#### 衞生署藥物辦公室 牌照及監察科

香港灣仔皇后大道東248號 大新金融中心20樓2001-2002室



#### DEPARTMENT OF HEALTH DRUG OFFICE

LICENSING AND COMPLIANCE DIVISION

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12 June 2025

To:

Authorized Sellers of Poisons

Licensed Wholesale Dealers

Licensed Pharmaceutical Manufacturers

# Launch of the Computerised Transaction Record for Antimicrobials

Following the letter issued by the Drug Office of the Department of Health ("the DH") on 27 June 2024<sup>1</sup>, regarding the development of the Computerised Transaction Record System for antimicrobials ("CTR"), we hereby notify all authorized sellers of poisons, licensed wholesale dealers and licensed pharmaceutical manufacturers (collectively referred to as "licensed traders") that the section of the CTR pertaining to licensed traders will be launched on 19 June 2025 to provide a convenient electronic recording system for licensed traders to record and view transactions related to antimicrobials.

The Government has all long been attached great importance to the necessity of tackling the issue of antimicrobial resistance ("AMR"). The High-Level Steering Committee on Antimicrobial ("Steering Committee") was set up in May 2016 to encourage collaboration, synergy and cross-fertilisation of all professional sectors under the "One Health" framework. The Government launched the second Hong Kong Strategy and Action Plan on Antimicrobial Resistance (2023-2027) ("Action Plan") in 2022 to map out strategies against the threat of AMR from 2023 to 2027. According to the Action Plan, one of the recommendations is to strengthen regulation on over-the-counter purchase of prescription-only antimicrobials, which includes amending relevant Ordinance(s) to mandate recording of antimicrobial prescription and dispensing data systematically through electronic means and ensure proper record keeping of antimicrobials along the supply chain, from wholesale to supply to end users, so as to combat the sales of antimicrobials without prescription.

<sup>&</sup>lt;sup>1</sup> Letter to Trade (Chinese only) "抗菌素電子交易紀錄系統平台" – (https://www.drugoffice.gov.hk/eps/upload/eps\_news/53700/EN/1/27%20June%202024%20Letter%20to%20Trade.pdf)

CTR is designed to provide licensed traders with a convenient electronic platform for recording and viewing transactions related to antimicrobial products. A dedicated portal has been developed to enhance accessibility, the CTR operates around the clock and is accessible on various electronic devices, including mobile devices, allowing users to manage their transaction records anytime and anywhere which enable licensed traders to effectively monitor their antimicrobial inventory in real-time. Through its track and trace function, the CTR supports the monitoring of antimicrobial inventory and facilitates efficient product recall when necessary. The DH can utilize the CTR to monitor antimicrobial records throughout the local supply chain, from wholesale to supply to end users, including prescription and dispensing information, so as to combat the sales of antimicrobials without prescription. CTR will facilitate the industry and relevant stakeholders while promoting the rational use and effective monitoring of antimicrobials.

Currently, submission of transactions records of antimicrobial through the CTR is voluntary. The DH hereby urges all licensed traders to begin using the CTR, to become familiarized with the data input requirements and related operation of the system as soon as possible so as to ensure full compliance with the relevant requirements once the legislation which mandate the submission of the transaction records takes via the CTR effect in the near future.

For enquiries, please send email to ctr info@dh.gov.hk.

Yours faithfully,

(John M. T. LAU) for Director of Health

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致: 各獲授權毒藥銷售商

各持牌批發商

各持牌藥劑製品製造商

### 抗菌素電子交易紀錄系統平台的啟用

繼衛生署藥物辦公室於2024年6月27日向業界發出有關開發抗菌素電子交易紀錄系統平台("系統平台")的信函<sup>1</sup>後,我們現致函通知各獲授權毒藥銷售商、持牌批發商和持牌藥劑製品製造商(統稱為"持牌藥商"),系統平台涉及持牌藥商的部份,將於2025年6月19日啟用。該系統旨在為持牌藥商提供一個便利的電子交易紀錄系統,以記錄和查看與抗菌素相關的交易記錄。

政府一直高度重視應對抗菌素耐藥性的必要性,並於2016年5月成立抗菌素耐藥性高層督導委員會(督導委員會),旨在鼓勵各專業界別在「一體化健康」框架下攜手協作及互相交流。政府於2022年發表第二份《香港抗菌素耐藥性策略及行動計劃》(2023-2027)(《行動計劃》),為2023年至2027年制訂應對抗菌素耐藥性威脅而採取的策略。《行動計劃》其中一個建議是加強監管在沒有處方下售賣抗菌素的行為,包括檢討並考慮修訂有關條例,規定以電子方式系統地記錄抗菌素處方及配藥資料,並確保在供應鏈(從批發到交付至最終使用者)內妥善保存抗菌素記錄,從而打擊無處方下售賣抗菌素的問題。

<sup>1</sup> 給業界的信"抗菌素電子交易紀錄系統平台"-

系統平台旨在為持牌藥商提供一個便利的交易紀錄系統,以記錄和查看抗菌素產品的交易紀錄。透過專門的網站,提升無障礙的瀏覽,系統平台全天候運作,可在各種電子設備(包括適用於流動裝置)上使用,使用者可隨時隨地管理其交易記錄,讓持牌藥商可實時有效地監控其抗菌素庫存。透過庫存監測及產品溯源功能,需要時可支援快速及有效的產品回收行動。衞生署亦可透過系統平台監察抗菌素在本地供應鏈(從批發到交付至最終使用者)的抗菌素記錄包括抗菌素處方及配藥資料,以打擊無處方下售賣抗菌素的問題。系統平台可為業界帶來便利,並共同推動抗菌素的合理使用和有效監控。

現時,透過系統平台提供交易記錄是自願性的。衛生署謹此呼 籲所有持牌藥商儘早開始使用系統平台,熟悉系統資料輸入的要求和相 關操作,以確保在有關強制使用系統平台提供交易記錄的法例生效時, 能全面遵守相關規定。

如有查詢,請電郵至ctr info@dh.gov.hk。

衛生署署長 (劉滿堂 堂) 代行)

二零二五年六月十二日

我們要建設一個健康的香港 並立志成為國際知名的公共衛生監管機構