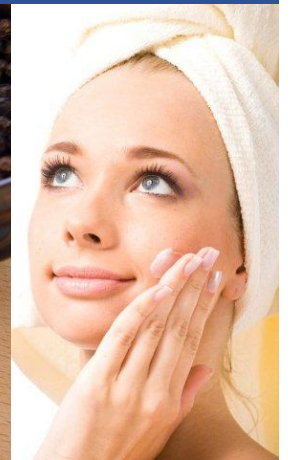




Company Profile



2009

Market Environment South Africa

Sub-Saharan Africa and with it South Africa is characterised by a large ethnic diversity, and a wide spectrum of diseases, ranging from European to tropical and sub-tropical. Especially in South Africa the need for quality medicine is constantly growing.

The South African pharmaceutical market is tightly regulated. South Africa is also a PIC/S member and adheres to these international standards.

According to regulations pharmaceutical products cannot be commercialised in South Africa before they are registered with the Medicines Control Council (MCC). This process currently takes up to two years.

Prerequisites for any (international) pharmaceutical company wishing to commercialize their products in South Africa are currently e.g.

- a) To be locally present, i.e. be a registered company with an office in SA; and
- b) To employ a Responsible Pharmacist (as a full-time employee); as well as
- c) To fulfil certain other regulatory infrastructure requirements.

These prerequisites often signify a high barrier to entry especially for international SMEs, who do not wish to invest heavily in staff and office infrastructure while no return through sales can be effected during the registration process.



Trinity Pharma (Pty) Ltd is a pharmaceutical company that is fully licenced in terms of the South African legislative requirements related to medical products.

Our aim is to support our clients and partners in every aspect of their market entry on the South African and/or Sub-Saharan pharmaceutical market.

(International) pharmaceutical companies receive a competent all encompassing solution with regards to market orientation, product registration, as well as marketing and distribution services.

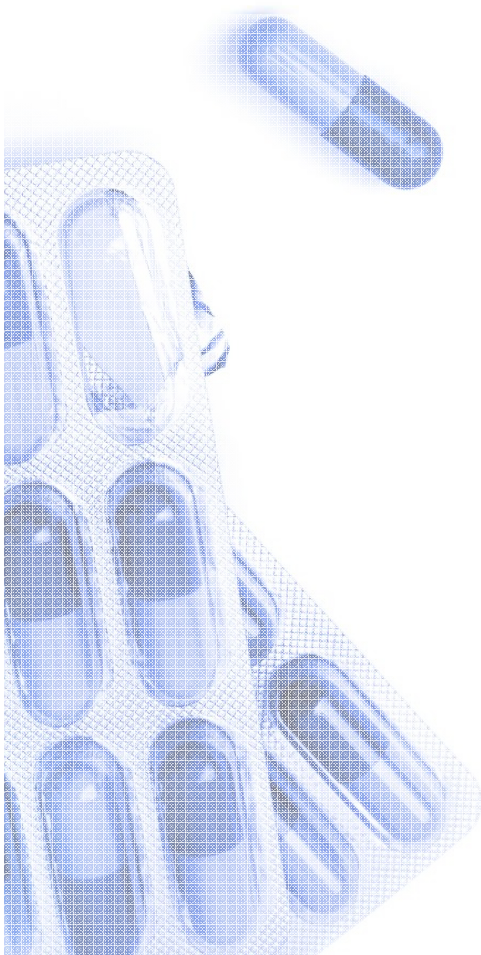
Trinity Pharma is in its origin a spin-off of well-known MRA Regulatory Consultants.

Our offices are strategically located in Pretoria, Gauteng; the major business hub in South Africa and with that also in Sub-Saharan Africa.

Trinity Pharma services a global customer base. Our clients currently include leading European, North American and Asian pharmaceutical companies, such as Heraeus Medical (Germany), Cuxson Gerrard & Co. (UK) and Torrent Pharmaceuticals (India).

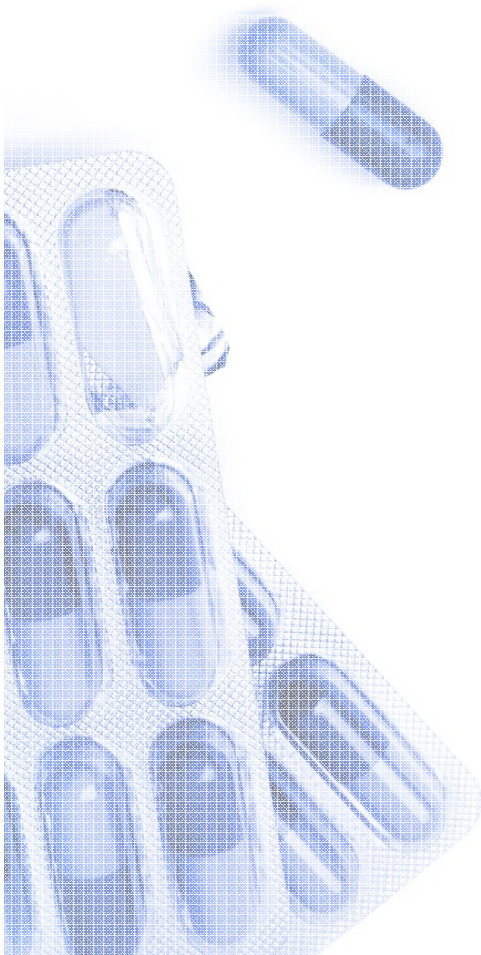
We currently focus on pharmaceuticals, bio-pharmaceuticals as well as registerable medical devices.

Furthermore we are also active in in-licensing and acquiring products for sale in South Africa under the Trinity Pharma umbrella and brands.



The Trinity Advantage

- Modular service offering
 - We are able to provide the service package that exactly meets your specific needs
- End-to-end support
 - We support you every step of the journey: from business development, through registration, to marketing and distribution
- Highly responsive and transparent method of working
- International team with multinational experience
- Extensive network within the South African Pharmaceutical Industry
 - Continuous and close interaction with the relevant industry associations and government bodies
 - We are active member of most relevant industry associations such as e.g. SAMED and IOD and take part in industry/ government interactions
- Longstanding regulatory experience
 - Over 20 years of experience in-house



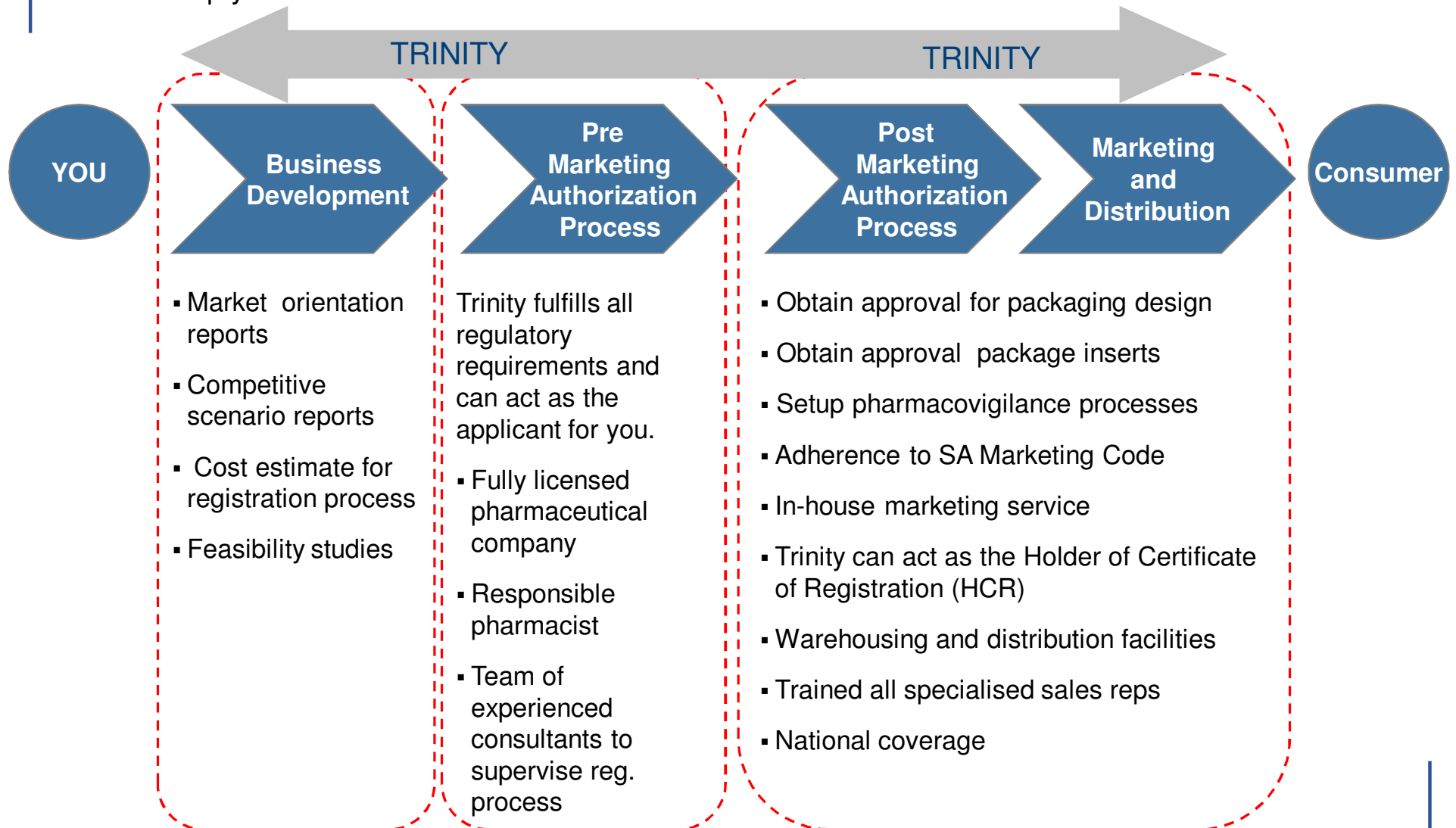
Typical path to market

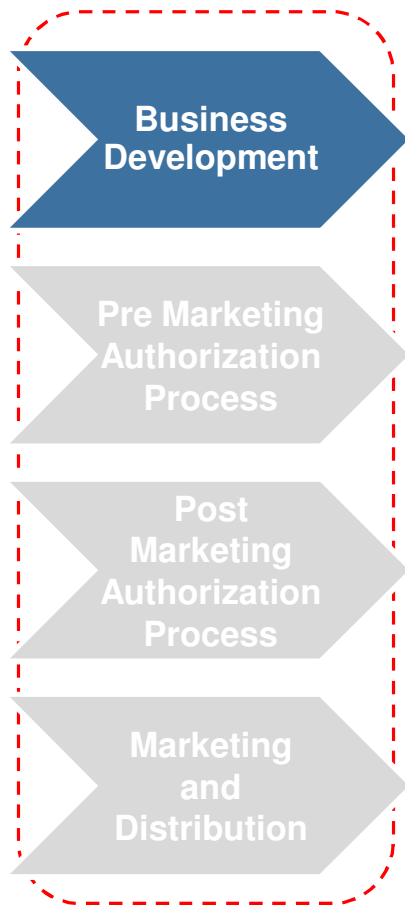
The following steps are prerequisites in the process of obtaining Marketing Authorization (Registration) and commercializing your products in South Africa:



The TRINITY path to market

Let us help you be successful in Africa:

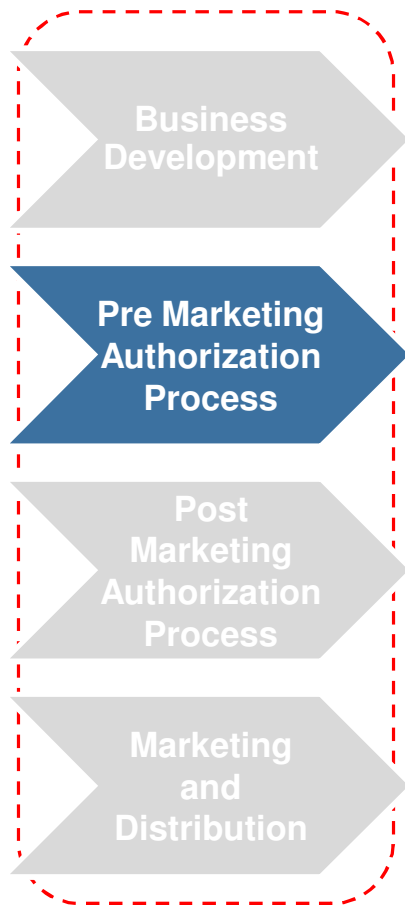




We strive to make your decision to enter the African market as sound as possible. Through our custom made market orientation reports you will be able to analyze the current market situation and decide whether it is the right time to launch your product.

We currently offer the following types of reports:

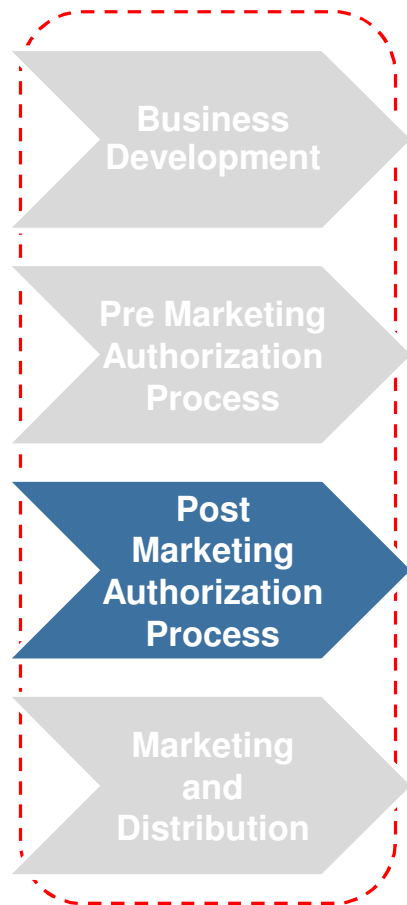
- 1. Market analysis** – Obtain an insight into the current market scenario for a family of products or a particular product. For example if you are looking to launch an analgesic then let us tell you what the current market for analgesics looks like in South Africa.
- 2. Competitive scenario reports** – Do you have a particular product in mind? Let us tell you who is the direct and indirect competitor for this product in South Africa and more details about the competition.
- 3. Feasibility Studies** – Based on our experience and expertise we will be able to guide you in building sales forecasts and assessing the feasibility of a particular product in South Africa.



The process of registering a product for sale in South Africa can be tedious and both time consuming as well as expensive if you do not have a local partner or subsidiary yet.

- Trinity Pharma is registered as a fully licensed pharmaceutical company and is in a position to act as the “Holder of the Certificate of Registration” (HCR) for you.
- As the HCR for your product we will continuously monitor the registration process and maintain your dossier for you even after the product is successfully registered.
- In the past years we have helped many international companies successfully register their products in South Africa at a lower cost as compared to doing it on their own.
- We will consult you at every stage to ensure a smooth and trouble free registration process.
- Our consultants are highly experienced in the entire registration process and we ensure the highest quality regulatory support.
- Our Responsible Pharmacist takes ownership of your regulatory needs.

Trinity services: Post registration activities



Following registration of the product we continue our oversight of regulatory requirements and ensure that your product is and remains in compliance with South African legislation and policies.

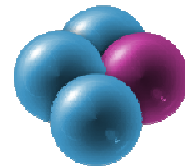
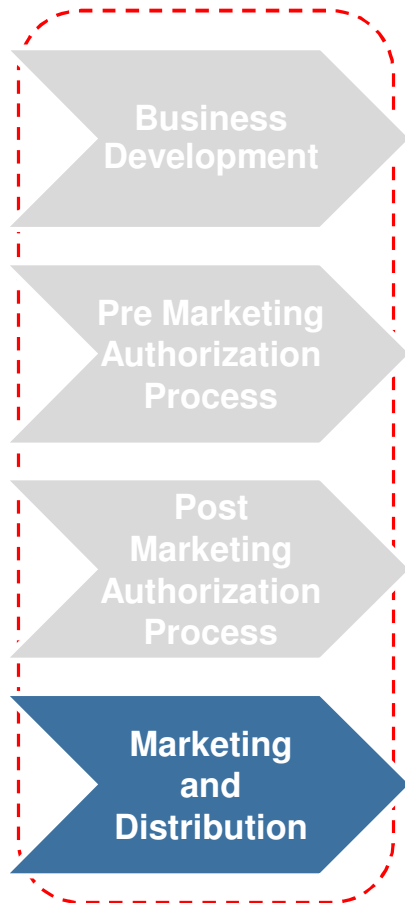
Some of the activities that we perform in this regard are:

- Pharmacovigilance e.g.
 - Reporting of adverse events
 - Product withdrawal or recall
- Post-registration amendments and dossier maintenance
- Marketing and advertising material review and approvals
- Training of sales representatives
- Final product release following importation or manufacture
- GMP compliance
 - Auditing in terms of the GMP requirements for applicants
 - Vendor inspections and approvals

Trinity services: Marketing and distribution



Once your product is registered we are also able to help you distribute and market it nationally across South Africa and other African countries.



Candela Health

Candela Health, our in-house marketing and distribution arm is fully equipped to market and sell your product. Currently at Candela we have a highly experienced and growing team of sales reps who are selling at :

1. Private and public hospitals
2. Clinics
3. General Practitioners and all specialized Medical Doctors

We can also participate in tenders where products qualify for this.

Our extensive network allows us to efficiently and in a cost-effective manner achieve maximum sales for your products.

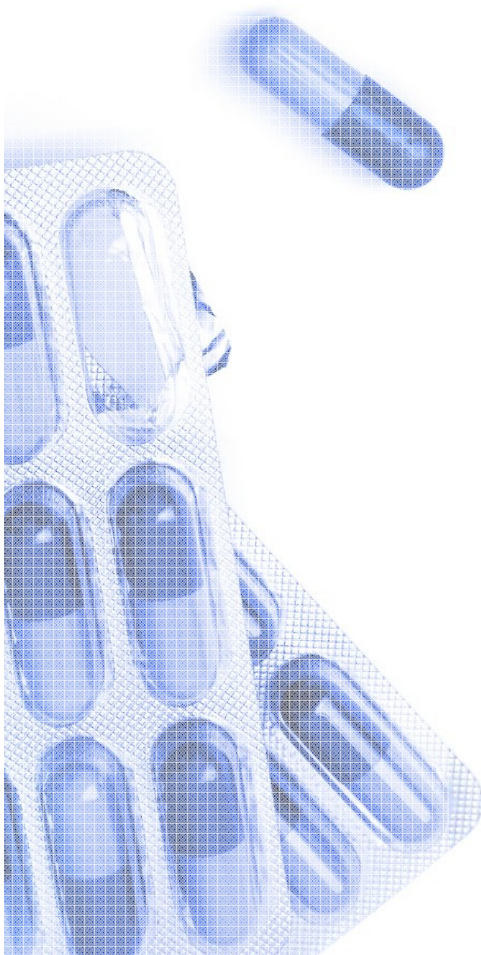
Trinity services: In-Licensing of products

We are always actively looking for opportunities to license your product and launch it in South Africa under our own umbrella brand.

In such a scenario we will acquire the license to market and distribute your product. We can also take on the responsibility to register the product with the relevant regulatory authorities.

We are already working with several international companies on this basis and would be very interested in learning more about your products available for licensing.

If you are interested in this business model then please do send us an email at info@tripharm.co.za and we will take it forward from there.



Contact Us...



Sina Eckhoff
Business Development Manager

Trinity Pharma Pty. Ltd.
381 Rossouw Street
Murrayfield 0184
Pretoria
South Africa
Tel.: +27 12 803 1039/ 6223
Fax: +27 12 803 3575
Email: sina@tripharm.co.za

or

visit our website at www.tripharm.co.za

