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HJI Submission (on the basis of a truncated time period¹)

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SUBMISSION: DISASTER MANAGEMENT ACT, 2002

**DRAFT AMENDMENTS TO REGULATIONS ISSUED IN TERMS OF SECTION 27(2) OF
THE DISASTER MANAGEMENT ACT, 2002**

‘CHAPTER 8: COVID-19 VACCINE INJURY NO-FAULT COMPENSATION SCHEME’

This submission draws on the following links:

- HJI’s Vaccine Access Timeline: 2020-2021
<https://healthjusticeinitiative.org.za/vaccine-equity-access-allocation/recent-work/>
- <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard>
- <https://ourworldindata.org/covid-vaccinations>

A: Background to the Health Justice Initiative

The [Health Justice Initiative](https://healthjusticeinitiative.org.za) (the ‘HJI’) is a dedicated public health and law initiative addressing the intersection between racial and gender inequality with a special focus on access to life saving diagnostics, treatment and vaccines for COVID-19, TB and HIV, drawing on the expertise of researchers in law, public policy, economics, and public health, as well as on universities and scientific experts in and outside of South Africa. The HJI works in partnership with other organisations that focus broadly on rights protections. Given South

¹ The HJI reserves it right to make additional and further submissions should the deadline be extended, and/or should the HJI deem it necessary for purposes of legal action.

Africa's massive inequality and dual health care system, we address the factors that influence inequity in health access (with a focus on medicine access) during pandemics, and beyond, with a focus on race, class, and gender. We are supported by a [Governing Board](#) and a [Reference Advisory Group](#).

In the past year we have for example intervened in cases involving excessive and exploitative pricing:

- In August 2020 the HJI, together with [Open Secrets](#), participated as joint amicus curiae in Babelegi Workwear and Industrial Supplies CC v The Competition Commission (CAC Case No: [186/CAC/JUN20](#)) regarding excessive and exploitative pricing of face masks during a pandemic. Babelegi was found guilty by the Competition Appeal Tribunal.
- In the same month, the HJI, together with Open Secrets, participated as [joint amici curiae](#) in the matter of Dis-chem Pharmacies Ltd v Competition Appeal Commission in which Dis-Chem appealed the Competition Tribunal's finding that its pricing of surgical masks was excessive and imposed a fine. Dis-chem withdrew its appeal.

B:

Context: 'A Ransom Situation'

1. We agree that we need to end the Covid-19 pandemic, and vaccines help us do that in our country and the region.
2. But, in a global context of vaccine apartheid where current estimates indicate that **1 in 4 people in the global north** have received a vaccine compared to **1 in 500 people in the global south**, due to limited and scarce vaccine supplies, it is unfortunate that the public has been asked to make comments within truncated time periods on a matter of national importance, where contractual agreements (deals) for supplies have already been secured, regrettably subject to Non-Disclosure Agreements (NDAs) that multinational companies have insisted on.
See: Our World In Data, Global Change Data Lab, University of Oxford
<https://ourworldindata.org/covid-vaccinations>
3. This suggests to us that the proposed vaccine injury compensation scheme and fund is a *fait accompli* on the part of government **and** vaccine manufacturers, rendering - on the face of it - the process to submit public comments a formality, as opposed to ensuring meaningful public engagement with also, oral or virtual hearings.
4. We note that pharmaceutical multinational corporations (MNCs), around the world have demanded the establishment of such schemes, and that South Africa is not the only government compelled to do so, failing which, the industry *will refuse* to supply countries with vaccine supplies (including South Africa).
 - a. This is threatened even in cases where the said vaccine was developed with considerable public funding and philanthropic investment.

- b. What we do not know is whether these companies will make a financial contribution to such schemes - were they not to, that would be unfair, immoral and highly unequal, to make profit off people but not sharing the costs of the harm burden, especially were the scheme to continue for years, beyond 2022.
5. Of course, we support the *aim* underpinning the scheme:
'The purpose of the Scheme is to provide expeditious and easy access to compensation for persons who suffer vaccine injury referred to in regulation 93(2) and (4)(b) as a consequence of a CoVID-19 vaccine contemplated in regulation 93(4)(c) being administered.'
6. However, we are concerned *inter alia* about the background, including the vaccine manufacturers' involvement and demands, the details, structure, criteria, funding model and administration. We are concerned that this process is so rushed, and that it caters to private commercial interests that are not fully disclosed or transparent, as yet.
7. We are also unaware if lawmakers have seen the terms and conditions of the country's vaccine supply/procurement agreements with individual manufacturers (especially Johnson & Johnson/Janssen and Pfizer Inc) as well as the COVAX and African Union Vaccine Acquisition Task Team (AVATT) agreements (the HJI has previously written to the National Department of Health (NDoH) indicating that these agreements should, at a minimum, be filed with the Speaker of Parliament).
 - a. These agreements have a direct bearing on the proposed vaccine injury scheme and fund contained in the draft [Regulations](#) issued on 15 April 2021 which is the subject of our submission, yet the agreements remain a secret, even though the South African public is paying for the acquisition of vaccines through national funding allocations.
 - b. According to the Minister and NDoH officials in various media interviews, the *terms and conditions* of these agreements cannot be disclosed because they are subject to NDAs as mandated and required by certain vaccine manufacturers, who are now also, it appears, to be demanding a state funded and state established no fault compensation scheme for vaccine related injuries or harm.
 - c. *Vaccine Procurement Agreements* are referenced in the draft Regulations, but the public has not been privy to it because it is being protected by NDAs. **We therefore call on Parliament to ensure transparency in all aspects of the country's vaccine procurement, and for all such agreements to be made public.**
8. The relevant and concerning clause is at Section 95 of the draft Regulations:

95. Scheme claim and claim through court process

3) A claim for damages through a court process arising from a vaccine injury referred to in regulation 93(2) and (4)(b) in relation to a vaccine contemplated in regulation 93(4)(c) and said to have been caused by the conduct of a vaccine manufacturer—

(a) may not be brought against the vaccine manufacturer; and

(b) **may only be brought against the National Government, to the extent that the National Government granted an indemnity to the manufacturer of the vaccine under the vaccine procurement agreement in terms of which the vaccine dose that was provided to the person was obtained (emphasis added).**

8. It is also unclear whether the State Law Advisor has provided a legal opinion on the following:
- a. Whether it is permissible to issue *Regulations* for the establishment of the scheme and fund under the Disaster Management Act (DMA), and not, for example under the National Health Act (NHA) or in the alternative, a special 'Covid-19 Act' (as other countries have done):
 - b. In this regard, we also have the following questions and urge lawmakers to obtain relevant State Law Adviser opinions:
 - i. Does the proposed compensation scheme and fund remain in place were the state of disaster to be lifted? (this has implications for how long the disaster will then have to be in place). We cannot have a situation where the disaster is extended indefinitely in order to only accommodate a vaccine injury scheme (which is premised on an unreasonable request by certain vaccine manufacturers in a pandemic).
 - ii. It is thus unclear how to read the draft Regulations (Section 96) if the disaster is not extended and ceases for example within the next 6-12 months and before the end goal of the national vaccination programme. Because the Regulations are issued under section 27(2) of the Disaster Management Act (DMA), which apply to declared states of disaster. In terms of section 27(5)(2), such declarations must be extended on a month to month basis. **Hence, Regulation 96 needs to be clarified as it may be in conflict with section 27 of the DMA if the state of disaster is not extended for whatever reason. This also opens the Regulations to legal challenges at present.**
 - c. For this reason, it may be better to locate the scheme in the National Health Act or a special COVID-19 Act, to ensure that there is proper and meaningful public participation in the laws governing the Covid-19 crisis in South Africa, and to provide appropriate legal clarity and certainty. Otherwise, we could have an indefinite state of disaster solely to cater for the vaccine injury scheme and fund.

TRUST AND VACCINE HESITANCY

9. Given delays by our government in securing, and rolling out vaccines, albeit amidst a context of global vaccine nationalism, coupled with a global lack of transparency on the part of the pharmaceutical industry that have insisted on NDAs in a pandemic, we believe that the vaccination programme of South Africa hinges on a high level of trust among the public.
10. Asking the 'public' to *comment on* and also *accept* a vaccine injury scheme and fund for Covid-19 within truncated time periods under the auspices of the DMA, without including the background and/or significant details, and with clauses that *fully indemnify* vaccine manufacturers against damages claims for products that the said manufacturers insist fall within their *exclusive* and intellectual property control, without a complete rationale for its need, does not foster trust, it undermines it.
11. The truncated period to comment is unfortunate because according to [affidavits](#) filed by the Department of Health in a recent legal matter ([Solidarity and Another v Minister of Health and 16 Others \(3623/21\)](#)) negotiations and discussions with certain vaccine manufacturers including Johnson & Johnson commenced as far back as 2020 already.
12. It is also ironic and deeply unfair, for vaccine manufacturers who have benefited from significant public funding for the research stage, who have held onto their Intellectual Property claims, to now seek to pass the *damages burden* or harm burden to the public and the state:
 - a. For example, [Wouters et al](#) in an article in the *Lancet* showed that at least \$10 billion in public and non-profit money was invested in research, development and production of COVID-19 vaccine candidates.
 - i. This includes \$1.5 billion from the US government towards Johnson & Johnson and \$445 million from the German government towards BioNTech with Pfizer. Yet these very companies are refusing to share the technology and know-how with the world to increase supplies for those most in need and form the basis of our vaccination programme (vaccine selection).
 - b. The said, companies also continue to treat publicly funded vaccines as a market commodity, but in this instance and for this purpose (compensation scheme) they are reportedly insisting on sovereign governments, including South Africa, to treat vaccine injury programmes as if it is a public good, in other words, established and underwritten by government with the public funding it, in the main. While the Regulations refer to 'other sources of funding' – it is unclear what this could mean. *Note: We include sub-licensees in the same category of 'vaccine manufacturers' for purposes of this submission. In South Africa, for example, this includes Aspen Pharmacare that has a 'fill and finish' license for Johnson & Johnson.*

13. We note that in some cases, reports have emerged that countries have been asked to offer 'sovereign assets' as surety, to permit state assets to underwrite such schemes: See for example the investigative report on Pfizer's conduct in Latin America: Madlen Davies 'Held to ransom': Pfizer plays hardball in Covid-19 vaccine negotiations with Latin American countries *Stat* 23 Feb 2021: https://www.statnews.com/2021/02/23/pfizer-plays-hardball-in-covid19-vaccine-negotiations-in-latin-america/?utm_campaign=rss
14. This is akin to a ransom situation and is unconstitutional in our view. But were civil society to legally interrogate the need for such a scheme to be established in the manner in which it is being presented, using the laws and processes available to us – the risk is that MNCs, who have already signed vaccine supply deals with government for an imminent and long-awaited vaccine roll out, could withdraw their supplies, citing breach or non-delivery (we are unaware of the details of the contracts as they have not been made public, this means we do not know what was agreed in full between government and the relevant vaccine manufacturers).
15. We therefore make this submission against a context of compulsion - reluctantly accepting the establishment of such a scheme on an expedited basis, because our people need vaccines urgently, given the sheer devastation of this pandemic on our health system, impact on mortality and morbidity, and on the economy, and levels of employment and people's livelihoods too. This does not mean that we fully support or even accept the *perimeters* of the proposed compensation scheme and fund - in the way that it is currently envisaged:
16. We appreciate that there is a body of thought that also suggest that:
- “Guaranteeing that recipients of COVID-19 vaccines are automatically eligible for compensation that covers not only health-care costs but also loss of livelihoods will help to maintain public vaccine acceptance. Uptake [of C-19 vaccines] will depend on securing sufficient vaccine supplies, creating a robust and equitable distribution scheme, and fostering public trust in the safety of the vaccines with adequate legal safeguards to prevent and compensate for inadvertent harm.”
- Fairgrieve, Duncan et al.** “In favour of a bespoke COVID-19 vaccines compensation scheme” *The Lancet Infectious Diseases* Volume 21, Issue 4, 448 - 450, available: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00065-7/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00065-7/fulltext)
- Also see: **Sam Halabi et al** “No-Fault Compensation for Vaccine Injury — The Other Side of Equitable Access to Covid-19 Vaccines” *N Engl J Med* 2020; 383:e125; available <https://www.nejm.org/doi/full/10.1056/NEJMp2030600>
17. We also do not want or support a situation where South Africa risks having serious injuries that are vaccine related (causal connection) in a handful of people but where the government is unable to offer compensation.
- a. However, where negligence on the part of manufacturers is involved, they cannot be fully indemnified, especially for negligence that is 'external' and outside of the control of South Africa's health institutions, workers and government.
- See for example the [contamination](#) of up to 15 million vaccine doses from Johnson and Johnson in Baltimore, USA in March this year. Had these

vaccines been administered to humans, it would be unreasonable in our view for damages claims to be lodged under the compensation scheme here. IT would also have significant financial implications and solvency would be at risk.

C:

International developments that have a bearing locally or offer useful guidance:

We note that the World Health Organization has established a '[No Fault Compensation Scheme](#)' for COVAX (GAVI), presumably also at the request of the pharmaceutical industry.

1. According to the WHO, the purpose 'is to provide fair no fault lump sum compensation in full and final settlement of any claims to individuals who suffer a serious adverse event (SAE) resulting in permanent impairment or death associated with the administration of a COVID 19 vaccine procured or distributed through the COVAX Facility in any Gavi Advance Market Commitment (AMC) eligible economies until 30 June 2022'.
2. It is important to note that COVAX has only secured deals with some vaccine manufacturers, not all, and that while South Africa is participating in the COVAX facility, for access to both Pfizer and Johnson & Johnson vaccines (for now), it is not to our knowledge regarded as an 'AMC eligible economy' even though it is self-financing its participation as a middle income country.

United States

The *US National Vaccine Injury Compensation Program* is set up for vaccine injuries generally, not just COVID-19. See: <https://www.hrsa.gov/vaccine-compensation/faq>

1. It provides for an alternative to personal injury lawsuits for resolving vaccine injury petitions.
2. [The Countermeasures Injury Compensation Program](#) (CICP) provides for benefits for "countermeasures" in instances where a person suffered a serious injury or a death of a loved one. Countermeasures are defined as "a vaccination, medication, device, or other item recommended to diagnose, prevent or treat a declared pandemic, epidemic or security threat".
3. COVID-19, Ebola, Zika, Anthrax, smallpox and a limited number of other health threats are listed and relate to pandemics, epidemic or security issues. The Programme is provided for under the [Fourth Amendment](#) to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration.
 - a. The Programme covers participants in authorised clinical COVID-19 trials, while health care workers administering the COVID-19 vaccine is immune from liability if certain provisions are met, except for "wilful misconduct" with

respect to all claims for loss caused by, arising out of, relating to, or resulting from the manufacture, testing, development, distribution, administration, and use of a COVID-19 vaccine.”

- b. Section XII of the Fourth Amendment provides for the time periods of liability protections. With some exceptions for routine childhood vaccinations it begins with a “Declaration of Emergency” and lasts until the final day of the Declaration of Emergency, or until 1 October 2024, whichever occurs first.
- c. Vaccines must be “authorised, approved and licensed” by the Federal Drug Authority, while COVID-19 vaccines must be ordered and administered according to the vaccine recommendations of the US’s Advisory Committee on Immunization Practices.

D: HJI Commentary on Draft Regulations

1. Above, we deal with the standing of the draft Regulations and its location under the DMA. Specifically, whether it is permissible to issue *regulations* for the establishment of the scheme and fund under the DMA, and not, for example under the NHA or in the alternative, a special ‘Covid-19 Act’ (as other countries have done).
2. In addition: The draft Regulations as they stand, contain minimal details and information on the specifics and cost of the proposed mechanism, it offers no real insight into how the mechanism will work. Key details and information are left to further *regulations and directives* and then within the control or discretion of the Minister/Director-General. For example:

Amounts and structure of compensation

The Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, must issue directions in terms of regulation 4 specifying the amounts and structure of compensation that will be provided under the Scheme. (section 90(2) of the Draft Regulations)

- a. This makes it difficult to comment on the mechanics of the fund, as mostly, it is still to be developed in the future.
- b. A worrying aspect is that the draft Regulations seek to set up a ‘fund’ which has money and funding implications, but is extremely vague about how the scheme will be funded, what it will cost, and what financial contribution the public or others will actually make.
- c. It is also not clear whether said vaccine manufacturers will contribute to the fund or whether they are given special exemption (and the rationale for such an approach then) - potentially leaving the entire financial burden of maintaining the fund to the state and in turn the public.
- d. In this respect **Section 90.3** provides:

The fund consists of:

(a) *funds appropriated by an Act of Parliament to the vote of Health or from contingencies in terms of appropriation legislation or the Public Finance Management Act; and*

(b) ***funds accruing from any other source (emphasis added).***

It is unknown what 'other sources' entail, and how those sources will or may be permitted to interact with the *administration* of the scheme (because of their partial contribution).

Also, whether such sources include vaccine manufacturers themselves – otherwise the state is effectively setting up a fund for the full financial benefit of the pharmaceutical industry.

3. It is concerning that the draft Regulations in **Section 95.3 (a) and (b) propose full indemnification of vaccine manufacturers** precluding and barring anyone in South Africa from taking action against a vaccine manufacturer (civil or criminal) even for negligence or conduct that took place outside of South Africa. This is in our view an unjustified restriction on the rights of people living in South Africa, under our Constitution and other laws.
 - a. It is also absurd and unfair to grant full indemnification to companies that are regarding the vaccine as their private property, where they are not treating it as a global common good (except for when it comes to harm mitigation).
4. We are concerned that as is, the scheme actually contributes to further inequality in the contractual and commercial relationship between private actors and the public in this pandemic in our country.
 - a. For example: The appeal mechanism and rules applicable to lodging an appeal against the Adjudication Committee is not particularly favourable for people with limited means of access to private legal services or even public legal services.
 - b. This could lead to a situation where wealthier people are able to benefit from the appeal mechanism, while ordinary poor and working-class people have no affordable appeal recourse.

Again, this highlights the injustice of the situation of establishing a scheme and fund under duress, to benefit the vaccine manufacturer industry, and not ordinary people.

5. There are no schedules for compensation levels, no claim criteria either that we can offer comment on. This critical aspect is also left to 'directions' to be issued later: See for example:

Amounts and structure of compensation

94. The Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, must issue directions in terms of regulation 4 specifying the **amounts and structure** of compensation that will be provided under the Scheme.

6. Because the **administrator** of the fund is yet to be determined (identity), it is impossible to make an evidence-based argument on the merits or demerits of the selection choice, suggesting it will not be open for public scrutiny.

- a. We are of course concerned that often with state administrators, there is a high risk of insufficient capacity, requiring greater outsourced personnel and costs.
 - i. If for instance Old Mutual or another private insurance company is tasked with this, we may want to introduce evidence to argue against such an appointment.
- b. It is unclear what is an 'institution or service provider' for the purposes of the draft Regulations?
- c. The HJI has been seized with the issue of [pandemic gouging](#) and corruption in the private sector in this pandemic, we are wary that one of the most important schemes/funds for South Africa could be: i) outsourced and/or ii) located within a national department that has limited actual experience of managing a solvent compensation fund.
- d. South Africa also has a history of uneven success [with compensation schemes run by the state and private sector](#), that is extensively researched and documented.
- e. It is also possible that departmental directives could be inequitable or unfair to the general public - what is the public recourse in such a situation?

Too much of the important detail for this proposed scheme is left to 'another time' - when we are faced with a pressing public health crisis now- and which needs to gain public trust immediately.

Which authorisations does the scheme cover:

1. To date, the Pfizer vaccine only has a s21 approval from SAHPRA, will this and other s21 authorisations also be included under the scope of the scheme?

Section 93. (1)

Subject to this regulation, a person who has suffered a vaccine injury referred to in subregulations (2) and (4)(b) caused by the administration of a COVID-19 vaccine contemplated in subregulation (4)(c) that is registered or otherwise approved by the South African Health Products Regulatory Authority and procured and distributed by the National Government, at a facility within the Republic specified in terms of subregulation (4)(d), is eligible for compensation under the Scheme.

2. We are aware that Sputnik V and Sinovac and Sinopharm vaccines are also awaiting SAHPRA approval - is the scheme also intended for vaccines supplies by companies other than Johnson & Johnson and Pfizer?
3. The draft Regulations are drafted on the basis that there will be permanent centralised state procurement and allocation of vaccines (mainly to address equity in allocation, not compensation). The HJI has supported this approach in a time of scarcity and because of global vaccine inequity (see our papers as friend of the court in (Solidarity and Another v Minister of Health and 16 Others (3623/21) and our Commentary on Governments Presentation of its 'Vaccine Strategy').
4. Should vaccination become a long term project, which some experts indicate that it may, given variants and resistant strains, and/or if vaccine manufacturers take a decision to sell to medical schemes and private health providers in the near future (as it is making all the access decisions, not government) the draft Regulations as drafted, do not cover privately acquired and administered vaccinations in that situation. This should be addressed upfront.

Causation:

We endorse the People's Health Movement - South Africa Submission on the draft Regulations, and include its submissions on **causation** here:

1. *The nub of the regulation is what kind of harm qualifies as a compensable injury. The regulation speaks about "severe injuries resulting in permanent or significant injury, serious harm to a person's health, other damage or death." This may be vague and subjective. COIDA [The Compensation for Occupational Injuries and Diseases Act, No. 130 of 1993] spends a lot of time defining what is and what is not covered, by comparison. It has a schedule of injuries/illness which default to being compensable. If you develop an injury or illness other than the listed conditions, you have to prove causality. The panel referred to in Paragraph 93.2 might issue a regularly updated list (Schedule) of side-effects and injuries that would minimise any burden on claimants to prove causality.*
2. *There is no mention of harms in which a vaccine reaction leads to aggravation of an existing condition.*
3. *The need to show causality (93.3) may be a huge barrier to ordinary people being able to access the fund, without the need for expert medical reports and lawyers. There needs to be an expeditious process cutting out the red tape which makes it straightforward for affected individuals to apply and get fair administrative process.*