



17 September 2021

Adjunct Professor John Skerritt
Deputy Secretary, Health Products Regulation
Department of Health
PO Box 100
Woden ACT 2606

Dear Professor Skerritt,

RE: Improving access to life-saving unapproved medicines via the Special Access Scheme Category A pathway in emergency situations

Thank you for your letter dated 10 September 2021 regarding improving access to life-saving unapproved medicines via the Special Access Scheme (SAS) Category A pathway in emergency situations. We are grateful that the TGA has consulted with the hospital pharmacy sector on a matter of great importance to us in providing care to patients who are seriously unwell.

SHPA has internally consulted with our Emergency Medicine and Critical Care Leadership Committees, who most frequently access unapproved medicines via the SAS Category A pathway in urgent clinical situations.

SHPA supports the TGA's proposal to make changes to Item 1 of Schedule 5A of the Regulations to specify that unapproved medicines must either be kept in a warehouse or properly secured area under the direct control of the sponsor or otherwise, supplied by the sponsor to a hospital or health care facility in order to deal with emergency situations, provided the hospital or healthcare facility has appropriate security and storage arrangements for the medicines.

This change would acknowledge and legitimise a longstanding practicality in the way SAS Category A medicines are procured and accessed and will continue to facilitate timely treatment with unapproved medicines to be used for life-saving and emergency care.

We understand these changes should, in theory, not have negative impacts on medicines sponsors and the reliability of supply of medicines accessed through SAS Category A, which naturally is our foremost concern with these critical medicines. We trust that support for these changes from pharmaceutical industry and wholesaler stakeholders has also been sought.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on yyik@shpa.org.au.

Yours sincerely,

A handwritten signature in black ink that reads 'K. Michaels'.

Kristin Michaels
Chief Executive



The Society of Hospital Pharmacists of Australia

PO Box 1774 Collingwood Victoria 3066 Australia

(03) 9486 0177 | shpa.org.au | shpa@shpa.org.au | ABN: 54 004 553 806