



**FOR IMMEDIATE RELEASE**

**HEALTH SCIENCES AUTHORITY  
PRESS RELEASE  
03 OCTOBER 2012**

**HSA ALERTS PUBLIC TO ADVERSE REACTIONS RELATED TO THE  
CONSUMPTION OF ADULTERATED HEALTH PRODUCTS, INCLUDING  
A FATAL CASE**

The Health Sciences Authority (HSA) alerts members of the public to two cases of patients suffering adverse reactions and one case of death after taking adulterated products sold as pharmaceutical and traditional herbal medicines. These products have not been approved by HSA and contain undeclared western medicines not stated in their labels. Two of these products were obtained from overseas and one locally from a friend.

These adulterated products are labelled as follows:

- i. 'FLUTULANG'**
- ii. 'KAPSUL GAUT' (Asam Urat)**
- iii. 'TRUE PROLIFE VEGROW'**

2 Three patients in their 50s and 70s have suffered adverse reactions from taking these products and were reported to HSA by the medical practitioners. The adverse reactions reported are as follow:

- i. One of the patients died from complications of a life-threatening skin reaction following the consumption of 'Flutulang';
- ii. Cushing's syndrome associated with 'Kapsul Gaut'; and
- iii. Giddiness, headache, shortness of breath and backache associated with 'True ProLife Vegrow'.

3 Upon investigations by HSA's Pharmaceutical Laboratory, the undeclared western drug ingredients are:

- i. 'Flutulang' contained phenylbutazone and chlorpheniramine;
- ii. 'Kapsul Gaut' contained dexamethasone; and
- iii. "True ProLife Vegrow" contained propoxyphenyl-thiohydroxyhomosildenafil, a chemical similar to sildenafil.

(Refer to **Annex B** for more information on the cases and the adulterants)

## HSA's Actions Taken

4 HSA's Enforcement Branch had recently conducted a field surveillance at 35 local shops selling Traditional herbal medicines and have ascertained that 'Flutulang', 'Kapsul Guat' and 'True ProLife Vegrow' were not sold in these shops. The HSA officers had also taken the opportunity during their surveillance rounds, to educate the dealers of these three products and that they have been found to be adulterated with potent western medicines.

## Public Advisory

5 Consumers who have purchased 'Flutulang' and 'True ProLife Vegrow' are advised not to consume them as they are adulterated with potent western medicines. If consumers have taken them, they should seek medical attention if they feel unwell or are concerned about their medical condition.

6 Those who have consumed 'Kapsul Gaut' (Asam Urat) are advised not to stop taking the product abruptly but to consult a registered medical practitioner as soon as possible as it contains a potent steroid. Stopping a potent steroid abruptly can lead to withdrawal symptoms such as weakness, fatigue, weight loss, nausea, diarrhoea, low blood pressure, joint pain and bowel obstruction due to the slowing down of intestinal contractions. Therefore, medical supervision is required to prevent steroid withdrawal when stopping steroid therapy in patients who have consumed high doses of steroids over a prolonged period of time.

7 Dr Raymond Chua, Group Director, Health Products Regulation Group in HSA says, "The consumption of such illegal and adulterated health products can lead to serious and life-threatening adverse events. Consumers are strongly advised to consult their doctors before consuming such health products even though they might appear to be safe and are obtained from familiar sources. Although these products could provide temporary relief from medical conditions such as aches and pains, they can also cause serious adverse effects which may be permanent and irreversible."

8 Consumers are advised not to purchase these three illegal health products if they should come across them. Members of the public and retailers who have encountered these illegal products or any other suspicious products, are encouraged to report them to the Enforcement Branch of HSA at Tel: 6866 3485 or Email: [hsa\\_is@hsa.gov.sg](mailto:hsa_is@hsa.gov.sg).

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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, 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.

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**Pictures of 'Flutulang'**



**Product description:**

'Flutulang' is packaged as a sachet of five different tablets – four round tablets (pink, green, yellow and white) and one yellow oval tablet.

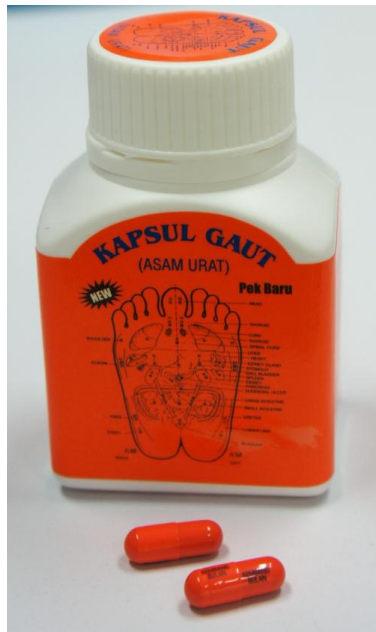
**Labelling in English (translated):**

<b>Product Name</b>	Flutulang
<b>Indication as on label</b>	For rheumatism. Relieves backache, muscle cramps, headache, toothache and lethargy. For gout. Improves appetite. Improves sleep. Revitalises.
<b>Instructions for dosage</b>	One packet to be taken once a day, after meals
<b>Packaged by</b>	Nusantara Buana Surya Jakarta, Indonesia

**Labelling in Bahasa Indonesia:**

<b>Product Name</b>	Flutulang
<b>Indication as on label</b>	Sakit rheumatic, sakit pinggang, pegal linu, sakit kepala/gigi, sakit encok/lesu, letih, nyeri pada tulang & otot, menambah nafsu makan dan membuat enak tidur, segar dibadan.
<b>Instructions for dosage</b>	Satu bungkus sekali minum sehabis makan
<b>Packaged by</b>	Nusantara Buana Surya Jakarta, Indonesia

**Picture of 'Kapsul Gaut (Asam Urat)'**



**Product Description:**

Kapsul Gaut (Asam Urat) comes in a bottle of 60 orange capsules.

**Labelling in English (translated):**

<b>Product Name</b>	Kapsul Gaut (Asam Urat)
<b>Indication on label</b>	Pain in bones/muscle, rheumatism, swelling of the knees and legs, fatigue, body ache, pain in the waist area
<b>Instructions for dosage</b>	Two capsules in the morning and two capsules at night, after meals
<b>Packaging</b>	60 capsules
<b>Distributor</b>	USTAZ HAFIZ No.63, Jitra, Kedah, Malaysia
<b>Active ingredients (as stated on label)</b>	Curcumae Ghizoma (15%), Zingiberis Phizoma (25%), Carryophili Flos (15%), Genda Rusae Folium (25%), Andrographidis Folium (20%)

**Labelling in Malay:**

<b>Product Name</b>	Kapsul Gaut (Asam Urat)
<b>Indication on label</b>	Sakit sendi, angin dalam urat, bengkak-bengkak kaki & lutut, kebas tapak kaki, cepat penat, lengoh badan, menguatkan buah pinggang
<b>Instructions for dosage</b>	2 kapsul pagi dan 2 kapsul malam selepas makan
<b>Packaging</b>	60 capsules
<b>Distributor</b>	USTAZ HAFIZ No.63, Jitra, Kedah, Malaysia
<b>Active ingredients (as stated on label)</b>	Curcumae Ghizoma (15%), Zingiberis Phizoma (25%), Carryophili Flos (15%), Genda Rusae Folium (25%), Andrographidis Folium (20%)

Picture of 'True ProLife Vegrow capsule 回春'



**Product Description:**

'True ProLife Vegrow capsule' comes in a blue box containing 3 smaller boxes, each enclosed with a blister pack of 10 capsules. The capsules come in a transparent shell containing brown powder.

**Labelling:**

<b>Product Name</b>	True ProLife Vegrow capsule 回春
<b>Indication on label</b>	Traditionally used for strengthening the body and maintenance of general health
<b>Instructions for dosage</b>	Take 1-2 capsules daily
<b>Packaging</b>	3 x 10 capsules
<b>Manufactured by</b>	Solar Victory Sdn. Bhd. No. 68, Jalan Tanming 6, Tanming Jaya Industrial Park, 43300 Seri Kembangan, Selangor.
<b>Ingredients (as stated on label)</b>	Each capsule (400mg) contains: Cortex Eucommia ulmoides (100mg); Herba Cynomorium songaricum (100mg); Ganoderma lucidum (70mg); Cortex Cinnamomum cassia (60mg); Radix Codonopsis pilosula (35mg); Radix Glycyrrhiza uralensis (35mg)

**More Information about the Case Reports of Adverse Reactions**

**i. 'FLUTULANG'**

A Malay woman in her 70s was hospitalised after taking 'Flutulang' to relieve muscle-ache. 'Flutulang' was tested to contain two undeclared medicinal ingredients – phenylbutazone and chlorpheniramine. The patient had previously developed a life-threatening adverse reaction known as Drug Rash<sup>1</sup> with Eosinophilia and Systemic Symptoms (DRESS)\* from taking phenylbutazone in 2006 from which she recovered without further complications.

In August 2012, she consumed an illegal health product, 'Flutulang' which her son purchased from Indonesia. She assumed she had taken the correct precautions as she had consumed it only after a close relative took it without any problems. Unknown to her, 'Flutulang' was adulterated with phenylbutazone, which had caused a similar serious adverse reaction for her in 2006. As a result of the exposure to the same drug a second time, she developed a similar form of rash on her neck and thighs, which subsequently progressed to Toxic Epidermal Necrolysis (TEN)<sup>2</sup>. She later passed away from the complications of the serious adverse reaction.

**ii. 'KAPSUL GAUT' (Asam Urat)**

The second case was of a Malay woman in her 50s who developed Cushing's syndrome after taking 'Kapsul Gaut', a traditional herbal remedy, for four months. She bought the product in Malaysia for the treatment of gout. The product claimed to contain herbal ingredients effective in the relief of pain, rheumatism and fatigue. It was tested to contain dexamethasone, a potent steroid. Upon stopping the product, the patient suffered from steroid withdrawal symptoms, including body weakness, aches and pains, diarrhoea and vomiting. She did not require hospitalisation, but was prescribed a tapering course of steroids to help her cope with the withdrawal symptoms and to wean her off her dependence on steroids. She has since recovered.

**iii. 'TRUE PROLIFE VEGROW'**

The third case involved a Malay man in his 70s who took 'True ProLife Vegrow' for three days, and developed giddiness, headache, shortness of breath and backache. He went to see a doctor and was advised to stop taking the product, after which he recovered in a couple of days. 'True ProLife Vegrow' was marketed as a traditional herbal product used for

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<sup>1</sup> Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) is a serious allergic reaction caused by certain drugs. It usually involves a rash, fever, swollen lymph nodes, blood abnormalities and inflammation of internal organs, and is potentially fatal.

<sup>2</sup> \*\*Toxic Epidermal Necrolysis (TEN) is a rare, life-threatening skin reaction that is usually caused by certain medications. It is characterised by widespread blistering or peeling of the skin, due to the separation of the top layer of the skin from its lower layers. It usually starts off with symptoms resembling a flu (e.g. fever), followed by a rash that extends all over the body, and commonly involves the mucous membranes (e.g. blistering of the mouth, ulceration of the eyes).

strengthening the body and for the maintenance of general health. It had been detected to be adulterated with propoxyphenyl-thiohydroxyhomosildenafil, a chemical similar to sildenafil. Sildenafil is a drug used medically for sexual enhancement. The man had obtained the product locally through a friend.

### **Information on The Potent Western Medicines Found as Adulterants in the Illegal Health Products**

1. **Phenylbutazone** is a non-steroidal anti-inflammatory drug (NSAID) and was used to treat rheumatoid arthritis and gout. Overdose or prolonged use can cause gastrointestinal ulcers, kidney damage or even death. Phenylbutazone-containing products are no longer registered in Singapore since 2006 as its risks of causing serious adverse events has been assessed to outweigh its benefits, as well as the availability of safer alternatives.
2. **Chlorpheniramine** is a type of antihistamine used to relieve allergic reactions, such as hay fever, rhinitis, urticaria and asthma. Side effects from unsupervised use include drowsiness, confusion and urinary retention.
3. **Dexamethasone** is a very potent steroid and is used for anti-inflammatory purposes (i.e. reduce pain and swelling). Unsupervised long-term use of dexamethasone can cause increased blood glucose levels leading to diabetes, high blood pressure, cataracts, muscular and bone disorders, and an increased risk of infections. Long term use of dexamethasone can also lead to **Cushing's syndrome**, a disorder that occurs when a person's body is exposed to high levels of steroid hormones. This condition is characterised by a round face or "moon face", and upper body obesity with thin arms and legs.

Patients who have taken high doses of steroids over a prolonged period of time may also suffer from withdrawal symptoms if the steroid consumption is stopped suddenly. Steroid withdrawal symptoms include weakness, fatigue, weight loss, nausea, diarrhoea, low blood pressure, joint pain and bowel obstruction due to the slowing down of intestinal contractions. Medical supervision is required to prevent steroid withdrawal when stopping steroid therapy in patients who have consumed high doses of steroids over a prolonged period of time.

4. **Propoxyphenyl-thiohydroxyhomosildenafil, a chemical similar to sildenafil** Sildenafil is used medically to treat erectile dysfunction. Its usage without proper medical advice and supervision can cause serious adverse events such as decreased or loss of vision and hearing, low blood pressure and other cardiovascular events such as stroke and myocardial infarction.