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Following the herd

COVID-19 & the challenge of herd immunity: what role can the law play, asks **Sarah Moore**

At 6:31am GMT on Tuesday 8 December, a 90-year-old British grandmother made world history. Margaret Keenan became the first person in the world to receive dose one of the two dose Pfizer/BioNTech COVID-19 vaccine outside of a clinical trial. Twenty one days later, as 2020 ended, Margaret received her second and final dose. In doing so she initiated a mass population vaccination programme that is likely to dominate the UK's public health agenda for years to come.

The objective of that agenda is to reduce the infection rate of COVID-19 in the UK. Science and medicine have played a fundamental role in getting us to this point but, as set out here, the law now has a potentially transformative contribution to make. By providing a 'safety net' permitting access to substantive compensation in the event that adverse health effects are experienced as a result of vaccination in the coming months, the law has the potential to counter trends in vaccine hesitancy. This will be key to ensuring that the early promise of the UK's vaccine programme can be delivered upon in practice.

In 2020, chief medical officer, professor Chris Whitty, entered *The Sun* newspaper's esteemed hall of 'pandemic pin-ups'.

In doing so, he brought the lexicon of health economics, virology and epidemiology to all of us—the masses. A key term in that lexicon is the concept of 'herd immunity'. As defined by the World Health Organisation, it is 'a concept used for vaccination, in which a population can be protected from a certain virus if a threshold of vaccination is reached' (*bit.ly/2K7OELm*).

Experts in the UK prompted controversy earlier in the year by suggesting that the most appropriate route to herd immunity might be to let the epidemic run its natural course with minimal medical and governmental intervention. With a vaccination programme now underway, there is every reason to hope that herd immunity in the UK can be achieved through mass vaccination.

Vaccine hesitancy

In September 2019 the government published research indicating that vaccine hesitancy or 'the delay in acceptance or refusal of vaccines despite the availability of vaccinations services' was rising globally (*bit.ly/34gqNjw)*.

During the course of 2020, in the context of COVID-19 vaccines in particular, targeted disinformation campaigns; confusion about reports of less well-studied vaccines being launched already, for example, in Russia and China; and memories of other rapid vaccine rollouts, such as the 1972 US swine flu vaccination (H1N1) which was linked with reports of vaccine induced Guillain-Barre syndrome, have all been cited as factors which may further exacerbate vaccine hesitancy in the UK.

UK first

Ironically, the speed with which the UK's Medicines and Healthcare Regulatory Authority (MHRA) was able to procure, licence and roll-out use of the Pfizer/BioNTech vaccine (and the Oxford-AstraZeneca vaccine in late December) may further feed UK rates of vaccine hesitancy.

A key factor in securing the MHRA's more rapid licensing of the Pfizer/BioNTech vaccine was the regulator's decision to approve supply under the emergency provisions of s 174 of the Human Medicines Regulations 2012. That provision permits the disapplication of the conventional route to drug licensing (as per s 46 of the regulations) in circumstances where 'the sale or supply of a medicinal product is authorised by the licensing authority on a temporary basis in response to the suspected or confirmed spread of (a) pathogenic agents'.

The MHRA moved fast to counter suggestions that speed had been prioritised over safety as per their press release of 2 December 2020 (*bit.ly/3oRYKPa*).

Caution urged by other regulators

In response to the MHRA's announcement that it had approved mass-population use of the Pfizer/BioNTEch vaccine for citizens of the UK, the European Medicines Agency (EMA), stated publicly that it had not chosen to use emergency approval procedures for the vaccine, but preferred to move more slowly ensuring that further evidence was obtained prior to mass population launch across Europe.

Pfizer insisted that they had provided the same packages of safety data to both the EMA and the MHRA, but that the regulators were using different processes to assess the information.

In the event, the EU regulator recommended the Pfizer/BioNTech vaccine for use in the block's 27 states on 21 December 2020.

The Brexit context

The different approach taken by the MHRA highlights the fact that the UK is no longer bound by EU rules and institutions. As we wave goodbye to the year that was 2020, the UK will also end the formal transition period out of the EU.

In that context, the UK's more rapid approval of the COVID-19 vaccine has been seen as providing political capital for those who supported the Brexit campaign, and has drawn negative comments from health ministers across mainland Europe—who have contrasted the UK's rapid approach, with what they deem the more robust approach of the EMA.

By fusing the Brexit debate, in the context of a global pandemic, with questions about the efficacy of the new stand-alone MHRA, acting for the first time in nearly 50 years outside of the established network of EU institutions, commentators are potentially fuelling concerns about the safety of the vaccine—and consequent vaccine hesitancy.

At the date of writing all reports indicate that there are no significant safety concerns with the Pfizer/BioNTech vaccine. However, on 9 December 2020 there were two reports of 'anaphylactoid reactions' in NHS workers who had received the vaccination, both of whom had prior histories of suffering severe allergic

reactions: Fortunately neither patient appears to have suffered significant harm.

Where the law comes in

A paper published by a multi-disciplinary group of academics at the British Institute of International and Comparative Law (BIICL) in November, highlighted the vital role that the law can play in supporting the acceptability of an emergency COVID-19 vaccine, through 'countering the trends of vaccine hesitancy' and thereby supporting the objective of herd immunity (*bit.ly/388KElN*).

The authors noted that providing recipients of new COVID-19 vaccines with recourse to compensation covering healthcare costs, any loss of livelihood and long term complications, can form an 'important foundation on which to build and maintain public vaccine acceptance'. In this context, the authors recommended urgent consideration of 'a bespoke COVID-19 vaccine compensation scheme'.

Existing legislation, such as the Product Liability Directive (85/374) or the Consumer Act 1987, provides a potential route for claimants to obtain compensation for injuries suffered directly from manufacturers but in practice claimants face significant hurdles—a conclusion supported by the Independent Medicines and Medical Devices Review panel, chaired by Baroness Cumberlege.

The BIICL paper recommended that the financial scheme should be based on a no-fault model, enabling swift and simple claimant access, and that the compensation available should be at a level which will incentivise individuals to use the scheme as opposed to more expensive and protracted litigation.

It concludes that 'being proactive in establishing such a fund will improve the chances of any immunization programme being effective and at the same time reduce the overall costs to society'.

COVID-19 & the Vaccine Damage Payments Scheme (VDPS)

Whether the BIICL paper was read in Whitehall, or not, the government have readily recognised the role that personal injury law must play in building and maintaining public confidence as the UK rolls out its mass population COVID-19 vaccination programme.

Just a day after the MHRA announced licensing of the Pfizer/BioNTech vaccine, on 3 December 2020, the government moved quickly to announce that it was taking the 'precautionary step' of adding the COVID-19 vaccine to the existing Vaccine Damage Payments Scheme (VDPS).

The Vaccine Damage Payments Act 1979 was set up in response to the Pearson Commission which recognised the part that a national compensation scheme could play in providing a 'safety net' for those injured as a result of government recommended vaccination programs. This scheme provides those who suffer severe disablement causatively linked with a vaccination, with a single tax free lump sum payment to a maximum of £120,000.

Adding diseases to the VDPS is not new. The scheme has been the subject of much criticism over the years because: (1) to obtain a payment an applicant must be able to demonstrate 60% disablement as a direct result of the vaccine; (2) the value of the award is low, particularly for those who suffer the most serious systemic harms as a result of vaccination; (3) the scheme is government funded—effectively indemnifying the manufacturer; and (4) the success rate for applicants is very low. In response to a Freedom of Information Act request in 2017, the government released data showing that between 1979-2017 there had been 6196 applications to the VDPS of which only 15% were successful. Data gathered more recently indicates the success rate currently is less than 2%.

While traditionally the VDPS does not prejudice the ability for a claimant to pursue a manufacturer in the courts in respect to alleged vaccine damage, in the context of COVID-19 the government has granted Pfizer civil immunity against litigation by virtue of s 174 of the Human Medicine Regulations 2012.

In the context of a global pandemic and an urgent need to 'on-board' individuals willing to opt for vaccination, the question is whether by adding COVID-19 to the VDPS the government has gone far enough in providing a safety net for those harmed by the vaccine, and comfort for those concerned about suffering harm? That safety net is crucial if the vaccine is going to deliver population wide immunity.

Providing a safety net fit for purpose

Other no-fault compensation schemes have been established in the UK historically, in the context of Thalidomide and vCJD (BSE), for example. In addition to providing injured persons with financial support, both schemes provide access to highly specialised medical care, financial planning and other forms of healthcare assistance. Reporting in July 2020 Baroness Cumberlege recognised the potential for redress schemes to improve the lives of those injured by medical products.

By adding COVID-19 to the VDPS within a week of the MHRA's approval of the Pfizer/BioNTech vaccine, the government has acknowledged the vital interplay between the law, public confidence and the success of a mass vaccination programme. Whether the government has gone far enough in the context of a febrile global debate about vaccination safety, fuelled by social media, dis-information campaigns, and Brexit politics, remains unclear. If we are to have any hope of looking back on 2020, this time next year, as an aberration—rather than the beginning of a 'new normal'—the government will need to keep this issue under close review. **NLJ**

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