7 January 2021

HJI's Commentary on the 3rd January 2021 presentation by National Minister of Health, Dr Zweli Mkhize; Professor Barry Schoub (MAC Vaccine Committee Chair) and DDG Anban Pillay (National Department of Health NDoH) on the 'COVID-19 Vaccine Rollout Strategy' of the SA Government

Introduction and background

1. The HJI has raised the issue of access to a safe and effective, and affordable vaccine/s for both the public and private sector in our country and the global south, calling also for equitable allocation of a vaccine in our country, for several months. This is because by about mid- 2020, reports indicated that there would be a global shortage of vaccines in the global south, in part due to limited supplies and global 'scarcity' fuelled by the stockpiling of wealthier nations and the invocation and applicability of Intellectual Property (Patent) rules in a pandemic.

2. We encouraged government and the private health sector to adopt a *single* Access and Equitable Allocation Plan, to ensure, that in this pandemic, that everyone, everywhere, who needs a vaccine, can access it. Where access is not based on wealth or medical insurance benefits.

3. This is important for social solidarity (#1Country1Plan) and is also in line with calls from health advocates in other parts of the global south too. It will lend itself to achieving herd immunity hopefully in our country and region. Public health principles also require that herd immunity can only be achieved by *widespread access* to vaccines. We are all protected when everyone is protected and non-infective.

4. In November 2020, because we were concerned about the lack of communication from those entrusted with and responsible for this function by law, we formally began correspondence with the Disaster Management Centre (DMC), COGTA and the Minister of Health, copying in various officials including the MAC Vaccine Advisory Committee Chairperson. Since then, we have sent three letters requesting a detailed response to several questions.[i]

5. We said in our letter on 15 November 2020 that:

> *"We are, however, concerned about the* ***government's readiness*** *in relation to the access and allocation of Covid-19 vaccines. Such concern is predicated on:*
>
> *1. South Africa's ability to access vaccines — once developed — in light of the predicted pricing, global shortage and high demand which may even require rationing.*
>
> *2. The determination of an equitable allocation of such vaccines within South Africa in light of the dual nature of our unequal health system and the vast disparities in access to the right to healthcare.*
>
> *3. An incomplete medicine pricing and patent framework where local laws that could benefit vaccine access, affordable pricing and equitable allocation, have not yet been passed."*

6. To date, only the DMC has replied, indicating (incorrectly, in our view) that the function of the national vaccine strategy is located solely in the NDoH.

7. We are yet to receive a formal response from the NDoH and COGTA, despite being promised one from the NDoH (Office of the DG) several times in late 2020.

8. We will continue our correspondence and consider all our options, while we also urge government to respond in writing to the questions we raised, in the interests of transparency and solidarity, given the presentation of 3 January 2021 as well.

COVID-19 Vaccine Rollout Strategy presented by Minister of Health

1. On 3 January 20201, finally, government broke its silence and indicated to the nation the status of various vaccine negotiations and its attempt/s to access limited supplies in a global pandemic, including through COVAX.

2. The PowerPoint presentation was shared on national television and through a zoom webinar for journalists and other interested parties.

See https://sacoronavirus.co.za/2021/01/03/south-africas-vaccine-rollout-strategy/

The NDoH/MAC PowerPoint Presentation dated 3 January 2021 can be accessed here: https://www.healthjusticeinitiative.org.za/post/vaccine-equity-access-and-allocation

HJI's preliminary comments on the COVID-19 Vaccine Rollout Strategy presentation

We have reviewed the presentation and applicable communiques / announcements over the last few days, in response to the Ministers presentation. At present, we would like to point out the following:

1. We welcome the Ministers briefing to the nation, albeit late, it broke a worrying silence.
2. We are encouraged that the Minister acknowledged that the nation is anxious, and in need of information, given the devastating impact Covid-19 is having on our country and especially on our health system.
3. We are hopeful that the Minister will continue weekly briefings so that *we and the media* do not have to piece together time sensitive information in this pandemic, and on this issue, in this manner. It is imperative that there is regular communication so that all sectors can play a part in meaningfully addressing this pandemic. This will help in part to address mistrust and vaccine hesitancy too, that is worryingly growing in our country.
4. We welcome the commitment to implement a single access and equitable allocation plan (combined procurement) for both the public and private health sectors in our country. This type of social solidarity, which involves all medical schemes, the business and private health sector, is unprecedented and should be recognised as such. In our view, it is appropriate and rational for a pandemic and a crisis such as the one we are facing.
    a. This will also ensure that those with medical insurance do not needlessly and without good cause get to the front of the queue, and that the vaccine is allocated on a proper, evidence and clinical need basis, an underlying equity principle which is universally endorsed. Where our entire population is subject to the same criteria and rules.
    b. Some people belonging to medical schemes may also benefit if price reductions through various deals are passed on to the entire population, providing of course, that vaccine supplies are urgently secured.
    c. Following from this important commitment by the private health sector, business, and medical schemes, we welcome the announcement on 5 January 2021 from the Council for Medical Schemes (CMS), the medical schemes regulator, that ALL schemes are required to also treat Covid-19 vaccination, inter alia, as a Prescribed Minimum Benefit (PMB), for all of its members.

       See: https://www.medicalschemes.com/files/Press%20Releases/PressRelease1Of2021.pdf
    d. Medical schemes in the country account for about 4 million members and a further 8 million beneficiaries (approximately), covering in total about 10-12 million of our people. So, this is very important.
    e. Medical Schemes also include lower income and public sector workers through schemes set up for state health care workers, state teachers, and the police as well as other public servants – 'GEMS' and 'Polmed', respectively. Members of Parliament (MPs) are also covered by 'Parmed, for example.
5. Following the presentation, by the evening of 3 January 2021, and as undertaken 'by the Minister of Health in his briefing, the previously unshared 'MAC Advisories on Vaccines' (***COVAX Participation; Vaccine Strategy; Vaccine Selection; Framework for Rational Allocation with Annexure A***) were also uploaded on the NDoH website: https://sacoronavirus.co.za/category/mac-advisories/

   17 September 2020 – MAC – One Advisory:

    a. At Page 2 it states: *'… wealthy countries have secured over 2 billion doses in deals … South Africa has also been approached by vaccine manufacturers to consider bilateral purchasing agreements. The risk of this agreement is that price negotiations are confidential, up-front payments may be lost should the vaccine not prove safe and efficacious, and South Africa will be limited to only a few vaccines through this mechanism and run the risk of not having a vaccine if these few candidates are not successfully licensed'.*
    b. Further, it indicates that the MAC was tasked with 'providing appropriate advice to the Minister regarding procurement and allocation of vaccines' (pg.2).
    c. The MAC further advised that COVAX:
        i. was only likely to cover about 3% of (presumably global south/poorer) country's populations (including SA) due to limited supplies; (pg. 3);

ii. that COVAX could potentially give SA access to 9 possible vaccine candidates (through the 'option 1' agreement);

iii. that the possible forfeit of a down payment could be **up to 20%** (thus, up to 20% of approximately ZAR 320-350 million) if a vaccine candidate did not come to market (pg. 5); and

iv. would charge about '**$10.55 - $22.10 (ex-factory), excluding delivery and logistic costs' for COVAX accessed vaccines (pg.5).**

d. The MAC also recommended:

i. Government exercise 'due diligence in confirming any arrangements with COVAX' (the COVAX contract was received on 15 September 2020 and MAC stated that SA and other countries would have little decision-making power with COVAX);

ii. That the NDoH should 'negotiate funding from medical schemes, National Treasury and the Solidarity Fund' and that 'bi-lateral discussions should continue' (pg. 4).

15 December 2020 - Three Advisories:

a. The advisories reference '273 vaccine candidates at the time, 14 in phase 3 clinical trials, 4/5 with preliminary or published data, with efficacy ranging from 70% - 95%'; selection criteria; and **research gaps especially for people with co-morbidities and pregnant women.**

b. **Annexure A** sets outs the '*Framework for Rational Allocation'* per the MAC, for limited supplies contexts, relying on *WHO SAGE* principles.

c. It also indicates that **'SOPs are being drafted for the roll out programme' and highlights the 'urgent need to put in place a multi-sectoral communications strategy'.**

d. The last page (pg. 6) of 'Annexure A' includes the **proposed allocation and distribution percentages per priority group** for South Africa.

HJI's Concerns as of 7 January 2021

A. While the 3 January 2021 presentation was the first step in what must now become a longer process of sharing timely information regularly and honestly, **Government is yet to respond formally and in writing to the HJI's request for information**. A written response is necessary because the presentation did not cover all aspects of the planning (and detailed plans) for *Covid-19 Vaccine Access and Equitable Allocation* in South Africa, the subject of our initial correspondence.

B. At the very least, the **DMC, COGTA and NCC must be part of future briefings as well as the National Command Council (NCC).**

C. Also, there is an unprecedented crisis which requires **all relevant Ministries and Departments and especially the National Treasury (e.g., to guarantee appropriate and timely budgets/financing); Department of Science and Innovation; and Department of Trade Industry and Competition**; to work together with all stakeholders. Our legal frameworks also require this.

D. In our correspondence with government, we drew their attention to the fact that the objective of the DMC is to 'promote an integrated and co-ordinated system of disaster management, with special emphasis on prevention and mitigation' which has a legal obligation to develop guidelines for the preparation of disaster management plans'. We wrote:

> *'The National Centre is accordingly the body mandated by statute to ensure South Africa has a co-ordinated and effective strategy to respond to a disaster. The affordable, equitable and transparent access to vaccines within the context of Covid-19 falls squarely within this mandate. Accordingly, the National Centre and all relevant institutional role-players responsible for managing this disaster are responsible for the development of disaster management plans and strategies for the affordability and allocation of vaccines.'*

E. The Presidency must lead and provide guidance on this matter and ensure that a multi-government department task team is established to take this matter forward. Each department has certain legislative obligations which it must meet. This is not just a health department function.

F. Apart from serious gender inclusion shortcomings in the composition of some of the task teams such as the *SA Vaccine Acquisition Task Team*, it is unclear if **representatives/members of Polmed and GEMS** will also be included, where the contribution of medical schemes itself is being addressed and finalised.

G. It is imperative that **Health Care Workers (HCWs) and those on the 'front line'** have a 'seat at the table' and on these teams, especially for the proposed national vaccination roll-out phases. Efforts have to be made to consult more broadly and urgently with HCWs and those workers in the front line at hospitals and clinics in our country.

H. In our correspondence with government, we indicated that in the absence of the existence of a reasonable, written, and equitable, *National Plan*, that government should convene an **urgent multi-stakeholder meeting**, to develop one. This request stands. This is because there is **no meaningful inclusion and involvement of community organisations, faith groups, social movements, worker formations, and civil society organisations** in these discussions and/or task teams nor it seems on the proposed *National Vaccine Coordinating Committee*. This must be remedied as a matter of urgency as the vaccination roll-out programme, once it starts, will require **all sectors** to contribute to its expansion and success.

I. Our greatest concern now lies in the fact that **our country has actually secured little to no access** of vaccine supplies in this pandemic. This is in part due to inexplicable delayed planning on the part of government and also due to self-created scarcity leading to on-going global shortages fuelled by intellectual property and patent protections of pharmaceutical companies, and hoarding or stockpiling by richer nations:

   i. We therefore do not believe that pharmaceutical companies are justified in enforcing **Non- Disclosure Agreements (NDAs)** in a pandemic, they serve no public or Constitutional interest. They are also contributing to distrust and a lack of transparency. All vaccine acquisition implicates public resources (even medical scheme funds, belong to its 'members'), hence transparency is critical.

   ii. Worse, several of these companies are releasing press statements and the like regarding their often unverified 'offers' for South Africa, meaning that they themselves are going outside of and possibly 'breaching' any NDA that they *may* have demanded in these discussions.

   iii. Presumably, NDAs have been entered into (if they exist) with the companies that our government is still negotiating with - including **Pfizer Inc; AstraZeneca; Johnson & Johnson; Moderna Inc; and CIPLA**.

   It is important that all of these pharmaceutical companies and their research partner institutions and shareholders understand that their actions are fuelling mistrust in our country – we expect them to commit to higher standards of transparency in their discussions with our government and its representatives, and to pricing transparency. A pandemic is not a time for secrecy.

   The NDAs should be lifted, they serve no public interest purpose. We have a right to know.

J. We were also surprised that the briefing and presentation did not mention our and the Indian governments **TRIPS Waiver Request** and on-going adversarial negotiations at the WTO in Geneva led by the DTIC. This is why DTIC must also be part of such briefings going forward.

   i. The proposed waiver is for some poorer countries, and potentially for us too, the only hope for quicker access to a vaccine and other interventions to manage and treat Covid-19 - because it seeks a temporary waiver of certain intellectual Property rules for Covid-19 related products and technologies. It could also enable greater manufacturing capacity in the global south and especially in Africa.

   ii. It is important that government shares details about these negotiations because it goes to the heart of limited global supplies, the power of richer nations and that of pharmaceutical companies in this pandemic. We cannot offer support on this important proposal in the absence of any or timely information.

   Note: Many rich nations including our trade partners, and Brazil (a BRICS partner) as well as the global pharmaceutical industry, are opposing the waiver request. And yet, despite their opposition, these countries and companies are rolling out vaccination programmes. And, in almost all cases, still refusing to share the vaccine know-how, inexplicably still not being regarded as a global 'public good'.

K. **Only state action can remedy this.** COVAX and bi-lateral negotiations will not guarantee us sufficient supplies, speedily. Yet despite this reality, our government is not to our knowledge, seeking state use licensing while it pursues the waiver request. We are unsure why not.

L. We also do not know who will pay **the balance of the COVAX payment** and urge government to ask the WHO or the UN to urgently intervene to mediate here, so that South Africa is also not (unfairly) treated as a middle-income country (MIC) for purposes of COVAX.

i. Also, **COVAX has many serious limitations** and due to its 'voluntary nature', no legal action can be taken against it by civil society as things stand, offering little to no recourse for us domestically.

ii. There are also concerns with COVAX's governance frameworks, tiered pricing model, pricing calculations, classification system, secrecy, and lack of transparency especially about the terms and conditions of its country and pharmaceutical company agreements, which it is treating as highly 'confidential'.

If the South African public is expected to foot the balance of the bill for COVAX, for limited supplies in the next few months, these issues must be elevated to global platforms such as the WHO and the UN, because as things stand, we have no recourse against the secrecy underpinning COVAX and its supplier agreements. We are now, as a result, at its mercy.

M. We note from the presentation and subsequent reports, that the **NDoH and the MAC** have been and are in on-going discussions with potential vaccine suppliers (as none are registered for use in South Africa as yet by SAHPRA):

i. Specifically, Government needs to advise the public how it will ensure that a 'low profit' or 'no profit' 'offer' is verified to be such, and confirm that the offer is indefinite, **not conditional for just for a 'few months' or to 'end 2021'** as some reports now suggest. This requires our government to develop certain **non-negotiable conditions** for finalising bi-lateral discussions with vaccine front-runner companies (none are registered for use yet).

ii. NDAs and the veil of secrecy around bi-lateral negotiations in South Africa may also mean that we **pay a higher price** for some vaccine candidates**, without reference to international benchmarking, pricing or offer transparency and even domestic price regulation.**

iii. We are unsure if any of the pharmaceutical companies listed in the briefing and who are pursuing bi-lateral discussions with our government have actually **filed patent applications with the CIPC** and/or the basis for their approval (if any) in a pandemic. Information about this must be shared publicly so that in certain instances, they can also be opposed by public interest groups (pre- and post-patent grant opposition). Amendments to our Patent laws, now residing in Parliament, will also assist with this. It is urgent that we pass them into law.

iv. We remain concerned that the global scarcity of vaccine supplies may lead to price-gouging or excessive pricing - we therefore **urge the Competition Commission to evaluate and assess all vaccine pricing claims to ensure price transparency in this pandemic, proactively and pre-emptively**.[ii] COVID monopolies are not the answer to our access challenges.

The HJI will provide further commentary on the proposed *Vaccination Roll-Out* programme for South Africa as details of that emerge (especially regarding priority groups and mechanisms to administer vaccines nationally). However, the **criteria for vulnerable populations or prioritised populations** requires urgent consensus and engagement with the public, and key health and other experts.

We certainly do not want a situation where those **most vulnerable**, due to their age, race, gender, sexual orientation, religion, pregnancy, health status, profession, nationality, wealth, income, employment status, housing status, living conditions, etc, are excluded from vaccination coverage, or last in line. The Constitution is very clear about this.

Concluding remarks

We are in a pandemic. This is no time for quiet diplomacy and long or drawn-out negotiations - our people are getting sick and dying, our health system is at strain, and pharmaceutical companies are refusing to share vaccine know-how and technology, even though some vaccines were researched here, and several vaccine candidates benefited from global public investment and philanthropic and institutional research support, running into billions of US dollars.

We need decisive state action, and proper planning and plans so that we can have a genuine People's Vaccine (a call that our President has led and endorsed).

We also strongly recommend that government urgently revamps the MAC Vaccine Advisory Committee/s, appoints additional expert committees and members that prioritise the voice of all communities and especially front-line workers, and brings on several multi-sectoral advisors and negotiators, as a matter of urgency.

Distrust is not going to help us move forward

Ends

For comment please contact Fatima Hassan (HJI Head)

[i]

a. 'Has the National Centre, developed guidelines concerning the development, review and updating of disaster management plans which deal with access to and allocation of vaccines (Vaccine Access and Allocation Plans)? If so, kindly provide us with a copy of the guidelines.

b. If the National Centre has not developed such guidelines, kindly advise on the steps which will be taken in order to comply with this statutory duty, as well as the proposed timeline.

c. Is there a plan to budget and prioritise vulnerable groups and key populations in relation to access to and allocation of vaccines? If so, what is the plan? It would be appreciated if we could receive a copy of any such plan.

d. Which specific institutions and national organs of state have been identified as the key institutional role-players involved in disaster management which would be required to develop Vaccine Access and Allocation Plans as part of their disaster management plans and strategies?

e. Have any of these key institutional role-players developed Vaccine Access and Allocation Plans? If so, kindly provide us with copies of the plans.

f. What specific steps have been taken by the National Centre to assist with the co-ordination and implementation of these plans if / when they are developed?

g. We assume that to the extent that Vaccine Access and Allocation Plans have been developed, they will be made public in the interest of transparency, accountability, and general good governance. It is in that context that we have requested copies of any guidelines and Vaccine Access and Allocation Plans. If you are for any reason unable to provide copies to us, please advise us as to the reason/s why, and how we may otherwise obtain a copy.

h. In the event that no Vaccine Access and Allocation Plans have been developed, we would respectfully request that you advise on the proposed timeline for the development of such plans and consider having an urgent multi-stakeholder engagement regarding the factors which should be considered while developing them.

See: https://www.dailymaverick.co.za/article/2020-12-01-health-justice-initiative-wants-details-of-states-plan-to-get-covid-19-vaccine-to-sa/

[ii] In July 2020, the HJI requested that the Competition Commission consider **pre-emptive price regulation** for this very reason. Failing which, we can challenge certain price determinations, only after the fact, and seek remedies and penalties against offending companies later. This is important in our view because it is uncertain whether the/a vaccine for Covid-19 for private sector use will be exempted from the ordinarily applicable medicine pricing framework (also called the "SEP" – single exit price).