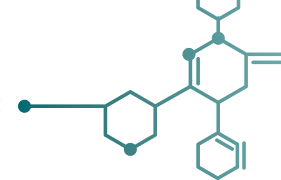








附錄 4

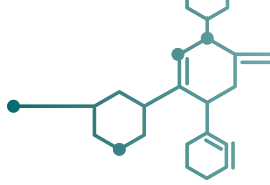
SASB 準則對照表

Code	Accounting Metric	Disclosure	參考章節	對應的 SDGs	頁次
Topic: Safety of Clinical Trial Participants					
HC-BP-210a.1	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	本公司針對臨床試驗之風險評估，由委外研究機構（CRO）執行，並以內部標準作業程序《Vendor Selection and Management》為主，規定執行臨床試驗中的品質保證及品質管理活動。目前沒有因違反 GCP 而與委外研究機構（CRO）中途中止的臨床試驗案件。每個臨床開發階段我們都有稽核（Audit）和查核（Inspection）的機制，並謹遵《赫爾辛基宣言》、《國際醫藥法規協和會藥品優良臨床試驗規範（ICH-GCP）》。在醫院正式啟動臨床試驗前，必須取得受試者的書面知情同意，並依照試驗計劃書的納入與排除條件嚴格篩選合適的受試者	1.3 生物新藥的研究發展		27
HC-BP-210a.2	Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)	藥華醫藥目前未有此情事			
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	藥華醫藥目前未有此情事			
Topic: Access to Medicines					
HC-BP-240a.1	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	本公司的 4 大聚焦疾病領域之一為罕見血液疾病截至本報告書出具前，用於治療真性紅血球增多症（PV）的藥品 BESREMi® 已於歐洲 18 個國家銷售。我們也自 2016 年開始，連續 6 年贊助舉辦亞洲骨髓增生性腫瘤國際研討會（MPN Asia），並於 2020 年贊助美國血液學年會（ASH），讓世界各地關注骨髓增生性腫瘤（MPN）疾病的醫師及學者們，都能夠持續獲得最新的研究及治療方式。本報告書第 6 章各小節，則詳細說明了我們依循 Access to Medicine Index, 2020 的框架所制定的「藥物近用」策略、執行計畫與其年度成果以及未來目標	1.5 積極佈局全球行銷策略 第 6 章	 	30 116~130



Code	Accounting Metric	Disclosure	參考章節	對應的 SDGs	頁次
HC-BP-240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	藥華醫藥目前未有此類藥品			
Topic: Affordability & Pricing					
HC-BP-240b.1	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period	藥華醫藥目前未有此情事			
HC-BP-240b.2	Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year	藥華醫藥目前尚未有於美國境內販售之藥品			
HC-BP-240b.3	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year	本公司的訂價策略是依各國的醫療費用可負擔能力 (affordability) ，並參考世界衛生組織 (World Health Organization, WHO) 發布的《WHO Guideline on Country Pharmaceutical Pricing Policies》制訂合理公平之價格。未來也將持續追蹤藥品價格於世界各國的訂定，以確保病人的可負擔性	6.4 穩定、安全、高品質的藥品供應鏈		127
Topic: Drug Safety					
HC-BP-250a.1	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	本公司已完成建置總公司藥物安全監視機制，子公司及其他藥品供應所在國家或地區依各地法規及藥品上市時程建置完成。我們將持續對上市後之新藥進行安全性監視及風險管控。目前尚未有於美國境內販售之藥品；已於全球銷售之藥品亦未有任何藥品不良反應通報、回收藥品等情事	3.6 有效的藥物安全監視與回收	 	80
HC-BP-250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System				
HC-BP-250a.3	Number of recalls issued; total units recalled				
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal				
HC-BP-250a.5	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type				

Code	Accounting Metric	Disclosure	參考章節	對應的 SDGs	頁次
Topic: Counterfeit Drugs					
HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	本公司已建立每批藥品的料號、批號與出廠活動紀錄確保批次流向與溯源性，以《產品代號及批號編碼程序書》等標準作業程序進行管理與追蹤。我們也訂有《產品二級包裝及序列化批次紀錄》，規範國外的委外加工廠進行產品商業化包裝和序列化的操作流程。預計於美國市場販售的 BESREMi [®] ，也已於 2020 年完成藥品序列化的導入	3.1 建構完善的供應鏈體系 3.6 有效的藥物安全監視與回收		64 83
HC-BP-260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	當獲報藥品有已知或可能的製造瑕疵、變質、仿冒品或任何其他嚴重的品質問題時，本公司 QA 部門將開展調查及啟動產品回收程序與回收行動。並依藥物危害等級，於一定期限之內將產品從使用端移除，並妥善處理回收品，主動通報當地主管機關	3.6 有效的藥物安全監視與回收		84
HC-BP-260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	藥華醫藥目前未有此情事			
Topic: Ethical Marketing					
HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	藥華醫藥目前未有此情事			
HC-BP-270a.2	Description of code of ethics governing promotion of off-label use of products	在藥品行銷與標示方面，我們嚴格遵循 WHO 與各國藥業行銷倫理規範，且為確保藥華醫藥同仁在與醫護人員互動合於合理規範以及相關的藥物與醫療法規，也都接受過內部教育訓練與法令宣導的藥品行銷倫理規範。更多說明詳見 2.3 法遵與誠信經營	2.3 法遵與誠信經營	 	48
Topic: Employee Recruitment, Developing & Retention					
HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	本公司透過薪酬福利、友善環境、人性化管理、暢通內部輪調及訓練發展等方式，塑造穩定留才的工作環境。我們深入各專業領域延攬生物醫藥及研發人才，積極招募醫學臨床及全球化管理專才。2020 年全球新招募超過 30 名研發及醫學研究專才，佔總員工人數之 10%	4.1 幸福職場		90
HC-BP-330a.2	(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others	2020 年度主管職留任率高達 93.94%，且近 3 年藥華醫藥的全體人員成長率皆持續穩定地成長。有關本公司新進與留任率等相關說明與計算，詳見 4.1 幸福職場	4.1 幸福職場	 	90



Code	Accounting Metric	Disclosure	參考章節	對應的 SDGs	頁次
Topic: Supply Chain Management					
HC-BP-430a.1	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	藥華醫藥目前雖未針對上游供應鏈進行外部稽核，但我們仍透過內部嚴謹的程序，嚴格監控原料、物料、儀器 / 設備供應商的篩選、評鑑與核准。我們每年也會定期進行供應商 / 承攬商考核，採取內部考核審查與實地稽核兩大制度併行。連續 2 年度，內部考核審查與實地稽核皆 100% 完成	3.2 當責的供應商管理	  	69
Topic: Business Ethics					
HC-BP-510a.1	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	藥華醫藥目前未有此情事			
HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals				
Activity Metrics					
HC-BP-000.A	Number of patients treated	累計至 2021 年第 1 季，BESREMI® 於歐洲 18 個國家銷售，提供近千名病患使用	1.5 積極佈局全球行銷策略	 	30
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	本公司已在全球啟動多國、多中心臨床試驗，累計全球超過 19 件的臨床試驗案，造福病患達 1,500 名	1.3 生物新藥的研究發展 6.2 創新藥物 解決未被滿足的疾病需求		26 122