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SOUTH AFRICA – LOCALISATION AND REGULATION
Impact on the Market
A COMPANY PERSPECTIVE

- Establishment Licensing
- Listing of Products for Sale in SA
- Localisation of products
ESTABLISHMENT LICENSING

1. Definition of a manufacturer, distributor and wholesaler
2. Appointment of the Authorised Representative
3. Quality Management System
4. Fees
5. Contracts and Quality Agreements
LISTING OF PRODUCTS FOR SALE

1. IVD and non-IVD products
2. Classification
3. GMDN code
4. Veterinary Products
5. Recognition countries
6. High-risk product requirements
LOCALISATION

Tenders/Supply of products to the Government

- Local secondary packaging
- Local labeling
- Local over-labelling
- Local kitting