FOR IMMEDIATE RELEASE



HEALTH SCIENCES AUTHORITY PRESS RELEASE

8 May 2009

HSA WARNS AGAINST CONSUMING *"XP TONGKAT ALI SUPREME"* CAPSULES FOUND TO CONTAIN UNDECLARED POTENT SUBSTANCE

The Health Sciences Authority (HSA) has detected an undeclared potent substance "tadalafil" in the product "*XP Tongkat Ali Supreme*". This is the first case in which HSA has detected a potent chemical substance impregnated in the capsule shells of the product to try and avoid analytical detection of the adulterant.

2 HSA has ordered a sales suspension and recall of adulterated "*XP Tongkat Ali Supreme*" from the market. To-date, no local reports of adverse reactions have been received in relation to the consumption of this product.

3 HSA issues this alert and urges the public not to purchase or consume this adulterated product, as shown in Annex A, which is sold in retail outlets and over the Internet. Members of the public should also not consume any stocks of this product that they may have in their possession.

About the Product

4 *"XP Tongkat Ali Supreme"* which is available in capsules, is marketed as a "traditional herbal supplement for men" and claims to be 100% natural. It is labelled to contain Tongkat Ali, a natural herbal ingredient.

5 On the basis that it contains only the herbal ingredients declared on its label, this product would be considered as a form of traditional medicine and is sold in Singapore without any registration or pre-market approval from HSA.

Undeclared Potent Ingredient Detected

6 Through its ongoing post-market intelligence of health products, HSA acted on a tip-off and conducted analytical tests on samples of "*XP Tongkat Ali Supreme*". HSA's Pharmaceutical Laboratory detected "tadalafil" present not in the contents of the capsule but in the capsule shell. 7 "Tadalafil" is the active ingredient in the prescription medicine *Cialis*, which is used for the treatment of male erectile dysfunction, and it is a potent drug that should only be used when prescribed by a doctor.

8 Consumption of "tadalafil" can potentially cause serious adverse reactions such as heart attack, stroke and severe hypotension, particularly in susceptible individuals with heart conditions and/or who are taking nitrate drugs. Uncontrolled consumption of "tadalafil" without proper medical supervision is especially dangerous.

Product Recalled Locally

9 *"XP Tongkat Ali Supreme"* is distributed in Singapore by the company CTI Biotechnology Pte Ltd. It is sold in retail shops as well as over the Internet by parties affiliated with the company. HSA has ordered the company to suspend sales of its product and to recall all stocks of its product from the market.

10 HSA is monitoring the recall closely to ensure that the company removes all remaining stocks of its product from the market as swiftly as possible.

11 This product is also known to be sold over the Internet. This alert is also issued to reach out to the wider segment of the public who may be exposed to this product through this channel. Members of the public are urged not to purchase "*XP Tongkat Ali Supreme*" over the Internet and/or consume any stocks of this product they may have bought over the Internet.

Public Advisory

12 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.

13 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.

14 HSA welcomes feedback and information on illegal activities involving health products, which HSA has been receiving from the public and media partners. The information from these additional 'eyes-and-ears' on the ground is a valuable contribution to the continuing fight against such illegal activities.

15 HSA continues to encourage the media and public to partner us in our efforts to combat illegal activities involving health products. Please call **Tel: 6866 3485** (24-hour line) or **Email:** <u>hsa_is@hsa.gov.sg</u> to report any suspicious activities.

16 Members of the public can also reach HSA at the above contacts on any further clarification about the recall of "XP Tongkat Ali Supreme".

17 HSA will continue with its investigations and take appropriate enforcement actions against any offenders. HSA will update the public when more information becomes 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 http://www.hsa.gov.sg/.

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.

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FRONT VIEW OF "XP TONGKAT ALI SUPREME"



BACK VIEW OF "XP TONGKAT ALI SUPREME"

