Arab Republic of Egypt
Cabinet of Ministers
Ministry of State for Environmental Affairs
Egyptian Environmental Affairs Agency (EEAA)
Environmental Management Sector

Environmental Impact Assessment Guidelines for Pharmaceutical Plants

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TABLES OF CONTENT

1 INTRODUCTION

1.1 Background

The purpose of these guidelines is to identify the main factors to be considered when preparing an Environmental Impact Assessment (EIA) study for a pharmaceutical manufacturing plant. Each project should be carefully assessed to identify the key issues and an EIA should be prepared to assess them, using these guidelines for assistance.

The EIA report should be submitted through the Competent Administrative Authority to the Egyptian Environmental Affairs Agency (EEAA). The Competent Administrative Authority for pharmaceutical industries is normally the Ministry of Industry and Mineral Resources, depending on the size of the industry.

The EIA system uses a list approach that screens projects into three categories based on different levels of EIA required according to severity of possible environmental impacts. The three categories are white (A), gray (B) and black (C).

The pharmaceutical industry follow two classification,, the gray (b) and the black (C). For gray list (B-category) projects the developer requested and Environmental Screening Form (B) from the competent administrative authority. Projects which only include packing of medicine and creams without processing of raw materials or the active ingredients, follow the B-category. Projects which include the production/processing of raw materials and active ingredients needs to submit a full EIA and the attached guidelines will assist in preparing such a report.

Use of these guidelines alone will not be sufficient to prepare an EIA. Reference should be made to relevant laws and other guidelines, such as law 4/1994 for the Environment and its Executive Regulations, Law 48/1982 protecting the River Nile and its waterways from pollution, Law 93/1962 concerning disposal of waste water to municipal sewers, relevant ministerial decrees, the general EEAA guidelines for Egyptian Environmental Impact Assessment, and other guidelines. Developers should be fully aware of their obligations under all laws and guidelines applicable to their situation.

2 OBJECTIVES OF THE ENVIRONMENTAL IMPACT ASSESSMENT

The aim of Environmental Impact Assessment is to enable the administrative competent authority, the local and central government, and the developer to properly consider the potential environmental consequences of a proposal, and to make recommendations to mitigate these consequences if necessary. It is important to provide sufficient information for the competent administrative authority and EEAA to assess the proposal. If sufficient information is not available in the presented study, the study will not be approved, and the developer will waste time in gathering the lacking information. The EIA thus provides the basis for sound environmental administration and management.

2.1 Production facilities covered by the guidelines

The pharmaceutical industry includes the manufacture, extraction, processing, purification, and packaging of chemical materials to be used as medications for humans and animals. Pharmaceutical manufacturing is divided into two stages: the production of the active ingredient or drug, primary processing, and secondary processing, the conversion of the active drugs into products suitable for administration.

The pharmaceutical industry manufactures bulk substance pharmaceutical intermediates and active ingredients, which are further processed into finished products.

The production of pharmaceutical products can be divided into three main stages:

1. Research and development.
2. The conversion of organic and natural substances into bulk pharmaceutical substances or ingredients through fermentation, extraction and/or chemical synthesis.
3. The formulation of the final pharmaceutical products.

The principal manufacturing steps are (a) preparation of process intermediates; (b) introduction of functional groups; (c) coupling and esterification; (d) separation process such as washing and stripping; and (e) purification of the final product.

Bulk pharmaceutical substances are used in the manufacture of dosage form of a formulated pharmaceutical products and are manufactured by:

1. Chemical synthesis.
2. Fermentation.
3. Isolation/recovery from natural sources.
4. A combination of reuse processes.

The facilities do normally also include storage facilities for:

- Raw material and auxiliaries, solids and liquids.
- Pharmaceutical products.
- Waste, solid and liquid.
- Hazardous waste, solid and liquid

The following areas, auxiliary to production are also found in most pharmaceutical facilities and should therefore, also be considered:

- Utilities (steam generation, cooling water, chilled water, etc.)
- Waste water treatment facility
- Solvent recovery
- Centralised abatement systems (e.g. incinerators, carbon absorbers, scrubbers, etc.)
- Cleaning process technique.

3 THE EIA PROCESS

The EIA should be prepared by a team of consultants with experience appropriate to the study of the different aspects of the development of a pharmaceutical industry. The team should be headed by a team leader with sufficient relevant experience, whose ultimate responsibility is to co-ordinate the inputs of the individual specialists and to provide an overview.

The EIA study could be done through a company or joint venture of consultants to ensure a full professional coverage.

The EIA process should proceed through a number of steps:

3.1 Description of the project: What type of projects, its size, components, and processes expected, all stages of implementation?

3.2 Screening: is a full EIA study required?

3.3 Scoping, or identification of potential environmental impacts: What has to be covered in the formal EIA and in what detail?

3.4 Baseline: What are the existing environmental conditions?

3.5 Prediction: What environmental impacts will the project have?

3.6 Evaluation: How will these impacts affect people and resources, and how significant are the resulting effects?

3.7 Mitigation: Can significant negative effects be avoided or made acceptable? Can benefits be enhanced?

For EIAs for pharmaceutical industries, members of, or advisers to, the team may include, but not necessarily be limited to, the following:

- An environmental management specialist with knowledge concerning noise, air emissions and waste water discharges
- A socio-economic specialist
- A landscape architect
- An industrial process engineer, specialised in pharmaceutical processes

Each member of the team, for their specialist subject(s), will follow the basic steps identified above. The number of experts required will depend on whether the proposal is for a development within an industrial estate, a development within an existing serviced industrial zone, or a development on a stand alone site.

4 GUIDELINES FOR THE EIA REPORT

This section provides advice on the content of formal EIA's for both developers and consultants involved.
The guidelines are not exhaustive. They are intended to identify the main issues of concern related to the construction or expansion of pharmaceutical plants. Developers must carefully assess each individual element of his project to ensure that all issues relevant to the site have been identified.

This Section provides guidance on the information to be included in an EIA in relation to the description of the proposed project. In describing the proposed project, all relevant phases of the project from construction to decommissioning and restoration should be considered.

The non technical summary should be around 4 pages, and certainly not longer than 10 pages (excluding plans). The main text of the EIA report should be around 60-70 pages, and certainly not longer than 100 pages. For more technically complex projects, technical appendices can be used to achieve this. Any individual technical appendix should be no longer than 20 pages (excluding plans, photos and drawings).

The following list sets out the key chapters that are required in an EIA for a pharmaceutical industry.

I Non Technical Executive Summary
II Description of the Proposed Industrial Development
III Background Information covering the Legislative Framework, Methodology, Consultation and Consideration of Alternatives
IV Description of the Existing Environment – the Baseline
V Prediction of Impacts and Evaluation of Significant Environmental Effects
VI Mitigation including the Environmental Management Plan and Monitoring
VII Conclusions

A. NON TECHNICAL EXECUTIVE SUMMARY

The summary should give an overview of the proposal, the alternatives considered, the time schedule for construction, the potential environmental impacts and their effects, and proposed mitigation measures. It will conclude by setting out the residual effects of the development after mitigation. It should be written in non-technical language to help all readers to understand it.

B. DESCRIPTION OF THE PROPOSED INDUSTRIAL DEVELOPMENT

B.1 Objectives and Scope of the Proposal

There should be a clear statement of the objectives and scope of the proposal including:

- A general description of the proposed built development or the land uses expected such as storage facilities (raw materials, product, waste etc.), buildings (administration etc.), installations (reactors, utilities, waste water treatment facility, centralised abatement systems, heat exchangers, stacks, etc.), tanks (above ground and underground) etc.
- The reason and need for the development;
- The proposed programme of construction works for development;
- The expected project life;
- Land ownership/tenure;
- Any designations such as zoning (including marine zoning) which affect the site. This includes to investigate if there is any protected zones in the surrounding areas, such as nature reserves, drinking water interests (ground water and/or surface water), recreational areas which will be affected by the proposed development.

B.2 The Location

A site description and maps, plans or photographs should be provided clearly identifying the location of the proposed development relative to:

- Land uses in the surrounding area, both urban and rural, e.g., housing, industrial activities, agriculture;
- Water bodies and surface water, e.g. rivers, lakes and canals and the use made of these, e.g. fishing, water supply, navigation, irrigation;
- Habitats both natural and man-made for flora and fauna;
- Infrastructure including transport and utilities;
- Any local or regional strategy such as management plans for nature conservation areas;
- Any historical sites or environmental protection areas.

B.3 Detailed Description and Layout of the Proposed Industrial Development and Associated Facilities

The following information should be provided:

- Site plans which must show the maximum land area affected by the proposal, including port facilities, residential areas, storage areas (e.g. raw material and fuel), pharmaceutical plant location, etc.
- Layout plan(s) of the development showing buildings, stacks, storage areas for raw material and waste, roads, parking, and infrastructure including all utilities, such as fuel filling station, power supply, water supply.
- Elevations, cross sections and plans of all built development supported by photomontages or similar to show the visual appearance proposed;
- A description of the extent and type of industrial development proposed including a description of the uses proposed and the processes to be used. This includes the following information:
  - Flow chart of the proposed activity. Use of raw materials, water catchments, port facilities, transportation, storage of raw materials, description of processes (types of reactors, preheaters, etc), storage silos, packing facilities etc. should be included.
  - Descriptions include the elements and materials used. These elements

can be divided into stages or streams of activity as appropriate. Descriptions include in-process recycling and contingency measures.
  - List of machinery and process equipment – technical information (such as capacity and expected hours of operation) and operational control measures. The conditions such as temperature, pressure, containment; and the control and monitoring systems should also be described.
  - An estimate of the essential types and expected consumption of raw materials and fuel types.
- Power supply requirements and proposed energy conservation measures such as energy consumption during port activities, pumping activities, transport activities (e.g. delivery of raw materials, transport of product), primary processing, and secondary processing and other processes.
  Furthermore, describe the energy conservation measures considered, e.g. heat exchanging.
- Proposed usage of water in the different industrial stages and sources of water supply (ground water, surface water and including discharges from any desalination plants) and options for water recycling and reuse;
- The specific methods and materials used to clean the equipment based on the ability of the cleaning process to remove the residues of raw materials, intermediates precursors, degradation products.
- Quantities of solid and liquid waste generated and the arrangements for collection, recycling, storage, treatment and disposal (solid waste, hazardous waste);
- Transportation description including internal and external transport activities (transport of raw materials and product by train, truck, ship).
- Details of access, parking, and loading/unloading arrangements;
- Description of unloading of raw materials and loading of product. What considerations have been made to prevent unnecessary dust nuisance during operation
- Details of storage facilities for raw materials, type of storage, size, number, surface coating, roofing, drainage, measures to prevent dust problems etc.
- Details of storage of any hazardous, toxic or inflammable substances;
- List of chemicals and raw materials used.
- Technical information of packing system, including expected dust, odour and noise emission and what preventive measures have been considered.
- Identification of the proposed means of surface water drainage;
- The anticipated employment in operation
- The anticipated operating hours (week days, week end and holidays)
- The anticipated hours for transportation (internal transportation at site, delivery of raw materials and transport of product).
- Monitoring program
  Describe the monitoring programme planned to control the processes during steady operation, e.g. temperature, O_2-content, water content.
- Risk management
  Evaluate the risk management considerations made during the programming/planning of the project., e.g.
  - monitoring of the processes
  - noise and odour during production processes
  - emergency and contingency planning

B.4 Site Preparation and Construction

A description of the construction works required prior to commencement of indus-

trial operations should be provided, including:

- Timing, staging and hours of construction work;
- Proposed construction methods including temporary works, the equipment to be used and methods of transport of the equipment to the site;
- Proposals for environmental management during construction, e.g. erosion and sediment control systems, wastewater holding tanks, noise mitigation strategies;
- Any land clearing and/or disposal of cleared material;
- Any stabilisation structures or earthworks including the dredging, reclamation, excavation or landfill associated with these;
- Quantities of material to be moved to or from the site, the method of disposal of excess material, and the sources of material to be brought to site;
- Details of the construction workforce, including source, expected numbers and fluctuations throughout the construction period.

Furthermore, an investigation of the types of previous activities on the land intended to be included in the proposed project should be provided:

- Previous activities that may have caused serious soil contamination and result in of any remediation measures
- Remediation of the site may be necessary prior to any building/construction activities
- What kind of remediation technology is possible (technical and economical)?
- What possibilities of soil treatment or disposal facilities exist?

B.5 Existing Development in the Locality

The description of the proposed pharmaceutical industry development project shall outline:

- The nature of any past, existing or planned urban or other development on the proposed site;
- Past environmental performance, including the impacts of existing development on the environment and the effectiveness of any impact mitigation when applied on the site;
- The relationship of the proposed development to any existing development in the neighbourhood.

C. BACKGROUND INFORMATION

C.1 Legislative Framework

This section should set out the laws considered during the planning of the project, e.g. Law No. 4/1994 on the Environment and its executive regulations, Governorate orders, land use, etc. A list of all approvals and licenses required under any legislation should be included. This list should identify the relevant authorities involved in the assessment and regulation of all aspects of the proposal.

C.2 Methodology

The procedures or methodology used in the EIA should be outlined. The basic methodology of EIA is to:

- Establish the baseline or existing situation and any changes anticipated without the development concerned;
- Predict the impacts that will occur with the development;
- Evaluate the effects of those impacts for people, flora and fauna and for things, i.e. environmental resources such as land, water and the atmosphere;

- Evaluate how mitigation can be used to reduce the effects of a development;
- Describe the residual effects after mitigation.

This chapter should include details of:

- How the impacts have been predicted;
- The criteria used for assessing the significance of effects for both people and environmental resources.

This should be supported where necessary with:

- Relevant guidelines issued by government authorities, provisions of any relevant environmental protection legislation, and relevant strategic plans or policies;
- Relevant research or reference material, meteorological data and relevant preliminary or pre-feasibility studies.

The outcome of the screening and scoping process should be summarised including:

- All issues identified;
- The key issues which will need a full analysis in the EIA;
- Those issues which will not need a full analysis in the EIA but which still need to be addressed in a limited way.

C.3 Consultation

The EIA should list who has been consulted, how they have been consulted and what their views are. Consultees should include relevant government agencies, NGOs and the public. A brief description of the reason for consultation and the outcome should be included.
For industrial development, agencies with regulatory powers or responsibilities in relation to planning control, roads and traffic, waste disposal, discharge limits to fresh waters, emissions to air, historic monuments, and conservation of natural resources must be consulted. These will include as a minimum the Egyptian Environmental Affairs Agency (EEAA), Governorate representatives, Ministry of Housing, Ministry of Reconstruction, Ministry of Transport, Ministry of Health, and relevant Community Development Associations (CDAs).

C.4 Consideration of Alternatives

The EIA should include a summary of alternatives to the development and the reasons why the proposed development is preferred.

Alternatives will include:

- Alternative locations;
- Alternative schemes and layouts of the development and services (these may be further developed under mitigation);
- Alternative management or operational practices (these may be further developed under mitigation); and
- The 'no development' alternative.

D. DESCRIPTION OF THE EXISTING ENVIRONMENT – THE BASELINE

D.1 Overview

An overview of the existing environmental setting should be provided in order to place the proposal in its local and regional context. The detailed baseline information considered important to EIA for the pharmaceutical industrial development proposals.

This includes:
- Land characteristics and use,
- Landscape Character and Existing View,
- Habitats, Flora and Fauna,

- Water including Hydrogeology, groundwater and water quality,
- Noise levels,
- Antiquities and other sites of historic and cultural significance,
- The social and economic context,
- Traffic flows and transport infrastructure,
- Utility service

Data must be relevant to the proposed development. The level of detail should match the level of importance of the issue in decision-making. To make the EIA report easier to read, it may be sensible to include the specialist detail for each of the following sections as a technical appendix to the report with a summary of each section in the main EIA report.

D.2 Land characteristics and use

All industrial development involves occupying land. The Baseline should therefore include:

- The existing surface characteristics such as topography soil characteristics, terrain stability and susceptibility to erosion or landslip;
- The existing land uses occupying the site;
- The existing surface characteristics of the surrounding area;
- The existing land uses occupying the surrounding area and particularly those land uses which would be sensitive to industrial development.

Note that the land characteristics and uses will also be relevant to other parts of the baseline, e.g. landscape and visual character.

D.3 Landscape character and existing views

Landscape quality may be affected by intrusion by industrial development and by loss of attractive features such as vegetation and hills. The baseline needs to describe:

- The existing character of the landscape both on the site and in the surrounding area;
- Views of the site from adjoining properties and public areas particularly where these are sensitive, e.g. residential, recreational or tourist areas.

D.4 Flora and Fauna

Flora and Fauna can be affected by emissions from pharmaceutical plants and by loss of habitats such as vegetation and water bodies. The baseline needs to describe:

- The existing habitats - terrestrial, aquatic or marine - both on site and in the surrounding area;
- The flora and fauna species present, their populations and their value which may reflect rarity, economic value and attractiveness.

D.5 Water including Hydrology, Groundwater and Water Quality

Pharmaceutical plant development may impact on the hydrology of an area and waterborne emissions may place the quality of both surface water and groundwater at risk. There is a need to understand the surface water drainage in the area even if this is very intermittent, e.g. flash floods every 50 years. Baseline data includes:

- Existing drainage. This includes the location and capacity of sensitive receptors like wadis, canals, drains and rivers; identification of areas prone to flash floods; depth to groundwater.
- Surface water and groundwater movement patterns. This includes groundwater hydrology, the range of water levels

and daily flushing regime in canals, drains and rivers; tidal ranges and wave climate in coastal areas and sediment transport processes.
- The quality of waters, both surface water and groundwater
- Abstraction of waters. This includes abstraction of groundwater, damming and intake of surface waters. The usage of the waters for irrigation, public water supply or watering of animals. The quantity abstracted.

D.6 Air quality

Baseline conditions include:

- Meteorological data particularly prevailing wind direction and strength, rain falls and temperature. Additionally, in relation to extreme situations like storms and draughts their occurrence and duration;
- Existing air quality particularly dust loading and existing sources of air emissions in the area
- Risk of inversion.

Existing air quality cannot be determined with any precision without sampling over an extended period. This is rarely practicable and a descriptive approach based on prevailing weather conditions and identification of the main local emission sources affecting air quality, e.g. road traffic, major heavy industries with stacks, is often a better approach. The most appropriate approach to atmospheric impacts is generally to prevent them at source. Most likely these data may be obtained from either the local airport or the local meteorological institute or department.

D.7 Noise levels

Noise levels are relatively easy to establish and this is best undertaken at the nearest sensitive receptor locations, e.g. residential areas or schools, to the pharmaceutical plant development. Existing sources of elevated noise levels, which might result in nuisance at a considerable distance to the source, should be taken into account.
If noise measuring equipment is available noise should be monitored over a number of 15 minute periods during a typical working day. Ideally, 4 or 5 periods should be monitored at each sensitive receptor location. This will establish the background noise levels and the extent to which these are exceeded during the period monitored. Where noise monitoring equipment is not available a descriptive approach identifying the main sources of existing noise and the extent to which these cause nuisance may be adequate.

D.8 Antiquities and other sites of historical and cultural importance

Existing sites may be directly disturbed by industrial development. Furthermore industrial development may affect the setting of antiquities or have adverse effects on them as a result of air or water pollution or vibrations caused by heavy vehicles. The baseline will need to:
- Identify any items of historical or cultural significance (both above and below water) on or in the area surrounding the site;
- Indicate the vulnerability of these to impacts from industrial development;
- Describe the use made of these sites, e.g. site frequented by tourists.

D.9 Social and economic context

Industrial development will generally impact on the local economy and may result in social change in area which mainly de-

pend on agriculture and other primary sectors. The baseline includes:

- The general economic context including employment levels, existing industries in the local area, other proposed developments;
- The general social context including educational levels in the local population, participation in formal economic activities – particularly by woman, local cultural values.

D.10 Existing transport infrastructure and traffic flows

Traffic is almost always an issue for industrial developments. The baseline includes:

- Existing transport infrastructure including roads, railways, port and canals;
- Existing traffic flows on that infrastructure and anticipated changes which would take place even if the development did not proceed.

D.11 Existing utilities infrastructure and usage

Industrial development will usually place demands on existing utility infrastructure notably water supply, sewage and waste water treatment, and electricity. The baseline includes:

- Existing utility infrastructure including water supply, sewage, waste water treatment works, power lines and transformer sub-stations;
- Existing capacity of and load on utilities infrastructure.

E. PREDICTION OF IMPACTS AND EVALUATION OF SIGNIFICANT ENVIRONMENTAL EFFECTS

E.1 Basic methodology

This chapter should include a discussion of impacts both:

- During construction and any built or engineered development, and
- In operation of the proposed industry.

Examples of potential impacts of industrial developments and their significant effects include (but are not restricted to):

- Landtake leading to the loss of ecological habitats with negative effects on flora and fauna populations;
- Construction works which directly damage the existing landform and add to the impacts by landtake
- Economic impacts during construction which may create job opportunities and increase local business;
- Economic impacts during operation which may create longer term benefits, such as the creation of job and business opportunities, which have positive effects on the economic welfare of the local population;
- The provision of proper services and infrastructure with wider benefits to those living and working in the local area;
- Dust generated during construction or operation which may affect human, plant and animal growth;
- Gaseous emissions to air resulting in negative effects on heath of the local population;
- Discharge of untreated or inadequately treated effluent to canals and drains with resulting effects on water quality and potential adverse effects on crops and health;
- Disposal of waste, particularly that containing toxic or otherwise harmful compounds with resulting effects on amenity, water quality and land quality and potential adverse effects on crops and health;
- Noise which may disturb people in their homes, schools and other sensitive uses;
- Traffic which may increase delays and result in traffic related effects such as road accidents and traffic noise;

- Impacts on existing utility infrastructure and possible benefits as a result of improved infrastructure;
- Risks to local people as a result of the storage and use of inflammable or toxic substances.

There is a need to distinguish between impacts which are:
- Positive or negative;
- Reversible or irreversible;
- Temporary or permanent;
- Short term or long term;
- Direct or indirect.

in assessing environmental impacts and the significance of their effects:
- Who or what is affected must be identified;
- How they are affected must be described;
- These effects must be evaluated against a set of consistent assessment criteria.

Criteria for evaluating the significance of impacts and their effects should be set in advance. They should be based on local standards wherever possible. Where these are not available, acceptable international standards should be used (e.g. WHO, US EPA, etc. guidelines). In all cases the choice of the appropriate standard must be robust, defensible and relevant to the local situation. If no suitable existing standard is available, then the criteria developed and used must be clearly explained in the EIA. The use of matrices can be very helpful in coordinating and summarising information for this section of the EIA report.

In this part of the report impacts should be considered before or without mitigation, except where the mitigation concerned is an integral part of the design and operation of the development.

E.2 Landtake

Industrial development almost always involves the development of land. Only where land has already been committed for the development of industry is landtake not an issue. This will occur where an industry moves on to an industrial estate which has already been developed with services and possible buildings.

Landtake may result in the partial or complete loss of:
- Ecological habitats with negative effects on flora and fauna population;
- Attractive landscape with negative effects on landscape character and the views enjoyed by people;
- Antiquities and sites of historical and cultural interest;
- Land in other uses, e.g. agricultural land or community facilities, with resulting impacts on peoples livelihood or social life.

Note that even where land is taken for industrial development careful design can reduce impacts by retaining residual areas in their natural or existing state.
Landtake is normally evaluated on the basis of the area of land lost and the sustainability of that land for other uses, e.g. agriculture, urban development, recreation.

E.3 Construction works

Construction works may directly damage the existing landform and add to the impacts by landtake. Even where the landtake for a development includes construction works which impacts existing features.
Key features which may be affected are:
- Surface water features,
- Landform,
- Existing vegetation,
- Antiquities

The effects are similar to those noted for landtake and in some cases these two impacts may be better considered together.

Landscape quality can be affected by intrusion by construction of industrial development and by loss of attractive features such as vegetation and hills during construction.

Loss of features is likely to have visual impact including changed or obstructed views. These could affect the views from adjoining properties and from surrounding land and water.

The impacts of construction works are generally identified on the basis of damage to existing environmental resources and the value of those resources.

E.4 Economic impacts during construction

All new industrial developments will involve some expenditure on construction. Where local contractors undertake this work there is an obvious benefit to the local economy; this is likely to be strengthened where the contractor makes purchases from other local businesses. In some cases contractors from outside the local area may win the construction contracts, while the benefit may be less, employment of local labour and purchases from local businesses will still benefit the local economy.

Estimates of benefits to the local economy can be based on an estimate of the number of local people employed during construction, the average duration of employment and the average rate of pay. Benefits to the local business can be based on an estimate of the proportion of construction spending which is spent in the local economy.

E.5 Economic impacts during operation

In operation industrial developments generally result in:

- Direct benefits the creation of job opportunities in the industries concerned;
- Benefits to other businesses in the locality as a result of multiplier effects;
- Losses to other local businesses in the locality as a result of competition.

In general the economic impacts of industrial development can be argued to be positive for the local population; this depends on the number of jobs created, the quality of those jobs and the net effects on local businesses.

Where new industries are introduced to an area an estimate should be made of the annual purchases of goods and services from existing businesses.

Estimating the negative impacts on existing businesses is more difficult. Often the presence of a number of similar businesses in an area is beneficial in that the local area gains a reputations in that industrial sector; furthermore the presence of several firms in the same industry may encourage the development of better skilled workforce.

E.6 Dust

Dust may be generated during construction of and in the operation of a pharmaceutical plant. During construction dust most often arises from vehicle movements on unsealed roads and from earthmoving operations using construction plant such as excavators. During operation of a pharmaceutical plant dust particles may be emitted from the following processes/activities:

- Mixing
- Compounding
- formulation
- Raw material storage
- Packing
- Transport between the processes
- Transport to and from the site

Depending on the process and the batch record requirements, the particulates (e.g. tablet dusts) may be recycled back into the formulation process. However, sometimes the particulates are collected for destruction or disposal.
Dust may be deposited on crops and in water bodies and watercourses; it may also reduce air quality with impacts on human health particularly where dust particles contain harmful matter. The generation of dust can have a negative effect on vegetation when emitted to the surrounding environment. The loss of vegetation produces extra runoff to the surrounding water bodies, which again can result in flooding. Existing dust levels in Egypt are strongly affected by weather and particularly the strength of winds from the desert areas to the east and west of the Nile Valley. At times the level of naturally occurring dust is such that dust arising from industrial development from whatever source is not likely to be noticed.

The accurate prediction of dust impacts is very difficult given the changing natural dust levels; an appropriate way of dealing with this subject is:

- To identify the main sources of dust attributable to the development and the scale on which dust may arise;
- To identify the people or resources that may be affected by this dust and the level of any nuisance caused;
- To consider what measures should be taken to reduce dust from sources associated with the development to an acceptable level.

This approach is effectively based on reducing any emissions to a level which will not cause nuisance rather than attempting to predict impacts with precision. Data programmes modelling the dispersion can be an efficient tool when predicting the future impact from pharmaceutical plants.

E.7 Gaseous Emissions to Air

Gaseous emissions to the atmosphere may be generated both during construction and operation of a pharmaceutical plant. Emissions to air may be gaseous or in the form of particles loaded by adsorbed gases; the latter can be regarded as a constituent of dust which has been dealt with earlier. An approximate ranking of emission sources is presented below in order of decreasing magnitude. The first four sources generally will account for the majority of emissions from a pharmaceutical plant.

- Dryers
- Reactors
- Distillation units
- Storage and transfer of raw materials and fuels
- Filtration
- Extraction
- Centrifugation
- Crystallization

Dryers are one of the largest sources of VOC (volatile organic compounds) emissions in bulk manufacturing. In addition to the loss of solvent during drying, manual loading and unloading of dryers can release solvent vapours into ambient air, especially when tray dryers are used. VOCs are also generated from reaction and separation steps via reactor vents and manways. Centrifuges may be a source of VOC emissions, especially in top loading types, where solids are manually scooped out.

Both particulates and VOCs may be formed during mixing, compounding, formulation and packaging steps. Because these compounds may pose a danger to workers, through direct inhalation, they are a principal concern. The impact can be extremely serious, e.g. where emissions contain harmful compounds such as dioxins.

Emissions to air from pharmaceutical plants may include Class A compounds which are those that may cause significant harm to human health and the environment. They include Montreal Protocol substances, as well as others identified from a review of the Class B compounds in a proposed EU directive "The Limitation of Organic Solvents from Certain Processes and Industrial Installations" and other international standards. Examples of Class A compounds include acetaldehyde, acrylic acid, benzyl chloride, carbon tetrachloride, chlorofluorocarbons (being phased out), ethyl acrylate, halons (being phased out), maleic anhydride, 1,1,1-trichlorethane, trichloromethane, trichloroethylene, and trichlorotoluene. Class B compounds are organic compounds with less environmental impact than Class A compounds. Examples include toluene, acetone, and propylene.

The odour level should also be taken into account, and it should be acceptable at the plant boundary.

Existing air quality in Egypt is strongly affected by weather and particularly the strength of winds from the desert areas to the east and west of the Nile Valley. At times the level of naturally occurring dust in such a gaseous emission is likely to be masked by the dust loading.

The accurate prediction of air quality impacts is very difficult given the changing natural dust levels; an appropriate way of dealing with this subject is:

- To identify the main sources of gaseous emissions attributable to the development, the scale on which they may arise, the likely presence of harmful gases and the worst case concentrations likely to arise in the atmosphere given the dispersion characteristics of the site;
- To identify the people or resources that may be affected by these emissions and the level of any nuisance caused; and
- To consider what measures should be taken to reduce or avoid gaseous emissions from sources associated with the development to an acceptable level.

As with dust, this approach is effectively based on reducing any emissions to a level, which will not cause nuisance rather than attempting to predict impacts with precision. However, it should be mentioned that data programs modelling the dispersion can be an efficient tool when predicting the future impact from the pharmaceutical plant.

E.8 Discharges to Water

Discharges to surface water and groundwater may be generated both during construction and operation of a pharmaceutical plant. Waterborne effluent may reduce water quality with impacts on:

- Human health particularly where water is used for irrigation or public water supply,
- Freshwater and marine flora and fauna.

During pharmaceutical manufacturing operations, effluent discharge is generated from process operations, as well as for other non-process purposes. However, the use and discharge practices and the characteristics of the wastewater will vary depending on the operations conducted at the facility. Additionally, in some cases, water may be formed as part of a chemical reaction.

Process water includes any water that, during manufacturing or processing comes into direct contact with or results from the use of any raw material or production of an intermediate, finished product, by-product, or waste. Process wastewater includes that was used or formed during the reaction , water used to clean process equipment and floors, and pump seal water. Non process wastewater includes non contact cooling

water (e.g. used in heat exchangers), non-contact ancillary water (e.g. boiler blow-down, bottle washing), sanitary wastewater, and wastewater from other sources (e.g. storm water runoff).

Pharmaceutical plants may have the possibility of implementing water conservation measures, including careful monitoring of water use, installation of automatic monitoring and alarm systems or in-plant discharges, implementation of alternative production processes, reuse of non-contact water as process makeup water, and treatment of contact cooling water to allow reuse. Furthermore, reduction of effluent discharge could be obtained by designing storm water systems and storage areas to minimize wash-off of solids and recycling cooling waters. Effluent water could be recycled and reused using cooling towers or ponds, settling ponds, containment ponds and clarifiers.

Pharmaceutical manufacturers generate process wastewater containing a variety of conventional parameters (e.g. BOD, TSS, and pH) and different chemical constituents. The ten chemicals mostly discharged by the pharmaceutical industry include methanol, ethanol, acetone, isopropanol, acetic acid, methylene chloride, formic acid, ammonium hydroxide, N,N-dimethylacetamide and toluene.

Most process wastewater should receive treatment, either in-plant at the process unit prior to commingling with other facility wastewater or prior to discharge to a permitted outfall. The treatment may be in the form of neutralization, equalization, activated sludge, primary clarification, multimedia filtration, steam stripping, secondary clarification, granular activated carbon, and oxidation. Furthermore, treatments as aerated lagoons , chlorination, waste stabilization ponds, and trickling filters may be used, but considered less advanced. Advanced biological treatment is used to treat biochemical oxygen demand (BOD_5), chemical oxygen demand (COD), total suspended solids (TSS), as well as various organic constituents.

Water quality impacts are easier to predict than air quality impacts. Predictions of changes in water quality can be based on:

- Anticipated effluent discharges including volume, the concentration of suspended solids, concentration of harmful substances like the above mentioned, etc;
- Baseline data for the recipient water resources both surface and underground.

The criteria for judging the significance of impacts will include the people or resources that may be affected by changes in water quality.

An alternative approach can be taken, based on improving effluent quality and reducing effluent volumes to levels which will not result in a significant impact on the water resources concerned.

E.9 Waste Disposal

Disposal of waste, particularly that containing toxic or otherwise harmful compounds, can potentially have adverse effects on amenity, water quality and land quality, on crops and peoples health.

Both hazardous and non-hazardous wastes are generated during all three stages of pharmaceutical manufacturing. These wastes can include off-spec or obsolete raw materials or products, spent solvents, reaction residues used filter media, still bottoms, used chemical reagents, dusts from filtration or air pollution control equipment, raw material packaging wastes, laboratory wastes, spills, as well as wastes generated during packaging of the formulated product.

Filter cakes and spent raw materials (plants, roots, animal tissue etc.) from fermentation and natural product extraction are two of the largest sources of residual wastes in the pharmaceutical industry. Other wastes include reaction residues and filtrates from chemical synthesis processes. These wastes may be stripped off any solvents which remain in them, and disposed as either hazardous or non-hazardous wastes. Most appropriately, solid wastes should be shipped off-site for disposal in a sanitary landfill or incineration at an approved incinerator.

However, waste is also generated when technical equipment is maintained (*Maintenance waste*: oils and other lubrication waste, spent organic solvents, sludge and solids from the paint and coatings, auto and truck assembly).

Issues to consider include:

- The existing condition of any water body or groundwater that may be changed as a result of waste disposal both during construction and in operation.
- Potential liquid and solid wastes to consider include:
  - run-off from wash-down areas, fuel storage facilities, roads and parking areas
  - waste disposal (litter or solid waste),
  - toxic and hazardous waste

An approach based on the precautionary principle is appropriate.

E.10 Noise

The potential sources of noise associated with a development need to be identified; these are likely to include:

- Construction noise (e.g. blasting, pile driving, compressors, etc.)
- Operation noise (e.g. vehicle movements and from operation of the conveyors, and packing machinery, both within and outside the factory).

If these are likely to be significant for particular receptors and resources, an assessment will need to be made of:

- Baseline conditions (including relevant meteorological and topographical factors, and existing major sources of noise);
- Proposed working hours during construction and operation;
- Where these impacts will be most important (e.g. housing areas and sensitive natural areas).

Data programmes modelling the noise level can help predicting the future impact from pharmaceutical plant.

E.11 Traffic

A traffic study should be carried out for heavy vehicle movements, on street parking, boat navigation, train movements etc. Issues to study should include:

- Assessing the impact of traffic generated during construction and operation on the local and regional transport network; issues to consider include
  - vehicle, train or boat size and types,
  - frequency of movements at various times of day and year (including the need for restrictions at night or peak periods),
  - safety issues:
- Estimating the average and peak movement and parking demands including the adequacy of on-site facilities.

E.12 Services and infrastructure

The provision of proper services and infrastructure for industrial development may have wider benefits for those living and working in the local area. However, the reverse can be true where industrial development takes place without adequate investment in services and infrastructure and; existing services and infrastructure may become overloaded and the local community may be adversely affected.

In general, the impact on services and infrastructure is likely to be fairly neutral; a significant benefit is only likely to occur where the industrial development enables a major improvement to local infrastructure, e.g. a water treatment works, which could not be funded by the existing level of development in the area

These impacts are generally dealt with by:
- Describing the anticipated changes in services and infrastructure provision,
- Considering the demands placed on provision by incoming industrial development, and
- Setting out how any changes in provision may benefit the local community.

E.13 Risk Assessment

Hazards can be assessed by:
- Identifying all materials stored which are classified as hazardous, their quantities and proposed safe storage and handling (e.g. fuel, raw materials, lubrication oils for maintenance and laboratory testing chemicals);
- Identifying potential hazards from fire, explosion or release of chemicals or polluted waters, natural occurrences such as floods, storms, landslip. (e.g. handling of fuels and packaging using high pressure, protection of storages from runoff waters, maintenance of discharge system for effluents, maintenance of machinery and abatement for air emissions, prevention of dust emissions from fugitive sources –like covering of transfer points and conveyors, water spraying point sources, paving, road wetting and wind barriers for open piles);
- Identifying potential risks to local people and local resources in the event of an emergency.

F MITIGATION

F.1 Mitigation strategy

This section considers the mitigation strategy, including the consideration of alternative opinions, and the extent to which this will avoid or reduce significant effects. The evaluation of the strategy will take into account its:
- Sustainability,
- Integration,
- Feasibility, and
- Compliance with statutory obligations under other licences or approvals.

The mitigation strategy should outline the environmental management principles to be followed in the planning, design, establishment and operation of the proposed development. It should include specific locational, layout, design or technology features and an outline of ongoing management and monitoring plans.

F.2 Specific mitigation measures

These include proposed mitigation and management measures to control impacts on (the examples mentioned are only some out of many measures that could be taken for additional information Pollution Prevention notes from United States and the European Union can be recommended):
- Land quality – measures include:
  - Stabilization works for cuttings, embankments and open channels,
  - Erosion and sedimentation control structures (e.g. wind barriers),

  - Landscaping and re-vegetation proposals,
  - Control and disposal of solid waste (e.g. reused as fuel or at other industries).
- Water quality – measures include:
  - Control and treatment of liquid effluent (e.g. recycling cooling waters, cooling towers, oil separators, sand traps, ponds and clarifiers)
  - Contamination and recovery facilities,
  - Procedures for handling, storage, transport and disposal of waste for all hazardous and dangerous material (e.g. recycling of waste as raw material(dust) or fuel(chemicals), closed storages secured from stormwater runoff.)
- Air quality – measures include:
  - Control of stack emissions (e.g. cyclones, fabric filters and scrubbers),
  - Control in fuel inputs (e.g. substitution of fuels with high sulphate or ash content)
  - Control of optimised kiln operation (e.g. gravimetric solid fuel feed, reduced flame and burning temperature)
  - Control of fugitive emissions (e.g. encapsulating/covering conveyors, waterspraying and ventilation systems with cyclones in closed storage areas);
  - By-pass dust should be treated by using nodulizers equipped on the by-pass systems of the dry lines of clinker production. By this, the excessive dust generated during the process of loading the dust into the trucks may be eliminated, saving space at dumping sites. It can also be treated by using a circulating fluidized bed roasting system, involving dust preparation for the fluidized bed.
- Noise – measures include:
  - Control of noise from plant and machinery to ensure compliance with relevant standards,
  - Sound attenuation measures such as wall and banks (e.g. maintenance on noisy machines, rubber curtains of openings at mills and grinders, noise adsorbing claddings and encapsulation)
- Habitats, flora and fauna – measures include:
  - Compensatory planting or restocking of indigenous species,
  - Provision of new appropriate habitat,
  - Opportunities for colonisation,
  - Careful timing of major disturbances,
  - Measures to control and prevent infestations at the site and to control spread into localities adjacent to the proposal.

Historical and cultural features – measures proposed should mitigate impacts and conserve antiquities and areas of historical or heritage significance during all stages of this development.

All measures must be compatible with the provision of relevant acts and laws.

F.3 Environmental Management Plan

An environmental management plan (EMP) is a document designed to ensure that the commitments in the EIA and subsequent condition of any approval or licence are carefully implemented. The EMP should demonstrate that sound environmental practices will be followed during the establishment, operation, rehabilitation and afteruse of the development. It should cover the following:
Management of construction impacts (e.g. landscape management plans);
Management of operational impacts (e.g. hazardous materials and fuel management, transport and packing management, maintenance and site security plans, emergency and contingency plans);

- Strategies and actions plans to feed information from monitoring into management practices;
- Public awareness and training programmes for operational staff;
- Indicators of compliance with licensing and approval requirements.

An EMP should include a monitoring plan that should be carefully designed and related to the predictions made in the EIA and the key environmental indicators. The EMP should outline the need for monitoring, its duration and reporting procedures.

Parameters which may be relevant include:

- Performance indicators in relation to critical operational issues including:
  - water quality (marine and fresh)
  - shoreline morphology and sediment budget,
  - soils and sediments
  - noise and air quality,
  - public health indicators,
  - land surface and hydrology,
  - flora and fauna.
- Waste management performance indicators in relation to recycling and reuse;
- Monitoring of complaints received

Monitoring procedures should cover the following:

- The key information that will be monitored (such as noise (low-frequency, infra sound and vibrations), dust (particulate matter) and air emissions (NO_x, SO_x, CO, H_2O %, etc.), wastewater (volume, suspended solids, pH, substances etc.), waste (solid waste and hazardous waste) and odour), its criteria and the reason for monitoring
- The monitoring locations (Air emission outlet: particulate matter, NO_x, SO_x; the boundary: noise, odour, particulate matter, NO_x, SO_x and other relevant substances; out door storage areas of raw materials: dust fall), intervals and duration
- Actions to be undertaken if the monitoring indicates a non-compliance or abnormality;
- Internal reporting and links to management practices and action plans;
- Reporting to relevant authorities and, if appropriate to the consent authority or the community such as reports on interruption of operation, operational journals, list of used raw materials, protocol on stored raw materials, dust fall reports from the storage areas for raw materials, noise documentation
- reports, odour and air pollution emission and immission concentration contribution reports, CO_2 % documentation reports, energy consumption reports, waste water reports etc.

G CONCLUSIONS

This should summarise the prediction and evaluation of impacts, proposed mitigation and alternative processes, and residual effects after mitigation. It will emphasise:

- The more important impacts
- Who or what these will affect
- Whether mitigation is possible
- The likely success of mitigation measures adopted or recommended to alleviate those impacts

This information can be presented either as text or as summary tables if desired.

After mitigation measures have been assessed, residual and/or cumulative effects may remain. It is useful to set these out in a table in which the level of significance of each effect is given.