



**FOR IMMEDIATE RELEASE**

**HEALTH SCIENCES AUTHORITY  
PRESS RELEASE  
18 OCT 2013**

## **HSA ALERTS PUBLIC TO “OXYELITE PRO” – AN UNREGISTERED MEDICINAL PRODUCT LINKED TO SERIOUS LIVER INJURIES**

The Health Sciences Authority (HSA) is alerting members of the public to an unregistered medicinal product labelled as “OxyELITE Pro”, which has been linked to numerous cases of serious liver injuries in the United States (US) and one case in Hong Kong. “OxyELITE Pro” is a medicinal product not approved for sale by HSA. However, investigations by HSA have found that the product is being sold illegally through the Internet in Singapore and some members of the public may have purchased the product from overseas.

### **More about “OxyELITE Pro”**

2 “OxyELITE Pro” is marketed overseas as a dietary supplement and as a fat burner to achieve rapid weight loss. It is labelled to contain herbal extracts. Preliminary laboratory tests conducted by HSA on the “OxyELITE Pro” capsules bought from an Internet seller have found the product to contain 1,3-dimethylamylamine (DMAA) and yohimbine which are potent western medicinal ingredients that are not allowed to be present in supplements sold locally. Health products containing such ingredients require registration as medicinal products and can cause serious adverse effects when consumed without medical supervision. Investigations are ongoing to detect other potentially undeclared ingredients which may have caused the liver injuries. See **Annex A** for photos of the seized product.

### **Cases of acute hepatitis in the US**

3 The US Food and Drug Administration (FDA) has recently reported 29 cases of acute non-viral hepatitis (liver injury) in the state of Hawaii. Although the actual cause of the liver injuries has not been identified, investigations have found that 24 of these cases were associated with the use of the medicinal product “OxyELITE Pro”. Eleven of the 29 cases have been hospitalised with acute liver injury: two of these cases have resulted in liver transplants and one person has died as a result of the complication of the serious liver injuries. The most commonly reported symptoms of liver injuries experienced by the patients include loss of appetite, jaundice, dark urine and light-coloured stools.

4 The US Centers for Disease Control and Prevention (CDC) is currently investigating other cases of liver injury in other US states that may be related to these events in Hawaii. The US FDA is also investigating the contents of the product “OxyELITE Pro”, and its manufacturing premises, as well as whether counterfeit products or any other ingredients could be related to these cases of acute liver injuries.

5 To date, HSA has not received any adverse reaction reports associated with the use of “OxyELITE Pro” although it could be possible that consumers who have suffered side effects may not have told their doctors or pharmacists about the use of this product. See

**Annex B** for the possible adverse effects of yohimbine and DMAA which include increased blood pressure, irregular or rapid heartbeats and chest pain. HSA is in contact with the overseas counterparts on their on-going investigations.

### **Public advisory**

6 In view of the seriousness of the liver injuries possibly related to “OxyELITE Pro”, HSA strongly advises members of the public who are taking this product to stop consuming it immediately. As a range of products is available under the brand name of “OxyELITE Pro”, it cannot be confirmed which specific formulation may be responsible for the liver injuries. As a precautionary measure, consumers are advised to stop taking this range of products labelled “OxyELITE Pro”. Members of the public are also advised to consult a doctor as soon as possible if they are feeling unwell after taking “OxyELITE Pro”.

7 Members of the public who have any information on the sale of this unregistered medicinal product may contact HSA's Enforcement Branch at Tel: 6866-3485 during office hours (Monday to Friday) or email: [hsa\\_is@hsa.gov.sg](mailto:hsa_is@hsa.gov.sg). Additionally, members of the public are encouraged to visit [www.healthdangers.sg](http://www.healthdangers.sg) to learn more about the dangers of buying illegal health products from dubious sources.

### **Warning and advice to sellers**

8 HSA warns sellers to stop the sales and distribution of “OxyELITE Pro” as this is an unregistered medicinal product. Anyone selling such products will face a penalty fine of up to \$10,000 and/or imprisonment for a period of up to two years under the Poisons Act.

## **HEALTH SCIENCES AUTHORITY**

**18 OCTOBER 2013**

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### **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at [www.twitter.com/HSAsg](http://www.twitter.com/HSAsg).

### **About HSA's Health Products Regulation Group**

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of

biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

# HSA ALERTS PUBLIC TO “OXYELITE PRO” – AN UNREGISTERED MEDICINAL PRODUCT LINKED TO SERIOUS LIVER INJURIES

Photos of “OxyELITE Pro” seized from an Internet seller



**List of potent medicinal ingredients detected in “OxyELITE Pro”**

**1. Yohimbine**

Some adverse effects associated with Yohimbine include insomnia, anxiety, palpitations (sensation of heart pounding, racing or skipped beats), chest pain, sweating, blurred vision and high blood pressure. Overdosage can cause low blood pressure, rapid heartbeats, seizures, paralysis and coma. Deaths from overdose have been reported.

**2. 1,3-dimethylamylamine (DMAA)**

1,3-dimethylamylamine (DMAA) is an active ingredient originally developed as a nasal decongestant. Adverse effects associated with DMAA include cardiovascular events such as heart attack, irregular heartbeats, tightening in the chest and increased blood pressure. Other effects include shortness of breath, seizures and other neurological and psychological conditions.