Covid Vaccine No-Fault Compensation Schemes Project

Advisory Board Meeting

15 June 2023 – Hybrid Teams and in person

Attendees: Linda Mulcahy (CSLS); Christopher Hodges (CSLS); Sonia Macleod (CSLS); Francesca Uberti (CSLS); Fumie Griego (IFPMA); Samallie Kiyingi (Afreximbank/AVAT); Richard Kingham (Covington & Burling LLP); Charlet Crichton (UK Covid Vaccine Family)

Apologies: Lorenz Ködderitzsch (J&J)

Agenda

1. **Introductions**
2. **Phase 1 summary** – SM
3. **Phase 2 plans** – SM & FU – updated plans attached, yellow highlights used for areas of concern. **Specific guidance is sought on:-**
    a. **Inclusion of countries** where there is not an NFCS? 8 countries suggested. Nepal was suggested but has been discounted as it is not feasible.
    b. Agree the **schemes to be included in the sampling frame** – 28 at present
    c. **Breakdowns of claimant data**. Happy to incorporate this suggestion, only question is on ethnicity, which we will put back to WHO group. We know that different jurisdictions collect different data, and some collect nothing at all.
    d. **Humanitarian populations of concern**. Raised by WHO working group. We cannot work out a workable way to ascertain this. Input welcome.
    e. Obtaining **data on claims** – this is sensitive data for manufacturers, potential solutions such as having a 'safe' data repository covered by legal privilege.
    f. **Administrative costs of the NFCS**. This is relatively straightforward for the multinationals, much more difficult for schemes that are part of a govt dept or that handle multiple claim types. We'd welcome your thoughts on this
    g. If **NFCS covers multiple vaccines/countermeasures/injuries** from other causes – do we want a breakdown of these? For example, if the scheme covers injuries caused by covid as well as those caused by the vaccine?

h. **Number of vaccine eligible for compensation.** For example, where a scheme only covers vaccines by specific manufacturers or those purchased by the State, but either other vaccines are used there or donated vaccines are used.

i. **Vaccine refusal** – difficult to ascertain. Thoughts on including this?

4. **Visitors, speakers, etc** – summary of past and upcoming visitors - FU
5. **AOB**

Minutes

1. Introductions from attendees and apologies from Lorenz Ködderitzsch.

2. SM gave a summary of phase 1 of the project, as per the slides.

3. SM detailed the objective for phase 2 – to assess how well selected covid vaccine NFCSs function using a balanced sample of the schemes investigated in phase 1.

4. SM set out the rationale for which NFCS should be included in phase 2. Schemes were included for the following reasons:-
   - NFCS which collected/published performance data
   - Multinational NFCSs as they are the major drivers of the expansion in coverage
   - NFCSs with particular points of interest.
   - German speaking countries with the help of Dr Herbert Woopen, a native German speaker.
   - Countries suggested by the WHO when they reviewed the phase 2 plans.
   - The UK and Australia as they are useful comparitors which were not included on any other basis.

Outcome - It was agreed that the following 28 NFCSs would be included in phase 2.

Countries which collect or publish NFCS performance data

No.	NFCS
1	New Zealand
2	Finland
3	US
4	Sweden
5	Poland
6	Norway
7	Denmark
8	Canada
9	Canada (Quebec)
10	France
11	Taiwan
12	Singapore

Multinational NFCSs

13	AVAT
14	COVAX
15	UNICEF

NFCSs with points of interest

16	Israel
17	Thailand
18	Peru

19	South Africa
20	Estonia
21	Italy

German-speaking countries

No.	NFCS
22	Germany
23	Austria
24	Switzerland

Additional countries suggested by WHO during phase 2 plan review

No.	NFCS
25	Vietnam
26	Indonesia
27	Philippines
28	Guatemala

Additional countries agreed by the Advisory Board

No.	NFCS
27	Australia
28	United Kingdom

5. The discussion moved on to what data each scheme should be asked to provide. The majority of categories were straightforward. Ethnicity was discussed as it is more complex in that some NFCSs do not collect it, and there are no consisted pre-codes across the schemes that do. It was suggested that the reasons for rejecting claims should include a pre-code for 'vaccine not covered'; the range of claims handling times should be requested; and the outcomes of appeals should be requested, recognising that this might be difficult for the NFCS if the appeal was to an external agency.

Outcome - The board agreed the following data should be included:-

a. **Who is making the claim? 3 pre-coded categories** 1) Vaccine recipient; 2) a representative of a live vaccine recipient; 3) a legal heir/estate/representative of a deceased vaccine recipient
b. Payments made by the scheme to representatives
c. **Demographics of the vaccine recipient**. Age; gender; nationality; citizenship; and ethnicity. It was noted that different scheme collect different data on **ethnicity so this has be an open question** asking schemes to provide any data they collect rather than a pre-code.
d. Rejected claims, numbers and pre-coded categories - **add vaccine not covered to the pre-codes**
e. **NFCS Spend**. Total set aside for compensation and actual spend for the years 2020, 2021 & 2022; ideally values for each award, but also ask for range and median value

f. **Claims handling**, average time from filing to decision – **add in range**
g. **Appeals/reconsiderations.** Internal and external appeals – **add in outcomes of appeals**
h. Proportion of claims relating to covid-19 vaccines if the scheme also handles other claim types.

6. SM raised the question of whether NFCS for covid injury rather than covid vaccine injury should also be included in the data gathering. It was decided that this is a different research question and that phase 2 is already ambitious.

Outcome – If they are found during this project NFCS for covid injuries will be noted, but we will not gather metrics on them.

7. It was agreed that during phase 2 data will be gathered for each NFCS on
    a. Population
    b. Vaccines given – including vaccine eligible under the NFCS

8. Gathering data on Vaccine hesitancy/vaccine refusal was discussed, but it was felt that this is not consistently defined between/across jurisdictions and is outside the scope of phase 2. We will return to this issue in phase 3.

Outcome – population and vaccination data, including vaccines eligible under the NFCS will be gathered in phase 2. Vaccine hesitancy/refusal data will not be sought.

9. Concerns were raised over improperly stored, counterfeit, fraudulent, expired etc medicines and whether this should be a concern for this project. During the discussion views it was determined that while this is a concern for medicines this did not appear to have been a major concern for vaccines purchased and administered by national governments of NGOs, and that the AVAT experience was that counties were very cautious about accepting vaccines unless they were sure they could deliver them to recipients using appropriate cold storage and prior to expiry dates.

10. Obtaining litigation data was discussed. This would enable a useful comparison between countries that have schemes and those which do not, such as France which has ONIAM and neighbouring Spain and Portugal which do not have schemes. Also countries which considered creating a scheme, but did not.

11. It was acknowledged that obtaining litigation data from manufacturers was likely to be very difficult due to commercial confidentiality. Options for providing a ‘safe’ data storage were discussed, including that even if a legal firm was used as the data repository the usual rules of legal professional privilege would apply, to be covered data would need to have been supplied for a privileged purpose.

12. Alternative public sources of information on litigation, such as court dockets, claimant lawyers and press articles were suggested. The VIOXX cases and the Scandinavian countries were mentioned as examples of situations where we know that there is

pharmaceutical litigation and the broad scale if it from press reports. These are not as accurate, but may be the only information that is available.

Outcome – SM would raise the question of obtaining litigation data at the IFPMA Vaccine Working Group meeting on 16 June 2023.

13. The interaction between NFCSs and litigation was raised as a factor which would need to be taken into account when considering litigation. For example the CICP in the US significantly restricts access to litigation – an individual must go through the scheme first and then reject the award. These contextual factors would need to be considered when examining litigation data.

14. Access to justice was raised as an issue, including cost barriers, difficulties obtaining legal representation when considering litigation and in some jurisdictions the long timeframes associated with litigation.

15. It was felt that a properly functioning NFCS that offered adequate compensation should provide improvements in access to justice. The aim of phase 2 is to assemble the metrics and they assess NFCS performance.

16. FU gave an update on speakers and visitors from phase 1, and future visitors.

17. No AOB was raised and thanks were given to all the Advisory Board participants.

18. The meeting closed with thanks to IFPMA for the grant which funds this research, which draws on a long tradition of research into NFCS at CSLS.