

MEDICINE AND THE LAW

Medical device regulation in South Africa: The Medicines and Related Substances Amendment Act 14 of 2015

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The Medicines and Related Substances Amendment Act 14 of 2015 has brought significant changes in the regulation of medical devices in South Africa (SA). The highlights include the establishment of a regulatory authority – the SA Health Products Regulatory Authority – the introduction of a tier-based licensing and registration system, and the restriction of bonusing and sampling for the sale of medical devices. The enactment of the new regulations is a positive development for the SA medical device industry. However, the impact depends on the implementation of these regulations. Conditions that will support the success of the regulations include creating a critical mass of skilled personnel and measures that ensure timely registration. SA can learn from the experiences and practices of other countries that have introduced medical device regulations in recent years.

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The passing into law of the Medicines and Related Substances Amendment Act 14 of 2015, and the subsequent establishment of the South African (SA) Health Products Regulatory Authority (SAHPRA) by the SA government, are milestones for the health sector. The new regulations amend the Medicines and Related Substances Control Act 101 of 1965 and also include the provisions of the Medicines and Related Substances Act 72 of 2008.^[1] Prior to the Medicines and Related Substances Amendment Act 14 of 2015, SA did not have a comprehensive regulatory framework that governed medical devices.^[2] Instead, the regulation of medical devices focused on electronic products only (electromagnetic medical devices or radiation-emitting devices), which were required to be registered before being sold, leased, used, operated or applied in SA.^[3] Other medical devices were left unregulated, leaving advertisers and marketers few legislative formalities with which to comply.^[4] This article assesses the implications of the Medicines and Related Substances Amendment Act 14 of 2015 for the medical device landscape in SA.

Changes in the regulation of medical devices

The Medicines and Related Substances Amendment Act 14 of 2015 brings significant changes to the regulatory regimen for medical devices. It defines medical devices broadly to cover everything from disposable syringes to magnetic resonance imaging (MRI) scanners. Its far-reaching regulatory changes range from the manufacture and distribution to the import, export and wholesaling of medium- and high-risk medical devices.^[5] The regulations stipulate new licensing requirements for medical devices, which apply to SA-based companies that manufacture, import, export, distribute and sell wholesale medical devices in the country.^[6] They outline licence application processes for manufacturers, wholesalers or distributors of medical and *in vitro* diagnostic (IVD) devices, procedures for device registration and requirements relating to advertising and labelling.^[7] The changes are meant to address the imbalances and gaps in the regulation of medical devices.^[1] The highlights of the regulations are discussed below.

Creation of a regulatory body

One of the fundamental changes brought about by the Medicines and Related Substances Amendment Act 14 of 2015 is the establishment of a body responsible for regulatory oversight of medicines, medical devices, complementary medicines, foodstuffs, cosmetics, and related substances.^[6,8,9] The Medicines Control Council (MCC) has been replaced as authority by SAHPRA, which is an organ of state outside of the public service, subject to the provisions of the Public Finance Management Act 1 of 1999.^[10] SAHPRA is vested with powers to make decisions and act through its board, consisting of 10 - 15 members with expertise in the fields of medicine, medical devices, IVD devices, vigilance, clinical trials, good manufacturing practice, public health and epidemiology, as well as the law, good governance, financial matters and accounting, information technology and human resource management.^[9] SAHPRA is empowered to register medicines, medical devices, complementary medicines, foodstuffs, cosmetics or IVD medical devices.^[11] A novel function assigned to SAHPRA is to ensure the periodic re-evaluation or re-assessment and monitoring of medicines, medical devices and IVD devices. The continuous monitoring and evaluation of the safety, efficacy and performance profile of medical devices provide an opportunity for the management of risks throughout the life-cycle.^[10] The new regulations empower SAHPRA to liaise with other medicine and medical device regulatory authorities or institutions globally to obtain and exchange information with regard to matters of common interest or specific investigations, and/or to enter into agreements.^[7,10] The structure, powers, functions and objectives of SAHPRA, which are clarified through the provisions introduced by means of the 2008 and 2015 Amendments, are wider in scope than those of the MCC.^[9]

Tier-based licensing and registration

The new regulations include a four-tier, risk-based classification system for obtaining device licences for manufacturers, importers and distributors.^[6] Medical devices and IVD devices are divided into the following classes, depending on risks relating to the patient, the

user or public health: Class A – low risk; Class B – low-moderate risk; Class C – moderate-high risk; and Class D – high risk.

The manufacture, importation, exportation and distribution, as well as the wholesaling of medical and IVD devices, are subject to regulations, depending on the level of risk and the intended use.^[6,12,13] All classes of medical devices are regulated in terms of the requirement for a medical device establishment licence, which authorises a company to manufacture, distribute or wholesale medical devices. The establishment licence precedes the registration of medical devices. Domestic manufacturers, distributors and wholesalers are required to apply for licences; foreign-based manufacturers are not.^[5] It is mandatory for foreign manufacturers to provide their importers and domestic distributors with basic device information, including Global Medical Device Nomenclature codes, Certificates of Free Sale from reference countries for Class C and Class D devices, and Certificates of Free Sale or Certificates to Foreign Countries for Class B and Class D devices.^[6]

The 2015 Act prohibits the importation of Class B, Class C or Class D medical or IVD devices that are not registered in SA for personal use, unless authorisation is granted by SAHPRA, stating the specified period and quantity.^[6,7] Manufacturers and distributors of moderate- to high-risk Class C and Class D devices and IVD devices are required to show proof of pre-market approval or registration for a medical or IVD device from at least one of the following regulatory authorities as part of their SA registration: the Australian Therapeutic Goods Administration, Brazil's National Health Surveillance Agency (ANVISA), Health Canada, the European Competent Authority, the Japanese Pharmaceuticals and Medical Devices Agency and the US Food and Drug Administration.^[12] The new regulations also have provisions for expedited registration, when the medical or IVD devices in question are in short supply, unavailable, or of national interest, or when the government invites an international tender and such medical or IVD devices are not already registered in SA.^[14]

Sale and distribution of medical devices

Under the new Act, only registered products may be sold in SA.^[7] The new regulation is explicit in that a manufacturer, wholesaler or distributor of medical or IVD devices is not allowed to manufacture, act as a wholesaler of, or distribute any medical or IVD device, unless it is a holder of a valid licence.^[4] The definition of 'sell' has been broadened to include advertising, thereby making it all-encompassing.^[6] The regulations forbid advertisement of any medical or IVD device, unless it complies with the prescribed requirements.^[7] The preceding regulation, the Medicines and Related Substances Control Act 101 of 1965, restricted bonusing and sampling of medicines only, but the new regulations include medical and IVD devices,^[4] which means that such devices cannot be supplied and sold in terms of a bonus, rebate or any other incentive scheme.

Implications of the changes

SAHPRA, by virtue of not being an organ of the state, but a self-funded, autonomous and semi-private entity at an arm's length from the legislature, is empowered to operate without much political interference.^[3] It is more independent than the MCC because it falls outside of the National Department of Health and is expected to generate the bulk of its own funding. Such a disposition enables the regulatory body to make its own decisions without being influenced and pressured by external forces. This differs from the previous regulations, which required the Minister of Health to approve new products, medical or IVD devices, resulting in the regulatory body being susceptible to political interference.^[9] However, SAHPRA has

been criticised by members of the medical device industry, who are of the view that the classification of medical devices would be more appropriately determined by their manufacturers, as they are experts in the field of medical technology.^[11] The Russian medical device regulator, Roszdravnadzor, experienced similar criticism, which led to the passing of a resolution in 2017, allowing medical device manufacturers in Russia to discuss with the authorities specific aspects of the regulatory process and requirements during the registration process.^[15] The provision for official consulting and direct communication between manufacturers and regulatory authorities in Russia is meant to ensure transparency and mutual co-operation in the implementation of medical device regulations.

The registration and licensing of medical devices by SAHPRA aims to bring into the market products that meet safety, performance and quality requirements. However, considering the previous MCC backlog of >2 000 applications awaiting registration and an average of 3 - 5 years for the registration of medicines,^[16] it is likely that the addition of medical devices to the scope of SAHPRA may result in further processing delays, especially if SAHPRA's processing capacity is not expanded substantially beyond that of the MCC. A study commissioned by the Minister of Health to investigate the slow pace at which medicines were being registered, ascribed delays to a lack of skilled human resources, poor infrastructure and inefficient regulatory processes, as well as the implementation of pro-generics policies without strengthening the regulator to handle the substantial increase in registration of applications that followed.^[17] With an added load of registering medical devices, SAHPRA may fail to keep pace with its broadened mandate, as it requires a wide spectrum of expertise to assess the range of products that will need registration. Lessons can be drawn from the Brazilian regulatory body, ANVISA, which experienced significant delays in the authorisation and placing of medical devices on the market, as there were long waiting times of up to 4 years for inspections.^[18] The delays presented formidable barriers in the trade of medical devices, which compelled the government to issue a new resolution in 2014, streamlining registration procedures and requirements. Under the new resolution, Class I and Class II medical devices are exempted from certification by ANVISA, but they should be produced according to good manufacturing practices, while Class III and Class IV medical devices do not have to wait for inspection of good manufacturing practices for the process of registration, revalidation or change of products to be initiated.^[18,19] This is similar to the case in SA under the new regulations, where Class A medical devices, which are equivalent to Class I and Class II in Brazil in terms of risk levels, do not require a licence for manufacture, import or export. However, all classes of medical devices will be regulated, be it through the establishment licence or the registration process.

The skills, knowledge and methods required to regulate medical devices and diagnostic products are different from those for medicines.^[20] As SAHPRA will inherit employees from the MCC, whose expertise is in the regulation of medicines, a shortage of skilled personnel to attend specifically to medical devices is likely, unless staff recruitment is undertaken and training is put in place. Regulating medicines and medical devices under the same ambit may result in the latter being compromised. Resources permitting, the creation of a medical device and diagnostic division within SAHPRA, with dedicated and appropriately trained staff, may ensure that medical devices receive sufficient attention. In India, rules with regard to drugs were applied to medical devices, which led to burdensome regulations that delayed the development of the medical device industry.^[21] This drove the country to enact the

Medical Device Rules of 2017, which separate the regulations for medical devices from those designed for the pharmaceutical sector.^[22] To speed up the process of registering medical devices, the new regulations in India make provisions for notified bodies, which are nationally accredited third-party entities licensed by the government to audit medical devices and their manufacturing sites for the verification of conformity to the quality management system and all other applicable standards.^[21]

The new regulations for medical devices in SA do not provide a timeframe for processing registration applications. This is likely to pose formidable challenges, bearing in mind that some devices have short life cycles owing to advances in technology. Lengthy registration processes will adversely impact the saleability of such medical devices, with some becoming obsolete pending registration. It is therefore imperative that mechanisms be put in place that ensure efficiency in the registration system to promote innovation and motivate manufacturers to register their products. Singapore, for example, in addition to setting up an expedited evaluation channel for the registration of Class C and Class D devices in 2013, has adopted a dynamic regulatory system for medical devices with less onerous requirements, lower registration costs and faster access to the market than the previous regulations.^[23] The new measures that have been implemented in Singapore are attractive to international companies, which comprise the bulk of the suppliers in the country's medical device sector.

The transition from the sale of medical devices in an unregulated environment to a regulated one can be daunting. SAHPRA, as a new regulatory body, cannot successfully implement medical device regulation on its own unless it is backed by the stakeholders in the medical device industry. For example, the manufacturers possess the necessary expertise and experience to offer valuable insight into how to execute the regulations, while physicians can ensure that they prescribe medical devices that are registered.^[24] Thus, the proactive engagement of different stakeholders from the medical device industry as partners in the implementation of the regulations will be beneficial. The coming into effect of the new regulations will not necessarily mean that all unregistered medical devices will disappear from the market after the transitional period. Instead, compliance will take effort and time.

Conclusion

The Medicines and Related Substances Amendment Act 14 of 2015 is a positive development in the regulation of medical devices in SA. Its impact on the medical device industry depends on implementation, and conditions must be created that are conducive to SAHPRA's execution of its mandate. SA can learn from the examples of other countries, particularly those with similar profiles, to aid SAHPRA in its task.

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