

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。	<ul style="list-style-type: none"> <li>● 錯誤的產品(標示與內容物不符) Wrong product (label and contents are different products)</li> <li>● 藥物強度不符，且具嚴重的醫療後果 Correct product but wrong strength, with serious medical consequences</li> <li>● 無菌注射性或眼用產品遭微生物汙染 Microbial contamination of sterile injectable or ophthalmic product</li> <li>● 具嚴重醫療後果的化學性汙染 Chemical contamination with serious medical consequences</li> <li>● 多種藥物及容器間產生混雜 Mix-up of some products (rogues) with more than one container involved</li> <li>● 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</li> </ul>
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。	<ul style="list-style-type: none"> <li>● 標示錯誤，例如:文字/圖示錯誤或遺失 Mislabelling, e.g. wrong or missing text or figures</li> <li>● 說明書或仿單的資訊遺失或錯誤 Missing or incorrect information (leaflets or inserts)</li> <li>● 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</li> <li>● 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)</li> <li>● 藥物發生混雜 Mix up of products in containers (rogues)</li> <li>● 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)</li> <li>● 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)</li> </ul>

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。	<ul style="list-style-type: none"> <li>● 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</li> <li>● 密封瑕疵 Faulty closure</li> <li>● 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</li> </ul>
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\* 參考 PIC/S PI 010-4 「PROCEDURE FOR HANDLING RAPID ALERTS AND RECALLS ARISING FROM QUALITY DEFECTS」