Subject: Outbreak of acute non-viral Hepatitis potentially with a range of OxyElite dietary supplement products.

An alert has been received from INFOSAN with regard to the Outbreak of acute non-viral Hepatitis potentially with a range of OxyElite dietary supplementary products. The ongoing incident of dietary supplement products in the OxyElite range leading to acute non-viral hepatitis have been identified in the USA, Ireland and New Zealand.

There have been 62 cases of acute non-viral hepatitis identified in the USA, 1 in Ireland and 2 in New Zealand up till 13 November 2013. The OxyElite products are used for a weight loss or muscle building dietary supplement.

The OxyElite products namely OxyElite Pro Super Thermo capsules; OxyElite Pro Ultra-Intense Thermo capsules; OxyElite Pro Super Thermo powder, and VERSA-1, OxyElite Powder Super T. Genie Caffeinated Beverage have been associated with severe liver disorders, including hepatitis and liver failure.

According to the FDA News Release, OxyElite Pro and another supplement called VERSA-1 were deemed to be adulterated. The products contained aegeline, a new dietary ingredient (i.e. an ingredient not marketed in the United States before Oct 15, 1994) that lacks a history of use or other evidence of safety.

This information is being brought to the notice of all stakeholders and public at large.

(Ms. Vinod Koivat)
Director (Codex)

INFOSAN documents (enclosed for information)

To:
1. All AOs, FSSAI
2. Custom Authorities
3. All Food Safety Commissioner of State/UT’s
4. DGHS, Ministry of Health & Family Welfare, GOI

Copy to:
1. PPS to CP
2. PS to CEO
Update - Outbreak of Acute Non-Viral Hepatitis Potentially Associated With a range of OxyElite Dietary Supplement Products

Alert details

The INFOSAN Secretariat has received updated information regarding the ongoing incident of dietary supplement products in the OxyELITE range leading to acute non-viral hepatitis.

As of 13 November 2013 there have been 62 cases of acute non-viral hepatitis identified in the USA, 1 in Ireland, and 2 in New Zealand (under investigation) with an unknown cause subsequent to the use of a weight loss or muscle building dietary supplement (OxyELITE product).

A recall of certain OxyELITE products is underway in the USA. The FDA is not aware of international shipments of the recalled product to foreign distributors or direct international consignees. The case in Ireland reported purchasing OxyELITE products online, however both cases in New Zealand purchased OxyELITE products from retail stores in New Zealand. The specific OxyELITE product consumed in New Zealand are not listed among products recalled by the USA company.

No causative agent or ingredient has yet been identified and investigations are still underway.

Given these developments, the INFOSAN Secretariat would like to emphasize our previous request to receive information about cases of acute non-viral hepatitis in other countries which could be linked to consumption of weight loss or muscle building dietary supplements. (Suggestion - insert information on the case definition for this event. Either draft or current and under review, would be helpful).

In addition, sharing any actions taken in response to this Alert would also be helpful as we try and summarize the international aspects of the event.

Please feel free to post directly on the INFOSAN Community Website by using the discussion function ("Discuss This" button on bottom of this page).

Below you will find additional details and links to public information provided from our INFOSAN colleagues in the USA, Ireland and New Zealand:

Information from US FDA:

https://extranet.who.int/infosan/print/1611

18-11-2013
On November 10, 2013 the U.S. Food and Drug Administration announced that USPlabs LLC, of Dallas, Texas, is recalling certain OxyELITE Pro dietary supplement products that the company markets. The company took this action after receiving a letter from the FDA stating that the products have been linked to liver illnesses and that there is a reasonable probability that the products are adulterated.

As of November 13, 2013, there have been 62 cases of acute non-viral hepatitis with an unknown cause subsequent to the use of a weight loss or muscle building dietary supplement identified nationally, with most of them being in the State of Hawaii. Fifty-one used the dietary supplement products labeled as OxyELITE Pro during the 60 days prior to illness. FDA has reviewed 46 medical records submitted to the FDA by the Hawaii Department of Health, the records indicated that 27 patients, or 58 percent, had taken a dietary supplement labeled as OxyELITE Pro prior to becoming ill. Seventeen of the 27 patients (or 63 percent) reported that OxyELITE Pro was the only dietary supplement they were taking. One death has occurred among these patients, another patient has required a liver transplant, and others await liver transplants.

Currently, FDA is not aware of international shipments of the recalled product to foreign distributors or direct international consignees. However, FDA is aware that the affected products was available through internet sales. Investigation is still ongoing additional information is forthcoming.

Additional information can be found on FDA’s website:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm374395.htm

Firm’s press release including products involved in the recall:
http://www.fda.gov/safety/recalls/ucm374394.htm

Information from the Food Safety Authority Ireland (FSAI):

One case of non-viral hepatitis has been reported in Ireland following the ingestion of OxyELITE Pro products, dietary supplements marketed for energy boost, muscle building, and weight loss. The FSAI and the Irish Medicines Board (IMB) has issued a joint warning not to purchase or consume certain food supplements, namely: OxyELITE Pro Super Thermo capsules; OxyELITE Pro Ultra-Intense Thermo capsules; OxyELITE Pro Super Thermo powder, and VERSA-1.

The OxyELITE Pro range is associated with severe liver disorders, including hepatitis and liver failure, with one case reported in Ireland to date. The case consumed OxyELITE Pro after purchasing it online.

Both OxyElite Pro and VERSA-1 are produced by USP Labs LLC in the USA. Although VERSA-1 has not been associated with liver disease, both it and OxyELITE Pro contain the ingredient aegeline, which cannot be excluded as a cause of illness. The OxyELITE Pro products were on retail sale in Ireland. Retailers have been requested to remove the products from sale.
The FSAI press release containing full details is available online:
http://www.fsa.ie/news_centre/food_alerts/oxyelite_warning.html

Information from New Zealand Ministry for Primary Industries (MPI):

MPI has advised people not to consume supplements labeled OxyELITE Pro and OxyELITE Powder Super T. Genic Caffeinated Beverage. This follows the identification of two cases in New Zealand among consumers of OxyELITE Pro Powder Super T. Genic Caffeinated Beverage. Both cases purchased the product in retail stores in New Zealand.

The MPI press release containing full details is available online:

Subsequent to the release of the above Director General statement, New Zealand MPI has advised that it is reviewing its classification of the two cases in light of further discussion on the case definition. At this time, both cases should be regarded as under investigation. MPI aims to have additional information available next week to clarify the status of these cases.

-----

The INFOSAN Secretariat will continue to provide updated details to this event as additional information becomes available.

Hazard:  
- Toxin/Chemical  
- Unknown

Countries:  
- Ireland
- New Zealand
- United States of America

Food category:  
Products for special nutritional use

Food involved:  
OxyElite (Dietary supplement for energy boost body building and weight loss)

WHO regions:  
- Region of the Americas
- Western Pacific Region
- European Region

Source URL: https://extranet.who.int/infosan/content/update-outbreak-acute-non-viral-hepatitis-potentially-associated-range-oxyelite-dietary-supplement