Arup Consulting Engineers

Pfizer Ireland
Pharmaceuticals,
Dún Laoghaire,
Co. Dublin

Aseptic Production
Expansion

EIS

ISSUE 1
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Pfizer Ireland Pharmaceuticals, Dún Laoghaire, Co. Dublin

Aseptic Production Expansion
EIS

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1. **INTRODUCTION**

1.1 **Introduction**

Pfizer Ireland Pharmaceuticals proposes to expand its Dublin Sterile Products Facility, at Pottery Road, Dún Laoghaire, Co Dublin. The project will result in an increase in the capacity of the plant to formulate sterile liquid and freeze-dried pharmaceutical products. The active pharmaceutical ingredients for the products will come from Pfizer’s pharmaceutical manufacturing plants in Ireland and overseas.

1.2 **Pfizer Ireland Pharmaceuticals Company Profile**

Pfizer Ireland Pharmaceuticals is a subsidiary of Pfizer Inc. of New York. Pfizer Inc. is a diversified, research-based health care company with approximately 135,000 employees worldwide. In 2003 it had sales of $48 billion in more than 100 countries.

Pfizer was founded in 1849 and by the early part of the 20th century had developed an expertise in fermentation, particularly for the production of citric acid. This expertise enabled the company to develop a process for the large-scale production of penicillin during the Second World War. From this beginning, Pfizer developed a large research programme after the war which eventually resulted in the discovery of one of the first major broad stream antibiotics - Terramycin®. Since then Pfizer has invested very significantly in research and as a result has introduced a steady stream of new products including market leaders such as Norvasc®, Zoloft®, Zithromax®, Diflucan®, Lipitor® and Viagra®.

The Dublin Sterile Products Facility at Pottery Road, Dún Laoghaire, has been in operation since 1972. It was originally owned by Warner-Lambert Ltd and became part of Pfizer Ireland Pharmaceuticals in 2000. Over 160 staff are employed at the plant which occupies a site of 6.89ha (17 acres). Refer to Figure 1.1 for the site location plan.

Sterile products manufacturing involves the formulation of pharmaceutical products into dose form, as sterile liquid or freeze-dried powders. This activity, also referred to as 'fill/finish', is undertaken using aseptic preparation methods. These methods involve ensuring that the products are not exposed to contamination by micro-organisms or dust. The ultra clean products, produced in this way, are referred to as sterile products.

While the primary focus of the Dublin plant is sterile manufacturing, the pharmaceutical ingredient for a number of proprietary human pharmaceutical products are also manufactured there.

The products manufactured and / or formulated at the Pfizer Dublin Sterile Products Facility are as follows:

<table>
<thead>
<tr>
<th>Product</th>
<th>Active</th>
<th>Indication</th>
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<tr>
<td>VTEND®</td>
<td>Voriconazole</td>
<td>Antifungal</td>
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<tr>
<td>Zithromax®</td>
<td>Azithromycin</td>
<td>Antibiotic</td>
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<tr>
<td>Zeldox®</td>
<td>Zonisamide</td>
<td>Antipsychotic</td>
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<tr>
<td>Cerebyx®</td>
<td>Fosphenytoin</td>
<td>Anti Epileptic</td>
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<tr>
<td>Prodil®</td>
<td>Fosfluconazole</td>
<td>Anti Fungal</td>
</tr>
<tr>
<td>Ketanest / Ketalar</td>
<td>Ketamine</td>
<td>General Anaesthetic</td>
</tr>
<tr>
<td>Liquid Thrombin</td>
<td>Thrombin</td>
<td>Clotting Agent</td>
</tr>
<tr>
<td>Elase®</td>
<td>Fibrinogen</td>
<td>Wound Healing</td>
</tr>
<tr>
<td>Fibrinuclease Powder</td>
<td>Fibrinogen</td>
<td>Wound Healing</td>
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The expansion project will result in increased capacity for the sterile fill/finish of existing products VFEND®, Zithromax® and Zeldox®. In addition, there will be capacity for freeze-dried and sterile liquid products, which are currently under development by Pfizer and which are expected to come to market in the next five to ten years.

The development will result in the Dublin Sterile Products Facility becoming the key location, within the global Pfizer organisation, for the production of freeze-dried and sterile liquid products.

1.3 Outline of the Plant Expansion Project

The expansion will involve:

- a building accommodating two new production modules and a new warehouse,
- a new laboratory and canteen building,
- a new central utilities building,
- a new security building, and
- various ancillary facilities.

The development will also include modifications to the existing pharmaceutical building and extensive site works and landscaping. The project will cost approximately $300 million and take almost two years to construct.

1.4 EIS Methodology

1.4.1 Contents of the EIS

This EIS has been prepared in accordance with the relevant provisions set out in the Planning and Development Regulations, 2001, Statutory Instrument (SI) No. 600 of 2001. These Regulations came into operation in 2002. The Regulations are made under the Planning and Development Act 2000 (No. 30 of 2000) and the Local Government Act 2001 (No. 37 of 2001).

Schedule 6 of SI 600 of 2001 specifies the information to be contained in an EIS, including the following:

- a description of the proposed development comprising information on the site, design and size of the proposed development
- a description of the measures envisaged in order to avoid, reduce and, if possible, remedy significant adverse effects
- the data required to identify and assess the main effects which the proposed development is likely to have on the environment
- an outline of the main alternatives studied by the developer and an indication of the main reasons for his or her choice, taking into account the effects on the environment'.

Information is also required on the following matters:

- a description of the physical characteristics of the whole proposed development and the land-use requirements during the construction and operational phases
- a description of the main characteristics of the production processes, for instance, nature and quantity of the materials used
an estimate, by type and quantity, of expected residues and emissions (including water, air and soil pollution, noise, vibration, light, heat and radiation) resulting from the operation of the proposed development.

Aspects of the environment likely to be significantly affected by the proposed development are also to be described, including in particular:

'human beings, fauna and flora

soil, water, air, climatic factors and the landscape

material assets, including the architectural and archaeological heritage, and the cultural heritage

the inter-relationship between the above factors.'

A description is required of the likely significant effects (including direct, indirect, secondary, cumulative, short, medium and long-term, permanent and temporary, positive and negative) of the proposed development on the environment resulting from:

'the existence of the proposed development

the use of natural resources

the emission of pollutants, the creation of nuisances and the elimination of waste',

and a description is required of the forecasting methods used to assess the effects on the environment.

A summary in non-technical language of this information is to be included, and any difficulties encountered in compiling the required information should be indicated.

Reference is made in this EIS to environmental impacts of various qualities, significance, duration and types. A glossary of impacts is provided in Appendix 1.1.

1.4.2 EPA Guidelines

This EIS has also been prepared with due regard to the guidelines on environmental impact statements published by the Environmental Protection Agency (EPA). This guidance is provided in ‘Draft Advice Notes on Current Practice in the Preparation of Environmental Impact Statements’, published in 2002, and ‘Guidelines on the Information to be contained in Environmental Impact Statements’ also published in 2002.

1.5 Pfizer Environmental Health and Safety Policy

The Dublin Sterile Products Facility is operated in accordance with the Pfizer Ireland Pharmaceuticals Environmental, Health and Safety Policy. A copy of the policy is provided in Section 3.8.3 below.

1.6 Regulatory Control of the Facility

The Dublin Sterile Products Facility operates under an IPC Licence, Licence Number 19, granted by the Environmental Protection Agency. Information on the licence is given in Section 3.9 below. The complete licence can be viewed on the EPA’s website www.epa.ie.

1.7 Consultation Process

Dún Laoghaire-Rathdown County Council Planning Department, Road Engineering Department and Drainage Department were consulted in the preparation of this Environmental Impact Statement.
1.8 Difficulties Encountered During the Study

No particular difficulties were encountered during the study.

1.9 References


Environmental Protection Agency (2002) Guidelines on the Information to be contained in Environmental Impact Statements


2. NEED FOR THE PROJECT

2.1 Introduction

This section presents the background to the proposed development, explains why Pfizer perceives the need for this development at this time, and outlines the alternatives considered.

2.2 Need for the Development

Currently, the aseptic filling and freeze-drying of many of Pfizer's products is undertaken by third parties. Pfizer identified the need to develop its own facilities to do this work in order to have a greater level of control over the quality, costs and logistics of its products. The facility will supply product to markets on a global basis.

Pfizer products have experienced continued market growth over recent years. This growth is forecasted to continue. In addition, new products are expected to come on stream as a result of Pfizer's investment in research and development. Additional aseptic filling and freeze-drying capacity will be required to bring these products to market.

2.3 Site Selection

Pfizer has aseptic filling and freeze-drying plants in a number of locations overseas. These plants were also considered for the project to increase the freeze-drying capacity. Pfizer also considered the possibility of a green field site for this expansion, but ruled it out for the following reasons:

a. The existing site would not have sufficient critical mass to stay in operation if an alternative site were to be developed. The failure to develop the site would most likely lead to its closure with all the associated social costs.

b. Pfizer has a large body of experience in sterile technology at Dún Laoghaire and there is a strong desire to build on that experience. By moving to a green field site a lot of that experience will be lost.

c. There is a large pool of suitably qualified labour in Dún Laoghaire-Rathdown, there is no guarantee that this would be available at a green field site.

d. Manufacturing of sterile pharmaceuticals is a very highly regulated industry. Operations are licensed by agencies such as Food and Drugs Administration (US) and Irish Medicines Board. Against this background it would be more expensive and take longer to bring a green field operation to commercial reality.

The existing Pfizer Dublin Sterile Products Facility was selected as being the most suitable for the proposed development for the following reasons:

- the plant is owned by Pfizer,
- the plant is zoned for the proposed use,
- the plant has sufficient space for additional development,
- the proposed operations are already carried out at the plant,
- the staff at the plant have the required high level of skills and expertise, and
- the development would complement, and make use of existing plant facilities and infrastructure.
2.4 Design Philosophy

2.4.1 Principal Design Objectives
The principal design objectives for the facility are:

- the existing production operations will continue,
- multi-product facility,
- quick change and short turn around between batches of products,
- operator intervention to be minimised,
- vial filling for vials between 1ml and 100ml,
- provision for sterile liquid filling and freeze-drying, and
- restricted access barrier systems, not full isolation, for the filling rooms, and
- products to be supplied to global markets and meet the regulatory requirements of the Food and Drugs Administration (US), and the EU and Japanese authorities.

The facility has been designed to operate circa 300 days per annum, 24 hours per day, 7 days per week.

2.4.2 Main Design Features
The design objectives were incorporated into a master plan with the following main features:

- two new production modules, in a two storey building with penthouse plant room, each module having 4 pass-through freeze dryers, 1 tilling line, 2 compounding areas, and support functions,
- new warehouse with capacity for 3000 pallets to serve the existing plant and two new production modules,
- the existing warehouse to be used for packaging operations,
- dispensing operation in the new warehouse,
- 1000m² of additional laboratories,
- new canteen and locker rooms,
- increase administration space by revamping the existing building,
- new utilities building, which should be expandable for future developments,
- sufficient car parking,
- building design features, finishes and colours to reduce the apparent mass of the buildings
- extensive landscaping and berms (mounds) to screen the new development to reduce noise and visual impact, and
- external equipment and potentially noisy activities located so that they are screened by buildings and berms.

The current aseptic production capacity of the Dublin Sterile Products Facility is approximately seven million vials per annum. One of the new production modules will increase the capacity by circa fourteen million vials per annum, and the second module will increase the capacity by another fourteen million vials per annum, approximately. These are
approximate numbers as the actual numbers of vials produced depends on a large number of variables.

2.5 Main Alternatives Considered

2.5.1 Technology Alternatives

The main technology options considered in the design of the new facilities were:
- sterile manufacturing or sterilisation on completion of the filling operation,
- restricted access barrier systems, or conventional clean rooms, or full isolation,
- pass-through or single-sided freeze-dryers,
- automated or manual loading and unloading of the freeze-dryers,
- size of freeze-dryers, and
- number of freeze-dryers per module.

The technology options selected are considered to be optimum for the products to be produced.

2.5.2 Alternative Site Layout Options

Initially, the gum base building was assessed for its suitability for conversion for use for aseptic production or as a warehouse. The building was considered unsuitable in its current form, and uneconomical to retro-fit for these uses. It was concluded that new buildings were required.

An exercise was then undertaken to determine the optimum site layout, which incorporated these design features. Three main options were considered as follows:

Option 1: all buildings located at the rear of the site, the warehouse located at the rear of the gum base building, with the central utilities building coupled to the warehouse,

Option 2: all buildings located at the rear of the site, the warehouse adjacent to the existing warehouse,

Option 3: all buildings located to the northwest of the gum base building.

A fourth option was also considered, which was a variation on Option 1, with the central utilities building separated from the new warehouse. This was option 1A. In each case, car parking and space for a construction compound would be located to the northwest of the gum base building. The options are shown in Figures 2.1.

The options were assessed based on the following criteria:
- functionality,
- capital and operating cost,
- programme constraints,
- future flexibility,
- ease of construction,
- aesthetics, and
- feasibility of reuse.
The assessment of options determined that option 1A was the optimum solution for the site.

2.6 Design Constraints

There were a number of constraints on the design of the new facility, including the following:

- the existing production operations in both the pharmaceutical building and the gum base building had to be maintained during construction of the new facilities,
- the existing site and surroundings, and the proximity of dwellings, constrained the type, size and layout of the development,
- Dún Laoghaire-Rathdown County Council had planning and road-widening requirements, and
- the topography of the site, and the floor levels of exiting facilities created integration and ease of construction issues.

The proposed design addresses these constraints.
3. SITE AND SCHEME DESCRIPTION

3.1 Introduction
This chapter presents a description of the Aseptic Production Expansion Project. The existing operations and neighbouring land uses are also described.

3.2 Plant Location and History
The Pfizer Dublin Sterile Products Facility is located on Pottery Road, Dún Laoghaire. The site is approximately 12km to the southeast of Dublin City centre and 3.5km southwest of the commercial centre of Dún Laoghaire. The general site location is shown in Figure 3.1 and the location on Pottery Road is shown in Figure 3.2.

Warner-Lambert Ireland Ltd was the original owner of the Pfizer Dublin Sterile Products Facility. Pfizer purchased Warner-Lambert Ireland Ltd in 2000. Pfizer Ireland Pharmaceuticals was formed at that time. The Warner-Lambert confectionery businesses were sold to Cadbury Schweppes and the pharmaceutical and health-care businesses were retained by Pfizer.

Warner-Lambert Ireland Ltd’s history in Dublin can be summarised as follows:
- In 1956 it opened a distribution centre to supply its products to the Irish market.
- In the early 1960s a manufacturing plant was established at Abbey Road, Blackrock, County Dublin. The company manufactured ethical and consumer products in this plant, which also functioned as a distribution depot, and employed 75 people.
- In 1972 the company moved to the current location at Pottery Road, Dún Laoghaire, when the Gum Base plant was opened. In 1973 a Finished Gum operation was established in the Gum Base building and employment increased to 300.
- In 1976 the General Diagnostics Building was constructed on the Pottery Road site, resulting in an increase in employment to 500. This plant manufactured medical diagnostic reagents. Suites to manufacture the drug substances Elase and Thrombin were added to the General Diagnostics Building in 1980.
- Aseptic production commenced in 1980.
- The gum base plant was leased to Cadbury Schweppes for three years.

3.3 Neighbouring Land Uses
Pottery Road forms the southwestern boundary of the site. The National Rehabilitation Hospital is located in extensive grounds which adjoin the site, to the north. Light industrial units and a sports ground are located to the northeast of the site. There is housing adjoining the site to the south and on the western side of Pottery Road. A number of small housing estates lie to the west of Pottery Road and are served by access roads from it. There are industrial plants on the western side of Pottery road, towards its northern end, close to its junction with Clonkeen Crescent. There are offices and laboratories for the Environmental Protection Agency to the south of the site and a petrol station further south, close to the junction of Pottery Road and Johnstown Avenue.