THE SOUTH AFRICAN LAW JOURNAL

VOL 141 PART 1 2024 FOUNDED 1884

TABLE OF CONTENTS (OVERLEAF)

NOTES

ARTICLES

BOOK REVIEWS

juta

CONTENTS

NOTES

ARTICLES

BOOK REVIEWS

ISSN 0258-2503

PO Box 24299, Lansdowne 7779

Exclusive distributors in North America: Gaunt Inc, Gaunt Building, 3011 Gulf Drive, Holmes Beach, Florida 34217-2199, USA
Tel: 941-778-5211. Fax: 941-778-525. E-mail: info@gaunt.com

TYPESET BY ELINYE ITHUBA DTP SOLUTIONS

PRINTED AND BOUND BY

EDITORIAL POLICY

The South African Law Journal is a peer-refereed journal which publishes original contributions on all fields of law. It provides a forum for scholars and practitioners, from South Africa and elsewhere, to reflect on issues that are internationally significant and locally relevant. The *SALJ* aims to be essential reading for those inside and outside South Africa who wish to keep abreast of the development of the South African legal order and its relationship to legal issues internationally. The *SALJ* is published four times a year.

SUBMISSION OF MATERIAL FOR PUBLICATION

All material for publication, including articles, recent case notes, correspondence, notes and comments, is to be sent to the Managing Editor, Professor Graham Glover. e-mail g.glover@ru.ac.za

Books for review are to be discussed with the Book Review Editor, Emeritus Professor Hugh Corder. e-mail hugh.corder@uct.ac.za

Subscriptions are to be addressed to orders@juta.co.za

GUIDELINES FOR THE SUBMISSION OF MANUSCRIPTS

Authors are requested to consult the section 'To contributors' at the end of this volume, where the conditions under which manuscripts will be considered for publication, as well as the rules of style to which authors should adhere, are set out. Please note that submissions not in house style will not be considered for publication.

ABSTRACTS

Authors of articles are required to prepare an abstract of no longer than 200 words. The abstract should summarise rather than introduce the argument of the article, and should contain appropriate key words.

Authors of notes are required to prepare an abstract of no longer than 100-150 words, briefly summarising the note, and to provide appropriate key words.

THE REGULATION OF HEALTH-RELATED DIRECT-TO-CONSUMER GENETIC TESTS IN SOUTH AFRICA BY THE MEDICINES AND RELATED SUBSTANCES ACT

AMY GOODEN[†]
Doctoral Fellow, School of Law, University of KwaZulu-Natal

DONRICH THALDAR[‡]
Professor, School of Law, University of KwaZulu-Natal;
Visiting Scholar, Petrie-Flom Center for Health Policy,
Biotechnology, and Bioethics, Harvard Law School

This article examines the regulation of health-related direct-to-consumer genetic tests ('HDGTs') in South Africa by the Medicines and Related Substances Act 101 of 1965 and its related regulations, namely the Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices and the draft Regulations Relating to Medical Devices, as well as the South African Health Products Regulatory Authority guidelines. Such regulation includes the classification, licensing, registration, marketing, labelling and importing of HDGTs. At a basic classification level, the manufacturer's intention determines whether HDGTs are medical devices and/or in vitro diagnostic devices ('IVDs'). Those HDGTs that are medical devices are also likely to be IVDs and are likely to be classified as Class B IVD medical devices, meaning that they pose low to medium risk. This is because the intended use of an HDGT is generally not as a diagnostic tool but as an informational tool, where the results are not definitive and additional testing is required. Accordingly, a licence is required to manufacture, import, export, sell or distribute HDGTs in South Africa. The classification of HDGTs also impacts the rules relating to labelling, advertising and importation.

Medical law – genetic testing – licensing, registration and labelling – medical devices

[†] BA LLB LLM (KwaZulu-Natal). *https://orcid.org/0000-0002-3986-7889.* This article is based on Amy Gooden *Unregulated or Not? A Legal Analysis of South Africa's Legislative Framework Relevant to Direct-To-Consumer Genetic Testing* (LLM thesis, UKZN, 2021), available at *https://researchspace.ukzn.ac.za/handle/10413/20488*.

[‡] BLC LLB MPPS (Pretoria) PhD (Cape Town) PGDip (Oxon). *https://orcid. org/0000-0002-7346-3490.* Work on this article was supported by the US National Institute of Mental Health and the U.S. National Institutes of Health (award number U01MH127690) under the Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa) programme. The content of this article is solely our responsibility and does not necessarily represent the official views of the US National Institute of Mental Health or the U.S. National Institutes of Health.

https://doi.org/10.47348/SALJ/v141/i1a6

I INTRODUCTION

Direct-to-consumer genetic testing has grown in popularity in recent years — especially abroad.[1] Unlike traditional genetic testing in the clinical context, this model tends to bypass healthcare professionals, with individuals being able to order testing kits, collect saliva samples, and receive the results themselves.[2] This has raised concerns, specifically about *health-related* direct-to-consumer genetic testing (for ease, we refer to this as HDGT), in contrast with other kinds of direct-to-consumer genetic tests, such as those used for genealogy purposes or to discover miscellaneous information — for example, earwax type or hair colour.[3] HDGTs may be defined as tests that aim 'to predict the risk of disease, screen for disease, direct clinical management, identify carriers, or establish prenatal diagnoses, clinical diagnoses, or prognoses in individual people or families'.[4] These tests aim to obtain risk assessments for the development of particular diseases and conditions, such as various cancers, Alzheimer's disease, and diabetes,[5] based on an individual's genetic profile.[6]

[1] Sharon A Thrush & Ruth McCaffrey 'Direct-to-consumer genetic testing: What the nurse practitioner should know' (2010) 6 *J Nurse Pract* 273; Grayson L Ruhl, James W Hazel, Ellen Wright Clayton et al 'Public attitudes toward direct to consumer genetic testing' (2019) *AMIA Annual Symposium Proceedings* 774.

[2] Jane Tiller & Paul Lacaze 'Regulation of internet-based genetic testing: Challenges for Australia and other jurisdictions' (2018) 6(24) *Front Public Health* 1; Pascal Borry, Martina C Cornel & Heidi C Howard 'Where are you going, where have you been: A recent history of the direct-to-consumer genetic testing market' (2010) 1 *J Community Genet* 102; Heidi Carmen Howard, Sigrid Sterckx, Julian Cockbain et al 'The convergence of direct-to-consumer genetic testing companies and biobanking activities: The example of 23andMe' in Matthias Wienroth & Eugénia Rodrigues (eds) *Knowing New Biotechnologies: Social Aspects of Technological Convergence* (2015) 60; Rajiv Sarin 'Ethics and clinical utility of direct-to-consumer genetic tests' (2015) 11 *J Can Res Ther* 1.

[3] Amy L McGuire, Barbara J Evans, Timothy Caulfield et al 'Regulating direct-to-consumer personal genome testing' (2010) 330(6001) *Science* 181; Adrian Burton 'Are we ready for direct-to-consumer genetic testing?' (2015) 14 *The Lancet* 138; Minna Ruckenstein 'Keeping data alive: Talking DTC genetic testing' (2017) 29 *Inf Commun Soc* 1026; C Dandara, J Greenberg, L Lambie et al 'Direct-to-consumer genetic testing: To test or not to test, that is the question' (2013) 103 *SA Medical Journal* 510.

[4] K A B Goddard, J Robitaille, N F Dowling et al 'Health-related direct-to-consumer genetic tests: A public health assessment and analysis of practices related to internet-based tests for risk of thrombosis' (2009) 12 *Public Health Genom* 93.

[5] Kathy Hudson, Gail Javitt, Wylie Burke et al 'ASHG statement on direct-to-consumer genetic testing in the United States' (2007) 110 *Obstet Gynecol* 1392; Tiller & Lacaze op cit note 2 at 1; McGuire et al op cit note 3 at 181; Stuart Hogarth & Paula Saukko 'A market in the making: The past, present and future of direct-to-consumer genomics' (2017) *New Genet Soc* 198; Borry et al op cit note 2 at 102.

[6] Stephanie Bair 'Direct-to-consumer genetic testing: Learning from the past and looking toward the future' (2012) 67 *Food & Drug LJ* 416.

https://doi.org/10.47348/SALJ/v141/i1a6

Variations in numerous genes combined with environmental factors, such as diet and lifestyle, may increase or decrease the likelihood of developing a condition.[7] Clearly, an HDGT can potentially have serious implications for a person's life.

Additionally, HDGTs have attracted ethical controversy.[8] These tests are offered to individuals who may not be ill and are generally stand-alone without confirmatory testing; they test for diseases and conditions that may have a severe impact on individuals but lack confirmed analytical and clinical validity; and they entail dangers inherent in new inventions — undetermined efficiency and deficient knowledge.[9] Accordingly, there is a rationale for regulating HDGTs. But how are these tests regulated?

Various South African statutes apply to the different aspects of health-related and non-health-related direct-to-consumer genetic testing. For example, the National Health Act 61 of 2003 ('the NHA') regulates the removal and collection of saliva samples (and by whom it may be done) as well as health research, which requires the approval of research protocols by a Health Research Ethics Committee. The Regulations Relating to the Use of Human Biological Material,[10] as well as the Regulations Relating to the Taking of [a] Buccal Sample or Withdrawal of Blood from a Living Person for Testing,[11] govern the removal and use of human biological material, such as saliva.

The Consumer Protection Act 68 of 2008 ('the CPA') and the Electronic Communications and Transactions Act 25 of 2002 ('the ECTA') impose consumer protection requirements relating to the advertising, disclosure and labelling of direct-to-consumer genetic tests. The Protection of Personal Information Act 4 of 2013 ('POPIA'), which regulates the consumer details that are entered into a direct-to-consumer genetic testing

[7] Dandara et al op cit note 3 at 510.

[8] Bartha Maria Knoppers, Denise Avard & Heidi Carmen Howard 'Direct-to-consumer genetic testing: Driving choice?' (2010) 10 *Expert Rev Mol Diagn* 965; Borry et al op cit note 2 at 101; Heidi C Howard & Pascal Borry 'Direct-to-consumer genetic testing: More questions than benefits?' (2008) 5 *Pers Med* 317; Laurie Udesky 'The ethics of direct-to-consumer genetic testing' (2010) 376(9750) *The Lancet* 1377; Paul G Sanfilippo, Lisa S Kearns, Philip Wright et al 'Current landscape of direct-to-consumer genetic testing and its role in ophthalmology: A review' (2015) 43 *Clin Exp Ophthalmol* 579; Burton op cit note 3 at 138; Alice K Hawkins & Anita Ho 'Genetic counseling and the ethical issues around direct to consumer genetic testing' (2012) 21 *J Genet Counsel* 367; Cheryl Berg & Kelly Fryer-Edwards 'The ethical challenges of direct-to-consumer genetic testing' (2008) 77 *J Bus Ethics* 19.

[9] Stuart Hogarth, David Barton & David Melzer 'The European IVD Directive and genetic testing' in Ulf Kristoffersson, Jörg Schmidtke & J J Cassiman (eds) *Quality Issues in Clinical Genetic Services* (2010) 57.

[10] GN R177 *GG* 35099 of 2 March 2012.

[11] GN R944 *GG* 34750 of 11 November 2011.

https://doi.org/10.47348/SALJ/v141/i1a6

provider website as *personal information*, and genetic data as both *personal information* and *special personal information*, provides for the collection and processing of this information, and regulates research undertaken by direct-to-consumer genetic testing providers. POPIA also provides for the exporting of genetic data from South Africa based on certain conditions.

The Regulations Relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes[12] regulate the exporting of saliva samples out of South Africa. The Department of Health's *Ethics in Health Research: Principles, Processes and Structures*,[13] which are made legally binding by reg 2*(a)* of the Regulations Relating to Research with Human Participants,[14] offer guidance to health researchers. Additionally, the Material Transfer Agreement for Human Biological Materials[15] ('the SA MTA') provides a framework for the transfer of biological material (and associated data) for research.[16]

A core component of the governance landscape that is relevant to HDGTs in particular — and the topic of this article — is the Medicines and Related Substances Act 101 of 1965 ('the Medicines Act'). The Medicines Act provides for the control of medical devices and their licensing, as well as the establishment of the South African Health Products Regulatory Authority ('the SAHPRA')[17] — previously the Medicines Control Council ('the MCC') — to oversee matters related inter alia to medical devices. In this context, the Medicines Act is supported by the Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices[18] ('the Medical Device Regulations') that govern the licensing, manufacture, registration, import, export, distribution, wholesale and advertising of medical devices and in vitro diagnostic devices ('IVDs'). The first question therefore is: does an HDGT qualify as a medical device and/or an IVD?

Interestingly, in the United States of America ('the US'), after a series of events involving direct-to-consumer genetic testing provider 23andMe, the Food and Drug Administration ('the FDA') now regulates HDGTs

[12] GN R181 *GG* 35099 of 2 March 2012.

[13] 2 ed (2015).

[14] GN R719 *GG* 38000 of 19 September 2014.

[15] GN R719 *GG* 41781 of 20 July 2018.

[16] For a critical analysis of the SA MTA see Donrich W Thaldar, Marietjie Botes & Annelize Nienaber 'South Africa's new standard material transfer agreement: Proposals for improvement and pointers for implementation' (2020) 21(85) *BMC Med Ethics* 1; Donrich Thaldar 'One material transfer agreement to rule them all? A call for revising South Africa's new standard material transfer agreement' (2020) 7(105) *Humanities & Social Sciences Communications* 1.

[17] SAHPRA has published various guidelines relating to the classification, licensing, and essential principles of medical devices and IVDs, amongst others.

[18] GN R1515 *GG* 40480 of 9 December 2016.

https://doi.org/10.47348/SALJ/v141/i1a6

as medical devices.[19] In the European Union ('the EU'), the In Vitro Diagnostic Medical Devices Regulation 2017/746 ('the IVDR') came into force in 2022, replacing the previous In Vitro Diagnostic Medical Devices Directive 98/79/EC ('the IVDD'). The IVDR applies to genetic testing (given that the IVDR defines in vitro diagnostic medical devices as comprising genetic testing)[20] — including direct-to-consumer genetic tests — but only those that are health or medical-related.[21] But what is the situation in South Africa? And what are the legal consequences? In this article, we answer these questions.

II ARE HEALTH-RELATED DIRECT-TO-CONSUMER GENETIC TESTS MEDICAL DEVICES?

First, we consider the concept of HDGTs. By examining the meaning of 'medical device' in South African law, this part determines whether HDGTs meet this definition. Before proceeding, it should be noted that in this article, we consider HDGTs as a whole, entailing all of its different aspects — from the testing kit to the analysis and provision of test results. However, some aspects of HDGTs may be more relevant in certain contexts than others, which will be highlighted where necessary.

[19] In 2013, the FDA barred direct-to-consumer genetic testing for health-related conditions in the US through the issuance of a warning letter to 23andMe, compelling the provider to cease offering such tests until it received FDA authorisation. The FDA stated that 23andMe's Saliva Collection Kit and Personal Genome Service ('PGS') — which offered health-related information on numerous diseases and conditions as well as information on non-disease traits and genealogy — was a medical device in terms of s 201*(h)* of the Federal Food, Drug, and Cosmetic Act 21 USC § 321(h) ('FDCA'), and therefore required pre-market approval. This was also because of the manufacturer's claims and based on the fact that there was no evidence regarding the success of the tests and the accuracy of the results. Patricia J Zettler, Jacob S Sherkow & Henry T Greely '23andMe, the Food and Drug Administration, and the future of genetic testing' (2014) 174 *JAMA Internal Medicine* 493; Arthur A Daemmrich '23andMe: The business and ethics of personal genetics testing' 2015 *University of Kansas School of Medicine* 7.

[20] Recital 10 of the IVDR; L Kalokairinou, HC Howard, S Slokenberga et al 'Legislation of direct-to-consumer genetic testing in Europe: A fragmented regulatory landscape' (2018) 9 *J Community Genet* 118.

[21] Article 2(2) of the IVDR defines an 'in vitro diagnostic medical device' as a medical device which provides information for inter alia the predisposition to a medical condition or disease. Reference to 'medical condition' and 'disease' implies that the clause is limited to health or medical-related genetic tests. GeneWatch UK provides that '[g]enetic tests which claim to predict disease risk or drug response, or diagnose a medical condition, clearly fall within the scope of the Regulation, whilst genetic ancestry or paternity tests do not'. GeneWatch UK 'The EU's In Vitro Diagnostics (IVD) Regulation: A summary of the regulatory requirements for software and genetic tests' 2017 *GeneWatch UK* 2; Sara A Mahmoud-Davis 'Direct-to-consumer genetic testing: Empowering EU consumers and giving meaning to the informed consent process within the IVDR and GDPR frameworks' (2020) 19 *Wash U Global Stud L Rev* 1.

https://doi.org/10.47348/SALJ/v141/i1a6

While the MCC — now replaced by SAHPRA — controlled the supply and distribution of medicines, medical devices were unregulated in South Africa until the first publication of the draft Regulations for Medical Devices[22] for public comment in 2011, the implementation of the current Medical Device Regulations in 2016, and, recently, the publishing of the draft Regulations Relating to Medical Devices[23] ('the draft Regulations') for public comment in 2021, which will repeal the currently applicable Medical Device Regulations.

Despite the above, there is little guidance in South Africa on whether HDGTs constitute medical devices.[24] According to the Academy of Science of South Africa ('ASSAf') & Department of Science and Technology ('DST') report on *Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications* ('the ASSAf Report'), medical devices 'include diagnostic tests and would therefore also cover genetic tests'.[25] This leads the ASSAf Report to recommend that SAHPRA should regulate genetic tests under the Medicines Act. However, the ASSAf Report does not mention HDGTs specifically. The ASSAf Report's reference to genetic tests may only refer to genetic tests in the clinical setting. This is because, while HDGTs sometimes purport to diagnose disease, most do not due to their lack of analytical and clinical validity, making definitive diagnosis problematic. Given the above, it is important to determine what is a medical device. The Medicines Act defines a medical device as

> 'any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article … –
>
> *(a)* intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following –
>
> …
>
> (vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
>
> *(b)* which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means'.[26]

The first part of the definition of medical device in s 1 of the Medicines Act mentions a variety of articles that are considered to be medical devices, which include other 'similar or related' articles.[27] The various devices

[22] GN R586 *GG* 34463 of 22 July 2011.

[23] GN 435 *GG* 44593 of 21 May 2021.

[24] ASSAf & DST *Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications* (2018) 75.

[25] Ibid at 75–6.

[26] Section 1 of the Medicines Act.

[27] Ibid.

https://doi.org/10.47348/SALJ/v141/i1a6

involved in HDGT may fall under the articles mentioned in the definition of a medical device above — for example, the tube for the collection of saliva samples and the machines used for DNA extraction, sequencing, and analysis may be instruments, apparatus, or implements; the DNA extractor and sequencer may be a machine or appliance; and then there is the software on these machines or appliances that assists in the extraction, sequencing, and analysis of DNA.

Paragraph *(a)* of the definition of medical device refers to the manufacturer's intention, which turns on what the manufacturer deems to be the device's purpose. Although prima facie HDGTs appear to be medical or diagnostic, given that they purport to determine predisposition to various diseases and conditions, this is not necessarily what the manufacturer intends. If the manufacturer — in most cases, the direct-to-consumer genetic testing provider — does not intend the device to be used to provide medical or diagnostic information, it does not qualify as a medical device in terms of the Medicines Act. This is evidenced by the fact that most direct-to-consumer genetic testing providers (including those based in South Africa), in their terms and conditions, include statements that their tests are informational and do not constitute medical diagnoses.[28] Given that being a medical device centres on the manufacturer's intention, where the manufacturer explicitly provides that the intention is for the tests to be informational or educational, there cannot be a medical or diagnostic intention, and such direct-to-consumer genetic tests will not qualify as medical devices.

Alternatively, some direct-to-consumer genetic testing providers make certain medical or diagnostic claims about their tests on their websites.[29]

[28] See, 23andMe 'Health + ancestry service' available at *https://www.23andme.com/dna-health-ancestry?mkpc=true*, accessed on 5 October 2019; 23andMe '23andMe for healthcare professionals' available at *https://medical.23andme.com/*, accessed on 5 October 2019; Ancestry 'Now your DNA reveals so much more with AncestryHealth' available at *https://www.ancestry.com/health*, accessed on 5 October 2019; MyHeritage 'Terms and conditions' available at *https://www.myheritage.com/terms-and-conditions*, accessed on 5 October 2019. For South African direct-to-consumer genetic testing providers see DNAlysis 'Privacy policy' available at *https://dnalysis.co.za/privacy-policy/*, accessed on 22 June 2020; GeneWay 'Frequently asked questions' available at *https://www.geneway.co.za/faq-frequently-asked-questions*, accessed on 22 June 2020.

[29] 23andMe is one of the few HDGT providers with a medical intention, thus going the regulation route and having their tests governed as medical devices in the US. Helix is another HDGT provider that is regulated as a medical device provider in the US: Zettler et al op cit note 19 at 493; Daemmrich op cit note 19 at 7–8; Robert C Green & Nita A Farahany 'The FDA is overcautious on consumer genomics' (2014) 505 *Nature* 286; Helix 'Helix Laboratory Platform granted the first and only FDA authorization for a whole exome sequencing platform' 11 January 2021 available at *https://www.helix.com/pages/helix-laboratory-platform-granted-fda-authorization*, accessed on 7 April 2021.

https://doi.org/10.47348/SALJ/v141/i1a6

If that is the manufacturer's intention, then such tests may qualify as medical devices. The definition of medical device makes a binary distinction — either there is an intention or not. But because the claims that various manufacturers make, as well as their intention, may be ambivalent in certain situations, the intention of the manufacturer will therefore need to be determined on a case-by-case basis to distinguish between those manufacturers with an intention — thus falling within the definition of medical device — and those without. This means that some HDGTs qualify as medical devices based on manufacturer intent, while others do not.

A medical device must also be able to perform certain functions. The definition of medical device stipulates certain purposes for which medical devices are intended to be used, either alone or jointly, the most relevant of which, for present purposes, is subpara *(a)*(vii).[30] This — specifically the meaning of 'medical or diagnostic purposes'[31] — requires further examination.

The medical or diagnostic nature of HDGTs does, in part, depend on the manufacturer's intention. The terms and conditions available on some direct-to-consumer genetic testing provider websites typically state that they are not medical professionals, and the tests are merely for informational or educational purposes and do not diagnose disease.[32] Given this, HDGTs generally cannot offer information for *diagnostic* purposes. Rather, they provide risk estimates and identify whether an individual possesses a particular genetic mutation that *may* lead to the development of a disease. Certain HDGT providers may either require or encourage consumers to consult with healthcare professionals regarding their test results, which only provide information on predisposition to disease. Assistance is recommended to ensure proper understanding and avoid harm and potentially unnecessary health decisions. In such instances, these tests may be seen to provide information for *medical* purposes, as the results obtained may lead healthcare professionals to suggest further tests or prescribe certain precautionary treatments. Once again, the meaning of 'medical or diagnostic purposes' will need to be determined on a case-by-case basis, depending on the manufacturer's intention and the nature of the HDGT.

Based on para *(b)* of the definition of medical device, we suggest that an HDGT cannot provide health-related information about an individual — its 'primary intended action'[33] — without a saliva sample, from which DNA is extracted, sequenced and analysed. But pharmacological,

[30] Section 1 of the Medicines Act.

[31] Ibid.

[32] See 23andMe citations op cit note 28; Ancestry op cit note 28; MyHeritage op cit note 28; DNAlysis op cit note 28; GeneWay op cit note 28.

[33] Section 1 of the Medicines Act.

https://doi.org/10.47348/SALJ/v141/i1a6

immunological or metabolic means may assist in testing by providing genetic information that influences test results. Processes occurring within the body, as well as genetics, determine the outcome of the test.

To conclude, while some HDGTs, intended by the manufacturer to offer information for medical or diagnostic purposes, meet the definition of a medical device in s 1 of the Medicines Act, others do not due to the manufacturer's intention.

III ARE HEALTH-RELATED DIRECT-TO-CONSUMER GENETIC TESTS IVDs?

Given that the definition of IVD includes a medical device, HDGTs that are not medical devices are automatically disqualified from being IVDs. Like medical devices, IVDs provide information for various purposes — including for certain diseases and conditions, as well as health status.[34] Therefore, the next step is to determine whether HDGTs that are medical devices meet the definition of an IVD. The Medicines Act defines an IVD as

> 'a medical device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes'.[35]

Interestingly, the draft Regulations have largely removed reference to IVDs (including the definition). As mentioned above, devices that are not medical devices cannot be IVDs. Devices can be either purely medical devices (non-IVDs) or IVD medical devices (devices that are both medical devices and IVDs) — devices cannot be IVDs only and will always be a form of medical device. Therefore, reference in the Medicines Act and the Medical Device Regulations to a medical device *or* IVD is incorrect because, in order to be an IVD, by definition, the device in question must also be a medical device. SAHPRA's 'Classification of Medical Devices and IVDs'[36] ('Classification Guidelines') distinguish between medical devices (non-IVDs) and IVDs (IVD medical devices). If the reference to IVD in SAHPRA's Classification Guidelines and the draft Regulations means IVD medical devices, then this should be clarified to avoid confusion.

The definition of IVD in the Medicines Act includes specimen receptacles, control materials, reagents, calibrators and software.[37] IVDs have no direct interaction with the human body. Because HDGT

[34] Robyn Howes 'SALDA in vitro diagnostics in South Africa' 2014 *SALDA* 2.

[35] Section 1 of the Medicines Act. An identical definition of IVD also appears in reg 1 of the Medical Device Regulations.

[36] Published in 2023.

[37] But it precludes non-IVDs for general laboratory use unless, given their characteristics, they are utilised for the specific purposes mentioned in the definition of IVD. Section 1 of the Medicines Act; reg 1 of the Medical Device Regulations. See also Howes op cit note 34 at 2.

https://doi.org/10.47348/SALJ/v141/i1a6

providers analyse the DNA of consumers extracted from saliva samples, the examination of 'specimens derived from the human body' occurs 'in vitro' — in line with the definition of IVD.[38] By doing this, the main purpose of an HDGT is to provide consumers with information regarding their susceptibility to various genetic diseases and conditions. This appears to be consistent with the definition of IVD. However, can this information provided by HDGT providers be used for 'diagnostic, monitoring or compatibility purposes'?[39]

While results regarding genetic predisposition provided to consumers through an HDGT may offer information for *monitoring* purposes, alerting them to potential conditions of which they may not have otherwise been aware, and allowing them to *monitor* and seek treatment, if necessary, given the uncertainty regarding the analytical and clinical validity of HDGTs, their ability to offer definitive and accurate information for *diagnostic* purposes remains questionable.[40]

However, IVDs are intended to provide information 'solely or *principally*'[41] for diagnostic, monitoring, or compatibility purposes. In the case of *Selection Park Investments (Pty) Ltd v Friedman*,[42] it was held that the ordinary dictionary meaning of the word 'mainly' also meant inter alia 'principally'.[43] Based on this, the purposes for which IVDs provide information are not limited to 'diagnostic, monitoring or compatibility'[44] and may extend to other purposes, such as informational purposes regarding genetic propensity and disease risk.

Based on the above, some HDGTs do not qualify as IVDs because they are not medical devices, given that the direct-to-consumer genetic testing provider does not intend these tests to be diagnostic or medical in nature.[45] But we suggest that HDGTs that are medical devices may also be IVDs as they provide information, primarily for monitoring purposes, but also for informational purposes, and involve the examination of samples in vitro.

[38] Section 1 of the Medicines Act; reg 1 of the Medical Device Regulations.

[39] Regulation 1 of the Medical Device Regulations.

[40] See Stephany Tandy-Connor, Jenna Guiltinan, Kate Krempely et al 'False-positive results released by direct-to-consumer genetic tests highlight the importance of clinical confirmation testing for appropriate patient care' 2018 *Genet Med* 1; Abigail Hoglund-Shen 'Direct-to-consumer genetic testing, gamete donation, and the law' (2017) 55 *Fam Court Rev* 475; Amanda K Sarata 'FDA regulation of laboratory-developed tests (LDTs)' 2019 *Congressional Research Service* 2; Megan A Allyse, David H Robinson, Matthew J Ferber et al 'Direct-to-consumer testing 2.0: Emerging models of direct-to-consumer genetic testing' (2018) 93 *Symposium on Precision Medicine* 118.

[41] Section 1 of the Medicines Act; reg 1 of the Medical Device Regulations (emphasis supplied).

[42] 1941 (2) PH M41 (W).

[43] *Selection Park Investments (Pty) Ltd v Friedman* 1941 (2) PH M41 (W) at 77.

[44] Section 1 of the Medicines Act; reg 1 of the Medical Device Regulations.

[45] Section 1 ibid.

https://doi.org/10.47348/SALJ/v141/i1a6

IV WHAT ABOUT SELF-TESTING?

Part of the attractiveness of direct-to-consumer genetic testing is that consumers can collect and send their own saliva samples and receive their results themselves at home, sometimes without the intervention of a healthcare professional. But is an HDGT a form of *self-testing*?

Determining whether a medical device covers self-testing has a bearing on its classification, labelling and registration. One of the requirements in the Medical Device Regulations and the draft Regulations for SAHPRA to grant a licence is that the requirements regarding the instructions for use have been followed. One of these requirements is that, where applicable, the fact that an IVD medical device is to be used for self-testing must be specified.

The Medical Device Regulations contain a definition of 'self-testing', which is defined as 'testing performed by a lay person'.[46] However, the definition does not specify the type of testing to which the definition applies. Self-testing is only mentioned under labelling (for medical devices or IVDs) and instruction requirements (for IVDs).[47] The fact that self-testing devices are included under labelling and instruction requirements for medical devices or IVDs suggests that they are classified as such — but only where they have a medical or diagnostic intention.[48] Although prima facie HDGTs may be thought of as devices used for self-testing, we believe this is not necessarily the case. The operative word is *testing*, and this is not something that consumers do themselves. Self-testing seems rather to refer to home pregnancy tests or blood glucose testing kits, where individuals take the sample, administer the test, and receive the results themselves. Unlike the case with pregnancy tests or blood glucose tests, the consumer, in the case of HDGTs, merely takes a sample for the actual test.

Interestingly, the draft Regulations have removed the definition of self-testing.[49] However, reference to self-testing nevertheless appears as one of the intended uses that must appear on a label for a medical device, where applicable,[50] and instructions on the use of IVDs.[51]

However, SAHPRA's Classification Guidelines suggest that HDGTs would be deemed self-testing. SAHPRA's Classification Guidelines define an 'IVD medical device for self-testing' as including

> 'IVDs intended for use in the collection of a sample by a lay person and, if the sample is tested by another person (e.g. a laboratory) the results are returned directly to the person from whom the sample was taken without

[46] Regulation 1 of the Medical Device Regulations.
[47] Regulations 22(1)*(p)*(vi) and 24(1)*(d)* of the Medical Device Regulations.
[48] Section 1 of the Medicines Act.
[49] Regulation 1 of the draft Regulations.
[50] Regulation 6(2)*(q)*(vi) of the draft Regulations.
[51] Regulation 8(3)*(e)* of the draft Regulations.

https://doi.org/10.47348/SALJ/v141/i1a6

the direct supervision of a health professional who has formal training in a medical field or discipline to which the test relates'.[52]

This echoes the meaning of an HDGT — namely, genetic tests where saliva samples are collected by laypersons, where the testing process bypasses healthcare professionals, and where results are sent directly to consumers. However, unlike the Medical Device Regulations, where self-testing might be interpreted as excluding situations wherein an individual does not perform the test themselves (as is the case with HDGT), SAHPRA's Classification Guidelines specifically recognise certain IVD medical devices as being for self-testing even where the testing aspect is done elsewhere, such as in a laboratory — as is the case with HDGT. Although the inclusion of the definition of self-testing in the Medical Device Regulations was a start, its removal from the draft Regulations means that SAHPRA's Classification Guidelines must provide guidance.

To summarise, whether an HDGT qualifies as a medical device depends on the manufacturer's intention. Additionally, those HDGTs that are medical devices are also likely to be IVDs (making them IVD medical devices), and they also meet SAHPRA's definition of an IVD medical device for self-testing.[53]

V CLASSIFYING HEALTH-RELATED DIRECT-TO-CONSUMER GENETIC TESTS

SAHPRA aims to regulate (as well as monitor, evaluate, investigate, control, license and register) health products, including medical devices and IVDs.[54] SAHPRA classifies medical devices and IVDs according to their quality, safety and performance.[55] Medical devices and IVDs may fall into Class A (low risk), Class B (low-moderate risk), Class C (moderate-high risk) or Class D (high risk), depending on their risk to patients, users or public health.[56] Unlike the Medical Device Regulations, which merely provide the different classes of medical devices and IVDs,[57] the draft

[52] SAHPRA op cit note 36 at 46.

[53] Ibid at 46.

[54] Sections 2A and 2B(1)*(a)* of the Medicines Act; SAHPRA 'Medical devices' available at *https://www.sahpra.org.za/medical-devices/*, accessed on 5 May 2020; Julie Oppenheim 'Medicines and Related Substances Amendment Acts come into force' Bowmans 9 June 2017, available at *https://www.bowmanslaw.com/insights/pharmaceuticals-healthcare/medicines-related-substances-amendment-acts-come-force/*, accessed on 22 July 2020; SAHPRA 'About us' available at *https://www.sahpra.org.za/who-we-are/*, accessed on 5 May 2020.

[55] SAHPRA op cit note 36 at 1.

[56] Regulation 11(1) of the Medical Device Regulations; reg 5(1) of the draft Regulations.

[57] Regulation 11(1) ibid.

https://doi.org/10.47348/SALJ/v141/i1a6

Regulations explicitly state that the Authority (SAHPRA) will classify medical devices.[58]

The draft Regulations further require SAHPRA to classify medical devices according to classification rules, which SAHPRA may determine in published guidelines.[59] SAHPRA published its latest version of their Classification Guidelines in 2023, which provide rules for the various types of medical devices that assist in determining which class they may fall into. The classification of HDGTs impacts inter alia on the registration, licensing, advertising, labelling, importing and exporting. In what follows, we analyse the Medicines Act, the Medical Device Regulations, the draft Regulations and SAHPRA's Classification Guidelines to determine into which class HDGTs that are *IVD medical devices* may fall.

(a) What is being classified?

What requires clarification is what aspect(s) of the HDGT process may be considered an IVD medical device and how it should be classified. An HDGT involves various devices that are used at different stages — for example, there is the tube into which consumers deposit saliva, which is used to store and transport the sample to the laboratory; the machines that extract, sequence, and analyse DNA to produce genetic data and test results as well as the chemicals or reagents allowing it to perform;[60] and the software that converts raw data into useable information and is utilised to interpret and analyse the results. It may assist in distinguishing between the product, kit or device used to collect and store a substance or measure a specific biomarker and the wider service in terms of which HDGTs are offered. While medical devices (the product) are legally governed by legislation, the service (the interpretation of test results) is subject to consumer protection and advertising laws.[61]

Although the various aspects involved in the stages of the HDGT process may be viewed as separate devices that may be classified differently, regard must also be had to the Medicines Act, the Medical Device Regulations, and the draft Regulations — which all refer to the licensing of medical devices (or IVDs), and mention manufacturing, distributing, importing, exporting and wholesaling. This must be considered when determining what is classified as an HDGT.

SAHPRA's licence grants a right to manufacture, distribute, import, export or sell a medical device in South Africa. It is neither the machines

[58] Regulation 5(1) of the draft Regulations.

[59] Regulation 5(2) and (3) of the draft Regulations.

[60] Catherine M Sharkey 'Direct-to-consumer genetic testing: The FDA's dual role as safety and health information regulator' (2019) 68 *DePaul LR* 361.

[61] Caroline F Wright, Alison Hall & Ron L Zimmern 'Regulating direct-to-consumer genetic tests: What is all the fuss about?' (2011) 13 *Genet Med* 296.

https://doi.org/10.47348/SALJ/v141/i1a6

that extract the DNA from the saliva sample and that sequence the DNA and analyse the genetic data to obtain the test results nor is it the software used on these machines that is relevant. In terms of an HDGT, it is not the machines and their software that direct-to-consumer genetic testing providers seek to manufacture, distribute, import, export, or sell (although this may be the case in certain circumstances, this would generally occur between companies and not to consumers, and it is not relevant here). What HDGT providers wish to obtain a licence for are the testing kits themselves, which are manufactured, sometimes imported, distributed and sold to consumers. In the current context, the testing kit itself is the most relevant device to consider.

While the consumer, when purchasing an HDGT, buys the product (and the accompanying service) in totality, the device that the consumer receives and that is used by them is the testing kit itself — specifically, the saliva collection tube and instructions. The DNA extraction or sequencing machines (and their related software) are not used by consumers — they form part of the testing process. This is also in line with the intended use of a medical device or IVD, which must appear on the label and in the instructions for use in terms of the Medical Device Regulations and the draft Regulations.

SAHPRA classifies various devices that are of relevance to the HDGT process differently. While IVD medical devices for self-testing are generally classified as Class C (subject to certain exceptions), an instrument for use in in vitro diagnostic procedures and specimen receptacles are Class A IVD medical devices.[62] However, specimen containers for use in self-testing and general laboratory tubes for containing and storing processed specimens are not specimen receptacles[63] and are thus not IVD medical devices.[64] But what happens when multiple IVD medical devices that form part of the same process are classified differently?

Some IVD medical devices are used together with other IVD medical devices, non-IVD medical devices or accessories.[65] The rules for classification are independently applied to each device. Where several IVD medical devices form part of a group, or where groups contain both IVD medical devices and non-IVD medical devices, the highest class for any

[62] A 'specimen receptacle' is a device intended by the manufacturer 'for the primary containment and preservation of a specimen derived from the human body for the purpose of in vitro diagnostic examination'. SAHPRA op cit note 36 at 37–8, 48–9.

[63] Ibid at 50.

[64] Ibid.

[65] An accessory is an item intended by the manufacturer to be used with an IVD, allowing the IVD to function as intended. Accessories are classified separately to the IVD. Ibid at 33.

https://doi.org/10.47348/SALJ/v141/i1a6

individual IVD or component determines the class of the group.[66] In line with this, the Medical Device Regulations provide that where a medical device or IVD is classified into more than one class, it must be placed 'in the higher of the risk classes'[67] — but this provision is not in the draft Regulations.

Although the most practical way to approach an HDGT may be to view the IVD medical device as the HDGT service as a whole[68] — rather than examining each aspect individually — and to see them as being provided as a group (in which case, the highest class of each IVD medical device would apply), these devices do not necessarily form part of the same group. Each device performs a different function and is used at a different stage of the testing process — all devices are not part of one kit that is used together and at the same time. In terms of registration, the Medical Device Regulations and the draft Regulations require an application to be made for each medical device.[69] Therefore, given that the various devices used in HDGTs are not grouped as part of the same 'kit', and because different individuals use each device at different stages in the testing process, it is likely that each device — namely, the testing kit, the machines, and the software — will be classified separately (and differently).

(b) Into what class do direct-to-consumer genetic tests fall?

What makes the determination of a class challenging is that different jurisdictions may vary in their classification of medical devices.[70] In South Africa, SAHPRA classifies medical devices (and IVDs) based on current safety, quality and performance standards.[71] While the Medical Device Regulations and the draft Regulations provide that SAHPRA is responsible for establishing the classification of medical devices (and IVDs in the case of the Medical Device Regulations),[72] SAHPRA's Classification Guidelines stipulate that manufacturers or distributors must ascertain a medical device or IVD's class based on the classification rules,[73] and SAHPRA only intervenes and determines the classification where there

[66] Ibid at 34.

[67] Regulation 11(4) of the Medical Device Regulations.

[68] This is supported by Allyse et al op cit note 40 at 119, who state that from an examination of 23andMe's pre-market application approved by the FDA the whole direct-to-consumer genetic testing process — from the time of purchase to the receiving of test results — is one device.

[69] Regulation 8(8) of the Medical Device Regulations; reg 9(1) of the draft Regulations.

[70] Brian Goemans & Robert McLaughlin 'Medical devices: An innovation guide from lab to commercialisation' *Route to Market Guide* (2018) 5.

[71] SAHPRA op cit note 36 at 1.

[72] Regulation 11(3) of the Medical Device Regulations; reg 5(1) of the draft Regulations.

[73] SAHPRA op cit note 36 at 5–6 and 32.

https://doi.org/10.47348/SALJ/v141/i1a6

is a dispute.[74] Greater harmony between the Medical Device Regulations, the draft Regulations and SAHPRA's Classification Guidelines would be of assistance to rectify this disparity.

The Medical Device Regulations and the draft Regulations require SAHPRA to classify medical devices (and IVDs) according to classification rules,[75] 'taking into account its design and intended use'.[76] In terms of SAHPRA's Classification Guidelines — which are based on the manufacturer's intention — the intended use of HDGTs, from the perspective of direct-to-consumer genetic testing providers, is generally to be informational or educational and to provide information regarding the *risk* of the development of certain diseases or conditions, rather than being medical or diagnostic.

Based on SAHPRA's Classification Guidelines, HDGTs do not appear to fall into the rules for the classification of medical devices (non-IVDs) and are therefore guided by the classification rules for IVD medical devices. SAHPRA's Classification Guidelines also contain seven rules related to the classification of IVD medical devices, the most relevant of which are rule three (detection of transmissible agents or biological characteristics posing a moderate public health risk or a high personal risk), rule four (IVD medical devices for self-testing) and rule seven (all other IVDs are Class B IVD medical devices). We examine each of these rules in turn.

According to rule three in SAHPRA's Classification Guidelines, IVDs intended inter alia for 'human genetic testing' are deemed to be Class C IVD medical devices.[77] This is because they pose a fair risk to public health or great individual risk, as incorrect results may cause individuals to make significant decisions regarding their health.[78] However, based on the other categories under this rule, and given that SAHPRA distinguishes between IVD medical devices for genetic testing and those for self-testing (although this is not confined to genetic testing), it appears that the genetic testing referred to is that conducted in the clinical setting, and not HDGTs.[79] The IVD medical devices under rule three also typically offer the crucial,

[74] Ibid at 7 and 34.

[75] Regulation 11(3) of the Medical Device Regulations; reg 5(2) and (3) of the draft Regulations.

[76] Regulation 11(5) of the Medical Device Regulations.

[77] SAHPRA provides examples of tests that detect Philadelphia chromosome, Huntington's disease or cystic fibrosis. SAHPRA op cit note 36 at 45.

[78] Ibid at 43.

[79] Other IVD medical devices falling under this classification rule refer to 'patients' — a term commonly used in the clinical setting. Furthermore, reference is made to inter alia 'screening for congenital disorders in the foetus' and 'to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient' — activities that would require the involvement of healthcare professionals. Ibid at 42–5.

https://doi.org/10.47348/SALJ/v141/i1a6

or only, grounds for correct diagnosis.[80] This is not the case with HDGTs, as such tests are generally not used in isolation and cannot be seen to provide an accurate diagnosis without further testing. Therefore, we suggest that although referring to human genetic testing, classification rule three does not apply to HDGTs.

Classification rule four in SAHPRA's Classification Guidelines specifically mentions 'IVD medical devices for self-testing', classifying them as Class C if the condition being tested for: (1) generally requires healthcare professionals to be involved in diagnosis or treatment; or (2) cannot be exactly understood by ordinary individuals, or needs supervision for safe treatment.[81] HDGTs seem to qualify in terms of both of these criteria. However, SAHPRA's Classification Guidelines provide an exception to the application of classification rule four, namely when the self-test results are preliminary and require additional testing.[82] We suggest that the results of HDGTs are indeed preliminary and require additional testing before a diagnosis can be made.

Therefore, an HDGT defaults to the safety-net provision of classification rule seven: all IVD medical devices not classified by any other classification rules are classified as Class B IVD medical devices.[83] These devices are those that pose a low to moderate risk to individuals. According to SAHPRA's Classification Guidelines, it is improbable that incorrect results by IVD medical devices in this class would negatively affect individuals, and these devices are often not the only source used for accurate diagnosis.[84] Given that HDGTs yield no definitive diagnosis but only information on one's genetic propensity for — or risk of — developing certain diseases or conditions, the classification of HDGTs in Class B seems to be the most accurate. This conclusion is also supported by the fact that many HDGT providers recommend that their consumers visit a healthcare professional with their results before making any medical decisions, which may lead to additional testing to acquire an accurate diagnosis.

VI LICENSING AND REGISTERING MEDICAL DEVICES IN SOUTH AFRICA

HDGTs that are not medical devices are not required to comply with the laws relating to the licensing and registration of medical devices. Therefore, this part elucidates what is required of local and foreign HDGT providers wanting to offer their HDGTs (that are medical devices) in South Africa.

[80] Ibid at 43.
[81] Ibid at 46.
[82] For example, a positive pregnancy self-test will usually involve a follow-up medical consultation, causing them to be classified as Class B IVD medical devices. Ibid at 37 and 52–3.
[83] Ibid at 38.
[84] Ibid at 51.

https://doi.org/10.47348/SALJ/v141/i1a6

SAHPRA refers to licensing medical device establishments and registering medical devices (and IVD medical devices). In terms of SAHPRA's 'Guideline for a Licence to manufacture, import, export or distribute medical devices & IVDs' ('Licensing Guidelines'),[85] medical device establishment *licences* are used to alert SAHPRA to manufacturers, importers and distributors of medical devices in South Africa and their risk classification.[86] The *registration* process — which is yet to be implemented — applies to medical devices (or IVD medical devices), focusing on their quality, safety and performance. In the following subparts, we analyse SAHPRA's licensing scheme for medical device establishments, followed by SAHPRA's registration scheme for medical devices.

(a) Licensing

Medical devices (and IVD medical devices) cannot be manufactured, imported, exported, sold or distributed in South Africa without a valid medical device establishment licence[87] — the requirements for which are expounded in the Medicines Act, the Medical Device Regulations and the draft Regulations.[88] One of three types of licences must be applied for, and HDGT providers may need to apply for one or more such licences, depending on the circumstances: (1) a manufacturer licence;[89] (2) a distributor licence;[90] and/or (3) a wholesaler licence.[91] Both the licence to manufacture and the licence to distribute medical devices include (and allow) the importing and exporting of medical devices.[92] Unlike the draft Regulations, the Medical Device Regulations specify that a licence must be applied for before commencing business.[93]

[85] Published in 2023.

[86] Ibid at 6.

[87] Section 22C(6) of the Medicines Act; SAHPRA op cit note 54.

[88] Section 22C(1)*(b)* of the Medicines Act; reg 5 of the Medical Device Regulations; reg 13 of the draft Regulations.

[89] To manufacture, label, pack, service, import, or export medical devices or IVDs. Regulation 5(1)*(a)*(i)*(aa)* of the Medical Device Regulations; reg 13(1)*(a)*(i) of the draft Regulations.

[90] To import, export and distribute medical devices or IVDs. Regulation 5(1)*(a)*(i)*(bb)* of the Medical Device Regulations; reg 13(1)*(a)*(ii) of the draft Regulations.

[91] To store, transport and deliver medical devices or IVDs. Regulation 5(1)*(a)*(i)*(cc)* of the Medical Device Regulations; reg 13(1)*(a)*(iii) of the draft Regulations. See also SAHPRA op cit note 54; Catherine Tomlinson 'IN-DEPTH: The tangled web of medical device regulation in SA' *Spotlight* 3 September 2020, available at *https://www.spotlightnsp.co.za/2020/09/03/in-depth-the-tangled-web-of-medical-device-regulation-in-sa/*, accessed on 5 December 2020.

[92] In terms of reg 13(1)*(a)* of the draft Regulations and reg 5(1)*(a)*(i) of the Medical Device Regulations.

[93] Regulation 5(1)*(a)* of the Medical Device Regulations.

https://doi.org/10.47348/SALJ/v141/i1a6

Before a medical device (or IVD medical device) is registered, a licence must be obtained.[94] In terms of s 22C(1)*(b)* of the Medicines Act, SAHPRA may grant a licence to manufacture, distribute or wholesale medical devices.[95] Without this, medical devices (and IVD medical devices) cannot be imported or exported.[96] These licensing requirements only apply to South African HDGT providers, but HDGT providers abroad that export their tests to South Africa must also provide importers and/or distributors with certain medical device information.[97] The level of risk and intended use of an IVD medical device determines the regulations applicable to its manufacture, import, export, distribution and sale.[98] A licence to manufacture, import or export applies to Class B medical devices.[99]

The provisions in the draft Regulations regarding licences remain largely unchanged from the Medical Device Regulations.[100] An application for a licence to manufacture, distribute or wholesale medical devices must be made to SAHPRA using a prescribed application form.[101] An 'Authorised Representative', a natural person residing in South Africa to oversee legal compliance, must also be appointed.[102] Proof of the particulars of the business owner and authorised representative, certification by a conformity assessment body, payment of the prescribed fee, and the furnishing of any

[94] T Saidi & T S Douglas 'Medical device regulation in South Africa: The Medicines and Related Substances Amendment Act 14 of 2015' (2018) 108 *SA Med J* 169.

[95] SAHPRA op cit note 85 at 8.

[96] Ibid at 8.

[97] Stewart Eisenhart 'South African medical device regulatory system set for implementation' Emergo 22 August 2016, available at *https://www.emergobyul.com/blog/2016/08/south-african-medical-device-regulatory-system-set-implementation*, accessed on 18 June 2020.

[98] Saidi & Douglas op cit note 94 at 169.

[99] It also applies to Class C and Class D medical devices. The requirements for manufacturer (including import or export) and distributor licences for Class B, Class C or Class D IVD medical devices are the same. The following information must be provided: (1) a list of all medical devices or IVDs imported into South Africa with the Global Medical Device Nomenclature Code; (2) for Class C and Class D medical devices or IVDs, proof of pre-market approval or registration from certain overseas regulatory authorities; (3) for Class B, Class C, and Class D medical devices or IVDs, Certificate of Free Sale from country of manufacture; (4) licence holders for Class C and Class D medical devices or IVDs must produce technical documentation if requested by SAHPRA; and (5) a certificate of conformance or analysis, where relevant. Class A IVD medical devices do not have to be licensed. SAHPRA op cit note 85 at 1, 6, 8 and 10; Tomlinson op cit note 91.

[100] Regulation 5 of the Medical Device Regulations; reg 13 of the draft Regulations.

[101] Regulation 5(1) of the Medical Device Regulations; reg 13(1) of the draft Regulations.

[102] Regulation 5(1)*(a)*(ii) of the Medical Device Regulations; reg 13(2) of the draft Regulations.

https://doi.org/10.47348/SALJ/v141/i1a6

additional information that SAHPRA requests, as well as the name and model of the medical devices to be manufactured, imported, or sold is also required.[103] If SAHPRA is satisfied that the applicant and the licence application adhere to the prescribed conditions, a licence is issued.[104]

(b) Registration

Medical devices (and IVD medical devices) must also be registered. However, unlike medicines, medical devices currently do not have a registration process in place in South Africa.[105] The registration of medical devices will entail a 'call-up' of certain devices or classes by SAHPRA through the publication of a notice in the *Government Gazette*.[106] According to the Medicines Act and the Medical Device Regulations, a medical device or IVD that is subject to registration cannot be sold or used in South Africa unless it is registered.[107] However, this provision is absent from the draft Regulations, and given that medical devices (although unregistered) are being sold, it appears that medical devices do not need to be registered before being sold in South Africa.[108] The Medical Device Regulations and the draft Regulations specify that an application to register a medical device must be made for each medical device or modification thereof.[109] Where the Medical Device Regulations provide that a *person* residing and doing business in South Africa may apply for registration of a medical device or IVD,[110] the draft Regulations specify that a manufacturer or distributor residing in South Africa must do so.[111]

The Medicines Act, the Medical Device Regulations and the draft Regulations contain requirements relating to applications for registering medical devices or IVDs.[112] Section 15(3)*(a)* of the Medicines Act states that a certificate of registration shall be granted if a medical device or IVD: (1) is fit for its intended purpose; (2) meets the stipulated requirements;

[103] Regulation 5(1) of the Medical Device Regulations; reg 13(1) of the draft Regulations.

[104] Regulation 5(4) of the Medical Device Regulations; reg 13(4) of the draft Regulations.

[105] Tomlinson op cit note 91; SAHPRA op cit note 54.

[106] SAHPRA has published a draft call-up plan which details the risk-based approach to be used in calling-up medical devices, prioritising those that are higher risk and vital for public health. Tomlinson op cit note 91.

[107] Section 14(1) of the Medicines Act; reg 11(2) of the Medical Device Regulations.

[108] Tomlinson op cit note 91.

[109] Regulation 8(8) of the Medical Device Regulations; reg 9(1) of the draft Regulations.

[110] Regulation 8(1) of the Medical Device Regulations.

[111] Regulation 9(2) of the draft Regulations.

[112] Section 15(1) of the Medicines Act; reg 8(5), (6) and (9) of the Medical Device Regulations; reg 9 of the draft Regulations.

https://doi.org/10.47348/SALJ/v141/i1a6

and (3) is safe, effective, of proper quality, and functions as intended.[113] If successful, each medical device or IVD is provided with a name and registration number, which is recorded in the register and on the registration certificate.[114]

Both the Medical Device Regulations and the draft Regulations require the application for registration also to include the completed application form obtainable from SAHPRA, a proposed label (where applicable), the instructions for use, a copy of the licence, a certified copy of the conformity assessment certificate (although the draft Regulations also permit a certified copy of the test results or inspection certification), any additional information that SAHPRA may require, and the application fee.[115] The requirements in the Medical Device Regulations and the draft Regulations relating to the information that must be included in the application form — including the particulars of the prospective holder of the certificate of registration[116] and the particulars of the medical device[117] — as well as the information to accompany an application for registration where a medical device is registered with a regulatory body outside of South Africa[118] are substantially the same.

An application for the registration of a medical device must be accompanied by several documents, one of which is the instructions for the use of the medical device (or IVD).[119] Both the Medical Device Regulations and the draft Regulations contain provisions on instructions for use, and separate them for medical devices[120] and IVDs.[121] Instructions for use for medical devices must contain inter alia the intended purpose and, where appropriate, the intended user; risks and possible side effects; and, where the user is not a healthcare provider, circumstances where a healthcare provider must be consulted.[122]

[113] Section 15(3)*(a)* of the Medicines Act.

[114] Section 15(4) and (5) of the Medicines Act.

[115] Regulation 8(3) of the Medical Device Regulations; reg 9(4) of the draft Regulations.

[116] Regulation 8(5)*(a)* of the Medical Device Regulations; reg 9(6)*(a)* of the draft Regulations.

[117] Regulation 8(5)*(b)* of the Medical Device Regulations; reg 9(6)*(b)* of the draft Regulations.

[118] Regulation 8(9) of the Medical Device Regulations; reg 9(7) of the draft Regulations.

[119] Regulation 8(3)*(c)* of the Medical Device Regulations; reg 9(4)*(c)* of the draft Regulations.

[120] Regulation 23 of the Medical Device Regulations; reg 7 of the draft Regulations.

[121] Regulation 24 of the Medical Device Regulations; reg 8 of the draft Regulations.

[122] Regulation 23 of the Medical Device Regulations; reg 7 of the draft Regulations.

https://doi.org/10.47348/SALJ/v141/i1a6

Although a registration process is yet to be implemented, SAHPRA has 'called up' medical device *establishments* and requires that those manufacturing, distributing and marketing medical devices be licensed. However, *medical devices* have not been called up. In addition to ensuring that the quality management systems in establishments are sound,[123] SAHPRA must ensure that medical devices demonstrate quality, safety and efficacy.[124] As the registration process for medical devices remains in development,[125] SAHPRA's licensing process contains certain 'quasi-registration' requirements, which involve providing information on both the company and the medical device.[126] Companies must demonstrate the existence of suitable quality management systems that enable the safe manufacture or handling of medical devices that are of sound quality.[127] The establishment licence process requires companies to provide SAHPRA with a list of medical devices to be manufactured, distributed or wholesaled in South Africa, as well as proof of the safety, quality and efficacy of certain medical devices.[128] While Class C and Class D medical devices require evidence of pre-market approval or registration in specified jurisdictions,[129] licence applications for Class B medical devices must include a Certificate of Free Sale from the country of manufacture or final assembly.[130]

As it is questionable whether SAHPRA will cope with the monumental task of testing the numerous medical devices on the market when they are called up for registration,[131] relying on the authorisation or registration of medical devices in other countries may offer an approach for local registration. However, the absence of testing and certification of medical devices in South Africa means that local HDGT providers must obtain

[123] A quality management system ensures the implementation of all elements of quality assurance, including agreements and contracts; documents and records; facility installation, maintenance and cleanliness; manufacturing and storage; training; plans for emergencies and recalls; and distribution. SAHPRA op cit note 54; SAHPRA op cit note 85 at 6 and 12; Tomlinson op cit note 91.

[124] Tomlinson ibid.

[125] SAHPRA op cit note 54.

[126] This includes a list of all medical devices to be manufactured, distributed, or sold in South Africa. SAHPRA op cit note 54; Tomlinson op cit note 91; SAHPRA op cit note 85 at 6–7 and 8–11.

[127] SAHPRA op cit note 54; SAHPRA op cit note 85 at 8 and 12; Tomlinson op cit note 91.

[128] Tomlinson ibid; SAHPRA op cit note 85 at 9–11.

[129] These are Australia, Brazil, Canada, the EU, Japan, the US, or pre-qualification by the World Health Organisation ('WHO'). Tomlinson op cit note 91; Saidi & Douglas op cit note 94 at 169; SAHPRA op cit note 85 at 9–11.

[130] A Certificate of Free Sale is proof that the medical device has received regulatory approval and is sold or distributed legally and freely. Saidi & Douglas op cit note 94 at 169; SAHPRA op cit note 85 at 9 and 10.

[131] Tomlinson op cit note 91.

https://doi.org/10.47348/SALJ/v141/i1a6

foreign pre-authorisation or registration in a recognised country to be granted an establishment licence and thus be permitted to market medical devices or IVDs in South Africa, especially where they are higher risk.[132]

(c) Conclusion on licensing and registration

To summarise, a licence is required to manufacture, import, export, sell or distribute HDGTs that are medical devices (or IVD medical devices) in South Africa. While neither Class A medical devices nor HDGTs that do not qualify as medical devices need to be licensed, it is necessary to license those posing a higher risk. Therefore, Class B IVD medical devices — which we suggest is the most likely classification for HDGTs — require a licence. HDGT providers operating in South Africa must apply for a manufacture, distribution or wholesale licence depending on their activities — without which HDGTs cannot be sold to the public. Although medical devices currently lack an established registration pathway in South Africa to sell their tests, HDGT providers are nevertheless required to be licensed with SAHPRA. While regulating establishments is a partial solution, it is imperative that SAHPRA further develops and refines these registration processes for IVD medical devices and the requirements to guarantee their quality, efficacy and safety.[133]

VII LABELLING OF MEDICAL DEVICES

The Medicines Act prohibits anyone from selling a medical device or IVD without a label.[134] Labels must appear on the device or packaging (where practical) and include stipulated details, as determined by SAHPRA.[135] The Medical Device Regulations expand on the particulars that a medical device or IVD label must contain, including the name and description of the medical device or IVD,[136] its intended use,[137] and any warnings or precautions.[138] The requirement that the label must be in English and appear on the medical device, on the packaging, or on the packaging of multiple medical devices remain largely the same in the Medical Device

[132] Ibid.
[133] Ibid.
[134] Section 1 of the Medicines Act defines a 'label' as any brand, mark, or description visible on, affixed to or packed with an article, and that refers to an article.
[135] Section 18(1)*(b)* of the Medicines Act.
[136] Regulations 22(1)*(a)* and *(b)* of the Medical Device Regulations.
[137] Regulations 22(1)*(b)* and *(p)* of the Medical Device Regulations.
[138] Regulation 22(1)*(o)* of the Medical Device Regulations.

https://doi.org/10.47348/SALJ/v141/i1a6

Regulations and the draft Regulations,[139] as do the particulars that must appear on the label of each medical device.[140]

To sell their products, HDGT providers must ensure that their tests are suitably labelled and do not contain any information that deviates from that which SAHPRA has approved.[141]

VIII ADVERTISING MEDICAL DEVICES IN SOUTH AFRICA

The CPA is South Africa's seminal consumer protection legislation and covers inter alia advertising, which binds those direct-to-consumer genetic tests that are not medical devices to its provisions. However, the Medicines Act also contains advertising provisions for medical devices and IVDs.[142] Medical devices or IVDs cannot be advertised for sale unless they adhere to certain conditions,[143] and the publication and distribution of false advertisements regarding medical devices or IVDs is prohibited.[144] As far as the statements to be contained in advertisements are concerned, the draft Regulations differentiate between registered and unregistered medical devices. Like the Medical Device Regulations, registered medical devices must not contain statements in advertisements that conflict with evidence in the application for registration of a medical device or IVD in terms of its quality, safety, or performance where it has been accepted by SAHPRA and forms part of the instructions for use.[145] However, reg 22(3)(*b*) of the draft Regulations requires advertisements for unregistered medical devices to adhere to the essential principles of safety and performance — which SAHPRA must determine.[146] This means that HDGT advertisements can neither make false claims regarding the efficacy and result nor recommend that a medical device or IVD be used for a purpose contrary to SAHPRA's mandate.[147]

[139] Regulation 22(2) of the Medical Device Regulations; reg 6(1) of the draft Regulations.

[140] Regulation 22(1) of the Medical Device Regulations; reg 6(2) of the draft Regulations.

[141] In terms of reg 21 of the Medical Device Regulations, advertisements for medical devices or IVDs may not consist of statements that differ from, or contravene, evidence in the registration application. Martha Smith 'Marketing, manufacturing, packaging & labelling, advertising' Pharma Boardroom 12 October 2018, available at *https://pharmaboardroom.com/legal-articles/marketing-manufacturing-packaging-labelling-advertising-south-africa/*, accessed on 16 January 2021.

[142] Section 1 of the Medicines Act describes advertising as any visual or verbal work that is shared or brought to the attention of the public.

[143] Section 18(2) of the Medicines Act.

[144] Section 20(1)*(a)* of the Medicines Act.

[145] Regulation 21(1)*(c)* of the Medical Device Regulations.

[146] In terms of the definition of 'essential principles' in reg 1 of the draft Regulations.

[147] Section 20(1) of the Medicines Act.

https://doi.org/10.47348/SALJ/v141/i1a6

Regarding the contents of advertisements, the draft Regulations are more comprehensive and require advertisements to contain additional information[148] compared to that required by the Medical Device Regulations. While the Medical Device Regulations simply require written advertisements for medical devices or IVDs to contain the name of the medical device or IVD and the registration number, where applicable,[149] the draft Regulations additionally require all advertisements for medical devices to contain inter alia the intended purpose[150] and any contra-indications or warnings.[151] Written advertisements must contain the medical device's class, the name and address of the holder of the certificate of registration, and the registration number where the medical device is registered.[152]

Unlike in the US, where HDGTs are widely advertised on television and in magazines,[153] South Africa currently has a smaller market — and seemingly stricter standards. The draft Regulations have amended the provision relating to advertising, which we suggest now provides greater clarity regarding the advertising of medical devices that is lacking in the Medical Device Regulations. While direct-to-consumer genetic tests that are not medical devices can be advertised freely to the public like other consumer goods, the Medical Device Regulations permit the advertising of Class B medical devices and IVDs to the public or laypersons.[154] The draft Regulations also permit the advertising of Class B medical devices (not IVDs) to the public but do not specify *laypersons*,[155] as is the case in the Medical Device Regulations. As we have suggested, HDGTs are likely classified as Class B IVD medical devices, so they may be advertised to the public.

(a) The South African Code of Marketing Practice for Health Products

The South African Code of Marketing Practice for Health Products ('the MCA Code')[156] was issued in terms of s 18C of the Medicines Act and

[148] Regulation 22(4) of the draft Regulations.

[149] Regulation 21(1)*(d)* of the Medical Device Regulations.

[150] Regulation 22(4)*(b)* of the draft Regulations.

[151] Regulation 22(4)*(c)* of the draft Regulations.

[152] Regulation 22(4)*(d)* of the draft Regulations.

[153] Seon-Hee Yim & Yeun-Jun Chung 'Reflections on the US FDA's warning on direct-to-consumer genetic testing' (2014) 12 *Genomics Inform* 152; Valerie Gutmann Koch & Kelly Todd 'Research revolution or status quo: The new common rule and research arising from direct-to-consumer genetic testing' (2018) 56 *Houston LR* 83.

[154] Regulation 21(1)*(a)* of the Medical Device Regulations; reg 22(1) of the draft Regulations.

[155] Regulation 22(1) of the draft Regulations.

[156] Marketing Code Authority ('MCA') *The South African Code of Marketing Practice for Health Products Code & Guideline* version 14 (2021).

https://doi.org/10.47348/SALJ/v141/i1a6

contains provisions relating to advertising medical devices and IVDs.[157] The MCA Code extensively covers the requirements for marketing and advertising health products in South Africa, which must align with the Medicines Act.[158] 'Health products' are defined in the MCA Code as inter alia 'medical devices, and IVDs as regulated by the Medicines Act'[159] — thereby encompassing HDGTs that are IVD medical devices.

Like the Medical Device Regulations, the MCA Code permits the advertising of Class B medical devices and IVDs to 'consumers'.[160] The MCA Code further states that companies must not provide consumers with information or guidance regarding their personal medical issues where requested, instead advising them to consult their healthcare practitioner.[161] The promotion of health products, including in electronic or digital media, must follow the MCA Code.[162] Advertisements should encourage consumers to consult their healthcare practitioners to ensure the health product's suitability.[163]

The MCA Code prohibits advertisements from offering virtual diagnoses, advice, or treatment.[164] Some HDGT providers offer genetic counselling as part of their service and advertise this — predominantly on their websites. However, such counselling is often not offered face-to-face, with HDGT providers instead relying on email communication and telephone or video calls.[165] By offering and advertising genetic counselling in this manner, HDGT providers are contravening the MCA Code.[166]

The MCA Code provides that material must be sufficiently comprehensive, thereby allowing consumers to develop their own assessment of a product's therapeutic value.[167] In line with the MCA Code, advertisements by HDGT providers are required to observe the 'minimum requirements' as provided for in the Medical Device Regulations.[168] They must be

[157] Ibid at 1.
[158] Ibid at 14.
[159] Ibid at xii.
[160] Ibid at 66.
[161] Ibid.
[162] Ibid at 33.
[163] Ibid at 15.
[164] Ibid.
[165] Some HDGT providers, as a substitute for face-to-face genetic counselling, include informational materials and videos on their websites, telephonic support, and online counselling by professionals contracted by the provider. Teresa Pàmpols Ros, José Miguel García Sagredo, Antonio Pérez Aytése et al 'Directed to consumer genetic testing: Perspective from the Ethics Commission of the Spanish Society for Human Genetics' (2019) 153 *Med Clin (Barc)* 37.
[166] MCA op cit note 156 at 15.
[167] Ibid at 21.
[168] 'Minimum requirements' denotes the legislative requirements for written advertisements provided for in the Medical Device Regulations. MCA ibid at xii.

accurate and balanced,[169] coherent,[170] unambiguous, reflective of current evidence,[171] presented objectively without exaggeration,[172] and must not create false hope for successful treatment[173] or guarantee the safety, quality or efficacy of a product.[174]

Advertising and marketing by HDGT providers can potentially be ambiguous.[175] Based on the MCA Code, scientific claims made by companies must be supported with evidence, and device safety, quality and efficacy must not be guaranteed.[176] The information must not be scant or misleading and should be sufficient to allow consumers to decide to undergo an HDGT or avoid it. HDGT providers may not make claims or use words regarding their products and services that exaggerate their tests' safety, usefulness, or non-diagnostic nature.[177] To comply with the MCA Code, HDGT providers must refrain from doing so.

(b) Medical Device Code of Ethical Marketing and Business Practice

The South African Medical Technology Industry Association ('SAMED') established the 'Medical device code of ethical marketing and business practice' ('the SAMED Code')[178] to regulate the ethical marketing of medical devices. The SAMED Code provides that advertisements for medical devices must adhere to the applicable laws and regulations,[179]

[169] MCA ibid at 66.
[170] Ibid at 18.
[171] Ibid at 21.
[172] Ibid at 21–2.
[173] Ibid at 67.
[174] Ibid.
[175] Ruth Saunders 'Legal implications of direct-to-consumer genetic testing for common diseases' (2010) 1 *QMLJ* 77.
[176] Covolo et al note that direct-to-consumer genetic testing is advertised despite the lack of supporting evidence. Loredana Covolo, Sara Rubinelli, Elisabetta Ceretti et al 'Internet-based direct-to-consumer genetic testing: A systematic review' (2015) 17(12) *J Med Internet Res* 11–12.
[177] For example 23andMe's website marketed its products and service as 'the first step in prevention', allowing consumers to 'take steps toward mitigating serious diseases'. Other HDGT providers use claims like 'let your DNA help you plan for the important things in life. Take charge of your health and wellness today', which exaggerate HDGTs' value in improving health. Other HDGT advertisements claim that 'knowledge is power', but for information to be empowering, it must be correct and relevant. Ryan Jaslow 'FDA warns 23andMe, tells genetic testing firm to halt sales' *CBS News* 25 November 2013, available at *https://www.cbsnews.com/news/fda-warns-23andme-tells-genetic-testing-firm-to-halt-sales/*, accessed on 25 October 2020; Allyse et al op cit note 40 at 117; Sara Chandros Hull & Kiran Prasad 'Reading between the lines: Direct-to-consumer advertising of genetic testing' (2001) 31(3) *Hastings Center Rep* 33.
[178] SAMED 'Medical device code of ethical marketing and business practice' (2021).
[179] Ibid at 32.

https://doi.org/10.47348/SALJ/v141/i1a6

namely the Medicines Act, the Medical Device Regulations and the draft Regulations, and must inter alia be: (1) clear and legible; and (2) in line with the approved instructions for use.[180]

Many of the principles contained in the MCA Code also appear in the SAMED Code. Information contained in advertisements, including claims and comparisons, must be correct, clear, impartial, just and founded on current assessments of the evidence.[181] Advertisements aimed at the public must adhere to the relevant regulatory framework. They must not create unrealistic expectations regarding the product's effectiveness or cause consumers to self-diagnose or treat potentially serious diseases incorrectly.[182] Advertisements must not deter consumers from obtaining medical advice.[183] All claims made in advertisements must be substantiated, except where claims are contained in the instructions for use that SAHPRA has approved.[184] Scientific information must be accurate, balanced and understandable to the intended audience.[185] Visual images used in advertisements must be in line with the SAMED Code and should not be misleading.[186]

Although the SAMED Code constitutes a mechanism of self-regulation and is only binding on its members,[187] those advertising HDGTs that are medical devices must therefore adhere to the provisions of the CPA, the Medicines Act, the Medical Device Regulations and the draft Regulations relating to advertising.

(c) Conclusion on advertising

To summarise, both the Medical Device Regulations and the draft Regulations permit the advertising of Class B medical devices (and IVDs) to the public or laypersons (in terms of the Medical Device Regulations).[188] While the Medicines Act, the Medical Device Regulations and various industry codes only apply to medical devices, the CPA governs the advertising of all goods offered within South Africa. Therefore, even direct-to-consumer genetic tests that are not medical devices must comply with the CPA.

[180] Ibid.
[181] Ibid.
[182] Ibid.
[183] Ibid.
[184] Ibid at 33.
[185] Ibid at 34.
[186] Ibid at 36.
[187] Ibid at 7 and 10.
[188] Regulation 21(1)*(a)* of the Medical Device Regulations; reg 22(1) of the draft Regulations.

https://doi.org/10.47348/SALJ/v141/i1a6

IX IMPORTING MEDICAL DEVICES INTO SOUTH AFRICA

The rules regarding importation only apply where the consumer is in South Africa but the HDGT provider is based in another jurisdiction — it neither applies to situations where both the consumer and the HDGT provider are in South Africa nor where a South African HDGT provider creates and develops its own tests locally.

While the importing of the testing kit is relevant, the exporting of such kits does not require in-depth examination. This is because, firstly, South African HDGT providers are not as established as those operating abroad, and it is therefore unlikely that they will export testing kits out of South Africa to consumers in other jurisdictions.[189] Secondly, when consumers who import HDGT kits send them back to the HDGT provider, they are not exporting the kit but rather the saliva sample.

Direct-to-consumer genetic tests that are not medical devices (and thus not IVDs) are treated the same way as most other consumer goods purchased from abroad — they can simply be bought by consumers and sent by direct-to-consumer genetic testing providers to South Africa without the need for licences or other documentation.[190] However, HDGTs that are IVD medical devices may come with certain importation requirements.

Importing or exporting medical devices or IVDs into or out of South Africa requires a licence. Only those who are licensed in terms of s 22C(1)*(b)* of the Medicines Act may import medical devices or IVDs into South Africa.[191] Unregistered medical devices or IVDs may only be imported into South Africa if SAHPRA has granted authorisation.[192]

The Medicines Act, when dealing with licences, refers to 'a medical device or IVD establishment, manufacturer, wholesaler or distributor'[193] and, as consumers are generally individual laypersons who use HDGTs

[189] Some international direct-to-consumer genetic testing providers have offices in South Africa and distribute their products globally, but the testing kits are imported into South Africa and then offered to consumers locally. Examples include HomeDNADirect, EasyDNA and DNAlysis. HomeDNADirect 'About us' available at *https://www.homednadirect.co.za/about-us/*, accessed on 22 June 2020; EasyDNA 'About us' available at *https://www.easydna.co.za/about-us/*, accessed on 22 June 2020; DNAlysis 'About' available at *https://dnalysis.co.za/about/*, accessed on 22 June 2020.

[190] The South African Revenue Service ('SARS') confirms that Customs can clear the importing of personal goods and, in most instances, individuals are not required to register as importers and obtain importer codes. South African Revenue Service 'FAQ: Do I need to register as an importer if I buy personal goods from abroad e.g. from Amazon?' 9 March 2021, available at *https://www.sars.gov.za/faq/faq-do-i-need-to-register-as-an-importer-if-i-buy-personal-goods-from-abroad-e-g-from-amazon/*, accessed on 7 May 2021.

[191] Regulation 3(3)*(a)* of the Medical Device Regulations.

[192] Regulation 3(3)*(b)* of the Medical Device Regulations.

[193] Section 22C(1)*(b)* of the Medicines Act.

https://doi.org/10.47348/SALJ/v141/i1a6

for their own purposes, it is unlikely that they will be holders of licences and will thus not be authorised to import HDGTs themselves. Where HDGTs are not developed in South Africa by the direct-to-consumer genetic testing providers themselves, the solution is for direct-to-consumer genetic testing providers to apply for licences to import HDGTs and allow consumers to purchase the tests locally from them.

SAHPRA's Licensing Guidelines prohibit any person from ordering or importing inter alia Class B medical devices or IVDs that are unregistered in South Africa for personal use, unless SAHPRA has granted authorisation.[194] As we have suggested that HDGTs are likely to be classified as Class B IVD medical devices, this provision affects them. The meaning of 'personal use' is unclear, but it appears that if a medical device (or IVD medical device) is registered in South Africa, then it can be ordered by any person for personal use. However, SAHPRA's registration process is currently in development, meaning that medical devices (or IVD medical devices) are not registered in South Africa but are rather registered elsewhere and approved for use in South Africa.[195] Given this, the licensing requirements must be relied on — meaning that a licence to import medical devices (or IVD medical devices) must be obtained in terms of the Medicines Act. Since such a licence is not issued to consumers,[196] it must instead be acquired by an HDGT provider in South Africa (if they are acquiring testing kits from manufacturers overseas).

However, consumers who order testing kits from South African HDGT providers that ship their products within the country do not need an import permit or licence. This is because the transaction occurs within South Africa and does not transcend its borders. However, HDGTs that are classified as Class B IVD medical devices must nevertheless be licensed with SAHPRA.

To summarise, individual consumers are excluded from importing HDGTs that are IVD medical devices into South Africa themselves, given that they are not 'a medical device or IVD establishment, manufacturer, wholesaler or distributor',[197] and can therefore not obtain an import licence as required by the Medical Device Regulations.[198] This seems to conflict with SAHPRA's Licensing Guidelines, which allow Class B IVD medical devices to be imported into South Africa for *personal use* if they are registered.[199] However, (1) SAHPRA's registration process remains

[194] SAHPRA op cit note 85 at 8; Saidi & Douglas op cit note 94 at 169.
[195] Tomlinson op cit note 91.
[196] Such licences are only issued to a 'medical device or IVD establishment, manufacturer, wholesaler or distributor'. Section 22C(1)*(b)* of the Medicines Act.
[197] Ibid.
[198] Regulation 3(3)*(a)* of the Medical Device Regulations.
[199] SAHPRA op cit note 85 at 8.

https://doi.org/10.47348/SALJ/v141/i1a6

in development, and (2) SAHPRA's guidelines only bind those with obligations to SAHPRA. Although the Medicines Act is authoritative and thereby prevents consumers from importing HDGTs that are Class B IVD medical devices into South Africa, it may nevertheless assist SAHPRA to introduce guidelines that update licensing and registration processes, provide a pathway for determining the safety, quality and efficacy of medical devices, address the overlapping legislation and codes, and cover HDGT providers and consumers more fully.

X CONCLUSION

This article has examined the regulation of HDGTs in South Africa and, after considering the Medicines Act, the Medical Device Regulations, the draft Regulations and SAHPRA's guidelines, found that determining whether an HDGT qualifies as a medical device is not straightforward. Whether a direct-to-consumer genetic test is a medical device depends on the manufacturer's intention. Those HDGTs that are medical devices may also be IVDs (making them IVD medical devices). Those HDGTs that are IVD medical devices require classification. Based on SAHPRA's Classification Guidelines, we suggest that HDGTs are likely to be classified as Class B IVD medical devices and, therefore, a licence is required to manufacture, import, export, sell or distribute them. Although medical devices currently lack an established registration pathway in South Africa, HDGT providers must be licensed with SAHPRA.[200]

There are inconsistencies and uncertainties regarding medical devices (and IVD medical devices). The draft Regulations are a positive development and, if promulgated, may serve to provide greater clarity regarding medical devices (and IVD medical devices), their licensing, and their classification. However, we suggest that SAHPRA should update its guidelines to align with the draft Regulations; proceed with the establishment of a registration pathway for medical devices (and IVD medical devices); provide a means for determining the safety, quality, and efficacy of medical devices; address the overlapping statutes, codes, and guidelines; and issue a directive to clarify the position and classification of HDGTs that qualify as medical devices (or IVD medical devices).

[200] In terms of the Medicines Act, the Medical Device Regulations and the draft Regulations.

https://doi.org/10.47348/SALJ/v141/i1a6

www.juta.co.za

SALJ0128

juta