附件 1

西藥品不良品或疑似不良品回收案件之危害分級

藥物危害分級	定義	範例*
第一級危害	係指經許可製造、輸入之藥物，經發現有重大危害，或有發生重大損害之虞者。	● 錯誤的產品(標示與內容物不符) Wrong product (label and contents are different products) ● 藥物強度不符，且具嚴重的醫療後果 Correct product but wrong strength, with serious medical consequences ● 無菌注射性或眼用產品遭微生物汙染 Microbial contamination of sterile injectable or ophthalmic product ● 具嚴重醫療後果的化學性汙染 Chemical contamination with serious medical consequences ● 多種藥物及容器間產生混雜 Mix-up of some products (rogues) with more than one container involved ● 複方產品中含有錯誤成分，並具嚴重醫療後果 Wrong active ingredient in a multi-component product, with serious medical consequences
第二級危害	經調查藥物確有損害使用者生命、身體或健康之事實，或有損害之虞者。	●標示錯誤，例如:文字/圖示錯誤或遺失 Mislabelling, e.g. wrong or missing text or figures ●說明書或仿單的資訊遺失或錯誤 Missing or incorrect information (leaflets or inserts) ●非注射性/眼用無菌製劑,具嚴重醫療後果的微生物汙染 Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences ●化學/物理性汙染(明顯不純物、交叉汙染、微粒物質) Chemical/physical contamination (significant impurities, cross-contamination, particulates) ●藥物發生混雜 Mix up of products in containers (rogues) ●檢驗結果與原核准規格不符(例如:含量測定、安定性試驗、容量/重量) Non-compliance with specification (e.g. assay, stability, fill/weight) ●藥物密封不良，具嚴重醫療後果(例如:細胞毒素、兒童安全容器、高效產品) Insecure closure with serious medical consequences (e.g. cytotoxics, child-resistant containers, potent products)

第三級危害	其他危害事實，且具有造成使用者權益受損或安全之虞者。	● 包裝瑕疵（例如批次編號、保存期限錯誤或遺漏） Faulty packaging, e.g. wrong or missing batch number or expiry date ● 密封瑕疵 Faulty closure ● 汙染（例如:微生物腐敗、灰塵或碎石、微粒物質） Contamination, e.g. microbial spoilage, dirt or detritus, particulate matter

＊ 參考PIC/S PI 010-4「PROCEDURE FOR HANDLING RAPID ALERTS AND RECALLS ARISING FROM QUALITY DEFECTS」