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The Pacing Problem in mHealth Regulation: Rethinking the 'Intended Use' Rule in the Governance of mHealth Apps in South Africa

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Abstract

The rapid proliferation of mobile health applications (mHealth apps) is transforming healthcare delivery in South Africa, offering AI-enhanced, data-driven tools for remote monitoring, diagnosis, chronic disease management, and personalised interventions. While these technologies are often celebrated for their potential to expand access and improve outcomes, their rapid evolution presents significant regulatory, clinical, and ethical challenges. This article interrogates South Africa's regulatory framework, with particular attention to the rule under the *Medicines and Related Substances Act* (MRSA), which classifies a product as a medical device based on the developer's declared purpose. Although this principle provides conceptual clarity in distinguishing between medical and non-medical devices, it proves increasingly inadequate for wellness and fitness apps whose advanced functionalities extend beyond general wellness into clinically significant domains, yet evade oversight because they are marketed as lifestyle tools. Such functions include predictive diagnostics, symptom checking, continuous monitoring of vital signs (e.g., heart rate, blood pressure, oxygen saturation), treatment recommendations, mental health assessments, and medication reminders. Drawing on the conceptual lens of the pacing problem, which is the misalignment between the speed of technological innovation and the slower adaptation of legal frameworks, the article shows how reliance on declared intent generates oversight gaps that expose users to risks ranging from clinical inaccuracy to data misuse. In response, it proposes a functionality-driven regulatory approach that evaluates mHealth apps based on their real-world capabilities and health implications rather than their declared purposes. Such an approach would enhance regulatory agility, align innovation with safety and ethics, and ensure that mHealth technologies realise their transformative potential without compromising public health protections.

***Keywords**:* mHealth apps; AI; mHealth regulation; intended use rule; pacing problem; regulatory adaptation; mHealth in South Africa.

1. Introduction

The rapid proliferation of digital health technologies, particularly mobile health applications (mHealth apps), has transformed healthcare delivery in South Africa. mHealth apps are software programs, either web-based or designed to run on mobile devices such as smartphones, tablets, and smartwatches,[1] and are increasingly driven by artificial intelligence (AI) and advanced algorithms to deliver a wide range of health-related services. The apps support both clinical and quasi-clinical functions such as symptom checking, remote patient monitoring, chronic disease management, medication reminders, health risk prediction, and personalised treatment recommendations, alongside general physical wellness. Users interact with mHealth apps through various modalities that collect data from sources such as interactive questionnaires, connected medical devices, and built-in features like cameras, motion sensors, and microphones. This data is then processed by algorithms to generate personalised

[1] Huckvale, "Unaddressed Privacy Risks."

diagnoses, treatment recommendations, and enable predictive analytics and automated decision-making,[2] making mHealth apps an important innovation in healthcare solutions.

While mHealth apps are often promoted through techno-optimistic narratives underscoring their transformative potential, such optimism, underpinning the broader push towards a digital health agenda, tends to obscure critical challenges and emerging risks, particularly those arising from their use and the serious implications these pose for the safety, reliability, and clinical efficacy of such technologies.[3] Growing evidence indicates that many mHealth apps, particularly those in the general wellness and fitness category and readily available on major app marketplaces like Google Play and Apple's App Store, are developed without undergoing adequate clinical validation.[4] As a result, many provide inaccurate or misleading information,[5] others raise ethico-legal concerns about informed consent and potential liability in case of errors,[6] and some apps lack robust security features, making user data vulnerable to breaches and misuse.[7] The risks posed by mHealth apps exemplify what scholars refer to as the 'pacing problem,' which is a concept that captures the constant misalignment between the rapid pace of technological innovation and the comparatively slow responsiveness of legal and policy frameworks to regulate these technologies.[8] In the South African context, however, existing research on mHealth regulation has predominantly focused on data privacy and security concerns.[9] While these are critical issues, there remains a notable gap in the literature: there is little attention to how such concerns, alongside broader safety and efficacy risks, intersect with the rapid evolution of mHealth technologies and the slow adaptation of regulatory frameworks. This leaves unaddressed the regulatory vulnerabilities that arise when wellness and fitness applications, often equipped with advanced capabilities carrying quasi-clinical implications, fall outside the scope of medical device regulation under the current intent-based classification system, a gap that this article seeks to address.

In South Africa, the *Medicines and Related Substances Amendment Act 14 of 2015* (hereafter MRSA) provides a legal foundation for classifying health products, including software applications, as medical devices based on the developer's declared 'intended use.' This principle determines whether an mHealth application falls within the scope of medical device regulation and thus under the oversight of the South African Health Products Regulatory Authority (SAHPRA).[10] However, this framework faces growing challenges from wellness and fitness apps that have evolved to include sophisticated, quasi-clinical features like continuous monitoring and AI-driven health advice, functionalities that carry significant health implications for user safety. Because these apps are often marketed for non-medical purposes, they can circumvent classification as a medical device, thereby avoiding the more stringent safety, efficacy, and oversight requirements under the MRSA.

This regulatory gap means that such apps fall outside the direct oversight of SAHPRA. Instead, they are governed only by general consumer protection and data privacy legislation, such as the *Consumer Protection Act* (CPA)[11] and the *Protection of Personal Information Act* (POPIA).[12] This situation creates a potentially risky oversight gap, as such apps may not be subject to the rigorous clinical validation, quality assurance, and post-market monitoring required for medical devices, thereby increasing the likelihood of user harm. Recognising this regulatory challenge, SAHPRA has begun taking steps to address it, most notably through the publication of recent guidance documents on the regulation of AI-enabled medical devices, which aim to enhance clarity around classification, safety evaluation, and performance monitoring.[13]

This article examines the regulatory limitations of South Africa's mHealth governance framework through the lens of the pacing problem, arguing that reliance on the intended use rule is increasingly inadequate in the context of rapidly evolving wellness and fitness applications. Drawing on a detailed analysis of relevant regulatory instruments, a comprehensive review of existing scholarship, and insights from an ongoing study on the regulation of mHealth in Sub-Saharan Africa, the article demonstrates

[2] Cortez, "FDA Regulation of Mobile Health."
[3] Akbar, "Safety Concerns with Consumer-facing Mobile Health"; Albrecht, "mHealth Apps and their Risks"; Eng, "The Promise and Peril of Mobile Health"; Haywood, "The Promise and Risks of mHealth"; Rowland, "Digital Health Technology."
[4] Akbar, "Safety Concerns with Consumer-facing Mobile Health"; Albrecht, "mHealth Apps and their Risks"; Haywood, "The Promise and Risks of mHealth."
[5] Wong, "Birth Control App Reported."
[6] Eng, "The Promise and Peril of Mobile Health"; Haywood, "The Promise and Risks of mHealth"; Rowland, "Digital Health Technology."
[7] Alder, "Jury Rules Meta Violated"; Botes, "Regulatory Challenges of Digital Health."
[8] Askland, "Introduction"; Ludlow, "Regulating Emerging and Future Technologies"; Marchant, The Growing Gap Between Emerging Technologies.
[9] Andanda, "Data Subject Privacy"; Klaaren, "South Africa's Technologies."
[10] SAHPRA, "Classification of Medical Devices and IVDs."
[11] *Consumer Protection Act No. 68 of 2008* (South Africa).
[12] *Protection of Personal Information Act No. 4 of 2013* (South Africa).
[13] SAHPRA, "Regulatory Requirements of AI and ML Enabled Medical Devices."

how the rapid advancement of mHealth technologies outpaces the capacity of current regulatory frameworks, leaving significant oversight gaps that threaten user safety and the effectiveness of mHealth interventions. Particular attention is directed towards wellness and fitness applications whose functionalities straddle the domains of wellness and clinical care. These tools blur the boundary between general self-care technologies and regulated medical devices, thereby underscoring the urgency of shifting towards a more adaptive, functionality-driven regulatory framework capable of addressing their evolving clinical significance. By highlighting the transformation of wellness and fitness applications into complex, sophisticated tools with implicit clinical functions, this article demonstrates that the gap between their real-world capabilities and the current regulatory scope is widening.

Contrary to the view that existing laws are inherently adaptable to technological change,[14] the article contends that South Africa's regulatory regime is failing to keep pace, leaving users increasingly vulnerable to harm. The article advances a functionality-driven regulatory approach that underscores the need for greater regulatory agility[15] in terms of assessing mHealth apps according to their real-world technical capabilities and potential health impacts, rather than relying primarily on the developer's declared intent.

The rest of the article is structured as follows: the next section analyses the mHealth landscape in South Africa, setting the contextual foundation for the discussion. This is followed by an examination of the current regulatory framework, with particular emphasis on the MRSA, the intended use rule, and other relevant legal and policy instruments. The subsequent section introduces the concept of the pacing problem, which then frames the analysis of how wellness and fitness apps are increasingly incorporating health-related functions that challenge the adequacy of the intended use rule. The discussion then turns to the limitations of the intended use rule, explicitly linking these shortcomings to the pacing problem. The article concludes by advancing a functionality-based regulatory model and demonstrating how such a policy shift could better align technological innovation with safety, ethics, and public health priorities.

2. The mHealth Landscape in South Africa

South Africa's approach to digital health has evolved through three key policy frameworks, each marking a distinct phase in the country's attempt to modernise its health information systems and harness mobile technology for public health benefits. The *eHealth Strategy for South Africa* (2012-2016)[16] laid the foundational vision for digital transformation in the health sector. It came at a time when the country's health information systems (HIS) were fragmented and paper-based, with the aim of establishing a unified, patient-centred national health information system. Its core objectives included the integration of electronic health records and developing a framework for interoperability, which is the ability of different digital systems to communicate and share information effectively. However, the strategy largely focused on institutional and infrastructure-level reforms, particularly on back-end systems rather than user-facing technologies like mHealth applications.

Recognising the potential of mobile phones to transform healthcare access, the government followed with the *mHealth Strategy* (2015-2019).[17] This strategy marked a shift towards leveraging mobile technology to enhance public health communication, strengthen health system performance, and empower patients through self-care and digital access to services. However, the mHealth Strategy still lacked a robust regulatory framework to guide the safe, equitable, and evidence-based development and integration of digital health technologies into existing HIS.[18]

The mHealth Strategy was followed by the *National Digital Health Strategy* (2019-2024) which represents a more integrated approach to digital health that seeks to consolidate the gains of the previous strategies while addressing their shortcomings by articulating a comprehensive vision for a coordinated digital health ecosystem that brings together people, technologies, and health system processes.[19] The strategy also acknowledges the challenges posed by the rapid evolution of technologies such as AI and algorithm-driven decision support tools, and more importantly signals a greater awareness of the need for regulation of emerging digital health technologies. Taken together, these three strategies illustrate a clear progression in South Africa's policy trajectory on digital health, shifting from foundational infrastructural capacity-building under the eHealth Strategy, to the targeted adoption of mobile health technologies in the mHealth Strategy, and ultimately to a system-wide digital transformation envisaged in the National Digital Health Strategy.

[14] Cachalia, "Digitalisation in the Health Sector."
[15] Brownsword, Regulating Technologies.
[16] National Department of Health, National eHealth Strategy.
[17] National Department of Health, mHealth Strategy.
[18] Mbunge, "Mobile Health Interventions."
[19] National Department of Health, National Digital Health Strategy.

Supported by this enabling policy environment, South Africa's mHealth landscape has expanded significantly over the past decade, driven by growing public health demands to improve access to healthcare services and information. The rapid uptake of wellness and fitness applications is underpinned by the increasing penetration of mobile technology, reflected in rising smartphone ownership, expanding internet access, and improving public awareness of the potential health benefits of digital tools, especially among younger, tech-savvy users who are integrating these tools into their daily lives.[20] In 2018, 51% of South African adults owned smartphones, a figure projected to increase by more than five million by 2023,[21] positioning the country as a continental frontrunner in mobile technology adoption.[22] The COVID-19 pandemic further accelerated this trend, intensifying demand for remote, personalised, and proactive healthcare solutions. By 2022, the number of mHealth apps in the country had nearly doubled from 101 initiatives in 2013 to 191.[23] Current data shows that 38% of the population use mobile phones to independently access health information, with this figure increasing to 44% among smartphone users.[24] This growing reliance on digital self-care tools mirrors a broader global pattern; for example, in the United States, an increasing proportion of individuals report believing that mHealth technologies can substitute for routine doctor visits, particularly for the management of minor ailments and chronic conditions.[25]

The phrase 'There is an app for everything'[26] is as much a ubiquitous truism in South Africa's digital health landscape, where mHealth apps have become widespread in addressing a wide range of healthcare needs. There are apps providing remote and virtual healthcare services,[27] health promotion initiatives,[28] self-management tools for chronic and other diseases,[29] and general physical wellness services.[30] These apps support functions such as monitoring vital signs (e.g., heart rate and blood glucose levels), providing symptom checkers, issuing medication reminders, and delivering motivational prompts, all offering novel and accessible avenues for supporting health and wellness.[31] For individuals managing chronic conditions like diabetes, these innovations promise greater autonomy, enabling users to track trends, adhere to treatment regimens, and make timely health-related decisions,[32] thereby literally placing aspects of diagnosis, treatment, and wellness into the palms of their hands.[33] For example, apps used for managing Type 1 Diabetes Mellitus such as Glucose Buddy, On-Track Diabetes, or Sugar Sense offer functionalities that include blood glucose logging, insulin and carbohydrate tracking, medication reminders, motivational feedback, and data sharing with healthcare providers.[34] These capabilities hold the potential to improve accessibility, efficiency, and the quality of care, thereby supporting South Africa' broader objectives of enhancing health outcomes. Such optimism is often situated within the paradigm of disruptive innovation,[35] which places considerable faith in the transformative capacity of these technologies to reshape existing healthcare practices and delivery models.

In the broader context of digital health, mHealth apps designed for general wellness and fitness are gaining popularity, with a growing number of individuals using these tools to track their wellness journeys or manage chronic conditions, whether 'for losing weight, staying fit, or watching what they eat.'[36] Several widely used apps such as Samsung Health, MyFitnessPal, Strava, Virgin Active, Nike Training Club, Flo Ovulation and Period, and FitOn,[37] offer personalised and goal-oriented experiences tailored to diverse user needs and fitness preferences. By integrating features such as activity tracking, real-time feedback, and progress monitoring, these apps enable South Africans to incorporate physical activity more seamlessly into their daily routines.[38] Their convenience, accessibility, and user-friendly interfaces enable users to set, track, and achieve fitness and wellness goals, thereby enhancing personal health agency. More broadly, these technologies exemplify a growing shift towards

[20] Dinath, "Choosing an Effective Mobile Health."
[21] Taylor, "Smartphone Users in South Africa."
[22] Silver, "Internet Connectivity"; Ojo, "mHealth Interventions in South Africa."
[23] Cargo, "South Africa mHealth landscape"; Digital Square, "Digital Health to Support HIV Care."
[24] Silver, "Internet Connectivity."
[25] Krouse, "iPads, iPhones, Androids;" Roth, "The mHealth Conundrum."
[26] NPR.org, "Op-Ed: There's an App for Everything."
[27] Farao, "Digital Health Communication"; Mbunge, "Virtual Healthcare Services."
[28] Comulada, "Using mHealth to Deliver"; Maraba, "Using mHealth."
[29] Mainoti, "Examining the Success Factors for Mobile Applications"; Botes, "Regulatory Challenges of Digital Health."
[30] Mbekwa, "Not Missing a Step."
[31] Ahmed, "Medication Adherence Apps"; Dinath, "Choosing an Effective Mobile Health"; Maraba, "Using mHealth"; Ndayizigamiye, "An Adoption Model of mHealth."
[32] Mainoti, "Examining the Success Factors"; Dinath, "Choosing an Effective Mobile Health."
[33] Lupton, "'It's Like Having a Physician in Your Pocket!'"
[34] Dinath, "Choosing an Effective Mobile Health."
[35] Christensen, The Innovator's Prescription; Sheppard, "mHealth Apps."
[36] Manuel, "South Africans Embrace Wellness."
[37] Similarweb, "Top Health & Fitness Apps."
[38] KLA, "Fitness Apps in South Africa."

data-driven self-care, in which digital platforms mediate health behaviours and decision-making within an evolving digital health ecosystem.

Several consumer-facing mHealth tools in South Africa, including those in the category of wellness and fitness apps, are incentivised by powerful stakeholders such as life insurers, healthcare funders, and employer-sponsored programs. For instance, the health tracking wearables market is dominated by private health insurers like Discovery Health and Momentum Metropolitan Life Limited. Discovery Health offers an incentive-based behavioural change program called Discovery Vitality. This program uses wearable devices such as smartphones, watches, GPS trackers, and heart rate monitors to encourage members to track physical activity and improve health. Participants accumulate points for engaging in prescribed health-promoting activities, which can be redeemed for rewards such as retail vouchers.[39] Vitality conducts due diligence on wearables and their manufacturers, assessing functionality (e.g., step counting and heart rate monitoring), ease of technical integration with the Vitality system, and data protection to ensure member privacy and security.[40] This process ensures the reliability and validity of devices in measuring physical activity, energy expenditure, and heart rate.[41]

However, it is important to underscore the glaring inconsistency at the heart of these initiatives wherein they presume a baseline of middle-class privilege – consistent and reliable access to smartphones, wearable devices and internet connection, private medical insurance, and digital literacy – that sharply contrasts with the lived realities of the majority in South Africa, where deep structural inequalities persist and large segments of the population remain excluded from both digital and healthcare infrastructures. As a result, many who are uninsured, live in low-income settings, and lack the financial or infrastructural means to participate in such programmes remain excluded. As such, despite the potential of these initiatives to promote preventive health and wellness, they risk reinforcing existing health inequities by directing innovation and resources towards already-served populations, leaving underserved communities behind. To this end, a more inclusive and responsive mHealth strategy must confront underlying structural inequalities and ensure that digital health solutions are not only technologically accessible, but also socially just, equitable, and subject to effective regulation.

3. Regulating mHealth Apps

The growing call for the regulation of mHealth technologies is not rooted in unfounded alarmism but in well-documented empirical evidence. A substantial body of research demonstrates that many mHealth apps fall significantly short of expected clinical, technical, and ethical standards, making them technically unreliable, clinically unsafe, and non-compliant with core principles such as safety, data privacy, and informed consent.[42] Consequently, these tools carry substantial risks of exposing users to harm or unintended results, whether through misdiagnosis, data breaches, or the dissemination of inaccurate or misleading health information.[43] Such concerns are as salient in South Africa as they are globally, reflecting shared vulnerabilities in the adoption and use of mHealth technologies. A notable example is the case of Natural Cycles, a fertility and contraception app marketed as a reliable alternative to traditional birth control methods. In Sweden, 37 women initiated legal action against the app after experiencing unintended pregnancies allegedly due to inaccurate ovulation predictions.[44] Similarly, Flo, a period and fertility tracking app, faced multiple lawsuits for unauthorised sharing of sensitive user data, violating privacy laws.[45] These cases underscore the potentially serious consequences posed by certain mHealth apps while highlighting the pressing need for stringent regulatory oversight to ensure accuracy, safeguard user safety, and protect privacy. Crucially, they also illustrate how wellness and fitness apps, often categorised as low-risk, can in practice carry significant clinical risks. In response to such challenges, South Africa has instituted enforceable regulatory frameworks aimed at protecting user safety, ensuring clinical effectiveness, and upholding ethical principles of data governance.

Against this backdrop, the question of how software-based, AI-powered health tools are classified under South African law becomes central to determining the scope of regulatory oversight. The primary legislative instrument governing such classification is the MRSA, which bases its determination on the key threshold question of whether a health app qualifies as a medical device.[46] The MRSA adopts a broad definition of a medical device to include, inter alia:

[39] Singh, "AI and Data in South Africa."
[40] FTI Consulting, "Overview of the Health Technology Sector."
[41] Fuller, "Reliability and Validity of Commercially Available Wearable Devices."
[42] Akbar, "Safety Concerns with Consumer-facing Mobile Health"; Albrecht, "mHealth Apps and Their Risks"; Botes, "Regulatory Challenges of Digital Health"; Eng, "The Promise and Peril of Mobile Health"; Haywood, "The Promise and Risks of mHealth"; Huckvale, "Smartphone Apps for Calculating Insulin"; Rowland, "Digital Health Technology."
[43] Semigran, "Evaluation of Symptom Checkers."
[44] Wong, "Birth Control App Reported."
[45] Alder, "Jury Rules Meta Violated."
[46] *Medicines and Related Substances Amendment Act of 2015* (South Africa), s 1.

> any instrument, apparatus … machine … software …
> (a) intended by the manufacturer to be used … for one or more of the following:
> (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
> (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury.[47]

From the definition above, the scope of what qualifies as a medical device is remarkably broad, covering tools or products designed for the prevention, diagnosis, or monitoring of health conditions.[48] It therefore follows that mHealth apps – including, as argued in this article, certain wellness and fitness apps whose advanced functionalities enable them to perform quasi-clinical tasks – as software operating in combination with smartphones, wearable sensors, or other mobile technologies, fall squarely within the scope of this statutory definition. Such tasks include heart rate monitoring, blood glucose tracking, symptom checking, medication reminders, diagnostic guidance, mental health screening, and decision support for treatment adherence, all of which mirror the core functions outlined in the legal definition of a medical device.

More importantly, however, the determination of whether products with such functionalities qualify as medical devices is contingent upon the principle of the developer's declared intended use, requiring the developer to explicitly designate the product for one or more of the medical purposes enumerated in law:

> 'intended purpose' means the objective, intended use or purpose… for which a medical device … is intended according to the data supplied by the manufacturer or authorised representative on the labelling, in the instructions for use and in the promotional materials.[49]

Two essential elements are central to the intended use principle: the *subjective* element, which is the app manufacturer's intent to create a device serving a medical purpose; and the *objective* element, which concerns whether the device actually fulfils that intended medical function in practice. Accordingly, for a software-based health technology to qualify as a medical device under this framework, it must satisfy both criteria, demonstrating a declared medical intent and delivering a function that aligns with that intent in actual use. This definitional alignment carries significant regulatory implications. Once a software application is classified as a medical device, it becomes subject to the provisions of the MRSA, including mandatory registration, adherence to quality assurance standards, and compliance with safety evaluation protocols.[50]

While the definition of a medical device may appear straightforward, its application becomes more complex in the context of wellness and fitness apps. These tools often support general wellbeing, fitness, or self-monitoring, but their subjective intent and objective function often do not align explicitly with medical use. Under South African law (MRSA[51], read with the 2016 Regulations relating to Medical Devices[52]), software qualifies as a medical device where its intended purpose, as indicated by the manufacturer, relates to diagnosis, prevention, monitoring, treatment, or alleviation of disease or injury. Conversely, software designed and presented solely to promote a healthy lifestyle will generally not be classified as a medical device because it is not intended, in regulatory terms, for a medical purpose. Even where wellness apps incorporate sophisticated features with health-related implications, they will typically fall outside medical-device classification if their stated purpose is framed as general wellness rather than clinical intervention. This grey zone raises ethical and regulatory concerns: as noted above, apps that provide misleading or inaccurate guidance can pose tangible health risks, underscoring the need for robust oversight to safeguard users and mitigate potential harm.

The MRSA designates SAHPRA as the body responsible for the classification and regulation of medical devices. SAHPRA determines a product's intended use by assessing its instructions for use, technical documentation, promotional materials, and the manufacturer's advertising claims.[53] The aim of this process is to ascertain whether the developer has explicitly stated that the product is intended for medical purposes. However, this creates a significant regulatory gap, as it can overlook cases where products perform functions with clinical implications, either because such uses are not explicitly stated by the developer or because they could have been reasonably anticipated but were not formally disclosed. By relying on the manufacturer's declared intent rather than the actual use of the app, the intended use rule allows products with advanced, quasi-clinical capabilities such as heart-rate monitoring, irregular rhythm alerts, symptom checking, or automated recommendations for chronic disease self-management to bypass the more rigorous safety, efficacy, and post-market surveillance requirements applicable to medical

[47] *Medicines and Related Substances Amendment Act of 2015* (South Africa), s 1.
[48] *Medicines and Related Substances Amendment Act of 2015* (South Africa), s 1; Townsend, "Software as a Medical Device."
[49] Department of Health, *Regulations Relating to Medical Devices*, s 1.
[50] *Medicines and Related Substances Amendment Act of 2015* (South Africa), s 3.
[51] *Medicines and Related Substances Amendment Act of 2015* (South Africa), s 1(h).
[52] Department of Health, *Regulations Relating to Medical Devices.*
[53] SAHPRA, "Classification of Medical Devices," 5.

devices under the MRSA. This is particularly prevalent in the case of wellbeing and fitness apps, which are often marketed without an explicitly stated medical purpose yet incorporate technical functionalities with direct clinical implications. For example, numerous apps available on commercial platforms offer functionalities such as heart-rate monitoring, symptom checking, and chronic disease management that may influence clinical decision-making or user health behaviour, despite not being classified as medical devices by their developers.[54] A content analysis of asthma-related apps revealed that many provided advice that could be construed as medical guidance, often without evidence of clinical oversight.[55] Such examples illustrate how actual functionality can exceed declared intent, creating a regulatory blind spot with potential consequences for user safety. From the illustration above, a critical regulatory ambiguity emerges: even when some apps perform functions that can have implications on health outcomes for users, they are often classified in the lowest risk category under existing South African regulations.[56] Such apps are typically designated as Class A devices due to their perceived low risk and therefore undergo minimal regulatory scrutiny. For Class A devices, the conformity assessment is conducted solely by the developer, without the involvement of an external notified body.[57] By contrast, higher-risk devices (Classes B, C, and D) require rigorous evaluation by a recognised certification authority. The classification of many such apps as Class A devices raises significant concerns about the adequacy of these processes, particularly when the developer's stated intent diverges from the app's actual functionality. It also raises questions about whether self-certification offers sufficient safeguards for end-users, especially in cases where apps provide advice that borders on clinical guidance. In a rapidly evolving digital health landscape, the assumption that such tools are inherently low-risk may expose users to harm, calling for more nuanced and functionality-driven regulatory mechanisms.

In addition to potential classification as a medical device under the MRSA, mHealth apps may also fall within the definition of a product under the *Consumer Protection Act* 68 of 2008,[58] thereby attracting liability under the CPA's strict liability regime. Under this framework, all parties in the supply chain, including developers, distributors, and retailers, may be held liable for harm caused by defective or unsafe products, regardless of negligence.[59] Such harm may encompass personal injury, death, illness, or economic loss suffered by users. The CPA defines a product as being reasonably suitable for its intended purpose and requires that all goods supplied must be of good working order and free from defects.[60] The CPA plays a crucial role in protecting users of mHealth apps by imposing strict standards on product safety, accuracy of information, and fair marketing practices. For instance, if an app provides inaccurate diagnostic information leading to inappropriate self-medication or delayed treatment, or if it fails to disclose limitations in its functionality such as the need for professional oversight, the CPA allows affected users to seek redress without having to prove fault. Similarly, if an app contains undisclosed defects that compromise user safety, developers and suppliers can be held liable for any resulting harm. In this way, the CPA complements the MRSA by offering an additional layer of consumer protection, reinforcing the importance of ensuring the safety, transparency, and reliability of mHealth technologies entering the South African market.

While the CPA establishes strict liability for defective or unsafe products, its application to mHealth apps is limited. On paper, the CPA could address problems such as misleading claims about app efficacy or harm caused by defective software, since it holds all parties in the supply chain liable regardless of negligence. In practice, however, the framework may be ill-suited to digital health tools. The CPA was designed around tangible consumer goods and traditional services; its mechanisms for redress do not adequately capture algorithmic errors or failures arising from complex data-driven functionalities. For example, a diabetes management app that incorrectly calculates insulin dosages due to a flawed algorithm does not neatly fit within the Act's traditional conception of a 'defect.' Similarly, apps that exaggerate their clinical reliability in marketing may technically fall under the CPA's prohibition of misleading representation, but enforcing such provisions requires levels of technical expertise and regulatory oversight that are currently lacking. As a result, while the CPA can theoretically provide remedies for consumers, in practice it leaves major gaps in safeguarding safety, efficacy, and reliability in the context of software-driven mHealth tools.

The *Protection of Personal Information Act 4 of 2013* complements the CPA by regulating the governance of personal and health-related data, which is an essential dimension of mHealth app use. Given that many mHealth apps continuously collect, process, and sometimes share sensitive personal information such as biometric data, sexual and reproductive health information, medication histories, and location data, POPIA sets out strict conditions for lawful data processing. It mandates that data be

[54] Boudreaux, "Evaluating and Selecting Mobile Health Apps"; Huckvale, "Apps for Asthma Self-Management"; Lupton, "Health Promotion in the Digital Era."
[55] Huckvale, "Apps for Asthma Self-Management."
[56] SAHPRA, "Classification of Medical Devices," 5.
[57] SAHPRA, Classification of Medical Devices, 5.
[58] *Consumer Protection Act No. 68 of 2008* (South Africa).
[59] *Consumer Protection Act No. 68 of 2008* (South Africa), s 61.
[60] *Consumer Protection Act No. 68 of 2008* (South Africa), s 55.

collected for a specific, clearly defined purpose (Section 13) and that processing, including sharing with third parties, occurs only with the user's voluntary and informed consent (Section 11).[61] Where consent mechanisms rely on vague or pre-selected terms, both POPIA and Section 48 of the CPA, which requires transparent and understandable agreements, may be contravened. POPIA also imposes a duty to notify users of data breaches that could compromise their privacy rights (Section 22). Although enforcement is still evolving, the Information Regulator has begun issuing warnings to non-compliant digital service providers.[62] Another crucial safeguard relevant to mHealth apps is Section 71 of POPIA,[63] which prevents users from being subjected to a decision that has significant consequences for them based solely on automated processing, and instead provides them the right to have a human review of such decisions.

Collectively, the CPA and POPIA provide a layered protection framework for mHealth users, safeguarding them from unsafe or misleading applications as well as from unethical or unlawful data practices. This dual protection is particularly critical in a regulatory landscape where, due to gaps in the intended use rule under the MRSA, many health apps blur the boundaries between wellness tools and clinical interventions. In such cases, users may be unaware of the full scope of an app's functionalities or of how and why their personal data is processed, shared, or monetised. However, while the CPA and POPIA establish important baseline safeguards, these general consumer and data protection measures lack the rigour and targeted oversight mechanisms embedded in medical device regulation.

South Africa's National Artificial Intelligence (AI) Policy Framework, adopted in October 2024, also introduces an additional governance layer relevant to AI-powered mHealth apps. The framework's ethical AI guidelines, which emphasise transparency, explainability, fairness, and accountability,[64] are particularly significant in addressing the opaque data-driven operations and decision-making processes of mHealth apps. Its provisions on ensuring human oversight of AI systems, along with commitments to bias mitigation and privacy protection, can help ensure that AI-driven health tools operate in ways that safeguard user rights and support informed decision-making. These safeguards can complement the intended use rule under the MRSA by adding explicit ethical and technical standards that apply irrespective of whether an app is formally classified as a medical device. However, the framework does not alter the core legal test for classification under the MRSA, which continues to be based on the developer's declared intent. As a result, wellness and fitness apps with advanced health-related functionalities but no explicit medical claims may still evade the stricter oversight applied to medical devices, leaving gaps in the regulatory net even under the AI policy regime.

4. The Pacing Problem: A Conceptual Framework

Despite the existence of multiple regulatory instruments that provide a foundational architecture for the governance of mHealth tools in South Africa, a significant challenge remains: the accelerating pace of technological innovation increasingly outpaces the ability of existing regulatory systems to adapt timeously and effectively, an issue acknowledged by the Intergovernmental Fintech Working Group (IFWG) in the National Treasury.[65] The relationship between technological evolution and the law is often depicted through metaphors of a competitive race, where the law is portrayed as an inevitable laggard.[66] This mismatch, often referred to as the 'pacing problem,' refers to the growing disconnect between the rapid advancement of technology and the slower evolution of regulatory systems designed to govern it. This disjuncture is not only temporal but also structural, as regulatory regimes are typically reactive and shaped by a complex interplay of political, procedural, and institutional constraints, whereas technologies, especially in the digital domain, tend to evolve iteratively, transcend national boundaries, and exhibit unpredictable applications and consequences.

This misalignment is particularly pronounced in the context of mHealth, where developers are constantly releasing innovative health apps powered by AI and big data, while the legal frameworks responsible for ensuring their safety, efficacy, and ethical use often lag behind. As illustrated in the preceding discussion, South Africa has made notable progress in establishing formal protections for users of digital health technologies through product safety standards, data privacy regulations, and medical device classifications. However, these regulatory mechanisms often remain insufficiently adaptive to the complex, fast-evolving nature of mHealth tools. Consequently, regulatory regimes become ill-equipped to address emerging risks such as the blurred lines between wellness and clinical tools. The result, this article argues, is a regulatory lag that exposes users to potential harm.

[61] *Protection of Personal Information Act 4 of 2013* (South Africa).
[62] Covington, "Information Regulator Issues First Enforcement."
[63] *Protection of Personal Information Act 4 of 2013*, s 71.
[64] South Africa, National Artificial Intelligence Policy, 10-11.
[65] South Africa, IFWG, Fintech Workshop Report.
[66] Askland, "Introduction;" Marchant, The Growing Gap Between Emerging Technologies.

One of the ways in which emerging technologies outpace and consequently render inadequate, existing regulatory frameworks is through their capacity to enable new forms of conduct and social relationships, not necessarily by producing entirely novel outcomes, but by altering the means through which familiar outcomes are achieved.[67] Legal systems are generally structured around established categories of conduct and modes of behaviour, making them ill-equipped to accommodate novel practices introduced by emerging technologies. When technologies shift these modes, such as by replacing close, face-to-face patient-practitioner interactions during medical consultations or routine check-ups with AI-driven mHealth symptom checkers or remote diagnostic tools, they can render existing laws ill-suited to effectively govern the new forms of engagement and health-related decision-making they produce. This reconfiguration of processes, rather than ends, complicates regulatory oversight by introducing uncertainty about how, when, and under which legal category a new technologically-mediated practice should be governed. In the context of mHealth apps, some wellness and fitness apps may deliver healthcare-like functions yet do not fit neatly within traditional legal definitions of medical devices, thereby complicating regulatory classification and accountability.

The regulatory challenge lies not simply in the emergence of new technologies, but in their capacity to fundamentally reshape the contexts, relationships, and behaviours that existing regulatory frameworks were originally designed for. As Bennett-Moses argues, the issue is not that law inherently fails in the face of novelty, but that legal frameworks are often premised on assumptions about human behaviour, institutional arrangements, and modes of interaction that technological innovation may render obsolete and no longer support.[68] Consequently, existing regulations may overreach or fall short in providing oversight altogether, misclassifying or inadequately addressing new forms of conduct that fall outside traditional regulatory categories but nonetheless warrant careful governance.

In the context of mHealth, certain apps that provide clinically relevant functionalities such as symptom checking, health monitoring, or treatment guidance may fall outside the scope of formal health regulation simply because they are not classified as medical devices, despite their potential to influence clinical decision-making and user behaviour. While South Africa's legal framework does include software within the definition of a medical device, its regulatory logic was conceived in a different technological paradigm, one premised on static, hardware-based medical devices and clearly defined categories of professional care.[69] When applied to dynamic, AI and data-driven technologies like mHealth apps, these frameworks may lose coherence, leading to regulatory uncertainty, weakened developer accountability, and increased risks for users. This underscores the urgent need for regulatory frameworks that are both conceptually agile and functionally responsive, capable of adapting to evolving sociotechnical landscapes while upholding core regulatory principles such as safety, fairness, and transparency.

When interrogating the pacing problem, it is important to recognise that the relatively conservative nature of regulatory systems, which is often viewed by outpacing advocates as a weakness, is not always a flaw. In many cases, this conservatism serves a vital legal function by preserving stability, ensuring predictability, and maintaining continuity within the rule of law. These qualities help guard against precipitous regulatory responses that may produce unintended consequences.[70] Scholars have cautioned that accelerating legal adaptation to match technological change can result in "bad laws," such as those that target the wrong issues, fail to anticipate future technological developments, or inadvertently stifle innovation.[71] Moreover, critics of the outpacing narrative argue that existing legal frameworks are often more adaptable than is typically assumed.[72] Therefore, according to this logic, claims about the law's inability to keep pace with technological advancements tend to overstate the problem, as many legal doctrines can be flexibly interpreted and applied to novel technological contexts without generating confusion or regulatory failure.[73] This perspective invites a more nuanced view of the pacing problem, one that balances the need for timely and responsive legal reform with an appreciation for the enduring value of regulatory stability.

5. Innovation, Expanding Functionalities, and Emerging Regulatory Challenges

Having examined a central legal principle in the regulation of mHealth apps – the intended use rule – alongside other relevant legislative frameworks, and having contextualised these within the concept of the pacing problem, this section turns to a key regulatory dilemma. Specifically, it considers how the accelerating pace of mHealth innovation is introducing advanced technical capabilities into wellness and fitness apps, which generates novel regulatory challenges and raises critical questions about the continued applicability and effectiveness of the intended use rule. Scholars examining the entanglements between

[67] Bennett-Moses, "Recurring Dilemmas."
[68] Bennett-Moses, "Recurring Dilemmas."
[69] Aspray, "Does Technology Really Outpace Policy"; Bennet-Moses, "Recurring Dilemmas."
[70] Marchant, The Growing Gap Between Emerging Technologies.
[71] Aspray, "Does Technology Really Outpace Policy."
[72] Bennet-Moses, "Recurring Dilemmas"; Cachalia, "Digitalisation in the Health Sector."
[73] Aspray, "Does Technology Really Outpace Policy"; Bennet-Moses, "Recurring Dilemmas."

law and technology argue that rapid technological advancements disrupt existing sociotechnical arrangements, generating regulatory gaps and introducing novel legal and ethical challenges.[74] These disruptions not only strain established governance frameworks but also pose significant risks to individuals.[75] The object of regulatory concern is not merely the emergence of new technologies or the advanced technical functionalities they introduce. Rather, it is the broader sociotechnical transformations enabled by these technologies that give rise to fundamental regulatory questions – transformations that reconfigure the relationships between individuals, institutions, and technological systems, thereby producing novel forms of conduct and generating new categories of risk to individuals and society.

Wellness and fitness apps exemplify this dynamic. They mediate new forms of subjectivity and risk, reshaping how individuals understand, monitor, and manage their health.[76] They blur established regulatory boundaries between general wellness and clinical practice, between consumers and patients, and between personal responsibility and institutional care. This introduces significant risks, chief among them concerns around algorithmic opacity, where users, clinicians, and even regulators are unable to determine how decisions or recommendations are generated by the apps, or the inability to know how accurate the algorithm's recommendations are – what is known as the algorithmic black box.[77] These different layers of nontransparency raise pressing questions about the clinical reliability, accuracy, and safety of outputs produced by these apps.[78] However, the regulatory concerns extend beyond the safety and efficacy of individual apps to the broader sociolegal implications of their integration into everyday health practices.

South Africa can draw valuable lessons from the European Union's *Artificial Intelligence Act* (AIA), officially known as Regulation (EU) 2024/1689 of the European Parliament and of the Council,[79] to address the risks of algorithmic opacity posed by wellness and fitness apps with quasi-clinical functions, thereby enhancing its own emerging AI governance. The AIA establishes a risk-based framework that treats AI systems embedded in tools that serve as medical devices as 'high-risk,' triggering requirements for technical documentation, transparency of capabilities and limitations, human oversight, and post-market monitoring.[80] This approach directly confronts the 'algorithmic black box' problem. For SAHPRA, these provisions suggest actionable reforms such as adopting a similar risk categorisation model to focus oversight on quasi-clinical apps and mandating AIA-level transparency regarding AI involvement, accuracy, and the necessity of professional medical advice. Wellness and fitness apps are often praised for enhancing user autonomy and encouraging proactive forms of health management. These apps enable individuals to monitor key health indicators such as blood pressure, glucose levels, heart rate, and cardiac rhythm, often in real time. By offering immediate access to physiological data, which is often accompanied by personalised recommendations, such tools support early detection of potential health concerns and foster greater independence in managing one's health. In this sense, mHealth apps increasingly function as digital proxies for certain professional healthcare services, facilitating forms of app-mediated self-monitoring and preliminary assessment that were traditionally within the exclusive domain of medical practitioners.[81] This technology-enabled shift not only decentralises aspects of healthcare delivery but also reconfigures the traditional doctor–patient relationship and contributes to the emergence of more cost-effective, user-driven care models.[82] In South Africa, 38% of the population report using mobile phones to access health information independently, and the figure rises to 44% among smartphone users.[83] This growing reliance on digital self-care tools reflects a broader global trend: for example, in the United States, studies show that a growing number of individuals believe that mHealth technologies can substitute for routine doctor visits, particularly for the management of minor or chronic conditions.[84] As users increasingly turn to these tools in lieu of professional care, the urgency for robust regulatory oversight becomes evident, both to safeguard patient safety and to ensure that this reconfiguration and redistribution of clinical responsibilities does not occur in a legal vacuum.

However, the main point this article underscores is that the more advanced functionalities incorporated in wellness and fitness apps blur distinctions between wellness promotion and clinical intervention, thereby making these tools operate in a regulatory grey zone. The question of liability becomes increasingly complex: when an app malfunctions or causes harm, does responsibility lie with the user, the developer, the vendor, or the software platform itself? These ambiguities reveal structural

[74] Bennett-Moses "Regulating in the Face of Sociotechnical Change."
[75] Hildebrandt, Smart Technologies and the End(s) of Law.
[76] Lupton, The Quantified Self; Boudreaux, "Evaluating and Selecting Mobile Health Apps."
[77] Deeks, The Double Black Box, 75-76.
[78] Townsend, "Software as a Medical Device."
[79] European Union, *Artificial Intelligence Act*, Regulation (EU) 2024/1689.
[80] European Union, *Artificial Intelligence Act*, Annex III, Articles 6 and 14.
[81] Krouse, "iPads, iPhones, Androids, and Smartphones"; Roth, "The mHealth Conundrum."
[82] Sheppard, "mHealth Apps."
[83] Silver, "Internet Connectivity."
[84] Krouse, "iPads, iPhones, Androids, and Smartphones"; Roth, "The mHealth Conundrum."

weaknesses in existing legal and professional accountability systems and highlight the pressing need for adaptive regulatory frameworks that can respond to these new modes of care delivery.

The widespread availability of mHealth apps through commercial marketplaces creates additional risks, particularly in the absence of professional medical oversight. When users rely on these tools for self-assessment, diagnosis, or treatment, the likelihood of misdiagnosis, delayed intervention, or inappropriate therapeutic decisions increases substantially.[85] This is especially concerning given the prevalence of low-quality or unverified apps. Magrabi et al. identify key regulatory challenges stemming from the versatility, accessibility, and decentralised development of mHealth technologies, many of which bypass traditional clinical governance mechanisms. Amateur developers, often lacking knowledge of health system requirements or ethical standards, can release apps directly to consumers without adequate safeguards. The direct-to-consumer model circumvents gatekeeping roles traditionally held by healthcare institutions, raising serious concerns about the accuracy of app-generated outputs, the competence of users to interpret these outputs, and the frequency of app updates or quality assurance.[86] As a result, these technologies expose critical blind spots in existing regulatory frameworks, which are still largely structured around assumptions of static clinical authority and clearly delineated medical devices. In this evolving landscape, governance models must be attuned to the hybrid, fluid, and socially embedded nature of mHealth interventions.

To ensure patient safety and clinical efficacy, the functionality of mHealth apps must align with evidence-based clinical standards. However, research reveals substantial gaps in this regard. For example, a study on wearable self-tracking devices in South Africa reported inconsistencies between app-generated data and insurer databases, with participants fearing negative repercussions such as increased premiums.[87] Similarly, another study reviewed 82 mobile apps designed for individuals with bipolar disorder and found that none were grounded in robust clinical evidence.[88] Even when apps perform well in controlled research settings, their reliability in real-world environments remains questionable due to contextual variability, inconsistent user input, and lack of oversight. Compounding these issues, the presence of mHealth apps on commercial platforms like Google Play or Apple's App Store may give users the false impression that these products have been subjected to rigorous regulatory scrutiny. Another reason for this is automation bias, which is the willingness of users to accept an app's recommendation because they believe that the technology has greater analytic capabilities than themselves.[89] This misperception contributes to misplaced trust in app functionality and undermines informed health decision-making. This illusion of reliability, combined with the absence of pre-market oversight, undermines consumer protection principles enshrined in both POPIA and the CPA, particularly in relation to informed consent, data security, and truthful representation. These issues point to a broader need for coordinated regulatory approaches that integrate clinical evaluation, consumer rights, and data protection into a unified framework for governing mHealth innovations. Such findings further emphasise the need for comprehensive regulatory mechanisms that ensure the clinical validity, safety, and ethical integrity of mHealth technologies before they reach the public.

6. Limitations of the 'Intended Use' Rule in Regulating mHealth Apps

As previously discussed, South Africa has made notable progress in establishing a regulatory framework for healthcare innovations, including software-based AI-powered solutions like mHealth apps. The intended use rule under the Medical and Related Substances Act provides the primary legal foundation for classifying and regulating such technologies as medical devices. However, the continued applicability and effectiveness of this regulatory principle to regulate these innovative mHealth technologies, particularly wellness and fitness apps, remains a significant challenge. This stems from deeper conceptual and structural limitations within the reliance on the intended use rule as the basis for classifying and regulating mHealth technologies. In the context of rapidly evolving digital tools that increasingly blur the line between general wellness and clinical care, this principle proves increasingly inadequate, leaving critical gaps in oversight and exposing users to potential risks.

We have highlighted that several mHealth apps often fall outside regulatory oversight simply because developers disclaim any formal medical purpose, instead declaring that the apps are for non-medical purposes, and hence result in them being classified under the general wellness and fitness category. The reliance on declared intent becomes problematic in contexts where the actual use of an app declared by the developer as meant for non-medical purposes may influence health-related outcomes. Moreover, the notion of '(non-)medical purpose' is inherently ambiguous, as the boundary separating apps for wellness

[85] Akbar, "Safety Concerns with Consumer-facing Mobile Health"; Wolf, "Diagnostic Inaccuracy of Smartphone Applications."
[86] Magrabi, "Why is it so Difficult to Govern Mobile Apps?"
[87] Ntshumi, "Not Missing a Step."
[88] Nicholas, "Mobile Apps for Bipolar Disorder."
[89] Deeks, The Double Black Box, 71.

solutions from those with medical functions is often indistinct. Apps initially framed as wellness tools may enable self-diagnosis or self-management of chronic conditions, thus entering domains traditionally governed by clinical regulation. The regulatory status of such apps is determined not by their real-world impact, but by a formalistic declaration that may understate their clinical relevance. This creates a substantial regulatory gap, whereby clinically significant tools escape formal oversight, thereby exposing users to potential risks without the protections afforded by more stringent regulatory scrutiny.

The concern about the clinical implications of apps that may be mis declared by their developers as having no medical intent, and therefore subsequently misclassified as non-medical tools emanates from the potential risks that may arise due to their advanced functionalities that incorporate health-related functions, yet such misclassification results in such apps escaping formal safety and efficacy evaluations.

The concern about the clinical implications of apps that may be misclassified under the intended use rule is far from hypothetical; it strikes at the heart of a growing regulatory dilemma in South Africa's mHealth landscape. As wellness and fitness apps increasingly incorporate advanced functionalities, the risks to users because of such misclassification become more pronounced. These advanced functionalities are not merely passive; they often guide users towards specific health-related outcomes. For instance, diabetes self-management apps may provide real-time advice on insulin dosing or carbohydrate intake based on tracked glucose levels. If these apps malfunction by generating inaccurate readings or flawed dosing guidance, they can expose users to serious health consequences such as hyperglycaemia.[90] When such tools, despite their capacity to influence clinical outcomes, are excluded from medical device regulation under the MRSA solely on the basis of their marketing as lifestyle products, they can operate without the stringent safety, efficacy, and accountability measures that formal oversight entails, leaving users vulnerable to potentially serious harm.

A compelling example from the South African app market that illustrates this regulatory ambiguity is the Discovery Health app, developed by Discovery Health, one of South Africa's largest private health insurers. Although marketed as a general wellness and fitness platform, the app incorporates advanced features with clear clinical implications. Branded as "the future of healthcare," the app promises to "unlock personalised health information" and provide "data-driven recommendation prompts to live a healthier life," positioning itself as a digital companion for proactive health management.[91] One of its most notable features is an AI-powered symptom checker, which allows users to "check your symptoms" and "get guidance," effectively enabling a form of self-diagnosis. The app also offers "personalised health nudges" based on the user's "unique health profile," a function that tailors wellness recommendations through algorithmic analysis of personal health data.[92] While these tools can empower users and support preventive care, they also blur the boundary between general wellness and clinical functions. The regulatory classification of the app, however, is not based on its real-world use or clinical relevance, but rather on Discovery's formalistic framing of it as a wellness tool. This enables it to operate outside the scope of stringent medical device regulation, despite its potential to influence health outcomes in ways traditionally reserved for professional medical judgement. The absence of tailored guidance in South African law makes it difficult to assess and regulate borderline cases, thereby increasing the risk that clinically relevant apps may be misclassified or escape scrutiny altogether. This regulatory gap underscores the need for a more differentiated and responsive framework that accounts for the blurring boundaries between wellness and medical applications.

7. Conclusion: Advancing Adaptive mHealth Regulation – From the 'Intended Use' Rule to a Functionality-Driven Framework

The foregoing discussion has highlighted the inherent limitations of relying on a developer's declared intent as the primary threshold for subjecting health tools to rigorous regulatory intervention, given that, in the context of wellness and fitness apps, it is this declared intent that determines whether such tools fall within the medical device category and are therefore subject to oversight. However, in the dynamic domain of mHealth, functionality, rather than declared intent, offers a more reliable and objective basis for determining the appropriate scope of regulation. A functionality-driven approach would assess what an app actually does in practice, including how it collects, processes, and communicates health-related data, irrespective of how its purpose is framed by the developer. Such an approach would reduce the risk of regulatory gaps by ensuring that apps with quasi-clinical capabilities are evaluated according to their real-world impact and potential risks, rather than the potentially narrow or strategically crafted intentions declared by developers. This shift would enable regulators to capture a wider range of health-affecting technologies that might otherwise evade oversight under the current intent-based framework. In South Africa, where SAHPRA's classification of medical devices under the MRSA depends primarily on intended use and is triggered

[90] Eng, "The Promise and Peril of Mobile Health."
[91] Discovery Limited, Discovery Health App.
[92] Discovery Limited, Discovery Health App.

only when explicit medical claims are made, adopting a functionality-driven model would significantly strengthen the regulatory impact and close the pacing gap between technological innovation and regulatory adaptation, thus reinforcing public health protections in the digital era.

Building on the critique of developer intent-based classification, adaptive regulation offers a pathway for aligning regulatory frameworks with the dynamic nature of digital health innovation. It recognises that laws must evolve in tandem with the technologies they govern, incorporating the assessment of apps' real-world use, ongoing post-market risk evaluation, and periodic revisions to address emerging risks. Crucially, it emphasises the proactive identification and mitigation of potential risks and ethical dilemmas before they materialise, thereby enhancing the responsiveness and resilience of regulatory oversight in the mHealth sector.

The rapid growth of wellness and fitness mHealth applications in South Africa reflects broader global trends in digital health innovation, offering new opportunities for user engagement, self-management, and preventative care. Increasingly, however, these technologies incorporate quasi-clinical functionalities such as monitoring vital signs, generating personalised health recommendations, or guiding chronic condition management that, consequently, blur the boundary between general wellness tools and regulated medical devices. SAHPRA's continued reliance on the intended use principle for classifying medical devices often fails to capture these functional realities, leaving tools with significant health-related implications outside the scope of medical device regulation simply because they are neither explicitly labelled nor intended by their developers for such purposes. This disconnect reflects the pacing problem, which is the persistent misalignment between the rapid evolution of mHealth technologies and the comparatively slow adaptation of regulatory frameworks. Addressing this gap requires institutionalising adaptive regulatory mechanisms, including functionality-based assessment criteria, iterative policy review, and risk-based oversight, to ensure that classification reflects real-world use rather than declared purpose alone. Embedding these models within existing governance structures would strengthen regulatory agility, reduce interpretive uncertainty, and better align South Africa's digital health governance with the evolving risks and societal stakes of a rapidly transforming mHealth ecosystem. In doing so, the country can realise the transformative potential of mHealth technologies in healthcare delivery while upholding ethical standards, safeguarding patient rights, and maintaining clinical integrity.

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