On 24 December 2015 the Medicines and Related Substances Amendment Act, 14 of 2015 was passed into law. We refer to this as ‘the 2015 Amendment’. The 2015 Amendment adds to the changes in the Medicines and Related Substances Amendment Act, 72 of 2008 (‘the 2008 Amendment’).

Neither the 2015 Amendment nor the 2008 Amendment are operative. When brought into operation, both of these Amendment Acts will result in significant changes to the regulatory regime currently in place under the Medicines and Related Substances Act (‘the Act’).

The 2015 Amendment also makes provision for the establishment of a new regulatory authority. The new authority will be required to implement the updated and extended legal regime which will now regulate all medicines, medical devices, IVDs, complementary medicines, cosmetics and food stuffs. The Medicines Control Council (MCC) will be replaced by this new regulatory authority, called The South African Health Products Regulatory Agency (SAHPRA).

As we understand it, SAHPRA is seen by the industry as an upgraded version of the MCC. It has been described as similar in model to the U.S. Food and Drug Administration (FDA) in that it will be more independent than the MCC, falling outside of the Department of Health and funded only partly by government with additional funds raised by way of fees charged and services rendered within its regulatory ambit.

Significantly, the 2008 Amendment also gives SAHPRA final authority over the approval of new products, medical devices or IVDs. This previously required the approval of the Minister of Health by way of resolution, which resulted in significant time delays and arguably left the MCC susceptible to political interference.

The envisaged structure, powers, functions and objects of SAHPRA are wider in scope than the MCC and are clarified through provisions added to the Act through the 2008 and 2015 Amendments. We set out below a short explanatory note on the revised and clarified role of the authority.

Who will form the initial staff body of SAHPRA?

All current employees of the Department of Health who are engaged in the regulation of medicines and health technologies and in radiation control will be designated as employees to be transferred to SAHPRA. The initial staff body of SAHPRA will therefore include all employees of the MCC at the time of transfer.

Like the MCC, SAHPRA will be an organ of state which will make decisions and act through its Board. SAHPRA will be led by its Chief Executive Officer and Vice Chief Executive Officer, who will both be appointed by the Minister of Health from the members of the Board.

The SAHPRA Board will consist of between 10 and 15 members, and will combine expertise in the fields of medicine, medical devices, IVD, vigilance, clinical trials, good manufacturing practice, public health or epidemiology, as well as the law, good governance, financial matter and accounting, information and technology and human resource management.

To assist in performing its functions, the Board will also have the power to appoint committees from among its members. This is presumably aimed at ensuring that the most suitable and adequately qualified people do ‘the job’.

What are the powers and functions of SAHPRA?

SAHPRA’s objects are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest.

SAHPRA’s powers and duties will include the following.

In relation to registration, SAHPRA will:

- determine which medicines, medical devices or IVDs shall be subject to registration;
- grant and issue or reject applications for certificates of registration;
- impose conditions on certificates of registration;
- publish the separate registers for medicines, medical devices and IVDs on its website, and
- authorise any person to sell a specified quantity of any particular products, medical devices or IVDs which are not registered.

In relation to packaging, SAHPRA will approve container or package labels and authorise any deviations from the requirements.

In relation to licensing, SAHPRA will grant or refuse to grant and renew licences to manufacture, to act as a wholesaler of or to distribute any medicine, Scheduled substance, medical device or IVD, and

Finally, SAHPRA has a broad mandate in the public interest to:

- by notice in writing require manufacturers or sellers to furnish information in relation to prohibited sales;
The CEO is tasked with resolving any appeals against decisions of SAHPRA. Once notified of the grounds of appeal, the CEO must meet with the appellant and try to resolve the matter without legal representatives. If this process fails, the matter is then referred to an appeal committee.

**When will SAHPRA begin to operate?**

SAHPRA will come into existence only once the Amendment Acts have commenced.

The transitional provisions in the 2015 Amendment state that the MCC continues to perform the functions it performed before the commencement date of the Amendment Act, but ceases to exist on the day immediately before the date of the first SAHPRA board meeting. The date of this meeting will be determined by the Minister of Health.

The Minister is also required to designate all relevant employees of the Department to SAHPRA at least 30 days before the commencement date of the Amendment Acts.

Although still very uncertain, it does seem that there is a push to implement and start giving practical effect to the Amendments during 2015. We therefore think it conceivable that the Authority will be brought into action sometime this year. Past implementation of amendments has been slow and sometimes stillborn. What we can expect in this New Year, of course, depends entirely on the decisions of government.

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[1] Product is defined as a medicine, a Scheduled substance or a cosmetic or foodstuff which contains a scheduled substance.