



PROGRESS REPORT



Aerial view of KPIL Factory

KEY:

1. Factory Building
2. Ware House
3. Water Tank & bore hole
4. Admin Block
5. Staff Outfit Changing facility
6. Boiler Room
7. Essential Staff Hostel
8. Perimeter Wall

AS OF NOVEMBER, 2019

1.0 INTRODUCTION

KAIRUKI Pharmaceuticals Industry Ltd is in the process of establishing an Intravenous Fluid (IV Fluids) manufacturing project by constructing, procuring and installing a modern Good Manufacturing Practice (GMP) compliant commercial IV fluids production plant in Tanzania. The project, estimated to cost a total of TSH 30.5billion from a secured local Bank loan entails investment in land and buildings, machinery and equipment and other support facilities for the establishment of the IV Fluids manufacturing unit.

The Project is being implemented concurrently into two sections/namely:

- a) Land acquisition and Building Super structures involving the Factory building Ware house, Bore hole, water storage tank, staff canteen & house, admin block outdoor, staff changing facilities etc. in the Zegereni area, Kibaha district, Cost Region, Tanzania by a local Construction Company from namely Dar es salaam, PETRA CONSTRUCTION CO LTD.
The contract with PETRA is under a Design and Build Delivery Method with an FIDIC/Turnkey arrangement.
- b) The internal workshop design, pharmaceutical machinery and Clean Room production, installation validation and training will be carried out by IVEN PHARMATECH ENGINEERING COMPANY of Shanghai China, which is also based on a Turnkey arrangement.

1.1 Contract Information

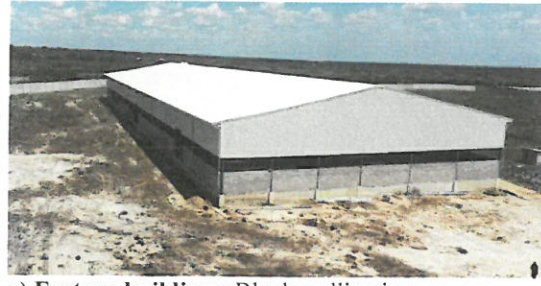
Employer	Kairuki Pharmaceuticals Industry Ltd
Designer & Builder	Petra Construction Co. Ltd
Site Possession Date	3 rd April 2018
Commencement Date	17 th April 2018
Contract Period	36 Weeks
Original Date of Practical Completion	16 th December 2018
Defects Liability Period	12 months
Revised Date of Practical Completion	10 th March 2020

Figure 1: Contract Particulars

1.2 Works Progress

Building	Works in Progress	Percentage Progress
Production Warehouse	Block walling,	95%
Storage Godown	Concrete bed	95%
Office Block	Paint works	90%
Hostel & Cafeteria	Finishing works on progress	95%
Waste Water Treatment Tank	Detail design completed	90%
Boiler House	Construction of boiler plinth	75%
Changing Rooms (2nr)	Finishing works on progress	99%
Fence & Gates	Plaster work completed	90%
1000m³ Water Tank	Interior paint	95%
Power House	-	
Security House (2nr)	-	
Paving, Pathways & Parking	-	
Soft Landscaping	-	

Figure 2: KPIL Superstructure construction progress in pictures



a) **Factory building** : Block walling in progress



b) **Factory building**: Interior Setting out for drainage pipeline



c) **Water storage tank** with office block in the background.



d) **Boiler room** under construction



e) **Technical Staff Hostel**: Aluminum windows fitting Completed



f) **Ware House**: Exterior view.



Figure 4: Contract signing ceremony with IVEN P.E. Co of Shanghai, China

2.1 PRODUCTS INFORMATION

Prospective machines will be phased, starting with 6000 Polypropylene Bottles (PP Bottle) per hour for 500 milliliters and 7000 bottles per hour for 100 milliliters.

2000 Non PVC soft bags per hour have been accommodated in the design for future expansion.

Initially the manufactured large volume fluids shall include; Sodium Chloride 0.9%, Ringers Lactate, Dextrose Saline, Dextrose 5% and Mannitol. Other products to be manufactured in the plant will include smaller volume (100ml) parenteral medicine, i.e Paracetamol, Metronidazole, Fluconazole and Ciprofloxacin during the first phase and medical products in the second phase.

2.2 MACHINERY PRODUCTION

Production of machines, equipment and clean room started in September 2019 and will be completed in December 2019.

PROJECT SCHEDULE OF PP BOTTLE IV SOLUTION PROJECT FOR KAIRUKI PHARMACEUTICALS

Time below doesn't include 1 month of China Spring Festival Holiday, and the possibility of delay caused by customs clearance in Dar-es-salaam

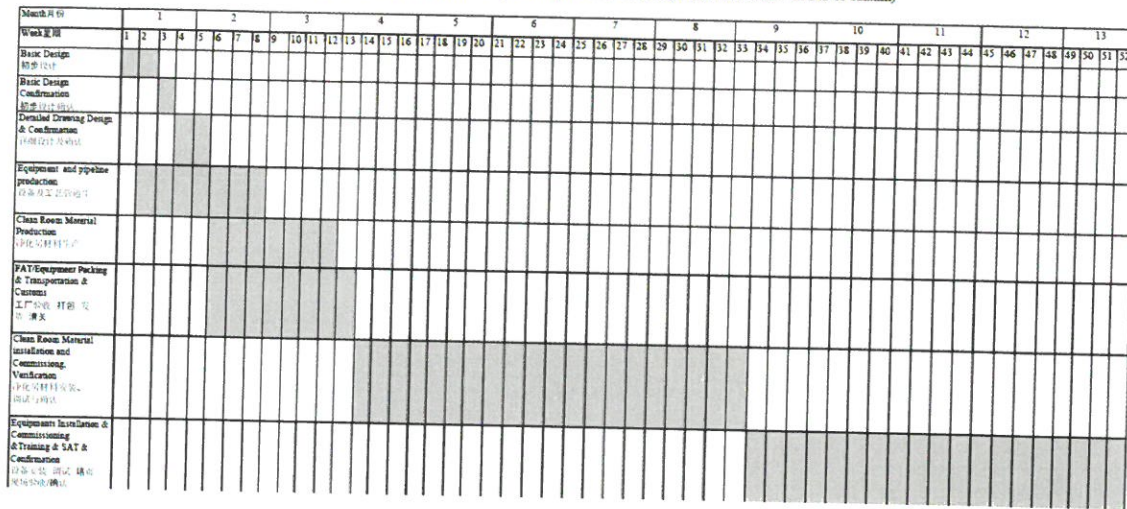


Figure 5: Project Implementation Schedule

2.3 SHIPPING OF MACHINES AND EQUIPMENT

Shipping of the machines and equipment is expected from End of December 2019 and will take 6-8 weeks to Dar es Salaam Port. The company is expecting strong Government institutional support with regard to the clearance issues to avoid un-necessary delays which are always very costly and infrastructure support especially passable roads as well !.

SN	Descriptions	SN	Descriptions
1	Preform & Hanger Injection System	10	Piping system
2	PP Bottle Blowing System	11	Clean room & HVAC
3	PP Bottle Washing-Filling-Sealing System	12	Stability chamber
4	Sterilizing system	13	Laboratory instruments & glass wares for PP bottle IV inspection
5	Semi-auto Inspection & auto packing system	14	Ancillary equipments for production and laboratory
6	Solution preparation system	15	Wastewater treatment
7	Pharmaceutical water treatment	16	Natural gas generator
8	Air compressor system	17	Building Management System
9	Boiler system	18	Water pretreatment

Figure 6: Group of machines and equipment to be imported

3.0 REGULATORY REQUIREMENTS & CERTIFICATIONS

3.1 Business and registration license BRELA ; Reg NO1223

3.2 TRA TIN NO:137-508-001

3.3 BUILDING PERMIT NO: 266/2018 DATED 09/01/2018

3.4 TMDA APPROVAL LETTER DATED 20TH MARCH 2019.

3.5 TANZANIA INVESTMENT CENTRE (TIC) CERTIFICATE OF INCENTIVES NO: 015068

3.6 ENVIRONMENTAL IMPACT ASSESSMENT CERTIFICATE; REGISTRATION NO:

3.7. FACTORY LAND TITLE- IN PLACE

EC/EIA/2019/0656

4.0 INVESTMENT CHALLENGES

In the process of establishing a pharmacy factory in the Zegereni area, Coast Region, we have had to contend with the following challenges:

1. *Non-existent and or inadequate Infrastructure.*

Poor road: The nearly 5 km dirt road, that connects our factory to the main road becomes impassable when ferrying construction materials and equipment especially during the rainy season. This will impede progress, especially during the transportation of highly sensitive and fragile equipment slated for transportation to the site between March and June as per contract agreement with our factory equipment manufacturers who have already expressed concern about this matter.

Recommendations

TARURA should construct the Morogoro – Zegereni road to bitumen standard.

Lack of steady and adequate power supply.

Though regionally designated as an industrial area, the Zegereni area, in which our factory is located and which already boasts the presence of more than 15 factories, does not have steady and adequate power supply. As if to add insult to injury, investors are expected to buy their own transformers whereas after installation these transformers automatically become the property of the Tanesco. Please note that in investor friendly countries such as Ethiopia we are reliably told, all power connection amenities and facilities are met by the power company. The investor pays only for the power. How could our products compete with those from companies which enjoy that kind of relief.

Recommendations

TANESCO to provide reliable and affordable Electric power

c) (i) **Lack of natural gas**

It is common knowledge that in manufacturing operations of the nature we are involved in, the use of natural gas would be cheaper than the direct use of electricity per unit. Although Tanzania is blessed with trillions of cubic feet of natural gas, the national gas exploration and distribution utility in the name of TPDC has, so far, not considered the need to supply the mushrooming factories in the Zegereni designated industrial area although some factories along the gas pipeline within the same region are being considered to receive gas supplies very soon. We beseech the powers that be to seriously consider supplying some of our country's abundant natural gas to the Zegereni industrial Area,

including our factory at KPIL as this will not only be good business for TPDC but also will bring down production costs of all products coming out of these factories and ,ultimately, engender competitiveness for our country's products manufactured in this area.

Recommendations

TPDC should look into the possibility of supplying the Zegereni Industrial area with ample natural gas which should lower production costs as it is a least costly energy and environment friendly option.

d) (i) **Lack of DAWASA services.**

The entire Zengereni industrial area including our factory lacks DAWASA services in form of clean water supply as well as liquid sewerage management infrastructure for the entire area involving a common **sewerage treatment** plant. This, together with other infrastructural issues mentioned earlier seems to have escaped the minds of the Zegereni Industrial area designators. Needless to mention that in many parts of the world, designated industrial areas are supplied with most of the above basic facilities as a ruse to attract investors.

Recommendations

DAWASA to supply the Zegereni Industrial area with clean potable water and to erect common liquid sewerage treatment plant(s) for the Zegereni designated industrial area.

2. ***Problems with regard to importation of construction materials and equipment.***

- a) Lack of smooth co-ordination between TRA and TIC results in un-necessary delays in clearing construction materials and equipment from the port. TIC is supposed to handle all of the investors.

Recommendations

With regard to (a) above, there should be a one-stop center to deal with the clearing of imported construction materials and equipment involving TIC.

- b) There is a critical lack of officers/operatives at TRA who are well versed with goods construction materials, raw materials as well as equipment meant for pharmaceutical factories. Knowledgeable officers would quickly recognize goods, equipment and materials meant for pharmaceutical factories and set them aside so as to enable proper taxes to be paid for them in a timely way. Lack of knowledgeable officers at TRA has resulted in unnecessary delays in authorizing our forms and, at times, in refusal to authorize them because of their inability to distinguish goods, materials and equipment meant for pharmaceutical industries and those meant for other industries.

Recommendations

TRA should either engage knowledgeable operatives/Officials or train them in distinguishing materials and equipment meant for pharmaceutical factories.

- c) We have witnessed a certain measure of lack of responsibility on the part of some TRA operatives leading to unnecessarily costly clearing delays of some of our goods and materials.

Recommendations:

TRA management should identify irresponsible and or incompetent officers in its employ and deal with them accordingly.

3). **Challenges with regard to securing loans from our local banks.**

- a) Most our local banks prefer to lend their money to ongoing/established projects rather than start-ups or green field projects, especially high-risk pharmaceuticals manufacturing projects in their attempt to minimize risk. At the same time, our government does not have plans to extend loans to private investors wishing to set up pharmaceuticals manufacturing plants as was the case in India and elsewhere in the world. Neither is our government willing to offer loan guarantees for prospective investor's projects with commercial banks. But in Ghana and Ethiopia, investors in pharmaceutical factories are assured of 60% of their loan which is given a guarantee by their own governments whereby they are expected to look for the remaining 40% from elsewhere so as to enable them to invest in pharmaceutical manufacturing in the context of the Public – Private – Partnership arrangement.
- b) Most of our local banks prefer to give short-term loans and the few that give long-term loans demand huge collateral which is a big challenge for local/indigenous investors. Moreover presently, there is only one investment bank in the name of TIB which is under-capitalized and, therefore, unable to extend substantial loans to capital intensive projects such as pharmaceuticals factories.

Recommendations:

Our commercial banks should lower their interest rates following the example of BOT and they should also give long – term loans to local pharmaceuticals investors. On the other hand, the government should offer loan guarantees to local pharmaceutical manufacturers following the examples of Ethiopia, Ghana, Tunisia, Egypt etc. Moreover the government should ensure TIB is sufficiently capitalized so as to enable it to offer substantial loans for capital intensive projects especially of the pharmaceuticals factory type.

4. **Qualified Human resources challenges:**

There is critical shortage of qualified pharmaceuticals manufacturing human resources at all levels in Tanzania to the extent that recruiting the essential technical staff at all stages of machinery construction and operation is unavoidable. But foreign technical staff are costly. Moreover, the procedure involved in securing such staff is cumbersome, costly, restrictive and counter-intuitive, especially in view of the government's expressed need to establish a robust local pharmaceuticals industry in the country.

Recommendations:

As it trains more qualified pharmaceuticals industry experts, the government should relax conditions for the recruitment of foreign experts in this sub-sector especially with regard to the time taken to grant work permits, the duration of time foreign experts can stay at the new pharmaceutical factories as they meteor our local experts.

5. **Pharmaceuticals Trade Issues**

Up-till-now, our government has been buying pharmaceuticals from foreign manufacturers by giving them an 80% LC guarantee but when it buys pharmaceuticals from local manufacturers, it pays them upon receipt of their goods in a period exceeding 60 days. This is a clear competitive disadvantage for the local manufactures! MSD now TMDA) has been offering a 15% incentive to local pharmaceuticals manufacturers and is now considering raising this figure to 25% but we still think given the challenges local pharmaceuticals investors have to contend with, this figure could be raised.

Recommendations:

The government should consider raising the current 15% incentive to local pharmaceuticals manufactures to between 30% - 35% so as to nurture them especially in view of the even more attractive incentives being offered to pharmaceuticals manufacturers in Ethiopia, Egypt, Tunisia and Ghana, all within the African common free trade area ACFTA so as to make Tanzania produced pharmaceuticals competitive on the continent.

6. Status and location of Pharmaceutical factories

Although Zegereni is a designated industrial area, it does not enjoy the status of an area of such designation as is the case with special Economic Zones, EPZ's or Industrial Parks etc. Where basic amenities, facilities and regulatory frameworks are favorable.

Recommendations:

The Zegereni designated Industrial area should be accorded special status enjoyed by other designated industrial areas such as EPZ's, Industrial Parks or Special Economic Zones. (SEZ's).