A vaccine for COVID 19 –risks and liabilities in international perspective

Wouter Pors, Evelyn Tjon-En-Fa and Flora Peel[1]

As the development of vaccines against COVID-19 is progressing, the question becomes urgent who will be liable if a vaccine is marketed and will cause unexpected adverse effects as a result of the requested speed and scope of vaccine programmes.

Pharmaceutical companies have requested to, *inter alia*, the EU that they be exempted from civil liability. They advocate that this be replaced by a compensation system that isn't based on the presumption of any fault – a system that has been tested for some 40 years now in several jurisdictions. EU officials confirmed to Reuters that product liability is one of the biggest contentious issues in European efforts to secure a vaccine. AstraZeneca have reportedly come to a deal with Europe, although the commission has not yet commented on the details of liability. According to a Reuters report on the 26th August, the EU commission would only offer partial protection to manufacturers against liability, 'hampering deals in contrast to US policy.' The administration of the vaccine therefore lays in the balance of political, economic and sociological interests.

In this article, we will discuss the legal background as well as potential solutions for this intricate problem.

Vaccine background

To market a medicinal product, such as a vaccine, a market authorisation (license) is always required. In this case, the European Medicines Agency (EMA) must grant approval. One must be able to prove that the drug is safe and effective by undertaking clinical trials.

These clinical trials take place through four phases that normally take several years. For vaccines this works as follows.

- Phase 0 is optional and intended to gather pharmacodynamics and pharmacokinetics data on the functioning of the medicine in the human body.

- Phase I is the first time the product is administered to humans, aiming to test the safety of a small dose on a very small group of individuals under a very strict controlled environment.

- Phase II further assesses safety as well as whether the product generates a positive effect producing an immune system response. Once Phase II has been completed, it has been established that the vaccine has no serious adverse effects and that is does have efficacy, but

[1] The authors thank Fenna Douwenga, associate at Bird & Bird in The Hague, for her valuable input.

only in a relatively small group of participants, which may not be representative of the whole population.

- During 'Phase III', the product is tested on a larger group of patients. Generally, this is not a problem with a medicine against a disease, as opposed to a vaccine, as the medicine can be administered to patients which already have contracted the disease. The effects of the medicine on those patients can then be analysed over some time to determine safety, including adverse effects, and effectiveness amongst the large group.

However, Phase III presents a problem with vaccines. A vaccine is administered to a group of healthy individuals to prevent them from becoming unwell as a preventative measure. The efficacy of the vaccine can only be determined by using a diverse large group of randomised and voluntary individuals who are vaccinated with the candidate vaccine and assessing the numbers of those that remain healthy after they have come in contact with the target virus. Of course, it is not allowed to deliberately expose people to a virus, for instance by injection, as that would be unethical. Therefore, you simply have to wait until a sufficient number of participants has been exposed to the virus in the course of their daily life. The amount of time this will take is unpredictable, although it is clear that the number of participants that need to have come in contact with the virus, which needs to be in the range of 1000 – 3000 to complete Phase III, will be reached earlier in an environment with a high number of infections.

In order to reduce this time delay and pass Phase III relatively efficiently, the pharmaceutical companies carry out the trials in a country with a high infection rate. In the current COVID-19 case, AstraZeneca and Oxford University have chosen to carry out clinical trials in the US, South Africa and Brazil.

The other option is to authorise the vaccine into the market earlier under a provisional market authorisation, relying upon a smaller trialled group in Phase III that has actually been in contact with the virus. However, this clearly poses a risk that adverse effects which only occur very rarely do not surface when the group of people that showed positive results was limited to just a few hundred. Those adverse effects could then surface later on. Also, it may only become clear after some time that in a small percentage of the population the vaccine doesn't produce an effective immune system response, meaning that such group is not protected against the virus. As a result, damage could be suffered, and liability claims against the manufacturer may arise when the vaccine is allowed on the market under a provisional authorisation.

Of course, in this situation, Phase III continues once the provisional market authorisation has been granted until at some point in time a number of 1,000 – 3,000 participants have been in contact with the virus. Phase III is then completed. If no significant adverse effects have surfaced and the vaccine has proved to be effective in the whole group, final marketing authorisation can be granted. On the other hand, if serious adverse effects have now surfaced, or a significant number of the participants have become ill after all, the provisional marketing authorisation can be revoked and the vaccine taken off the market.

This means that there is a time window between the grant of the provisional market authorisation and the completion of Phase III during which there is a risk that would normally not exist if the vaccine was only put on the market after completion of Phase III.

Coronavirus vaccine

Due to the extreme time pressure of finding a COVID-19 vaccine, the completion of Phase III of the trials is vital. However, if tested in the normal way, it may not reach the market until mid-2021. Should the vaccine be entered into the market too early, there are concerns of illness or even fatality due to potentially unknown adverse effects or lack of efficacy in a small part of the population. It is also possible, of course, for the vaccine to enter the market early and safely, producing no damage nor side effects, but this cannot be predicted with enough certainty at sufficiently short notice.

Dr Jonathan Sheffield (National Institute for Health Research/ Dept of health and social care COVID-19 Liaison Director for Research) has claimed that it is the removal of “dead time” in funding and legal processes that must be sped up, and not the clinical phases themselves. However, that does not solve the problem, because the uncertainty about the actual length of the Phase III trials remains. Currently funding is not a problem; the pharmaceutical companies have taken care of that. Also, EMA can speed up the legal process sufficiently.

The manufacturers and pharmaceutical companies do not want to bear the risks of entering the vaccine into the market early, although based on public interest and health to prevent as many deaths and illnesses as possible, if that means that they have to carry the full risk of a market introduction when Phase III has not yet been completed. It may be that adverse effects or lack of efficacy later on occur in a very small part of the people to whom the vaccine is administered, but since the intention is to vaccinate the whole population, that might still pose a considerable financial risk. That risk would not exist, or at least to a much smaller extent, if the vaccine is introduced after Phase III is completed. That smaller risk is a risk that pharmaceutical companies usually take and that is part of their business model, but the larger risk of early introduction is not. Because of this, they have requested a "comprehensive no-fault and non-adversarial compensation system, and an exemption from civil liability".

‘No-fault compensation systems’

Worries about litigation and liability have previously delayed the availability of vaccines, even as other parts of the emergency response have been accelerated. For example, during the 2009 H1N1 influenza pandemic (swine-flu), WHO reduced the process of authorising drug approval from the usual 12–24 months to as little as one day. However, the legal concerns could not be solved in similar time.

Evidently, there is much debate from all parties to find the best solution in these challenging times, maintaining public health and trust whilst ensuring manufacturers are incentivized to develop life-saving vaccines in global pandemics. Governments are investing billions into vaccine production in favour of public interest and protecting health. Pharmaceutical companies are faced with the

challenge of unknown potential liability the vaccine may create, which prevents their ability to insure or protect against the risk of loss.

As mentioned in the introduction, EU officials have informed Reuters that product liability is one of the biggest contentious issues in European efforts to secure a vaccine. AstraZeneca have reportedly come to a deal with Europe, although the commission has not yet commented on the details of liability. According to a Reuters report on the 26th August, the EU commission would only offer partial protection to manufacturers against liability, 'hampering deals in contrast to US policy.' The administration of the vaccine therefore lays in the balance of political, economic and sociological interests.

Global approaches

The US has been at the forefront of developing no-fault compensation programmes for vaccines. In light of their legal system allowing for substantial claims including punitive damages, this is hardly surprising.

The National Childhood Vaccine Injury Act of 1986 (NCVIA) established the Vaccine Injury Compensation Program (VICP). This acts as a no-fault alternative to tortious claims resolving vaccine injury claims. Congress introduced the VICP to protect pharmaceutical companies following much discussion of civil liability claims against Pertussis vaccine manufacturers (1980s), that had resulted in a flood gate of lawsuits. Consequently, the number of vaccine manufacturers in the US dropped precipitously.[2] The VICP, however, only offers limited protection. The vaccines must be listed by the statutes on a 'Vaccine Injury Table' – injuries known and expected to be caused as minor side effects. Furthermore, the act is only applicable in the US and does not have extraterritorial application.

In the US, the "2005 Public Readiness and Emergency Preparedness Act (PREP)" more broadly excludes tort claims from products that help to control a public health crisis. This act has been triggered in relation to COVID-19 in the US by the Secretary of HHS declaring a public health emergency, effective from February 4th, 2020. These provisions mean that qualified pandemic products are "*immune from liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a Declaration has been issued with respect to such countermeasure.*"

Europe

Much alike the VICP, the UK introduced the Vaccine Damage Payments Act 1979 (VDP Act) very early on. This Act established a national fund to provide compensation to those injured by vaccines. As in the US, it was enacted following the Pertussis vaccine health concerns in the 1980s. The injuries must be contained in a statutory list to qualify under this act. However, with regard to the COVID-19 vaccine,

[2] **Toward a Global Solution on Vaccine Liability and Compensation** – https://www.fdli.org/wp-content/uploads/2019/03/Winter.pdf - *JOHN D. WINTER, CASSYE COLE, AND JONAH WACHOLDER (Patterson Belknap Webb & Tyler LLP)*

the problem is not only injury from adverse effects, but also a potential lack of efficacy in parts of the population.

An interim solution is possible via a provisional market authorisation. For example, if it has been established in Phase III that 200 vaccinated people have been infected with the virus without becoming unwell, the Phase III research continues, and the final market authorisation is granted when 3000 vaccinated test subjects have been infected without becoming ill. There is therefore a short period of time with an increased safety risk, until final clarity is obtained. The manufacturer of the vaccine only needs protection for this short period of time. In addition, the Conditional Marketing Authorisation Regulation provides for this provisional market authorisation. However, this regulation does not provide any limitation of the manufacturer's liability.

The 1985 EU Product Liability Directive has an exception if the manufacturer can prove "*that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered*" (article 7(e)). This Directive has been implemented in each of the EU member states. However, this directive does not provide certainty to exemption of liability, which a specific emergency provision would clearly provide. Besides, it could be argued that there is a way to enable discovery of the defect, namely by completing Phase III, and this is already available. That would defeat the exception. Furthermore, most EU jurisdictions have a separate tort-based ground for civil liability for manufacturers that – in short – market a product when taking health risks that could be prevented or reduced by more severe testing.

It is also unclear whether the manufacturer's liability insurance would cover liability in this case. The clarity of this lays in the law that governs the insurance contracts and the extent of the policy conditions. This uncertainty could be solved using an emergency law. The problem for insurers is their inability generally to change their policy terms unilaterally and in the interim period but can see potentially unmanageable risks arising. And once the policy can be renewed, negotiations about premium increases will be very complicated. Also, it's conceivable that the companies now expecting to produce and market millions of vaccines will face difficulties in re-placing their risks. Insurers and re-insurers might be very reluctant to take on these large-scale risks, without having certainty yet about the position of governments. Interestingly though, according to the Financial Times, investors are also pouring billions into insurance companies, despite the risks, in the hope it will justify price increases for new policies.

Possible solutions

Although very common in the US, emergency laws protecting manufacturers of vaccines are not as usual in Europe.

Product liability is regulated at EU level, and therefore in principle, the emergency solution should also take place at EU level. Due to the urgency of the matter, a regulation would be far more efficient with better paperwork than a directive. A directive must still be implemented by member states, taking up valuable time that may not be available.

It is highly conceivable that the insurance companies, together with the pharmaceutical companies, may ask governments for an emergency no compensation fund should a generic legal exclusion of liability (as in the US) were to not occur, to at least share the risks amongst themselves and with governments Such funds could either be established on an EU level or on a country-by-country basis. Clearly an EU-wide fund will have many advantages, but the time to set up such a structure is extremely limited. Additionally, we believe that any exemption or limitation of civil liability imposed by the EU or national government could only be possible should the vaccination of citizens be voluntary.

There would be a possibility to balance all interests if an exemption or limitation would as a minimum be limited to vaccines that were administered in the relatively short period between the provisional authorisation and the completion of Phase III. On the one hand this would probably cover the most pressing need from industry, as it would specifically relate to the additional risk for industry compared to a normal market introduction. On the other hand, it would constitute only a moderate limitation of the ability of patients to claim damages, also taking into consideration that patients would always have the option to await the outcome of Phase III before getting a vaccination. In addition, if communicated clearly to the public, it should have no or almost no effect on the public's trust in vaccination programmes. Finally, the size of an eventual EU-fund will probably not be all too burdensome for the member states when compared to the socio-economic impact of a significant delay in rolling out vaccine programmes.

No fault compensation funds are in widespread use across strongly developed vaccine markets, with as many as 19 jurisdictions already having a system in place.[3] These compensation programmes remove vaccine injury from tortious claims and become publicly administered, protecting vaccine manufactures and continuing to stimulate vaccine innovation, keeping costs low for public programmes. Global compensation funds also help to protect those in low income countries for vaccine related injuries.

A no-fault vaccine programme generally has the following features, according to a detailed Canadian study of vaccine-injury compensation programmes across the world:[4]

- The recognition that there are situations of unavoidable or unintended medial injuries that merit compensation. Traditional tort litigation is premised on the principle aim to punish wrong-doings (punitive) and to deter the public from doing harm to others (deterrence). A no-fault system sets that principle aside.
- Because there is no fault presumed, compensation is needs-based rather than punitive, and is therefore both relatively modest and proportionate to the injury.

[3] See: https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001911#pmed.1001911.ref020
[4] See: https://munkschool.utoronto.ca/wp-content/uploads/2012/07/Keelan-Wilson_NoFaultVaccine_CPHS_2011.pdf; the enumeration in this paragraph is close to a literal quote from this study, but with a few amendments and additions.

- Unlike jury trials as customary in many common law-countries, no-fault compensation processes are more likely to be consistent both in the type of award and in the amount of compensation.
- No-fault programmes can rapidly resolve injury claims by either using a fixed table of vaccine-associated injuries or an administrative or judicial review of each case (as opposed to civil litigation which is always adversarial, almost always more expensive and very often more time consuming).[5]
- No-fault compensation programmes move vaccine injury cases out of the tort arena into a publicly administered or regulated programme. This not only saves legal fees but also helps to stimulate vaccine innovation and manufacturing thereby keeping the costs of vaccines low for public programmes.[6]
- Giving those injured access to a reasonable, restitutive process weakens the power of vaccine's fiercest critics.

The Financial Times have reported the concern of an EMA board member who represents the patient's interests about the impact on vaccination compliance: will more people be turned away from the vaccination in general? However, this can be counteracted entirely by the emergency law stating that this solution should only apply to this specific emergency, the COVID-19 pandemic. Information on why this solution was chosen, namely to prevent as many illnesses and deaths as possible, should also be provided. Conceivable adverse effects, or those known to occur (especially if mild to a serious COVID-19 infection) could be outlined, much like in the UK VDP statutory list and those contained in the US VICP.

The EMA should not be presenting this request from the industry as "pharma pressure"; the delay in the availability of vaccine is caused by regulations, and the solution is requested in the interest of public health. The manufacturers should not be unfairly burdened with the additional regulatory risks should the vaccine be desired earlier than normal status quo to deal with the global pandemic.

[5] The study refers to Bismark, M., and R. Paterson. 2006. "No-fault compensation in New Zealand: harmonizing injury compensation, provider accountability, and patient safety." Health Affairs 25(1): 278–83

[6] The study refers to Evans, G. 1996. "National Childhood Vaccine Injury Act: revision of the vaccine injury table." Pediatrics 98 (6 Pt 1):1179–81. 2006. "Update on vaccine liability in the United States: presentation at the National Vaccine Program Office Workshop on strengthening the supply of routinely recommended vaccines in the United States, 12 February 2002." Clinical Infectious Diseases 42 Suppl. 3:S130–7