CANADA

House of Commons Debates

VOLUME 138 • NUMBER 070 • 2nd SESSION • 37th PARLIAMENT

OFFICIAL REPORT
(HANSARD)

Friday, February 28, 2003

Speaker: The Honourable Peter Milliken

INQUIRY OF MINISTRY
DEMANDE DE RENSEIGNEMENT AU GOUVERNEMENT

CANADA

PREPARE IN ENGLISH AND FRENCH MARKING "ORIGINAL TEXT" OR "TRANSLATION"
PRÉPARER EN ANGLAIS ET EN FRANÇAIS EN INDIQUANT "TEXTE ORIGINAL" OU "TRADUCTION"

QUESTION NO./N° DE LA QUESTION	BY / DE	DATE
Q-45	Mr. Cummins (Delta-South Richmond)	November 7, 2002

REPLY BY THE MINISTER OF STATE AND
LEADER OF THE GOVERNMENT IN THE HOUSE OF COMMONS
RÉPONSE DU MINISTRE D'ÉTAT ET
LEADER DU GOUVERNEMENT À LA CHAMBRE DES COMMUNES

SIGNATURE
MINISTER OR PARLIAMENTARY SECRETARY
MINISTRE OU SECRÉTAIRE PARLEMENTAIRE

QUESTION

Q-45 — November 7, 2002 — Mr. Cummins (Delta—South Richmond) — Following the Mefloquine adverse event monitoring report received on August 26, 2002 by Health Canada indicating a murder and an attempted suicide: (*a*) what investigation has been carried out by Health Canada and other government agencies; and (*b*) what was the result of these investigations?

REPLY / RÉPONSE

ORIGINAL TEXT / TEXTE ORIGINAL ☑ TRANSLATION / TRADUCTION ☐

I am informed as follows:

HEALTH CANADA

The Canadian Adverse Drug Reporting Monitoring Program (CADRMP) in Health Canada is responsible for the collection and assessment of adverse reactions that have been submitted by health professionals or consumers, either directly or through manufacturers. Information on all reported adverse reactions is maintained in a computerized database and is used as part of the continuing assessment of marketed health products. It is important to remember that reports to the CADRMP represent the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established. Adverse reaction information is used to help ensure the benefits of a marketed health product continue to outweigh the risks, to continuously update the labelling and product information for a marketed health product, and to inform health care professionals and consumers about adverse reactions.

Since mefloquine was marketed in Canada (1993) to October 8/2002, the Canadian Adverse Reaction Monitoring Program (CADRMP) has received a total of 65 reports in which mefloquine was listed as suspected or interacting drug.

Health Canada analyzes adverse reaction reports to discover potential health product safety signals. A signal is considered to be the preliminary indication of a product-related issue, for example a report of an unusual or unexpected adverse event, or an increase in the number of reports of a particular adverse event. The identification of a signal is not by itself the proof of the association of an adverse reaction to a health product, but it triggers the need to further investigate a potential association. Health Canada's regulatory actions are based on a scientific analysis of cases and are taken according to the regulatory framework in place. This includes updating the product monograph. Since Lariam® (mefloquine) was approved in 1993, the Product Monograph has been revised seven times.

Health Canada continues to monitor the adverse reaction profile of mefloquine. The Marketed Health Products and Therapeutic Products Directorates are working in collaboration to ensure that measures are taken to address safety issues and make sure that the information in the Canadian Product Monograph is accurate, current, and reflective of the Canadian experience. With regard to Lariam (mefloquine), there was a Communique in the Canadian Adverse Reactions Newsletter (Volume 8, No 1, January 1998) on the neuropsychiatric reactions with the prophylactic use of this antimalarial drug. The Canadian Product Monograph of Lariam (mefloquine) contains all information on very rare neuropsychiatric reactions reported in some patients as well as cautions to be considered by physicians when prescribing this drug.

Because information that could identify the patient or the reporter in an adverse reaction report is confidential as per section 19(1) of the *Access to Information Act*, Health Canada cannot comment on investigations of any case by Health Canada or other government agencies.

NATIONAL DEFENCE

a) The Department of National Defence reviewed the report.

b) Given that the report deals with incidents that the Department examined in the past, no further investigation is deemed warranted.