



No-fault compensation systems and legislative liability protections white paper

In the face of an emerging pathogen with pandemic potential, innovative pharmaceutical companies, researchers, governments, funders, manufacturers, distributors, providers, and healthcare professionals across the world will again answer the call to develop and deliver novel vaccines to avert or control a newly emerging pandemic threat. A key learning from the COVID-19 pandemic was that, for these efforts to be successful, we must not only expedite the development and approval of pandemic vaccines, but also support their rapid distribution to and acceptance by potentially billions of individuals in mass vaccination programs around the world. Public understanding of the efficacy and safety profiles of the products developed for a potential pandemic is critical to that public acceptance, but more is needed to manage alleged vaccine-related adverse events and ensure continued vaccine uptake.

Accordingly, we call for the pandemic response to include well-designed no-fault compensation (NFC) systems that provide an administrative, non-judicial process for individuals to seek compensation for allegedly vaccine-related injuries as an essential element to achieving rapid vaccine uptake. Importantly, an NFC system should be coupled with legislative liability protections for entities throughout the supply chain whose ability to efficiently develop, distribute, and administer vaccines may be hindered by excessive litigation.¹

It is important to act now to ensure that governments and other stakeholders either have in place or can implement NFC systems and legislative liability protections upon the emergence of new pandemic threats. During the early months of the COVID-19 pandemic, we saw the profound challenges associated with trying to adopt these measures in the midst of an ongoing pandemic. These challenges delayed public access to NFC systems and likely undercut the effectiveness of global vaccination programs. While successful NFC programs were already well established in several countries, their use was greatly expanded during the COVID-19 pandemic to cover COVID-19 vaccines, and in some cases additional products, in 147 countries. Governments should act now to either implement permanent NFC systems and liability protections for all vaccines, or at least ensure that a framework is in place that automatically comes into operation upon the declaration of future pandemic threats. We call for governments to build on what has been established for COVID-19 and can be applied to future pandemics. Concretely, this means implementing fit-for-purpose NFC systems along with liability protections that will be ready for the next pandemic threat.

I. Why do we need NFC systems and legislative liability protections?

Well-designed NFC systems can enhance vaccine confidence and uptake by providing efficient access to compensation while mitigating the risks associated with costly and time-consuming vaccine litigation. Just as they did during the COVID-19 pandemic, developers and manufacturers will research, register, manufacture, and supply novel pandemic vaccines in accordance with applicable laws, regulations, and good industry practices. Novel pandemic

¹ While this paper focuses on pandemic preparedness context, NFC systems may prove equally valuable in other contexts, including with regard to routine vaccination programs.



Vaccines Europe
An industry for healthy lives

vaccines require rigorous studies on safety and efficacy while a vaccine is under development, and regulatory authorities must work with manufacturers to review and approve novel pandemic vaccines on an expedited timeline, assessing the vaccine's benefit in the context of the risk posed by an emerging pandemic.

Despite these efforts, some people may experience adverse events following immunization, as is the case for all vaccines. And, regardless of whether these adverse events are actually caused by novel pandemic vaccines, such events could lead to personal injury lawsuits alleging that a serious injury resulted from the negligence of some person or a defect in the vaccine. Such litigation may be brought not just against vaccine developers and manufacturers, but also healthcare professionals and institutions, public health authorities, and other entities involved in the development, manufacture, and deployment of vaccines such as governments and non-government organizations. History has shown that injured people can remain uncompensated for a long time, assertions concerning vaccine safety can remain unresolved, and public confidence in vaccination programs can be significantly undermined.² Put simply, vaccine litigation entails delay and expense for the individual, without necessarily achieving the most important goal: ensuring that people who experience injuries allegedly caused by vaccines receive prompt and appropriate compensation.

Well-designed NFC systems can play an important role in mitigating the risk of vaccine hesitancy, which can be fueled by uncompensated (and potentially unsubstantiated) injuries and potential litigation. No-fault compensation is an approach based on the principle that injured parties can be compensated without having to prove that any person or entity is at fault for their injury, and without having to prove that the vaccine is defective. In contrast, most NFCs require establishing, based on a reasonable standard such as “preponderance of the evidence,” that administration of the vaccine caused the injury. In the context of novel pandemic vaccines, this would mean that families with individuals who experience an alleged vaccine-related injury, disability, or death could secure prompt compensation for injuries without having to incur the cost, delay, and uncertainty of proving that the vaccine was defective in court, or that the healthcare provider, company, or government is otherwise at fault for their injury. NFC systems thus provide more efficient and expeditious relief to those injured which, in turn, helps to preserve confidence in vaccination, spur vaccine uptake, and ensure that government spending on vaccination programs maximizes efficiency. An effective NFC program would be particularly critical in the event of the emergence of an extremely contagious and virulent pandemic pathogen. More broadly, NFC systems serve as a tangible example of the immunization social contract: Governments ask people to be vaccinated not only for their own health but also for the health of the larger community. In return, those vaccinated know they will be taken care of in the highly unlikely case of an alleged vaccine-related injury.

For NFC systems to best achieve their desired outcomes, they should be coupled with legislative liability protections for entities throughout the supply chain whose ability to efficiently develop, distribute, and administer vaccines may be hindered by excessive litigation. By adjusting the baseline liability standard for injuries allegedly caused by vaccines, such

² See e.g., Goldberg, R. (2013) 'Medicinal product liability and regulation.', Oxford: Hart Publishing., pg. 22. Available at: <https://dro.dur.ac.uk/11068/1/11068.pdf?DDD19+jrvs91+dul4eg+dlc4pz+jrvs91> (accessed 20 October 2022).



Vaccines Europe
An industry for healthy lives

protections can incentivize claimants to seek relief through NFC systems, while further mitigating the risk of resource-intensive litigation. Critically, such measures would extend liability protections to entities not typically covered by contractual indemnification arrangements, such as healthcare professionals and public health and humanitarian agencies like the International Red Cross that deploy vaccines to high-risk populations such as refugees. Such liability protections, coupled with well-designed NFC systems, will enhance public confidence and vaccine uptake by providing access to fair and rapid compensation in case of injury. Again, putting a fit-for-purpose legal liability framework in place before the next pandemic will be critical to rapid vaccine roll-out and should be considered as a basic prerequisite of pandemic preparedness. Where appropriate, legislative provisions governing liability for vaccine-related injuries may be supplemented by contractual indemnification arrangements.

II. What are the building blocks of well-designed NFC systems?

While national and regional NFC systems should be tailored to function effectively within existing legal regimes, experience has demonstrated at least eight key structural building blocks that jurisdictions should consider as they design and implement NFC systems:

1. **No-fault system:** Claimants should at most only be required to demonstrate a causal link between the vaccine and the relevant damages, without the need to prove negligence, fault, or product defect.
2. **Administrative structure:** Systems should be administered by a public administrative body. Systems should include an adequate funding mechanism, and additional financing sources can be added. NFC systems are preferably funded by government authorities so that they can become an enduring part of the civil compact.
3. **Governance structure:** Administrative bodies should include representation from diverse stakeholders, and the compensation process and related decisions should be both efficient and transparent. Decision-making panels should be composed of experts with clearly defined expertise (medical, legal, etc.).
4. **Covered vaccines:** NFC systems should at a minimum cover injuries allegedly resulting from pandemic vaccines. Systems may also cover injuries from other classes of vaccines, but to ensure adequate resources and tracking, NFC funding should be separate for pandemic vaccines. Anyone receiving covered vaccines in the relevant jurisdiction should be eligible to apply for compensation.
5. **Covered damages:** Systems should cover a broad class of damages, including death, injury, disability, pain, and suffering, and other forms of economic and potentially non-economic loss resulting from the injury. To avoid inefficient use of administrative resources, minor and transient injuries, e.g., a sore arm or headache, should not be covered.
6. **Compensation:** The level of compensation offered by the system, as supplemented by other governmental arrangements (e.g., social security programs), should be fair and sufficient both to provide quick and lasting relief and to mitigate any economic harm



caused by alleged vaccine-related adverse events. Consistent with the NFC designed by the WHO for the Covid-19 pandemic, the system should require that persons accepting compensation awards agree not to initiate personal injury litigation.

7. **Accessible and efficient procedures:** To function effectively, NFC systems must be known, accessible, and effective. NFC systems should use simple and easily available intake forms. Bringing claims should not require legal assistance and should be free of charge. The review and decision-making process should be well-defined and easily understood by claimants, and systems should have efficient timelines for processing claims and rendering decisions. NFC systems should allow claimants to appeal decisions within the compensation system and finally through the courts, with any judicial appeal being directed against the compensation system (not against the manufacturer or any other party). Jurisdictions should implement strategies to ensure broad public awareness of their compensation system, and systems need to be properly resourced, scalable, and have the proper infrastructure to handle the case load. Finally, systems should adopt a “learn as you go” approach, making administrative adjustments, as appropriate, to continuously improve their processes and delivery.
8. **Transparency:** NFC systems should include formal, well-defined transparency measures, such as mandatory annual reports and/or requirements to regularly provide public access to system information (e.g., claims received, claims accepted, and compensation amounts), while protecting individual privacy.

III. **Is there a precedent for deploying NFC systems and legislative liability protections in the pandemic context?**

Yes. In response to the COVID-19 pandemic, NFC systems were established in every region of the world and across a range of economies, often coupled with legislative liability protections. These NFC systems cover people in 147 countries, and include a combination of national, regional, and global NFC systems. Notably, the COVAX facility’s global NFC program covers people in 92 low- and lower-middle income economies;³ the regional African Vaccine Acquisition Trust (AVAT) covers members of the African Union;⁴ and the UNICEF Multilateral Organization (MLO) NFC system covers vaccines distributed by UNICEF in 18 countries in South Asia and the Western Pacific.⁵ Research led by Oxford University is ongoing to assess and compare the NFC programs developed in response to the COVID-19 pandemic. The results of this research as well as other available evidence should inform the design and implementation of future NFC systems.

³ See COVAX No-Fault Compensation Program for AMC Eligible Economies, <https://covaxclaims.com/>. COVAX is a worldwide initiative aimed at equitable access to COVID-19 vaccines directed by the GAVI vaccine alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization (WHO), alongside delivery partner UNICEF. It is one of the four pillars of the Access to COVID-19 Tools Accelerator, an initiative begun in April 2020 by the WHO, the European Commission, and the government of France as a response to the COVID-19 pandemic.

⁴ See AVAT No-Fault Compensation Scheme, <https://avatclaims.com/>.

⁵ See UNICEF COVID-19 Vaccine Facility No-Fault Compensation Scheme, <https://c19vaccinenfc.com/>.



Due to the lack of an existing framework for the adoption of NFC systems and legislative liability protections in most jurisdictions at the start of the pandemic, COVID-19 vaccine recipients in many countries did not gain access to NFC systems until months after vaccines became available. This could be avoided in future pandemics by acting now to lay the groundwork for the adoption of NFC systems and legislative liability protections in response to emerging pandemic threats.