Template for adverse event report assessment against VSIG criteria

Note, not all sections of the template will need to be completed depending on the case.

TGA ID number	
Date of birth/ age	
Sex	
Ethnicity	
Jurisdiction	
Date of referral from AEMS	
Date reported to the TGA	NB: this is the 'received date' in CRM
Reporter	Indicate whether consumer/ patient or State JIC or health professional etc
Vaccine involved	
Trade name of the vaccine	
Date vaccination received	
Dose number in series	
Batch number	
National Immunisation Program (NIP) Schedule (last updated, and TRIM link)	Indicate when the vaccine in question is recommended to be given according to the NIP schedule
Date of symptom onset	
AEFI PTs coded	

Management of the event	e.g., self, ED presentation, GP management, hospital admission
Outcome of the event	e.g., resolved, resolving, fatal
Other details about the reaction from the case narrative	

Australian product information	
Name, version, date last updated, TRIM link	Indicate whether the AEFI is listed in any sections of the PI (eg 4.2, 4.4, 4.8)
If the AEFI is adequately described in the PI, cease assessment here and send your assessment to the Vaccine STRS Stream Lead. Do not complete additional boxes below.	
Australian immunisation handbook (AIH) information	
Chapter, date last updated, TRIM link	Indicate whether the AEFI is described in the AIH or whether there is information about evidence against causation
If the AEFI is adequately described in the AIH, cease assessment here and send to the Vaccine STRS Stream Lead. Do not complete additional boxes below.	
The AEMS search, Vigibase search, Literature Search and International PI search boxes below are optional. If the individual AEFI report appears that it might meet VSIG criteria, the evaluator should complete any or all of these boxes that they feel are required to confidently determine if VSIG criteria are met.	
AEMS search	
Search details	This may be required if there is concern about an increased frequency of an AEFI that is listed already in the Aus PI
VigiBase search	
Search details	
Literature search	

Search details	
International PIs	
Name, version, date last updated, TRIM links	

Is the case eligible for assessment?	Yes/ No If no, what information is missing?
AEFI of concern	
Is the AEFI serious?	Y/N and briefly explain
Is the AEFI unexpected?	Y/N and briefly explain
Is there an obvious non-vaccine cause?	Y/N and briefly explain
Is there strong evidence against causation?	Y/N and briefly explain
Has an AEFI of concern been identified?	
1. No	
2. Yes, but further information is required to complete the assessment against VSIG criteria	
3. Yes, and no further information is required	

1. If an AEFI of concern has not been identified, do not complete the next table (benefit-risk and public confidence) but proceed straight to the recommendation
2. If an AEFI of concern has been identified (based on current information) but there is insufficient information to complete the assessment, do not complete the next table until further information has been received.
3. If an AEFI of concern has been identified and the case has sufficient information, proceed to the next table.

Benefit-risk and public confidence	
Does this individual AEFI report have the potential to change the favourable benefit-risk balance of a vaccine in a National or State Immunisation Program?	Y/N and details
Does the individual AEFI report have the potential to threaten public confidence in vaccine safety?	Y/N and details

Recommendation
e*.g., I have considered this report against the criteria for convening the Vaccine Safety Investigation Group (VSIG), outlined at TRIM D18-10878760. In my opinion, based on the information above, this individual Adverse Event Following Immunisation report* ***does not meet the criteria for convening VSIG*** *because* *- an AEFI of concern has not been identified and the case is considered ineligible for assessment OR* *-an AEFI of concern has not been identified OR* *-an AEFI of concern has been identified but this report does not have the potential to change the favourable benefit-risk balance of a vaccine in a National or State Immunisation Program or to threaten public confidence in vaccine safety.* *e.g., I have considered this report against the criteria for convening the Vaccine Safety Investigation Group (VSIG), outlined at TRIM D18-10878760. In my opinion, based on the information above, this individual Adverse Event Following Immunisation report* ***does meet the criteria for convening VSIG b****ecause the case is eligible for assessment, an AEFI of concern has been identified and the AEFI has the potential to change the favourable benefit-risk balance of a vaccine in a National or State Immunisation Program or to threaten public confidence in vaccine safety.*