

Introduction:

We are a firm of solicitors who act for GPDF Limited (“GPDF”) and we have been instructed, together with David Lock QC, to consider the merits of any potential legal challenge in England and Wales to the decision made by the UK Government to change its guidance on the COVID-19 vaccination programme. Roddy Dunlop QC has advised upon the position regarding any potential legal challenge in Scotland and his view is that the position in Scotland does not differ from the position in England and Wales in any material respect.

This note applies only to the law and jurisdiction of (i) England and Wales; and (ii) Scotland (to the extent that it incorporates the advice of Roddy Dunlop QC) and is a generic summary for LMCs to assist their constituent GPs and it is no substitute for fact specific advice.

Background:

On 30 December 2020, the Medicines and Healthcare products Regulatory Agency (“MHRA”) authorised the AstraZeneca (Oxford) vaccine (the “Oxford Vaccine”) for deployment across the UK, alongside the existing Pfizer/BioNTech vaccine (the “Pfizer Vaccine”).

Following the commencement of the COVID-19 vaccination programme, the UK Government changed its guidance about how long patients should wait between vaccinations and extended the recommended window from 21 or 28 days to circa 12 weeks. The UK Government has justified its decision on the basis that using the limited supply of vaccines to give more people the first dose will afford greater protection to the population as a whole.

Following this change in guidance, we understand that concerns have been raised about the potential legal and practical implications for GPs engaged in rolling out the vaccination programme. Accordingly, the main issues are addressed below.

Negligence / Liability:

Provided patients are given proper advice, a GP following the revised UK Government guidance should not be legally liable if a patient contracts COVID-19 during the now extended window between receiving the first and second dose of either the Oxford Vaccine or the Pfizer Vaccine. Nor will GPs incur professional/regulatory liability. The reasons for this are twofold.

1. GPs work within the limited framework of a state-funded healthcare system, under the constraints of UK Government’s instruction and direction. The decision of when to provide the second dose of a vaccine does not rest with GPs; it is a question of policy which rests with the UK Government. A GP should not be held legally responsible for any risk that materialises as a result of their compliance with policies over which they have no control.
2. Both the Oxford Vaccine and the Pfizer Vaccine have been approved under the Human Medicines Regulations 2012 (the “HMR”). Regulation 245 of the HMR grants healthcare professionals immunity from civil liability in relation to medicinal products recommend or required in response to the spread of pathogenic agents. Regulation 323 of the HMR provides for this same immunity to be applicable in Scotland. In other words, healthcare professionals should not be held liable in the civil courts in connection with the COVID-19 vaccines.

Further, the vaccination programme falls *outside* of the normal contractual arrangement between a GP practice and NHS England. Accordingly, no liability could arise in that context either. Equally, a patient who does not get a second vaccine from a doctor within 28 days has no basis to complain to the GMC.

Patient Trust / Expectation:

If it is claimed that the GP promised to give a patient the second dose of a vaccine within a timeframe, that promise is highly unlikely to be legally enforceable. This is due to the framework GPs work within (as discussed above), the supervening acts of Government which have arguably rendered performance of that promise impossible and also because the Courts of England and Wales are not prioritising challenges relating to COVID-19. Even if a legally enforceable promise did exist, it would be a matter of public law and therefore should not give rise to any damages.

Notwithstanding this, patients may legitimately expect that when a public body, such as the NHS, promises to do something, they will be required to uphold that promise. Where patients in the early tranches were given fixed appointment dates to receive their second dose of a vaccine, it is recommended that these appointments be honoured although it is highly unlikely that individual GPs would have any exposure to a successful legal claim or complaint from a patient whose fixed appointment for a second dose of the vaccine had been cancelled. Where a patient has not been given a fixed appointment to receive the second dose of a vaccine (and merely a general assurance that they would be contacted with a view to their second dose being booked within 21 or 28 days), their appointment to receive the second dose should be scheduled in line with current Government guidance (i.e. after 12 weeks).

Judicial Review:

Although we are aware of public reports of potential judicial review proceedings over the decision to extend the window between the first and second doses of the COVID-19 vaccines, having given due consideration to matters, presently it is not recommended, nor proposed, that GPDF takes any such action in either England and Wales or in Scotland.