SINCE PUBLICATION, THIS COMPANY HAS BEEN RESTRUCTURED AND ITS WEBSITE WAS SHUT DOWN. PLEASE READ THE ARTICLE BELOW AND REFER TO MY HOME PAGE FOR A TESTIMONIAL FROM THE FORMER CEO.

Active Pharmaceutical Ingredients in the pharmaceutical industry: A South African perspective.

What are Active Pharmaceutical Ingredients (APIs)?

A packet of medication reaches its intended consumer, stylishly packaged and ready to administer in the most sensible way to relieve or treat specific symptoms. But what part of that little pill is effective at providing relief from medical ailments?

That small component that makes it all better, is the API - a component of the medication that is produced from a predetermined, highly regulated concentration of raw minerals.

In many cases, medications can contain several APIs in combination in order to treat different symptoms simultaneously. Additional components that make up the composition of the final drug include the excipient. This may include several other components that help deliver the API effectively into the patient's system.

For example, in South Africa, the common pain and fever medication, Panado, contains the globally accepted API, Paracetamol (also known as acetaminophen in various other countries).

Globally, APIs undergo rigorous testing, standardization, and approval before distribution and formulation by various pharmaceutical companies. In turn, these pharmaceutical companies redistribute these formulations under their own brand names to target consumers who suffer from specific ailments.

A more detailed process of the manufacture and distribution process of pharmaceuticals is depicted in the diagram below (Rönninger and Garbe, 2016):

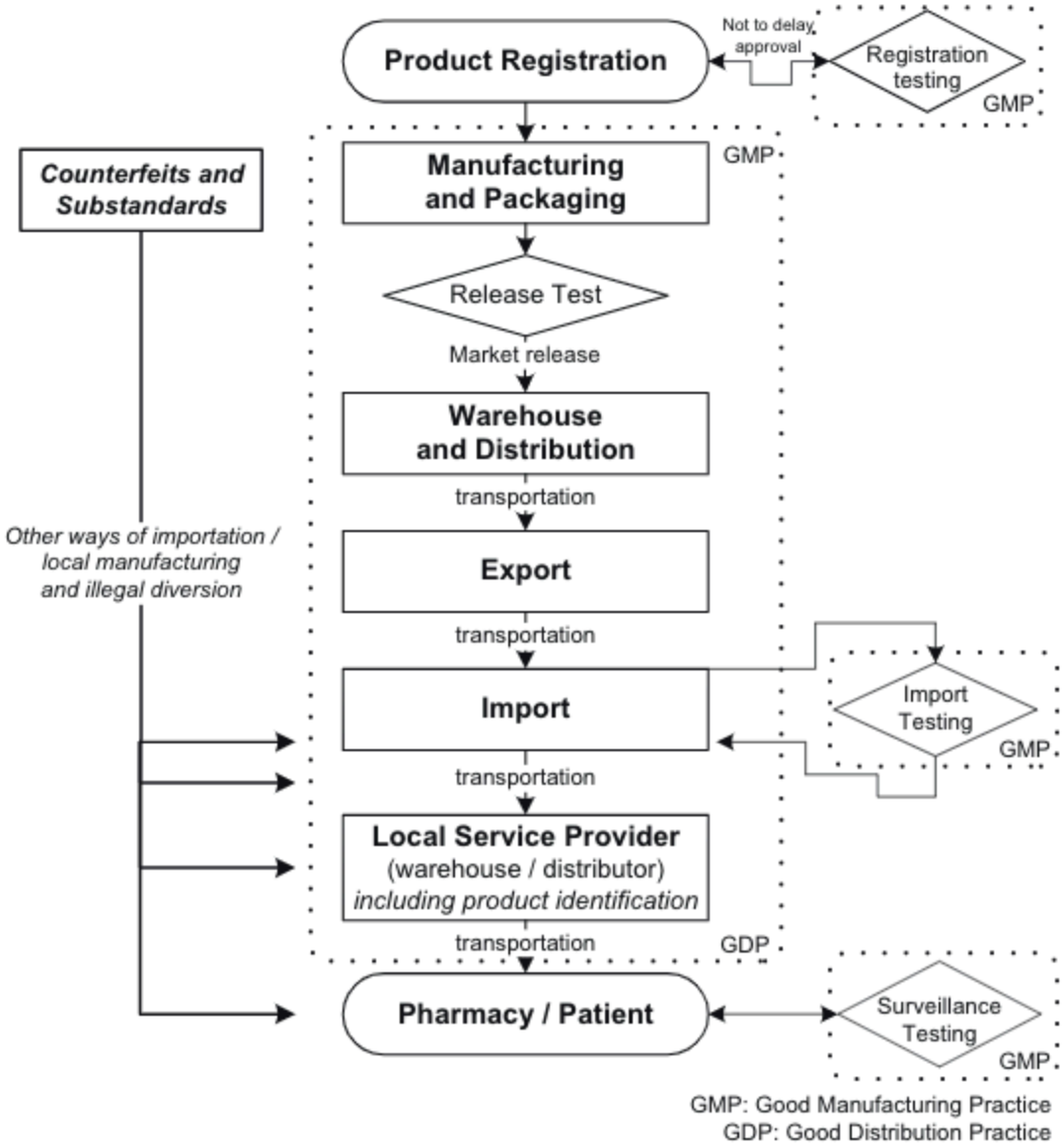


Figure 1: Product flow and distribution activities for pharmaceutical products (directly taken from Rönninger and Garbe, 2016)

Unique pharmaceutical requirements for the South African market

According to current growth trends, the global pharmaceutical industry is projected to reach $160.7 billion by 2024.

Among this global market, the African continent places a disproportionately high burden on specific diseases, with South Africa having the 5th highest worldwide pharmaceutical

expenditure per capita worldwide. In fact, the African continent accounts for 75% of the world's HIV/AIDS infections and 90% of malaria-related deaths reported worldwide.

These numbers are further reflected in the unique API requirements for the manufacture of sufficient pharmaceuticals to serve the needs of consumers in Africa. Some of the diseases and relevant API examples for South Africa include:

- HIV/AIDS
    - API: Lamivudine, Nevirapine, Efavirenz, Atazanavir, Abacavir, Tenofovir disoproxil fumarate
- Tuberculosis
    - APIs: Ciprofloxacin, Linezolid, Pyrazinamide
- Malaria
    - APIs: Artemisinin, OZ439, Hydroxychloroquine
- Antibiotics and antifungals
    - APIs: Flucytosine (Antifungal), Cefotaxime (Antibiotic)
- Diabetes
    - APIs: Vildagliptin

Where do APIs come from in the South African pharmaceutical industry?

There are only a small number of firms worldwide that produce finished pharmaceutical products that are able to manufacture all their own API needs. In the South African market, this number remains negligible.

As a result, drug companies procure the APIs on the open merchant market, either from local companies or companies abroad.

Local Production

Although there are about 37 sub-Saharan African countries that produce pharmaceuticals for local and export markets, South Africa currently dominates the sector with more than 70% of pharmaceutical production in the area.

There are some obvious benefits to local API production that include strong economic benefits to the country through job creation and greater control over supply/demand sustainability.

However, local API production remains limited due to some insurmountable obstacles to local production. Some of these may include a lack of local expertise and limited resources (infrastructure, laboratories, facilities).

Despite numerous incentive campaigns to drive increased API production in African countries, pharmaceutical companies are still relying heavily on imported APIs from high-volume production companies to sustain the high demand. For example, South Africa's Deputy Minister of Higher Education, Training, Science and Innovation recently said, "South Africa is the largest procurer of antiretrovirals in the world… and sadly, 100% of the APIs used to make ARVs are imported."

Importation from high-volume production countries

Historically, API manufacturers were isolated to a few Western countries. However, driven by lower costs, API production has gradually shifted towards production in Eastern pharmaceutical firms located in India and China.

Unfortunately, an unavoidable drawback to this strategy is that shipping, transportation and storage of these imported APIs dramatically reduce their shelf-life for downstream formulations and consumer use.

The benefits of using imported APIs for secondary local drug formulation can however not be ignored: it does not require substantial long-term investment in technical knowledge and infrastructure.

But how can these countries produce cheaper APIs?

They have lower costs of infrastructure, labour, and transportation and they can produce these APIs on a very large scale. More alarming, however, is that they implement fewer environmental regulations and are, in some cases, less stringent on quality control strategies.

For example, earlier this year, the death of 70 children in western Africa was linked to an Indian-produced API contained within a local cough syrup. Read more about this tragedy here.

To avoid similar tragedies, procuring APIs from these low-cost primary production sites with questionable regulatory requirements calls for stringent post-importation testing. This can establish the concentration, purity and general accuracy of the APIs before secondary formulation.

Post-importation testing in South Africa

The South African landscape for post-importation testing of APIs has come a long way and the country is currently the leader in high-quality, standardized testing on the continent. Post-importation testing in South Africa is highly regulated and stringent, providing safe, reliable API analyses for downstream pharmaceutical formulations.

Testing facilities and services provided at LabSPACE Africa are no different.

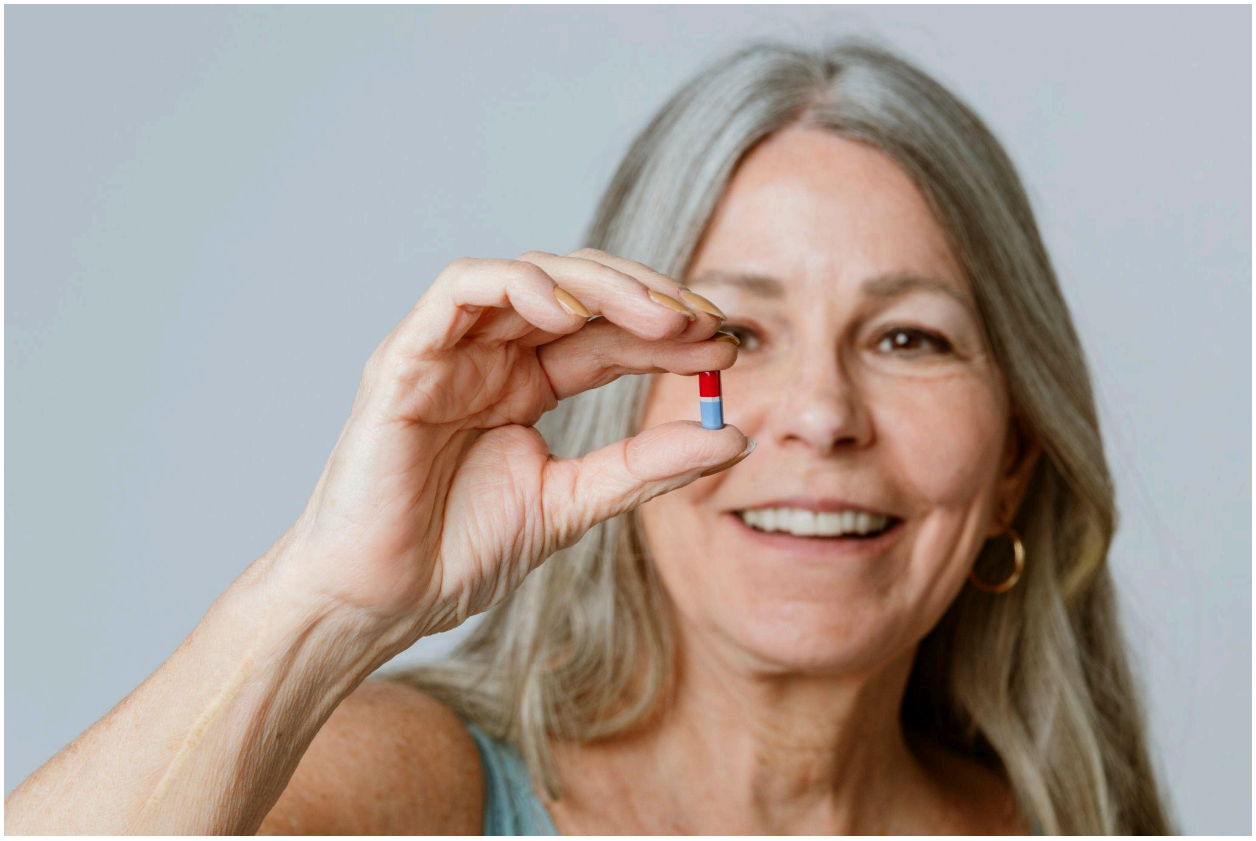
Here at LabSPACE, we have positioned ourselves to follow the European Pharmacopoeia (ESP) and United States Pharmacopoeia (USP) standards using HPLC, LC-MS and FTIR methods supplied with the product dossier. Alternatively, we can develop and validate new methods according to the requirements set by our clients due to our access to a wide range of relevant instruments and expertise.

Future prospects for APIs in Africa

Despite the heavy disease burden on the South African pharmaceutical market, the country currently relies heavily on imported primary APIs for downstream formulations and drug production.

Although investment in the long-term future production of local APIs is on the cards (read more here), South Africa must stongly invest in high-quality standardized post-importation testing of imported APIs. Aside from APIs, as part of the local pharmaceutical industry, there is a strong need for testing of imported antibodies, hormonal treatments and large-molecule biological treatments.

Fortunately, world-class facilities for standardized, stringent post-importation testing can provide South Africans with the peace of mind that their medicines meet the highest standards when it reaches the pharmacy shelves.



Reach out to LabSPACE Africa to find out about our internationally recognized Analytical Testing Facilities and testing procedures available for API standardization.

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