新冠疫苗接種異常事件的呈報

Reporting of Adverse Event Following Immunization (AEFI) of COVID-19 Vaccine

衞生署
Department of Health

簡介會大綱
Briefing Content

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《預防及控制疾病（使用疫苗）規例》（第599K章）Prevention and Control of Disease (Use of Vaccines) Regulation, Cap. 599K

- 根據《預防及控制疾病(使用疫苗)規例》(法例第599K章)，醫務衞生局局長須訂立機制，以監察任何發生在該等接種者身上的，與施用認可使用的疫苗相關的異常事件。

- According to the Prevention and Control of Disease (Use of Vaccines) Regulation, Cap. 599K, the Secretary for Health must put in place a mechanism for monitoring any adverse event occurred to the recipients associated with the administration of the authorized vaccines.

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新冠疫苗接種須知 Factsheet of COVID-19 Vaccine

衛生署
Department of Health

科興 Sinovac

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新型冠狀病毒滅活疫苗(Vero細胞)
COVID-19 Vaccine (Vero Cell), Inactivated

CoronaVac「克爾來福」

接種須知
Vaccination Fact Sheet

衛生防護中心 Centre for Health Protection
衛生署 Department of Health

1 甚麼是「克爾來福」及其用途

「克爾來福」適用於預防新型冠狀病毒(SARS-CoV-2) 感染所致的2019冠狀病毒病(COVID-19)。
「克爾來福」適用於3歲及以上人群的預防接種®。
在政府疫苗接種計劃下，此疫苗產品現時是根據《預防及控制疾病 (使用疫苗) 規例》(第599K章) 為指明目的獲認可使用，而非根據《藥劑業及毒藥條例》(第138章) 在香港註冊使用。

® 有關以「克爾來福」疫苗為3歲以下兒童接種，請參考「6個月大至3歲以下幼童接種克爾來福疫苗的補充資料」

☐ 我 (及陪同人士) 已經閱讀及明白以上第一項的資料

2 在使用「克爾來福」前，需要瞭解甚麼事項[1]

以下為不應給予「克爾來福」的情況

如有以下情況，請在適當的 ☐ 加✓，並告訴在場的醫護人員。	我有以下情況:
• 對「克爾來福」或其他滅活疫苗；或「克爾來福」疫苗中的任何成分 (活性*或非活性成分*，或生產工序中使用的任何物質) 有過敏史。	☐
• 過往發生過疫苗嚴重過敏反應 (如急性過敏反應、血管神經性水腫、呼吸困難等)。	☐
• 患有嚴重神經系統疾病 (如橫貫性脊髓炎、格林巴利綜合症、脫髓鞘疾病等)。	☐
• 未控制的嚴重慢性疾患。 (註：常見的慢性病包括糖尿病、高血壓和冠心病等。慢性病人感染新冠病毒後的重症和死亡風險較高。如健康狀況穩定，藥物控制良好的慢性病人應接種新冠疫苗以作保護。如你不確定控制情況 / 最近病情出現變化 / 需要調較藥物 / 需要轉介等，請先與你的家庭醫生或主診醫生商討何時適合接種。)	☐

* 包括：滅活的新型冠狀病毒 (CZ02株)、氫氧化鋁佐劑、磷酸氫二鈉、磷酸二氫鈉、氯化鈉及注射用水。
[1] 根據藥廠提供資料

注意事項

- 目前暫未獲得本疫苗的保護持久性數據，接種後仍需根據疫情防控需要採取必要的防護措施。
- 患有急性疾病、慢性疾病的急性發作期、嚴重慢性疾病、過敏體質和發熱者需慎用；必要時經醫生評估後延遲接種。
- 糖尿病患者或有驚厥、腦癇 (前稱癲癇)、腦病或精神疾病史；或有這些病症的家族史者需慎用。
- 患有血小板減少症或出血性疾病者，肌肉注射本疫苗可能會引起出血，需慎用。
- 尚未獲得本疫苗對免疫功能受損者 (例如惡性腫瘤、腎病綜合症、愛滋病患者) 的安全性和有效性數據，此類人士接種本疫苗應基於個人考慮。
- 注射免疫球蛋白者應至少相隔1個月以上方可接種本疫苗，以免影響免疫效果。
- 接種本疫苗後出現任何神經系統異常反應者，禁止再次使用。
- 與其他疫苗一樣，無法確保本疫苗對所有接種者均產生保護作用。
- 接種疫苗後，觀察十五分鐘。

育齡期婦女

在臨床試驗中接種「克爾來福」後意外妊娠的婦女中收集到的數據非常有限，尚不足以判斷接種本疫苗後可能導致發生異常妊娠情況的風險。

懷孕期或哺乳期女性

目前尚未獲得孕婦及哺乳期婦女使用「克爾來福」的臨床試驗數據。

兒童和青少年

第一及第二期臨床研究資料顯示，「克爾來福」疫苗於3至17歲兒童及青少年能產生免疫力、安全及耐受性良好。此外，現時仍持續進行的第三期臨床研究顯示「克爾來福」疫苗於這年齡組別的耐受性良好。現時中國內地已為3至17歲兒童及青少年接種超過二億劑「克爾來福」疫苗。根據大規模接種計劃的已知數據顯示，「克爾來福」疫苗沒有重大安全問題。

60歲及以上人群

對60歲及以上人群而言，接種「克爾來福」的效益一般而言高於不接種任何疫苗的風險。第 I 及 II 期的數據顯示，疫苗對60歲及以上人群是安全的，亦能有效誘發免疫反應及產生抗體。

其他藥物和「克爾來福」

- 與其他疫苗同時接種：「克爾來福」尚未進行同期 (先、後或同時) 接種其他疫苗對本疫苗免疫效果影響的臨床研究。
- 與其他藥物同時使用：具有免疫抑制作用的藥物，如免疫抑制劑、化療藥物，抗代謝藥物、烷化劑、細胞毒素類藥物、皮質類固醇類藥物等，可能會降低人體對「克爾來福」的免疫反應。
- 正在接受治療的患者：對於正在使用藥物的人群，為避免可能的藥物間相互作用，接種「克爾來福」前建議諮詢醫生意見。

3 如何給予「克爾來福」[1]

接種途徑為於上臂三角肌區域進行肌肉注射。
就聯合科學委員會聯同專家顧問團有關疫苗接種間隔及劑數的建議，請參閱補充接種須知「我應接種多少劑新冠疫苗？」。
2019冠狀病毒病的康復者請參閱「曾感染 2019 冠狀病毒病人士接種新冠疫苗須知」。

4 可能出現的副作用[1]

在十八歲或以上人士可能出現的副作用

	副作用	可能影響患者比例
十分常見	• 接種部位：疼痛 • 頭痛 • 疲乏	≥ 10%
常見	• 接種部位：腫脹、痕癢、紅斑、硬結 • 肌肉痛 • 噁心 • 腹瀉 • 關節痛 • 咳嗽 • 發冷 • 痕癢 • 食慾減退 • 流鼻水 • 口咽痛 • 鼻塞 • 腹痛	1% -10%
偶見	• 注射部位發熱 • 嘔吐 • 過敏反應 (包括急性過敏反應) • 皮膚、黏膜異常 • 發燒 • 震顫 • 潮紅 • 水腫 • 頭暈 • 嗜睡 • 不適 • 打噴嚏 • 吞嚥痛	0.1% -1%
罕見	• 接種部位：出現皮疹/丘疹 • 肌肉痙攣 • 眼瞼水腫 • 眶周腫脹 • 流鼻血 • 腹脹 • 便秘 • 嗅覺減退/ 嗅覺喪失 • 眼充血 • 潮熱 • 打嗝 • 結膜充血 • 喉部刺激 • 多汗症 • 皮膚發暖 • 肢體疼痛 • 背痛 • 肌肉病變 • 潰瘍性結腸炎 • 盲腸炎 • 腦癇	0.01% - 0.1%
十分罕見	• 貝爾面癱# #於香港在獲授權後觀察所得	<0.01%
嚴重	• 在臨床試驗中，識別出八種嚴重異常反應，包括肌肉病變、潰瘍性結腸炎、過敏反應、蕁麻疹、發燒、盲腸炎、腦癇及皮疹	

在三至十七歲兒童或青少年可能出現的副作用

	副作用	可能影響患者比例
十分常見	• 接種部位疼痛	≥ 10%
常見	• 注射部位硬結、腫脹 • 皮膚和黏膜異常 • 噁心 • 咳嗽 • 流鼻水 • 發熱 • 食慾減退 • 頭痛 • 疲乏 • 喉嚨痛	1% -10%
偶見	• 注射部位痕癢、紅斑 • 腹瀉 • 肌肉痛 • 咽部紅斑 • 腹痛 • 腹脹 • 淋巴結炎 • 眼皮炎 • 過敏反應 • 嘔吐 • 咽喉痛 • 上呼吸道感染 • 上腹痛 • 頭暈 • 胸口不適	0.1% -1%
嚴重	• 截至2021年11月，尚未發現經研究者判斷與接種本疫苗有關的嚴重異常事件。	

在上市後安全性監測/境內或境外的上市後監測中觀察到/ 自發報告的不良反應，這些不良反應無法準確地估計其發生頻率或確定其與本品接種之間的因果關係。包括：聲帶息肉，帶狀皰疹，心悸，心臟顫動，鼻炎，眩暈，耳鳴，感覺減退，暈厥，格林巴利綜合征，貝爾氏麻痹，大腦梗死，肌無力，咽部紅斑，呼吸困難，過敏性休克，過敏性皮炎，斑丘疹，血管性水腫，過敏性紫癜，腹部不適，胸痛，胃腸疾病，蒼白，血小板減少性紫癜，血壓升高，發聲困難，急性胰激障礙，難受，心動過速。

5 接種疫苗後的異常事件報告

衛生署設有對藥物的異常反應的呈報系統，收集接種疫苗後出現異常事件的報告，目的是監察新冠疫苗的安全。若你在接種疫苗後，出現懷疑的異常事件，在徵詢醫護人員(例如：醫生、牙醫、藥劑師、護士及中醫師) 意見時，若他們認為可能與接種疫苗有關，可提醒醫護人員向衛生署呈報接種新冠疫苗後的異常事件。

為持續監測與接種2019冠狀病毒病疫苗有關的安全及臨床事件，衛生署及與政府合作的相關機構 (包括香港大學) 有機會查閱及使用你在接種疫苗時所收集的個人資料及由醫院管理局、私營醫療機構及醫護人員持有的臨床資料，惟有關資料必須為此目的而查閱及使用。

若在接種24小時後注射部位的發紅或觸痛增加，或若你的副作用使你擔心，又或副作用似乎不會在幾天內消失，請聯絡你的醫生。

在你就醫時，請確保將接種疫苗的詳情告知醫護人員，並向他們出示你的接種疫苗記錄卡(如有)。他們會進行適當的評估，如有需要，會向衛生署呈報任何判斷為在醫學上需關注的接種疫苗後異常事件，讓衛生署採取進一步行動和評估。

請你允許醫護人員報告接種疫苗後異常事件時，在你同意下將異常事件個案和個人及臨床資料轉交衛生署以持續監察接種新冠疫苗的安全及臨床事件。

給醫護人員的信息：

請進行醫學評估，若你認為和疫苗相關的接種疫苗後異常事件是醫學上需關注，請通過以下網站向衛生署藥物辦公室作網上呈報
https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html

如果疫苗接種者在接種疫苗後出現嚴重的異常事件，請把接種者轉介到醫院。

☐ 我已閱讀及明白此疫苗接種須知內的所有內容及個人資料收集目的聲明，並同意在2019冠狀病毒病疫苗接種計劃下向本人/本人的子女/本人的受監護人*注射2019冠狀病毒病疫苗；及衛生署及與政府合作的相關機構 (包括香港大學) 查閱及使用(i) 本人/本人的子女/本人的受監護人*的個人資料及(ii) 由醫院管理局、相關私營醫療機構及醫護人員持有關於本人/本人的子女/本人的受監護人*的臨床資料，以便衛生署持續監測與接種2019冠狀病毒病疫苗有關的安全及臨床事件，惟有關資料必須為此目的而查閱及使用。

*請刪去不適用者

更多有關疫苗及副作用資訊，請瀏覽網站
www.covidvaccine.gov.hk
繁體中文版　簡体中文版

版本日期: 2023年4月3日　最新資訊請參閱網上版本

新冠疫苗接種須知 Factsheet of COVID-19 Vaccine

衛生署
Department of Health

復星醫藥/德國藥廠BioNTech
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信使核糖核酸新冠疫苗
COVID-19 mRNA Vaccine

Comirnaty「復必泰」

(核苷修飾 nucleoside modified)

接種須知
Vaccination Fact Sheet

衛生防護中心 Centre for Health Protection
衛生署 Department of Health

1 甚麼是「復必泰」及其用途

「復必泰」是適用於預防由SARS-CoV-2病毒引起的COVID-19的疫苗並有以下四種配方。

「復必泰」	劑量	合資格年齡組別
成人配方	復必泰原始株 30 微克/劑	成年人和 12 歲或以上的青少年
兒童配方	復必泰原始株 10 微克/劑	5 至 11 歲兒童
幼兒配方	復必泰原始株 3 微克/劑	6 個月至 5 歲以下幼童
二價疫苗	復必泰原始株 / Omicron變異株 BA.4-5 (15/15微克)[@]/劑	12 歲或以上合資格人士

本疫苗可使免疫系統（人體的天然防禦系統）產生對抗該病毒的抗體和血細胞，從而預防COVID-19。
由於復必泰不含有產生免疫力的病毒，故不會導致COVID-19。

在政府疫苗接種計劃下，四種復必泰配方現時都是根據《預防及控制疾病（使用疫苗）規例》(第599K章)為指明目的獲認可使用，而非根據《藥劑業及毒藥條例》(第138章)在香港註冊使用。

@ 每劑含 15 微克mRNA 原始株及 15 微克mRNA Omicron變異株 BA.4-5。根據現有臨床數據，受試者於完成基礎疫苗接種後接種復必泰二價疫苗或原始株疫苗作為加強劑後，接種復必泰二價疫苗後所產生針對 Omicron變異株 BA.4-5 的抗體水平及增幅都較接種原始株疫苗為高。

2 在使用「復必泰」前，需要瞭解甚麼事項

不應給予「復必泰」[1]

- 如果你曾對「復必泰」或其活性物質或其他成分有過敏反應

包括：[(4-羥丁基) 氮雜二基] 雙(己烷-6,1-二基) 雙(2-己基癸酸酯)(ALC-0315)/2-[(聚乙二醇)-2000]-N,N-二十四烷基乙醯胺 (ALC-0159)/1,2-二硬脂醯-sn-甘油-3-磷酸膽鹼 (DSPC)/膽固醇 / 氯化鉀* / 磷酸二氫鉀* / 氯化鈉* / 磷酸氫二鈉二水合物* / trometamol^ / trometamol hydrochloride^ / 蔗糖 / 注射用水

*只在成人配方的成分
^只在兒童配方、幼兒配方、復必泰二價疫苗的成分

警告和注意事項[1]

如果你有以下情況，使用本疫苗前，請諮詢您的醫生、藥劑師或護士：

- 以往在接種「復必泰」或任何其他疫苗後，你曾出現過嚴重過敏反應或呼吸問題。
- 你對疫苗接種過程感到焦慮，或曾在任何針頭注射後暈倒。
- 患有嚴重疾病或伴有高燒的感染。但是，如果你出現輕微發燒或上呼吸道感染（如感冒），仍可以接種本疫苗。

[1] 根據藥廠提供資料

- 有出血問題，容易出現瘀青或正在使用預防血凝塊的藥物。
- 由於HIV 感染等疾病或使用影響免疫系統的藥物 (如皮質類固醇)，令你的免疫系統減弱。
- 接種復必泰後，出現心肌炎 (心臟肌肉發炎) 及心包炎 (包圍心臟的外膜發炎) 的風險會增加。這些情況可於接種後數天之內出現，主要發生於 14 天內。個案更常於接種第 2 劑疫苗後及年輕男士身上。與 12 至 17 歲相比，5 至 11 歲兒童患心肌炎和心包炎的風險似乎較低。接種疫苗後，請注意心肌炎及心包炎徵兆的出現，如氣促、心悸、胸口痛。一旦出現這些徵兆，請立即向醫護人員求助。市民在接種「復必泰」疫苗後一星期內應避免劇烈運動。

與任何疫苗一樣，接種「復必泰」疫苗後可能無法保護所有接種「復必泰」的人士，亦未清楚你將受到多長時間的保護。

兒童

兒童應接種合乎年齡的疫苗和劑量。
詳情請參閱「兒童及青少年接種新冠疫苗注意事項及常見問題」。

其他藥物和「復必泰」

如果你正使用、最近已經使用或可能需要使用其他藥物或近期接種過任何其他疫苗，請告知你的醫生或藥劑師。

懷孕和哺乳

如果你正在懷孕或認為你可能懷孕，在接種本疫苗前請告知你的醫生、護士或藥劑師。目前，尚無關於懷孕期間使用復必泰二價疫苗的資料。然而，針對在懷孕中期和晚期接種最早獲批准的復必泰疫苗之孕婦，大量資料顯示並沒有對懷孕或新生嬰兒造成負面影響。雖然目前在懷孕頭三個月接種疫苗之後的懷孕結果相關資料有限，但並未發現流產的風險有所改變。復必泰可在懷孕時使用。

目前，尚無關於在母乳喂哺期間使用復必泰二價疫苗的數據，不過預期不會對母乳喂哺的新生兒／嬰兒產生影響。在接種最早獲批准的復必泰疫苗後進行母乳喂哺的婦女之數據中，未顯示有對母乳喂哺的新生兒／嬰兒有不良反應的風險。復必泰可在母乳喂哺時使用。

經考慮海外就懷孕及哺乳的婦女接種信使核糖核酸新冠疫苗的建議及世界各地累積相關現實的安全數據，聯合科學委員會聯同專家顧問團建議她們可跟隨一般成年人的安排，接種信使核糖核酸疫苗「復必泰」。

駕駛車輛和操作機器

第 4 節 (可能的副作用) 中提到的疫苗接種的某些影響可能會暫時影響您的駕駛車輛或操作機器的能力。請在這些影響消失後再駕駛車輛或操作機器。

「復必泰」成人配方含有鉀和鈉

本疫苗每劑含<1 mmol (39 mg) 的鉀，即基本上「無鉀」。
本疫苗每劑含<1 mmol (23 mg) 的鈉，即基本上「無鈉」。

3 如何給予「復必泰」

在你上臂#肌肉內注射「復必泰」。
#聯合科學委員會聯同專家顧問團尤其建議兒童及青少年可於大腿前外側中段部位進行肌肉注射。

就聯合科學委員會聯同專家顧問團有關疫苗接種間隔及劑數的建議，請參閱補充接種須知「我應接種多少劑新冠疫苗？」。
2019冠狀病毒病的康復者請參閱「曾感染2019 冠狀病毒病人士接種新冠疫苗須知」。

關於「復必泰」的使用，如還有任何疑問，請諮詢醫療團隊。

4 可能出現的副作用[1]

與所有疫苗一樣，「復必泰」可能引起副作用，但並非所有人均會出現副作用。

	副作用	可能影響患者比例
非常常見	• 鬧情緒 (6個月至少於2歲) • 注射部位：疼痛、腫脹 • 疲倦 • 頭痛 • 睡意 (6個月至少於2歲) • 肌肉痛 • 寒顫 • 關節痛 • 腹瀉 • 發燒 12至15歲之青少年出現上述部分副作用的機會可能會較成年人略多。	>1/10
常見	• 注射部位發紅 (“非常常見”於6個月至11歲) • 噁心 • 嘔吐	≤1/10
不常見	• 淋巴結腫大 (接種第3劑後較為常見) • 感覺不適 • 手臂疼痛 • 失眠 • 注射部位發癢 • 過敏反應如皮疹 (“常見”於6個月至少於2歲) 或瘙癢 • 感到虛弱或乏力 / 困倦 • 食慾下降 (“非常常見”於6個月至少於2歲) • 過度出汗 • 夜間盜汗 • 頭暈	≤1/100
罕見	• 暫時性一側面部下垂 • 過敏反應 (如蕁麻疹或面部腫脹)	≤1/1,000
非常罕見	• 可導致氣促、心悸、胸口痛的心臟肌肉發炎 (心肌炎) 及包圍心臟的外膜發炎 (心包炎)	≤1/10,000
未知	• 嚴重過敏反應 • 接種手臂大範圍腫脹 • 面部腫脹 (面部腫脹或出現於曾接受面部皮膚填充劑注射的人身上) • 導致皮膚出現紅點或紅色斑塊，呈靶狀或像似由淺紅色環狀包圍內為一暗紅中心點的「牛眼」之皮膚反應 (多形性紅斑) • 異常皮膚感覺，例如刺痛或爬行感 (感覺異常) • 感覺或敏感度減退，尤其皮膚上 (感覺減退) • 月經過多 (大多數個案性質屬非嚴重及暫時性)	無法根據現有資料估算

5 接種疫苗後的異常事件報告

衛生署設有對藥物的異常反應的呈報系統，收集接種疫苗後出現異常事件的報告，目的是監察新冠疫苗的安全。若你在接種疫苗後，出現懷疑的異常事件，在徵詢醫護人員 (例如：醫生、牙醫、藥劑師、護士及中醫師) 意見時，若他們認為可能與接種疫苗有關，可提醒醫護人員向衛生署呈報接種新冠疫苗後的異常事件。

為持續監測與接種2019冠狀病毒病疫苗有關的安全及臨床事件，衛生署及與政府合作的相關機構 (包括香港大學) 有機會查閱及使用你在接種疫苗時所收集的個人資料及由醫院管理局、私營醫療機構及醫護人員持有的臨床資料，惟有關資料必須為此目的而查閱及使用。

若在接種24小時後注射部位的發紅或觸痛增加，或若你的副作用使你擔心，又或副作用似乎不會在幾天內消失，請聯絡你的醫生。

在你就醫時，請確保將接種疫苗的詳情告知醫護人員，並向他們出示你的接種疫苗記錄卡(如有)。他們會進行適當的評估，如有需要，會向衛生署呈報任何判斷為在醫學上需關注的接種疫苗後異常事件，讓衛生署採取進一步行動和評估。

請你允許醫護人員報告接種疫苗後異常事件時，在你同意下將異常事件個案和個人及臨床資料轉交衛生署以持續監察接種新冠疫苗的安全及臨床事件。

給醫護人員的信息：

請進行醫學評估，若你認為和疫苗相關的接種疫苗後異常事件是醫學上需關注，請通過以下網站向衛生署藥物辦公室作網上呈報
https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html
[只提供英文版本]

如果疫苗接種者在接種疫苗後出現嚴重的異常事件，請把接種者轉介到醫院。

☐ 我已閱讀及明白此疫苗接種須知內的所有內容及個人資料收集聲明，並同意在2019冠狀病毒病疫苗接種計劃下向本人／本人的子女／本人的受監護人*注射2019冠狀病毒病疫苗；及衛生署及與政府合作的相關機構 (包括香港大學) 查閱及使用 (i) 本人／本人的子女／本人的受監護人*的個人資料及 (ii) 由醫院管理局、相關私營醫療機構及醫護人員持有屬於本人／本人的子女／本人的受監護人*的臨床資料，以便衛生署持續監測與接種2019冠狀病毒病疫苗有關的安全及臨床事件，惟有關資料必須為此目的而查閱及使用。

*請刪去不適用者

更多有關疫苗及副作用資訊，請瀏覽網站
www.covidvaccine.gov.hk

繁體中文版　簡体中文版

版本日期: 2023年3月28日　最新資訊請參閱網上版本

給醫護人員通訊
Dear Healthcare Professional Letter

香港特別行政區政府
衞生署藥物辦公室
香港九龍觀塘巧明街 100 號
友邦九龍大樓 20 樓 2002-05 室

本署檔號 Our Ref.:
電　　話 Tel.: (852) 3974 4117
圖文傳真 Fax: (852) 2186 9845

THE GOVERNMENT OF THE HONG KONG SPECIAL ADMINISTRATIVE REGION
DRUG OFFICE
DEPARTMENT OF HEALTH
Suites 2002-05, 20F, AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong, Kowloon

22 February 2021

Dear Healthcare Professionals,

Reporting of Adverse Event following Immunization (AEFI) of COVID-19 Vaccine

I am writing to appeal to you to report suspected AEFI of COVID-19 vaccine to the Drug Information and Pharmacovigilance Division of the Drug Office, Department of Health (DH).

As we all know that COVID-19 vaccine is one of the critical interventions against COVID-19 pandemic, the unprecedented rapid development of the COVID-19 vaccines on novel platforms followed by its rapid deployment on a mass scale poses unique challenges in monitoring vaccine safety. Timely reporting of adverse events following COVID-19 immunization is the first step in ensuring the continued safety of the vaccine. The Government has procured COVID-19 vaccines to serve the whole of the Hong Kong population and would arrange for members of the public to receive vaccination as early as possible under the set priority. It is very important that report of AEFI can provide vital information for monitoring the safety of the vaccine. Therefore, your proactive support in identifying the association between AEFI and the vaccine, and timely report to us via the dedicated COVID-19 Vaccine Adverse Event Online Reporting system at (https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html) shall make contribution to the success of immunization programs.

Some common minor reactions after vaccinations such as minor local reactions and low-grade fever are not required to be reported. Nevertheless, you are encouraged to report AEFIs if they are doubtful of the relationship or clinically significance between the vaccine and the AEFI concerned. Additional information on the reporting of COVID-19 Vaccine Adverse Event can be found in our guidance at the above mentioned website.

Please refer to the attached Annex for a summary guidance of Reporting of AEFI of COVID-19 vaccines. You may also wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

衞生署
Department of Health

給醫護人員通訊
Dear Healthcare Professional Letter

衛生署
Department of Health

Reporting of
ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)
of COVID-19 VACCINES for Healthcare Professionals

DO YOUR PART TO MONITOR COVID-19 VACCINES' ADVERSE EVENTS !

1

Monitor whether a patient experienced an adverse event after COVID-19 vaccination.

2

Report adverse events to the Drug Office of the Department of Health using COVID-19 Vaccine Adverse Event Online Reporting system.

3

Contact Drug Office of the Department of Health if you have any questions about AEFI reporting at 2319 2920.

QUESTIONS & ANSWERS

What is an AEFI?
An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

What is an AESI?
According to World Health Organization (WHO), an Adverse Event of Special Interest (AESI) is a pre-identified and predefined medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further special studies.

What types of adverse events should be reported?
You should report any event which may be related to vaccine. Of particular importance are events which are serious, or unusual or unexpected events. Submitting a report does not mean that the vaccine caused the event.

Why is it important to report an AEFI?
When you report an AEFI you provide vital information that is needed to monitor vaccine safety. This information is also used to report on vaccine safety to the public, which contributes to the success of COVID-19 immunization program.

What does NOT need to be reported?
Some common or mild events do not need to be reported. These include: low-grade fever or minor local reactions.

Who should report an AEFI?
Healthcare professionals (e.g. physicians, nurses and pharmacists) are encouraged to voluntarily report AEFIs. Reports should be made using the COVID-19 Vaccine Adverse Event Online Reporting system.

If in doubt, please report.
You do not need to be certain that the adverse event is related to the COVID-19 vaccine.

The COVID-19 Vaccine Adverse Event Online Reporting system, the list of AESI adopted by the Department of Health, and the Guidance for Healthcare Professionals - Reporting of Adverse Event Following Immunization of COVID-19 Vaccine are all available at:
https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html

疫苗接種異常事件
Adverse Event Following Immunization - AEFI

- 根據世界衞生組織（WHO）的指引，疫苗接種異常事件(AEFI) 是指接種疫苗後發生的任何異常醫學事件，並不一定與疫苗的使用有因果關係。

- According to WHO, AEFI refers to any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine

衞生署
Department of Health

嚴重的疫苗接種異常事件 Serious AEFI

嚴重的疫苗接種異常事件(Serious AEFI)是指在接種疫苗後出現的以下情況：

- 致命；
- 危及性命；
- 導致病人入院或延長住院時間；
- 引致持續性或重要的殘疾 / 功能喪失；
- 導致先天性異常 / 胎兒缺陷；
- 需要醫療介入以防止上述任何一種結果（醫學上重要的）

A serious AEFI is any untoward medical occurrence which follows immunization that:

- results in death;
- is life-threatening;
- requires in-patient hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability/ incapacity;
- is a congenital anomaly/birth defect;
- requires intervention to prevent one of the outcomes above (medically important).

衞生署
Department of Health

非預期的疫苗接種異常事件
Unexpected AEFI

- 非預期的疫苗接種異常事件(AEFI)是指所涉異常事件的性質、嚴重程度、專一性，或結果與本地產品標籤所載的資料或說明不符。

- An unexpected AEFI is an AEFI whose nature, severity, specificity, or outcome is not consistent with the term or description used in the local product labelling

衞生署
Department of Health

嚴重或非預期新冠疫苗接種異常事件
Serious or Unexpected AEFI of COVID-19 Vaccines

衛生署
Department of Health

- 急性外周面部癱瘓(貝爾面癱) Acute peripheral facial paralysis (Bell's Palsy)
- 類速發嚴重過敏反應 Anaphylactoid reaction
- 速發嚴重過敏反應Anaphylaxis
- 由醫護人員或公眾認為免疫接種相關的任何其他嚴重和異常情況 Any other severe and unusual events that are thought by health workers or the public to be related to immunization
- 死亡(與新冠疫苗接種相關異常事件) Death when associated with COVID-19 vaccine adverse event
- 殘疾(與新冠疫苗接種相關) Disability when associated with COVID-19 vaccine
- 腦脊髓炎Encephalomyelitis
- 腦病Encephalopathy
- 吉蘭．巴雷綜合症 (又名吉．巴氏綜合症) Guillain Barré Syndrome
- 住院治療(與新冠疫苗接種相關異常事件) Hospitalization when associated with COVID-19 vaccine adverse event
- 心肌炎 / 心包炎Myocarditis/ Pericarditis
- 膿毒症Sepsis
- 敗血症Septicaemia
- 血小板減少症/ 血栓伴血小板減少綜合症 Thrombocytopenia/ Thrombosis with thrombocytopenia syndrome (TTS)
- 中毒性休克综合症Toxic shock syndrome
- 橫貫性脊髓炎Transverse myelitis

疫苗接種關注事件
Adverse Event of Special Interest - AESI

- 根據世界衞生組織（WHO）的指引，疫苗接種關注事件（AESI）是一件預先確定和預先定義的，醫學上需關注重要的事件，可能與疫苗有潛在的因果關係，需要進行仔細的監測和通過進一步的特殊研究確認。

- According to WHO, an AESI is a pre-identified and pre-defined medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further special studies

衞生署
Department of Health

新冠疫苗的疫苗接種關注事件例子
Examples of AESI for COVID-19 Vaccine

- 兒童多系統炎症綜合症 Multisystem inflammatory syndrome in children
- 急性呼吸窘迫綜合症 Acute respiratory distress syndrome
- 急性心血管損害 Acute cardiovascular injury
- 凝血紊亂 Coagulation disorder
- 急性腎損傷 Acute kidney injury
- 全身性驚厥 Generalized convulsion
- 吉蘭．巴雷綜合症 (又名吉．巴氏綜合症) Guillain Barré Syndrome
- 急性肝損傷 Acute liver injury
- 嗅覺喪失、味覺喪失Anosmia, ageusia
- 凍瘡類損傷Chilblain – like lesions
- 單器官皮膚血管炎 Single organ cutaneous vasculitis
- 多形性紅斑 Erythema multiforme
- 速發嚴重過敏反應 Anaphylaxis
- 急性無菌性關節炎 Acute aseptic arthritis
- 腦膜腦炎 Meningoencephalitis
- 急性播散性腦脊髓炎 Acute disseminated encephalomyelitis

衛生署
Department of Health

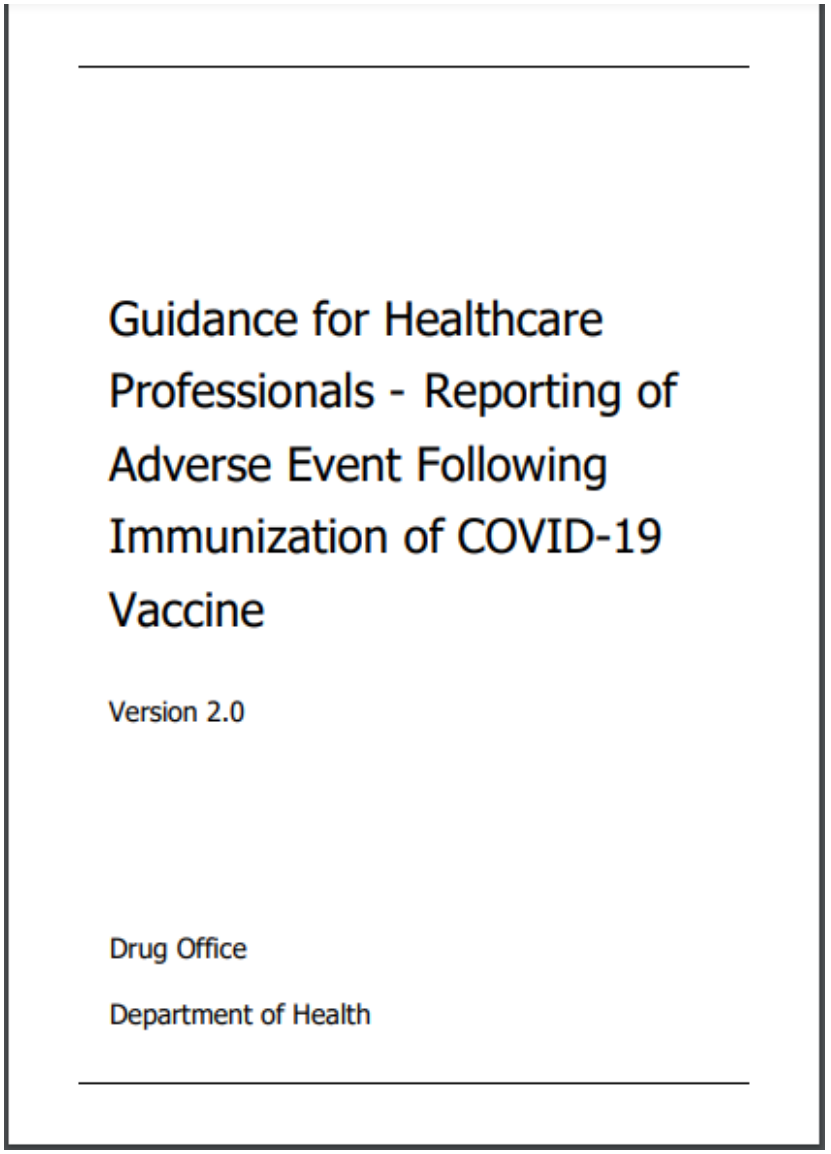
Source: https://www.who.int/publications/m/item/aesi-form-covid-19-vax?ua=1 (Version: May 2020)

藥品異常反應呈報
Adverse Drug Reactions (Reporting)

https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html

衛生署
Department of Health

醫護人員指引
Guidance for Healthcare Professionals



Guidance for Healthcare Professionals - Reporting of Adverse Event Following Immunization of COVID-19 Vaccine

Version 2.0

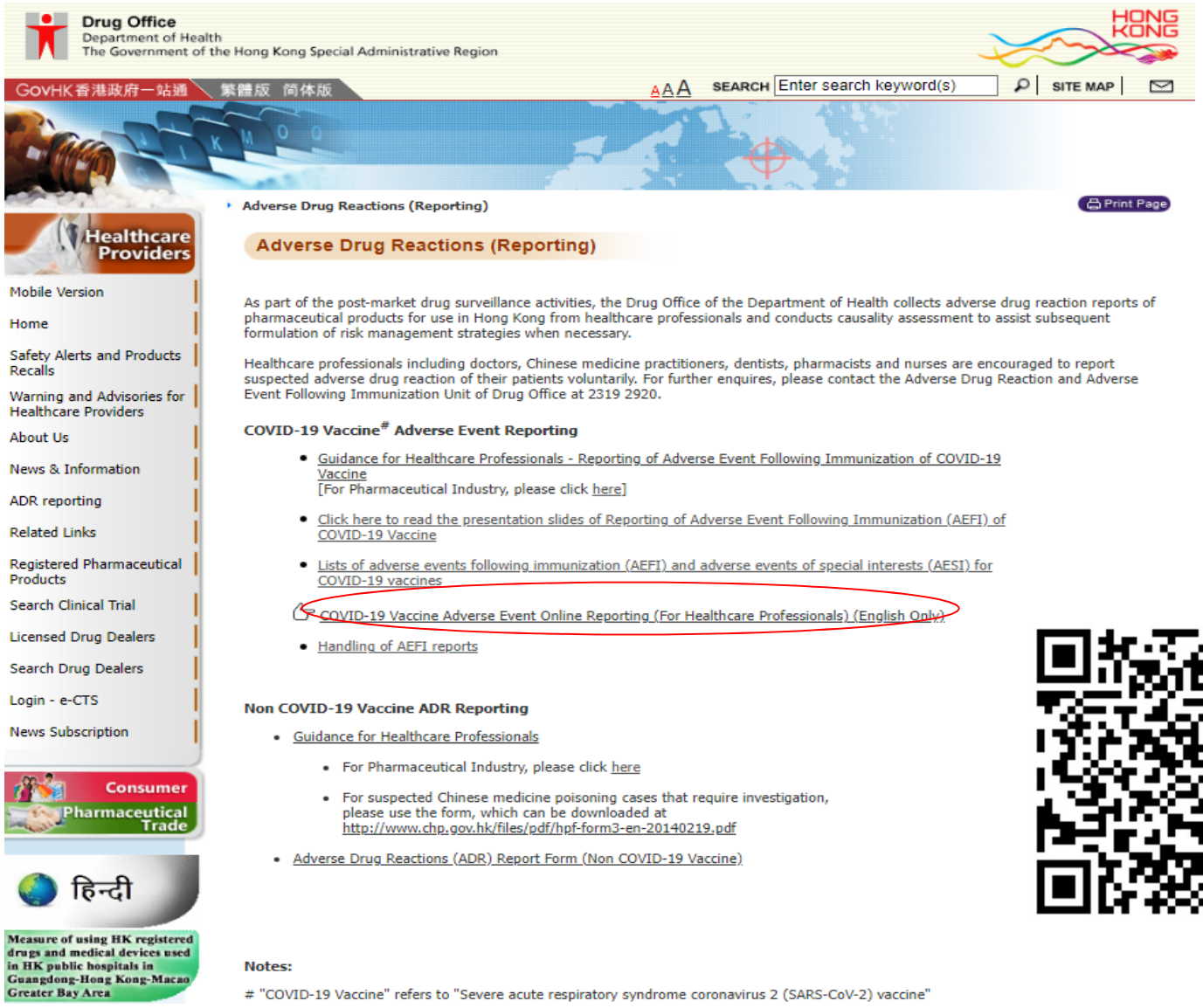
Drug Office

Department of Health

衞生署
Department of Health

藥品異常反應呈報
Adverse Drug Reactions (Reporting)

https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html



Drug Office
Department of Health
The Government of the Hong Kong Special Administrative Region

HONG KONG

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Consumer
Pharmaceutical Trade

हिन्दी

Measure of using HK registered drugs and medical devices used in HK public hospitals in Guangdong-Hong Kong-Macao Greater Bay Area

Adverse Drug Reactions (Reporting)

Print Page

Adverse Drug Reactions (Reporting)

As part of the post-market drug surveillance activities, the Drug Office of the Department of Health collects adverse drug reaction reports of pharmaceutical products for use in Hong Kong from healthcare professionals and conducts causality assessment to assist subsequent formulation of risk management strategies when necessary.

Healthcare professionals including doctors, Chinese medicine practitioners, dentists, pharmacists and nurses are encouraged to report suspected adverse drug reaction of their patients voluntarily. For further enquires, please contact the Adverse Drug Reaction and Adverse Event Following Immunization Unit of Drug Office at 2319 2920.

COVID-19 Vaccine# Adverse Event Reporting

- Guidance for Healthcare Professionals - Reporting of Adverse Event Following Immunization of COVID-19 Vaccine
  [For Pharmaceutical Industry, please click here]
- Click here to read the presentation slides of Reporting of Adverse Event Following Immunization (AEFI) of COVID-19 Vaccine
- Lists of adverse events following immunization (AEFI) and adverse events of special interests (AESI) for COVID-19 vaccines
- COVID-19 Vaccine Adverse Event Online Reporting (For Healthcare Professionals) (English Only)
- Handling of AEFI reports

Non COVID-19 Vaccine ADR Reporting

- Guidance for Healthcare Professionals
  - For Pharmaceutical Industry, please click here
  - For suspected Chinese medicine poisoning cases that require investigation, please use the form, which can be downloaded at http://www.chp.gov.hk/files/pdf/hpf-form3-en-20140219.pdf
- Adverse Drug Reactions (ADR) Report Form (Non COVID-19 Vaccine)

Notes:

"COVID-19 Vaccine" refers to "Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine"

衛生署
Department of Health

私隱政策
Privacy Policy

Privacy Policy

STATEMENT OF PURPOSES

Purpose of Collection

This personal data are provided by reporter for the purposes of reporting adverse event following immunization of the vaccine recipient to the Department of Health (DH). The personal data provided will be used by DH for the following purposes:

(a) follow-up of the case report; and
(b) surveillance of drug-related events.

2. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to assess the report properly.

Classes of Transferees

3. The personal data you provide are mainly for use within DH. Apart from this, the data may only be

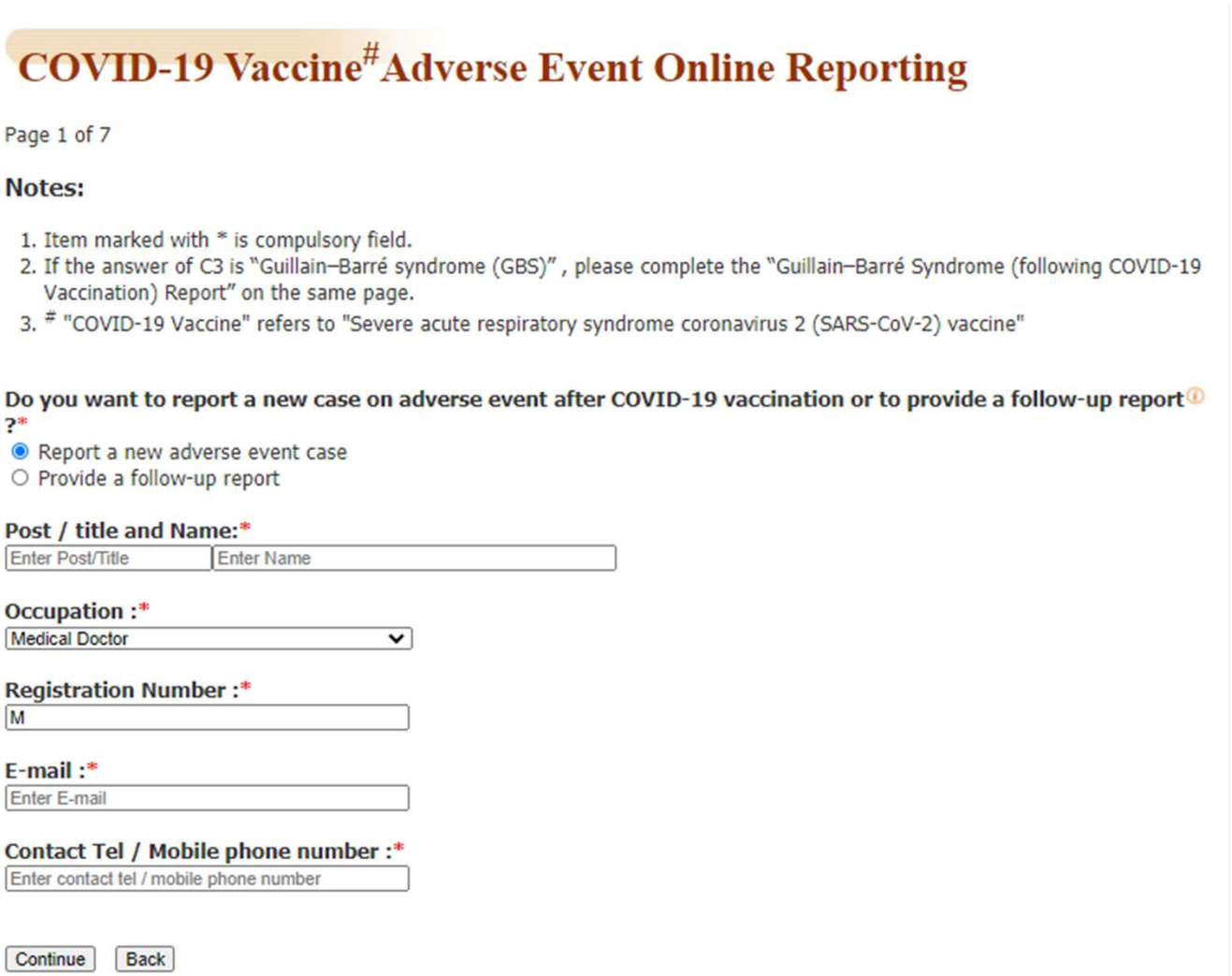
You need to read the complete content of the Statement of Purposes before you are able to click the check box below.

☐ I have read, understood and agreed to the above Statement of Purposes.
☐ I confirmed that prior consent has been sought from vaccine recipients if personal data (e.g. HKID) is disclosed in this report.

Continue Cancel

衞生署
Department of Health

接種新冠疫苗異常事件網上呈報系統
COVID-19 Vaccine Adverse Event Online Reporting system



COVID-19 Vaccine# Adverse Event Online Reporting

Page 1 of 7

Notes:

1. Item marked with * is compulsory field.
2. If the answer of C3 is "Guillain–Barré syndrome (GBS)" , please complete the "Guillain–Barré Syndrome (following COVID-19 Vaccination) Report" on the same page.
3. # "COVID-19 Vaccine" refers to "Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine"

Do you want to report a new case on adverse event after COVID-19 vaccination or to provide a follow-up report ?*

- (•) Report a new adverse event case
- ( ) Provide a follow-up report

Post / title and Name:*

Enter Post/Title | Enter Name

Occupation :*

Medical Doctor

Registration Number :*

M

E-mail :*

Enter E-mail

Contact Tel / Mobile phone number :*

Enter contact tel / mobile phone number

Continue | Back

衛生署
Department of Health

疫苗接種者資料
Vaccine Recipient Information

COVID-19 Vaccine#Adverse Event Online Reporting

Date of Report: [redacted]
Page 2 of 7

Section (A): Vaccine Recipient Information

A1. Enter surname, Enter first name (as shown in the HKID):
Enter surname , Enter first name

A2.1. Date of birth:
Enter Day / Enter Mo / Enter Yea (dd/mm/yyyy) Or **A2.2 Age in years:** Enter age

***A3.1. Sex:**
○ Male ○ Female

A4. Ethnic group:
○ Chinese ○ Asian (not Chinese) ○ African ○ Caucasian
○ Unknown ○ Others, please specify Enter ethnic group

***A5. HKID / Identity Document Number:**
○ HKID ○ Identity Document

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衛生署
Department of Health

新冠疫苗
COVID-19 Vaccine

COVID-19 Vaccine# Adverse Event Online Reporting

Date of Report: [redacted]

Section (B): COVID-19 Vaccine#

*B1. Date given: Enter date given (dd/mm/yyyy)

B2. Time: Enter h : Enter n (am / pm)

*B3. Vaccine brand name:
- CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated
- Comirnaty COVID-19 mRNA Vaccine 30mcg/dose (Adult)
- Comirnaty COVID-19 mRNA Vaccine 10mcg/dose (Children)
- Comirnaty COVID-19 mRNA Vaccine 3mcg/dose (Toddler)
- Comirnaty Original/Omicron BA.4-5 Bivalent Vaccine 15/15mcg/dose

B4. Dose no.:
- 1st dose
- 2nd dose
- 3rd dose
- 4th dose
- Others Enter details

B5.1. Vaccine batch number: Enter batch no.

B5.2. Vaccine expiry date: Enter Mo / Enter Yea (mm/yyyy)
B6.1. Diluent batch number (if applicable): Enter diluent batch number
B6.2. Diluent expiry date (if applicable): Enter Mo / Enter Yea (mm/yyyy)

B7. Administration route:
- Intramuscular
- Subcutaneous
- Intranasal
- Others Enter details

B8. Administration site:
Right arm Left arm Right leg Left leg Others Enter details

B9.1. Vaccination facility:
HA clinic Private hospital Community vaccination centre
Private clinic Outreach team

B10. Vaccination facility address:
Enter address

B11. Vaccination facility tel. no.: Enter Tel No

* B12. Was the concerned vaccine stored in condition according to the recommendations of the manufacturer prior to administration? (For storage condition details, please refer to product package insert)
Yes No Unknown

* B13. Was the temperature of the vaccine storage refrigerator monitored?
Yes No
Unknown

* B14. Did the handling method of the vaccine comply with the recommendations of the manufacturer? (Please refer to product package insert)
Yes No
Unknown

* B15. Was there any suspected sterility or quality issue of the vaccine administered?
Yes
No Unknown

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Department of Health

異常事件
Adverse Event

COVID-19 Vaccine# Adverse Event Online Reporting

Date of Report: [redacted]
Page 4 of 7

Section (C): Adverse Event

***C1.1. Adverse event: (can tick more than 1 box if appropriate)**

- ☐ Acute aseptic arthritis Δ
- ☐ Acute cardiovascular injury Δ
- ☐ Acute cardiovascular injury (Arrhythmia) Δ
- ☐ Acute cardiovascular injury (Coronary artery disease) Δ
- ☐ Acute cardiovascular injury (Heart failure) Δ
- ☐ Acute cardiovascular injury (Microangiopathy) Δ
- ☐ Acute cardiovascular injury (Stress cardiomyopathy) Δ
- ☐ Acute disseminated encephalomyelitis Δ
- ☐ Acute kidney injury Δ
- ☐ Acute liver injury Δ
- ☐ Acute respiratory distress syndrome Δ
- ☐ Acute Pancreatitis Δ
- ☐ Acute peripheral facial paralysis (Bell's palsy) Δ
- ☐ Anaphylactoid reaction
- ☐ Anaphylaxis Δ
- ☐ Anosmia, ageusia Δ
- ☐ Chilblain-like lesions Δ
- ☐ Coagulation disorder Δ
- ☐ Coagulation disorder (Haemorrhagic disease) Δ
- ☐ Coagulation disorder (Thromboembolism) Δ
- ☐ COVID-19 disease Δ
- ☐ Death Δ
- ☐ Disability
- ☐ Encephalomyelitis
- ☐ Encephalopathy
- ☐ Enhanced disease following immunization (Vaccine-associated enhanced disease)
- ☐ Erythema multiforme Δ
- ☐ Fever ≥38°C
- ☐ Generalized convulsion Δ
- ☐ Guillain–Barré syndrome (GBS) Δ
- ☐ Hospitalization
- ☐ Hypersensitivity reactions
- ☐ Injection site abscess (bacterial / sterile)
- ☐ Meningoencephalitis Δ
- ☐ Multisystem inflammatory syndrome in children Δ
- ☐ Myocarditis Δ / Pericarditis
- ☐ Narcolepsy Δ
- ☐ Neuralgia
- ☐ Neuritis
- ☐ Paraesthesia
- ☐ Radiculoneuropathy
- ☐ Rhabdomyolysis Δ
- ☐ Sepsis
- ☐ Septicaemia
- ☐ Severe allergic reaction
- ☐ Severe local reaction
- ☐ Single Organ Cutaneous Vasculitis Δ
- ☐ Subacute thyroiditis Δ
- ☐ Thrombocytopenia Δ / Thrombosis with thrombocytopenia syndrome (TTS)
- ☐ Toxic shock syndrome
- ☐ Transverse myelitis Δ
- ☐ Type I Diabetes Δ
- ☐ Vasculitis
- ☐ Others, Please specify: Enter event +

Δ Adverse Event of Special Interest.

C1.2. If more than the above selected events, please list below:

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Department of Health

異常事件
Adverse Event

COVID-19 Vaccine# Adverse Event Online Reporting

Date of Report: [redacted]
Page 4 of 7

Section (C): Adverse Event

*C1.1. Adverse event: (can tick more than 1 box if appropriate)

- ☐ Acute aseptic arthritis Δ
- ☐ Acute cardiovascular injury Δ
- ☐ Acute cardiovascular injury (Arrhythmia) Δ
- ☐ Acute cardiovascular injury (Coronary artery disease) Δ
- ☐ Acute cardiovascular injury (Heart failure) Δ
- ☐ Acute cardiovascular injury (Microangiopathy) Δ
- ☐ Acute cardiovascular injury (Stress cardiomyopathy) Δ
- ☐ Acute disseminated encephalomyelitis Δ
- ☐ Acute kidney injury Δ
- ☐ Acute liver injury Δ
- ☐ Acute respiratory distress syndrome Δ
- ☐ Acute Pancreatitis Δ
- ☐ Acute peripheral facial paralysis (Bell's palsy) Δ
- ☐ Anaphylactoid reaction
- ☐ Anaphylaxis Δ
- ☐ Anosmia, ageusia Δ
- ☐ Chilblain-like lesions Δ
- ☐ Coagulation disorder Δ
- ☐ Coagulation disorder (Haemorrhagic disease) Δ
- ☐ Coagulation disorder (Thromboembolism) Δ
- ☐ COVID-19 disease Δ
- ☐ Death Δ
- ☐ Disability
- ☐ Encephalomyelitis
- ☐ Encephalopathy
- ☐ Enhanced disease following immunization (Vaccine-associated enhanced disease)
- ☐ Erythema multiforme Δ
- ☐ Fever ≥38°C
- ☐ Generalized convulsion Δ
- ☐ Guillain–Barré syndrome (GBS) Δ
- ☐ Hospitalization
- ☐ Hypersensitivity reactions
- ☐ Injection site abscess (bacterial / sterile)
- ☐ Meningoencephalitis Δ
- ☐ Multisystem inflammatory syndrome in children Δ
- ☐ Myocarditis Δ / Pericarditis
- ☐ Narcolepsy Δ
- ☐ Neuralgia
- ☐ Neuritis
- ☐ Paraesthesia
- ☐ Radiculoneuropathy
- ☐ Rhabdomyolysis Δ
- ☐ Sepsis
- ☐ Septicaemia
- ☐ Severe allergic reaction
- ☐ Severe local reaction
- ☐ Single Organ Cutaneous Vasculitis Δ
- ☐ Subacute thyroiditis Δ
- ☐ Thrombocytopenia Δ / Thrombosis with thrombocytopenia syndrome (TTS)
- ☐ Toxic shock syndrome
- ☐ Transverse myelitis Δ
- ☐ Type I Diabetes Δ
- ☐ Vasculitis
- ☐ Others, Please specify: Enter event
- ☐ Others, Please specify: Enter event
- ☐ Others, Please specify: Enter event
- ☐ Others, Please specify: Enter event

Δ Adverse Event of Special Interest.

C1.2. If more than the above selected events, please list below:

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異常事件
Adverse Event

***C2. Adverse Event Details:**

Events	Date and time of onset (dd/mm/yyyy)	Event recovered?	Date and time of recovery (dd/mm/yyyy) *(if applicable)*
	Enter date of onset Enter hou : Enter min (○am / ○pm)	○ Yes ○ No ○ Recovering ○ Unknown	Enter date and time of reco Enter hou : Enter min (○am / ○pm)
	Enter date of onset Enter hou : Enter min (○am / ○pm)	○ Yes ○ No ○ Recovering ○ Unknown	Enter date and time of reco Enter hou : Enter min (○am / ○pm)
	Enter date of onset Enter hou : Enter min (○am / ○pm)	○ Yes ○ No ○ Recovering ○ Unknown	Enter date and time of reco Enter hou : Enter min (○am / ○pm)
	Enter date of onset Enter hou : Enter min (○am / ○pm)	○ Yes ○ No ○ Recovering ○ Unknown	Enter date and time of reco Enter hou : Enter min (○am / ○pm)
	Enter date of onset Enter hou : Enter min (○am / ○pm)	○ Yes ○ No ○ Recovering ○ Unknown	Enter date and time of reco Enter hou : Enter min (○am / ○pm)
	Enter date of onset Enter hou : Enter min (○am / ○pm)	○ Yes ○ No ○ Recovering ○ Unknown	Enter date and time of reco Enter hou : Enter min (○am / ○pm)

Expand

C3 Descriptions of adverse events, with timeline, signs and symptoms:

C4. Treatment of adverse event, with dosage, frequency, route & duration:

異常事件
Adverse Event

C5.1. Examination and laboratory result, with timeline & reference range:

Type of examination / laboratory test	Test Date (dd/mm/yyyy)	Result	Reference range
Enter type of examination	Enter test date	Enter result	Enter reference range
Enter type of examination	Enter test date	Enter result	Enter reference range
Enter type of examination	Enter test date	Enter result	Enter reference range
Enter type of examination	Enter test date	Enter result	Enter reference range
Enter type of examination	Enter test date	Enter result	Enter reference range
Enter type of examination	Enter test date	Enter result	Enter reference range

Expand

C5.2. Descriptions of examination and laboratory test result:

C6. Adverse event category (can tick more than 1 box if appropriate):
☐ Allergic reaction ☐ Local reaction ☐ Systemic reaction ☐ Neurological disorder

***C7. Severity (can tick more than 1 box if appropriate):**
☐ Vaccine Recipient died (Died on Enter date (dd/mm/yyyy)
(Cause of death Enter Details)
Autopsy done? ○ Yes, on Enter date (dd/mm/yyyy) ○ No
○ No, planned on Enter date (dd/mm/yyyy)
at Enter Ho : Enter Mir (○ am / ○ pm)

☐ Life threatening
☐ Involved or prolonged inpatient hospitalization (Admitted on Enter date (dd/mm/yyyy)
(Hospitalized for Enter Da days or discharged on Enter date (dd/mm/yyyy)
☐ Hospitalisation NOT required

***C8. Sequelae (can tick more than 1 box if appropriate):**
☐ Involved persistent or significant disability or incapacity
☐ Congenital anomaly or birth defect
☐ Medically important event or reaction (Details Enter Details)
☐ None of the above

***C9. Is this case a part of a cluster (Two or more cases of the same adverse event related in time, place or the vaccine administrated)?**
○ Yes (Details: Enter details) ○ No ○ Unable to assess

***C10. If yes,**
-How many other cases have been detected in the cluster? Enter No. **cases**
-Did all the cases in the cluster receive vaccine from the same vial?
○ Yes (Details: Enter details)
○ No (Details: Enter details)
○ Unknown

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進一步疫苗接種者資料 Further Vaccine Recipient Information

COVID-19 Vaccine# Adverse Event Online Reporting

Date of Report: [redacted]
Page 5 of 7

Section (D): Further Vaccine Recipient Information

D1. History of similar event:
○ Yes
○ No ○ Unknown

D2. History of adverse event after vaccinations:
○ Yes
○ No ○ Unknown

D3. Allergies to vaccine, drug or food:
○ Yes
○ No ○ Unknown

D4. Pre-existing comorbidity / congenital disorder:
○ Yes
○ No ○ Unknown

D5. Pre-existing acute illness 30 days prior to vaccination:
○ Yes
○ No ○ Unknown

D6. COVID-19 tested positive prior to vaccination:
○ Yes
○ No

D7. Hospitalization 30 days prior to vaccination:
○ Yes
○ No ○ Unknown

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進一步疫苗接種者資料
Further Vaccine Recipient Information

D8. Details of All Drug Therapies / Vaccines prior to Adverse Event:

All Drug Therapies/Vaccines Prior to Adverse events	Please tick the suspected drug	Daily Dosage (dose number for vaccines e.g. 1st DTP)	Route	Date Begun (dd/mm/yyyy)	Date Stopped (dd/mm/yyyy)	Reason for Use
Enter Therapies/Vaccines	☐	Enter Daily D	Enter Route	Enter Date	Enter Date	
Enter Therapies/Vaccines	☐	Enter Daily D	Enter Route	Enter Date	Enter Date	
Enter Therapies/Vaccines	☐	Enter Daily D	Enter Route	Enter Date	Enter Date	
Enter Therapies/Vaccines	☐	Enter Daily D	Enter Route	Enter Date	Enter Date	
Enter Therapies/Vaccines	☐	Enter Daily D	Enter Route	Enter Date	Enter Date	
Enter Therapies/Vaccines	☐	Enter Daily D	Enter Route	Enter Date	Enter Date	

D9. Family history of disease relevant to the adverse event or allergy?

○ Yes
○ No ○ Unknown

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呈報者資料
Reporter Information

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Department of Health

COVID-19 Vaccine# Adverse Event Online Reporting

Date of Report:
Page 6 of 7

Section (E): Reporter Information

*E1. Reporter Name:

*E2.1. Occupation: Medical Doctor Chinese Medicine Practitioner Dentist Nurse Pharmacist

*E2.2. Registration no.:

E3. Sector of service: Private Public

E4. Address: Enter address

E5. Contact Tel / Mobile phone number:

E6. Comment of the reporting healthcare professional / vaccine recipient, acquaintance of vaccine recipient on the causality of adverse event.

E7. Have you reported this case to other party? (can tick more than 1 box if appropriate)
Yes (Manufacturer (Company Name: Enter manufacturer)
Distributor / Importer (Company Name: Enter distributor / importe)
Others Enter detail)
No

*E8. Do you agree Drug Office to pass the anonymized details of this case to the authorization holder / registration certificate holder of the COVID-19 Vaccine# for their global safety signal monitoring?
Yes No

Section (F): Report type

*F1. Type of report:
Spontaneous Literature Study Solicited

(Revised in 02/2021)

Please enter the five letters as shown above.

Preview Back

因果關係評估 Causality Assessment

- 這是一個系統性地對疫苗接種異常事件(AEFI)的評估，目的是確定事件與所接種疫苗之間因果關係的可能性。
- 因果關係評估有助於判定這種關係的關聯程度。
- Causality assessment is the systematic review of data about an AEFI case; it determines the likelihood of a causal association between the event and the vaccine(s) received.
- It is meant to assist in determining the level of certainty of such an association.

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因果關係評估流程
Flow of Causality Assessment

呈報疫苗接種異常事件 Report AEFI

- 資料核實 Information verification
- 嚴重的疫苗接種異常事件由專家委員會評估 serious AEFIs assessed by Expert Committee

因果演算 Causality Algorithm

- 時間關聯性Temporal relationship
- 其他原因 Alternate explanations
- 相關證明 Proof of association
- 先前證據 Prior evidence
  - 研究或文獻紀錄 Record from research or journal
- 基於人群的證據 Population-based evidence
  - 背景數據 Background rate
- 生物學的合理性 Biological plausibility
- 疫苗供應商及世衛提供的相關資料數據Relevant data provided from the vaccine manufacturer and WHO VigiLyze

分類 Classification

- 與免疫接種因果關係一致 Consistent with causal association to immunization
- 不確定 Indeterminate
- 與免疫接種的因果關係不一致 Inconsistent with causal association to immunization
- 無法分類 Unclassifiable

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Thank You

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