

## COMPANY PROFILE



### ***Background***

Umsebe Healthcare is a manufacturer, importer, distributor and exporter of medicines in South Africa, with a focus on niche sector products addressing unmet medical needs in our society, as well as issues that threaten the security of supply, and hence access to, medicines. “Umsebe” translates into “Ray of light” in the indigenous language of Zulu, and was conceptualised as a ray of light in our healthcare delivery system, and was formed at a time when one of the two founding members of the company fought alongside her terminally ill child, and sadly lost the dreaded battle against cancer. The provision of treatment for unmet medical needs became an unequivocal focal area for the organisation.

### ***Licensing***

Umsebe Healthcare is fully licensed as a manufacturer, importer and exporter in South Africa and performs medicine and combination medicine-medical device distribution in niche markets under agreement with international suppliers as part of a vested long term partnership agreement. The company provides full legal responsibility to the South African authorities for the medicine registration and compliance with the marketing authorisation, and in addition to the authorities, to the South African consumer, for the release and sale of product to the local market and performance of all post-marketing surveillance activities within the South African and SADC markets.

### ***Medicine and Medical Device Registration and Early Market Access***

Umsebe Healthcare, provides expert regulatory services in the areas of medicine and medical device registration and on regulatory market access strategy, to enable quickest regulatory route to market, via a sound, robust scientific basis for registration and a quality assured submission dossier, ensuring the quickest turn-around time to successful product approval. KD Consulting Pharmaceutical Solutions is a sister company to Umsebe Healthcare and is a leading specialised pharmaceutical consulting practice delivering regulatory affairs, quality assurance, risk management, pharmacovigilance and compliance services and solutions through a robust scientific approach, being backed by over a decade of consulting practice experience in Africa and by professional service delivery.

During the product licencing phase, Umsebe is able to offer healthcare professionals and patients with unmet medical needs early access to treatment via Named Patient Access. Umsebe holds a notable reputation on successful Section 21 (named patient access) permit approval for access to un-licensed medicines.

### ***Sales, Marketing and Distribution***

Umsebe Healthcare is a level 1 contributor in respect of Broad Based Black Economic Empowerment in South Africa, and may not only offer advantageous registration timelines as the SAHPRA use this criteria as a tool to aid industry transformation going forward but can and shall offer significant leverage for selective procurement by both in the national state healthcare system and in the private healthcare sector. Umsebe confers the advantages of preferential procurement to all its supply partner, affording compounded value in the engagement. Umsebe Healthcare partners with a third party logistics provider for specialised distribution infrastructure in support of niche medicine supply to the private sector hospital network throughout South Africa, but is equally geared and ready for an upscale in distribution volume and intensity. The Umsebe team is supported by a small core sales and marketing team providing an undiluted focus but nationwide coverage on addressing rare disease and unmet medical needs.

### ***Management and Resourcing***

Umsebe Healthcare is directly managed by both founding members who remain actively involved in the business, and the company works hand-in-hand with 'sister-company' KD CONSULTING PHARMACEUTICAL SOLUTIONS, a specialised Regulatory Affairs and Quality Systems focused consulting practice, in the provision of full regulatory support of the regulatory affairs function and support of the Quality Assurance functions of the company. KD Consulting is a prominent player in the regulatory and quality services consulting sector with 12 years of experience within the consulting arena, consulting to multiple pharmaceutical industry clients with a strong track record of successful, high quality scientific filings and is supported extensively by the 'word of mouth' recommendations from its multinational pharmaceutical and medical device company client base. KD Consulting is an active and participative member of various industry bodies, including but not limited to the Pharmaceutical Society of South Africa (PSSA), the South African Association of Pharmacists in Industry (SAAPI), The South Africa Medical Device Association (SAMED), The Health Products Association (HPA) and the South African Animal Health Association (SAAHA).

Umsebe Healthcare is adequately technically and scientifically resourced by the highly skilled team at KD CONSULTING PHARMACEUTICAL SOLUTIONS, wherein the varying resource demands that Umsebe Healthcare may experience can adequately be supplied in accordance with need.

## ***Positioning***

Umsebe Healthcare is a young, driven and agile company able to offer undiluted focus is addressing the successful product registration, marketing and distribution needs of those specialized pharmaceutical and biotechnology products in its portfolio, especially to companies who keep their primary focus on innovative product development. Umsebe has offices in Cape Town, South Africa, and is opportunely positioned in the gateway to Africa for maximum exposure into this promising market.

To discuss your specific needs and how Umsebe Healthcare can assist in bringing your products to the South African and Southern African markets, please contact us further:

**Dineshree Naiker (B.Pharm)**

Managing Director

Tel: +27 (0) 82 615 7827

[dineshree@umsebe.com](mailto:dineshree@umsebe.com)

**Kacy Rajappen (B.Pharm)**

Regulatory and Quality Director / Responsible Pharmacist

Tel: +27 (0) 82 873 3925

[kacy@umsebe.com](mailto:kacy@umsebe.com)