

# Pharma company hails new medicines control body

Although there have been grumbings about the establishment of new medicines regulation body and the natural medicines sector is seriously concerned about an apparent bias against them, one of the large generics companies is definitely chuffed with its progress.



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## Proactive approach to tackling backlog

“If the groundwork set by the Medicines Control Council (MCC) in the past few months in preparation for the much-anticipated launch of the South African Health Products Regulatory Authority (SAHPRA) is anything to go by, it could usher in a new and much more effective era for the local pharmaceutical sector,” a statement by Pharma Dynamics says.

SAHPRA is the new regulatory authority set to take over from the MCC from April next year, since the MCC in its current form has struggled to cope with the volume of applications it receives for new medicines and clinical trials. Based on industry figures, registering new products could take anything from three to five years.

“The MCC’s proactive approach to tackle the backlog of particularly medicine registrations in recent months, has seen them making inroads into the somewhat sceptical pharmaceutical sector, which has been hamstrung by the inefficiencies within the system for years.”

Erik Roos, CEO of Pharma Dynamics, says even though SAHPRA will only officially come into existence once the amendment acts have commenced, he is encouraged by the active nature in which the MCC has interacted with the ITG (industry task group) and are attempting to address the pharmaceutical industry’s concerns. This proactive action by the MCC is sure to create positive momentum for SAHPRA’s launch.

## Optimism not shared in all quarters

However, in July, Dalene Totten, editor of *Natural Medicine* magazine, said in an [article](#): “The cost of compliance allows for unfair commercial advantage to the bigger pharmaceutical manufacturers, loss of diversity, and the removal from the market, of the vast majority of health products not manufactured by drug companies.”

She went on to explain that the cost of having the prerequisite equipment to produce natural products that meet the new standards is likely to put a lot of small suppliers out of business.

“In the end, the new regulations will severely restrict the public’s access to natural health products, and manufacturers, wholesalers, retailers, direct marketers, prescribing practitioners and the public will lose. The only winners will be the pharmaceutical industry.”

## **Better relationship**

However, given that his company is on the other side of the fence, Roos sees it differently: “During the past quarter, key MCC officials, who have been tasked with establishing the new regulatory body, have initiated a series of meetings and roundtable discussions with various industry organisations as a way to openly engage with stakeholders, which has helped to develop fresh solutions to various challenges we face as an industry. Their hands-on approach has set in motion a circle of feedback and responsiveness, which augers well for the entity’s new transformative future and activation of SAHPRA.”

“There also appears to be much better collaboration between the industry and the MCC and there is a greater willingness to work together towards a common goal,” he says.

## **Similar structure to FDA**

In the MCCs defence, the regulatory body has been severely understaffed with part-time academics trying their best to meet the increased demands of the industry. Roos points out that years ago, the model on which the MCC was based was considered best practice, but is now completely out of step with what is being done elsewhere in the world.

“SAHPRA’s new structure will follow a similar model to the US Food and Drug Administration (FDA) in that it will be more independent than the MCC. Another benefit is that it will only be partly funded by government with additional funds being raised by way of fees charged and services rendered within its regulatory ambit. This will not only enhance the entity’s ability to attract and retain the necessary skills and resources it requires to function optimally, but is critical to its success,” he concludes.