



australasian society of clinical immunology and allergy

28 February 2019

Associate Professor Mark Lane
President, Royal Australasian College of Physicians (RACP)
145 Macquarie Street Sydney 2000
Email: president@racp.edu.au

Dear Associate Professor Lane,

Subject: Authorised Prescriber endorsement for non-TGA registered skin testing reagents and systems

Following discussions at the recent ASCIA Council meeting on 16 February 2019, we write to you on behalf of all Full (Ordinary) ASCIA members who are also Fellows of the RACP. We request that the RACP provide ASCIA with an updated letter that allows these members to become authorised prescribers for skin testing reagents and systems for the diagnosis of allergic diseases, that are not TGA registered. The RACP previously provided ASCIA with a letter in 2010, which is no longer accepted by the TGA. Please find attached background information that explains the need for Authorised Prescriber endorsement.

For your reference, the Royal College of Pathologists of Australasia (RCPA) has provided the attached letter for Full (Ordinary) ASCIA members who are also Fellows of the RCPA. This letter has been accepted by the TGA. It has also been used successfully as a template for HRECs to provide a letter of endorsement for those ASCIA members who work in hospitals with access to a HREC, but who are not Fellows of the RCPA, when applying for Authorised Prescriber status.

Full (Ordinary) members of ASCIA, with Fellowship of RACP (not RCPA) who do not have ready access to a HREC, for example those in sole private practice, are therefore currently significantly disadvantaged. This is because they are unable to apply for Authorised Prescriber status to use non TGA registered skin testing reagents and systems for the diagnosis of allergic diseases. Whilst they can access such products using the TGA Special Access Scheme (SAS) C, this is not a feasible solution for busy allergy clinics with large numbers of patients.

We look forward to your response.

Yours sincerely,

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

Dr Brynn Wainstein
ASCIA President

A handwritten signature in black ink, appearing to be "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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ATTACHMENT

Background information: The need for Authorised Prescriber endorsement for access to non-TGA registered skin testing reagents and systems for the diagnosis of allergic diseases

Skin prick testing is the primary mode of testing for immediate IgE-mediated allergy. This testing is widely practised, carries very low risk of side effects to patients, and provides high quality information when performed optimally and interpreted correctly. Furthermore, unlike serum specific-IgE measurement, the results of skin testing are immediately available, allowing medical practitioners to rapidly provide advice and management plans to their patients.

The discontinuation of TGA registered skin testing reagents by Hollister-Stier in 2008 and a subsequent fragmentation of supply since then has made it necessary for medical practitioners in Australia to use skin testing products that are not TGA registered. This requires either endorsement as a TGA Authorised Prescriber or a Special Access Scheme (SAS) C application, as detailed below.

Endorsement from medical colleges (e.g. RACP or RCPA) is necessary for ASCIA members who do not have ready access to a hospital Human Research Ethics Committee (HREC), particularly for those who work in private practice.

TGA Authorised Prescriber and SAS C applications

A. Section 19(5): Obtain "Authorised Prescriber status" by endorsement from a medical college - ASCIA has obtained endorsement letters for Full (Ordinary) ASCIA members who are fellows of the Royal College of Pathologists of Australasia (RCPA) to enable access to unregistered skin testing products. For details go to www.tga.gov.au/form/authorised-prescribers

B. Section 19(5): Obtain "Authorised Prescriber status" by endorsement by an ethics committee - ASCIA members who work in hospitals and/or universities with access to a human research ethics committee (HREC) can obtain endorsement from an HREC to enable access to unregistered skin testing products. For details go to www.tga.gov.au/form/authorised-prescribers

C. Special Access Scheme (SAS) Category C: This is a notification pathway which allows health practitioners to supply goods that are deemed to have an established history of use without first seeking prior approval. The goods deemed to have an established history of use are specified in a list along with their indications and the type of health practitioner authorised to supply these products for the respective indications. For details go to www.tga.gov.au/form/special-access-scheme
To use the SAS online system go to www.tga.gov.au/special-access-scheme-online-system

Patient consent should be obtained when using unregistered skin testing products, with any of the above options. Completed forms are for your record only and do not need to be sent to the TGA.

The above information is also available on the ASCIA website
www.allergy.org.au/members/ascia-member-access-to-spt-reagents