Medicines Control Council – half a century of regulatory progress

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On 12 December 2017, the South African Medicines Control (MCC) met for what may well be the last time, bringing to an end half a century of medicines regulatory practice, and considerable progress.

The Drugs Control Act (Act 101 of 1965) was first brought into effect in 1967, and has remained in effect for 50 years, albeit with many amendments and name changes. The Act has now been more fundamentally amended to replace the MCC with the South African Health Products Regulatory Authority (SAHPRA). This represents far more than just a change in name.

In a review of the existing testing facilities for medicines in South Africa (then conducted by the South African Bureau of Standards Pharmaceutical Products Laboratory), Rauch wrote in 1961 that all was not well "in the field of manufacture of pharmaceutical products, their supply and usage". He argued that "[i]t is essential for doctors, in carrying out their practices and treating illness and disease, that they should know exactly what they give when administering chemotherapy. This can only be achieved when the purity, performance, and stability of more products can be substantiated by an independent test authority such as the Bureau of Standards". However, as in many other parts of the world, the aftermath of the thalidomide disaster demanded attention to more than purity or quality. As was also mandated by the Harris-Kefauver Amendments in the United States, the newly-minted Council had to pay attention to evidence of quality, safety and efficacy. From the very first certificate of registration issued by the Council (for phenoxymethyl penicillin tablets, sold as "V-Cil-K"), it took almost two decades to work through the pharmacological classifications and issue "call-up" notices for each.

More recently, the MCC has embarked on the challenging task of regulating discipline-specific complementary medicines and health supplements, as well as medical devices. In both of those areas, the same risk-based approach is being followed, with higher risk products prioritised for early regulatory intervention. However, there remains a gaping hole – an appropriate and effective regulatory scheme for African traditional medicines.

It is worth reflecting, though, on the extent to which the challenge posed by Rauch in 1961 has been met over the past 50 years. Have pharmacists, medical practitioners, and the public been able to rely on the products in the marketplace, and therefore trust the regulatory efficacy of the MCC? In 1998, while acknowledging the challenges facing the MCC and the need for reform, Folb wrote: "What has never been suggested in criticism of the MCC are impropriety, dishonesty, graft, irregularities, lack of fairness, or departure from the principles of natural justice which govern South African administrative laws and thus the operations of the Council". Perhaps the most sensitive measure of the trust that has been built over half a century is the extent to which generic medicines have been able to gain a share of the local private sector market. In 2017, the MCC registered its first biosimilar product, a follow-on version of filgrastim. The MCC is a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and has been admitted as an observer at the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Under SAHPRA, the entire decision-making model of the MCC will change. Rather than entrenching the power to take decisions in the Council, made up of part-time appointees, predominantly from academia, SAHPRA will rely on the staff to take decisions on a continuous basis, under the authority of a Chief Executive Officer (CEO). Fiduciary oversight will be provided by a Board, appointed by and accountable to the Minister of Health. The MCC will cease to exist the night before the first meeting of that Board, which has now been appointed and is in the process of being oriented to the tasks that lie ahead.

Over the years, the MCC has also relied on a series of expert committees, each chaired by a member of Council. Under the amended legislation, the SAHPRA CEO will have the power, in consultation with the Board, to appoint advisory committees. Moving from the previous Council-driven decision-making model to the new staff-driven model is far from trivial. Greater transparency in the entire process will go a long way to building on the trust that has been created over the past half a century. At the very least, this demands urgent attention to the unconstitutional "secrecy" clause in the Medicines and Related Substances Act.

An effective national medicines regulatory authority is an absolute requirement for any health system that wishes to deliver equitable access to safe, effective and affordable medicines and other health technologies. SAHPRA must be seen to deliver, and to improve on what has been achieved in half a century of regulatory progress.

Disclaimer: The author is a member of the Medicines Control Council and two of its expert committees, but writes in his personal capacity.

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