

NATIONAL



AUTHORITY

17th July 2019

1211/ID/NDA/07/2019

The Permanent Secretary
Ministry of Health
Plot 6, Lourdel Road, Nakasero
P.O Box 7272, Kampala
UGANDA

Dear Dr. Atwine,

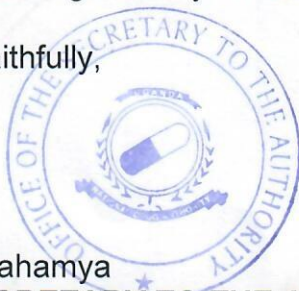
COMMITTEE MEETING ON PHARMACEUTICAL INDUSTRIAL PARKS

Reference is made to the meeting held on 12th July 2019 on the above subject.

National Drug Authority (NDA) is committed to sharing guidance on the requirements for Pharmaceutical Industrial Park and procedures for establishing a pharmaceutical manufacturing industry. The documents are hereby attached for your reference.

Yours faithfully,


David Nahamya
AG. SECRETARY TO THE AUTHORITY



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Promoting and protecting public health
through the effective regulation of human
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Guidance for Planning of Pharmaceutical Industrial Park

Guidance for Planning of Pharmaceutical Industrial Park

The 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027 was put in place to provide a framework upon which regional and national strategies were aligned in an effort to strengthen the sector. The strategic interventions focus on supporting the local production of advanced formulations for non-communicable diseases, APIs & excipients, veterinary medicines as well as harnessing the potential of traditional medicines and natural products. Specifically, R&D, strategic use of IPRs/benefit sharing and incentives use to attract interest and investment in niche areas. The EAC Secretariat has prioritized the pharmaceutical sector as a strategic value chain that can enable job creation and facilitate socio economic transformation in the region as espoused in the regional pharmaceutical manufacturing plan of action 2017-2027.

In line with the plan, Uganda has put in place incentive packages to attract Investment in local pharmaceutical manufacturing including the setting up of an industrial park exclusive for pharmaceutical manufacturing.

Therefore, this guidance is prepared to assist and to guide the park developer for planning of infrastructure to be provided in industrial park required for pharmaceutical manufacturing.

Definitions:

1. Industrial park means a project in which plots of developed space or built up space or a combination, with common facilities and quality infrastructure facilities, is developed and made available to the units for the purposes of industrial activities or housing for industrial labor in accordance with this scheme
2. Infrastructure facility means facilities required for development, operation and maintenance of the industrial park which includes roads (including approach roads), water supply, sewage and effluent treatment facilities, solid waste management facilities, telecom network, power distribution lines, storage, facilities for fire prevention, gas/steam supply facilities including common boiler facilities etc., drainage lines, infrastructure for communication facilities, fire prevention system etc.



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3. Industrial activity means –

- i. Manufacturing activity as defined in interpretation and section 39 of the National Drug Policy and Authority Act Cap 206;
- ii. Research and development on drugs as defined in the interpretation section of the National Drug policy and Authority Act Cap 206.

4. Industrial unit means a unit which is, -

- (i) located in the Industrial Park;
- (ii) a separate and distinct entity assessable to tax under the provisions of the income tax Act.
- (iii) carrying out industrial activity

5. Developer: Developer means individual or legal entity who intends to participate in development of Industrial park having area of more than 20 hectares with requisite capability of fund participation/ technical skill/ expertise in creation of infrastructure of Industrial Park.

6. Common facility means facilities required for proper functioning of industrial park and commonly shared by all the units located in the industrial park and include facilities like lifts, corridors, industrial canteens, convention/ conference halls, parking, Space reserved for fire prevention, Common ETP, security service, first aid center, safety service training facilities.

7. Allocable area means area available for allocation to the units for industrial activity and shall exclude the area utilized for providing common and required infrastructure facilities.

8. Commencement of Industrial Park: The Industrial Park will be treated as commenced when all required and proposed infrastructure facilities is put under use and at least one unit in park starts its production.

9. Completion of Industrial Park: As per policy, when minimum number of units required to be set up are functional, the project will be treated as completed.



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Basic Criteria's for Pharmaceutical Industrial park

1. The Industrial Park shall have minimum area of 20 hectares
2. The Industrial Park shall have minimum 10 functional industrial units in 20 hectares and minimum 2 industrial units for each additional area of 5 hectares or part thereof.
3. The developer of Industrial Park shall adhere to the provisions of Land and National Environmental Management Acts and conditions laid down under them as far as land related regulations are concerned.
4. It is the responsibility of the developer to get all necessary permissions and purchase the land free from all encumbrances and mortgage, and to get it converted to industrial use .
5. Industrial Park is required to have minimum infrastructure facilities required for the park namely internal roads, water distribution network, drainage treatment, effluent treatment, power distribution network, storage facilities, communication network and other facilities.
6. The Industrial Park shall have Fire safety measures as well as common effluent treatment plant and Solid waste disposal facilities.
7. The Industrial Park shall follow the guideline of the nearest urban area physical planning authority for common facilities, like road, common plot etc. The width of main entry road shall not be less than 24 meters. There shall be provision for road side plantation also.
8. In all industrial plots measuring 1000 sq m and above, 10% of the total area shall be provided as amenity open space to a maximum of 2500 sq m. Such an amenity open space shall have a means of access and shall be so located that it can be conveniently utilized in case of emergency.
9. For Industrial workers housing facility maximum 5% of the total area can be reserved and for office building & other amenities 5% of the total area in addition can be provided.



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- a. Housing facility shall include dormitory and multistory affordable housing type with one BHK facilities for workers of the industries located in the same industrial park only, and it is with all necessary amenities including common area, electricity, sewage, etc.
 - b. Area reserved for housing shall be at one place only (for parks of up to 100 hectare of area) and can be provided at maximum two places for parks of more than 100- hectare area.
 - c. Other amenities like Fire & Safety facilities, Security facilities, Canteen, Bank, ATM, School , Primary health Centre, Substation for electricity, Ancillary logistic facilities like warehouse/cold storage, go down etc. These amenities shall be made available on rental/lease basis only by the developer.
10. No Commercial activity other than amenities specified above is allowed within the area of Industrial Park.
11. The minimum percentage of the area to be allocated for industrial use shall not be less than 65 % of the total area.
12. All the industrial parks shall provide fire prevention facilities and appropriate access for it.
- 13. Water Use:**
- It is suggested that 45 liters/ person/ day and for factory 135 liters/person/ day shall be met.
 - The developer shall check the water availability as per norms keeping in mind the number and nature of industry, proposed workers to be employed and number of housing units proposed to be constructed.
 - It is the responsibility of developer to provide sufficient water to the industries in the Industrial park.
 - Normally, the developer of the park shall ensure minimum water demand of 55 KL/Hectare/day for the industries.
- 14. Power Supply:**
- The developer shall provide source and transmission of power within the park at the planning stage.



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- As a thumb-rule, provision of 150 KVA power supply per hectare may be considered for chemical industries (including pharmaceuticals). In case specific power point loads are known prior to planning of the park, sufficient provision shall be made for that.

15. Sewage and Effluent Disposal:

- The developer will design the waste water handling at the rate of 80% of the water quantity to be supplied to the industries. Developer shall make adequate provision for collection, conveyance, treatment and disposal of effluent as prescribed by the competent authority (NEMA)
- Material of construction for collection and conveyance system shall be chemical resistant.
- As far as possible, the developer shall provide proper system to control and monitor effluent collection, conveyance treatment and disposal. Provision of such system will be helpful in seeking the approval of the competent authority.
- The developer shall get Environmental Clearance as per NEMA Act as amended from time to time.

16. There shall be ample facilities and social infrastructure like healthcare Centre, gender specific toilets, training facilities, canteen/ restaurant, worker specific amenities like drivers/ technical/ non-technical employees, proper eco-friendly and green environment plantation, etc.