



australasian society of clinical immunology and allergy

17 January 2019

Adjunct Professor John Skerritt
Deputy Secretary, Health Products Regulation Group
Therapeutic Goods Administration (TGA)
PO Box 100
WODEN ACT 2606
Email: PSAB.Communications@tga.gov.au

Dear Adjunct Professor Skerritt,

ASCIA response to TGA approval of BICOM

On behalf of ASCIA, we write to you to express our concerns about the recent TGA approval of the BICOM medical device. The BICOM is essentially a variation of the Vega device and the consumer publication Choice states:

The BICOM is a bio-resonance machine said to pick up "specific frequency patterns" from a patient (or from substances that harm or stress the organism) via electrodes. It claims to be able to test and treat allergies including food allergy, hay fever and skin rashes.

For your reference, the full Choice article is available at www.choice.com.au/health-and-body/conditions/hayfever-and-allergies/articles/food-allergies-and-intolerances

The device has been the subject of a number of complaints in Australia and the UK. Despite the company being unable to provide any evidence it can detect or treat allergies and food intolerances, it continues to be advertised, used by natural practitioners and is listed as a medical device with the TGA.

We are particularly concerned that people with severe IgE mediated allergy (at risk of anaphylaxis) may be misled about the prospects for cure, and therefore be in danger if they use BICOM for treatment.

We therefore request that the TGA reconsider approval of the BICOM device. We also welcome further discussions with the TGA about this issue.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Brynn Wainstein".

Dr Brynn Wainstein
ASCIA President

A handwritten signature in black ink, appearing to read "Jill Smith".

Jill Smith
ASCIA CEO

ASCIA is the peak professional body of clinical immunology and allergy specialists in Australia and New Zealand
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