

NAVIGATING HEALTHTECH

LEGAL SOLUTIONS FOR A

TRANSFORMING INDUSTRY

WEBBER WENTZEL

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Technology is revolutionising the healthcare industry. The global migration to digitised systems, accelerated by the Fourth Industrial Revolution, has resulted in ever-increasing volumes of data and interconnected devices (Internet of Things), connecting the digital, biological, and physical worlds. These advancements are enhancing patient outcomes through improved access, organisation and analysis of health data. The provision of e-patient care continues to benefit from HealthTech innovations such as machine learning, smartphone applications, wearable devices, robotic surgeons, and diagnostic and treatment applications. However, these technologies raise complex legal challenges, including intellectual property, data protection, regulatory compliance, liability, employment (including issues related to remote work, talent retention, and the impact of AI on the workforce), insurance, and market access requirements.

Webber Wentzel has extensive experience advising in relation to legal matters affecting the digital world. As a full-service firm, we advise clients across all legal areas to navigate technological developments in HealthTech. Our expertise spans intellectual property protection and enforcement, data privacy and cybersecurity, regulatory frameworks, contractual agreements with technology providers, litigation relating to product liability, disputes, data breaches, and labour-law related matters. We assist clients in complying with evolving laws and regulations, including those governing medical devices, AI applications, and healthcare professionals, enabling innovation while maintaining patient safety.

Partner with a legal firm
that understands both
the technology and the law.
Let's shape the future of
healthcare together.

CONTACT OUR AUTHORS



Bernadette Versfeld
Partner
+27 11 530 5404
bernadette.versfeld
@webberwentzel.com



Chetan Vanmal
Partner, TAX: Indirect (VAT & Customs)
+27 11 530 5204
chetan.vanmali
@webberwentzel.com



Dhevarsha Ramjettan
Partner
+27 11 530 5707
dhevarsha.ramjettan
@webberwentzel.com



Leigh Lambrechts
Partner
+27 21 431 7328
leigh.lambrechts
@webberwentzel.com



Lenée Green
Partner
+27 11 530 5014
lenee.green
@webberwentzel.com



Lisa Swaine
Partner
+27 11 530 5341
lisa.swaine
@webberwentzel.com



Martin Versfeld
Partner
+27 11 530 5322
martin.versfeld
@webberwentzel.com



Prelisha Singh
Partner
+27 11 530 5419
prelisha.singh
@webberwentzel.com



Tim Ball
Partner
+27 21 431 7372
tim.ball
@webberwentzel.com



Wendy Tembedza
Partner
+27 21 431 7291
wendy.tembedza
@webberwentzel.com



INTELLECTUAL PROPERTY

Intellectual property (IP) rights lie at the heart of the commercialisation of all technologies. On the one hand, technology developers need to secure and enforce IP protection for technological developments to profit from their research and development activities. On the other hand, technology implementers need to manage the risk of infringing third-party IP rights.

We have significant expertise in advising leading industry players on protecting and leveraging value from their intellectual property rights, as well as avoiding and/or defending infringement claims brought by third parties.

Our IP specialists have extensive experience advising clients in the healthcare sector, particularly in relation to:

- protection and management of IP assets;
- commercialisation of IP and how these assets can be protected by registration, monetised by licensing, distribution, technology transfer, investment agreements, research and collaboration agreements, franchise agreements, global joint ventures and assignment;
- monitoring and enforcement of IP assets;
- IP dispute resolution and litigation;
- due diligences and audits of IP assets;
- structuring of IP ownership and securitisation of IP assets to leverage their maximum potential; and
- IP exchange control and tax advice which is particularly important for the transfer of rights across South African borders.



BIG DATA

The Fourth Industrial Revolution has accelerated the availability of vast quantities of electronic data, alongside a proliferation of interconnected devices. The complementary use of big data and these devices has created opportunities to enhance patient care through sophisticated data analysis. In a world where data (including personal data) is integral to ensuring accurate outcomes for patient care, navigating the regulatory landscape governing the processing of personal data is critical.

Our expertise in data privacy and protection assists clients in navigating the highly regulated space surrounding the processing of personal data. By merging our understanding of global data protection laws with detailed knowledge of South African data protection regulation, particularly the nuances relevant to processing special personal information such as health or medical data, we help clients understand the implications of using personal data in various contexts.



TECHNOLOGY

The provision of e-patient care will continue to benefit from advancements within the HealthTech space. In many cases, realising the full value of HealthTech tools requires collaboration between healthcare providers and technology companies. These partnerships are crucial in enabling innovation and ensuring effective service delivery in a rapidly evolving digital health landscape. The dynamic nature of the technology industry also means that HealthTech development is deeply influenced by broader technology trends. The cross-border and cross-sectoral nature of our work allows us to support clients with insight into these trends and how they shape HealthTech innovations, both locally and globally.

We have extensive experience negotiating contractual agreements with a wide range of technology providers, including those involved in software development, electronic hardware, data processing outsourcing, and data products (such as cloud infrastructure and data centres). These engagements remain central to ongoing developments in the HealthTech sector. We also advise clients on the interplay between artificial intelligence (AI), medical devices and healthcare professionals (HCPs), particularly in relation to the legal frameworks that may impact these technologies and the professionals who use them. Our team assists clients in navigating complex regulatory requirements, enabling them to innovate confidently while maintaining compliance and prioritising patient safety.



REGULATORY

AI, medical devices and healthcare services are subject to a complex and overlapping legal framework. This framework cuts across various legislation regulating medical schemes, pharmaceuticals, health professions, including doctors, nurses, pharmacists, and medical technologists.

We advise a broad range of stakeholders, including large pharmaceutical companies, healthcare professionals, new market entrants, and established businesses, on legal and regulatory issues arising under statutes such as the Medicines and Related Substances Act, the National Health Act, the Pharmacy Act, the Medical Schemes Act, the Health Professions Act, and the Nursing Act. Our advice is often provided in the context of specific commercial transactions or as stand-alone legal opinions.

Our team also offers specialist regulatory advice tailored to the HealthTech sector. Our experience includes:

- **Medical device licensing:** Advising on the licensing of medical device manufacturers, distributors, and wholesalers.
- **Advertising and marketing:** Ensuring compliance with regulatory requirements relating to the advertising and promotion of medical devices and related health products.
- **Healthcare business models:** Assessing the legality of various commercial models in the healthcare sector.
- **Product classification:** Advising on the appropriate legal classifications for product models such as mobile applications, diagnostic AI tools and wearables, whether as medicines, medical devices, medical schemes, insurance products, healthcare services or otherwise.
- **Investment structuring:** Supporting the structuring of investments and other large transactions in the pharmaceutical and hospital/health establishment industry, for both corporates and healthcare professionals.
- **Compliance and licensing:** Providing broad advice on compliance with regulatory frameworks, including the South African Health Products Regulatory Authority (SAHPRA) requirements, and guidance on licensing of medical device establishments.
- **Communication strategies:** Advising on compliant marketing and public communication. This includes reviewing advertising materials, substantiating product and service claims, advising on digital communications, and developing compliant internal and external communication policies.
- **Data and cyber regulation:** Guiding clients through the regulatory landscape of data protection and cybersecurity, including compliance with the Protection of Personal Information Act, 2013 (POPIA) and other relevant data privacy regulations. This involves advising on the collection, storage, and processing of personal health information, data breach responses, and cybersecurity best practices.
- **E-commerce compliance:** Assisting HealthTech companies in establishing and maintaining compliant e-commerce platforms. We advise on online transactions, consumer protection obligations, and digital marketing regulations under the Electronic Communications and Transactions Act, 2002 (ECTA), the Consumer Protection Act, 2008 (CPA), and other applicable laws.
- **Anti-bribery and anti-corruption compliance:** Advising on compliance with anti-corruption laws such as the Prevention and Combating of Corrupt Activities Act, 2004 (PRECCA) and, where applicable, the Financial Intelligence Centre Act, 2001. Our support includes policy development, risk assessments, employee training, and implementation of ethical business practices.
- **National Health Insurance (NHI):** Advising on the implications of the National Health Insurance Act, 2023, including how it may intersect with private healthcare, medical insurance, and the broader regulatory changes impacting HealthTech operations.



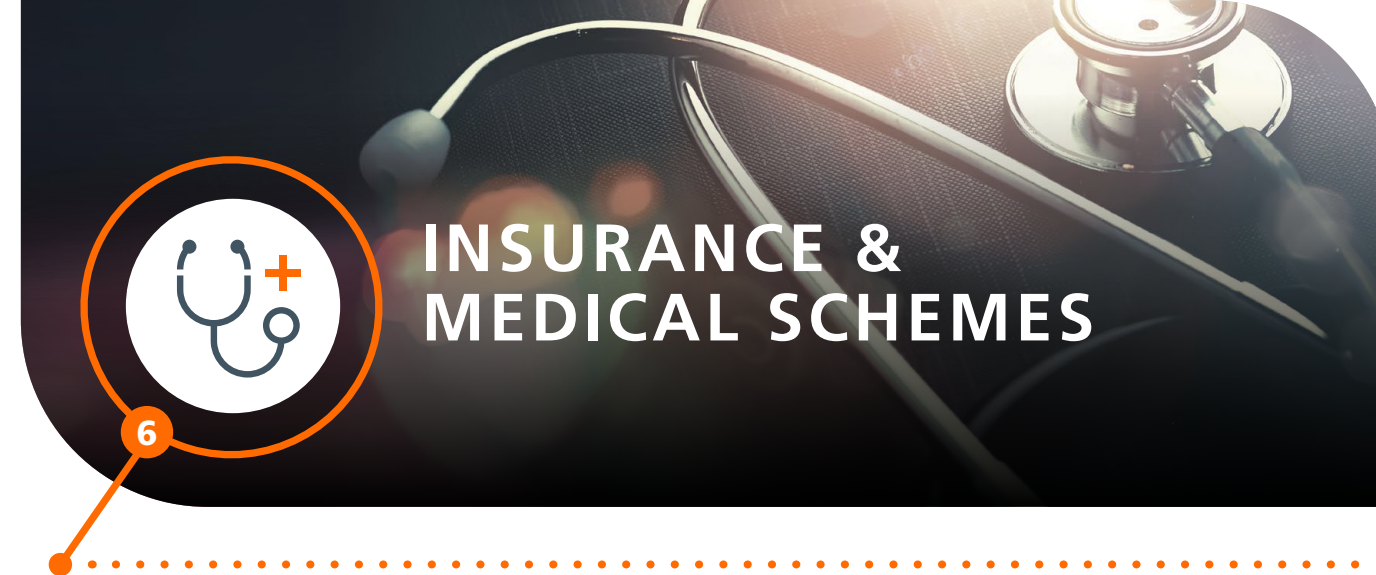
Our competition law specialists have over 25 years of extensive healthcare regulatory experience, and have advised across the full healthcare supply chain.

Our services include:

- Assisting with the management of risks associated with sharing competitively sensitive information on joint IT platforms.
- Engaging with suppliers and customers regarding the legality of pricing strategies.
- Managing the sharing of clinical data to improve outcomes without breaching regulatory compliance.
- Advising on:
 - managed care organisations;
 - distribution arrangements;
 - alternative reimbursement models, including global fee and capitated fee arrangements;
 - potential technology joint ventures; and
 - exclusive agreements and licensing arrangements.
- Preparing complex merger filings to help secure approval by drawing on our deep understanding of the industry and providing efficient, proactive advice on the likelihood of the approval being granted.
- Applying for exemptions from the application of the Competition Act to

facilitate necessary collaboration in the healthcare space.

- Making representations during market inquiries, including the recent Health Market Inquiry.
- Providing ongoing compliance training, with a focus on how health sector participants can not only manage their risks but also identify and pursue strategic opportunities.



The structuring and implementation of insurance policies within the healthcare sector, including those relating to medical schemes, require careful navigation of complex and intersecting regulatory frameworks. These include the Medical Schemes Act, insurance-related legislation, and oversight by the Council for Medical Schemes. Our team works closely with clients to ensure compliance and manage legal risks across a wide spectrum of healthcare insurance matters.

We advise on a wide range of insurance-related issues, offering services that include:

- **Product insurance:** We guide clients in interpreting and navigating the terms and clauses of insurance policies, ensuring a clear understanding of coverage and obligations. We also engage with the Council of Medical Schemes and other regulators to assist clients in addressing and resolving regulatory challenges.
- **Policy structuring:** We provide strategic advice on the structuring of insurance policies, including the regulatory interplay between medical schemes, health insurance, and medical

insurance. This includes advising on compliance with applicable laws and aligning policy structures with business models.

- **Risk mitigation through insurance:** We assist clients in identifying and managing operational and legal risks through various insurance products, including product liability insurance, cyber risks liability insurance, general liability insurance, and professional indemnity and malpractice insurance.





FUNDING IN HEALTHTECH

Access to funding is a key driver of innovation and growth in the HealthTech sector. Whether through debt, equity, or hybrid instruments, HealthTech companies require financing structures that align with their business models and comply with the relevant regulatory frameworks. Understanding the financial ecosystem, as well as the risks and opportunities within it, is critical for sustainable growth and operational success.

We advise clients on a wide range of funding structures, including:

- **General banking and finance:** Advising on leveraged finance, debt restructuring, and the implementation of tax-efficient instruments tailored to meet the specific needs of HealthTech businesses.
- **Structuring and compliance:** Supporting clients in structuring financing agreements that are both commercially and legally compliant, ensuring alignment with applicable tax, corporate, and regulatory considerations.



EMPLOYMENT

In the rapidly evolving Healthtech landscape, protecting your confidential information and ensuring workforce stability are paramount. Our legal team offers specialised expertise in employment law tailored to the unique challenges and opportunities within this innovative sector.

We provide comprehensive counsel to Healthtech companies on a broad spectrum of employment-related issues, including:

- **Strategic employment agreements:** Drafting robust and forward-thinking employment contracts designed to safeguard your company's interests in an agile environment. This includes bespoke clauses covering intellectual property ownership, confidentiality, and post-termination obligations, crucial for protecting groundbreaking health technologies and sensitive data.
- **Enforcement of restraint of trade and non-solicitation covenants:** Vigorously defending your business against unfair competition by drafting, implementing, and enforcing effective restraint of trade and non-solicitation clauses. We provide strategic advice and representation in disputes arising from departing employees or competitors seeking to leverage confidential information or poach key talent.
- **Workforce incentivisation and retention:** Structuring innovative compensation and retention programmes, including performance-based incentives, long-term retention bonuses, and equity participation schemes,

to attract, motivate, and retain top-tier talent in a competitive market.

- **Confidential investigations:** Leading sensitive internal investigations into suspected data breaches, unauthorised disclosure of confidential information, and breaches of company policies, including those involving breaches under the Employment Equity Act. We offer expert guidance on incident response, regulatory compliance, and damage mitigation.
- **Global mobility and talent transfer:** Facilitating the seamless cross-border transfer of critical talent through advice on immigration pathways, intra-company transfers, and compliance with international employment regulations, ensuring your global operations are supported by the best minds in Healthtech.

Our deep understanding of both employment law complexities and the specific regulatory and commercial demands of the Healthtech industry positions us as an invaluable partner in safeguarding your most critical assets: your innovation and your people.



DISPUTE RESOLUTION

As healthcare technology continues to evolve, so too does the complexity of legal disputes that arise in this sector. HealthTech companies face an expanding spectrum of litigation risks ranging from product liability and professional negligence to cyber liability and regulatory compliance. Increasing digitisation and the integration of AI in healthcare have introduced new areas of exposure for both established industry players and emerging innovators. Legal challenges may involve individual claims, regulatory enforcement, or class action lawsuits, and may stem from data breaches, system failures, supply chain issues, or operational disruptions.

We advise and represent clients in a wide range of disputes and legal proceedings in the HealthTech sector, including:

- **Product liability:** As healthcare technology advances, so do liability risks, particularly around defective medical devices and software. Claims may relate to design or manufacturing defects, inadequate warnings, or failure of technology to perform as intended, resulting in harm to patients. We assist clients by:
 - representing manufacturers and healthcare providers in defending against claims related to product defects and patient injuries; and
 - advising on compliance with applicable safety standards and regulations to minimise liability exposure.

- **Operational and commercial disputes:** Disputes frequently arise from contractual agreements between healthcare providers and technology vendors, including issues with service delivery, performance expectations, and software implementation. We assist by:
 - providing representation in breach of contract and performance-related disputes; and
 - offering alternative dispute resolution (ADR) mechanisms to limit operational disruption and reputational harm.
- **Class action lawsuits:** HealthTech companies may face class actions arising from alleged consumer fraud, misleading advertising, adverse product effects, or defective design. We have advised and acted for insurers of pharmaceutical companies and manufacturers of prostheses and implants, as well as medical practitioners and hospitals involved in defending class actions linked to allegedly defective products. We assist clients by:
 - developing robust defence strategies tailored to the nuances of class action litigation; and
 - negotiating favourable settlements to protect clients' commercial and reputational interests.
- **Forensic investigations:** Forensic investigations are crucial in disputes involving fraud, misconduct or data breach. We assist by:
 - conducting thorough forensic analyses in collaboration with technical experts; and
 - using investigative findings for litigation or to provide expert testimony in court proceedings.

- **Supply chain disputes:** The complexity of the HealthTech supply chain presents ongoing risks of delivery delays and quality control issues. We support clients by:
 - representing healthcare providers and manufacturers in disputes involving non-performance or substandard products; and
 - advising on contract terms that mitigate risk and clearly define performance and quality standards.
- **Data privacy and compliance disputes:** With the increasing reliance on personal health data, disputes related to data protection legislation compliance, including POPIA and the Promotion of Access to Information Act, 2000 (PAIA) are on the rise. Our services include:
 - advising clients on litigation involving data breaches and privacy violations; and
 - guiding healthcare providers in compliance to minimise future legal exposure.
- **AI and predictive analytics disputes:** The use of AI in healthcare raises novel liability and ethical considerations. We assist clients by:
 - addressing disputes arising from AI-assisted diagnostics and clinical decision-making, including liability claims linked to patient harm; and
 - advising on legal frameworks applicable to the use of AI in healthcare, helping clients mitigate risk while pursuing innovation.



Tax considerations are critical to the success of HealthTech ventures, particularly in an increasingly globalised and regulated environment. Companies operating in this sector must carefully navigate domestic and international tax frameworks to structure their operations in a commercially viable and tax-efficient manner. As HealthTech businesses expand across borders and scale rapidly through joint ventures, investments, and mergers, they are exposed to a range of complex tax risks and opportunities. These include transfer pricing, indirect tax, employee incentives, and cross-border structuring, areas in which specialist tax advice is essential to support sustainable growth and regulatory compliance.

Our areas of expertise include:

- **Corporate tax:** Advising on all aspects of corporate taxation, including mergers and acquisitions, initial public offerings, and private equity-related transactions.
- **Debt restructures:** Assisting clients in navigating complex debt restructuring transactions, ensuring alignment with their commercial goals and tax compliance requirements.
- **Employees' tax and incentive schemes:** Advising on the tax treatment of remuneration, benefits, and the design and implementation of employee share incentive schemes to support talent retention and incentivisation.
- **Indirect tax:** Advising clients in relation to VAT and Customs & Excise matters, including compliance, structuring and dispute resolutions.

- **International tax and transfer pricing:** Assisting clients with cross-border related party transactions, offering guidance on transfer pricing to ensure alignment with the arm's length principle, and resolving complex cross-border pricing issues, with insights from multiple jurisdictions.
- **Exchange control:** Advising on exchange control matters affecting cross-border investments, repatriation of profits, and foreign operations, ensuring full compliance with the South African Reserve Bank requirements.
- **Tax dispute resolution:** Representing clients at all stages of tax disputes, from engagement with the South African Revenue Service through to litigation, offering practical and strategic solutions to resolve complex matters.
- **Structuring and platform optimisation for growth:** Advising on large-scale structuring projects, including the establishment of holding companies for offshore interests, assets, and activities, and the design of efficient platforms to support international expansion of HealthTech businesses.
- **Joint ventures and cross-border structuring:** Acting for multinationals in structuring joint ventures across multiple jurisdictions, advising on optimal tax jurisdictions and funding structures to support the joint venture's commercial objectives).



We offer a market-leading tax advisory service, with an integrated, multi-skilled team comprising both lawyers and accountants.



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CORPORATE

Corporate law plays a crucial role in the healthcare sector by providing the legal framework within which healthcare organisations operate. The formation, governance, and transactional activities of healthcare entities, such as hospitals, clinics, pharmaceutical manufacturers, and health-focused NGOs, are all governed by complex regulatory and corporate compliance considerations. As the healthcare sector continues to evolve with increasing public-private collaboration and cross-border investment, legal support in structuring, financing, and governance becomes essential to ensure both compliance and operational success.

Our diverse and full-service corporate team regularly advises clients in the healthcare sector, supporting them throughout the business lifecycle. Our experience includes:

- **Entity formation and structuring:** Advising on the formation and structuring of healthcare entities, such as private hospitals and clinics, pharmaceutical companies, and healthcare-related non-governmental organisations. Our advice includes selecting the appropriate legal structure (eg private company, non-profit company), which impacts the organisation's operational scope, funding capabilities, and tax treatment.
- **Mergers, acquisitions, and joint ventures:** Advising on transactions within the healthcare sector, including hospital group mergers and healthcare system

integrations, acquisitions of medical suppliers and private medical practices, and strategic alliances between healthcare providers, funders, and insurers. These transactions are often complex and require careful navigation of both commercial and regulatory issues.

- **Local and foreign investment:** Advising on a range of local and international investments in the healthcare sector, including private equity investments into hospital groups and healthcare networks, compliance with broad-based black economic empowerment (B-BBEE) ownership requirements, and ethically compliant ownership and management structures in regulated sectors such as health.
- **Governance and oversight:** Supporting clients in meeting their corporate governance responsibilities under the Companies Act, 2008. This includes advising on board and shareholder structures, governance frameworks, and compliance with directors' duties and fiduciary obligations.
- **Public-private partnerships (PPPs):** Advising on and facilitating PPPs between government and private healthcare providers. These arrangements are key to expanding access to healthcare services, developing health infrastructure, and delivering healthcare to underserved communities.



ABOUT WEBBER WENTZEL

We are a leading full-service law firm on the African continent, providing clients with seamless, tailored and commercially-minded business solutions within record times. Our alliance with Linklaters and our relationships with outstanding law firms across Africa ensure that our clients have the best expertise wherever they do business.



Chambers Africa Awards



International Tax Review EMEA



African Legal Awards



African Legal Awards

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