



Department  
of Health &  
Social Care

## **Vaccine Damage Payment Scheme (VDPS) and COVID-19 vaccination compensation**

Slide 1: Overview

Purpose of meeting
<p>These slides will cover:</p> <ul style="list-style-type: none"><li>• Short background to the VDPS, and an outline of potential reform options, explored in more detail in the submission sent on Wednesday 11<sup>th</sup> May</li><li>• Background on international approaches to C-19 vaccine damages, the evidential thresholds for successful claims, and consideration of options beyond VDPS reform (with Annex on adverse events reported to COVID-19 vaccine manufacturers)</li></ul>
Background to the VDPS
<p>The VDPS is not designed as an alternative to litigation and does not prejudice the right of the claimant to pursue a legal claim against the manufacturer of the vaccine. It is a additional fixed sum of £120k which makes no assessment of individual circumstances or harm.</p> <p>COVID-19 was added to the VDPS in December 2020 at the request of COVID vaccine suppliers, alongside HMG indemnifying them. This has taken VDPS from around 70 cases a year to 60 a week, leading to NHSBSA taking the service over from DWP in November 2021.</p> <p>VDPS considers causation using a balance of probability. The bar for causation under the VDPS is much lower than would be required for a legal case, and therefore a settled VDPS claim does not indicate any likely outcome in a subsequent litigation.</p> <p>This is why, despite causation not yet being established for the COVID vaccine, the first VDPS COVID-19 claims are due to be fully processed under the current system w/c 23 May 2022.</p> <p>The main criticisms of the VDPS are slow processing payment timelines for claimants, the payment amount being too low (payment not having increased since 2007), the disability threshold being too high.</p> <p>Work is already underway to modernise and improve the VDPS (a previously paper-based system), with huge strides made in relation to increasing administration staff, rapidly bringing in a flexible clinical assessment contract to support processing claims, implementing an ongoing modernisation process, and setting time limits for the provision of medical records.</p>

## Slide 2: Vaccine Damage Payment Scheme (VDPS) potential reform options

Option	Overview	Impact	Issues/Risks
<b>Reform 1</b>	<p><u>Increase the payment of £120k in line with inflation.</u></p> <ul style="list-style-type: none"> <li>Depending on measure this could increase payments from between £161k to 176k.</li> <li>It is estimated this would increase the cost of the scheme by between £360k to £1.5m</li> </ul>	<ul style="list-style-type: none"> <li>Shows demonstrable action on one of the key criticisms of no increase since 2007, without need for significant changes that would delay Covid processing.</li> <li>Potential for putting in a permanent inflationary mechanism.</li> </ul>	<ul style="list-style-type: none"> <li>As with other VDPS reform options there is currently no funding identified for this change.</li> <li>Requires affirmative order but can be done in parallel to the processing of Covid claims at end of May.</li> <li>Could be challenged as not being sufficient, but defensible given causation not yet fully established with the Covid vaccines and legal recourse remains open.</li> <li>Complaints from those who have missed uplift, but options to backdate could be looked at to mitigate.</li> </ul>
<b>Reform 2</b>	<p><u>Decrease the disability threshold:</u></p> <ul style="list-style-type: none"> <li>lowering from the current threshold of 60% disability, to 50% or 40%</li> <li>60% is equivalent to the loss of one hand ('severe disability')</li> <li>There are two clinical assessments made to claims – causation on balance of probabilities, then a disability assessment.</li> </ul>	<ul style="list-style-type: none"> <li>Potentially increase the numbers who can potentially get a payment access the scheme.</li> <li>Would acknowledge impact on people's lives of all disabilities, not only those over 60%.</li> </ul>	<ul style="list-style-type: none"> <li>Requires primary legislation to change, delaying COVID claim processing due to start end of May.</li> <li>Unclear of the current need. Only one claim in recent years has been rejected due to the disability assessment for non-covid vaccines. Most are rejected on the basis of the causation.</li> <li>Unclear on costs as no Covid cases have been processed yet so challenging to model the impact of this change.</li> <li>Lower bar may increase the number of claims and appeals to the scheme, increasing administration costs as well as payments.</li> <li>The current 60% figure aligns to other DWP benefits for severe disability. A new rationale would have to be sought.</li> </ul>

- Finance consideration:** To note that any addition or changes to the VDPS (beyond administrative changes working with NHSBSA as already planned and underway) would be an unfunded pressure. Potential options would need to be assessed and costed prior to any decisions being made.

### Slide 3: VDPS potential reform options continued...

Option	Overview	Impact	Issues/Risks
<b>Reform 3</b>	<u>Graduate payment downwards from 60%</u> <ul style="list-style-type: none"> <li>With smaller sums paid for disabilities of 50%, 40% and so on.</li> </ul>	<ul style="list-style-type: none"> <li>Allows the scheme to provide payments to more people</li> <li>As for Reform 2 – recognising impact on people who are less disabled by a vaccine as well.</li> </ul>	<ul style="list-style-type: none"> <li>Risks as for Reform 2 with increased costs, as more attractive for applications and appeals, requires primary legislation</li> <li>Delays to processing claims as would require renegotiation of the clinical contracts and engagement with experts on all 18 diseases in the scheme. This is because a more refined, more complex assessment process is likely to be needed for claimants at lower thresholds.</li> <li>Causality harder to define for lower levels of disability so may have little impact causing claimant frustration, or may have to increase the threshold for causation to avoid a flood of low level claims and fraud.</li> <li>Increased risk of legal challenge from appearing more akin to a compensation scheme (this would apply to all vaccines not just COVID).</li> </ul>
<b>Reform 4</b>	<u>Graduate payment sums based on level of disablement over 60%.</u>	<ul style="list-style-type: none"> <li>Would recognise greater need of people more significantly disabled by a vaccine</li> <li>Potential presentational benefits for COVID claimants</li> </ul>	<ul style="list-style-type: none"> <li>Requires primary legislation to change, delaying COVID claim processing due to start end of May.</li> <li>Whilst scheme does not provide causality, increasing payments could appear to be admission of causality.</li> <li>Increased risk of legal challenge from appearing more akin to a compensation scheme (this would apply to all vaccines not just COVID).</li> </ul>
<b>Closure of the VDPS</b>	<u>Retire the VDPS</u> <ul style="list-style-type: none"> <li>Questionable whether delivers its twin objectives of improving vaccine confidence and supporting those harmed by a vaccine.</li> </ul>	<ul style="list-style-type: none"> <li>Could allow resource to be reallocated to more effective measures, including alternatives which might better meet the twin objectives.</li> <li>Although claimants can take legal action against manufacturers, and claim benefits associated with any disablement, removal of the VDPS option could make this route clearer, enabling them to access more support to those seriously harmed by vaccines.</li> </ul>	<ul style="list-style-type: none"> <li>Public perception of vaccines may be damaged if we close the scheme in the current context.</li> <li>May also negatively impact relationships with vaccine manufacturers given contractual links to VDPS.</li> <li>Would take time, especially if establishing a parallel scheme before closure.</li> <li>In short term cost of running the VDPS would still be incurred such as the clinical contract with a third party supplier.</li> </ul>

## Slide 4: C-19 vaccines compensation and damage payments - International Comparisons

**International Context:** Most comparable countries have followed a similar approach to the UK, with existing legislation or schemes extended to cover COVID-19. Some countries – e.g. Canada - have leveraged the Covid-19 pandemic to establish new no-fault Vaccine Injury Support Programmes (VISP).<sup>[1]</sup>

Country	Detail + Eligibility	Claims Procedure + Reimbursement	Can still pursue claims?
<b>USA</b>	Added to existing programme (CICP). CICP requires “compelling, reliable, valid, medical and scientific evidence” to prove causation beyond reasonable doubt.	Administrative applicant process (rather than judicial) with high burdens of proof and little transparency. No judicial appeal permitted. Income: \$50K/year; Death: \$300K	Yes – but medical and legal fees not re-imbursed
<b>Canada</b>	Established new pan-Canadian no fault VISP (2020): requires evidence of “serious and permanent injury” where a “probable link” can be established.	An initial screening of vaccination proof, medical report and clinician report.	Can pursue litigation. Required to repay if court awards settlement.
<b>France</b>	C-19 added to existing no fault compensation for medical accidents attributable to activities carried out as part of C-19 vaccination campaigns. The scheme is similar to the VDPS, but covers a broader range of harms than just the vaccine.	Requires proof of damage suffered, causality decided by discretion of the court. Free of charge to claimant, 6 month turn around to share outcome.	Can refuse the offer and make an appeal to the admin court. If accepted no additional monies.
<b>Australia</b>	Established a time- limited COVID-19 vaccine claims scheme to compensate moderate to significant clinical conditions following an adverse reaction.	Tier 1 and 2: compensation can only be claimed for past loss, future loss and pain + suffering. T1: between \$1k - \$20k T2: \$16k+ Tier 3 (death): one-off lump sum \$644,640 (+ compensation for each dependant)	Yes. If successful in court claimant must pay money back to the Scheme.
<b>Japan</b>	Long-established no-fault compensation scheme for people who have adverse drug reactions to vaccines or drugs. Specific C-19 compensation fund added to scheme in Feb21.	Benefits authorised if causation is recognised. £295,000 for death; £33,800 long-term disablement; £1,400 for funeral costs	Possible to raise in civil court.
<b>COVAX</b>	World first global vaccine injury scheme: requires evidence of “serious adverse event” resulting in permanent impairment or death.	Claims reviewed by clinical panel and administered by an independent claims administrator. Specific formula to calculate pay.	Individuals who accept compensation are precluded from courts

[1] British Institute of International and Comparative Law. Keelan, J. 2021. *Covid-19 Vaccine Injury Compensation Schemes: Comparative Perspectives*, 6 July, Online [accessed 15 April: <https://www.youtube.com/watch?v=e1kxgi1BP0>]



Slide 5: Examples of thresholds and conditions for successful claims in the UK

Claim area	Detail	Approach + Threshold
Sodium Valproate in pregnancy	Recommendation within the Independent Medicines and Medical Devices Safety Review to establish redress scheme for those who experienced avoidable harm.	The Government did not accept this recommendation. The Government’s overall position on redress is that litigation, either against clinicians for clinical negligence or manufacturers for defective products, is the right means for patients to pursue compensation. Ministers took the decision to focus funds on initiatives which improve future safety.

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VDPS	Set up in 1979 - Payment of £120k offered to people severely disabled as a result of vaccination.	The claimant must prove that on the Balance of Probability to have been severely disabled (defined as 60%+ disablement) as result of vaccination against specified diseases.
COVID-19 Vaccine litigation	If an individual wishes to pursue litigation in relation to COVID-19 vaccination, the most likely routes that claims could take are through the Consumer Protection Act, personal injury negligence claim or other negligence claim (though claim routes available depend on the specific regulations it was authorised under). Currently no litigation claims have been issued.	Under the Consumer Protection Act, the claimant must prove a product defect, the damage and the causal link between the defect and the damage (so causality of harm is not by itself sufficient). The ordinary standard of proof is balance of probability, but a case in 2017 indicated that in cases of scientific uncertainty, the courts are entitled to make a finding that a link is proven where the link is the “most plausible explanation” but it can neither be formally established nor ruled out.

\*BoP – Balance of probabilities

## Slide 6: Consideration of options beyond VDPS reform

Option	Rationale	Risks/ Issues	RAG RATING
<b>No further action at this point in time</b>	The VDPS already provides significant financial assistance to those who may have been harmed by vaccines. Claimants to VDPS can also pursue legal action to claim compensation (though VDPS amount would be deducted from any award). Presents low legal risk at this stage.	There has been parliamentary and public commentary that the VDPS does not currently provide sufficient support to those potentially harmed by COVID-19 vaccines.  VDPS claimant can still pursue legal claim.	<b>AMBER/GREEN</b>  <u>Continue to keep under review.</u>
<b>Create ADR mechanism (in response to future litigation claims)</b>	Potential to mirror ADR schemes used for <u>I&amp;S</u> or other govt schemes. ADR conducted on an entirely confidential and without prejudice basis. Any resulting agreement is likewise confidential and cannot be referenced or produced in formal proceedings.	No guarantee that all of the points in dispute will be agreed. May not be appropriate for complex cases.  Potential merit for future management of litigation but difficult to advise in advance of any litigation claims.	<b>AMBER</b>  <u>Continue to keep under review.</u>
<b>Create “No-Fault” compensation scheme for COVID-19 vaccines</b>	Emphasis is on the recognition to compensate those injured/deceased without entering civil justice system.	Claimants could still pursue a legal claim for compensation. VDPS is already in place for COVID-19. Scientific understanding of potential links between in early stages. Would likely set unhelpful legal precedent from litigation perspective and likely risk of successful challenge in adopting different approach for COVID-19 compared to other conditions in VDPS. Unfunded and could incur high costs to tax-payer depending on future claims.	<b>AMBER/RED:</b>  <u>Recommend not to take forward at this point in time.</u>
<b>Individual ex-gratia payments</b>	Provide a one-off payment based on social or moral obligation. Govt would not admit any legal liability.	Does not prevent litigation. Would set precedent for other vaccines/schemes. Unfunded and requires HMT approval.	<b>RED:</b>  <u>Recommend not to take forward.</u>

## Annex A: Adverse events reported to manufacturers + MHRA yellow card scheme

**Report from manufacturers :** 17 cases of adverse events have been reported to C-19 vaccine manufacturers to date, ranging in severity from claims detailing headaches to death. No legal proceedings have **currently** been initiated. HMG, as well as Moderna and AZ, have been directing enquiries towards the VDPS.

Vaccine	Adverse Event
Pfizer	Bilateral unprovoked pulmonary embolism
AZ	Loss of work
Pfizer	Fever, vomiting, cough, respiratory problems and heart attack
Pfizer	Hospitalised with racing pulse and headache
Moderna	Infection and rash
Pfizer	Death as a result of an 'enlarged heart'
Pfizer	Paralysis from the waist down
Pfizer	Heart attack; damage to the heart
AZ	Pemphigus disease
AZ	Guillain-Barre Syndrome and Co-morbidities
AZ	Guillain-Barre Syndrome
AZ	Vaccine induced Idiopathic thrombocytopenia Purpura
AZ	Acute health problems including joint pain, fatigue
Pfizer	Abdominal cramps; bleeding; miscarriage
AZ	Haemorrhagic extension of right middle cerebral artery infarct and vaccine-induced immune thrombosis and thrombocytopenia (VITT)
AZ	Transverse Myelitis - rendered immobile due to spinal inflammation
Moderna	IBS, mental and physical fatigue

### Yellow Card Reporting: current summary

- To date, the MHRA has received 2096 reports of suspected adverse events where the patient died shortly after vaccination.
- Up to 20 April 2022, the MHRA has received 441 reports of major thromboembolic events (blood clots)\* following AZ vaccination.
- The MHRA has so far received 1217 reports of myocarditis and 878 reports of pericarditis, all vaccines considered.
- 5 fatal suspected myo/ pericarditis events are associated with the Pfizer vaccine. 4 fatal suspected myo/ pericarditis events are associated with AZ.

\* On 6 Dec. 2021, £1.6M study launched to investigate blood clotting cases post vaccination. Results for this study are expected on Sep. 2022.



Notes Summary:

No speaker notes are contained in this presentation.