

Recall Coordinator Deij Date 26/4/11

Is the product in the notification a therapeutic good? (i.e. it is not a food, cosmetic or excluded good)

☒ YES - continue with checklist ↓☐ NO = 'Not a therapeutic good' → Screening complete (Refer to _____)

Has a tampering incident of an Australian supplied product been identified?

☒ NO - continue with checklist ↓☐ YES - see Tampering SOP - 'Sponsor Non Recall Action' path → Screening complete (assessment)

Are there any similar reports on RAMP?

☒ NO - continue with checklist ↓☐ YES - order any relevant files to review previous actions, identify duplicate entries or identify trendOutcome ☐ Unique notification - continue with this checklist ↓☐ Not relevant → Screening complete (refer to e-file)Does the notification refer to a possible or actual recall of an Australian supplied therapeutic good?☒ YES - continue with checklist ↓☐ N/A - Sponsor/manufacture advises no Australian supply

→ Screening complete (refer to delegates - send email 'Overseas recall not affecting Australia')

☐ NO - seek information from ARTG, Client, TGA library databases or Internet (Print any relevant results)→ Outcome ☐ Medicine Defect* → Screening complete (refer to Raymond Wilson - no RAMP entry)☐ Device Incident* → Screening complete (refer to IRIS)☐ Illegally supplied product → Screening complete (refer to RCU)☐ O/S GMP failure → Screening complete (refer to OMQ)☐ Export list does not include Australia → Screening complete (refer to e-file)☐ An AUSTRALIAN supplier CANNOT be identified → Screening complete (refer to e-file)

*includes adverse reactions, notices of 'out of stock' or cessation of marketing

Has the sponsor started any market action in Australia?

☒ NO - continue with checklist ↓☐ UNKNOWN (Overseas Recall) → 'Sponsor Non Recall Action' path → Screening complete (assessment)☐ YES → 'Recall not notified to the TGA' path → Screening complete (assessment)

What market action is proposed?

☐ Recall action (i.e. Recall, Recall for Product Correction, Hazard Alert)

→ 'Sponsor Recall Action' path - continue with checklist ↓

☒ Non Recall action (i.e. Safety Alert, Product Notification, No Action, Product Withdrawal, Quarantine)

→ 'Sponsor Non Recall Action' path - continue with checklist ↓

Have the six essential sets of information been provided in at least summary form?

Problem Product Product Distribution Hazard Proposed Action & Timeline

☐ YES → Screening complete (assessment)☐ NO - seek information from the sponsor. Details _____→ Outcome ☐ information provided → Screening complete (assessment)