

# Health Global Liability Declaration Form – Pharmaceuticals Section Addendum



## Health Global Liability Declaration Form 2024 - 2025

### Addendum – Pharmaceuticals Section

Further clarity in relation to the Pharmaceuticals section of the Health Global Liability Declaration Form was requested at the NSW Directors of Pharmacy meeting held on 25 July 2023:

#### Pharmaceuticals section in the Health Global Liability Declaration Form 2024 – 2025

 Insurance for NSW	<b>HEALTH GLOBAL LIABILITY DECLARATION FORM</b> PHARMACEUTICALS TRAINING AGENCY 04 - UAT TMF DECLARATION 2024/2025 - HEALTH GLOBAL LIABILITY DECL...
Health Global Liability Training Resource: Click <a href="#">here</a> to download the How-To Guide to assist you in completing this Section.	
<b>Pharmaceuticals</b>	
Do any of your health facilities produce or manufacture pharmaceuticals in accordance with the Therapeutic Goods Act 1989 (Cth)?	
<input checked="" type="radio"/> Yes <input type="radio"/> No	
Please provide the annual \$ value for following dates:	
Actual: 01/07/2022 - 30/06/2023	
Estimate: 01/07/2023 - 30/06/2024	
<b>Pharmaceuticals - Actual annual \$ value</b>	
Enter numeric response	
Please fill out the missing field.	
<b>Pharmaceuticals - Estimated annual \$ value</b>	
Enter numeric response	
Please fill out the missing field.	
<b>Please list the general categories of pharmaceuticals which are anticipated will be produced or manufactured in the period 01/07/2023 to 30/06/2024</b>	
Enter text response	
Please fill out the missing field.	

### Pharmaceuticals

Insurance for NSW (IfNSW) brings together information via an annual declaration process for use within IfNSW and for sharing with actuaries and reinsurers. Our interest is the dispensing, production or manufacture of products which would see the health agencies have a responsibility for the safety of those products under Australian Consumer Law (ACL). ACL contains specific guidance relating to Product Liability:

[Product liability | Product Safety Australia](#)

The liability provisions of the ACL generally apply to a manufacturer that supplies consumer goods in trade or commerce. A manufacturer may be a company that:

- makes or assembles the goods
- imports the goods (if the maker of the goods does not have an office in Australia)
- uses its own brand name in relation to the goods
- promotes itself to the public as the manufacturer of the goods
- permits another person to promote the goods as having been manufactured by the company.

Product liability includes liability arising out of goods and products manufactured, constructed, erected, installed, altered, repaired, serviced, treated, sold, supplied or distributed by the agency covered by the TMF after it has left the agency's custody and control.

Agencies have a responsibility for safety for the following pharmaceuticals and these should be declared:

1. pharmaceuticals which are 'produced' or 'manufactured' (for example, processed, assembled, packaged, sterilised, tested) and released for supply; and
2. dispensed pharmaceuticals ('goods') which are 'made' or 'assembled', even if not sold, but are administered to patients, whether within the agency or elsewhere. This includes manipulation of a commercially available product in accordance with the manufacturer's instructions in order to produce a medicine in a 'ready to administer' form for example, reconstitution of oral antibiotic mixtures and aseptic transfer to a sterile device.

Dispensing of pharmaceuticals which have not been altered in any way, for example, dispensing of tablets in the same prepared commercial form as that received by the agency, should not be declared.

### Calculation of estimated annual \$ value

If your agency responds "Yes" to the question in relation to production or manufacture of pharmaceuticals, the annual \$ value of pharmaceuticals as at the following dates are requested:

- Actual 01/07/2022 - 30/06/2023
- Estimate 01/07/2023 - 30/06/2024

The annual \$ value is the annual sale value or equivalent sale value of the products. The calculation may include actual sales only, or actual sales plus an estimate for dispensed pharmaceuticals (which fall inside the 'manufactured' category as above) where no sale exists.

Where the pharmaceuticals have actually been 'sold' or are expected will be sold, the \$ value is the remuneration which the agency received, or estimates will receive, for those pharmaceutical products.

For those pharmaceuticals which require manipulation in order to reach a 'ready to administer' form, it is suggested that agencies estimate the cost based on an approximate percentage of that pharmaceutical which required, or will require, manipulation prior to being administered to patients and apply that percentage to the purchase price of that pharmaceutical. This approximation may be based as per the general categories listed below, rather than for each individual pharmaceutical which may be dispensed by the agency.

Our expectation is that agencies will declare an approximate 'best estimation' \$ figure for the actual or estimate annual values requested.

### Categories of pharmaceuticals

Examples of general categories of pharmaceuticals include, but are not limited to: analgesics, antiarrhythmics, antibiotics, anticoagulants/thrombolytics, anticonvulsants, antidepressants, antidiarrhoeals, antiemetics, antifungals, antihistamines, antihypertensives, anti-psychotics, antipyretics, antivirals, bronchodilators, cytotoxics, diuretics, expectorants, hormones, hypoglycaemics, immunosuppressives, laxatives, muscle relaxants, sedatives, and vitamins.

If you have any further questions, please contact your Client Engagement Manager or email [declarations@icare.nsw.gov.au](mailto:declarations@icare.nsw.gov.au).