

Protests hobble drugs regulator

● *Pickets block delivery of documents to medicines watchdog and slow down issuing of special permits for urgent applications*

Tamar Kahn
Science and Health Writer

SA's medicines regulator has been forced to put in place contingency plans to try and minimise the disruption to essential services caused by protests at the health department's offices in Pretoria.

The South African Health Products Regulatory Authority (Sahpra) is responsible for ensuring that medicines sold in SA are safe and effective. It is housed in the health department's Civitas building, where staff have been protesting since April over the poor state of their working environment.

On Wednesday, the department was forced to call in the police to ensure staff were able to enter the building in the face of unionised employees picketing at the entrance to the building, according to department spokesperson Popo Maja.

The protest action at the building has hampered Sahpra's day-to-day operations, which include registering medicines and issuing special permits that

allow critically ill patients to be treated with unregistered products in an emergency.

"At present, the delivery of paper documents to the Sahpra office is a challenge," it said in a notice to stakeholders published on its website on Tuesday.

The body provided the phone numbers of a list of staff who could be contacted by pharmaceutical companies to help with urgent submissions.

Aspen Pharmacare's head of strategic trade Stavros Nicolaou said the protest action had affected the drug maker's ability to make submissions to the regulator. "Aspen's manual submissions cannot be accepted. Industry is negotiating for electronic submissions for priority products," he said.

Aspen Pharmacare is Africa's biggest generic drug manufacturer. It not only needs to register new products, but also frequently needs to submit documents to amend existing dossiers – for example, if it needs to change the supplier of an ingredient for a product it has already registered.

Sahpra acting CEO Portia Nkambule said the organisation intended to move into a new building with state-of-the-art IT systems in the medium term.

Earlier in August, the Public Servants Association of SA said the Civitas building was found to pose a health risk to staff by the National Occupational Safety Association, which deals with occupational-risk management.

Maja said the building continued to be plagued by leaks, intermittent water outages and a malfunctioning air-conditioning system, despite a massive R1bn renovation project undertaken by the department of public works in 2004.

"We appeal to our staff and unions to exercise restraint and not impinge on the constitutional rights of others who want to work," he said.

National Education, Health and Allied Workers' Union spokesperson Khaya Xaba said the union's members had not blocked the entrance to the building on Wednesday, adding that it was not safe to work in.

kahnt@businesslive.co.za



Building blocks: The SA Health Products Regulatory Authority is based at the Civitas building in Pretoria, which has been deemed an unsafe workspace. Protesting workers are demanding that their safety concerns are addressed. /Marianne Pretorius