Reporting of unexpected serious adverse events following immunisation with COVID-19 vaccines by Health Bureau, Department of Health and Hospital Authority
Investigation Report

On 23 October 2022, this Office received a complaint against the Health Bureau ("HHB"), the Department of Health ("DH") and the Hospital Authority ("HA") from the complainant.

The Complaint

2. The complainant alleged that her father received the first dose of COVID-19 vaccine on 16 July 2021, suffered an acute heart attack on 19 July, and died on 6 August. Queen Mary Hospital ("QMH") informed her that the case had been reported to relevant departments. The complainant wanted to know more about the relationship between her father's condition and the vaccination, as well as the Government's follow-up actions. QMH provided her with HA's general enquiry hotline. On 11 August, she called the number to enquire about how reported cases were followed up, and the answering staff provided the telephone numbers of the Centre for Health Protection ("CHP") and QMH's Patient Relations Officer. When the complainant called CHP, its staff said that he did not have the information; her details would be passed to the relevant department, which would call her back. The staff was unable to provide the telephone number of the relevant department, and could only provide the telephone number of the Indemnity Fund for Adverse Events Following Immunisation with COVID-19 Vaccines ("AEFI Fund"). The complainant provided the staff with her father's information and her own contact details, and expressed her wish to follow up the case. On 12 August, HHB called back the complainant and advised her to call the Patient Relations Office ("PRO") of QMH for enquiries. On 13 August, the complainant called PRO of QMH. Its staff replied that PRO was unable to follow up and investigate an adverse event following immunisation ("AEFI"), and could only provide her with the telephone number of the AEFI Fund. The complainant called the AEFI Fund. The answering staff said that they were employed by AXA China Region Insurance Company Limited ("AXA"), which was appointed by the Government for the administration of the AEFI Fund, and could not provide information about investigation of adverse events. On 16 August, the complainant tried to follow up the case through a medical social worker of QMH, but to no avail. On 18 August, the complainant called the HHB staff who had contacted her by phone previously, and told the staff that PRO of QMH was unable to

assist her. The HHB staff replied that they were only responsible for administrative work; given that the hospital possessed the most comprehensive information about the event, she advised the complainant to contact QMH again. On 20 August, the complainant called PRO of QMH, but the PRO staff was still unable to assist her.

3. On 31 January 2022, the complainant submitted a claim to the AEFI Fund. Several weeks later, AXA replied that she was not entitled to any compensation according to the report of the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation ("Expert Committee"). In response to her enquiry as to how the Expert Committee had ruled out the causality between an event and COVID-19 immunisation, AXA staff said that he was unable to provide relevant information. The complainant did not accept his answer, and the staff said that he would follow up the case. Since then, the same staff had called her every one to two months, but all along could not provide relevant information or contact details of the departments concerned. In a telephone conversation with the complainant in early October, the staff said that the only telephone number he could provide was 1823.

4. The complainant complained about the extremely low transparency of the Government in handling serious AEFIs with COVID-19 vaccines. Apart from failing to provide any channels for family members to understand its course of actions (**Allegation (1)**), the Government also refused to provide the assessment report or summary on serious AEFIs prepared by the Expert Committee (**Allegation (2)**). Its practices were extremely unfair to the public.

Process of Investigation

5. Pursuant to The Ombudsman Ordinance, a full investigation was initiated against HHB, DH and HA regarding this complaint on 28 October 2022. After consolidating the information from DH and HA, HHB replied on 26 January 2023. On 14 March, a draft investigation report was issued to HHB, DH and HA for comments. On 2 May, HHB gave a consolidated reply, and DH provided supplementary information. To further investigate the case, this Office wrote to HHB, DH and HA on 22 May. HHB gave a consolidated reply on 16 August incorporating the information from DH and HA. After considering all relevant information and responses from departments, this Office completed this investigation report on 5 September.

Our Findings

Pharmacovigilance System for COVID-19 Immunisation

6. In response to the COVID-19 outbreak, the Legislative Council ("LegCo") enacted in 2020 the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) ("the Regulation"), a bylaw under Cap. 599 of the Laws of Hong Kong. Pursuant to the Regulation, the former Secretary for Food and Health, now the Secretary for Health, was empowered to authorise the emergency use of COVID-19 vaccines in Hong Kong for a specified purpose. However, due to the rapid development of COVID-19 vaccines, close monitoring might be required to ensure the safety and to identify potential signals that may indicate causal association between previously unknown adverse events and the vaccines. Hence, section 7(3) of the Regulation requires the Secretary to put in place a mechanism for monitoring any adverse events which may be related to the vaccines. As directed by the Secretary, DH set up a pharmacovigilance system for COVID-19 immunisation under the existing drug surveillance programme to collect from healthcare professionals and the pharmaceutical industry reports of AEFIs with COVID-19 vaccines used in Hong Kong. Its main purpose is to detect potential signals of possible side effects of the vaccines rather than to follow up individual cases.

7. To monitor AEFIs, the Director of Health has appointed the Expert Committee to conduct independent assessment of potential causal link between AEFIs and COVID-19 vaccines used in Hong Kong (i.e. causality between the medical events occurred to vaccine recipients and vaccination), and to provide expert advice to the Government on vaccine safety matters. DH's Drug Office provides professional and administrative support for the Expert Committee.

8. Separately, DH has partnered with the University of Hong Kong to operate an active surveillance programme for Adverse Events of Special Interest related to COVID-19 vaccines, namely the COVID-19 Vaccines Adverse Events Response and Evaluation Programme, thereby providing more data on the safety profile of COVID-19 vaccines through big-data analysis and scientific studies designed as needed[1].

9. As regards release of information, according to the risk communication plan on clinical events following immunisation formulated by the Expert Committee, a report on the safety monitoring of COVID-19 vaccines[2] was published and updated on the

[1] Further details and studies published under the Programme are available on: https://www.hkcare.hku.hk/

[2] For relevant information, see https://www.covidvaccine.gov.hk/vaccine and https://www.covidvaccine.gov.hk/dashboard/safety/aefi

Government's thematic website periodically (on a quarterly basis with effect from 2023). Relevant information and data were also released periodically on the website. Moreover, AEFI-related information and data were disseminated through a weekly press release entitled "Update on monitoring COVID-19 vaccination" (frequency of issue adjusted to once a month with effect from December 2022), and on the thematic website periodically. Through the above channels, members of the public could obtain information or the hyperlink to DH's Drug Office, and find the contact details of DH on the website.

Background of Establishment of AEFI Fund

10. Given the emergency use of vaccines, the LegCo Finance Committee approved funding in February 2021 for setting up the AEFI Fund to provide immediate financial support for eligible persons who have proof of suffering unexpected serious adverse events (including death and serious injury) associated with vaccines administered under the Government's COVID-19 Vaccination Programme. The AEFI Fund is an administrative arrangement providing urgent financial assistance for eligible affected persons who are awaiting or do not intend to undertake civil action against vaccine manufacturers, without going through complicated legal proceedings. The right of affected persons in seeking legal recourse for damages or loss against vaccine manufacturers will not be affected by whether or not payment has been received from the AEFI Fund. Claimants can still undertake civil action against any persons liable for their bodily injury, but cannot receive double indemnity.

11. AXA is the third-party Administrator appointed by HHB to process public enquires, applications, etc. for the AEFI Fund in accordance with the service contract[3].

DH's Principles and Procedures for Handling AEFIs

12. DH's pharmacovigilance system for COVID-19 immunisation collects and assesses AEFIs reported by healthcare professionals and the pharmaceutical industry. HA's healthcare professionals can report AEFIs through the established reporting system with DH, while other healthcare professionals and the pharmaceutical industry can report through the Drug Office's dedicated COVID-19 Vaccine Adverse Event Online Reporting System. Based on recommendations of the World Health Organisation ("WHO") and advice of the Expert Committee, DH encourages healthcare

[3] Details of the AEFI Fund are available on thematic website: https://www.covidvaccine.gov.hk/AEFI_Fund

professionals to report 16 serious or unexpected AEFIs[4] for closely monitoring the safety of vaccines.

13. Upon receipt of a report, DH would immediately contact the reporting healthcare professional to obtain further information. According to the established mechanism, all important cases are considered by the Expert Committee, while other serious or unexpected AEFI cases are assessed by DH based on the WHO causality assessment algorithm. DH and the Expert Committee are aware of the public's concern about the efficacy and side effects of COVID-19 vaccines. Hence, at the April 2021 meeting of the Expert Committee, a feedback mechanism has been set up to notify the reporting parties of the causality assessment outcomes of AEFIs. After the Expert Committee has completed the causality assessment of serious AEFIs, DH's Drug Office will notify the reporting healthcare professionals or organisations (including HA) of the outcomes, thereby enabling them to understand the assessment outcomes of the cases reported and the actual operation of the pharmacovigilance system.

14. DH has discussed with the relevant vaccine suppliers on the possible side effects of the vaccines identified by the pharmacovigilance system, and requested the suppliers to include information on the side effects in their vaccine information. In mid-2021, the Expert Committee has identified possible side effects, namely Bell's Palsy and myocarditis, associated with the two COVID-19 vaccines used in Hong Kong. Based on the potential signals of side effects identified by the Expert Committee, the Government has adjusted the inter-dose interval for one of the vaccines to reduce the risk of myocarditis in adolescents following immunisation.

15. The primary objective of the pharmacovigilance system is to identify signals of possible side effects. The WHO causality assessment guidelines and algorithm are not applicable to the investigation or interpretation of the causes and management of adverse drug reactions or AEFIs. Normally, reporting of AEFIs does not involve personal data of identifiable individuals, nor will drug regulatory authorities contact the vaccine recipients in respect of individual cases. However, given the need to verify the vaccination information of recipients (such as vaccine name and batch number, date of vaccination, number of doses, etc.) under the pharmacovigilance system specially set up for AEFIs with COVID-19 vaccines this time, and the implications of the Expert Committee's assessment outcomes for the processing of the AEFI Fund, AEFI reports include the names and identity card numbers of recipients.

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[4] For details about the Drug Office's online reporting system and the list of 16 serious or unexpected AEFIs, see https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html

16. The causality assessment outcomes are required for processing applications under the AEFI Fund. Therefore, if the vaccine recipients or their families have applied for the AEFI Fund, the Expert Committee has agreed that DH, at the request of AXA, can notify AXA of the assessment outcomes for application processing. However, in actual operation, as DH's routine drug surveillance programme, the pharmacovigilance system for COVID-19 immunisation is not set up for the AEFI Fund, but for the holistic purpose of monitoring the systemic signals of vaccine safety. Consequently, DH will not approach the vaccine recipients or their families in respect of AEFIs. Applicants should contact the AEFI Fund Administrator for enquiries about the progress of their applications. After completing assessment, the Expert Committee may re-assess cases at the request, supported by new clinical information, of the vaccine recipients or their families, or the reporting healthcare professionals.

17. DH explained that it is not the responsibility of the Expert Committee to prepare assessment reports, nor is it required to compile assessment reports when conducting causality assessment. However, in response to requests from individual affected persons or their families for access to their own assessment reports, the Expert Committee agreed to set up a mechanism to further facilitate them. The Drug Office notified AXA of the relevant mechanism and arrangements on 13 April 2022. Applicants for the AEFI Fund can apply for the causality assessment reports from the Expert Committee through AXA. Under the "users pay" principle, the current administrative fee for provision of assessment report by DH/Expert Committee is $670.

HA's Role and Reporting System

18. Under DH's pharmacovigilance system for COVID-19 immunisation, HA is a reporting party responsible for notifying DH of AEFIs, and providing supplementary information in response to DH's enquiries. After reporting, DH is responsible for reviewing the data and case assessment.

19. In early 2021, HA established a reporting channel in its intranet's Advance Incident Reporting System ("AIRS"), encouraging healthcare professionals of public hospitals to report AEFIs. When healthcare professionals suspect, after clinical assessment, that a patient's clinical condition may be related to COVID-19 immunisation, they may report the adverse event through HA and classify it as an adverse drug reaction case. Designated staff of each cluster (usually pharmacy staff) would be notified to review the case and would forward a notification email to DH

within 24 hours upon receiving the notification. For cases of serious AEFIs including death, Guillain-Barré Syndrome, Transverse Myelitis or admission to the Intensive Care Unit ("ICU"), HA Chief Pharmacist's Office will add a verbal notification to DH's responsible staff for follow-up action. HA has informed healthcare and pharmacy personnel of the above notification system and procedures by email.

AEFI Fund Application Procedures

20. All serious AEFIs should be reported by healthcare professionals through DH's pharmacovigilance system. After a report or information is received, the Expert Committee will assess the potential causality between the case and immunisation. A lump-sum will be paid out at a level corresponding to the event specified under the AEFI Fund if the following two conditions are met:

(1) there is certification by a registered medical practitioner of the serious adverse event; and

(2) the assessment outcome of the Expert Committee cannot rule out that the event is not associated with the administration of a vaccine under the Government's COVID-19 Vaccination Programme.

21. The Expert Committee's assessment outcome is a professional and independent judgement based on clinical evidence and the WHO algorithm without prejudice to the legal liabilities of any persons. The thresholds for paying out under the AEFI Fund are relatively lenient, i.e. the Expert Committee's assessment outcome is "unable to rule out association with administration of vaccine", "consistent with causal association with immunisation" or "indeterminate".

22. For eligible cases, the AEFI Fund Administrator will assess and propose an appropriate level of payment based on the severity assessment scheme and the medical records provided by relevant healthcare institutions. The proposal will then be reviewed by HHB for approval.

23. According to the Government's paper submitted to the Finance Committee in February 2021, the AEFI Fund's terms and conditions stipulate that if the serious adverse event is confirmed to be unrelated to the vaccination in the assessment outcome of the Expert Committee, the application will be rejected. The affected person can still undertake civil action for damages or loss against the vaccine manufacturer.

HHB's Procedures for Handling Enquiries on Reported Cases of AEFIs

24. Generally, upon receipt of enquiries, HHB would check with DH whether the case has been reported by HA. As personal privacy is involved, HHB would advise the enquirer to approach the attending healthcare professionals (or PRO of the hospital concerned in HA cases) directly for details. HHB would also explain the AEFI Fund's terms and procedures (including the possibility to submit an application before causality assessment for the event is concluded by the Expert Committee) to the enquirer, and leave a contact telephone number for future enquiries.

Sequence of Events

25. According to information provided by HHB, DH, HA and the complainants, the sequence of events of this case was as follows:

	Date	Event
	2021	
(1)	16 Jul	The complainant's father received the first dose of COVID-19 vaccine at a vaccination centre.
(2)	19 Jul	The complainant's father collapsed at home after a heart attack. He was admitted to QMH and then transferred to ICU for further treatment. A doctor reported his case as an AEFI with COVID-19 vaccine, classified as an adverse drug reaction case, via HA's AIRS.

	Date	Event
(3)	20 Jul	On the morning, QMH Pharmacy forwarded the reported case to DH by email. Given the patient's serious condition and admission to ICU, HA Chief Pharmacist's Office added a verbal notification to DH's responsible staff for follow-up action on the same morning; healthcare staff also informed the patient's family of the reporting. DH contacted the reporting healthcare staff to obtain the patient's background and clinical information. DH also contacted the vaccination centre where the vaccine was administered to the patient to obtain information on his condition during vaccination. The vaccination centre advised that he had not had any vaccination problem at the time of administration and during the observation period thereafter, and that he had not complained of any discomfort.
(4)	6 Aug	The complainant's father passed away in the hospital.
(5)	11 Aug	HA Head Office's General Enquiry Unit received a call from the complainant, who asked how her father's reported case would be followed up. After learning that the complainant's enquiry was related to an AEFI and patient services of QMH, which were under the purview of CHP and QMH, the staff provided the relevant telephone numbers, including the CHP hotline for COVID-19 and the number of PRO of QMH, for her further action. As understood by DH, the complainant called the CHP hotline of DH on the same day. The call was answered by 1823 staff, who referred the case to the former Food and Health Bureau ("FHB") directly on the same day. FHB was notified by 1823 of the complainant's enquiry about her father's death case; she also asked how FHB would follow up the case after it was reported by the hospital and whether extraction of human tissues for laboratory testing was required.

	Date	Event
(6)	12 Aug	A staff of the former FHB contacted the complainant after obtaining information about the death case from DH. The complainant was advised to ask PRO of QMH about whether laboratory testing of human tissues was required. The staff also explained the AEFI Fund's terms and procedures (including the possibility to submit an application before causality assessment for the event is concluded by the Expert Committee), and left a telephone number for future enquiries. FHB notified 1823 of having returned the complainant's call; the enquiry case was completed and no further action was required.
(7)	13 Aug	The complainant called PRO of QMH. She said that her father had passed away on 6 August; he had been in good health with no history of heart disease, and received a dose of COVID-19 vaccine three days prior to his admission to hospital. As such, she enquired whether the cause of his death was related to the vaccination. A Patient Relations Officer explained that QMH had reported the case to DH in accordance with the guidelines, and that the hospital's duty was mainly to provide clinical treatments to the patient and report the case in accordance with the guidelines, while the causality between the patient's death and the vaccination had to be assessed by the Expert Committee. The Patient Relations Officer also provided the telephone number of AXA for her to make further enquiries. On the same day, DH informed HA of the causality assessment outcome of the complainant's father's case (i.e. the Expert Committee found no causal relationship between the case and COVID-19 immunisation).
(8)	16 Aug	The complainant called the medical social worker of QMH for assistance in her father's case.
(9)	17 Aug	After obtaining information from ICU, the medical social worker informed the complainant that QMH had reported her father's case to DH.

	Date	Event
(10)	20 Aug	The complainant called the Public Relations Officer of QMH, saying that she had called the AEFI Fund; its staff told her that the AEFI Fund had not received her application, and advised her to contact the Public Relations Officer to find out more about the relationship between the patient's death and vaccination. The Public Relations Officer explained the hospital's role again, and gave assistance in her application for medical records.
	2022	
(11)	31 Jan	AXA received an application for the AEFI Fund from the complainant regarding her father's case.
(12)	9 Feb	AXA asked DH for the Expert Committee's causality assessment outcome on the case.
(13)	22 Feb	After receiving DH's reply, AXA informed the complainant of the Expert Committee's assessment outcome, and that her application was rejected according to the terms and conditions of the AEFI Fund. The complainant asked AXA for the grounds of the Expert Committee's assessment.
(14)	7 Apr	AXA told the complainant that it would be informed by DH of the Expert Committee's assessment outcomes on the cases with applications submitted for the AEFI Fund, and offered to contact her again after finding out from DH how to obtain the Expert Committee's assessment report.
(15)	Feb to Jun	After consulting the Expert Committee, DH discussed with the former FHB and AXA about setting up a mechanism for applicants to obtain through AXA the Expert Committee's assessment reports on relevant cases, and formulated the arrangements in detail.

	Date	Event
(16)	10 Jun	AXA informed the complainant that she could pay a data access fee of $560 [5] to DH to obtain the Expert Committee's assessment report. However, the complainant told AXA that she did not agree to pay the fee but requested to have direct dialogue with the Expert Committee.
(17)	1 Sep	The complainant told AXA that she disagreed with the Expert Committee's assessment outcome on the case, and reiterated her wish to have direct dialogue with the Expert Committee.
(18)	2 Sep	AXA contacted the complainant again and told her that there were no means to communicate with the Expert Committee directly. The complainant said that it was not necessary to contact her again unless there was new progress.
(19)	30 Sep	AXA informed the complainant that she might call 1823 to make her request to contact the Expert Committee.

Response from HHB

26. In response to the serious epidemic outbreak, the Government introduced the COVID-19 Vaccination Programme as an emergency measure since early 2021. In this connection, scopes of multiple departments/organisations with new work arrangements and procedures were involved in the safety monitoring of COVID-19 vaccines, the reporting of adverse events, the causality assessment and the AEFI Fund. It took time for communication and coordination at the initial stage. The follow-up actions on the occurrence of AEFIs focused on the consideration of detecting the side effects of vaccines and processing applications for the AEFI Fund submitted by affected persons or their families, and the information disseminated was comprised mainly of overall data. After review, HHB considered that there was room for improvement in communicating with individual affected persons or their families and disseminating information. Had HHB ensured earlier coordination and clarification of the roles of various parties and their division of duties, it believed that communication with the persons concerned on the causality assessment outcomes could have been enhanced. With the accumulation of experience, HHB has strengthened liaison with relevant

[5] The latest fee is $670.

departments/organisations, and will review and explore any room for improvement from time to time.

27. HHB added that both DH and HA concurred that the Government should not approach and inform the persons concerned or their families (including patients or their families who have not applied for the AEFI Fund) of the Expert Committee's causality assessment outcomes, because the Government is not in a position to answer any further enquiries relating to the assessment, and is concerned that the process of relaying might cause unnecessary misunderstanding. In cases of AEFIs with COVID-19 vaccines, healthcare professionals responsible for the patients' medical treatments should communicate with them and provide clinical follow-up services as appropriate. If individual patients or their families ask for the causality assessment outcomes, healthcare professionals will assist in relaying such information.

28. Regarding the handling of the complainant's case, HHB said that AXA was in possession of only the Expert Committee's assessment outcome but not the assessment report, and hence could not provide her with further information. Moreover, since the CHP hotline received a large number of COVID-19 enquiries every day during the outbreak, some of the incoming calls were diverted to 1823 for answering. As such, the complainant might feel frustrated in attempting to contact the department. HHB asked for her understanding.

Response from HA

29. According to HA, QMH reported the case to DH in late July 2021 (see **paragraph 25(3)**), and healthcare staff informed the patient's family on the same day. Subsequently, a Patient Relations Officer explained the duties of the hospital and the Expert Committee to the complainant, and provided the telephone number of the AEFI Fund (see **paragraphs 25(7) and (10)**). HA considered QMH to have handled the case in accordance with the established practice at that time.

30. In the light of this case, at the pharmacy service and operation meeting held on 30 November 2022, HA reminded all hospital pharmacy managers and pharmacists that if enquiries are received from patients or their families about the assessment outcomes, they should contact the Chief Pharmacist's Office for case updates or the Expert Committee's assessment. However, apart from the assessment outcomes, HA was not in possession of relevant information to explain what the Expert Committee had considered for the assessment or to provide further details. Therefore, if patients or

their families requested an explanation of the assessment outcomes or further details, staff should advise them to contact DH/AEFI Fund (where applicable) directly to obtain the latest and accurate information.

Latest Developments

31. Subsequent to our referral of this complaint, AXA submitted the case of the complainant's father to the Expert Committee again in November 2022, and DH put forward the case for re-assessment by the Expert Committee at its meeting in December 2022. The Expert Committee upheld the original assessment outcome that her father's AEFI was inconsistent with causal association with COVID-19 immunisation (i.e., no causal relationship).

Our Comments

Allegation (1)

32. HHB, DH and HA have explained the roles of various parties and their procedures for handling cases of AEFIs with COVID-19 vaccines (see **paragraphs 6–9, 12–19**). As explained by HHB and DH, the reporting system for AEFIs was introduced for safety monitoring of COVID-19 vaccines, and DH would disseminate and update regularly the data of clinical events received and summary reports by means of press release and its thematic website. This Office considers that DH's regular release of information on vaccine safety, which can enhance the transparency of vaccine information and help boost public confidence in the vaccines and vaccination coverage, is commendable.

33. In this case, after HA reported the case of the complainant's father to DH on 20 July 2021, DH notified HA of the causality assessment outcome on 13 August in accordance with the prevailing mechanism for handling AEFIs with COVID-19 vaccines. HA did not contact the vaccine recipient's family in respect of the reported case thereafter. The mechanism at that time had not put in place any procedures to inform individual affected persons or their families of the assessment outcomes (see **paragraphs 18–19**). No one would approach and inform affected persons and their families who had not applied for the AEFI Fund of the follow-up actions, including the assessment outcomes, after HA had reported their cases. Apparently, HHB assumed that all affected persons or their families would definitely apply for the AEFI Fund and receive the assessment outcomes via AXA, without even considering that some of them

would like to know the outcomes, or intend to decide whether or not to apply for the AEFI Fund after obtaining the outcomes. No explanation about the relevant mechanism and procedures was available on the thematic website or in public domain. There was no way for affected persons or their families to know the channels for obtaining the contact information of the departments responsible for monitoring of vaccines, and how to check on the progress of follow-up actions and the Expert Committee's assessment outcomes.

34. In our view, the authorities' initial follow-up actions on the occurrence of AEFIs focused on the consideration of detecting the side effects of vaccines and processing applications for the AEFI Fund submitted by affected persons or their families, and the information disseminated was comprised mainly of overall data. There was indeed insufficient transparency in the communication with individual affected persons or their families and the release of information. It is not an unreasonable expectation of affected persons and their families to be notified of the assessment outcomes after their cases have been reported. Moreover, the processing and assessment outcomes of reported cases may affect the confidence in vaccines of the persons concerned and their families, as well as that of their relatives and friends. From the perspective of promoting vaccination, it is particularly essential for the Government to enhance the communication with the persons concerned and the transparency of information. This Office accepts the authorities' explanation for not approaching and informing the persons concerned or their families (including those who have not applied for the AEFI Fund) of the Expert Committee's causality assessment outcomes (see **paragraph 27**). Nevertheless, this Office considers that the authorities should have explained to the public how to obtain the assessment outcomes and the procedures for handling such enquiries. This Office recommends that HHB and DH provide on the relevant websites an estimated time frame for handling reported cases, and clarify that individual affected persons or their families who have not applied for the AEFI Fund but would like to obtain the causality assessment outcomes of their reported cases may contact the healthcare professionals for enquiries. HHB should also strengthen the relevant guidelines, thereby instructing staff or healthcare professionals to clearly explain the operational procedures of existing mechanism when answering such enquiries. Information about the mechanism for handling AEFIs with COVID-19 vaccines should also be available on the thematic website for public reference.

35. Regarding the complainant's allegations against DH and HA, this Office considers both DH and HA to have reported the relevant case in accordance with the

mechanism (see **paragraphs 13, 16, 18 and 19**) and there was no impropriety.

36. Based on the above analysis, The Ombudsman considers **Allegation (1) substantiated** on the part of HHB, and **unsubstantiated** on the part of DH and HA.

Allegation (2)

37. Regarding the complainant's allegation that the Expert Committee refused to provide assessment report or summary, AXA has explained why it could not provide the report at that time (see **paragraph 28**). DH explained that the Expert Committee is not required to compile assessment reports when conducting causality assessment (see **paragraph 17**), but in this case no one has ever informed the complainant of this. It was not until more than one year after the implementation of the Vaccination Programme did DH, HHB and AXA set up a mechanism for applicants to obtain assessment reports prepared by the Expert Committee on request (see **paragraph 17**), and the complainant was only informed in June 2022 that the authorities had standardised the procedures with a fee payable to DH (see **paragraph 25(16)**). This Office considers the authorities too slow in handling requests from applicants for assessment reports, nor have they ever explained that the Expert Committee did not have such reports. This could have given applicants the impression that the departments refused to release information. In any case, HHB and DH have now incorporated the procedures for obtaining assessment reports into the mechanism. This Office urges HHB and DH to inform the persons concerned or their families of how to obtain the assessment reports (including the fee charging criteria, etc.) from the Expert Committee, and the information should also be available on the thematic website for public reference.

38. Based on the above analysis, The Ombudsman considers **Allegation (2) unsubstantiated**.

Conclusion

39. Overall, The Ombudsman considers the complaint **partially substantiated** against HHB, and **unsubstantiated** against DH and HA.

Recommendation

40. The Ombudsman recommends that HHB give details on the relevant websites about how to obtain the causality assessment outcomes in respect of AEFIs (especially

for those who have not applied for the AEFI Fund), and update the relevant guidelines, thereby instructing staff or healthcare professionals to clearly explain the operational procedures of existing mechanism to enquirers (see **paragraphs 34 and 37**).

41. This Office will follow up with HHB on the recommendation in **paragraph 40**.

Office of The Ombudsman
September 2023

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