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No-Fault Compensation Systems for Medical Products


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Product Liability: Background and Introduction

Product liability regimes in Europe represent a balance between the interests of consumers and producers, explicitly referenced as a 'fair apportionment of risk' in the second and seventh recitals to the Product Liability Directive 85/374/EEC. Redress for harms resulting from the use of products typically requires the injured party to prove contractual breach, fault (e.g. negligence) or, even in the case of no-fault regimes, a defect in the relevant product, together with a causative relationship with the injury experienced.

Product liability systems are often criticised from the consumer perspective as being too heavily weighted in favour of industry, on the basis that the requirements for redress are too stringent. However, the balance that they strike seeks to ensure that such claims do not act as a brake on innovation. The costs of redress are inevitably spread to society at large to some extent via the sale price of products and insurance. However, at the same time the pursuit of redress via liability systems tends to stigmatise the producers of defective products and may therefore act as a deterrent to negligence and poor workmanship.

The balance under existing product liability regimes in Europe has been subject to particular scrutiny in the context of the COVID-19 pandemic and the exceptional measures introduced to address it. These have highlighted the potentially significant disadvantages of a fault- or defect-based liability system, with the consequence that increased consideration has been given to no-fault compensation ('NFC') systems as providing possible alternative mechanisms of redress.

Products Introduced in a Pandemic: The Example of Vaccines

The COVID-19 pandemic has stimulated the development and supply of a large number of new medical products, including both medicines and medical devices, as well as personal protective equipment ('PPE') falling outside the definition of medical devices. However, it is mainly in the context of COVID-19 vaccines, administered at unprecedented speed, at a population level, that current consideration of alternative means of product liability redress has arisen.

While the development, manufacture and supply of medicinal products, including vaccines, is subject to high levels of regulatory control, absolute safety is not possible. Medicines may be marketed only after assessment of their quality, safety and efficacy and following confirmation by the competent regulatory authority that the potential benefits of use outweigh the potential risks.

This is not a one-time assessment: evidence of risk and benefit continues to accumulate from real-world use and post-marketing studies, and is subject to continuing regulatory review. For COVID-19 vaccines, the risk–benefit balance is continually reassessed in the context of developing information about potential unwanted effects associated with vaccine administration, together with increasing knowledge of COVID-19 infection, the emergence of new variants of the virus, and the efficacy of vaccines in countering the incidence and severity of the disease.

The protection of public health during a pandemic requires fast and efficient development of products such as vaccines. It is also necessary for such products to be accepted by the population for whom they are intended. In the case of vaccines, this requires use of the product by a sufficiently large proportion of the population to achieve community immunity. Irrespective of the size of the clinical development programme or extent of the regulatory assessment, public confidence in a vaccine developed rapidly in the context of a pandemic may be affected by concerns that the data are less complete than those for vaccines developed under more normal conditions, particularly if the vaccine is authorised under emergency use provisions or granted a conditional (rather than a full) marketing authorisation.

Furthermore, vaccines administered under accelerated timelines to a significant proportion of the population, will inevitably be associated temporally with adverse effects, including in those individuals who were previously in good health and at limited risk from the disease, with the associated possibility of adverse media publicity.

In these circumstances, the willingness of people to accept vaccines and, consequently, the sufficiently widespread use of such products in the public interest, can be impacted by the knowledge that individuals have some protection from the risk of adverse consequences of rare but significant unwanted effects, through the availability of appropriate compensation regimes.

It is also important to ensure that specialist innovators, manufacturers and other stakeholders are motivated to produce and supply such products quickly and at sufficient scale to have the desired impact, and are not deterred from doing so by the unknown and unquantifiable liability risks that accelerated development and regulatory approval necessarily entail.

An efficient compensation mechanism is therefore important as a means of securing public trust in vaccination in the public interest.

Litigation and Product Liability

One means of securing compensation is litigation. However, litigation is an inefficient means of delivering relief to individuals and is associated with particular disadvantages, in terms of cost and delay. The uncertain nature of litigation means that an injured party may spend years pursuing compensation through the courts, only to have their claim ultimately dismissed.

Furthermore, civil litigation regimes can differ significantly from country to country, which may lead to unfair variation in the degree of recourse available to injured individuals.

Product liability claims in respect of vaccines can be difficult and expensive to bring. Liability under, for example, the European Union ('EU') Product Liability Directive requires proof of defect as well as causation. A product is only defective when it falls below the standard of safety that persons generally are entitled to expect. This entitlement to safety will depend upon all the circumstances, including considerations such as development and supply of the vaccines in an emergency (pandemic) situation. In addition, a development risk defence is available in many countries, according to which the manufacturer of a product may be relieved of liability if the state of scientific and technical knowledge at the time the product was put into circulation was not such as to enable the defect to be discovered.

Even if product liability claims might ultimately not succeed, getting to that point via litigated individual or group claims will: take a long time; involve both injured parties and producers in significant legal costs, consuming resources that could unquestionably be better deployed elsewhere; and cause significant damage to the reputation, and therefore the public acceptance, of vaccines.

Government Indemnities and Litigation

In practice, manufacturers of vaccines would probably be reluctant to expose themselves to the full risks of paying compensation and bearing the full cost of litigation resulting from vaccines developed and deployed in an emergency context. As seen during the COVID-19 pandemic, that is likely to mean that in order to secure manufacturing and supply contracts for new vaccines that are critical for dealing with a public health emergency, a government or public authority may be required to grant manufacturers a contractual indemnity against product liability risk. Depending on the terms of the particular indemnity, this may result in injured vaccine recipients pursuing claims against the manufacturer, who then looks to the relevant government for reimbursement under its contractual indemnity, creating two expensive layers of potential dispute.

No-Fault Compensation Systems

In these circumstances, some countries have introduced NFC systems to provide compensation for medical injuries, particularly those associated with vaccination. The 'no-fault' descriptor refers to the fact that, in contrast with standard civil liability mechanisms, there is no requirement for a claimant to prove fault on the part of a potential defendant. Instead, medical evidence is required in order to establish that the product caused or contributed to the injury. There is no standard way of implementing an NFC system beyond these basic features, but typically the process is intended to be quite different from the pursuit of compensation via litigation, being administrative rather than adversarial, and operated by e.g. a panel of state-appointed medical or other experts who determine issues of causation of injury and the appropriate level of compensation for the person making the claim.

In some countries, NFC systems for vaccine-related injuries existed prior to the COVID-19 pandemic, and these existing systems were repurposed to cover COVID-19 vaccine injury. In other cases, wholly new systems have been put into place by bespoke legislation.

Typically, such systems have parameters restricting access to compensation, such as: a requirement to establish causation; a level of injury or loss, based on e.g. severity or duration, below which no recovery is possible; and sometimes a cap on damages. Sometimes compensation is only payable in respect of injuries caused by compulsory vaccination, although some countries appear to have relaxed this requirement in relation to COVID-19 vaccines, which were generally recommended but not mandatory.

There is considerable variation in approach. For example, the pre-existing UK statutory vaccine damage payment system applies only in cases of significant disability (at least 60%) and sets compensation at a level far below ordinary common law compensatory damages for such injuries. The UK Government confirmed that the system would apply to COVID-19 vaccine injuries, but has otherwise made no adjustment.

In Sweden, there was a pre-existing insurance-based system under which injuries resulting from medicinal products (not limited to vaccines) are covered by an insurance fund, to which the pharmaceutical industry and the government both contribute. The Swedish system has been expanded to permit those suffering from COVID-19 vaccine injury to recover. According to the rules of the system, recovery is only possible if the injury suffered is deemed disproportionate to the expected benefits of the treatment, and the type or severity of the injury is such that it could not reasonably have been predicted. Nevertheless, the success rate for claimants seeking compensation through the scheme is around 35%.

Other Scandinavian countries (Denmark, Finland, Norway) have similar, albeit slightly more or less generous systems, with no-fault compensation paid in around 50% of cases for vaccine injuries.

In Estonia, a new vaccine insurance system has been introduced from 1 May 2022. It will operate retrospectively for those suffering injuries in 2021. Compensation will be payable where individuals have died, or where they have suffered adverse effects for four months or more. The amount of compensation depends on the damage suffered, but is capped at EUR 100,000.

Usually, the existence of such compensation systems does not prevent individuals from pursuing their claim via normal civil law proceedings against the manufacturer, but civil law rules prevent double recovery.

Advantages of an NFC System

The existence of an NFC system for vaccine injury should mean that individuals who suffer more serious injuries as a result of vaccination secure prompt compensation for their injuries without incurring the cost, delay and uncertainty of the judicial process associated with proving that a healthcare provider, company, government or other entity is at fault for that injury, or that a product was defective.

The relative speed, ease, and predictability of compensation under an NFC system makes the process much more reassuring for injured individuals and may reduce the negative effects of litigation to a significant degree. However, the advantages of such a system are reduced where compensation is reserved for the most severe injuries, and where the amount of compensation does not reflect that which would be awarded by a court for similar injuries.

From a manufacturer's perspective, the scope of any NFC system, and whether this precludes parallel or sequential claims through the courts, may determine whether it is viewed as an acceptable solution. In particular, any arrangement whereby low-value or weak claims are compensated through the NFC system, with strong or high-value claims proceeding by way of litigation, whether to top up awards made through the NFC mechanism or as independent actions, may not be attractive.

Broader Implications for Product Liability?

The advantages of NFC systems are clear in the vaccine context and have been used successfully to provide compensation for injuries caused by medical products generally and in the context of clinical negligence. However, because healthcare provision, levels of compensation, and approaches to recovery vary significantly across different jurisdictions, it is difficult to see that any standard, one-size-fits-all system could be implemented. It might be possible for a transnational organisation, such as the EU, to define baseline requirements for NFC systems and require these to be set up in Member States, assuming that the requirements did not conflict with other provisions of Union law or with principles of subsidiarity. However, at present there seem to be no plans to introduce even such modest requirements at EU level.

As governments and transnational organisations grapple with issues of how to apply standard product liability regimes to other sorts of innovative products involving new technologies, NFC systems may start to be considered as alternative means of providing redress outside the contexts in which they have been traditionally used. Their viability in the long term will depend upon the extent to which traditional liability systems appear genuinely inadequate to the challenge of new technologies, and upon the appetite in government and industry for funding real alternatives.

Adela Williams is a partner in the London office of Arnold & Porter, specialising in product liability litigation (unitary actions and group litigation), principally involving life sciences clients and including claims involving unlicensed medical products in the research context as well as marketed products. Such litigation has often involved co-ordinating proceedings within Europe and advising on forum and other jurisdictional issues. Past cases include the fetal anticonvulsant litigation and the successful defence of group litigation involving more than 100 claims relating to the "third generation" oral contraceptive pill on behalf of two of the defendant manufacturers.
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Arnold & Porter is an international law firm with over 1,000 attorneys in 16 offices in the US, London, Brussels, Frankfurt, Shanghai and Seoul. With 40 partners and counsel specialising in product liability matters, the firm is one of the most experienced firms internationally, providing clients with an integrated product liability service on a transatlantic basis.
The European product liability group is a recognised leader in the UK and Europe, with comprehensive experience in handling the defence of claims. Its lawyers have been at the forefront of "group action" litigation, with experience derived from the successful defence of many major multi-claimant cases that have been brought in the UK and EU over the last 30 years. In the US, the firm has acted both as national counsel for companies and as trial counsel in cases involving personal injury and property damage claims.

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