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R2-bn PPE Scandal involves hundreds of unlicensed suppliers - *Daily Maverick* (2 October 2020)

Emergency procurement for the Covid-19 pandemic saw South Africa's nine provincial health departments flush a jaw-dropping R2-billion to hundreds of unlicensed suppliers of personal protective equipment and other medical goods.

Scorpio's months-long data investigation into Covid-19 expenditure reveals that the nine health departments collectively sourced PPE and related goods from 550 companies. Of these suppliers, only 155, or 28%, were licensed by the South African Health Products Regulatory Authority (Sahpra), the country's watchdog for medical devices, PPE and related products for the healthcare sector.

The departments altogether spent roughly R2.5-billion on millions of surgical masks, respirators, digital thermometers and other goods for staff and patients at government hospitals and clinics. The R2-billion paid to unlicensed vendors means nearly 80% of the provincial health departments' expenditure for these vital goods ended up in the accounts of companies that aren't subjected to any regulatory oversight.

At least R650-million was spent on goods classified as Class B medical devices from some 80 unlicensed suppliers. These items, including respirator masks and digital thermometers, are subjected to stricter regulation and unlicensed suppliers could be charged and even sentenced to time in jail.

These revelations come amid fears that PPE of inferior quality may have jeopardised the safety of healthcare workers who risked their lives on the frontlines of South Africa's battle against Covid-19.

Our latest investigation draws on reams of procurement data released by the National Treasury in late August in a bid to bring about much-needed transparency in the wake of the country's multi-billion rand expenditure drive in the early months of the pandemic. We compared the Treasury data to Sahpra databases bearing the names of nearly 2000 companies who are licensed to manufacture, import or sell medical goods in South Africa.

This exercise revealed that each of the nine provincial health departments apparently eschewed licensed companies, some considerably more so than others, and instead directed a disconcertingly high proportion of their PPE spend towards unlicensed vendors.

The data confirms that the unprecedented emergency procurement for Covid-related goods attracted swarms of opportunistic operators who had no business in supplying health departments with controlled medical products.

The 550 unlicensed suppliers include a motley crew of IT firms, travel agencies, events and catering businesses, construction and engineering companies, transport and logistics operators, solar power installers and even auto repair shops. Scores more appear to be jack-of-all-trades "consultancy" or "trading" businesses with no apparent footprint in any identifiable industry.

In some instances, health departments funnelled virtually every last cent that they spent on PPE and other Covid-related products to unlicensed companies.

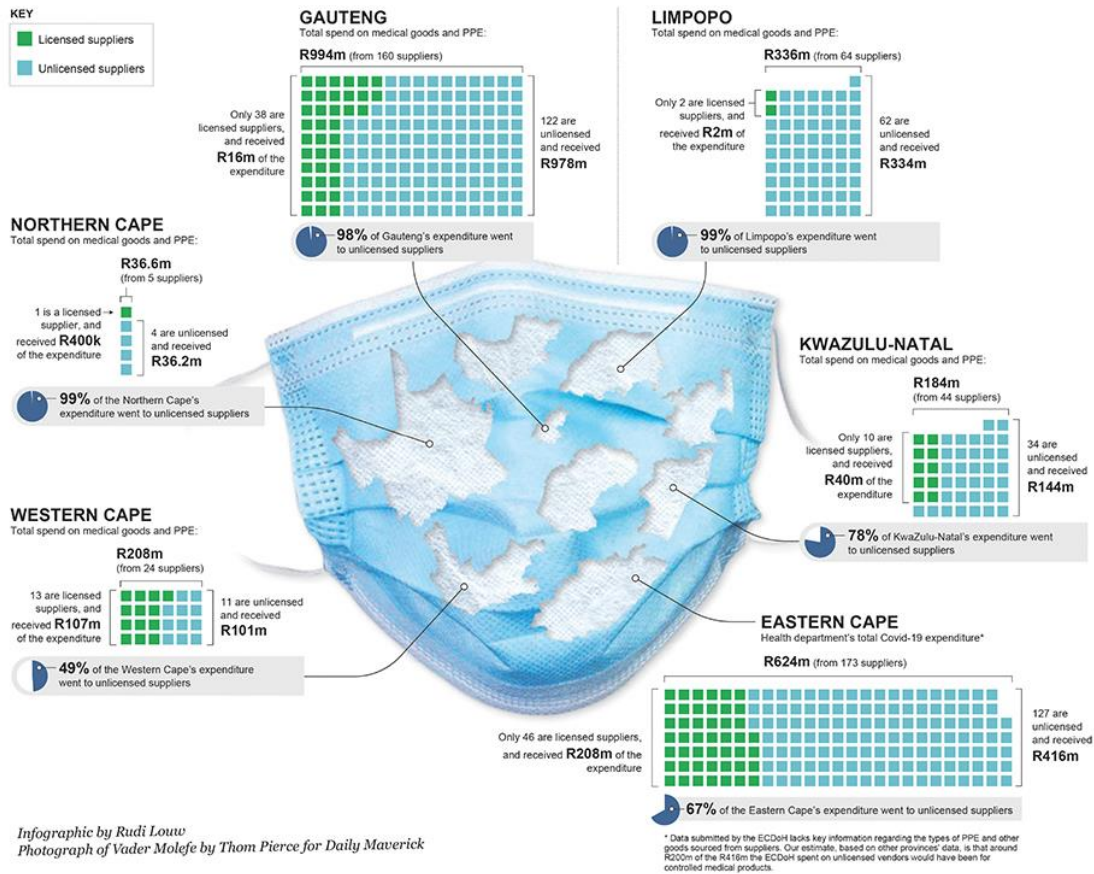
The health departments of the three worst-performing provinces in our analysis — Gauteng, Limpopo and the Northern Cape — each channeled more than 98% of their expenditure for controlled products to unlicensed suppliers. The Gauteng department of health spent R994-million on surgical masks, respirators, gloves, other PPE and digital thermometers, of which a whopping R978-million was reserved for unlicensed suppliers.

North West (94%), the Free State (82%) and KwaZulu-Natal (78%) also channeled alarming proportions of their PPE spend to unlicensed vendors.

The dubious procurement practises extended to all provinces. The two best-performing health departments, according to the available data, were those of Mpumalanga and the Western Cape. However, neither department has cause for celebration. Both managed to spend nearly half of their PPE budgets on products from unlicensed suppliers.

Analysing the disclosure reports and expenditure records from the Gauteng and the Eastern Cape health departments proved particularly challenging. Neither province included details on what exactly products they sourced from their respective suppliers. An earlier leaked dataset on Gauteng's expenditure filled most of the gaps for that province. Efforts to obtain the required records from Eastern Cape health officials were fruitless. Our figure for that province's payment to unlicensed suppliers for regulated or controlled medical goods and PPE is an estimate based on its total expenditure on unlicensed companies.

Provincial health departments' PPE and medical goods expenditure from unlicensed suppliers



In all, the Eastern Cape department of health procured R624-million worth of goods related to the pandemic. Unlicensed companies received R416m, or 66%, of this expenditure.

“All tenders relating to Covid-19 are the subject of an internal auditing process on the instruction of the MEC. There is a verification process of all these tenders, deliveries, and so forth, before any payment is made. That process is currently underway,” said Eastern Cape department of health spokesperson Sizwe Kupelo.

For our investigation, we focussed on seven products that require varying degrees of Sahpra oversight — surgical masks, respirators, aprons, surgical gowns, boot covers, digital thermometers and surgical gloves.

If these products are to be used in a clinical setting, manufacturers and suppliers need to be licensed by Sahpra.

But South Africa’s regulatory environment is replete with loopholes and grey areas — suppliers of three-ply surgical masks, for instance, aren’t required to be licensed if their masks are of the non-sterile variety.

This, however, should not have opened the floodgates for procurement from so many unlicensed suppliers, several role-players in the country’s medical goods environment told Scorpio.

The nine health departments nevertheless spent more than R650-million on respirator masks and digital thermometers from 76 unlicensed suppliers.

“There is no excuse, a procurement officer at a health department needs to check if a supplier is licensed by Sahpra,” said one industry insider who has helped draft regulations for medical devices. This source asked to remain anonymous because the organisation she works for does not allow her to speak to the media.

For Kingsley Tloubatla, chairperson of the Black Pharmaceuticals Industry Association (BPIA), the matter is “unambiguous and clear”. Tloubatla, who also runs a Sahpra-licensed medical goods company, says the Medicines and Related Substances Act prohibits companies or individuals from selling medical devices, including PPE, without a license.

Tloubatla is incensed by the fact that the provincial health departments spent most of their money on goods from unlicensed companies while businesses like those that belong to the BPIA had gone to great lengths to secure their licenses from Sahpra.

Apart from concerns over the quality of the items sourced from unlicensed vendors, Tloubatla also feels that South Africa missed a great opportunity to breathe new life into the ailing local medical goods sector.

“We should have used this crisis to re-industrialise the health-care manufacturing sector, which closed around 37 plants in the past 20 years. This would have created sustainable job opportunities for South Africans,” said Tloubatla.

“Some of the KN95 masks we received were the wrong shape and did not fit very well.”

While regulatory uncertainty and ambiguity may exist around some of the items, the licensing requirements for two of the products in our purview are clear. Suppliers of respiratory masks and infrared thermometers need a license from Sahpra. Unlicensed business owners trading in these products face possible criminal charges.

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The Gauteng department of health bought at least five million respirator masks, at a cost of about R350-million, from 14 vendors who don’t have the required license. These figures may climb as more detailed data on this province’s PPE procurement becomes available.

Spokesperson for the Gauteng provincial government, Thabo Masebe, said they will only comment once an ongoing Special Investigating Unit (SIU) probe has been concluded.

“The irregularities being investigated by the SIU include the issues you are referring to,” said Masebe.

A senior staffer at one of Gauteng’s public hospitals said healthcare workers were “very nervous” about the quality of the PPE they were made to use. He spoke on condition of anonymity for fear of reprisal.

“Some of the KN95 masks we received were the wrong shape and did not fit very well,” he told us.

“We had an enormous amount of healthcare workers who got infected with coronavirus, maybe some of this was as a result of poor-quality PPE. It is sad, it was avoidable,” he said.

The procurement data for North West and the Western Cape, and our subsequent interaction with these provinces’ health departments, yielded equally alarming observations regarding the regulation of medical goods in South Africa.

Although Gauteng led the pack by a considerable margin, most of the provinces procured alarming quantities of respirator masks and digital thermometers from unlicensed suppliers.

Expenditure for such items bought from unlicensed companies totalled R90-million in Limpopo and R55-million in KwaZulu-Natal. The latter department did not provide a response to detailed queries.

We asked Neil Shikwambana, spokesperson for Limpopo’s department of health, about his province’s total expenditure of R334-million for goods from unlicensed vendors, including respirator masks, digital thermometers, sterile gowns and sterile gloves.

“Not all PPE item suppliers need to be registered or licensed by Sahpra,” maintained Shikwambana.

He said Sahpra, which replaced the Medicines Control Council in 2018, is still in a “transitional state” and that its regulation of medical goods like PPE is still in a “transitional stage”.

Not so, claim several of our sources.

The BPCI’s Tloubatla said the transition period expired before the health departments embarked on their respective Covid-19 expenditure drives.

Shikwambana did not reply to queries regarding those products, such as respirators and digital thermometers, his department had bought from companies that would certainly have required Sahpra licenses.

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When asked about the registration status of Biovission, one of North West’s respirator suppliers, the province’s health department sent us a letter from the company.

“This is to confirm that our company Biovission [is] duly authorized and licensed by South African Health Products Regulatory Authority to supply respirator N95 masks,” reads the letter.

Lekgethwane eventually conceded that the department may have erred in its efforts to secure much-needed PPE.

But our research showed this company does not have the necessary license.

We asked the company’s owner, Kabelo Maake, whether he had lied to the department.

“There were technicalities on the letter that I provided to [the] health department which I’ve already send them another email to say we out source from the companies that are registered with SAHPRA, NOT US REGISTERED WITH SAHPRA, (sic)” Maake responded by email.

The department, too, seemed to believe that this posed no problem. In response to queries about another unlicensed supplier of respirators and digital thermometers, department spokesperson Tebogo Lekgethwane stated that this company had also procured its stock from licensed vendors.

Sahpra assured us that this practice was not above board.

“The activity is regarded as wholesaling. A company must be licensed with Sahpra to conduct wholesaling of medical devices,” explained Sahpra spokesperson Yuven Gounden.

A third unlicensed supplier of respirators to North West simply submitted a certificate of compliance from a Chinese entity called the Shenzhen Hauwin Testing Certification Company.

The Western Cape department of health initially maintained that suppliers of KN95 respirators did not fall under Sahpra’s watch, but it later conceded that this was not the case.

Lekgethwane eventually conceded that the department may have erred in its efforts to secure much-needed PPE.

“The early stages of Covid-19 required urgency in dealing with the emergency at hand. The need to save lives was paramount. Where there are suspicions of wrongdoing, the department is in the process of conducting its own internal investigation. Auditors are also busy internally scrutinising all transactions and there will be accountability.”

Officials from the Western Cape department of health procured respirators valued at more than R28-million from a solar-power company and an auto-repair business.

Greenstar Power Solutions supplied KN95 masks valued at nearly R23-million, making this one of the province’s most lucrative Covid-19 contracts.

Owner Rudi Lee Willemse said the Western Cape department of health at no point informed him that he needed a license.

Bradly Swartz’ auto-repair business, Swartz Networks Solutions, supplied nearly R6-million worth of KN95 masks. He also stated that he had been unaware of any licensing requirements.

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“However, at the time of the purchase (14 and 28 April), there were no KN95 masks available in the country due to the export embargo imposed by the US. The department had to find an alternative method [and] thus explored options to purchase KN95 masks,” explained the WCDoH.

Albeit unlawful, the department insisted that these purchases were not done without strict oversight.

“Products were verified through the department’s internal quality control process. This process included a panel of clinical experts to review the product samples provided by prospective suppliers. The main aim of this process was to ensure quality and safety in the absence of stock at national level,” the department said in a statement.

Sahpra, meanwhile, says it is busy investigating a large batch of unlicensed PPE companies with the assistance of the SIU and the Hawks.

“Over 100 companies are being investigated by Sahpra for supplying PPE for medical purposes without Sahpra’s medical devices license,” said Gounden.