

Drug listing delays laid at door of MCC

- Analysts say political interference at regulator hurts sector

Londiwe Buthelezi

DELAYED approval of clinical trials, lengthy periods for medicines registration, the resultant loss of profits and limited access to newer and cheaper generic drugs are all compromising the local pharmaceutical industry.

Now health economists are pointing at political interference as the root cause of this malfunctioning system and they warned yesterday that international drug companies might lose interest in the South African market if the problems were not addressed.

Last month South Africa's only locally owned clinical re-search organisation able to do first-time human drug trials, QdotPharma, closed its doors.

The Medicines Control Council (MCC) was blamed for not approving clinical trials on time and for the massive back-log in new drugs registration.

Listed drug manufacturer Adcock Ingram said it had more than 600 medicines that were waiting for registration. Some of these had been with the MCC since 1999.

Cobus Venter, the director at health economics firm Econex, said the MCC's function was to ensure adherence to adequate safety standards and if registration took a long time due to those concerns then it was not negative for the sector.

"If, however, registration in South Africa is significantly slower than in other jurisdictions then the longer-term impact will indeed be negative due to pharmaceutical companies simply losing interest in our very small market. More significant, though, is the impact that slow registration has on the availability of latest generation treatment options as this negatively affects patient care," Venter said.

However, he said it could be argued that the therapeutic values of the "newest" drugs did not always significantly



Adcock Ingram's factory in Aeroton in Soweto. The pharmaceutical manufacturer has more than 600 medicines awaiting registration at the Medicines Control Council, some from 1999. photo: leon Nicholas

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enhance patient outcomes while they often came at significantly higher costs. Alex van den Heever, the chair of social security systems administration at the University of the Witwatersrand and a health economist, said the problem was that the MCC was not run independently, nor was it impartial.

"There is a lot of political interference. The administration of the organisation has been politicised and it is run as a

government department as opposed to an independent body," he said.

He said an overhaul or substitution of the MCC should include the removal of the supervisory structure, and changes of organisational design and the funding model.

From a regulation point of view, the new Medicines and Related Substances Amendment Act did not make these change and therefore the interference was likely to continue.

Health Minister Aaron Motsoaledi said in April that the MCC would be replaced by a new body, the SA Health Products Regulatory Authority.

Anban Pillay, the head of pricing at the Department of Health, said yesterday that a list of academics to be trained in medicine regulation was being finalised. This would help

beef up personnel at the MCC and later form part of the new authority.

He said delays were caused by the fact that the evaluators at the MCC were academics and not department employees.

"They are deployed in universities and can't be doing this work all the time," Pillay said.

He said the skills needed by the evaluators could not be obtained at a university, hence the shortage. The department has invited overseas regulatory authorities to train academics.

Aspen chief executive Stavros Nicolaou said the industry realised it was difficult for the MCC to meet the expectations of both companies and the government. He said both sides acknowledged that the MCC was underresourced but the new authority would hope-fully address that.

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