**Sample Policy olicyPolicle**

**THERAPEUTIC PRODUCT RECALL NOTIFICATION**



**Aim:**

To ensure that all Therapeutic Product Recall Notifications are handled in a safe, consistent and timely manner across all areas of [**HEALTH SERVICE**].

**Rationale:**

Faulty or defective products, medications and equipment have the potential to adversely affect patients and staff. It is vital that the organisation has a robust system to ensure that all notifications related to product safety are handled in such a way that potential for harm is minimised. Recall Health is a national safety and quality initiative developed by HS1 Australia and the National Electronic Health Transition Authority (NEHTA) to provide a single electronic therapeutic product recall notification system.

**Policy:**

1. [**HEALTH SERVICE**] will utilise Recall Health as the primary system for notification of Therapeutic Product Recall.
2. The [**HEALTH SERVICE**] Clinical Products Manager will function as the Primary Contact for the Recall Health System.
3. It is the responsibility of the Clinical Products Manager to coordinate all Therapeutic Product Recall Notifications and to ensure the prompt and effective response to such notifications.
4. All notifications regardless of source are to be forwarded promptly to the Clinical Products Manager.
5. All notifications are to be entered onto the “Recalls / Safety Alerts and Product Quality Tracking

System” spreadsheet located at [**HEALTH SERVICE URL**]. This spreadsheet will record details of notification including supplier, issue, action taken and reconciliation of item with supply.

1. That all product recalls, safety alerts and notifications are handled in a consistent manner regardless of product or source of notification.
2. That all breeches of policy and procedure are entered to VHIMS RiskMan and investigated promptly.

[**HEALTH SERVICE]** © POL0478 – Page 1 **THERAPEUTIC PRODUCT RECALL NOTIFICATIONS** **POLICY**

**Annexes:**

**Related AWH Documents:** Therapeutic Product Recall Notification Procedure.

**Accreditation Standards:** EQuIP National Standard 15.

**Other Relevant Information:**

**References:**

**Contact Point:** Director of Corporate Services.

**In consultation with:**

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| **TITLE / POSITION** | | |
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| **THIS SECTION FOR QUALITY & CLINICAL GOVERNANCE OFFICE USE ONLY** | | |
| **Approved by Executive / Delegate:** | **Date Approved:** | **SharePoint Location:** |
| Director of Corporate Services | 13 May 2014 | Policies… |
| **Responsible Department:** | **Date for Review:** | **Linked Documents:** |
| Director of Corporate Services | 13 May 2017 |  |
| **Version No:** | **Original Approval Date:** | **Previously Named As:** |
| **4** | August 2006 | Product Recall, Safety Alert and Product  Quality Alerts Notification Policy |

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