

## Stockouts: The legal framework

Sasha Stevenson  
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### The legal obligations to ensure the availability of essential medicines



- + The stockouts seen across the country violate obligations in each column. These include:
  - + Obligations under the **Constitution** to provide for access to healthcare services and not to reduce the level of healthcare provided as well as to promote the efficient, economic and effective use of resources;
  - + Obligations under the **National Health Act** 61 of 2003 to provide healthcare services and to plan, manage and control the cost of doing so; and
  - + Obligations under the **Public Finance Management Act** 1 of 1999 to ensure the proper and efficient use of public funds, including proper stock control and to prevent fruitless and wasteful expenditure.
  - + Obligations under the **Pharmacy Act** to ensure adequate stock levels

## Constitution

- + Section 27(1)(a) of the Constitution affords everyone in South Africa "*the right to have access to health care services*" - Includes positive and negative right
- + Section 195 of the Constitution requires that public administration must be "*[e]fficient, economic and effective use of resources must be promoted*" (s 195(1)(b)). Moreover, public administration must be "*development-oriented*" (s 195(1)(c)), "*accountable*" (s 195(1)(f)) and must *respond to people's needs* (s 195(1)(e)).
- + The state is bound to respect, protect, promote and fulfill the rights to *life* (s 11) and *dignity* (s 10). This means that the state may not through bureaucratic inefficiency, inaction or mismanagement permit people to suffer and die because they cannot access life-saving medicines and medical supplies.

## National Health Act

- + The **Minister** must "endeavour to protect, promote, improve and maintain the health of the population" and ensure the provision of health care services.
- + The **MEC** must "*ensure the implementation of national health policy, norms and standards in his province*" (s 25(1)).
- + The **Head of Department** is under a number of obligations under the NHA. His obligations include the duty to:
  - + "plan, co-ordinate and monitor health services and evaluate the rendering of health services" (s 25(2)(f));
  - + "plan the development of public and private hospitals, other health establishments and health agencies" (s 25(2)(j));
  - + "control and manage the cost and financing of public health establishments and public health agencies" (s 25(2)(k)); and
  - + "control the quality of all health services and facilities" (s 25(2)(n)).

## Public Finance Management Act

- + The PFMA is designed to regulate **financial management** in the national and provincial governments to ensure that public money is spent effectively and to prevent or appropriately deal with fruitless and wasteful expenditure.
- + The PFMA places a number of obligations on the accounting officer of a department. In terms of section 36 of the PFMA, the Head of Department in a provincial health department is the accounting officer.
- + As accounting officer, the Head of Department is responsible for:
  - + ensuring that the Department has "*an appropriate procurement and provisioning system which is fair, equitable, transparent, competitive and cost-effective*" (s 38(a)(iii))

## PFMA Treasury Regulations

- + The PFMA Treasury Regulations explicitly deal with an accounting officer's obligations with regard to maintaining adequate stock levels.
  - + The accounting officer to "ensure that proper control systems exist for assets and that - (a) preventative mechanisms are in place to eliminate theft, losses, wastage and misuse; and (b) stock levels are at an optimum and economical level". Regulation 10.1.1
  - + The accounting officer is also obliged to ensure that processes (whether manual or electronic) and procedures are in place for the "effective, efficient, economical and transparent use of the institution's assets" (regulation 10.1.2).

## Pharmacy Act and Rules

- + The Rules Relating Good Pharmacy Practice set out the minimum standards for the practice of pharmacy and are binding on all pharmacists.
- + Regulation 2.4 deals with the Minimum Standards for **Institutional Pharmacies**, which includes medicines depots:
  - + the Responsible Pharmacist must "must ensure that all medicine storage areas are inspected regularly (at least monthly) to at least ensure that: ... (iv) stock levels are adequate to ensure the continuous supply and accessibility of medicine at all times, including the availability of essential drugs as per the latest edition of the [Essential Drug List] / Formulary (as applicable)".

- + In addition, the Responsible Pharmacist must ensure that:
  - + *"[a]dequate inventory control systems for pharmaceutical stock held in the pharmacy and or pharmacy store as well as for ward and clinic pharmaceutical stock must be maintained by:*
    - + (i) *Establishing minimum and maximum stock/re-order levels;*
    - + (ii) *stock control accounting for pharmaceutical products, received into and removed from stock (reg 2.4.2(h)(i))."*
- + Responsible Pharmacists must also have written policies to ensure "product *availability when required*" (reg 2.3.1(a)), and that the "*procurement and distribution process is fully documented*" (reg 2.3.1(b)).

### With whom do the legal obligations to prevent / deal with stockouts lie?

- + National Department of Health – responsible for stockouts at all levels including supply
- + Provincial Department of Health - responsible for stockouts at provincial, depot and facility levels
- + Responsible pharmacist at Depot level - responsible for stockouts at Depots and facilities
- + Responsible pharmacist at facility level – responsible for stockouts at facilities

## What can be done legally

- + Reminding DOH parties of their obligations
- + Litigation?
- + Section 100? National intervention in provincial administration.
  1. When a province cannot or does not fulfil an executive obligation in terms of the Constitution or legislation, the national executive may intervene by taking any appropriate steps to ensure fulfilment of that obligation, including –
    - a) issuing a directive to the provincial executive, describing the extent of the failure to fulfil its obligations and stating any steps required to meet its obligations
    - b) assuming responsibility for the relevant obligation in that province to the extent necessary to maintain essential national standards or meet established minimum standards for the rendering of a service

## For now...

### Stop Stockouts Project

+A partnership between TAC, HIV Clinicians Society, RHAP, MSF, RuDASA and SECTION27

+Project objectives:

1. Monitor and report on drug stock outs across the country
2. Follow up on selected stock outs to ensure that they are resolved
3. Create "intelligence": navigating the drug supply chain
4. Analyse collated data to assist NDOH and other policy makers in understanding the root causes of stock outs within the public health system.