

《國內定期安全報告應提供內容》

I. 藥品資料：

1. 藥品學名
2. 藥品商品名（英文）
3. 藥品商品名（中文）
4. 劑型、劑量
5. 製造廠
6. 製造廠所在國家
7. 藥品許可證持有廠商（中文）
8. 藥品銷售數量（採建議推廣，請廠商盡可能提供。）

II. 安全性資料涵蓋之監視期間及範圍

III. 不良反應資料收集：

1. 國內嚴重藥物不良反應案件
2. 國內非嚴重藥物不良反應案件(以 Line listing 方式)
3. 國外嚴重藥物不良反應案件
4. 國外非嚴重藥物不良反應案件(以 Line listing 方式)
5. 學術期刊文獻及學術研討會上發表的 case report 收集而來

Summary of PSUR for <Drug name>

(Period covered:___)

Table I : Summary by number of cases

Reports Included	Number Of Cases	
	Taiwan	Other countries
Serious		
Non Serious		
Total (Serious + Non Serious Cases)		

Table II : Tabulation of all Adverse Drug Reactions by SOC in Taiwan (Period covered:___)

MedDRA System Organ Class	Serious Case	Non Serious Cases	Total	Cumulative Total
Blood and lymphatic system disorders				
Cardiac disorders				
Ear and labyrinth disorders				
Eye disorders				
Gastrointestinal disorders				
General disorders and administration site conditions				
Hepatobiliary disorders				
Immune system disorders				
Infections and infestations				
Injury, poisoning and procedural complications				
Investigations				
Metabolism and nutrition disorders				
Musculoskeletal and connective tissue disorders				
Neoplasms benign, malignant and unspecified (including cysts and polyps)				
Nervous system disorders				
Pregnancy, puerperium and perinatal conditions				
Psychiatric disorders				
Renal and urinary disorders				
Reproductive system and breast disorders				
Respiratory, thoracic and mediastinal disorders				
Skin and subcutaneous tissue disorders				
Vascular disorders				
Total				
Cumulative Total				

Table III : Tabulation of all Adverse Drug Reactions by SOC in Others Countries (Period covered: ___)

MedDRA System Organ Class	Serious Case	Non Serious Cases	Total	Cumulative Total
Blood and lymphatic system disorders				
Cardiac disorders				
Ear and labyrinth disorders				
Eye disorders				
Gastrointestinal disorders				
General disorders and administration site conditions				
Hepatobiliary disorders				
Immune system disorders				
Infections and infestations				
Injury, poisoning and procedural complications				
Investigations				
Metabolism and nutrition disorders				
Musculoskeletal and connective tissue disorders				
Neoplasms benign, malignant and unspecified (including cysts and polyps)				
Nervous system disorders				
Pregnancy, puerperium and perinatal conditions				
Psychiatric disorders				
Renal and urinary disorders				
Reproductive system and breast disorders				
Respiratory, thoracic and mediastinal disorders				
Skin and subcutaneous tissue disorders				
Vascular disorders				
Total				
Cumulative Total				