



**The Legal Gap in Vaccine Injury Compensation: Advocating for The Implementation  
of a No-Fault Scheme for State-Approved Vaccines in Kenya**

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Strathmore University Law School

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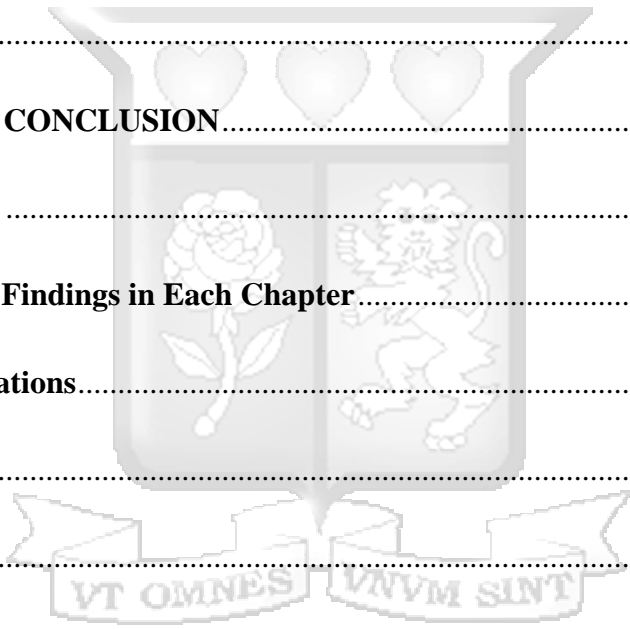
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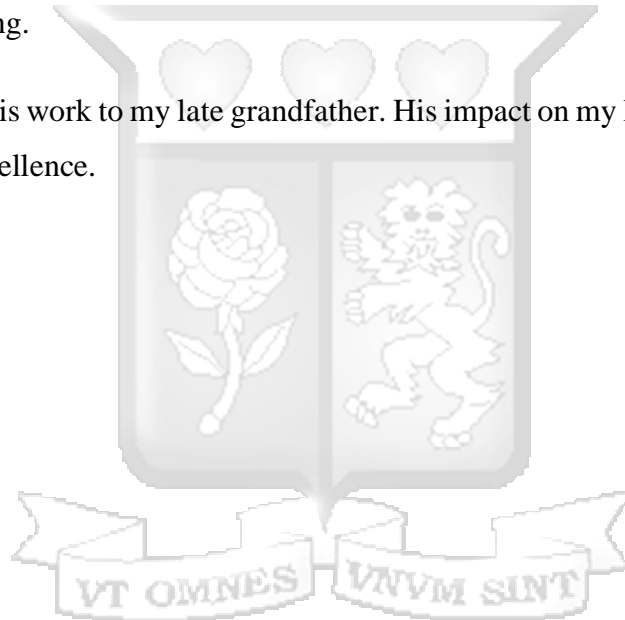
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Lastly, I dedicate this work to my late grandfather. His impact on my life continues to inspire me to strive for excellence.




## DECLARATION

I, Michelle Grace Adhiambo Odhiambo, do hereby declare that this research is my original work and that to the best of my knowledge and belief, it has not been previously, in its entirety or part, submitted to any other university for a degree or diploma. Other works cited or referred to are accordingly acknowledged.

Signed:  .....

Date: 14<sup>th</sup> March 2025 .....

This dissertation has been submitted for examination with my approval as University Supervisor.

Signed:  .....

Claude Kamau

Date: 14<sup>th</sup> March 2025 .....

## **LIST OF ABBREVIATIONS**

AEFI - Adverse Event Following Immunization

COVAX - COVID-19 Vaccines Global Access

COVID-19 - Coronavirus Disease 2019

GAVI Global - Alliance for Vaccines and Immunizations

KEPI - Kenya Expanded Program on Immunization

KNPP - Kenya National Pharmaceutical Policy

MoH - Ministry of Health

NCIP - National Council of Immunization Program

PPB - Pharmacy and Poisons Board

UK - United Kingdom

USA - United States of America

VDPS - Vaccine Damages Payments Scheme

WHO - World Health Organization



## LIST OF CASES

*G (A Minor) v Secretary of State for Work and Pensions* (2017), Court of Appeal (England and Wales).



## LIST OF LEGAL INSTRUMENTS

### *International Instruments*

Equality Act, 2010.

Vaccine Damage Payments Act, 1979.

The Vaccine Damage Payments (Specified Disease) Order 2020.

### *Local instruments*

Constitution of Kenya, (2010).

Consumer Protection Act

Guidelines for Monitoring, Reporting and Managing Adverse Events Following Immunization (AEFI) in Kenya - Pharmacy and Poisons Board

Health Act, (Act No. 21 of 2017).

Kenya National Immunization Policy Guidelines, 2023.

Persons with Disabilities Act, 2003.

Pharmacy and Poisons Act, 2023.

Social Assistance Act.

Work Injury Benefits Act, 2007.

## **ABSTRACT**

*The deployment of vaccine programs in Kenya is governed by various legal and ethical frameworks. However, the absence of a national no-fault vaccine injury compensation scheme leaves individuals who suffer adverse effects without adequate legal protection or financial redress. Currently, Kenya's fault-based system requires victims to prove negligence via tort claims, creating significant barriers to compensation for those with and undermining public trust in vaccination efforts. This study critically examines the legal and policy gaps in compensation for adverse effects following immunization and explores how Kenya can establish a no-fault compensation model that aligns with global best practices.*

*The study uses a comparative legal analysis to evaluate the legislative, judicial, and administrative framework of the UK's Vaccine Damage Payment Scheme (VDPS) as a possible model for Kenya to follow. The study also employs doctrinal and policy analysis to evaluate the effectiveness of Kenya's existing legal provisions and their compatibility with a no-fault scheme.*

*The results of findings show that although vaccination programs in Kenya have advanced significantly, those who suffer from adverse effects after immunization, especially those who cannot afford legal claims, have limited access to justice due to the absence of a formal vaccine injury compensation scheme. The research highlights key challenges, including jurisprudential gaps, regulatory ambiguities, and financial sustainability concerns.*

*This study contributes to the discourse on health law, equity, and public trust in vaccination programs, offering a new perspective on the role of a no-fault compensation scheme in Kenya's legal system. It recommends legislative amendments, administrative reforms, and sustainable funding mechanisms to facilitate the establishment of a fair, transparent, and accessible vaccine injury compensation scheme. By addressing this legal gap, Kenya can enhance public confidence, align with international standards, and uphold the constitutional right to health.*

# CHAPTER ONE: INTRODUCTION

## 1.1 Background

Vaccination is the artificial induction of immunity in the body of an organism via a vaccine.<sup>1</sup> It is a major form of prevention of infectious diseases or lowering the chance of severe disease for individuals.<sup>2</sup> It is a crucial public health strategy endorsed by international bodies as a means of controlling epidemics and safeguarding populations through widespread immunity. The World Health Organization has estimated that vaccination prevents 3.5–5 million deaths per year.<sup>3</sup>

Vaccination has long been recognized as a cornerstone of public health in Kenya, guaranteeing its citizens, both adults and children, protection against a range of infectious diseases. In Kenya, the oversight of national vaccination programs involves a multi-layered institutional structure. The Ministry of Health leads policy formulation and coordination of healthcare services in Kenya. The PPB has the overall responsibility of regulation and pharmacological surveillance ensuring that all health products, including vaccines, used in the country are of good quality, are efficacious and are safe for use.<sup>4</sup> The Pharmacy and Poisons Act (Cap 224) has been a central piece of legislation in this regard as it confers wide-ranging powers and functions to the Pharmacy and Poisons Board.<sup>5</sup> At the county level, local health departments are responsible for the implementation and distribution of vaccines, ensuring that national policies are effectively translated into community-level interventions.

Despite their significant benefits, vaccines are not entirely free of risks. These risks are a rare phenomenon but can occur because vaccines cannot be 100% safe or effective for everyone. After all, each person's body can react differently. Adverse events following vaccination (AEFI) are any untoward occurrences following immunization, regardless of a direct causal link with the vaccine. These harmful outcomes range from minor reactions, such as soreness or fever, to more serious complications that may have lasting health

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<sup>1</sup> *What do vaccines do?* History of Vaccines <https://historyofvaccines.org/vaccines-101/what-do-vaccines-do> on 18 February 2025.

<sup>2</sup> Caddy S L, 'Coronavirus: few vaccines prevent infection – here's why it is not a problem' *The Conversation*, 5 January 2021 "[Coronavirus: few vaccines prevent infection – here's why that's not a problem](#)". *The Conversation* on 18 February 2025.

<sup>3</sup> "Vaccines and immunization". *World Health Organization*.

<sup>4</sup> World Health Organization Regional Office for the Western Pacific, 'Immunization Safety Surveillance: Guidelines for immunization programme managers on surveillance of adverse events following immunization' World Health Organization, 2013.

<sup>5</sup> Section 3, Pharmacy and Poisons Act, (2023).

impacts, such as physical injuries, psychological harm, or even death.<sup>6</sup> Serious adverse events following immunization, though rare, have the potential to dent public confidence in immunization and cause refusals for immunization. This can result in populations that are susceptible to disabling and life-threatening vaccine preventable diseases.<sup>7</sup>

Globally, vaccine injury liability models have emerged as a critical policy tool to provide compensation to those adversely affected by vaccines.<sup>8</sup> No-fault schemes ensure that compensation is provided based on accountability rather than liability; thus, financial redress is given without the need for the injured party to prove fault or negligence ensuring justice for affected individuals. The Global Advisory Committee on Vaccine Safety stated that no-fault schemes are considered a measure to maintain confidence in immunization programs, as they increase the adequacy and fairness of compensation by providing clear criteria and processes to access compensation for vaccine injuries.<sup>9</sup>

Kenya's approach to vaccine injury compensation primarily operates on common law tort claims, which rely on a fault-based system. This requires individuals to prove negligence in the manufacture or administration of vaccines and product liability to receive compensation.<sup>10</sup> For example, in 2017, the High Court ordered the Busia County Government to compensate victims of malaria vaccines due to professional negligence.<sup>11</sup> However, these cases are often lengthy which causes the claimants suffering while dealing with their injury without recourse through compensation, especially for a vulnerable

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<sup>6</sup> Scott L D, 'Vaccine related injury: Problems and solutions' *Journal of Law, Medicine & Ethics*, 31(3), 2003, 419-428.

<sup>7</sup> Guidelines For Monitoring, Reporting And Managing Adverse Events Following Immunization (AEFI) In Kenya.

<sup>8</sup> Holland M S, 'Liability for vaccine injury: the United States, the European Union, and the developing world' *67 Emory LJ*, 2017, 415.

<sup>9</sup> 'Injury compensation' WHO Weekly Epidemiological Record, 25 January 2019, <https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/pharmacovigilance/injury-compensation> on 20<sup>th</sup> February 2025.

<sup>10</sup> Harrington D N, 'COVID-19 vaccine safety and compensation: The case of Sputnik V' The Elephant - African analysis, opinion, and investigation, 27 November 2023, <https://www.theelephant.info/opinion/2021/06/18/covid-19-vaccine-safety-and-compensation-the-case-of-sputnik-v/> > on 18<sup>th</sup> February 2025.

<sup>11</sup> Odanga I, 'Busia to pay Sh42m to victims of toxic jab' Health, 29 October 2019 <https://www.standardmedia.co.ke/health/article/2001347325/busia-to-pay-sh42m-to-victims-of-toxic-jab> > on 18<sup>th</sup> February 2025.

person.<sup>12</sup> Also, such a system poses significant challenges, including high legal costs and the difficulty of obtaining evidence against manufacturers or healthcare providers.<sup>13</sup>

In Kenya, the Work Injury Benefits Act provides for compensation to an employee for an injury that occurs in the course of work. This could apply to healthcare workers, frontline responders, teachers and other essential workers because employers may mandate vaccinations for workplace safety. If an employee suffers a vaccine-related injury due to an employer-mandated vaccine, they might claim compensation under this Act. However, consumers who are not workers are not protected by this provision.

Various countries expanded their vaccination programs in response to the COVID-19 pandemic.<sup>14</sup> In 2021, due to the global increase in the demand for COVID-19 vaccines, Kenya had to rely on donations to fulfil the demand for vaccination in the country. COVAX has been instrumental in securing vaccine doses while providing a compensation scheme for AEFI without resorting to lengthy proceedings. This scheme is open to eligible individuals in 92 low- and middle-income countries, including Kenya, is specific to COVID-19 vaccines distributed through COVAX and does not cover other vaccines or those procured outside this mechanism.<sup>15</sup> The COVAX compensation scheme is time-bound, with its duration linked to the pandemic. Under this scheme, compensation is provided for serious adverse events associated with COVAX-distributed vaccines to reduce the need for court cases, which can be both time-consuming and costly.<sup>16</sup>

Despite the introduction of the COVAX no-fault compensation scheme, several challenges persist in Kenya. The Kenyan government has warned insurance companies against offering coverage for vaccine side effects, terming such practices unethical and unnecessary.<sup>17</sup> This position limits avenues for individuals seeking compensation for vaccine-related injuries

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<sup>12</sup> Wanyoro C, 'Court orders hospital to pay woman Sh25m for negligence' Nation, 29 June 2020 [https://nation.africa/kenya/counties/meru/court-orders-hospital-to-pay-woman-sh25m-for-negligence--205572?utm\\_source=chatgpt.com](https://nation.africa/kenya/counties/meru/court-orders-hospital-to-pay-woman-sh25m-for-negligence--205572?utm_source=chatgpt.com) on 18<sup>th</sup> February 2025.

<sup>13</sup> Harrington D N, 'COVID-19 vaccine safety and compensation: The case of Sputnik V' The Elephant - African analysis, opinion, and investigation, 27 November 2023, <https://www.theelephant.info/opinion/2021/06/18/covid-19-vaccine-safety-and-compensation-the-case-of-sputnik-v/> > on 18<sup>th</sup> February 2025.

<sup>14</sup> Halabi S, Ginsbach K., Gottschalk K, Monahan J and Murungi J, 'No-fault vaccine injury compensation systems adopted pursuant to the COVID-19 public health emergency response' *Emory Int'l L. Rev.* 2022, 55.

<sup>15</sup> COVAX AMC, 'Program Protocol' 16 September 2024 <https://covaxclaims.com/> on 18<sup>th</sup> February 2025.

<sup>16</sup> COVAX AMC, 'COVAX No-Fault Compensation Program for AMC eligible economies' 16 September 2024 <https://covaxclaims.com/> on 18<sup>th</sup> February 2025.

<sup>17</sup> Jerving S, August 122021, Kenya calls insurance for COVID-19 vaccine side effects "unethical." *Devex.* <https://www.devex.com/news/kenya-calls-insurance-for-covid-19-vaccine-side-effects-unethical-100593> > on 18<sup>th</sup> February 2025.

related to COVID-19 vaccines. During this time, there was also a lot of misinformation and disinformation on the vaccines for COVID-19, which led the public to doubt whether the vaccines could be harmful to people's physical and mental health.<sup>18</sup> The Ministry of Health also banned the administration of the Russian Sputnik V Vaccine until further notice as it was being imported by the private sector.<sup>19</sup> Also, the Sputnik V vaccine was controversial as Russia claimed to provide partial indemnity for all doses, even when the Russian government had approved its use before completing large-scale human trials.<sup>20</sup>

Agencies such as the WHO and various international health ethics bodies advocate for the incorporation of fair compensation mechanisms as an integral component of vaccination programs.<sup>21</sup> Ethical principles such as beneficence, non-maleficence, and justice demand that states assume responsibility for any harm resulting from public health interventions that are undertaken for the collective benefit. These guidelines underscore the importance of having transparent, accessible, and equitable vaccine injury compensation schemes that operate on a no-fault basis, ensuring that every individual who suffers an adverse event is met with a prompt and just response.<sup>22</sup>

In 2022, the PPB developed an online AEFI system.<sup>23</sup> Through AEFI surveillance, it is possible to identify, collect and analyse real-time data on vaccine-related injuries.<sup>24</sup> It has a role, but it could do better on the response to these adverse events comprehensively. Data from the Kenya National Vaccine Safety Surveillance System indicate that adverse events following vaccination (AEFI) are reported at a rate of approximately 1 in 10,000 vaccinations. While this incidence rate is comparable to global figures, the absence of a

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<sup>18</sup> During this time there was also a lot of misinformation and disinformation on the vaccines for COVID-19,  
<sup>19</sup> Harrington D N, 'COVID-19 vaccine safety and compensation: The case of Sputnik V' The Elephant - African analysis, opinion, and investigation, 27 November 2023, <https://www.theelephant.info/opinion/2021/06/18/covid-19-vaccine-safety-and-compensation-the-case-of-sputnik-v/> > on 18<sup>th</sup> February 2025.

<sup>20</sup> Ivanova P, & Boadle A, 'Confident Russia vows to shoulder some of the legal liability of its COVID-19 vaccine' *Insurance Journal*. 2020 <https://www.insurancejournal.com/news/international/2020/09/23/583733.htm> on 18<sup>th</sup> February 2025.

<sup>21</sup> 'Injury compensation' WHO Weekly Epidemiological Record, 25 January 2019, <https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/pharmacovigilance/injury-compensation> on 20<sup>th</sup> February 2025.

<sup>22</sup> Halabi, S., Heinrich, A., & Omer, S. B. (2020). No-Fault compensation for vaccine injury — the other side of equitable access to COVID-19 vaccines. *New England Journal of Medicine*, 383(23), e125.

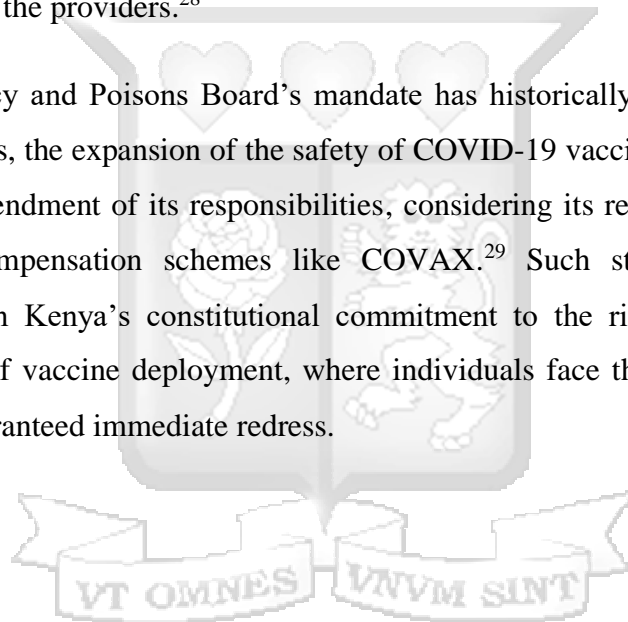
<sup>23</sup> Ppb\_Admin. (2022, June 26). Kenya drug regulator unveils new system to report adverse events through Phone – April 13, 2022 - Pharmacy and Poisons Board.< <https://web.pharmacyboardkenya.org/kenya-drug-regulator-ppb-unveils-new-system-to-report-adverse-events-through-phone/> > on 18<sup>th</sup> February 2025.

<sup>24</sup> World Health Organization Regional Office for the Western Pacific. Immunization Safety Surveillance: Guidelines for immunization programme managers on surveillance of adverse events following immunization (second edition) [Internet]. World Health Organization; 2013.

dedicated compensation mechanism has led to public apprehension. Reports from international media and peer-reviewed studies reveal that vaccine hesitancy in Kenya has been partly fuelled by the occurrence of AEFIs.<sup>25</sup>

The tension is compounded by an evolving global public health landscape. Comparative analysis with different jurisdictions reveals that countries with vaccine injury compensation schemes tend to exhibit higher levels of public confidence in vaccination programs.<sup>26</sup> Public trust in vaccines is important to the success of any vaccination program to achieve high vaccine coverage.<sup>27</sup> Public awareness of vaccine safety has increased because of increased access to information through various media; healthcare providers have also become more vigilant because of strengthened AEFI training therefore, more information is demanded by both the public and the providers.<sup>28</sup>

While the Pharmacy and Poisons Board's mandate has historically encompassed diverse regulatory functions, the expansion of the safety of COVID-19 vaccines in the 21st century necessitates an amendment of its responsibilities, considering its reliance on international vaccine injury compensation schemes like COVAX.<sup>29</sup> Such studies underscore the disconnect between Kenya's constitutional commitment to the right to health and the practical realities of vaccine deployment, where individuals face the rare risk of adverse events without guaranteed immediate redress.



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<sup>25</sup> Malande O O, Munube D, Afaayo R N, Chemweno C, Nzoka M, Kipsang J, Musyoki A M, Meyer J C, Omayo L, & Owino-Okongo L, 'Adverse events following immunization reporting and impact on immunization services in informal settlements in Nairobi, Kenya: a prospective mixed-methods study' 40 *PubMed*, 2021, 81.

<sup>26</sup> Keane MG, Moloney T, Lee C, O'Sullivan M, & Long J 'Vaccine injury redress programmes. An evidence review' 2019.

<sup>27</sup> Guidelines For Monitoring, Reporting And Managing Adverse Events Following Immunization (AEFI) In Kenya.

<sup>28</sup> WHO, 'Global Manual on Surveillance of Adverse Events Following Immunization' 2014

<sup>29</sup> Harrington D N, 'COVID-19 vaccine safety and compensation: The case of Sputnik V' The Elephant - African analysis, opinion, and investigation, 27 November 2023, <https://www.theelephant.info/opinion/2021/06/18/covid-19-vaccine-safety-and-compensation-the-case-of-sputnik-v/> > on 18<sup>th</sup> February 2025.

## **1.2 Statement of Problem**

Section 3B(t) of the Pharmacy and Poisons Act (Cap 224) mandates that the Pharmacy and Poisons Board shall perform any other function relating to the regulation of medicinal substances. However, it fails to establish a no-fault vaccine injury compensation policy for addressing adverse vaccine events after immunization. This legal gap undermines public trust in engaging with vaccination programs and contradicts Kenya's broader policy objective of upholding the right to health—a right enshrined in the constitution.

## **1.3 Research Hypothesis**

1. The absence of an explicit no-fault vaccine injury compensation policy for vaccine adverse events is correlated with decreased public trust in vaccination programs in Kenya.
2. The omission of a clear legislative mandate for vaccine injury compensation by the Pharmacy and Poisons Board in Section 3B of the Pharmacy and Poisons Act contributes to an underdeveloped institutional framework for managing vaccine adverse events.
3. Section 3B(t) allows the Pharmacy and Poisons Board to incorporate a no-fault vaccine injury compensation policy and thus will enhance the establishment of a robust compensation mechanism, thereby improving public trust in vaccination programs.

## **1.4 Research Objectives**

1. To analyse Kenya's current legal framework for vaccine deployment and rollout and assess its role in fostering public confidence in immunization and vaccination programs.
2. To explore the factors that have contributed to the absence of a clear legislative function for vaccine injury compensation by the Pharmacy and Poisons Board in Section 3B of the Pharmacy and Poisons Act of Kenya.
3. To evaluate and propose how the Pharmacy and Poisons Board can leverage its mandate under Section 3B(t) to implement a no-fault vaccine injury compensation

policy for vaccine adverse events, drawing on best practices identified through comparative legal analysis.

### **1.5 Research Questions**

1. What is Kenya's current legal framework for vaccine deployment and immunization?
2. What factors have led to the omission of a clear legislative function for vaccine injury compensation by the Pharmacy and Poisons Board in Section 3B of the Pharmacy and Poisons Act?
3. How can the Pharmacy and Poisons Board utilise its mandate in Section 3B(t) to implement a no-fault vaccine injury compensation policy and facilitate compensation of vaccine adverse events based on best practices identified through comparative legal analysis?

### **1.6 Justification**

The study intends to address the gap in the literature on the matter of a no-fault-based vaccine injury compensation scheme for vaccine injuries in Kenya, as compensation is limited to only fault-based litigation that requires civil cases. The research aims to discuss the importance of ensuring fair and accessible compensation for vaccine injuries, thus protecting vulnerable populations and ensuring ethical standards of social justice and equity. The findings will guide policymakers, researchers, and legal practitioners in drafting a national fault-based vaccine injury compensation scheme for vaccine injuries, which would create a positive impact on public trust in vaccination programs and state accountability.

### **1.7 Theoretical Framework**

#### **1.7.1 Virtue Ethics**

Virtue ethics is a philosophical approach that emphasizes the role of character and virtue in moral philosophy rather than either doing one's duty or acting to bring about good consequences. It is primarily concerned with the development of virtuous character traits such as courage, temperance, justice, and prudence.<sup>30</sup> According to virtue ethics, a virtuous person is someone who has developed these traits to a high degree and can navigate complex

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<sup>30</sup> Aristotle, *The Nicomachean Ethics*, Oxford University Press, 2009.

moral situations with wisdom and discernment, making ethical decisions that reflect their moral behaviour.<sup>31</sup> This approach contrasts with deontological ethics, which focuses on rules and duties, and consequentialism, which emphasizes the outcomes of actions.

Benbow argues that virtue ethics can ethically justify and morally support vaccination programs, associated compensation schemes and voluntary vaccinations. Virtue ethics supports a vaccine injury scheme by emphasizing the cultivation of virtues such as compassion, justice, and prudence. Vaccination programs contribute to the common good by preventing diseases and promoting public health.<sup>32</sup> Individuals who choose to participate in vaccination programs demonstrate virtues like prudence and courage. Therefore, the government shows compassion and justice by providing compensation to those injured by vaccines.<sup>33</sup>

Virtue ethics also applies to vaccine injury schemes by emphasizing the moral character and virtues of individuals and society in addressing the consequences of vaccination. Virtue ethics highlights the importance of compassion and justice in supporting those who suffer from vaccine injuries. By providing compensation and care, society acknowledges the sacrifices made by individuals for the common good and ensures that they are treated fairly and with empathy.

The implementation of a vaccine injury scheme reflects the virtue of prudence, as it involves careful planning and foresight to address potential adverse effects.<sup>34</sup> It also underscores the responsibility of society to protect and support its members, especially when they contribute to public health efforts. By establishing a fair and transparent vaccine injury scheme, society fosters trust and solidarity among its members. This trust is crucial for the success of vaccination programs, as individuals are more likely to participate when they believe that their well-being is valued and protected.

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<sup>31</sup> Study Of Ethics (Morals), Steemit <https://steemit.com/steemng/@otega/study-of-ethics-morals?sort=votes> on 20<sup>th</sup> February 2025.

<sup>32</sup> Benbow D I, Virtue ethics and the United Kingdom (UK) Vaccine Damage Payment Scheme (VDPS), 44: 3 *Journal of Social Welfare and Family Law*, 2022, 391-410.

<sup>33</sup> Benbow D I, Virtue ethics and the United Kingdom (UK) Vaccine Damage Payment Scheme (VDPS), 44: 3 *Journal of Social Welfare and Family Law*, 2022, 391-410.

<sup>34</sup> Benbow D I, Virtue ethics and the United Kingdom (UK) Vaccine Damage Payment Scheme (VDPS), 44: 3 *Journal of Social Welfare and Family Law*, 2022, 391-410.

Virtue ethics emphasizes the importance of the common good and the well-being of the community.<sup>35</sup> Vaccination programs are essential for preventing the spread of infectious diseases. By supporting those who experience vaccine injuries, society demonstrates a commitment to the common good and the protecting the health of the public.

In summary, virtue ethics supports vaccine injury schemes by promoting virtues such as compassion, justice, prudence, and responsibility, which contribute to the overall moral integrity and well-being of society. This expectation forms the ethical and legal foundation for compensatory mechanisms like vaccine injury compensation schemes. When such mechanisms are absent or inadequate—as is the case with the current gap in Kenya’s legal framework—the state can be seen as failing in its contractual duty to promote the well-being of its citizens and also be seen as a failure to uphold virtues such as justice and can, therefore lead to decreased trust in vaccination programs.

A virtuous policymaker would recognize that ensuring just compensation aligns with the common good, reinforcing ethical governance and public confidence. By actively incorporating a compensation mechanism, the Pharmacy and Poisons Board would demonstrate compassion, addressing public concerns and fostering a culture of trust and ethical responsibility in healthcare governance.

### **1.7.2 The Theory of Justice as Fairness**

John Rawls, a prominent American philosopher, introduced the Theory of Justice as Fairness, that provides that justice should be the first virtue of social institutions and that fairness is the most fundamental aspect of justice.<sup>36</sup> The theory is grounded in two primary principles: the Greatest Equal Liberty Principle and the Difference Principle.<sup>37</sup>

The Greatest Equal Liberty Principle posits that each person has an equal right to a fully adequate scheme of equal basic liberties, which is compatible with a similar scheme of liberties for others. This principle prioritises the protection of individual rights and freedoms.<sup>38</sup> The Difference Principle allows social and economic inequalities only if they are to the greatest benefit of the least advantaged members of society and attached to offices

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<sup>35</sup> Benbow D I, Virtue ethics and the United Kingdom (UK) Vaccine Damage Payment Scheme (VDPS), 44: 3 *Journal of Social Welfare and Family Law*, 2022, 391-410.

<sup>36</sup> Rawls J, *Theory of Justice*, revised edition, Harvard University Press, United States of America, 1971, 3.

<sup>37</sup> Said M Y, & Nurhayati Y, ‘A review on Rawls’s Theory of Justice’ 1(1), (*International Journal of Law, Environment, and Natural Resources*, 2021, 29-36.

<sup>38</sup> Rawls J, *Theory of Justice*, revised edition, Harvard University Press, United States of America, 1971, 13.

and positions open to all under conditions of fair equality of opportunity.<sup>39</sup> In Kenya, individuals from low-income or rural areas are disproportionately affected by vaccine injuries due to limited healthcare access and legal resources. A national VICP based on a no-fault compensation model would reduce the economic burden on vulnerable individuals, ensuring that they receive fair and timely compensation without the need for protracted litigation.

Rawls introduces the concept of the "original position" and the "veil of ignorance" as thought experiments to determine the principles of justice that rational individuals would choose under conditions where they do not know their place in society, their class, race, gender, or individual abilities.<sup>40</sup> This ensures that the principles chosen are fair and impartial, as they do not favour any particular position in society. However, the lack of a compensation scheme assumes that only those with financial means can seek redress through litigation, which contradicts the principles of fairness and equal basic rights.

The Theory of Justice as Fairness is particularly suitable for this study as it addresses the core issues of fairness, equity, and justice in social institutions—key concerns when examining vaccine injury compensation. Rawls's theory suggests that policies should be designed with fairness and equality in mind. Policies must not only be fair but also be perceived as fair to maintain public trust.

## **1.8 Literature Review**

### **1.8.1. Global Perspectives On Vaccine Injury Compensation Models**

Daniels & Francis argue that a no-fault compensation system to redress AEFIs, which does not require claimants to prove negligence, is critical in sustaining public confidence in vaccination programs. These models are seen as providing timely and equitable redress for vaccine injuries, even though they are rare, thereby supporting the overall public health objective of high vaccination coverage.<sup>41</sup>

Conversely, critics of current vaccine injury compensation models point to potential limitations such as under-compensation, narrow eligibility criteria, and administrative

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<sup>39</sup> Rawls J, *Theory of Justice*, revised edition, Harvard University Press, United States of America, 1971, 13.

<sup>40</sup> Rawls J, *Theory of justice*, revised edition, Harvard University Press, United States of America, 1971, 11.

<sup>41</sup> Drislane S, 'Why has Australia not enacted a no-fault compensation scheme for adverse events following vaccination? Exploring the potential for citizen collective action to influence the policy agenda' 2023.

complexities. Khan et al provide a critique that many vaccine injury compensation schemes are designed with the legal and healthcare infrastructures of developed countries in mind and may not be directly transferrable to developing regions. This raises an important question on whether models like the VDPS and VICP can be adapted effectively for the Global South, where resources, legal systems, and public health challenges differ significantly.<sup>42</sup>

In this regard, the schemes also differ significantly among these developed countries. In contrast to the United Kingdom's approach, the United States operates under a different framework called the Vaccine Injury Compensation Program (VICP). However, the VDPS of the United Kingdom is administered through a centralized, government-run mechanism that leverages the country's common law traditions and emphasizes immediate, standardized payouts while the USA's VICP is more decentralized, involves a higher administrative burden, and requires extensive evidence for off-table claims and a significantly higher level of epidemiological evidence.<sup>43</sup>

This study aims to fill a knowledge gap in the literature by focusing on the challenges and opportunities for implementing fair vaccine injury compensation in a developing country context. These distinctions are critical in understanding the potential challenges and advantages of transplanting such models to the Global South, where limited administrative infrastructure and public mistrust in the government may hinder implementation. This raises the question of whether a universal standard for vaccine injury compensation should be established, ensuring that all national governments implement fair and effective compensation schemes tailored to their respective socio-legal contexts.

### **1.8.2. Distinctions Between No-Fault and Fault-Based Compensation Systems**

Fault-based compensation systems require the injured party to prove that the injury was caused by another party's negligence or fault. This system is prevalent in tort law and traditional insurance claims. Fault-based systems involve legal proceedings where evidence of negligence or fault must be presented, and compensation is awarded based on the degree

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<sup>42</sup> Crum T, Mooney K and Tiwari B R, 'Current situation of vaccine injury compensation program and a future perspective in light of COVID-19 and emerging viral diseases [version 1; peer review: 1 approved, 1 approved with reservations]' *F1000Research*, 2021, **10**:652.

<sup>43</sup> Benbow D I, Virtue ethics and the United Kingdom (UK) Vaccine Damage Payment Scheme (VDPS), 44: *3 Journal of Social Welfare and Family Law*, 2022, 391-410.

of fault and the extent of the injury. As Lobo states: “[t]he central idea is that the supplier of a product is responsible for the damages that may arise insofar as it has put the good in the market. No tort or negligence from his part is required nor has to be proved”.<sup>44</sup>

The primary advantage of fault-based systems is accountability. By requiring proof of fault, these systems ensure that the party responsible is held accountable for their actions. This accountability serves as a deterrent, discouraging negligent behavior by imposing financial consequences. Additionally, in fault-based systems, compensation is proportional to the degree of fault and injury.<sup>45</sup> However, fault-based systems also have their drawbacks. Legal proceedings can be lengthy and complex, requiring substantial evidence and legal expertise. This complexity can be a barrier for individuals with limited resources, making it difficult for them to pursue claims. Moreover, the adversarial nature of fault-based claims can be emotionally taxing for all parties involved, adding stress to an already challenging situation.

No-fault compensation schemes allow individuals to receive compensation for injuries without the need to prove fault or negligence.<sup>46</sup> These systems are designed to provide quicker resolution of injury claims outside of courts and more equitable compensation, reducing the burden on both the legal system and the injured parties.<sup>47</sup> Typically, no-fault systems involve administrative processes where claims are evaluated based on predefined criteria. Examples of such systems include the National Vaccine Injury Compensation Program (VICP) in the United States.<sup>48</sup>

One of the primary advantages of no-fault systems is their efficiency.<sup>49</sup> Claims are processed faster since there is no need to establish fault, which can be a lengthy and complex process. Additionally, these systems are more accessible, providing easier access to compensation for individuals who might otherwise be unable to prove fault. This accessibility is particularly important for vulnerable populations who may lack the resources to pursue legal action.

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<sup>44</sup> Lobo F, ‘Restructuring the Global Vaccine Industry’ 134, *South Centre Research Paper*, 2021, 70.

<sup>45</sup> Studdert DM, Mello M M, Brennan TA, ‘Medical Monitoring for Pharmaceutical Injuries: Tort Law for the Public’s Health?’ 289(7), *JAMA*, 2003, 889–894.

<sup>46</sup> Looker C and Kelly H, ‘No-fault compensation following adverse events attributed to vaccination: a review of international programmes’ 89(5), *Bulletin of the world health organisation*, 2011, 371–378.

<sup>47</sup> Kloss D, *Occupational health law*. John Wiley & Sons, 2020.

<sup>48</sup> National Childhood Vaccine Injury Act (United States of America) (as amended) 42 U.S.C.

<sup>49</sup> Keren-Paz T, ‘No-fault (strict) liability for injuries from innovative treatments: fairness or also efficiency?’ *Law, innovation & technology*, 11 (1), 2019, 55–74.

Furthermore, no-fault systems reduce litigation costs, benefiting both claimants and defendants by lowering legal expenses.<sup>50</sup>

Both no-fault and fault-based compensation systems have distinct advantages and challenges. In addition, there is the proposed hybrid model, that combines the strengths of both systems to provide comprehensive and fair compensation.<sup>51</sup> This study aims to evaluate how global no-fault vaccine injury compensation models can be adapted to fit Kenya's unique legal, healthcare, and socio-economic context and boost public trust in vaccination programs, ensuring that individuals harmed by adverse reactions receive fair and timely compensation.

### **1.9 Research Methodology**

This study will use a doctrinal legal research methodology, which involves systematic investigation and analysis of existing laws and regulations. The chosen methodology gets data from primary legal sources and secondary sources. The primary sources are laws that govern vaccination in Kenya, such as the Constitution of Kenya, the Pharmacy and Poisons Act and the Health Law (Amendment) Act, 2019. The secondary legal data involves documentaries, library research, and internet research, with literature from journals, news articles, blog writings, and books. The research methodology is appropriate because it serves as a foundational tool for legal professionals, scholars, policymakers, and individuals seeking to navigate the complexities of the legal system and find inadequate laws.

### **1.10 Chapter Breakdown**

Chapter One will provide a background to the study, a statement of the problem, a hypothesis, research questions, research objectives, a theoretical framework, methodology, and justification for this study.

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<sup>50</sup> Looker C and Kelly H, 'No-fault compensation following adverse events attributed to vaccination: a review of international programmes' 89(5), *Bulletin of the world health organisation*, 2011, 371–378.

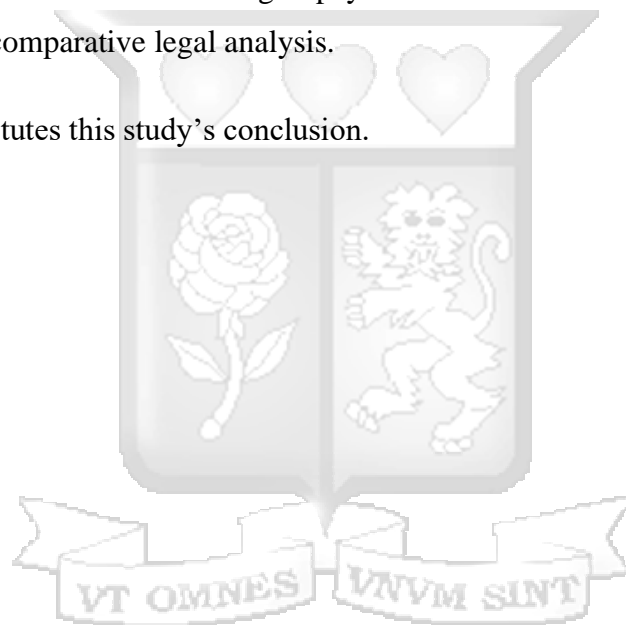
<sup>51</sup> Moscou K, Kohler, J C, 'Matching safety to access: global actors and pharmacogovernance in Kenya- a case study' *Global Health* 13, 2017, 2017.

Chapter Two will be an analysis of Kenya's current legal framework for vaccine deployment and regulation and assess its role in fostering public confidence in immunization and vaccination programs.

Chapter Three will explore an analysis of the absence of a clear legislative mandate in the health regulatory framework that causes the lack of a national compensation scheme in Kenya for vaccine injury using literature and data. This will reveal significant shortcomings in protection for the citizens who are administered these vaccines in cases of injury in these regulatory frameworks.

Chapter Four will discuss the lessons learnt from the United Kingdom on implementing a comprehensive no-fault vaccine damages payment scheme for vaccine adverse events, identified through comparative legal analysis.

Chapter Five constitutes this study's conclusion.



# CHAPTER TWO: ANALYSIS OF THE LEGAL FRAMEWORK ON VACCINE REGULATION AND IMMUNIZATION

## 2.1 Introduction

This Chapter will answer the first research question on the analysis of Kenya's current legal framework for vaccine regulation and immunization. The deployment and administration of vaccines in Kenya are governed by a legal framework comprising constitutional provisions, statutory enactments, regulatory guidelines, and judicial interpretations. These laws provide the foundation for ensuring vaccine safety, efficacy, and accessibility while addressing ethical and public health concerns. This chapter will address two key questions; what the law is about and what is the relevance of the law.

## 2.2 Legal and Policy Framework

### 2.2.1 Constitutional and Statutory framework

#### (a) The Constitution of Kenya, 2010

The Constitution is the supreme law and provides the fundamental basis for healthcare services, including vaccination programs. Article 19(2) provides that the purpose of recognising and protecting human rights and fundamental freedoms is to preserve the dignity of individuals and communities and to promote social justice and the realisation of the potential of all human beings.<sup>52</sup> Article 28 of the Constitution of Kenya provides that every person has inherent dignity and the right to have that dignity respected and protected.<sup>53</sup> If a person suffers a serious adverse reaction following immunization, denying them compensation would violate their dignity, as it disregards the harm suffered. In jurisdictions with vaccine Injury Compensation Programs (VICPs), the principle of fairness is used to justify the need for state intervention in protecting affected individuals. The government, therefore, must ensure that vaccination programs align with these ethical principles of social justice and fairness. The lack of a state-driven vaccine injury compensation mechanism does not align with Article 28 by ensuring that affected individuals are treated with dignity and fairness, rather than being left to bear medical costs alone.

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<sup>52</sup>Article 19(2), *Constitution of Kenya*, (2010).

<sup>53</sup>Article 28, *Constitution of Kenya*, (2010).

Article 43(1)(a) guarantees every Kenyan the right to the highest attainable standard of health, including healthcare services, and as such, this right extends to vaccination programs.<sup>54</sup> Article 43 (2) also provides that a person shall not be denied emergency medical treatment.<sup>55</sup> These rights are classified as economic and social rights, therefore vulnerable individuals who suffer from vaccine-related injury that results in permanent disability, loss of livelihood, or long-term medical costs should therefore be liable to appropriate social security by the state as they are unable to support themselves and their dependents as per Article 43(3).<sup>56</sup>

Article 46 protects consumer rights; therefore, consumers have the right to the protection of their health, safety, and economic interests.<sup>57</sup> Vaccines are consumer products, and those who receive them are consumers entitled to protection against unsafe, defective, or harmful medical products. The Pharmacy and Poisons Board (PPB) and the Kenya Bureau of Standards (KEBS) have a legal obligation to ensure that all vaccines meet quality, safety, and efficacy standards before deployment by conducting pre-market approval, post-market surveillance, and recall of defective vaccines.

Under the Constitution of Kenya (2010), individuals can be granted compensation for a right or fundamental freedom in the Bill of Rights that has been denied, violated, infringed, or threatened. The Judiciary determines compensation based on the circumstances of each case.<sup>58</sup> Compensation amounts may vary depending on the causality of the injury, damage, or loss, and legal recourse is available for disputes concerning claims. In applying any right under Article 43, if the State claims that it does not have the resources to implement the right, a court, tribunal or other authority shall be guided by the following principles— it is the responsibility of the State to show that the resources are not available, in allocating resources, the State shall give priority to ensuring the widest possible enjoyment of the right or fundamental freedom having regard to prevailing circumstances, including the vulnerability of particular groups or individuals; and the court, tribunal or other authority may not interfere with a decision by a State organ concerning the allocation of available

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<sup>54</sup>Article 43(1)(a), *Constitution of Kenya*, (2010).

<sup>55</sup>Article 43(2), *Constitution of Kenya*, (2010).

<sup>56</sup>Article 43(3), *Constitution of Kenya*, (2010).

<sup>57</sup> Article 46, *Constitution of Kenya*, (2010).

<sup>58</sup>Article 23(3)(e), *Constitution of Kenya*, (2010).

resources, solely on the basis that it would have reached a different conclusion.<sup>59</sup> The State has the mandate to take legislative, policy and other measures, including the setting of standards, to achieve the progressive realisation of the rights guaranteed under Article 43.<sup>60</sup> Although all these articles in the Constitution provide a strong foundation for compensation mechanisms, Kenya lacks a dedicated law or fund for a vaccine injury compensation scheme.

### **(b) The Pharmacy and Poisons Act, Cap. 244**

This Act establishes the Pharmacy and Poisons Board (PPB), which is the regulatory authority responsible for overseeing health products, technologies and poisons in Kenya, thus is mandated to oversee the registration, safety, and distribution of vaccines.<sup>61</sup> Under Section 2, it provides that a vaccine is part of the definition of a health product.<sup>62</sup>

Section 3B provides the functions of the Pharmacy and Poisons Board, which includes approving and registering all medicines, vaccines, and related medical products before they are sold or distributed in Kenya and regulating the importation and exportation of pharmaceutical products to ensure compliance with legal and safety standards.<sup>63</sup> One of its main functions is pharmacovigilance, which refers to monitoring and evaluating the safety, quality, and efficacy of medicines in the market while investigating adverse drug reactions and counterfeit drugs. The Pharmacy and Poisons Board has established a monitoring and response system for Adverse Events Following Immunization (AEFI) to ensure those affected receive immediate medical attention through the AEFI online portal or AEFI report form within 24 hours.<sup>64</sup>

### **(c) The Consumer Protection Act, Cap. 501**

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<sup>59</sup> Article 20(5), *Constitution of Kenya*, (2010).

<sup>60</sup> Article 21(2), *Constitution of Kenya*, (2010).

<sup>61</sup> Section 3, Pharmacy and Poisons Act, (2023).

<sup>62</sup> Section 2, Pharmacy and Poisons Act, (2023).

<sup>63</sup> Section 3B, Pharmacy and Poisons Act, (2023).

<sup>64</sup> Pharmacy and Poisons Board, 'Guidelines for Monitoring, Reporting and Managing Adverse Events Following Immunization (AEFI) in Kenya' - Pharmacy and Poisons Board, Pharmacy and Poisons Board, 25 October 2023 <https://web.pharmacyboardkenya.org/download/guideline-for-monitoring-reporting-and-managing-adverse-events-following-immunization-ae-fi-in-kenya/> on 20<sup>th</sup> February 2025.

The Consumer Protection Act safeguards consumers against defective products, misleading information, and unfair trade practices.<sup>65</sup> It applies to vaccines by ensuring transparency and accountability from manufacturers and distributors. Courts can apply consumer protection principles to hold vaccine manufacturers, healthcare providers, or the government accountable if vaccines are improperly administered or defective.

During outbreaks such as the COVID-19 pandemic, the government may fast-track vaccination campaigns under emergency conditions. In such cases, manufacturers and healthcare providers might be protected from liability through indemnity agreements, limiting individual compensation options if an AEFI occurs.<sup>66</sup> If a vaccine causes harm leading to medical costs, disability, or loss of income, affected individuals should be protected from economic hardship under consumer protection laws which supports the need for a state-funded Vaccine Injury Compensation Program (VICP) to provide timely compensation.

#### **(d) The Health Act, Cap. 242**

Section 5(3)(a) provides that the national and county governments shall ensure the provision of free and compulsory vaccination for children under five years of age.<sup>67</sup> The compulsory nature of the vaccination policy of young children is justified by the need to protect them from preventable diseases, thus underlining the state's commitment to protecting public health.

Section 66 states that “Any medicine, vaccine or other health product and technology intended for sale to members of the public shall be eligible for licensing only after due assessment, it is found to achieve the therapeutic or the intended effect it claims to possess or which may reasonably be attributed to it; it is sufficiently safe under the normal conditions of use and it is made and packaged according to satisfactory standards.”<sup>68</sup> The Act

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<sup>65</sup> The Consumer Protection Act, (2013).

<sup>66</sup> Halabi S. ‘Solving the COVID-19 vaccine product liability problem’ *Center of the Study of the Administrative State Working Paper*, 21-11.

<sup>67</sup> Section 5(3)(a), *Health Act*, (Act No. 21 of 2017).

<sup>68</sup> Section 66, *Health Act*, (Act No. 21 of 2017).

establishes standards for healthcare facilities and professionals, ensuring that services—including vaccination—are delivered safely and effectively.

By ensuring that healthcare delivery is regulated and held to high standards, the Act helps build public trust. This is critical for the success of immunization programs and for encouraging high vaccine uptake. A well-regulated health system, as promoted by the Health Act, reinforces transparency in both routine care and in handling adverse events, which is vital for maintaining confidence in public health interventions.

### **2.2.2 Policy Framework**

#### **a) Kenya National Immunization Policy Guidelines, 2023**

The Kenya National Immunization Policy Guidelines, 2023, provide a framework for the implementation, planning and monitoring of vaccination programs.<sup>69</sup> The Guidelines strengthen Kenya's Expanded Program on Immunization (KEPI) to ensure routine vaccinations for children and adults and introduce strategies for mass vaccination campaigns during outbreaks.

It includes guidelines for vaccine procurement, storage, distribution, and administration. It also has set out both long-term and short-term steps to be followed when monitoring adverse events following immunization (AEFI).<sup>70</sup> The policy mandates monitoring and reporting of vaccine-related adverse effects by the health workers through the Pharmacy and Poisons Board (PPB). This ensures early detection of severe vaccine reactions but does not automatically entitle affected individuals to compensation.

These guidelines were created to align with the country's commitment to universal immunization coverage and compliance with the World Health Organization standards. Kenya's policy aims to align with WHO guidelines, which encourage governments to establish compensation mechanisms, especially when vaccines are introduced under emergency use, such as the COVAX No-Fault Compensation Program which was adopted in the country.<sup>71</sup>

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<sup>69</sup> Ministry of Health of Kenya, *National Policy Guidelines on Immunization*, 2023.

<sup>70</sup> Ministry of Health of Kenya, *National Policy Guidelines on Immunization*, 2023.

<sup>71</sup> 'COVAX No fault compensation' July 5 2021 <https://www.who.int/initiatives/act-accelerator/covax/no-fault-compensation> on 18<sup>th</sup> February 2025.

### **2.3 Relevance of the Law to the Issue of Compensation for Vaccine Injuries**

The lack of a specific compensation mechanism in Kenya's vaccine laws raises concerns about the protection of individuals who experience vaccine-related injuries. This gap necessitates legislative reforms to ensure comprehensive protection and accountability. Even though the Pharmacy and Poisons Board plays a central role in ensuring vaccine safety and efficacy, its current legal mandate does not extend to providing compensation for vaccine-related injuries. Expanding its role to include oversight of a no-fault vaccine injury compensation scheme would align with global best practices and fulfil the government's ethical obligations to protect public health. Countries with well-defined vaccine injury compensation schemes have demonstrated higher public confidence in vaccination initiatives as seen in the USA and UK.<sup>72</sup> Adopting a similar approach in Kenya would reinforce trust in vaccine safety and regulatory oversight.

### **2.4 Conclusion**

Kenya's legal framework for vaccine deployment incorporates multiple statutes and regulatory bodies. Through the answering of the chapter's research question through legal analysis it is revealed that Kenya has gaps in addressing post-vaccination injuries, particularly concerning compensation mechanisms in the statutory framework. Strengthening the legislative and policy framework to include a comprehensive vaccine injury compensation scheme would enhance public clarity in vaccine compensation and ensure equitable redress for affected individuals.

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<sup>72</sup> Goldberg R, 'Vaccine damage schemes in the US and UK reappraised: making them fit for purpose in the light of Covid-19' 42(4), *Legal Studies*, 2022, 576-599.

## **CHAPTER THREE: ANALYSIS OF THE POSSIBLE IMPEDIMENTS IN ADOPTING A NATIONAL VICP**

### **3.1 Introduction**

The chapter is an exploratory chapter to answer the second research question and discuss the omission of a clear legislative function for vaccine injury compensation by the Pharmacy and Poisons Board in Section 3B of the Pharmacy and Poisons Act. This omission contributes to an unethical institutional framework for managing vaccine adverse events in Kenya as it does not follow international standards set by the World Health Organization. This analysis explores the possible causes for the absence of a vaccine injury compensation scheme, examining economic, legal, institutional, and political factors, as well as the jurisdiction and jurisprudence surrounding vaccine injury compensation.

### **3.2 Possible Causes for the Lack of a National VICP**

Current analysis of the global situation of vaccine injury compensation schemes shows that there are none in Africa or South America.<sup>73</sup> International best practices, such as the no-fault compensation schemes in countries like the United States, Canada, and various European nations, demonstrate the importance of vaccine injury compensation schemes for these risks and enhance public confidence in vaccination programs.<sup>74</sup> However, the absence of a national vaccine injury compensation scheme in Kenya is not an isolated anomaly but the outcome of multiple interrelated factors that lead to the lack of the mandate of the PPB to provide compensation for AEFI. At the heart of the debate over vaccine injury compensation is the ethical obligation of the state, through the Pharmacy and Poisons Board, to protect its citizens. Vaccination programs, while designed to prevent disease and promote public health, must also be implemented in a manner that upholds the principles of justice and fairness. While the global trend emphasizes comprehensive safety nets, the regional absence reflects structural, economic, or political challenges specific to these areas.

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<sup>73</sup> Crum T, Mooney K, Tiwari BR 'Current situation of vaccine injury compensation program and a future perspective considering COVID-19 and emerging viral diseases' 10:652, 2021.

<sup>74</sup> Mungwira R G, Guillard C, Saldaña A, Okabe N, Petousis-Harris H, Agbenu E, Rodewald L, & Zuber P L F, 'Global landscape analysis of no-fault compensation programmes for vaccine injuries: A review and survey of implementing countries' 15(5), *PLoS ONE*, 2020.

### 3.2.1 Political Economy and Legislative Priorities

Policymakers in Kenya are often forced to balance competing healthcare priorities, such as managing immediate public health crises, improving healthcare infrastructure, and addressing fiscal constraints.<sup>75</sup> Public trust and confidence in vaccination programs are heavily influenced by the effectiveness of communication strategies used by health authorities.<sup>76</sup> In Kenya, vaccine hesitancy has been exacerbated by misinformation on vaccine safety and potential long-term effects.

During the COVID-19 vaccination campaign, misinformation spread rapidly, fuelled by social media and conflicting statements from government officials. Some social media posts on Facebook suggested that citizens were sceptical about the efficacy of specific vaccines donated to Kenya, citing suspension of the same vaccines in other countries at the time.<sup>77</sup> This occurred with the Sputnik vaccine, the importation of which was eventually banned in Kenya.<sup>78</sup> In some regions, surveys suggested that vaccine hesitancy rates increased by up to 20% during peak misinformation periods highlighting that conflicting government statements and misinformation on social media platforms contributed to widespread public uncertainty.<sup>79</sup>

Political considerations further complicate the issue. The Ministry of Health's investment in healthcare, particularly in preventive measures like vaccinations, can lead to cost savings and improved health outcomes. For example, HPV vaccinations have been shown to reduce the risk of cervical cancer by up to 50%, highlighting their cost-effectiveness.<sup>80</sup> However, the Ministry of Health may not have the purchasing power to purchase vaccines for its citizens which further underscores the Kenya's dependency on external funding and aid to

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<sup>75</sup> 'Healthcare in Kenya: challenges and opportunities' MedEx.Health, 24 December 2001 <https://www.medex.health/en/blog/healthcare-kenya-challenges-and-opportunities> on 20<sup>th</sup> February 2025.

<sup>76</sup> United Nations Children's Fund Kenya, 'Building confidence in the COVID-19 vaccine in Kenya: UNICEF Kenya Insights for Impact Project with Data for Good at Meta'

<sup>77</sup> United Nations Children's Fund Kenya, 'Building confidence in the COVID-19 vaccine in Kenya: UNICEF Kenya Insights for Impact Project with Data for Good at Meta'

<sup>78</sup> 'Kenya stops private import of COVID-19 vaccines' Reuters, 2 April 2024 <https://www.reuters.com/article/health-coronavirus-kenya/kenya-stops-private-import-of-covid-19-vaccines-idUSL8N2LV1DN/> on 20<sup>th</sup> February 2025.

<sup>79</sup> Orangi S, Mbuthia D, Chondo E, Ngunu C, Kabia E, et al, 'A qualitative inquiry on drivers of COVID-19 vaccine hesitancy among adults in Kenya' 4(3), PLOS Global Public Health, 2024.

<sup>80</sup> P4H Network, 'Health investments key to Kenya's economic growth, new study reveals - P4H Network' 6 June 2024 <https://p4h.world/en/documents/health-investments-key-to-kenyas-economic-growth-new-study-reveals/> on 20<sup>th</sup> February 2025.

acquire vaccine doses. This was particularly evident during the COVID-19 vaccination campaign as the reliance on temporary international mechanisms, such as the COVAX No-Fault Compensation Program during the COVID-19 crisis.<sup>81</sup> COVAX has been created as a mechanism to promote vaccine access in all countries that otherwise may be unable to afford COVID-19 vaccine doses by engaging the international community to join in regardless of their income levels.<sup>82</sup> While COVAX provided temporary coverage for COVID-19 vaccines, it was not a long-term solution, nor did it address injuries arising from vaccines outside the initiative.<sup>83</sup> While these temporary measures provided a stopgap solution, they were not designed to serve as a permanent substitute for a national scheme. The reliance on such external frameworks may have inadvertently reduced the urgency for domestic legislative reform. Policymakers, reassured by the availability of international support, may have deprioritized the development of a home-grown solution that is better suited to Kenya's unique legal and administrative context. Kenya's reliance on temporary frameworks demonstrates a clear dependency on external solutions rather than establishing a permanent governmental body tasked specifically with vaccine injury compensation which further illustrates the institutional inertia that pervades Kenya's public health administration.

### 3.2.2 Underfunding of the Health Sector

The COVID-19 pandemic exposed existing health system weaknesses in Kenya, including underfunding of the health sector.<sup>84</sup> According to the National COVID-19 Vaccines Deployment and Vaccination Plan for 2021, it costs the country Ksh6 billion to procure and distribute vaccines for routine immunization. Gavi contributes about Ksh3.8 billion or equivalent to 63 percent, and the Government 1.4 billion, equivalent to 23 percent.<sup>85</sup>

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<sup>81</sup> D'Errico S et al, 'First Do No Harm; No-Fault Compensation Program for COVID-19 Vaccines as Feasibility and Wisdom of a Policy Instrument to Mitigate Vaccine Hesitancy' *Vaccines MDPI*, Switzerland, 2021.

<sup>82</sup> GAVI, 'The Vaccine Alliance (2020) COVAX explained' <https://www.gavi.org/vaccineswork/covax-explained>, on 20<sup>th</sup> February 2025.

<sup>83</sup> Bustamante T L, Lago J Magliolo M & Segal L, 'A new treaty on pandemics: some key issues from a global south perspective' *International Economic Law Clinic*, Vernier, 2021, 23.

<sup>84</sup> African Population and Health Research Centre 'It's time Kenya government, including counties, invested more in immunization' *Nation*, 15 June 2021 <https://nation.africa/kenya/brand-book/aphrc-funding-immunization-in-kenya-3438518> on 20<sup>th</sup> February 2025.

<sup>85</sup> African Population and Health Research Centre 'It's time Kenya government, including counties, invested more in immunization' *Nation*, 15 June 2021 <https://nation.africa/kenya/brand-book/aphrc-funding-immunization-in-kenya-3438518> on 20<sup>th</sup> February 2025.

Kenya procured vaccines for Covid-19 estimated at an indicative price of Ksh770 per dose to immunize the projected 30% percent of the public and received just over one million doses of the Oxford-AstraZeneca Covid-19 vaccine as part of the COVAX Facility.<sup>86</sup> Not only is immunization an expensive exercise, but in this environment, vaccine injury compensation is frequently perceived as a lower priority compared to more immediate health needs.

Moreover, the economic implications of not having a comprehensive vaccine injury compensation program extend beyond the immediate costs associated with vaccine injuries. Public health economists warn that lower vaccine uptake—partly driven by public apprehension over potential adverse effects—can precipitate outbreaks of preventable diseases. Such outbreaks invariably lead to increased healthcare expenditures, lost productivity, and broader economic strain on the healthcare system. For example, during the COVID-19 pandemic, several counties experienced dips in vaccination rates that correlated with surges in misinformation and reported adverse events. These disruptions, albeit limited in scope, underscore the potential long-term economic consequences of public mistrust.

Beyond the direct costs associated with adverse events, there are broader economic consequences that arise from diminished public trust and reduced vaccine uptake. Lower vaccination rates can lead to outbreaks of preventable diseases, resulting in increased healthcare costs, lost productivity, and overall economic strain on the healthcare system.<sup>87</sup>

A well-designed compensation scheme could serve as both a financial safety net for affected individuals and a confidence booster for the public. By ensuring that victims receive timely support, Kenya could mitigate the broader social and economic burdens that arise from vaccine-related injuries.

Logistically, the development of a centralized compensation scheme requires substantial planning and resource allocation. The process involves standardizing protocols, training personnel, and establishing integrated data systems for real-time monitoring. Although these initial investments may be considerable, the long-term benefits—in terms of both public health outcomes and economic stability—are likely to outweigh the costs. Learning from

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<sup>86</sup> African Population and Health Research Centre ‘It’s time Kenya government, including counties, invested more in immunization’ Nation, 15 June 2021 <https://nation.africa/kenya/brand-book/aphrc-funding-immunization-in-kenya-3438518> on 20<sup>th</sup> February 2025.

<sup>87</sup> News Desk, ‘Concerns Rise Over Kennedy’s Vaccine Scepticism and Public Health Impact’ Orbital Affairs, 29 November 2024 <https://www.orbitalaffairs.com/concerns-rise-over-kennedys-vaccine-skepticism-and-public-health-impact/> on 20<sup>th</sup> February 2025.

international best practices, such as the efficient no-fault compensation systems in developed countries, can provide a valuable blueprint for Kenya as it seeks to modernize its approach to vaccine safety.

### **3.2.3 Jurisprudential Considerations and the Role of Legal Precedents and Advocacy**

In many jurisdictions, jurisprudence plays a crucial role in clarifying the scope and application of legislative mandates. In Kenya, however, the jurisprudence surrounding vaccine injuries is underdeveloped. The lack of judicial activism in this area can be attributed to several factors. First, vaccine-related injuries are statistically rare, leading to limited case volume and, consequently, a dearth of substantive jurisprudence on the matter. Second, the judiciary is reluctant to expand the interpretation of statutory provisions in the absence of an explicit legislative framework addressing vaccine injury. Without compelling case law affirming the state's responsibility to provide redress for vaccine injuries, there is little impetus for legislative reform. The lack of explicit statutory provisions creates a jurisdictional ambiguity that undermines the establishment of a unified national scheme. Legal scholars and public health experts have noted that, in the absence of clear mandates, courts have rarely ventured into interpreting the existing laws to extend compensation coverage for vaccine-related injuries.

There are few landmark cases that have directly addressed the state's liability in the use of funds received from the Global Alliance for Vaccines Immunization (GAVI), which were designated to support child immunization under the Kenya Expanded Programme of Immunisation (KEPI).<sup>88</sup> This judgement enables the public to be able access to relevant information on vaccination programs and ensure public accountability for health programs funds.<sup>89</sup>

However, the courts have not been compelled to interpret existing laws in a manner that would force the government to create a no-fault vaccine injury compensation scheme. Therefore, affected individuals must pursue remedies through traditional litigation and

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<sup>88</sup> Kenya K, 'Kenyan High Court orders Ministry of Health to disclose vaccine funds information' KELIN Kenya, 25 September 2023 <https://www.kelinkenya.org/kenyan-high-court-orders-ministry-of-health-to-disclose-vaccine-funds-information/> on 20<sup>th</sup> February 2025.

general medical negligence laws, often against well-resourced opponents such as state agencies or pharmaceutical companies.<sup>90</sup> While there may be some cases addressing vaccine injuries under general medical negligence laws, these cases often face significant challenges in proving fault and securing compensation.<sup>91</sup>

Public awareness and advocacy play a crucial role in driving legislative reform. In jurisdictions where vaccine injury compensation schemes exist, sustained public pressure and well-organized advocacy groups have often been instrumental in pushing for change. In Kenya, however, the rarity of vaccine-related injuries—combined with a low level of public awareness about the issue—has meant that there has been insufficient pressure on lawmakers to address the gap. Organizations like Kenya Legal & Ethical Issues Network on HIV and AIDS (KELIN) have successfully advocated for transparency in vaccine funding, demonstrating the effectiveness of civil society in pushing for accountability and disclosure in health-related matters.<sup>92</sup>

Furthermore, the media and civil society organizations in Kenya have not, until recently, given sustained attention to the need for vaccine injury compensation. In the absence of significant public debate and advocacy, policymakers are less inclined to prioritize reforms that address what may be perceived as a marginal issue in the broader context of national health policy. In many countries, sustained public debate and strong advocacy from civil society have been pivotal in driving legislative change. In Kenya, however, the issue of vaccine injury compensation has not captured sustained public attention. With vaccine-related injuries being statistically rare, the voices of affected individuals have remained unheard, and media coverage on the subject has been sporadic at best. Without a groundswell of public demand, legislators have little external pressure to prioritize this issue amid a crowded policy agenda.

Politically, there is a need to prioritize vaccine injury compensation as part of a broader commitment to public health. Policymakers must balance immediate fiscal and health crises

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<sup>90</sup> Mputhia C, 'Legal options in case of COVID-19 jab injury' *Business Daily*, 11 April 2021 <https://www.businessdailyafrica.com/bd/lifestyle/personal-finance/legal-options-case-of-covid-19-jab-injury-3358596> on 20<sup>th</sup> February 2025.

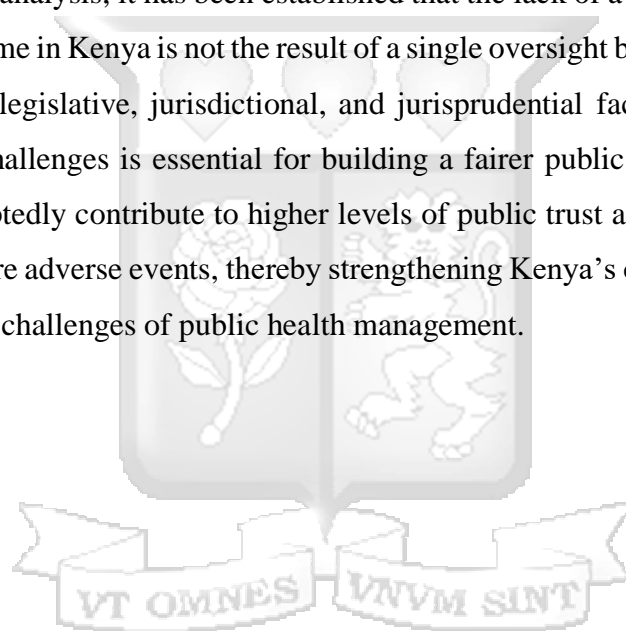
<sup>91</sup> Looker C & Heath K 'No-fault compensation following adverse events attributed to vaccination: a review of international programmes' *Bulletin of the World Health Organization online version*, 3. 2011.

<sup>92</sup> Kenya K, 'Kenyan High Court orders Ministry of Health to disclose vaccine funds information' *KELIN Kenya*, 25 September 2023 <https://www.kelinkenya.org/kenyan-high-court-orders-ministry-of-health-to-disclose-vaccine-funds-information/> on 20<sup>th</sup> February 2025.

by drawing on international best practices and adapting them to the local context which can help build a framework that not only addresses the current gap but also reinforces ethical obligations and social justice.

### **3.3 Conclusion**

In conclusion, this chapter has effectively answered the research question by demonstrating the factors that have contributed to the omission of a clear legislative mandate for vaccine injury compensation—specifically in Section 3B of the Pharmacy and Poisons Act—which has led to an underdeveloped institutional framework for managing vaccine adverse events in Kenya. Through analysis, it has been established that the lack of a national vaccine injury compensation scheme in Kenya is not the result of a single oversight but rather a multifaceted problem rooted in legislative, jurisdictional, and jurisprudential factors. Recognizing and addressing these challenges is essential for building a fairer public health system. Such a system will undoubtedly contribute to higher levels of public trust and protect the rights of those who suffer rare adverse events, thereby strengthening Kenya’s capacity to confront the ongoing and future challenges of public health management.



## **CHAPTER FOUR: COMPARATIVE ANALYSIS**

### **4.1 Introduction**

This Chapter is an analytical chapter to answer the third research question on how the Pharmacy and Poisons Board can utilise its function in Section 3B(t) of the Pharmacy and Poisons Act to implement a vaccine injury compensation scheme and facilitate compensation of adverse events following immunization, based on best practices identified through comparative legal analysis.

The sections of this chapter include a justification for choosing the United Kingdom as a comparative country and a discussion of the legal framework of the United Kingdom that provides for the national Vaccine Damages Payment Scheme. It will also discuss the academic debate that has occurred globally with the Global North utilising these vaccine injury compensation schemes and whether it is viable in the Global South, where Kenya is situated, by highlighting scholarly discussions. This chapter also offers lessons to be learnt from the United Kingdom in implementing a national vaccine injury compensation scheme in Kenya to protect the public health rights of its citizens.

### **4.2 Justification For Choosing the United Kingdom for This Study's Comparative Analysis**

The United Kingdom and Kenya are both common law jurisdictions.<sup>93</sup> This means that any statutory interpretations, administrative practices, and judicial precedents in the United Kingdom are more likely to resonate with Kenyan legal principles. Kenya's policy-making process and legislative framework are more aligned with the United Kingdom's approach due to its history as a British colony.<sup>94</sup> This alignment could facilitate the drafting, debate, and eventual adoption of a vaccine injury compensation scheme modelled after the United Kingdom's scheme.

The United Kingdom's Vaccine Damages Payment Scheme (VDPS) is characterised by its centralized, government-administered approach, clear statutory provisions, and accessible

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<sup>93</sup> Black's Law Dictionary, 10<sup>th</sup> ed.

<sup>94</sup> Kenya Law, 'What is Law Reporting?' <https://www.kenyalaw.org/kl/index.php?id=124> on 18<sup>th</sup> February 2025.

claim procedures.<sup>95</sup> These features are particularly significant when considering the practicalities of implementing a comprehensive vaccine injury compensation scheme in Kenya, where resource constraints and the need for administrative simplicity are paramount and might be preferable over the more complex, tax-funded administrative structure of the USA’s National Vaccine Injury Compensation Program (VICP). The VDPS’s focus on providing a standardized, prompt benefit to claimants aligns with the objectives of enhancing public trust and ensuring equitable compensation—an essential consideration for Kenya’s vaccination programs.

In addition, the historical evolution and legislative codification of the VDPS, notably under the Vaccine Damages Payment Act 1979, offer a robust and well-documented model that has withstood public scrutiny and debate, especially after the COVID-19 pandemic.<sup>96</sup> This extensive body of online articles and academic commentary provides a rich source of empirical and normative data that can inform policy adaptation in Kenya. Collectively, these factors underscore why the United Kingdom serves as an ideal comparative benchmark.

### **4.3 The United Kingdom Regulatory and Judicial Landscape on Models for Vaccine Indemnity**

#### **4.3.1 Relevant Law and Regulations**

The Vaccine Damages Payment Scheme (VDPS) was established in 1978 in the United Kingdom and was subsequently codified into law under the Vaccine Damages Payment Act 1979 which was enacted to pay damages for injuries resulting from the administration of recommended vaccines.<sup>97</sup>

The legal provisions of the Act specify detailed eligibility criteria and procedural requirements for compensation of an adverse event. The scheme covers both childhood vaccines, including those for diphtheria, tetanus, poliomyelitis, measles, rubella,

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<sup>95</sup> National Research Council (US) Division of Health Promotion and Disease Prevention, *Appendix E: Vaccine-Injury Compensation in Other Countries in Vaccine Supply and Innovation*, National Academies Press, Washington DC, 1985.

<sup>96</sup> ‘Vaccine expert Professor Finn joins call for major reforms to vaccine damage payment scheme’ Leigh Day, October 29, 2024 - <<https://www.leighday.co.uk/news/news/2024-news/vaccine-expert-professor-finn-joins-call-for-major-reforms-to-vaccine-damage-payment-scheme/>> on 18<sup>th</sup> February 2025.

<sup>97</sup> Vaccine Damage Payments Act, (United Kingdom).

tuberculosis, smallpox and, in certain cases, adult vaccines like COVID-19 and influenza.<sup>98</sup> The Vaccine Damage Payments (Specified Disease) Order 2020 added COVID-19 to the list of diseases to which the 1979 Act applies.<sup>99</sup>

The Act provides for the definition of severely disabled as quantified as an impairment of 60 per cent or more.<sup>100</sup> This could be a mental or physical disability and will be based on a medical examination by a physician appointed by the Secretary of State of the Department of Health and Social Care.<sup>101</sup> Eligibility extends not only to individuals directly vaccinated but also to cases where a disability arises from maternal vaccination or from contracting a disease through contact with a vaccinated person, provided that the exposure occurs within specific timeframes.<sup>102</sup>

The administrative structure of the VDPS is comprised of administrative entities like the Department of Health and Social Care is the overall authority while the National Health Service Business Services Authority (NHSBSA) handles the processing and assessment of claims.<sup>103</sup> Funding for the VDPS is provided through the central Government.<sup>104</sup>

Claim procedures under the VDPS require an injured individual to submit a claim within six years of the injury.<sup>105</sup> The Secretary of State must be satisfied that a person was severely disabled as a result of vaccine damage, determined on the balance of probability and a causal link is established and disablement suffered is 60%.<sup>106</sup> Once a claim is approved, the scheme provides a flat-rate, lump-sum benefit, with the maximum award per claim capped at

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<sup>98</sup> Vaccine Damage Payment: Eligibility [Vaccine Damage Payment: Overview - GOV.UK](#) on 18<sup>th</sup> February 2025.

<sup>99</sup> Elmer V, 'Bread and circuses: Who's behind the Oxford vaccine for COVID-19?' A Communist in Hong Kong, 8 May 2024 <https://architectsforsocialhousing.co.uk/2020/11/25/bread-and-circuses-whos-behind-the-oxford-vaccine-for-covid-19/> on 18<sup>th</sup> February 2025.

<sup>100</sup> Section 1(4), *Vaccine Damage Payments Act*, (United Kingdom).

<sup>101</sup> Vaccine Supply and Innovation - NCBI Bookshelf, *Vaccine-Injury compensation in other countries*, National Academies Press (US), 1985.

<sup>102</sup> Section 1(3), *Vaccine Damage Payments Act*, (United Kingdom).

<sup>103</sup> 'Vaccine Damage Payment Scheme (VDPS), NHSBSA' <https://www.nhsbsa.nhs.uk/vaccine-damage-payment-scheme-vdps> on 16<sup>th</sup> February 2025.

<sup>104</sup> Faculty of Law, 'United Kingdom Covid vaccine NFCS' <https://www.law.ox.ac.uk/nofault-compensation-schemes-for-covid-19-vaccines/united-kingdom-covid-vaccine-nfcs> on 18<sup>th</sup> February 2025.

<sup>105</sup> Section 3(1)(c)(iii), *Vaccine Damage Payments Act*, (United Kingdom).

<sup>106</sup> Section 1(1), (4), 3(5), *Vaccine Damage Payments Act*, (United Kingdom). Note that the onus of proof is not expressly discussed in the Act.

£120,000.<sup>107</sup> The sum is not considered compensation but rather a benefit.<sup>108</sup> Moreover, over time, parliamentarians have emphasized that it is intended to “ease the present and future burdens of those suffering from severe vaccine damage, and their families.”<sup>109</sup> Thus, injured persons may pursue civil remedy as further legal action, as this payment is not intended to fully redress all economic losses; rather, it is a statutory benefit. It is important to note, however, that the amount of any payment received by the compensation scheme will be deducted from the court award.<sup>110</sup>

A notable feature of the VDPS is its stringent stance on fraudulent claims. Any person found to be making a fraudulent claim is liable for a fine of £1,000 or £400 in the Isle of Man.<sup>111</sup> This provision underscores the government’s commitment to maintaining the integrity of the scheme.

#### 4.3.2 Judicial Interpretations

In the landmark case of *G (A Minor) v Secretary of State for Work and Pensions*, a child vaccinated against pandemic influenza A (H1N1) on 10 December 2009 in the United Kingdom and subsequently developed narcolepsy and cataplexy.<sup>112</sup> His symptoms included frequent, unprovoked episodes of daytime sleepiness, sudden loss of muscle tone—sometimes leading to collapse—as well as behavioural disturbances (hallucinations, night terrors, and impaired social functioning).

His parents' claim under the Vaccine Damage Payments Act 1979 was initially rejected by the Department for Work and Pensions (DWP) on the grounds of insufficient evidence linking the vaccine to his condition. However, after further submissions, including specialist testimony from Professor Gingras and reports from educational and medical experts, the First-tier Tribunal (FTT) found that although the child did not meet the 60% disablement

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<sup>107</sup> *G (A Minor) v Secretary of State for Work and Pensions* (2017), Court of Appeal (England and Wales).

<sup>108</sup> *Hansard* HC Deb, vol 352, col 719, Mr Alistair Darling, 27 June 2000. The scheme is not regarded as a compensation scheme: *ibid*, col 726. See also *Hansard* HC Deb, 24 March 2015, col 458 WH, Parliamentary Under-Secretary of State for Health (Jane Ellison).

<sup>109</sup> *Vaccine Damage Payments Act 1979 Statutory Sum Order 2 - Hansard - UK Parliament*, June 26, 2007.

<sup>110</sup> Vaccine Supply and Innovation - NCBI Bookshelf, *Vaccine-Injury compensation in other countries*, National Academies Press (US), 1985.

<sup>111</sup> National Research Council (US) Division of Health Promotion and Disease Prevention, *Appendix E: Vaccine-Injury Compensation in Other Countries in Vaccine Supply and Innovation*, National Academies Press, Washington DC, 1985.

<sup>112</sup> *G (A Minor) v Secretary of State for Work and Pensions* (2017), Court of Appeal (England and Wales).

threshold at the date of the assessment, the condition was lifelong and reasonably foreseeable to worsen.<sup>113</sup> The Upper Tribunal (UTJ) upheld the FTT's decision, noting the importance of accounting for future disablement.

The case clarified that the assessment is not confined solely to the disablement existing on the specific date of the administrative decision. The tribunal is permitted to consider the likely progression of a lifelong condition, as provided by medical evidence and expert testimony. By affirming that future disablement may be considered, the Court's decision effectively broadened the interpretative framework of the Vaccine Damage Payments scheme.<sup>114</sup> This has ensured that the scheme remains responsive to the realities of conditions that may worsen over time, thereby extending its protective scope providing a pivotal judgement in shaping the country's vaccine injury scheme landscape.

It is important to note that when a claim is denied, the claimants are allowed to go to a specialised tribunal.<sup>115</sup> To appeal the decision of the body that grants the payment of damages which is currently the NHS Business Services Authority.<sup>116</sup>

#### **4.4 The Academic Debate on Models for Vaccine Indemnity**

##### **4.4.1 Challenges of the current model of VDPS in the United Kingdom**

Despite its successes, the VDPS has faced criticism. Since the inception of the VDPS, there have been 6,799 claims, 946 of which have resulted in awards: a success rate of 13.9%, which is extremely low.<sup>117</sup> By far, the majority of claims to the VDPS have been disallowed on the basis that the vaccination did not cause the disability and determination of causation continues to be a major source of difficulty in Tribunal appeals.<sup>118</sup> Sarah Moore argues that

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<sup>113</sup> Goldberg R, 'Vaccine damage schemes in the US and UK reappraised: making them fit for purpose in the light of Covid-19' 42(4), *Legal Studies*, 2022, 576-599.

<sup>114</sup> *G (A Minor) v Secretary of State for Work and Pensions* (2017), Court of Appeal (England and Wales).

<sup>115</sup> Section 4(1), *Vaccine Damage Payments Act*, (United Kingdom).

<sup>116</sup> < [researchbriefings.files.parliament.uk/documents/CDP-2022-0154/CDP-2022-0154.pdf#page=11.10](https://researchbriefings.files.parliament.uk/documents/CDP-2022-0154/CDP-2022-0154.pdf#page=11.10) > on 16<sup>th</sup> February 2024.

<sup>117</sup> Goldberg R, 'Vaccine damage schemes in the US and UK reappraised: making them fit for purpose in the light of Covid-19' 42(4), *Legal Studies*, 2022, 576-599.

<sup>118</sup> Goldberg R, 'Vaccine damage schemes in the US and UK reappraised: making them fit for purpose in the light of Covid-19' 42(4), *Legal Studies*, 2022, 576-599.

the 60% threshold is too high and that an individual with a 59% disability under the VDPS would have no other route to financial compensation other than through the courts.<sup>119</sup>

The VDPS has incurred more costs in administration than it has paid out in claims. Since November 2021, the government has spent over £25 million on processing claims, while only £23.6 million has been paid to victims. Claimants have reported significant delays in the assessment of their cases. As of early 2025, nearly 1,000 individuals were waiting over 12 months for a decision, with more than 280 waiting over 18 months. This slow response time has left many victims in critical need without timely support, leading to frustration and further criticism of the scheme's effectiveness.<sup>120</sup>

The VDPS is designed as a one-off payment scheme rather than a comprehensive support program for those affected by vaccine injuries. Sarah Moore finds that the financial support of £120,000 is insufficient to cover ongoing care needs or lost income due to severe disabilities resulting from vaccinations and wonders whether the maximum payout should be adjusted to better reflect the severity of injuries.<sup>121</sup> She argues that a more responsive and generous compensation scheme could enhance trust in vaccines by reassuring the public that they will be supported in the event of adverse reactions, especially during the COVID-19 vaccination campaign.<sup>122</sup>

Benbow recommends that the VDPS be reformed to remove the eligibility criteria concerning age.<sup>123</sup> The Act provides that eligible vaccine recipients (except for vaccines against poliomyelitis, rubella and meningitis c, as per S.1(3)) must have been under the age of eighteen unless there was an outbreak of the disease.<sup>124</sup> In 2018, the Department of Health

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<sup>119</sup> Moore S, 'The Vaccine Damage Payment Scheme is outdated and urgently needs reform' *Leigh Day*, 13 May 2024 - <<https://www.leighday.co.uk/news/blog/2024-blogs/the-vaccine-damage-payment-scheme-is-outdated-and-urgently-needs-reform/>> on 18<sup>th</sup> February 2025.

<sup>120</sup> Team, & Eastwood N, 'Vaccine injury scheme has cost taxpayers more to run than it has paid out to victims' *The Telegraph*, 22 January 2025 - <<https://www.telegraph.co.uk/news/2025/01/14/vaccine-injury-scheme-taxpayers-paid-out-victims/>> on 18<sup>th</sup> February 2025.

<sup>121</sup> Moore S, 'The Vaccine Damage Payment Scheme is outdated and urgently needs reform' *Leigh Day*, 13 May 2024 - <<https://www.leighday.co.uk/news/blog/2024-blogs/the-vaccine-damage-payment-scheme-is-outdated-and-urgently-needs-reform/>> on 18<sup>th</sup> February 2025.

<sup>122</sup> Moore S, 'The Vaccine Damage Payment Scheme is outdated and urgently needs reform' *Leigh Day*, 13 May 2024 - <<https://www.leighday.co.uk/news/blog/2024-blogs/the-vaccine-damage-payment-scheme-is-outdated-and-urgently-needs-reform/>> on 18<sup>th</sup> February 2025.

<sup>123</sup> Benbow D I, 'Virtue ethics and the United Kingdom (UK) Vaccine Damage Payment Scheme (VDPS)' 44(3), *Journal of Social Welfare and Family Law*, 2022, 391–410.

<sup>124</sup> Section 2(1)(B), *Vaccine Damage Payments Act*, (United Kingdom).

admitted that excluding adults from the scheme breaches the public sector equality duty.<sup>125</sup><sup>126</sup> He says that the government recommends routine vaccines, and those who decide to ensure that they, and their children, receive them are acting virtuously and thus, in the rare, but anticipated, circumstances that damage occurs, the state should demonstrate compassion and compensate injured recipients irrespective of their age.<sup>127</sup>

## 4.5 Lessons That Can Be Drawn from The Above Analysis for Kenya

### 4.5.1 The Legal and Regulatory Framework

Kenya currently lacks a unified statutory framework and relies on a patchwork of policies and tort law remedies for vaccine injuries. In Kenyan law, there is no direct equivalent statutory threshold for defining severe disability in the context of vaccine injuries. However, comparable definitions can be drawn from some statutes. The Persons with Disabilities Act, 2003 defines disability as "a physical, sensory, mental or other impairment, including any visual, hearing or physical incapability, which impacts social, economic, or environmental participation."<sup>128</sup> The Work Injury Benefits Act, 2007, categorizes the degree of disablement based on percentage ratings assigned to different injuries.<sup>129</sup> The Social Assistance Act, provides support based on medical assessment but lacks specific numerical thresholds A person with severe mental or physical disability shall be eligible for social assistance the person's disability renders them incapable of catering for their basic needs; and there is no known source of income or support for the person.<sup>130</sup>

Kenya's current policies on immunization programs might lag below international standards of medical ethics in the Global North.<sup>131</sup> This is because of the difference in economic and

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<sup>125</sup> Section 149(1)(A), Equality Act (United Kingdom).

<sup>126</sup> 'Government agrees to rethink vaccination compensation age-bar after admitting equality rule breach' *Hodge Jones & Allen*, 19 March 2018 -< <https://www.hja.net/news-and-insights/press-releases/personal-injury/government-agrees-to-rethink-vaccination-compensation-age-bar-after-admitting-equality-rule-breach/> > on 18<sup>th</sup> February 2025.

<sup>127</sup> Benbow D I, 'Virtue ethics and the United Kingdom (UK) Vaccine Damage Payment Scheme (VDPS)' 44(3), *Journal of Social Welfare and Family Law*, 2022, 391–410.

<sup>128</sup> Section 2, *Persons with Disabilities Act* (2003).

<sup>129</sup> Section 30(1), *Work Injury Benefits Act* (2007).

<sup>130</sup> Section 23, *Social Assistance Act* (2013).

<sup>131</sup> Ochomo E O, Tonui P, Muthoka K, Amboka S, Itsura P, Orang'o E O, Rosen B, Loehrer P, & Cu-Uvin S, 'Addressing HPV vaccine hesitancy: unveiling concerns and building trust perspectives of adolescent girls and parents in Kisumu County, Kenya' *Ecancer*, 2024, 1735.

political views between Kenya and the United Kingdom in prioritising a vaccine injury compensation scheme.

Kenya can benefit from developing comprehensive legislation that details the scope of vaccine indemnity, eligibility criteria, time limits for claims and the nature of compensable injuries. This clarity would help avoid ambiguity in claim processing and enhance predictability and fairness in the enforcement process. The United Kingdom, which is a Global North country, has a clearly defined statutory framework under the Vaccine Damages Payment Act 1979 with centralized administration of the Department of Health and other delegations to other Health institutional bodies.

For Kenya, granting the mandate to the Pharmacy and Poisons Board as the centralized administrative body within the Ministry of Health could streamline the process, ensure consistency in decision-making, and facilitate the efficient allocation of public funds for vaccine injury compensation. Adapting these elements to Kenya's socio-legal context would help create a system that is both protective and accessible to claimants. Transparent practices will be essential for building and maintaining public trust in both the vaccine rollout and the compensation system.

#### **4.5.2 The Judicial Interpretations**

In Kenya, it is primarily a fault-based system with a heavy reliance on civil litigation, and the claimant must prove negligence in the administration of the vaccine. Many people, however, might lack the resources to challenge the government that endorses certain vaccines. In the United Kingdom, it is a dual-track system as the Vaccine Damage Payments are not an exclusive remedy; claimants retain the right to pursue further damages through civil litigation.<sup>132</sup> In the case of *G (A Minor) v Secretary of State for Work and Pensions* underscores the importance of a holistic, dynamic approach to assessing disablement, one that goes beyond a snapshot of a claimant's condition at a single point in time.<sup>133</sup> Instead, it advocates for considering the progression of a lifelong condition, ensuring that

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<sup>132</sup> Mungwira R G, Guillard C, Saldaña A, Okabe N, Petousis-Harris H, Agbenu E, Rodewald L, & Zuber P L F, 'Global landscape analysis of no-fault compensation programmes for vaccine injuries: A review and survey of implementing countries' 15(5), *PLoS ONE*, 2020.

<sup>133</sup> *G (A Minor) v Secretary of State for Work and Pensions* (2017), Court of Appeal (England and Wales).

compensation reflects both current impairments and the anticipated future impact. This forward-looking assessment is essential in addressing the realities of conditions that may worsen over time, thereby providing a fairer and more comprehensive compensation scheme.

In addition, the judgment highlights the critical role of expert evidence in complex medical cases. By relying on detailed and authoritative medical testimony, decision-makers can arrive at more informed and nuanced conclusions regarding a claimant's long-term disablement. For Kenya, integrating robust expert input into its legal and administrative processes would enhance the accuracy and fairness of disability assessments. Moreover, aligning statutory interpretation with the legislative intent—as demonstrated by considering both present and future disablement—ensures that claimants receive appropriate support based on the true extent of their condition.

Finally, the clarity and transparency in the reasoning provided by the court serve as a model for procedural fairness. The use of specialized vaccine damage tribunals in the UK—which include legal and medical experts—ensures that claims are assessed thoroughly and impartially. Kenya might adopt a similar approach by establishing dedicated vaccine tribunals that can adjudicate vaccine injury claims based on a “balance of probabilities” standard, which requires that a claimant proves their case that the injury is more likely than not over 60%, which will provide a solid framework for future cases. This would help ensure that claims are evaluated with the necessary expertise and contextual sensitivity.

By Kenya, adopting a similar dual pathway ensures that while a no-fault scheme provides prompt, efficient, standardized benefits, those with more significant or complex injuries can still seek additional legal redress. However, careful integration is needed to prevent duplicative or excessive compensation. Kenya can learn from this dual-track approach by ensuring that administrative procedures are well-resourced and capable of handling routine cases while preserving judicial avenues for exceptional or disputed cases.

#### **4.5.3 The Academic Debate**

Kenya's efforts to establish a vaccine indemnity framework can benefit significantly from the lessons learned through the challenges faced by the Vaccine Damages Payment Scheme (VDPS) in the UK. The UK's experience demonstrates that schemes designed for developed

countries are not directly transferable to the Global South due to differences in legal traditions, administrative capacities, and public health priorities. For Kenya, it is essential to develop a framework that reflects its unique legal heritage and resource constraints while carefully considering the feasibility, scalability, and overall impact of any proposed model to effectively address the existing gap in vaccine compensation.

Unlike high-income countries that can rely on robust public funds, Kenya may struggle to finance a comprehensive vaccine injury compensation scheme without external support. Therefore, a funding model that guarantees continuous support is crucial. This model could combine donor assistance, international aid, and modest levies on vaccine doses, ensuring the scheme remains robust without placing undue burdens on the public or the healthcare system.

The UK's system also emphasizes the importance of adapting compensation to the nature and severity of vaccine-related injuries. Kenya has a unique opportunity to design a flexible scheme that adjusts benefits based on the specific risks and impacts associated with different vaccines. Such an approach would not only offer equitable and proportionate compensation but also accommodate future changes in vaccine technology and evolving public health needs such as the debate regarding whether compensable injuries and maximum payouts should vary according to vaccine type or injury severity—for instance, whether compensation for death should differ from that for severe non-fatal injury.

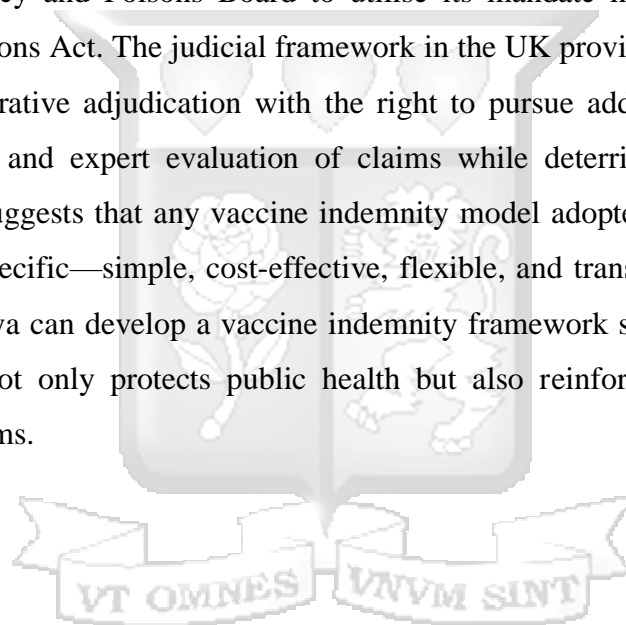
The effective administration of any vaccine injury compensation scheme requires a strong legal and administrative framework. Kenya may need to invest in training legal professionals and healthcare workers—especially those within regulatory bodies like the Pharmacy and Poisons Board—to manage claims efficiently. Establishing clear guidelines, well-defined eligibility criteria, and streamlined claim procedures is essential. Moreover, adapting evidentiary standards to the local context will help ensure that the system processes claims fairly and transparently without overburdening the legal infrastructure.

A hybrid approach, inspired by the centralized administration used in the UK model, could serve Kenya well. This would involve providing standardized baseline benefits while incorporating mechanisms for more rigorous assessment—such as specialist tribunals for severe or disputed cases—to ensure that compensation truly reflects the severity of injuries without sacrificing consistency or fairness. Such a system could also help build public trust

by clearly communicating how claims are evaluated, the criteria for assessing injuries, and the rationale behind compensation decisions. Kenya must explore these issues in depth to ensure that its model is both fair and context-specific, aligning compensation levels with the actual impacts on individuals and families.

#### **4.6 Conclusion**

The United Kingdom's regulatory and judicial landscape shows how it has addressed the challenges of vaccine injury compensation via a national damage payment scheme, thus offering a model for Kenya to emulate. On the legal and regulatory front, Kenya can benefit from adopting clear, codified legislation on compensation for vaccine adverse events to enable the Pharmacy and Poisons Board to utilise its mandate in Section 3B(t) of the Pharmacy and Poisons Act. The judicial framework in the UK provides useful guidance on balancing administrative adjudication with the right to pursue additional civil remedies, ensuring thorough and expert evaluation of claims while deterring fraud. Finally, the academic debate suggests that any vaccine indemnity model adopted in the Global South must be context-specific—simple, cost-effective, flexible, and transparent. By integrating these lessons, Kenya can develop a vaccine indemnity framework specifically tailored for the country that not only protects public health but also reinforces public trust in its vaccination programs.



## **CHAPTER FIVE: CONCLUSION**

### **5.1 Introduction**

This chapter summarises the key findings of the study in each chapter. It also provides recommendations for addressing the identified gaps in Chapter 3 of a national vaccine injury compensation scheme and highlights them at an administrative, judicial, and legislative level within the health industry in Kenya and concludes with reflections on the study's contributions to legal scholarship and policy development.

### **5.2 Summary of Findings in Each Chapter**

Chapter one introduced the research problem, objectives, and significance of the study. It highlighted the need for Kenya to establish its no-fault vaccine injury scheme for all state-approved vaccines, including those imported by the private sector.

Chapter two explores a review of Kenya's health regulatory framework on vaccines and immunization using various health statutory legislations and legal frameworks.

Chapter three explores analysis of the possible gap in the health regulatory framework that causes the lack of a national compensation scheme in Kenya for vaccine injury using literature and data and thus revealed significant shortcomings in protection for the citizens who are administered these vaccines in cases of injury in these regulatory frameworks. The chapter emphasized the need for reforms to align Kenya's policies with global best practices.

Chapter four analyses the rationale for selecting the United Kingdom as a comparator using the comparative analysis approach with Kenya. It analyses the regulatory and judicial landscape of the Vaccine Damages Payment Scheme in the United Kingdom, highlighting key lessons for Kenya. The chapter emphasised the importance of vaccine injury compensation, comprehensive compensation guidelines, and judicial oversight in ensuring participant protection.

Chapter five concludes this study by summarising the findings of each chapter and offering recommendations to address the legal issue of the lack of a national no-fault compensation scheme for vaccine injuries in Kenya.

### 5.3 Recommendations

This study proposes the following recommendations:

1. Since the Pharmacy and Poisons Act is the primary legislation that governs the regulation of vaccines in Kenya, this study proposes an amendment to section 3B of the Act with regards to include the functions of the Pharmacy and Poisons Board.
  - a. Section 3B can be amended to add another function of the PPB to manage vaccine injury compensation claims. The Pharmacy and Poisons Board would be a perfect body to manage the vaccine injury compensation scheme. The PPB would be responsible for processing and adjudicating claims, maintaining an up-to-date registry of compensated cases, and ensuring compensation for victims.
2. At the legislative level, the Pharmacy and Poisons Board should propose a regulatory instrument that addresses vaccine injury compensation. Establishing an effective vaccine injury compensation scheme also requires a well-defined institutional framework with clear roles for all stakeholders. This new legislation should delineate the scope of vaccine injury compensation, define eligibility criteria and the percentage of injury to claim compensation, and set forth standardized procedural requirements for claim adjudication. Integrating vaccine injury compensation into the broader public health strategy will necessitate extensive stakeholder consultation with legal experts, healthcare professionals, and representatives from civil society which would result in a statutory framework that is well-adapted to Kenya's socio-legal context.
3. At the executive level, based on the analysis of the Vaccine Damages Programme Scheme in the United Kingdom, Kenya should adopt a no-fault model that incorporates the strengths of the UK scheme. Such a model would provide prompt, standardized benefits to claimants without the requirement of proving negligence while still preserving the right to pursue additional compensation through civil litigation in cases of severe or disputed injuries. In terms of funding, a sustainable financial model is paramount to the success of the compensation scheme. The government should allocate primary funding from national public funds, thereby guaranteeing a stable financial base. In addition, the introduction of a modest levy

on every vaccine dose administered could create a dedicated revenue stream, similar to mechanisms employed in other jurisdictions, without unduly burdening the healthcare system. In the scheme's initial stages, international support from donor agencies and technical assistance from global organizations may be necessary to offset resource constraints. Furthermore, exploring public-private partnerships could provide supplementary funding while ensuring that the overall public nature of the scheme remains intact.

4. At the administrative level, the Pharmacy and Poisons Board should utilise technology to streamline claim submissions and adjudication processes, which will further help to reduce administrative burdens. Drawing inspiration from the United Kingdom's approach, Kenya should implement stringent verification procedures, such as mandatory medical examinations and comprehensive documentation requirements, to confirm the causal link between vaccination and injury. A clearly defined claim window—such as a six-year deadline post-injury—should be established, along with guidelines on maximum payout amounts indexed relative to the per capita income of Kenya, thereby balancing immediate relief with the potential for further legal redress when warranted. The establishment of a tiered penalty system—imposing significant fines and potential legal consequences for fraudulent claims—will help protect public funds and maintain trust in the scheme. Regular audits conducted by independent bodies should be instituted to monitor compliance and ensure transparency in claim processing. The PPB should also provide alternative avenues for appeal (such as specialized vaccine tribunals) to ensure fair reconsideration of borderline claims. In addition, a multi-stakeholder oversight committee comprising representatives from the government, legal experts, healthcare professionals, and civil society organizations should be established to provide strategic guidance, facilitate regular reviews of the scheme's performance, and ensure accountability throughout the scheme's operation. The PPB should collaborate with community leaders, religious organizations, and civil society to raise awareness about the compensation scheme to the public.
5. At the judiciary level, Kenyan courts may need to develop jurisprudence around what qualifies as 'severe disability' in vaccine-related cases, potentially considering case-by-case assessments while still utilising a rigid percentage of severe disability. The judgement of the case of *G (A Minor) v Secretary of State for Work and Pensions*

can help set precedent in the future cases in Kenya where the Judiciary can consider the progression of a lifelong condition caused by an adverse event due to immunization that can worsen over time even though it doesn't meet the eligibility requirements of 'severe disability' in the proposed vaccine injury compensation scheme thereby still ensuring that the individual is compensated for both current impairments and the anticipated future impact.

#### **5.4 Conclusion**

In summary, this study has identified various lessons from the United Kingdom that can be utilised in Kenya in the development of a national vaccine injury compensation scheme to address the issue of the lack of protection for its citizens from vaccines that cause injury. This promotes accountability by the government to provide good vaccines for the public, enhances public trust in vaccination programs and upholds citizens' rights to health. This study also contributes to the field of public health law by providing actionable recommendations for creating a national model for a vaccine injury compensation scheme in Kenya without relying on international frameworks like the COVAX No-Fault Compensation Program.



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