

Scope of Practice Pilots Endorsement

The following Endorsement attaches to and forms part of Your Pharmacy Business Insurance policy (GLD89433 11/2021) as from 06/04/2024:

Section – Professional Indemnity/ Additional Benefit

Scope of Practice Pilots

Notwithstanding general exclusion:

> 'Experiments or Testing':

We will Cover You for Your:

- a. civil liability in respect of any Claim as a result of a breach of professional duty by You where such Claim is first made against You and notified to Us during the Period of Cover; or
- b. Inquiry Legal Costs in respect of any Inquiry where notice of such Inquiry is first served on You and notified to Us during the Period of Cover:

arising from the provision of healthcare services by You as a pharmacist in a Scope of Practice Pilot:

Provided that:

- i. You are appropriately trained and qualified to participate in the Scope of Practice Pilot; and
- ii. You are authorised under applicable laws, and have obtained approval to participate in the Scope of Practice Pilot; and
- iii. You have made all reasonable attempts to comply with all relevant published professional and government protocols, including but not limited to government approved training, standards, directives and clinical guidelines in respect of the approved Scope of Practice Pilot:

Provided further that:

We will not Cover:

- iv. You acting in the capacity of a Principal Investigator, Sponsor or Human Research Ethics Committee (HREC) convenor.

For the purpose of this exclusion, Sponsor, Principal Investigator and Human Research Ethics Committee means the roles and responsibilities of Sponsor, Principal Investigator and Human Research Ethics Committee as set out in the:

- a. Australian Clinical Trial Handbook issued by the Therapeutic Goods Administration or any subsequent, replacement or similar document issued by an official body responsible for the regulation of clinical trials; or
- b. legislation, standards or guidelines issued by any government or regulatory body in relation to clinical trials or therapeutic goods that may reference these roles and responsibilities including but not limited to the Therapeutic Goods Act and any subordinate legislation, subsequent amendment, re-enactment, replacement or successor legislation; or
- c. international or peer recognised equivalent definitions attributed to these roles and responsibilities including but not limited to ISO14155 (Clinical investigation of medical devices for human subjects – Good Clinical Practice).

Section – Public and Products Liability/ Additional Benefit

Scope of Practice Pilots

Notwithstanding general exclusion:

> 'Experiments or Testing':

We will Cover You for Your civil liability in respect of any Claim for Bodily Injury, Property Damage or Advertising Liability where such Claim is first made against You and notified to Us during the Period of Cover as a result of an Occurrence happening in connection with Your Business participating in a Scope of Practice Pilot:

Provided that:

- i. You are appropriately trained and qualified to participate in the Scope of Practice Pilot; and
- ii. You are authorised under applicable laws, and have obtained approval to participate in the Scope of Practice Pilot; and
- iii. You have made all reasonable attempts to comply with all relevant published professional and government protocols, including but not limited to government approved training, standards, directives and clinical guidelines in respect of the Scope of Practice Pilot:

Provided further that:

We will not Cover:

- iv. You acting in the capacity of a Principal Investigator, Sponsor or Human Research Ethics Committee (HREC) convenor.

For the purpose of this exclusion, Sponsor, Principal Investigator and Human Research Ethics Committee means the roles and responsibilities of Sponsor, Principal Investigator and Human Research Ethics Committee as set out in the:

- a. Australian Clinical Trial Handbook issued by the Therapeutic Goods Administration or any subsequent, replacement or similar document issued by an official body responsible for the regulation of clinical trials; or

- b. legislation, standards or guidelines issued by any government or regulatory body in relation to clinical trials or therapeutic goods that may reference these roles and responsibilities including but not limited to the Therapeutic Goods Act and any subordinate legislation, subsequent amendment, re-enactment, replacement or successor legislation; or
- c. international or peer recognised equivalent definitions attributed to these roles and responsibilities including but not limited to ISO14155 (Clinical investigation of medical devices for human subjects – Good Clinical Practice).

General Definitions

Scope of Practice Pilot

means a clinical trial or clinical research that is:

- a. conducted primarily for the purpose of changing the scope of practice of pharmacists; and
- b. approved by a State, Territory or Federal Government agency or authority; and
- c. conducted solely in Australia:

but does not include any clinical trial or clinical research that:

- i. involves a novel medicine, combination therapy or device; or
- ii. is sponsored, designed or developed by or on behalf of a pharmaceutical company or clinical trial company.

