

**Department for Health and Social Care**

**Proposal to amend the Human Medicines Regulations 2012 to support the ongoing supply and deployment of vaccinations across the UK**



**A response by the Association of Personal Injury Lawyers**

**November 2025**

## **Introduction**

APIL welcomes the opportunity to respond to the Department of Health and Social Care's consultation on amendments to the Human Medicines Regulations 2012 regarding vaccination.

Our response to this consultation reflects the perspective of our members who have supported individuals affected by vaccine-related injury or bereavement. We did not respond to the consultation questions, but provided comments on the proposals and the current operation of the Vaccine Damage Payment Scheme.

We understand the benefits of vaccination for public health and that the success of the national vaccination programme is of great importance to the UK and the UK's public health. Despite the success of vaccination programmes across the globe, it is accepted that vaccines are not without risks and that, regardless of whether there has been negligence or not, adverse events do occur, and that these adverse events can be severe. As a result, all developed countries have adopted statutory vaccine injury compensation schemes in some shape or form. The philosophy underpinning many of these schemes is that a society which requires its citizens to be protected by a vaccination programme should accept the responsibility for the few who suffer injury as a result of it. The Pearson Commission, when examining the arguments in favour of compensation for damage caused by vaccination, concluded that "there is a special case for paying compensation for vaccine damage where vaccination is recommended by a public authority and is undertaken to protect the community."<sup>1</sup>

We strongly believe that the Government should review and reform the Vaccine Damage Payment Scheme to address its current shortcomings, to reassure vaccine confidence in the UK, and prepare for the likelihood of any future pandemics.

We have concerns with the proposals in this consultation, and we believe that the regulatory controls for the supply and administration of vaccines should revert to pre-pandemic standards. The changes to the regulations were brought in as an emergency measure to respond to the pandemic and are, in our view, not justified anymore.

## **Regulatory controls**

We do not agree with the proposals to retain and expand regulations which were introduced under sunset provisions in the Human Medicines Regulations 2012 (Regulations). The changes to the regulations were brought in as a measure to respond to the pandemic, an

---

<sup>1</sup> The Pearson Commission report, paragraph 1,398.

emergency situation as described in s.345 of the Regulations and are not justified beyond the scope of those defined circumstances. The emergency no longer exists and the expedited and more expansive regulatory controls for vaccine prescribing should not become the norm. Sunset provisions were introduced for a good reason, so that when the pandemic was over, the regulatory controls would revert to normal. Effective regulation and safeguards are key to maintaining public confidence in vaccination.

New vaccine products have caused an unprecedented number of concerns about adverse reactions and an unprecedented increase in applications to the Vaccine Damage Payment Scheme (VDPS). As of 9 September 2024, there had been 14,844 applications to the VDPS relating to COVID-19 vaccines for the period from January 2021 to September 2024 (i.e. 3.5 years). Contrast this with the figure of 6,799 applications in total over the period from 1977 to 2020/1 i.e. 44 years. Before the pandemic, the application rate averaged out at around 154 applications per year (but note the significant spikes c.1977/8), whereas during the pandemic, annual applications rose to 4,241 applications per year.<sup>2</sup>

### **Vaccine Damage Payment Scheme (VDPS)**

We believe that the UK Government should assure consumers that, in the event of an adverse reaction to a vaccine resulting in significant injury, they will be able to obtain full compensation for the injuries suffered. The current operation of the VDPS does not go far enough.<sup>3</sup>

We strongly believe that the Government should review and reform the VDPS to address its shortcomings. The scheme set up by the existing Vaccine Damage Payments Act 1979 was not fit for purpose even before the outbreak of the Covid-19 pandemic. The debate surrounding the Bill was described by Lord Allen of Abbeydale as follows: “the Bill was discussed by one and all on the basis that it was a temporary measure which would hold the field until conclusions had been reached on the recommendations of the Royal Commission”<sup>4</sup>.

The temporary became the permanent and has remained largely unchanged ever since. The Act's faults include:

- The Act requires the claimant to prove that they have suffered ‘severe disablement’ to an extent of 60 per cent or more. This too high.<sup>5</sup>
- At that severe level of disablement, the scheme pays a one-off, derisory £120,000 compensatory lump sum.
- Cases are scientifically and/or medically complex, but there is no provision for legal costs or any other support for those who wish to make a claim under the scheme.

We believe the reforms introduced to the VDPS should include an adjustment of the current lump-sum available, revised eligibility rules, and increased funding to improve the scheme's efficiency and the support provided to claimants.

---

<sup>2</sup> NHS Business Services Authority FOI request ref: FOI-02148.1

<sup>3</sup> Please see the Witness Statement of Ms Sarah Moore to the UK COVID-19 Inquiry Module 4

<sup>4</sup> UK Parliament. (1984, March 7). Vaccine Damage Payments Act 1979: Anomalies. Hansard, 449

<sup>5</sup> For example, as of 1 July 2024, the NHS Business Services Authority had received 14,088 claims to the Vaccine Damage Payment Scheme (VDPS) relating to COVID-19. Of the 6,062 unsuccessful claims, 360 claims, or 2.6%, were rejected on the grounds that the 60% disability threshold had not been reached. <https://questions-statements.parliament.uk/written-questions/detail/2024-07-17/11>

Studies of different international compensation schemes for vaccine injury have identified important considerations that we believe should be taken into account. One study suggests that countries with low approval rates of applications, such as the United Kingdom, may need to reassess their stringent standards to ensure fair treatment of claimants. This paper also highlights the need for ongoing re-evaluation of claims based on the latest scientific findings to reflect new and emerging products and data on rare adverse events to ensure fair compensation and maintain public trust in vaccination programs.<sup>6</sup>

Professor Duncan Fairgrieve in the study *Comparing No-Fault Compensation Systems for Vaccine Injury* summarises four hallmarks of a successful scheme: (1) accessible, with low legal and financial barriers; (2) transparent decision-making process and compensation framework; (3) timely, with clear and short time-frames for compensation decision-making; and (4) deliver an amount of compensation that has a reasonable relationship with the harm and provides a realistic alternative to a legal claim.<sup>7</sup>

Payment under the Vaccine Damage Payments Act 1979 does not preclude consumers from pursuing a product liability claim under the Consumer Protection Act (CPA). However, advancing a claim against a vaccine manufacturer in the UK is extremely difficult. In fact, there has never been a successful claim against a vaccine manufacturer in this country. Claimants face costs of around £5m to £10 million to bring a case to trial. Because of the poor prospects of success, it is very unlikely to find solicitors who would be willing to embark on bringing such a claim to trial.

There is a need for the Government to review and reform the VDPS to ensure that it is fit for purpose, fair and maintains vaccine confidence. A society which requires its citizens to be protected by a vaccination programme should accept the responsibility for those who suffer injury as a result of all vaccinations licensed in this country.

Any queries related to this response should be directed, in the first instance, to:

Ana Ramos

Legal Policy Officer

[Ana.ramos@apil.org.uk](mailto:Ana.ramos@apil.org.uk)

---

<sup>6</sup> Chao-Fang Chu et al., Comparative analysis of fourteen COVID-19 vaccine injury compensation systems and claim approval rates

<sup>7</sup> Fairgrieve et.al., Comparing No-Fault Compensation Systems for Vaccine Injury