# HSA

#### FOR IMMEDIATE RELEASE

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## HSA ALERTS PUBLIC TO ADULTERATED HEALTH PRODUCTS PURCHASED OVERSEAS THAT HAVE CAUSED SERIOUS ADVERSE REACTIONS

The Health Sciences Authority (HSA) alerts members of the public to two cases of patients suffering serious adverse reactions after consuming adulterated products (i.e. products which contain undeclared medicinal ingredients) for the relief of pain and gout. There was also a third case which involved a patient who experienced rapid relief of her migraine symptoms after taking another adulterated product. All three products were sold under the guise of herbal or traditional medicines. These products were obtained from overseas and are not approved by HSA (Please refer to Annex A for pictures and labels of the products).

#### **Details of Adulterated Products and Adverse Reactions**

- 2 Two patients in their 30s and 60s suffered serious adverse reactions of Cushing's syndrome after consuming GINSENG BAJI GU CI WAN(人参巴戟舒筋骨刺丸) and TU CHONG GINSENG WAN LE SEANG(杜仲人参万里香)respectively to relieve pain and gout. The cases were detected separately by an astute Traditional Chinese Medicine (TCM) physician and a doctor who subsequently reported them to HSA.
- 3 The third case involved a patient in her 50s who experienced rapid relief of her migraine symptoms after consuming X-TRACT NATURE which led the doctor to suspect possible adulteration of the product. X-TRACT NATURE and GINSENG BAJI GU CI WAN (人参巴戟舒筋骨刺丸) each carried a product registration number, purporting to be licensed from its country of origin, but which have both been verified by HSA to be faked.
- Tests done at HSA's Pharmaceutical Laboratory confirmed that these capsules were adulterated with undeclared potent medicinal ingredients as follows:

Product	Undeclared medicinal ingredients
GINSENG BAJI GU CI WAN(人参巴戟舒筋骨刺丸)	Dexamethasone and chlorpheniramine

Product	Undeclared medicinal ingredients
TU CHONG GINSENG WAN LE SEANG (杜仲人参万里香)	Dexamethasone and chlorpheniramine
X-TRACT NATURE	Prednisone, phenylbutazone, chlorpheniramine and paracetamol

(Please refer to <u>Annex B</u> for more information on the cases and the dangers of the undeclared medicinal ingredients.)

The presence of potent steroids, i.e., dexamethasone and prednisone, in the products is of serious concern as they can cause serious adverse effects such as increased blood glucose leading to diabetes, high blood pressure, and eye, muscular and bone disorders. Sudden stopping of the consumption of these products can also cause serious withdrawal symptoms such as weakness, fatigue and bowel obstruction, especially when these products are taken for more than a few weeks.

#### **Public Advisory**

- Members of the public who have purchased the above products are advised not to consume them. Those who have consumed these products are advised to consult a medical practitioner as soon as possible and they should NOT stop taking the product abruptly as they contain potent steroids. Stopping steroids abruptly can cause serious withdrawal symptoms.
- Associate Professor Chan Cheng Leng, Deputy Group Director, HSA's Health Products Regulation Group says, "The harmful effects of adulterated health products are real and evident from the many reports of adverse reactions that HSA received. Consumers are strongly advised against taking health products that offer quick relief for ailments such chronic pain from gout, arthritis and migraines. Often, these products contain potent medicinal ingredients that are not listed on the packaging. This is very dangerous for consumers who take these products. It is almost impossible for the consumer to tell from the packaging whether a product is adulterated or not and the best practice is to avoid buying and consuming these products."
- Consumers are advised not to purchase these 3 illegal 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: <a href="mailto:hsa\_is@hsa.gov.sg">hsa\_is@hsa.gov.sg</a>.

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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 <a href="http://www.hsa.gov.sg/">http://www.hsa.gov.sg/</a>.

For more updates on public health and safety matters, follow us on Twitter at <a href="https://www.twitter.com/HSAsg">www.twitter.com/HSAsg</a>.

#### 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 ADULTERATED HEALTH PRODUCTS PURCHASED OVERSEAS CAUSING SERIOUS ADVERSE REACTIONS

#### Picture of the 3 adulterated health products



From left to right: GINSENG BAJI GU CI WAN(人参巴戟舒筋骨刺丸), TU CHONG GINSENG WAN LE SEANG(杜仲人参万里香), and X-TRACT NATURE.

#### Picture of GINSENG BAJI GU CI WAN(人参巴戟舒筋骨刺丸)



#### **Product Description:**

GINSENG BAJI GU CI WAN(人参巴戟舒筋骨刺丸)comes in a bottle of 40 black pills.

#### Information on original packaging (in Chinese and Malay):

Product	GINSENG BAJI GU CI WAN(人参巴戟舒筋骨刺丸)
Brand	飞马商牌
Indications	腰酸骨痛,风湿痳痹,关节疼痛,筋骨无力,手足钓挛,偻痳质斯
Instructions for dosage	每日二至三次,每次 2-3 粒,用温开水送服,儿童减半。
Precautions:	禁忌: 萝卜及生冷食物。 孕妇禁食。
Active ingredients	麝香- SHE XIANG- 5mg杜仲- EVCONIA UIMDIDES- 20mg天麻- GASTRODIA ETATE BL- 10mg人参- GINSENG- 10mg鹿茸- DEER HORNS- 10mg当归- LIGUSTICUM- 13mg

	川芎 - CNIDUM OFFCINALEM - 12mg 甘草 - GLYEYRAHZAGLABRA - 12mg 千金藤 - CHIEN GIN DREN - 10mg
Distributor:	YUNJIAN TRADING
	6, Green Garden, Penang
Manufacturer:	YUZUN PHARMACEUTICAL
	70, Off Chain Ferry Rd, Butterworth

#### Information on original label (translated):

Product	GINSENG BAJI GU CI WAN(人参巴草	<b></b> 我舒筋骨刺丸)
Brand	飞马商牌	
Indications	Lumbago spasm of muscular rheumati and feebleness of knee etc. 腰酸骨痛,风湿痳痹,关节疼痛,筋骨 Menghentikan sakit sendi, sakit pingga mengendurkan urat dan mellcinkan pe	无力,手足钓挛,偻痳质斯 ang dan kaki,
Instructions for dosage	To be taken two to three times a day 2 warm water. 每日二至三次,每次 2-3 粒,用温开水 2-3 pil sakali, 2-3 kali sehari dengan ai	· 送服,儿童减半。
Precautions:	Prohibition: Raw and cold foodstuffs. 禁忌: 萝卜及生冷食物。 Not to be taken for pregnant women. 孕妇禁食。	
Active ingredients	原香 - SHE XIANG 杜仲 - EVCONIA UIMDIDES 天麻 - GASTRODIA ETATE BL 人参 - GINSENG 鹿茸 - DEER HORNS 当归 - LIGUSTICUM 川芎 - CNIDUM OFFCINALEM 甘草 - GLYEYRAHZAGLABRA 千金藤 - CHIEN GIN DREN	- 10mg - 10mg - 13mg
Distributor:	YUNJIAN TRADING 6, Green Garden, Penang	
Manufacturer:	YUZUN PHARMACEUTICAL 70, Off Chain Ferry Rd, Butterworth	

#### Pictures of TU CHONG GINSENG WAN LE SEANG(杜仲人参万里香)





#### **Product description:**

TU CHONG GINSENG WAN LE SEANG (杜仲人参万里香) is packaged in a white bottle of black pills.

#### Information on original packaging (in Chinese and Malay):

Product	TU CHONG GINSENG WAN LE SEANG(杜仲人参万里香)
Brand	<b>鹿牌注册商标</b>
Indications	风湿骨痛,腰酸背痛,筋骨无力,关节炎肿 Untuk menghilangkan penyakit segal-segal tulang, bengkak sendi, sakit pinggang, sakit urat, sakit tangan dan kaki
Instructions for dosage	每日三次每次三粒,用开水送服。 3 biji sekali, 3 kali sehari dengan air panas selepas makan

#### Information on original label (translated):

Product	TU CHONG GINSENG WAN LE SEANG(杜仲人参万里香)
Brand	Deer brand registered trademark
Indications	Rheumatism, back pain, limb weakness, arthritis
Instructions for dosage	3 pills three times a day To be consumed with warm water

#### **Pictures of X-TRACT NATURE**





#### **Product Description:**

X-TRACT NATURE comes in a white bottle packed with light and dark blue capsules.

#### Information as quoted on original packaging (in Indonesian and English):

Product	X-TRACT NATURE
Indication	Berfungsi untuk melancarkan sirkulasi darah, metabolisme tubuh, melindungi fungsi hali sehingga meningkatkan daya tahan tubuh. Mengatasi/mencegah stroke, diabetes, asma, perdarahan, peradangan dan memperlambat degeneratif (penuaan).
	Function for blood circulation, metabolism, protect the liver function thereby increasing endurance. Overcome/prevent stroke, diabetes, asthma, bleeding, inflammation and slow the degenerative (aging).
Instructions for dosage	Pada saat ada gangguan sehari 2x2 kapsul, disarankan minum air 10 gelas sehari untuk membuang toxin dari tubuh. Pemeliharran 1x1 kapsul.
	2 time 2 capsule / day Maintenance 1 time 1 capsule / day

	Suggested drink 10 cups/day to excrete toxin
Ingredients	Chevikol, Betlephenol, Sirkuiterpen, Styptic, Diatase, Arecoline, Tanin and Eugenol.
	Substance of Styptic, Substance of Betlephenol, Diatase, Substance of Aluephenol, Substance of Tanin, Sircuiterpen
Attention:	Obat selalu disimpan tertutup dan ditempat kering & sejuk. Tidak diberikan pada wanita hamil atau yang sedang menyusui termasuk anak dibawah 12 tahun.
	Put the extract nature in close bottle, and prohibition to cure of pregnant and lactating women, include children under twelve years old.
Formulated by	Dr Muhammad. T, MPH., SpKL

#### MORE INFORMATION ABOUT THE CASE REPORTS OF ADVERSE EVENTS

## GINSENG BAJI GU CI WAN(人参巴戟舒筋骨刺丸)& TU CHONG GINSENG WAN LE SEANG(杜仲人参万里香)

- 1. A Chinese patient in her late 30s took GINSENG BAJI GU CI WAN(人参巴戟 舒筋骨刺丸)for about 4 months to help relieve the pain triggered by her foot bone spurs. She started to display symptoms of a 'moon face', swelling of the neck and unexplained weight gain over a short period of time.
- 2. A Chinese man in his late 60s was taking TU CHONG GINSENG WAN LE SEANG (杜仲人参万里香) for nearly 5 years to treat gout. He suffered from Cushing's syndrome as a consequence of taking the product.

#### X-TRACT NATURE

3. The third case involved a Malay woman in her mid-50s who consumed 2 bottles of X-TRACT NATURE and who experienced rapid relief of her migraine symptoms. The reporting doctor became suspicious after observing the unexpectedly rapid therapeutic effect of X-TRACT NATURE and reported the case to HSA.

## Information on the Potent Western Medicines found as adulterants in the illegal health products

1. Dexamethasone and Prednisone are very potent corticosteroids and used for anti-inflammatory purposes (i.e. reduce pain and swelling). Unsupervised long-term use of dexamethasone and prednisone 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 corticosteroids can also lead to Cushing's syndrome, a disorder that occurs when a person's body is exposed to high levels of steroid hormones, which is characterised by a round face or 'moon face', and upper body obesity with thin limbs.

Patients who have taken high doses of corticosteroids 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.

- 2. Phenylbutazone is a non-steroidal anti-inflammatory drug (NSAID) and was used to treat rheumatoid arthritis and gout. Overdosage or prolonged use can cause gastrointestinal ulcers, kidney damage or even death. Phenylbutazone-containing products are no longer registered in Singapore since 2006 as the risks of it causing serious adverse events have been assessed to outweigh its benefits, as well as the availability of safer alternatives.
- 3. Paracetamol is a mild analgesic and commonly used to relieve fever and headaches. Long term use without appropriate medical supervision may trigger gastrointestinal disorders and may cause kidney or liver damage.
- **4. 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.