



COVID-19 and European Pharmaceutical Law  
An EPLR Series

COVID-19, Vaccines, BREXIT and  
Vaccine Damage Claims

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### COVID-19, Vaccines, BREXIT and Vaccine Damage Claims

There is currently an enormous international effort in progress to invent, test and obtain regulatory approval for a COVID-19 vaccine (or more accurately, a vaccine against SARS-CoV-2, the underlying virus). It is right to consider now, how such a vaccine will get regulatory approval, how such approval might be affected by BREXIT, and if no-fault vaccine damage schemes may apply to any such novel vaccine. These are the topics addressed below:

#### Brexit

The UK remains deemed a member of the EU until 31 December 2020 (article 7, [Withdrawal Agreement](#)), so until then, market authorisation for a COVID-19 vaccine will likely come from the European Medicines Agency (EMA). If such a vaccine can become a Centrally Authorised Product (CAP) by 31 December 2020 (the date on which the UK ceases to be deemed a member of the EU) then the vaccine will automatically acquire UK Market Authorisation (UK MA). If the application for CAP has been made prior to 31 December 2020 but is determined after that date then the applicant will, most likely (subject to any deal with the EU to the contrary) be able to re-use the EU CAP application as an application for a UK MA (including the opinion of the EU Committee for Medicinal Products for Human Use where the UK concurred with that opinion). Otherwise, unless any deal with the EU says differently, any vaccine for COVID-19 seeking authorisation wholly in 2021 or beyond, will have to obtain a separate UK MA.

There is not, at the time of writing, any EMA fast-track procedure for such a vaccine yet in place – unlike for [pandemic flu vaccines](#), but the EMA has constituted a special task force to rapidly gather and assess data on COVID vaccines – which includes setting up a procedure for the “fast-track approval” of vaccines and other medicines (see section 5.2 of [this document](#) and Article 5 of [this Decision](#)). The EMA may use the [PRIME Scheme](#) or accelerate assessments which may lead to conditional marketing authorisation. As of 24 April 2020, the EMA reported that “*EMA is also in discussion with developers of a dozen potential COVID-19 vaccines. Two vaccines have already entered phase I clinical trials*” (see [here](#)).

The MHRA, the UK regulator, is putting in place [measures](#) to support the development of a vaccine, including providing rapid

scientific advice, review, and approvals where necessary. The MHRA can give a conditional MA in exceptional circumstance. Clinical trials are already authorised (see [here](#)).

### Side Effects

It is likely that any vaccine so authorised will not have been tested to the same degree as a vaccine produced under less urgent circumstances. The usual timescale for the test of a vaccine to approval is over 2 years (although note the "pandemic paradigm" [here](#)). Further, most vaccines, as with all medicines, carry a risk of potential adverse events (side effects), although the vast majority are mild and transient. Some of these will be known about and will be communicated to patients prior to administration, but some will not be known about at that time, and may not be discovered until after significant numbers of people have received the vaccine, indeed the side-effect condition may be so rare that it may take some time for its signal to be recognised in the epidemiology (cf Narcolepsy and Pandemrix (the swine flu vaccine), Miller, *Risk of Narcolepsy in Children and Young People receiving AS03 Adjuvanted Pandemrix influenza vaccine* [BMJ 2013;346:f794](#)). There are likely to be significant post-marketing pharmacovigilance obligations imposed, not least through a conditional market authorisation.

The British Medical Association (BMA) has [noted](#) that

*"The arrival of a pandemic will also require the rapid development and deployment of vaccinations and anti-virals. The urgency of the event will mean that the normal procedures for development and licensing may have to be suspended or adapted to the demands of the emergency. In turn this could lead to health professionals using large numbers of relatively novel and untested pharmaceutical interventions. Mass use of untried vaccine could result in numerous adverse events. Issues of liability will therefore have to be addressed as a matter of urgency by the Government."*

### Vaccine Damage Claims

In fact, as to the BMA's concern, the UK Government already has, since 1978, a Vaccine Damage Payment Scheme which can be applied to any COVID vaccine. The UK Government provides a guaranteed payment of £120,000 (which is treated as a payment of account of damages in any later civil action) if you have suffered severe disability as a result of vaccination against a list of diseases. The scheme was described by the Upper Tribunal in [this case](#) which was upheld on appeal in the [Court of Appeal](#). The Government will have to decide whether to add any COVID vaccination to that list. There is no need to show fault to obtain a payment, just causation on the balance of probabilities and severe disability. Severe disability is defined as "at least 60% disabled" (there is a table of [comparative disabilities](#) and note 60% = Loss of a hand or of the thumb and four fingers of one hand or amputation from 11.5 centimetres below tip of olecranon or amputation at knee resulting in end-bearing stump or below knee with stump not exceeding 9 centimetres). Claims are made to and decided by the [Vaccine Damage Payment Unit](#) with medical assistance. There is a right of appeal (essentially a re-hearing) to the First-Tier Tribunal – a specialist administrative social security tribunal in the UK, which sits with medical expert members as well as legally qualified judges. Appeals from that Tribunal are to an expert legal tribunal – the Upper Tribunal, on points of law alone (further appeals can be made, but are rare as they have to relate to points of public importance).

Access to the statutory scheme will be important as it will be very difficult, if not impossible, to establish liability for vaccine damage against a manufacturer in the UK Courts under the Consumer Protection Act (CPA) (which implements Council Directive 85/374/EEC – the Product Liability Directive) or in negligence. Claims in the UK fail, not least on defect and causation grounds. The English Court of Appeal, in [Bailey and others v GlaxoSmithKline \[2019\] EWCA Civ 1924](#), endorsed the "holistic approach" to product safety set out by Hickinbottom J (now LJ) in [Wilkes v DePuy International Limited \[2016\] EWHC 3096 \(QB\)](#), which was also followed by Andrews J in her judgment in [Gee v DePuy International Limited \[2018\] EWHC 1208 \(QB\)](#). This takes into account the benefits and risks of a medicine when assessing its safety and thus whether it is defective.

This allows the Court to weigh any risks of side effects against the utility/benefits of any vaccine. A similar approach has also been followed in other European jurisdictions – including in [France](#). As to the problems with proving causation see, by way of example the story of the MMR litigation as told in [R. Goldberg, "Medicinal Product Liability and Regulation" \(Oxford: Hart Publishing 2013\)](#). Further, the development risks defence (DRD) under the CPA (which does not require a finding of negligence) would, at the very least, pose likely insuperable problems for a potential claimant as it enables the manufacturer to rely on the fact that the objective state of scientific and technical knowledge, at the time the vaccine was put into circulation, was not such as to enable the existence of the defect (i.e. that the vaccine acts in a way which causes a (unknown at the time of production) side-effect) to be discovered. Similar considerations would make establishing negligence very difficult, if not impossible.

The position is the same in Italy, where (as of 2018) *"no product liability claims against vaccine manufacturers have been reported"* (see para 8, Rajneri and others [Remedies for Damage Caused by Vaccines](#) European Review of Private Law I-2018 [57-96]) but where there is a much used state compensation fund. Germany has an enhanced pro claimant special product liability law for vaccines as well as a social security type fund. The special law includes a presumption in favour of causation in the individual case, if generic causation (i.e. that the injury in question is capable of being caused by vaccine) is made out. Damages are however, capped at EURO5 600,000. Few cases appear to have succeeded, despite the law being "stacked" in favour of claimants. France also has a compulsory vaccination state compensation fund. As to vaccine product liability civil claims in France, it has been noted that *"...efforts to establish causation in product liability cases were bound to remain fruitless, as even the most plaintiff-friendly appellate courts refused to regard the vaccine against hepatitis B as inherently defective."*

It therefore appears clear, that throughout Europe, those who suffer from, hopefully rare, disabilities arising from any COVID-19 vaccine will have to rely on State-funded social security type regimes. Governments should give consideration now, as to whether it is appropriate to use existing schemes, or whether a novel scheme should be put together for a COVID-19 Vaccine. Some individuals may feel more inclined to have the vaccine, and thus to contribute to the national effort to acquire herd immunity, if they knew that they would be financially supported in the event of a side-effect causing them to become disable or ill. There is a clearly a role to play for such schemes in providing reassurance to the public and encouraging vaccine take up.