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PHARMA LAW
BRIDGING THE GAP

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WHAT IS THE DIFFERENCE BETWEEN

'REGISTRATION' + 'LICENSING'?

Quite a lot.

The words "registration" and "licensing" used in the Medicines Act and its regulations have different meanings and cannot be used interchangeably.

Registration pertains to medicines, medical devices and IVDs.

In general, the sale of these products is prohibited if they are subject to registration and are not registered. On successful application for the registration of a medicine, SAHPRA issues an applicant a certificate of registration. The applicant then becomes the holder of a certificate of registration

Registration also pertains to health care professionals

It refers to the registration of healthcare professionals with the Health Professions Council of South Africa (HPCSA), allied healthcare professionals with the Allied Health Professions Council of South Africa (AHPCSA), nurses with the South African Nursing Council (SANC) and pharmacists with the South African Pharmacy Council (SAPC), amongst others.

Licenses, on the other hand, allow for specific acts to be performed

Certain healthcare professionals require licenses to compound and dispense medicines depending on their scope of practice.

Manufacturers, wholesalers or distributors of medicines, scheduled substances, medical devices or IVDs require licenses to manufacture, import, export, act as wholesalers or distributors of these products.

A clear distinction can thus be made between "registration" and "licensing" referred to in the Medicines Act and its regulations.

I hope this insight has simplified the difference between "registration" and "licensing"

The Pharmalaw company values include punctuality, honesty, transparency and we strive for excellence in everything we do. I would like to meet you and discuss ways in which my expertise could benefit your organisation.