Strengthening antivenom access in South Africa: Regulatory priorities and policy actions

R Majeed,[1] J Bester,[2] MA Strydom[1]

[1] Department of Pharmacology, Faculty of Health Sciences, School of Medicine, University of Pretoria, South Africa

[2] Department of Physiology, School of Biomedical Sciences, University of the Witwatersrand, South Africa

Corresponding author, email: ramsha.1133@gmail.com

Abstract

The critical antivenom shortage in South Africa is a consequence of fragmented regulations, constrained manufacturing capacity and weak stakeholder coordination. The snakebite envenoming (SBE) burden is preventable if access and equity are prioritised. Priority barriers were identified using the nominal group technique (NGT) through two expert consultations with members of the South African National Snakebite Advisory Group (NSAG). Experts emphasised urgent reforms to regulation, improved surveillance, supply chain governance and clinical guidance. Recommended actions include listing SBE as a notifiable medical condition, streamlining Section 21 import authorisation processes, strengthening national stockholding strategies, and restructuring South African Vaccine Producers (SAVP) through a public-private partnership. Through strong stakeholder engagement and leveraging technical expertise, the chronic antivenom shortage could be reversible. Without immediate regulatory and strategic reform, preventable deaths and disability from snakebite will continue.

Keywords: snake antivenom, access, South African Vaccine Producers, SAHPRA, regulations, stakeholders

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Introduction

In 2017, the World Health Organization (WHO) listed snakebite envenoming (SBE) as a priority neglected tropical disease, and in 2019 introduced an ambitious roadmap to reduce the burden by 2030.[1] After Asia, the disease burden is heaviest in sub-Saharan Africa.[1] A recent incidence study from South Africa reported 3496 cases from 2011 to 2024, with highest prevalence in KwaZulu-Natal. Most victims were males, bitten between November and March, and largely by *Bitis arietans*.[2] The incidence was determined in the study through hospital reports, Afritox Telelog database of the Poison Information Helpline of the Western Cape (PIHWC) and the National Snakebite Database established by the National Snakebite Advisory Group (NSAG).[2]

Although only 4.5% hospitals reported snakebites, there were inconsistencies across datasets regarding victims' age and snake species. Snakebites not resulting in hospitalisation go underreported. Reliable epidemiological data are not available due to underreporting and patients not accessing health facilities physically, leading to an under evaluation of the epidemiology.[3]

The South African Vaccine Producers (SAVP) is the sole manufacturer of antivenom in South Africa, and until recently its product was the only polyvalent antivenom available in sub-Saharan Africa, further exacerbating concerns regarding the security of supply.[1] SAVP products include equine antivenoms; monovalent antivenom against the Boomslang (*Dispholidus typus*), and polyvalent antivenom targeting the ten medically important snakes: the Puff adder (*Bitis arietans*), Gaboon adder (*Bitis gabonica*), Rinkhals (*Haemachatus haemachatus*), Green mamba (*Dendroaspis angusticeps*), Jameson's mamba (*Dendroaspis jamesoni*), Black mamba (*Dendroaspis polylepis*), Cape cobra (*Naja nivea*), Forest cobra (*Naja melanoleuca*), Snouted cobra (*Naja annulifera*) and the Mozambique spitting cobra (*Naja Mossambica*). Antivenom for Exotic Saw-Scaled Viper (*Echis ocellatus*) is also available.[4]

The region relies on imports, disregarding the toxin specificities which vary geographically. The absence of clinical testing and economical deficits allow variable-quality and inadequately evaluated products to circulate in the African markets, dampening confidence in antivenom.[1] Solano et al. mentions that procurement of SAVP polyvalent and monovalent antivenom outside South Africa is difficult, due to high costs and worsening of the supply chain.[5] The South African Health Products Regulatory Authority (SAHPRA), under the medicines and related substance act (Act 101 of 1965), regulates antivenoms. SAHPRA implements the legal framework for regulation, control, manufacture, import, distribution and sales of medicines. As such, antivenoms undergo registration, and manufacturers must establish safety and good manufacturing practice (GMP) compliance. The Act requires a legal framework requiring pharmacovigilance activities, including adverse event reporting, labelling and monitoring.[6]

Section 21 of the Medicines Act dictates authorisation of locally unregistered products. In the absence of medicine shortages, foreign products may be imported only in emergency situations. The legal pathway is managed by SAHPRA, although administrative complexity may result in delayed access during clinical emergencies.[7] This is relevant due to the recent adoption of the World Health Organization Good Manufacturing Practice (WHO-GMP) approved PANAF-Premium (Snake Venom Antiserum – Pan Africa), produced by Premium Serums and Vaccines (India) while the SAVP antivenom supply chain remains challenged.[8-9]

Recent national shortages reported since mid-2024 were associated with a temporary suspension in SAVP production.[10] A communication by the National Health Laboratory Service (NHLS) on 23 September 2025 announced resumption of both the polyvalent and monovalent antivenom production.[11] Despite this, the challenges of SBE extend beyond production capacities, to quality assurance, regulatory oversights, eroding confidence of usage, fractured health infrastructures and under reporting.[12] The gaps are glaringly reflected by the absence of policy-based publications collating national data on SBE and providing practical solutions. This is supported by a previously conducted scoping review of literature, which showed alarming deficit of research studies focused on antivenom regulations in sub-Saharan Africa.[13] The problems are extensive but where should our efforts be concentrated to solve the crisis at a national level? Drawing from expert consensus, this paper identifies key challenges affecting snake antivenom supply in South Africa and proposes actionable, evidence-informed policy recommendations to improve patient access and equity.

Methods

This study employed nominal group technique (NGT) interviews. The challenges regarding snake antivenom access explored in a previously conducted scoping review[13] were contextualised to the South African setting. Through expert consultation, the priority barriers to access were identified, ranked, and corresponding action points proposed.

Study participants

Ethics approval was obtained by the University of Pretoria Research Ethics Committee. Participants in the interviews were members of the NSAG, recognised as key opinion leaders. The group is made up of healthcare professionals, herpetologists, academic experts and experienced practitioners in snakebite treatment and management. Members were invited via email, and the scoping review was provided as pre-reading. Informed consent was obtained, and demographic information was collected. A total of 11 participants took part, and two interview sessions were conducted to allow sufficient time for discussions. It is recommended to have up to nine participants in one NGT session.[14] The session allocation was guided by participant availability at the scheduled times; the grouping was not intentional.

Group discussions

The interviews were conducted virtually on Microsoft Teams by the principal investigator (PI). Figure 1 shows the meeting workflow. The session opened with the research question; *'What are the priority regulatory challenges affecting the snake antivenom access and availability in South Africa?'*

This was followed by a 10-minute individual self-reflection period, where participants contemplated and wrote their ideas in response to the research question. After this, round-robin sharing of ideas was initiated, where each member voiced one idea per turn, and it was noted on the whiteboard by the PI. Once all ideas were listed, a group discussion ensued whereby the members were provided a chance to clarify each idea in turn. The ideas were then grouped into similar themes.

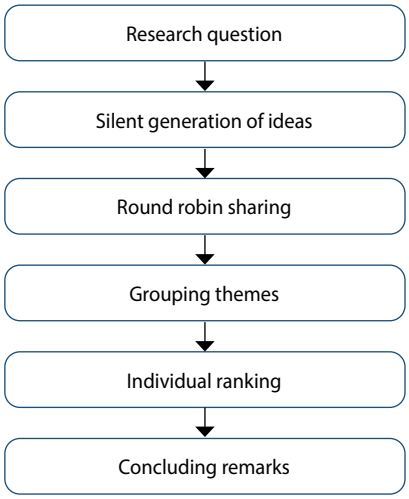

Figure 1: The workflow used during the virtual interviews

A five-minute period was provided to the experts, to rank their top five priority challenges on mentimeter.com.[15] The data from the discussion whiteboard was cleaned and shared with the experts after the meeting and they provided possible action points via email.

Data analysis and policy brief

The results of the group discussion were used to rank the challenges regarding antivenom access in South Africa, based on priority. The selected problems were charted next to action points. The results from the focus group interview were used to make actionable recommendations to the policymakers.

Results

Several themes emerged from the interviews, which were then ranked by the participants according to priority. The results of the NGT sessions are provided in Figure 2 and Figure 3.

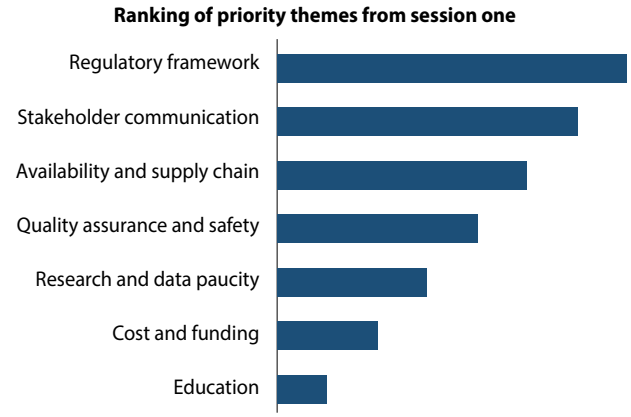

Figure 2: The priority challenges affecting snake antivenom access to patients in South Africa ranked by experts who participated in the first NGT session

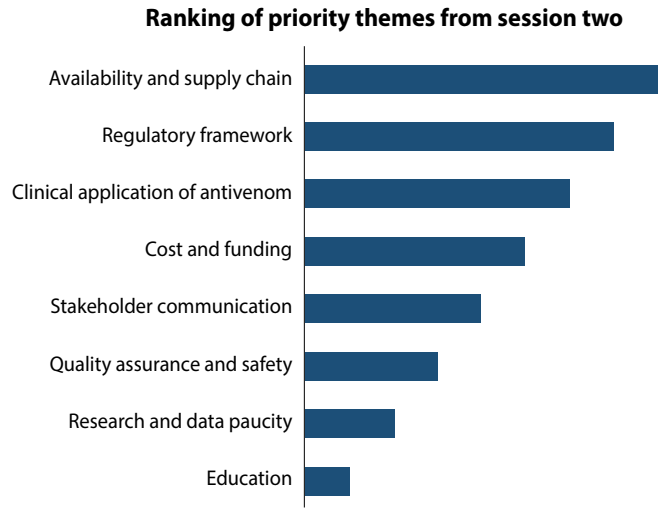

Figure 3: The priority challenges affecting snake antivenom access to patients in South Africa ranked by experts who participated in the second NGT session

As shown in Figure 2, seven themes surfaced in the first meeting with five participants. Regulatory frameworks took precedence, while cost and funding, and education were not ranked as priority. In the second meeting with six participants (Figure 3), there were eight themes with addition of clinical application of antivenom. Availability and supply chain was the principal challenge, followed by regulatory framework. Both groups included stakeholder communication as a major obstacle.

The inclusion of clinical use of antivenom and choosing availability as a major barrier could be attributed to some members in group two being healthcare professionals who manage snakebites and directly engage with patients. Group one which was largely made up of medical doctors and conservationists steered towards organisational failures and stakeholder communication.

Table I provides a summary of each theme and the challenges identified by the participants which hinder access to patients.

Table I: A summary of key barriers to antivenom access for each theme, according to the participants

Theme	Challenges
Regulation and governance	Snakebite envenoming is not a notifiable medical condition (NMC) in South Africa, resulting in the absence of a formal national reporting system and limited transparency regarding antivenom availability. Experts highlighted reliance on manufacturer-provided guidance due to the lack of nationally standardised treatment protocols, including the non-registered products such as PANAF-Premium which has been widely adopted under Section-21 of the Medicine Control Act 101 of 1965 in South Africa. Ambiguity exists regarding regulatory requirements for WHO prequalification and product approval. Outdated and unclear package inserts further limit safe administration. The classification of SAVP polyvalent antivenom as a Schedule 2 medicine was viewed as an additional regulatory constraint to emergency access.
Supply chain failure	South Africa relies on a single domestic manufacturer the SAVP, with no alternative suppliers or strategic stockpiling mechanisms. There is no centrally coordinated system for tracking inventory or maintaining emergency reserves. Frequent hospital-level stockouts were reported, and no national policy mandates stocking of antivenom in health facilities. Access is particularly limited in rural areas due to health system constraints, financial barriers, logistical delays and unreliable cold-chain infrastructure linked to electricity instability. Regulatory pathways for emergency importation were described as unclear and difficult to operationalise.
Stakeholder communication	Communication between regulatory authorities, manufacturers, clinicians and policymakers was described as inconsistent. Experts indicated that technical expertise is frequently excluded from policy-level decisions and that there is no formal platform for national coordination. This lack of structured engagement contributes to misaligned priorities, delayed responses during shortages and inconsistent messaging across institutions responsible for antivenom governance.
Quality assurance and safety	Participants raised concerns regarding inconsistent application of WHO quality assurance standards, allowing poorly evaluated products to circulate the market. Adverse reactions, particularly anaphylaxis in children, have eroded clinician confidence in antivenom use. Insufficient species-specific antivenoms and disregard for regional venom variation were also identified. Limited transparency regarding venom sourcing, animal husbandry and production methods was reported, alongside a lack of accessible toxicological data such as lethal dose 50 (LD_{50}) values and potency testing outcomes
Data and research gaps	South Africa lacks a national surveillance system for snakebite, resulting in limited epidemiological visibility and unreliable burden estimation. There is little published research evaluating antivenom effectiveness under local conditions. Experts also highlighted the absence of pharmacokinetic studies and insufficient exploration of methods to extend antivenom shelf life, leading to unnecessary wastage and contributing to chronic shortages.
High costs and no funding	The cost of antivenom was widely regarded as a major access barrier. Facilities are often required to pay before delivery, and pricing through intermediaries was reported to inflate costs. Dedicated public funding for snakebite management is limited, and current procurement systems were perceived as vulnerable to non-transparent pricing practices. These financial barriers further restrict availability in under-resourced hospitals and for uninsured patients.
Clinical application	No South African hospitals are formally designated as snakebite referral centres. Clinicians lack standardised, locally appropriate dosing protocols, particularly for imported products such as PANAF-premium. Experts reported that manufacturer guidance frequently does not align with real-world clinical presentations, resulting in empiric dose escalation and inconsistent management practices across facilities.
Non-priority challenges	In medical schools, there is limited education and training on SBE management, and hence some practitioners are likely to be unaware of treatment guidelines. Adding on, venom collectors are not allowed to capture snakes from certain localities (e.g., Western Cape), preventing antivenom development against native species. The usual practice is to collect venom from adult snake specimens. The exclusion of juvenile snakes may not be representative of real life SBE scenarios.

Actionable recommendations

There is an urgent need to mobilise available resources, take advantage of stakeholder expertise and advocate for SBE to be a priority disease in South Africa.

1. *Liaise with the National Institute of Communicable Disease (NICD) to strengthen surveillance*

SBE should be listed as a category two NMC within a phased implementation plan. The department of health (DOH) should implement the reporting of snakebites as mandatory by all health professionals, within seven days of diagnosis, via an electronic system. The DOH should assemble a surveillance team to collect epidemiological information, establish a centrally managed database and publish monthly surveillance reports on the National Institute of Communicable Diseases (NICD) website. The NSBD established by NSAG can be a blueprint for this.

2. *Engage with SAHPRA to reform Section 21 applications and approvals for medical emergencies*

Policymakers are encouraged to engage with SAHPRA to introduce an abridged version of Section 21 application for imported antivenoms which are WHO approved, considering it as a medicine for use under public health emergency (PHE) within a phased implementation plan. A rapid review task team can streamline the process by negating the application fee and allowing rolling submission of data with post approval pharmacovigilance based on risk assessment and decrease administrative burden.

3. *Designated regional referral centres should be developed*

Collaborate with the DOH to expediate funding to build envenomation units in a public hospital per province within a phased implementation plan. Healthcare professionals in the unit must be trained in management and identification of snakebites. The unit would stock antivenom, have resuscitation facilities and protocols to minimise surgical procedures, and have laboratory and diagnostic capabilities.

4. *Establishing a national snakebite task force to consolidate information*

A stakeholder group representing snakebite expert community (NSAG members, clinicians, venom suppliers, SAHPRA, DOH, pharmacists, laboratory experts, academics and poison centres) chaired by the NHLS, with the purpose of consolidating information. The task team would be responsible for evaluating antivenom nationally, defining minimum standards, publish comprehensive treatment guidelines, develop dosing protocols (for products like PANAF-Premium) and product feedback which is not solely based on manufacturers' discretion. A website is much needed whereby all information regarding treatment guidelines, antivenom access and availability in district hospitals can be consolidated.

5. *Restructure SAVP as a public-private manufacturing partnership (PPP) to channel funding and galvanize antivenom production*

The implementation of PPP in vaccine manufacturing has demonstrated success. It would be beneficial to consult with the NHLS to develop a PPP model for SAVP, leveraging the technical capacity of the manufacturer with private funding to drive production. A blended finance model can be adopted, whereby the private entity provides capital in exchange for equity, or low-interest loans for SAVP to kickstart production in its full capacity again.

Conclusion

South Africa's antivenom crisis reflects years of structural neglect rather than technical impossibility. Snakebites are a public health problem, solvable by implementing policy changes to manage antivenom better. The urgent challenges are linked to regulatory gaps and supply chain failures. The recommendation for policymakers is to take advantage of technical expertise to restructure policies and actively engage with key stakeholders like SAVP and SAHPRA to streamline current processes. SAVPs antivenom is an excellent product, stockpiles can be recovered by implementing funding models such as PPP. South Africa's public health strategy to combat SBE should align with the WHO roadmap for 2030. To adopt a multifaceted approach to coordinate a response against snakebites and strive to achieve the sustainable development goal 3 (SDG) for health equity for all. The policy changes proposed in the study are feasible, cost-effective and urgently required.

Conflict of interest

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ORCID

R Majeed https://orcid.org/0000-0003-1960-4210

J Bester https://orcid.org/0000-0002-8931-9194

MA Strydom https://orcid.org/0000-0001-8144-4970

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