

The Australasian College of Cosmetic Surgery

Raising Standards, Protecting Patients

MEDIA RELEASE

For immediate release

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BOTULINUM TOXIN WARNING THOUSANDS MAY BE EXPOSED TO RISK OF SERIOUS HARM

The Australasian College of Cosmetic Surgery today warned about the illegal importation and use in Australia of unapproved Botulinum toxin

ACCS President Dr Colin Moore FRCS FRACS FACCS said the College was deeply concerned about information it had received including firsthand patient information that unscrupulous doctors may be illegally importing and administering Botulinum toxin and fillers sourced from China over the Internet.

The ACCS has presented this information to the Therapeutic Goods Administration and filed a complaint with the Medical Board of Australia.

Dr Moore warned that health consumers should be suspicious of advertisements or coupons for anti-wrinkle injections at prices well below the cost of approved prescription only medicines.

"The ACCS has liaised closely with the TGA about this very serious danger to patients' health. And as a result of our consultations, we are pleased that the College's concerns are being taken seriously by the TGA and investigated thoroughly," Dr Moore said.

The Therapeutic Goods Administration has approved only two versions of Botulinum toxin for importation and use in Australia, both of which are produced and supplied according to very strict standards.

"The risk to patient safety arising from using such illegal drugs is extremely serious. This may only be the tip of the iceberg for counterfeit and illegally imported drugs. Just one injector can put thousands of patients at risk of harm," Dr Moore warned.



As recently as December last year, the US Food and Drug Administration warned of similar activity in the US after prosecuting several doctors. The FDA has also issued warnings to other doctors and the general public:

The manufacture and handling of these products may not be of suitable quality to ensure safety or efficacy, and the products have not been proven to be safe and effective... The FDA is very concerned that [unapproved] products... may cause harm to patients, because they may be unsafe or ineffective...

[and] may be from unknown sources, may have unknown ingredients, may be counterfeit, or may not have been manufactured, transported or stored under proper conditions... and standards. Such products put patients at risk of exposure to ineffective or dangerous products.

"Given the serious potential health risk that the importation and use of unapproved drugs, including Botulinum toxin and fillers pose to the Australian community, the ACCS has recommended to the TGA that it issue a similar warning to Australian health practitioners and the general public," Dr Moore said.

The College has commended the patient concerned for coming forward with her concerns so that investigatory action can be taken. The College has also expressed its confidence and appreciation to the TGA for its prompt response to this serious threat to patient safety.

The College strongly advises anyone considering having a cosmetic procedure to consult with an appropriately trained practitioner and assure themselves that they are using only approved drugs. Visit the College's website <u>http://www.accs.org.au/</u> for further information and a copy of the College's patient information brochure, "Things you should know".

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For further information or interviews, contact:

Alan Jones m. 0420 757 009 Blanche Wilkie m. 0425 279 091

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The Australasian College of Cosmetic Surgery is a multi-disciplinary body of general surgeons, plastic surgeons, dermatologists, ear nose and throat surgeons, ophthalmologists and other doctors who specialise in cosmetic medicine and surgery. The goal of the ACCS is to ensure the safe provision of cosmetic surgery and cosmetic medical procedures to the Australian general community through supply of appropriately trained and certified medical practitioners.

For additional information about the ACCS, please visit: <u>http://www.accs.org.au/</u>