# Health Sciences Authority

#### FOR IMMEDIATE RELEASE

### HEALTH SCIENCES AUTHORITY PRESS RELEASE

**4 FEBRUARY 2010** 

## HSA WARNS AGAINST TAKING "THE NEW MILLENNIUM MALE HORSE POWER CAPSULE" FOUND TO CONTAIN UNDECLARED POTENT SUBSTANCES

The Health Sciences Authority (HSA) has detected two undeclared potent substances, in a complementary health product labelled "The New Millennium Male Horse Power Capsule" which claims to be a "natural aphrodisiac and strength enhancer". The undeclared substances, yohimbine and dehydroepiandrosterone (DHEA), can cause serious side effects when consumed without professional medical supervision.

- To date, no adverse events associated with this product have been reported to HSA. However, as the product has been marketed locally, HSA is warning members of the public who may have bought this product to stop consuming it as it may cause serious health hazards in susceptible persons, e.g. those who have existing medical conditions.
- 3 "The New Millennium Male Horse Power Capsule" is distributed locally by American Bioceutics Labs LLP and manufactured by AIE Pharmaceuticals Inc. based in the United States. Only one shipment of this product had been imported so far, and it is sold locally under the batch number of B/N 786-01-09. All remaining stocks of the product have been seized from the distributor.

#### **About the Product**

4 "The New Millennium Male Horse Power Capsule", also known as "Natural Vigor" in the United States is packaged in white plastic bottles, and its label makes a slew of claims, such as "help men supplement 5 major needs of their masculine bodies, replenishes and restores energy in men, natural aphrodisiac and strength enhancer". (See Annex A for the photograph of this particular product and its packaging.)

Samples of "The New Millennium Male Horse Power Capsule" were sent for analytical tests at HSA's Pharmaceutical Laboratory as part of the routine product quality sampling checks conducted by HSA for marketed health products. Test analysis found the product to contain yohimbine and DHEA. Each capsule of the product was found to contain about 10.8mg and 7.5mg of yohimbine and DHEA respectively. If taken at the dose recommended on the label of two capsules a day, the consumer will be taking an equivalent of a therapeutic dose of yohimbine (between 15-30mg a day).

#### **About Yohimbine**

Yohimbine is derived from the bark of the central African tree *Pausinystalia yohimbe*. It is traditionally used for sexual dysfunction, including impotence although convincing evidence of such an effect is lacking. Some of the serious side effects that are associated with yohimbine include severe hypotension, heart conduction disorders, and death. Yohimbine should not be used in patients with kidney or liver disease, mental illness, those with a history of gastric or duodenal ulcers and those with chronic inflammation of the sexual organs or prostate glands. It should also not be used with mood-modifying drugs or tyramine-containing foods, e.g. cheese, avocadoes.

#### About dehydroepiandrosterone (DHEA)

7 DHEA is a hormone that has been used for erectile dysfunction and for improvement of well-being and sexuality by healthy men and women who have sex hormone insufficiency although well documented evidence of its effect is lacking. DHEA can cause adverse effects such as hair loss, voice deepening, insulin resistance, changes in menstrual pattern, liver dysfunction, abdominal pain, and high blood pressure. When used in very high doses it can cause mild insomnia.

#### **Public Advisory**

- 8 HSA strongly advises anyone who has purchased this product not to consume it. In the event they have consumed this product, they should seek medical advice if they feel unwell or are concerned about their health. Consumers who develop any unexpected reactions to a traditional or herbal medicine are also advised to inform their doctors.
- 9 HSA also advises members of the public who have concerns or problems relating to their sexual health to seek advice from qualified healthcare professionals, and to be cautious of dubious and unproven products touting to "enhance male performance" and other similar claims.
- HSA welcomes feedback and information from the public and media partners on illegal activities involving health products. Information from these additional 'eyesand-ears' on the ground is a valuable contribution to the continuing fight against such illegal activities. Please call **Tel:** 6866 3485 (24-hour line) or **Email:**

hsa is@hsa.gov.sg to report any suspicious activities. Members of the public can also reach HSA at the above contacts on any further clarification about the "The New Millennium Male Horse Power Capsule".

11 HSA will continue with its investigations and take appropriate enforcement actions against any offenders. HSA will update the public when more information is available.

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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. It operates the national blood bank, Bloodbank@HSA, securing the nation's 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>.

#### 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.

# HSA WARNS AGAINST TAKING "THE NEW MILLENNIUM MALE HORSE POWER CAPSULE" FOUND TO CONTAIN UNDECLARED POTENT SUBSTANCE

#### 1. Photograph of "THE NEW MILLENNIUM MALE HORSE POWER CAPSULE"



#### 2. Product Labelling

Labelling in English:

Product name	The New Millennium Male Horse Power 600mg Capsule
Manufacturer / Distributor	AIE Pharmaceuticals Inc. / American Bioceutics Labs LLP
Ingredients	L-Arginine 250mg, Hawthorne Berry 100mg, Gingko Biloba 50mg, Maca 200mg, Passion Flower, Saw Palmetto, Korean Ginseng, Avena Sativa, Pumpkin seeds, Zinc, Vitamin E.
Indications as on label	Today's modern men lead an active and demanding lifestyle. Food alone may not be sufficient to meet the body's daily needs. Health Supplements like MALE HORSEPOWER was specially created by our Egyptian, American and Indian Scientists & Doctors to help men supplement five major needs of their

masculine bodies: L-Arginine is a naturally occurring amino acid known for its ability to relax the small blood vessels, leading to increased circulation of blood in the tissues. Ginkgo Biloba works by increasing blood flow to the brain and throughout the body's network of blood vessels that supply blood and oxygen to the organ systems. Korean Ginseng replenishes & restores energy in men and is known for its circulatory improvement benefits and is beneficial for aging skin. Avena Sativa Wild Oats has been used as a natural aphrodisiac and strength enhancer by men throughout history. Pumpkin Seeds are a balanced source of good proteins, magnesium, zinc, copper, potassium, niacin, folic acid, riboflavin and thiamin. They also contain pantothenic acid, unsaturated oils and anti-oxidants.

## Instruction for dosage

Adult men should take One (1) capsule in the morning and a second capsule in the evening after a meal with a tall glass of water (350ml). Due to its gradual effect, optimal effectiveness should be felt within a few days of continuous uninterrupted usage.