

DECLASSIFIED
DÉCLASSIFIÉ
Date: May 2, 2002
Classification: HPFB PROTECTED/PROTEGE OGPSA

QUESTION PERIOD NOTE
NOTE POUR LA PÉRIODE DE QUESTIONS

CBC TV's Health Matters is proposing to air a story on E.M. Power
ISSUE / SUJET: CBC is investigating the notion that the company TrueHope/Synergy has found a legal loophole through the Health Products and Food Branch Inspectorate's "Importation of Human-Use Drugs for Personal Use Enforcement Directive" to market and sell an unapproved product to Canadians.
SOURCE: CBC TV Health Matters

PROPOSED RESPONSE (English) / RÉPONSE PROPOSÉE (anglais):

- The *Food and Drugs Act and Regulations* apply to the advertisement, sale and importation for [redacted] sale of drugs.
- It has been the policy of the Health Canada to permit individuals to import a three-month supply of a drug for their own personal use.
- This policy does apply to drugs that may be available for sale in other countries, but which are not approved for sale in Canada. This approach is comparable to policies in other countries.
- This policy does not allow the importation of drugs which are prohibited by law.
- The *Controlled Substances Act* and the *Food and Drugs Act* and their *Regulations* prohibit the importation of controlled drugs and prescription drugs except under prescribed conditions.
- It is not the intent of this policy to allow individuals/companies to

advertise and sell drugs to Canadians as a way to by-pass regulatory requirements.

- **Health Canada assesses each situation to determine how a drug is being advertised and sold in Canada, whether there is any regulatory contravention, and finally, proceeds in accordance with the Health Branch and Food Branch Inspectorate's Compliance and Enforcement Policy.**

BACKGROUND / CONTEXTE:

E.M Power is a vitamin/ mineral supplement that is being promoted for various Central Nervous System disorders such as bipolar depression, anxiety, and schizophrenia. Because this product is sold for these claims, this product is considered to be a drug and requires a Drug Identification Number to be sold on the Canadian market.

The Health Products and Food Branch Inspectorate (HPFBI) has investigated Synergy's website advertisement and sale of the unapproved drug E.M. Power. Health Canada has advised Synergy/Truehope that sale of a drug without a Drug Identification Number is a violation to the *Food and Drugs Act*. This was addressed through regulatory letters sent in October 20, 2000 and April of 2001. Website advertisement is part of the total representation of a drug.

Following discussions with the Western Operational Centre of HPFBI on May 16, 2001, Synergy agreed to modify its website to comply with the Food and Drugs Act and Regulations. The Western Operational Centre received a letter dated May 29, 2001 from Synergy's legal representation stating that Synergy Group of Canada no longer maintains the website at www.truehope.com; that the website had been modified and is now owned by a US corporation. Health Canada does not normally investigate US websites. However, upon a recent check it does not appear that the website is american. HPFBI will need to research this further for the investigation to proceed.

Also, Dr. Bonnie Kaplan of the University of Calgary had begun clinical trials on E.M. Power, without first obtaining approval from Health Canada. The HPFB Inspectorate investigated this, and informed Ms. Kaplan of the regulatory requirement to file a Clinical Trial Application (CTA) before any clinical trials may be undertaken

Dr. Bonnie Kaplan has been notified that clinical trials must cease. Dr. Bonnie Kaplan has re-confirmed that the clinical trials have stopped. Dr. Kaplan is working

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2001(b)(c)

2021(b)(c)

Bonnie Kaplan has re-confirmed that the clinical trials have stopped. Dr. Kaplan is working with HC

CBC produced a story exposing the sale of EM Power + by Synergy/Truehope in Canada as part of a "clinical research project" . This was aired May 27. A reporter working on the piece says they have a tape of a salesperson at the Synergy/ Truehope Headquarters in Lethbridge, Alberta, making health claims about the product and inviting patients to buy it for \$200 and take part in the clinical study. The reporter says the salesperson also recommends the patient stop taking his current medications and order EM Power + from the United States for personal use. We have requested these tapes. Anthony Stephen , Director from Synergy contacted the Inspectorate on May 30, 2002. A teleconference involving the Inspectorate and Anthony Stephan and David Hardy has taken place on May 31, 2002.

Health Canada recieved an Access to Information (ATI) request for all written records received by or sent to the Minister of Health, Natural Health Products , Therapeutic Products Directorate and the Health Product and Food Branch Inspectorate regarding E.M. Power. Records involving the investigation were disclosed

Information was disclosed to the applicant May 14, 2002.

Health Canada will further investigate any additional information of noncompliance as it becomes available .

Remarks/ Remarques:

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