we do have the power to stop a clinical trial or to go in and investigate it. That's not an issue, and we have done that and we do that.

What is being suggested I think by the Auditor General's office is that we also ought to have in place a standard audit process where, on a regular basis, we follow up, perhaps on a random percentage, the clinical trials that are taking place. So we're moving from a situation where we would act if we knew that a problem had arisen to a situation where we act on a continuous basis, whether there's indication of a problem or not.

Perhaps we should have been auditing clinical trials in the past. The problem is one of resources and priorities.

Ms. Marlene Jennings: Mr. Michols, it's been a minimum of five years, if not longer, since this problem came to the light of day publicly. There is a clear problem—and I do have questions for Brigadier-General Auger—and I find it difficult to accept that five, if not six, years later Health Canada still has not instituted a program of auditing, spot auditing, whatever you want to call it, of any usage of unlicensed drugs either through the clinical trials or through your safety monitoring study.

You say you're looking at it. In your own document you say that:

> The implementation of an audit system would further ensure that research in Canada is conducted in accordance with these high standards and increase the integrity of data generated in support of drug marketing applications.

Well, I don't think the light bulb just went on now. So I think if it would increase the integrity of the data... That notion was known five or six years ago.

As for the issue of not having sufficient resources, if you don't have sufficient resources, then I think you don't just sit on your hands; you also have an obligation as a civil servant to make that known—to the standing committees, if necessary.

• 1655

Mr. Dann Michols: You're absolutely right. We do say and we do mean that introducing an audit program will potentially make the system safer. But I would suggest to you that there are other uses for a dollar, and there are other places that dollars could be used in order to improve the process. And we have been doing that over the last five years. I'm not sure this was the highest priority. The clinical trial system in Canada is very safe. This putting an audit process in will add an element of safety, but the system was not unsafe.

Ms. Marlene Jennings: Then why in your presentation did you not simply say that while the Auditor General has proposed that Health Canada should put into place an audit system of clinical trials, Health Canada has studied that proposal and has determined that in terms of its priorities and the reliability and integrity of the data that is being produced by clinical studies without that audit system, and given the budget constraints, we're not going to proceed with it?

In this document and the presentation you just made, you lead us to believe that you are going to institute an audit system. Now you're telling me that when you have one dollar and you have to decide where to put it, given that Health Canada feels that the integrity of the data being generated now is sufficiently high, spending that one dollar there to create an audit system is not the best use of that dollar. This means that Health Canada has decided it's not going to institute an audit system. Is that my understanding?

Mr. Dann Michols: No. I was answering your question as to why we didn't do it five years ago. We are doing it now, and we are coming, as you know, into a period where resources are not quite as restrained as they have been in the past. We have implemented a number of changes and improvements within the drug regulation system across the board, and we are at the point now, because we are also introducing a number of regulatory changes in the general clinical trial process, whereby introducing an audit system is one of the higher priorities. We have the resources, or they will be made available for us, to do it. Now is the time to do it.

It was not an unsafe system in the past.

Ms. Marlene Jennings: I never wanted to imply that.

The Vice-Chair (Mr. John Richardson): Mr. Michols, we've gone considerably over. Marlene, I've given you licence of over three minutes.

Ms. Marlene Jennings: I have a couple of questions, or one question.

The Vice-Chair (Mr. John Richardson): I'll let you ask it when we come around again, if there's time here. I'll have to go to Mr. Clouthier. He's anxious to get at this question.

Ms. Marlene Jennings: Are you really anxious, or do you want to give me your time?

Mr. Hec Clouthier: Go ahead, Marlene, ask him one question.

Ms. Marlene Jennings: Thank you.

Mr. Hec Clouthier: Is she cutting into my time?

The Vice-Chair (Mr. John Richardson): Yes.

Ms. Marlene Jennings: You just said go ahead. You can't take it back.

Mr. Hec Clouthier: One question.

Ms. Marlene Jennings: Thank you.

[*Translation*]

Under the National Defence Act, members of the Canadian Armed Forces can be subject to disciplinary measures if they refuse to submit to a treatment or take medication or submit to vaccination when they have been given the order to do so. That was the situation when our Canadian troops were sent or deployed to Somalia. Is that still the case today? What do you do when the use of a drug not listed by Health Canada but that can be used within the context of a review or a clinical trial requires, according to the protocol, the express and written consent of the person? I'd like to know.

We know you did not respect the protocol. I do not accept the explanation of a misunderstanding in communications between the two directorates, but I'll set that aside.

Even today, how do you reconcile participating in a test for which, according to the protocol, express and written consent of the individual is required, and the implementation of the National Defence Act, which provides that a soldier or a member of the Armed Forces may be subject to discipline if the test is refused?

Bgen Claude Auger: There are two aspects to your question.

Ms. Marlene Jennings: Yes.

Bgen Claude Auger: The first has to do with the protection provided by a drug or vaccination for the members of a troop being deployed in a theatre of operations. The role of the health services is to determine and evaluate the risks compared to the advantages offered by the protection provided by the drug or vaccination and to make recommendations to the Chief of Defence.

• 1700

The authority to order or not order this protection or to take administrative and disciplinary action is not our jurisdiction. That's up to Defence. As there are presently legal proceedings underway, I must refuse to answer.

Ms. Marlene Jennings: So you refuse to comment. You're here as the representative of the Canadian Armed Forces and I'm asking you how you reconcile the participation in a clinical trial where the protocol requires express consent and the application of the National Defence Act which forces a soldier or a member of the Armed Forces to submit to vaccination or take a drug if ordered to do so under the threat of sanctions. If this person does not give consent—the person doesn't even have the right to give it—if that person refuses then that person may be subject to disciplinary action.

I'm trying to understand how you can reconcile both horns of this dilemma. I don't even understand how Defence can participate in clinical trials as one of the criteria is obtaining consent.

Bgen Claude Auger: In a protocol—

[*English*]

The Vice-Chair (Mr. John Richardson): General, you have about 25 seconds left. It took three and a half minutes to get to the question.

[*Translation*]

Bgen Claude Auger: In a specific research protocol where consent is necessary—

[*English*]

Ms. Marlene Jennings: That was quick too.

[*Translation*]

Bgen Claude Auger: —I suppose that the administrative decision concerning those people who would refuse the treatment could very well be that they not be deployed. That would be my recommendation, but that kind of decision is not mine to make.

Does that answer your question?

[*English*]

The Vice-Chair (Mr. John Richardson): And the time is up. As I cannot see Mr. Hector Clouthier leaving without a question, I'm going to give him licence here to have two minutes to put a question and answer.

Mr. Hec Clouthier: Two minutes, okay. Thank you very much, Mr. Chair.

First of all, maybe it's more of an observation. Mr. Michols, it seems quite clear to me that Health Canada somehow had better find the funds to do a sufficient audit or else you shouldn't put any of these drugs up for clinical trials.

One interesting thing you did say is that you deemed that they were safe. Now, correct me if I'm wrong, but if you put a drug like mefloquine into the hands of the military—and I know you were saying there seemed to be a lack of communication in this one particular instance, so let's look at the other 99% of the instances—would they have been responsible to do their own audit on it and report back to you? Forget about the mess that happened here; somehow there was some lack of communication—but in any other drug.

Mr. Dann Michols: In the case of all drugs, when we approve a clinical trial—and we approve it because they have highly qualified medical officials that are running these trials—it is their responsibility to report the adverse drug reactions.

Mr. Hec Clouthier: Back to you?

Mr. Dann Michols: Back to—

Mr. Hec Clouthier: Health Canada?

Mr. Dann Michols: —the manufacturer, who is required to report them to us.

Mr. Hec Clouthier: Okay, regarding mefloquine, could the military have used that without Health Canada giving them the okay?

Mr. Dann Michols: No.

Mr. Hec Clouthier: Okay.

A voice: But they did.

Mr. Hec Clouthier: You had the first say. No, they gave it—

A voice: They did.

Mr. Dann Michols: I'm sorry, on this point, no. If it was an unapproved drug, they would have had to seek approval from us for access to the drug.

Mr. Hec Clouthier: Health Canada gave it to them. You gave them the permission to use the unapproved drug.

Mr. Dann Michols: Through the safety monitoring study that was set up, they were one of the sites involved.

Mr. Hec Clouthier: Okay, there was a mess.

But I'll ask one short question, just so Madam Barrados won't feel out of place here. I did notice in your presentation you said there were 69,000 doses in 1992 at CFB Petawawa. Have you kept track of them? That's my riding. Where did they go? Do you know? If they make the race horses go faster, I'll take them.

Ms. Maria Barrados: It's a good question. There weren't records, and that's the point we're making in the note. The records weren't really kept, so it's a question for DND.

Mr. Hec Clouthier: So they're floating out there somewhere.

The Vice-Chair (Mr. John Richardson): They're lost.

Ms. Maria Barrados: I don't know.

The Vice-Chair (Mr. John Richardson): I'm afraid, Hec, that's the end of your two minutes.

Mr. Hec Clouthier: Okay.

The Vice-Chair (Mr. John Richardson): I think we'll go over to Mr. Perron now for four minutes of time, and Beth Phinney for four minutes of time.

[*Translation*]

Mr. Gilles Perron: For once, I can feel a sort of consensus around this table. That's very rare. To quote my friend Clouthier, it's a mess. It's a real dog's breakfast.

• 1705

I'll try to get on the same wavelength as Mr. Auger. On page 9 of your presentation, you say that you're preparing a detailed pamphlet on medication, vaccinations and so forth. I won't quote it back at you. When this pamphlet is ready, will it be given to all those using the same system?

Bgen Claude Auger: The implementation of this project is underway. We have pamphlets on a vaccination for anthrax, on the HI-6 antidote, on vaccination for plague and other diseases. We're still progressing in that direction to cover all medication that might be used by the summer of the year 2000.

Mr. Gilles Perron: I hope that you'll also be dealing with the drug for malaria, the one we're talking about.

Bgen Claude Auger: Mefloquine is now a listed medication that is prescribed to Armed Forces personnel. It is described in the documents and they get the information contained in the research study on the drug during its distribution.

Mr. Gilles Perron: Some people stated that they had felt secondary effects, as you say. On the list of secondary effects you reeled off before, there are some that I wouldn't want to have to deal with personally because I wouldn't be here to do my work this afternoon.

Bgen Claude Auger: As I was saying, Mr. Perron, there are possible secondary effects but they only affect 1 out of every 10,000 patients who take the drug. This is documented in the research study. The minor secondary effects are also documented. They vary between 1 out of 250 to 1 out of 500. So they're not very frequent, they are relatively minor and don't lead to stoppage of the medication.

Mr. Gilles Perron: Whether the medication is taken while using alcohol or not.

Thank you, Mr. Chairman.

[*English*]

The Vice-Chair (Mr. John Richardson): Thank you, Mr. Perron. Ms. Phinney.

Ms. Beth Phinney: I just have a couple of questions. Mefloquine was approved or licensed in Canada in January 1993, is that correct, Mr. Michols?

Mr. Dann Michols: Yes.

Ms. Beth Phinney: According to the assistant auditor general's report, the final report of the manufacturer was April 1993. In her report it says that on page 25. I'm just worried as a Canadian about licensing. The final report from the manufacturer comes out after the drug has been approved in Canada. Now, yes, it was approved in Europe and the United States, but I'm just wondering what standard we're using if we approve it, we license it January 1993, and the final report from the manufacturer was presented in April 1993.

I'll continue on. In that report, only 65.1% of the patients who took it were accounted for. There was no reporting on the other people who had taken the drug. I'll just ask you to comment on that. It was given to our armed forces, and nothing was done about getting results from them until October 1994, when “the use of the drug by Canadian soldiers in Somalia became a media issue”. Then Health Canada asked the manufacturers for copies of those records of the people who had taken them earlier. But before that, Health Canada had never asked for those records.

So when you approved them, you didn't even have the records on the 65.1% who had taken it and had been recorded, because when you went to National Defence and asked for them, they didn't have them. They said they must be with the manufacturers. They didn't have the records; they said they would be with National Defence. National Defence didn't have them. And you didn't go any further than that, but it was approved. There's a little concern for me in all of that.

• 1710

Mr. Dann Michols: That's a reasonable question.

The evidence submitted by the manufacturer to seek approval from us, which we gave in January 1993, contained the results of many more studies worldwide than just this particular safety monitoring study. So we were dealing with evidence from other clinical trials and with evidence that had already been approved in different countries and so on. Obviously the evidence that was being gained through this safety monitoring study was there as well. I think maybe the misconnection there is that we were only relying on this particular safety monitoring study in order to determine whether or not we should approve the drug. There was far more evidence than just that.

Ms. Beth Phinney: So there are 21 principal investigators. I presume that's around the world.

Mr. Dann Michols: No, these are within Canada.

Ms. Beth Phinney: It says that the manufacturers filed a report on the study, which included the results reported by all 21 principal investigators. Is that just in Canada?

Ms. Maria Barrados: Those were in Canada.

Ms. Beth Phinney: During your comments you said that didn't mean you weren't monitoring the results. But I think the Auditor General's report commented on the fact that you don't do the monitoring; the manufacturer would do the monitoring. Is this because we don't have any place in the drug section of Health Canada to do monitoring ourselves due to the cutbacks or whatever it is? Is there any way you could do this monitoring yourself?

Mr. Dann Michols: We're not doing an audit.

Ms. Beth Phinney: No, I'm talking about monitoring.

Mr. Dann Michols: We monitor in terms of receiving the adverse drug reactions and keeping track of them as a clinical trial is underway, and we have the power —

Ms. Beth Phinney: But you didn't worry about not being able to do that on however many thousand pills you sent over—

Mr. Dann Michols: That's right. But we were not doing an in-depth audit, and we were not doing an audit then because we did not—

Ms. Beth Phinney: But you weren't monitoring it either.

Mr. Dann Michols: Well—

Ms. Beth Phinney: You're separating the two, but you didn't monitor it either.

The Vice-Chair (Mr. John Richardson): I think we had better have an answer before we cut each other off so quickly on that.

Mr. Dann Michols: Your point is well taken. We did not monitor each dose that was delivered through this particular safety study. That's true.

Ms. Beth Phinney: If the data from the international studies are enough, why insist on a Canadian trial?

Mr. Dann Michols: These were 21 principal investigators in Canada. It's not necessarily enough. We like to see a cross-section, but we do accept data from international studies.

Ms. Beth Phinney: You're saying you went by that because you didn't have the results yet—

Mr. Dann Michols: No, we had—

Ms. Beth Phinney: You didn't have the results from the 21 Canadian studies until after you had given the licence. The manufacturer's report wasn't even out. You gave the licence the year before.

The Vice-Chair (Mr. John Richardson): I'd have to say we're at the six-minute mark here, and we're going to call it there. I'm going to take licence as the chair.

Hoffmann-La Roche, in its patient product information, describes mefloquine as performing an unknown mechanism action in the body.

In your opinion, did Health Canada properly screen Lariam for the use of Canadian Forces deployed in Somalia? Lariam is produced by the Swiss company, La Roche, which acknowledges in the fact sheet that accompanies each prescription that its exact mechanism action is unknown. It says that if signs of unexplained anxiety, depression, restlessness, or confusion are noticed, the drug should be discontinued immediately.

In their literature it also says that it affects the cognitive powers of a human being. Now, if it affects cognitive powers, they wouldn't know what was wrong with them. They couldn't know they had been affected. They wouldn't know if they were in a situation on that delivery. That's one thing I thought I'd throw in, because nobody brought up those two items about the loss of cognitive powers.

Anyhow, if anyone has any information to give me that this is not a fact, I'd appreciate it. If it was a reality, then I don't know how we could have dealt with it.

• 1715 

Mr. Dann Michols: My response again would be a general one. When we review a drug and when we approve a drug, we are looking at a relationship between the benefits and the costs. So we look to see who benefits and how they benefit from the particular product, and we look to see what risks are presented. In the case of cognitive problems, that does not happen in 100% of the cases, so that's taken into consideration. That could be one of the side effects, as General Auger mentioned. That has to be considered. The physicians prescribing the drug have to be aware that is a possibility. That's the information we approve. Then they have to judge on a case-by-case basis the benefits and the risks for that patient.

The Vice-Chair (Mr. John Richardson): On that note, I'll use the gavel. Thank you very much for coming and making a presentation on a very sticky area.

The meeting is adjourned.