

COVID-19 vaccines: in favour of a bespoke compensation scheme for adverse effects

A briefing paper

Introduction

This is a briefing paper on behalf of a group of specialists drawn from different disciplines setting out the arguments in favour of a bespoke compensatory scheme for adverse effects to a COVID-19 vaccine(s). As set out below, it is our view that a no-fault compensation scheme could play a valuable role in relation to the acceptability of emergency COVID-19 vaccines.

Background: Acceptability of COVID-19 vaccines and the importance of legal safeguards

Ensuring widespread uptake of any COVID-19 vaccine will be crucial to easing social distancing regulations and ensuring a gradual return to normal public and economic life. Uptake will depend on securing sufficient vaccine supplies and creating a robust distribution scheme. It will also depend on widespread public trust in the safety of the vaccine (or vaccines), the diligence of the manufacturers and health workers producing and distributing them, and the adequacy of legal safeguards to prevent and compensate for inadvertent harm.

The unprecedented speed of vaccine development and the necessary scale of rollouts are likely to pose significant challenges for uptake. Survey data on vaccine attitudes and sociological research indicate a worrying increase of popular vaccine hesitancy at the global and national level. Complete rejection of vaccination remains rare and limited to a small percentage of populations. In most cases, hesitancy, where people delay, pick-and-choose, or even outright refuse vaccination, is related to specific vaccines and specific points in time.¹

It is, therefore, vital to invest sufficient resources in creating conditions which maximise uptake and minimise opportunities for hesitancy to arise. The time to do so is now. The novel technology platforms on which COVID-19 vaccines will be based, targeted disinformation campaigns, and reports of less well-studied vaccines being launched in Russia and China are already contributing to uncertainty about the safety of leading vaccine candidates. Once rollout starts, existing concerns will likely be exacerbated by any reports of adverse effects – whether confirmed to be connected to vaccines or not. In 1976, fears of an imminent pandemic triggered the rapid development and nationwide rollout of a new vaccine against swine flu (H1N1) in the US. The absence of significant H1N1-mortality and reports of vaccine-induced cases of Guillain-Barré syndrome in the population led to an abrupt halt of the vaccination program, a political crisis within the Ford Administration, and a change of leadership within the American Centers for Disease Control and Prevention (CDC).² Rumours and conspiracy theories about the safety and rationale for vaccination are also likely to occur. While often illustrative of issues of trust for the intentions of those in power, these rumours can be detrimental to vaccine campaigns. Since 2019, rumours of infertility caused by the new Ebola vaccine, which was initially rolled out on an

¹ A.de Figueiredo, C.Simas, E.Karafillakis, P.Paterson, H.J.Larson. "Mapping global trends in vaccine confidence and investigating barriers to vaccine uptake: a large-scale retrospective temporal modelling study" *Lancet*. 2020.

² D.J.Sencer and J. Donald Millar. "Reflections on the 1976 swine flu vaccination program." *Emerging infectious diseases* 12, no. 1 (2006): 29; Harrison, Mark, 'Pandemics', in Mark Jackson (ed.), *The Routledge History of Disease*. Abingdon (= Routledge) 2017, pp. 129-46

emergency basis, have reduced vaccine uptake and triggered attacks on vaccine workers in West Africa.³

Maintaining public trust in vaccines despite scepticism will depend on effective public health messaging, transparent regulatory decision-making, and effective legislative safeguards. Historically, public acceptance of a vaccine has strongly correlated with trust in the governmental and non-governmental organisations rolling out a vaccine.⁴ Following the publication of what would later be revealed to be flawed and unethical research linking the MMR vaccination to autism in 1998, concerted messaging and catch-up campaigns by public health experts with the aid of regulators, have managed to maintain a comparably high uptake of the vaccine in most European countries.⁵ By contrast, uptake of polio vaccination in Pakistan plummeted after it emerged that a polio-vaccine drive had been used to gather information on the whereabouts of Osama Bin Laden by the US Central Intelligence Agency (CIA).⁶ In the context of the UK, recent opinion polls suggest growing public dissatisfaction with the official UK pandemic response as well as with prolonged restrictive public health regulations.⁷ This may well compromise authorities' ability to respond effectively to rumours, conspiracy theories, and reports of adverse effects.

To ensure a successful COVID-19 emergency vaccine rollout, regulators will have to ensure that trials of every candidate are conducted as thoroughly as possible and communicated well and that commercial producers maintain the highest standards of production. They will also have to pre-empt public criticism, adverse publicity, and damaging legal proceedings by guaranteeing that victims of adverse effects are rapidly and adequately compensated. This pre-emption will avoid a repetition of historical vaccine tragedies like the 1955 Cutter incident, during which inadequate official specifications and production shortcomings resulted in the vaccination of around 200,000 US children with a virulent live polio strain, 200 cases of paralysis, and ten deaths.⁸ The Cutter incident led to much improved regulatory requirements for manufacturers but also laid bare the dangers of emergency mass-rollouts of new biologics and the need for adequate compensation for the families of polio victims, many of whom had to resort to individual litigation to obtain compensation. The result was public distrust in vaccine standards, financially crippling lawsuits for manufacturers, which later contributed to the passage of the 1986 US National Vaccine Injury Compensation Program, and significant emotional burdens for many families.⁹ Guaranteeing that recipients of new COVID-19 vaccines are automatically eligible to compensation that covers not only healthcare costs but also loss of livelihoods and long-term complications can form an important foundation on which to build and maintain public vaccine acceptance.

³ Y.Wang, M.McKee, A.Torbica, D.Stuckler. "Systematic Literature Review on the Spread of Health-related Misinformation on Social Media" *Soc Sci Med*. 2019;240. doi:10.1016/j.socscimed.2019.112552.

⁴ S.Blume, *Immunization: how vaccines became controversial*. Reaktion Books, 2017.

⁵ G.Millward, *Vaccinating Britain : Mass Vaccination and the Public since the Second World War.*; 2019.

⁶ CY Bahk, M.Cumming, L.Paushter, LC Madoff, A.Thomson, JS.Brownstein. Publicly available online tool facilitates real-time monitoring of vaccine conversations and sentiments. *Health Aff*. 2016;35(2):341-347. doi:10.1377/hlthaff.2015.1092.

⁷ See e.g. <https://yougov.co.uk/topics/politics/trackers/government-approval>

⁸ C.Jacobs, *Jonas Salk: A Life.*; 2015.

⁹ P.A.Offit, *The Cutter incident: How America's first polio vaccine led to the growing vaccine crisis*. Yale University Press, 2007.

Compensation and Acceptability

Like many immunisation programmes, a COVID-19 immunisation programme has two main aims: first the protection of the vaccinated individuals against the disease; and second a reduction in community transmission through a reduction in the number of susceptible individuals. Because of the very steep gradients in the risk of severe disease and mortality according to age, the balance between these aims will be different in different age groups. The old and very old will be vaccinated to protect them against disease, whereas the young will be vaccinated to reduce transmission, thereby protecting the old and allowing a gradual reopening of society. It is also likely that health and social care workers will be required by regulators such as the GMC and NMC and by employers to have COVID-19 vaccination if they want to continue working in patient/client facing roles, thereby introducing something close to mandatory vaccination for certain groups.

For most vaccines, there is no link between individual protection and the likelihood of experiencing severe side-effects and given the age gradient in risk of severe COVID-19 the same is very likely to be true for COVID-19 vaccines. Although we may *ex post* be able to explain some of the specific instances of side-effects, they will *ex ante* be randomly distributed among those who are vaccinated. This situation means that those who experience severe side-effects as a result of vaccination are essentially experiencing harm for the benefit of others. As a result, there is a strong ethical requirement for adequate compensation when severe side-effects occur. The good citizen or good health care worker who has been vaccinated, primarily for the benefits of others and of society as a whole should not be left to carry potentially life-changing side-effects without compensation. This view follows both from general considerations of fairness, and from more specific consideration concerning how society ought to reciprocate when its members suffer significant harm while engaging in activities that provide societal benefits and that are encouraged by society¹⁰ (cf. the military covenant).

There are many avenues to potential compensation for a victim of adverse effects of COVID-19 to pursue. These include a damages claim under either the implemented provisions of the Product Liability Directive (“PLD”), or the tort of negligence, or a claim under the no-fault scheme created by the Vaccine Damage Act 1979 Scheme. As discussed below, however, none of these are particularly well-suited to the current pandemic and are thus not likely to provide the necessary reassurance to the general public to assist in encouraging a high take-up of any vaccine.

CPA - Product Liability

Under the Product Liability Directive¹¹ (implemented in the UK by the Consumer Protection Act 1987), a producer is liable to compensate a claimant for damage caused by a defective product. This no-fault regime for product liability is the obvious starting point for a claim in damages in case of an adverse effect caused by a COVID-19 vaccine. There are however major obstacles for such a claimant to overcome. Whilst there is no specific defence under the PLD for producing products during a health emergency, there are potential ways in which this particular context may impact on liability under PLD.

¹⁰ Holm, S., 2020. *A general approach to compensation for losses incurred due to public health interventions in the infectious disease context*. Monash Bioethics Review, pp.1-15.

Attwell, K., Drislane, S. and Leask, J., 2019. Mandatory vaccination and no-fault vaccine injury compensation schemes: An identification of country-level policies. *Vaccine*, 37(21), pp.2843-2848.

¹¹ Directive 85/374 of 25 July 1985.

This issue has been examined in detail in a previous paper to which readers are referred,¹² and only a brief appraisal will be made here.

In terms of the notion of defect, the central element of the PLD, the claimant will need to show that the product in question did not “provide the safety which a person is entitled to expect, taking all circumstances into account.” The notion of defect is a subtle and complex one which requires an objective assessment by reference to the public at large, and the standard of safety a consumer may legitimately expect.¹³ In the absence of any case law, it is unclear whether the occurrence of the pandemic and the urgency engendered by this health crisis would be a legally relevant circumstance to be taken into account so as to modify the normal assessment in terms of defect and entitled safety expectations, and if so, how much weight would be attributed to it.¹⁴

One particular issue, however, will be the way in which the benefits of a product may be weighed against its risks when considering whether it is defective. How should the benefits of a COVID-19 vaccine be taken into account, in terms of the entitled level of safety expectation in respect of risks, including adverse effects to the vaccine? The answer to this question remains uncertain and none of the cases across Europe have yet provided a definitive response to this conundrum. Whilst some early English cases indicated that a product’s benefits were not relevant,¹⁵ later cases, have reached the opposite result at least where the design of the product is being challenged.¹⁶ Other European jurisdictions, such as Germany and France, have on the other hand embraced consideration of risk/benefit more readily.¹⁷ At a European level, the European Court has not directly addressed the question.¹⁸

A related issue is whether regulatory approval is relevant, particularly where the process of scrutiny or standards applied have altered in response to the health emergency. Under English law, the relevance of a product’s compliance with regulations has been examined in two recent cases, with a result that whilst the regulatory context is of relevance,¹⁹ it is also clear that there is no general regulatory compliance defence in English law.²⁰ A similar approach has been taken in other countries.²¹ Where emergency procedures are used the regulatory approval might be taken as evidence of expectations in those circumstances or those circumstances might render any regulatory approval less relevant to the civil liability standard if that is seen as being constant.

¹² D.Fairgrieve, P.Feldschreiber, G.Howells and M. Pilgerstorfer, “Products in a Pandemic : Liability for Medical Products and the Fight against Covid-19” (2020) *European Journal of Risk Regulation* 1. Available at : https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3584265

¹³ C-503/13 *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt* [2015] 3 CMLR 173 at [37]-[38].

¹⁴ See further D.Fairgrieve, P.Feldschreiber, G.Howells and M. Pilgerstorfer, noted above.

¹⁵ *A v National Blood Authority* [2001] 3 All ER 289, at [68] and [71].

¹⁶ *Wilkes v Depuy* [2016] EWHC 3096 at [13], [65]-[66], [82] and *Gee v DePuy* [2018] EWHC 1208 at [161]. See also comments in the Court of Appeal in *Seroxat Group Litigation* [2019] EWCA Civ 1926 at [8].

¹⁷ See generally E. Rajneri, J-S. Borghetti, D. Fairgrieve and P. Rott, “Remedies for Damage Caused by Vaccines: A Comparative Study of Four European Legal Systems” (2018) *European Review of Private Law* 57.

¹⁸ Note however that in *Boston Scientific*, defect was assessed without any reference to the benefits or utility of the product. Furthermore, in C-621/15 *W v Sanofi Pasteur*, AG Bobek rejected a submission that a broad assessment of cost/benefit was required when considering a vaccine (at [85]-[88]). However, in the English case of *Gee v DePuy* [2018] EWHC 1208, it was held that the AG’s opinion was directed at a particular submission in *W*, and only to suggest that a balance of costs and benefits was not necessarily required (ibid at [149]-[150]).

¹⁹ *Wilkes v Depuy* [2016] EWHC 3096 at [100] – [101]; *Gee v DePuy* [2018] EWHC 1208, at [176.]

²⁰ See *Gee v DePuy* [2018] EWHC 1208, at [173].

²¹ See further D.Fairgrieve, P.Feldschreiber, G.Howells and M. Pilgerstorfer, noted above.

A particular pertinent issue in respect of emergency vaccines is the developments risks defence which provides an exculpatory route for the producer when the defect could not have been known about (see Article 7(e) PLD). The burden is squarely placed on the producer to establish the defence, thereby suggesting a narrow role for the defence, and this somewhat controversial defence is in practice rarely invoked by defendants. The one European case on this topic, *Commission v United Kingdom*, confirmed that the defence was concerned with the most advanced state of knowledge²² and whilst confirming the test was objective, gave some relief to producers by determining “the relevant scientific and technical knowledge must have been accessible”.²³ Could it come to the avail of producers of COVID-19 vaccines? That will obviously depend upon the exact factual matrix, but the defence is intended to protect innovators against unknowable risk, not against products that have discoverable defects, but which were produced in haste to meet an emergency. AG Tesouro in the aforementioned European case noted the practicability of measures as being irrelevant to the defence,²⁴ and the resultant judgment implies that anything that would have been discovered by established scientific and technical testing procedures would have been discoverable. The defence is only likely to be of assistance where there is a new risk that could not have been discovered by established testing procedures.

Causation may also be an obstacle to the recovery of compensation. Subject to EU principles of effectiveness and equivalence, the rules of causation that fall to be applied under the PLD are subject to national law.²⁵ In *W v Sanofi*, the European Court gave some guidance in a vaccine case. The Court held that the burden of establishing causation would be excessively difficult for a consumer to discharge if national law prohibited recourse to circumstantial methods of proof and instead required proof through scientific or medical research.²⁶ Conversely, national rules were not allowed to make it too easy for the claimant, and thus evidence must be “sufficiently serious, specific and consistent” to establish that the defect as the most plausible explanation for the damage.²⁷ Causation may be particularly difficult to prove in vaccine cases where there will be considerable uncertainty about the attribution of adverse effects, given that the initial rollout will predominantly be to older persons and those with underlying health conditions.

Common law

Under the common law of negligence, where duties of care are owed as a matter of course by manufacturers to consumers of their products, certain of the issues referred to the section above on the PLD will reappear, such as the impact of the regulatory system in case of highly regulated products such as vaccines. Additionally, the standard of care in negligence which will be assessed objectively in a demanding manner in this context will pose an additional obstacle to surmount.

No-fault Vaccine Damage Act 1979 Scheme

Another route to compensation under the current system would be a claim under the Vaccine Damage Act Scheme. The scheme was created by virtue of the Vaccine Damage Payments Act 1979 subsequent

²² C-300/95 *Commission v United Kingdom* [1997] 3 CMLR 923 at [26].

²³ *Ibid* at [28].

²⁴ *Ibid* at [20].

²⁵ See generally R. Goldberg, *Causation and Risk in the Law of Torts: Scientific Evidence and Medicinal Product Liability* (Hart, 1999) at 23.

²⁶ C-621/15 *W v Sanofi Pasteur* at [30]-[32].

²⁷ *Ibid*, at [37.]

to the Pearson Commission and allows for the provision of a lump-sum payment for persons who have been severely disabled as a result of vaccination against a series of specified diseases, which now includes diphtheria, tetanus, whooping cough, measles, rubella, smallpox, pandemic influenza A (H1N1), rotavirus, influenza, meningitis W and meningitis B. Under this scheme, the vaccination must have occurred in the UK, and (with some exceptions),²⁸ the vaccination must have occurred when the claimant was either under eighteen or during an outbreak of the disease in the UK or the Isle of Man.²⁹ The scheme is premised on no-fault liability, so there is no requirement to show negligence or any other type of fault.

The main weakness of the scheme is that there is an upper limit of £120,000³⁰ and so awards will often be a lot less than tort law damages for similar harm. This payment contrasts unfavourably with an average payment under the US National Childhood Vaccine Injury Act of over half a million dollars (between 2006-2016).³¹ Another issue is that of causation: ³² recent figures show that over 65% of claims fail for that very reason.³³ Under the scheme, a child victim's case was recently taken to the Court of Appeal by the State arguing damages should not be assessed based on future needs.³⁴ The Court sided with the victim, but this attitude is unlikely to inspire confidence in the scheme without significant amendment. None of this bodes well in terms of reinforcing the acceptability of COVID-19 vaccine given the potential for side effects.

Our Proposal: a bespoke COVID-19 vaccine compensation regime

In order to provide reassurance to those administered COVID-19 vaccines, it is our view that a bespoke COVID-19 vaccine compensation regime should be created without delay. In order to avoid expending resources on the costs of the litigation system, it would be preferable to divert victims to a compensation fund specifically created to adverse effects caused by COVID-19 vaccine(s). Such a regime should be based on a no-fault model, with a simple, swift and accessible procedure, providing fair and equitable compensation to those who have suffered an adverse effect. Compensation should be based on need and whilst not premised on tort principles *stricto sensu*, the sums available would need to be sufficiently high that victims are not tempted to turn to litigation to top-up the award. Behavioural science suggests such schemes will be only attractive if they represent a better bargain than gambling on the uncertain outcome of litigation³⁵. Being proactive in establishing such a fund will improve the chances of any immunisation programme being effective and at the same time reduce overall costs to society. It also fits in with a philosophy that prefers to nudge citizens to make the choices the state wants rather than imposing a system and removing existing rights. This approach would be consistent with the recommendations made by the recent Cumberlege report dealing with just such cases of injury caused by healthcare products.³⁶

²⁸ Poliomyelitis, rubella, meningitis C, human papillomavirus, pandemic influenza A (H1N1), and meningitis W (before 26th birthday).

²⁹ Section 2(1) of the Vaccine Damage Payments Act 1979.

³⁰ Vaccine Damage Payments Act 1979 Statutory Sum Order 2007.

³¹ Admittedly this under a different damages regime where medical expenses recovery is more significant than in Europe.

³² R.Goldberg, *Medicinal Product Liability and Regulation* (Oxford: Hart Publishing 2013), p 11.

³³ See generally E. Rajneri, J-S. Borghetti, D. Fairgrieve and P. Rott, above, at 90.

³⁴ *Secretary of State for Work and Pensions v G* [2017] 1 WLR 1956.

³⁵ However, the projected costs of the scheme should not primarily be compared to the projected cost of a compensation scheme based on litigation. Account should also be taken of the potentially large societal costs of a loss of public confidence and low vaccine uptake delaying the reopening of society.

³⁶ *First Do No Harm : The Report of the Independent Medicines and Medical Devices Safety Review*, 2020.

We suggest that the principles governing such a scheme should be as follows:-

- **Principle 1.** The COVID-19 scheme should be a stand-alone and bespoke one, outwith the Vaccine Damage Act 1979 scheme and governed by separate principles.
- **Principle 2.** The scheme should be based on a no-fault model and as a basic principle, compensation should be automatically made available where a COVID-19 vaccine has been found to cause harm without the need for the patient to establish and prove a defect in the product / or fault of the manufacturer.
- **Principle 3.** The scheme should identify situations where the vaccination has been medically associated with a particular adverse effect and presume a logical sequence of cause and effect on showing of a proximate temporal relationship between the vaccination and the injury.
- **Principle 4.** The quantum of financial redress of any award should be fair and equitable, and be close enough to the level of damages awarded before the courts to dissuade resort by those injured to litigation.
- **Principle 5.** The scheme should be free to access by any affected patients, and funding provision and support should be made available to affected patients to assist them in making applications and fully quantifying their current and future needs and past losses.
- **Principle 6.** The existence of the scheme should not affect the availability of litigation through the courts. The scheme should simply supplement the current dispute resolution system and affected patients will remain free to bring legal proceedings in the normal way.
- **Principle 7.** The scheme should be publicised at the same time as the launch of the immunisation programme, with proper public outreach and dissemination of information regarding the scheme to the general public.

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³⁷ For further details of our work in this area, see : <https://www.biicl.org/projects/emergency-products-and-covid-19>