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ATTACHMENT A.1 – NON-TECHNICAL SUMMARY

Scope

Pfizer Ireland Pharmaceuticals is applying for an Integrated Pollution Prevention and Control Licence review, for its Dublin Sterile Products Facility at Pottery Road, Dún Laoghaire, County Dublin. The Pfizer Dublin Sterile Products Facility currently operates under Integrated Pollution Control Licence Register Number 19, issued by the Environmental Protection Agency to the site in 1995. The plant requires an IPC Licence, under the EPA Acts 1992 and 2003, an is applying for an IPC licence review for Class 5.16 the use of a chemical or biological process for the production of basic pharmaceutical products. This review is being undertaken in light of the provision of a new production building and ancillary facilities which will constitute a significant increase in production at the facility and to incorporate the requirements of the EPA Acts 1992 and 2003 and the IPPC Directive as appropriate.

Introduction

Pfizer Ireland Pharmaceuticals is a subsidiary of Pfizer Inc., New York. Pfizer Inc. is a diversified, research-based healthcare company with approximately 135,000 employees worldwide. In 2003 it had sales of $48 billion in more than 100 countries. Since its foundation in 1849, Pfizer has invested significantly in research, and has produced 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, when it was developed from a brownfield site. It was originally owned by Warner-Lambert Limited, and became part of Pfizer Ireland Pharmaceuticals in 2000. Approximately 190 staff are currently employed at the plant, which occupies a site of circa 6.9 hectares (17 acres). Figure 1, indicating the location of the site is included in attachment A. 1.1.

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

Brand Name	Active Product	Benefit
VFEND®	Voriconazole	Anti Fungal
Zithromax®	Azithromycin	Antibiotic
Zeldox®	Ziprasidone	Anti Psychotic
Cerebyx®	Fosphenytoin	Anti Epileptic
Prodif®	Fosfluconazole	Anti Fungal
Ketanest/Ketalar	Ketamine	General Anaesthetic
Elase®	Fibrinolysin	Wound Healing
PEG-HGH	Genotropin	Human Growth Hormone

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Pfizer Ireland Pharmaceuticals are currently undergoing a site expansion project. This expansion will result in an increase in the capacity of the plant, to formulate sterile liquid and freeze-dried pharmaceutical products. The active pharmaceutical ingredients will come from Pfizer's pharmaceutical manufacturing plants in Ireland and overseas.

The expansion project will increase the 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. The aseptic production capacity of the Dublin Sterile Products Facility is currently approximately seven million vials per annum. When the proposed expansion in completed, the total production capacity will be approximately 35 million vials per annum.

Current Plant Layout, Facilities and Activities

There are two main buildings on the 6.89-hectare site - a two-storey pharmaceutical building and a single-storey gum base building, currently leased to Cadbury Schweppes. There are also a number of ancillary buildings and facilities on the site, including a security gatehouse, parking areas, single-storey office accommodation, a switch room, cooling towers, an emergency generator, a waste storage compound, refrigeration units, a wastewater balancing and neutralisation plant, and firewater retention tanks. A drawing indicating the current site layout is included in attachment A. 1.2.

The main production activity on site is the formulation of sterile liquid and freeze dried products. Powdered active pharmaceutical ingredients, manufactured at Pfizer plants in Ireland and overseas, are compounded in aqueous solutions, sterile filtered and filled into sterile glass vials, which range in size from 2ml to 30ml. This activity, also referred to as 'fill/finish', is undertaken using aseptic preparation methods. Aseptic means the absence of bacteria and 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.

Water for injection, which is water treated to achieve a very high standard of purity, is produced on site and used in the solutions. Some of the sterile liquid vials are freeze-dried. The filled vials are then either individually labelled and packed for distribution and sale, or packed in bulk cartons and sent to another Pfizer facility for later labelling and packing.

While the primary focus of the Dublin plant is sterile manufacturing, the pharmaceutical ingredient for one of the biological pharmaceutical products is also manufactured there. In this biologics production activity the active pharmaceutical ingredient is produced by extracting proteins using a fractionation process.

The production processes on site are batch operations. Very detailed equipment cleaning protocols are implemented between batches, using detergent and hot water, or isopropyl alcohol. The sterile suites and other process areas are disinfected periodically.

The company operates a two shift, 5-day week starting at 7am on Monday and ending at 10pm on Friday

Future Plant Layout, Facilities and Activities

The site development project involves the construction of two main new buildings, and ancillary facilities. There will be some mostly internal modifications to the existing pharmaceutical building. The new site layout following expansion is included in attachment A. 1.3. The new buildings will be as follows:

- A new production building which will be circa 168m by 56m in plan and approximately 24m in height, and which will accommodate two production modules and a warehouse. This building will be two storeys high, with a penthouse plant room
- A laboratory and canteen building, which will be two storeys with a penthouse plant room. This building will be L-shaped, with a road frontage of circa 35m and a depth of circa 46m,
- A security building, located close to the new main entrance. This will be a small, single-storey building with an irregular floor plan,
- A central utilities building will be approximately 36m by 19m in plan, two storeys in height, and located to the north of one of the existing production buildings,
- Various other works including the construction of pipe racks, installation of new diesel-tired emergency generators, relocation of the existing waste compound, relocation of the site entrance, and the construction of a car park,
- Some modifications, mostly internal, to the existing pharmaceutical building, and
- Extensive site works and landscaping, including mounding around the perimeter to screen the development thereby reducing noise and visual impact.

The buildings will be fabricated from conventional construction materials such as steel and concrete.

Environmental Management of the Activity

The Pfizer Dublin Sterile Products Facility is committed to good environmental practice. Pfizer operates an Environmental, Health and Safety Management System and has procedures and equipment in place to respond to emergencies, and ensure that any releases from the activity will not cause a significant environmental impact.

The management system ensures regular monitoring of emissions is carried out to ensure compliance with legal and regulatory requirements and best practices. Waste management practices are continuously improved and updated in line with changes in technologies, BAT and legislative updates. Where feasible, waste minimisation programmes are employed, for the efficient use of resources hence reducing the environmental impact of Pfizer operations.

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Pfizer carry out regular energy and water conservation audits in order to develop objectives and targets to reduce consumption of these resources on site.

In accordance with Pfizer Corporate guidelines, in the event of cessation of the activity, detailed divestiture plans will be put in place to ensure:
a) full legal compliance and
b) protection for subsequent users of the land from the implication of Pfizer's activities.

Air Emissions from the Installation

The primary sources of air emissions currently from the plant, result from the biologics production process and weighing of materials in the sterile production dispensary. The biologics process results in a source of T.A Luft Class 1 organics while the production dispensary produces a source of particulates. Both of these air emissions are monitored and controlled by abatement systems on site. The average concentration released from these emission points are 25% of the T.A Luft Class 1 organics limit and 40% of the T.A. Luft particulates limit respectively. The particulate emission point will become removed and will no longer be in operation from quarter 2, 2006 as a result of the new site development project.

Following the completion of the expansion project, the primary source of air emissions from the site will be the new boilers. The boilers will be natural gas fuelled. A computer emission dispersion model was used to study the impact of the current and proposed boilers on air quality in the vicinity of the site. The computer modelling showed that the predicted ground level concentrations of emissions from the plant will be within the relevant air quality standards. The emissions to air from the development will have a negligible impact on air quality in the vicinity.

The operation of the development does not have a significant effect on the global climate, or on local climate.

Effluent Generation and Treatment

Wastewater arises from several sources in the facility. Process effluent results from the cleaning of process equipment, the washing of vials, and the washing of floor and wall surfaces and wastewater from the protein extraction fractionation process in the biologics production area. Equipment is washed with hot water and detergent, or isopropyl alcohol. The other equipment washings and floor washings contain low levels of detergent or disinfectant.

The steam boilers, purified water and water for injection production systems, freeze dryers, cooling towers and chillers produce wastewater streams. The wastewater streams arising from this equipment contain dissolved salts as well as residues of proprietary chemical formulations used to treat the boiler and cooling water.

Sanitary wastewater arises from the canteen, washrooms and toilets, and is similar in composition to normal domestic sewage.

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The volume and characteristics of effluent are variable. To ensure that the effluent characteristics and flow volume meet the Integrated Pollution Control licence limits, the effluent is collected in a balancing tank, and neutralised by the addition of acid or caustic soda if necessary. The wastewater is then monitored for pH prior to being discharged from site to the Local Authirity sanitary sewer in Pottery Road. Pfizer carries out regular monitoring of the effluent released from the site to ensure compliance with specified regulatory limits.

Sanitary wastewater is combined with the process effluent downstream of the monitoring point, prior to discharge into the Local Authority sanitary sewer in Pottery Road.

The Local Authority sewer in Pottery Road is connected to the Shanganagh Works. At the Shanganagh Works there is primary screening prior to discharge through a one-mile long sea outfall. Dún Laoghaire-Rathdown County Council plans to construct a sewage treatment plant at Shanganagh. The treatment plant will be designed to meet the requirements of the EU Urban Wastewater Directive (1991).

The wastewater streams from the expansion project will be similar to the streams from the existing plant. The balancing and neutralising system will operate in line with the existing system but will have a greater capacity, sufficient for the expansion project. There will be increased volumes of wastewater generated in the proposed development, but the biological and chemical loading will not significantly change from its current level. The increased volume will be within the licensed limits.

No significant residual impact on the environment is anticipated as a result of the effluent released from the development.

Waste Management

Pfizer has a well-developed waste management strategy, which is aimed at determining the most environmentally beneficial methods for controlling the generation, management and ultimate reuse or disposal of all wastes.

Waste streams arising from the development include hazardous wastes such as reject pharmaceutical vials, waste liquid product, waste chemicals, waste pharmaceuticals, product contaminated packaging and laboratory waste, and non-hazardous wastes including office paper, cardboard and canteen waste. Simialar waste streams will result form the new development.

Pfizer strive where possible to minimise wastes arising from the processes, and also endeavour to find re-use, recovery and recycling options for wastes.

Wastes arising from the plant are not expected to cause a significant environmental impact.

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Noise

Pfizer carries out environmental noise surveys at their site on Pottery Road on an annual basis. These surveys have been used in the noise impact assessment for the site, in order to predict noise levels in the vicinity of the plant from the new plant and equipment.
During the operation of the plant, noise from the existing and new development will not cause the relevant guideline night time and day time noise limits to be exceeded at the noise sensitive locations. The noise impact from the development will be negligible.

In addition to this, the noise impact associated with site traffic and additional vehicle movements on public roads as a result of the new development, is predicted to be minimal.

Ground and Groundwater

The bedrock under the site is expected to be granite, associated with the Leinster Batholith, overlain by topsoil over stiff silty sandy gravelly clay or dense sandy gravels. There are no releases to ground from the site, however the early editions of the Ordnance Survey maps indicate that part of the site was previously a quarry or sand pit. The site investigations indicate that the pit was filled with material, which included municipal refuse, some time before 1969.

The bedrock underlying the site and surrounding area is relatively impermeable. The groundwater under the site is monitored on a regular basis by Pfizer. While the groundwater is classified as slightly contaminated, the quality of the groundwater leaving the site is not significantly different from the quality of the groundwater entering the site. This suggests that there are sources of groundwater contamination upstream of the site, and that the material in the filled sand pit on site is not having a significant negative effect on the quality of the groundwater as it flows under the site.

The development does not have a significant impact on ground or groundwater.

Surface Water

There are no surface waters (streams or drainage ditches) within the site or at the site boundaries. The Deansgrange Stream runs on a northwest-southeast axis, to the west of Pottery Road, at a distance of approximately 150m from the site.

Rainwater runoff from roofs, site roads, hard standings and car park areas is collected in a dedicated surface water drainage system. The surface water discharged from the site is monitored continuously for pH. If the levels fall outside the preset limit the outlet valve can be closed and the water retained.

Following monitoring, when the surface water falls within preset limits, rainwater from the site discharges to the Dún Laoghaire-Rathdown storm water sewer in Pottery Road. The sewer discharges to the Deans Grange stream.

This system will continue to function as it does currently, following site development, to ensure that Pfizer does not to have a significant impact on surface waters.

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Fire Water Containment

In the event of a fire on site, there would be the possibility that the water used for fire fighting could become contaminated with chemicals and that this contaminated water could drain into the ground or, via the storm water system, into the Deans Grange stream. To ensure that this will not happen, a system has been provided for the containment of water used for fire fighting. The firewater retention system will continue to function as it does currently following site development, diverting all surface water to retention tanks upon the initiation of the site fire-pumps.

Summary

The contents of this application details the information to support the application by Pfizer Ireland Pharmaceuticals for a reviewed Integrated Pollution Prevention and Control Licence for Class 5.16 the use of a chemical or biological process for the production of basic pharmaceutical products for its Dublin Sterile Products Facility at Pottery Road, Dún Laoghaire, County Dublin.

This review is being undertaken in light of the provision of a new production building and ancillary facilities which will constitute a significant increase in production at the facility and to incorporate the requirements of the EPA Acts 1992 and 2003 and the IPPC Directive as appropriate.

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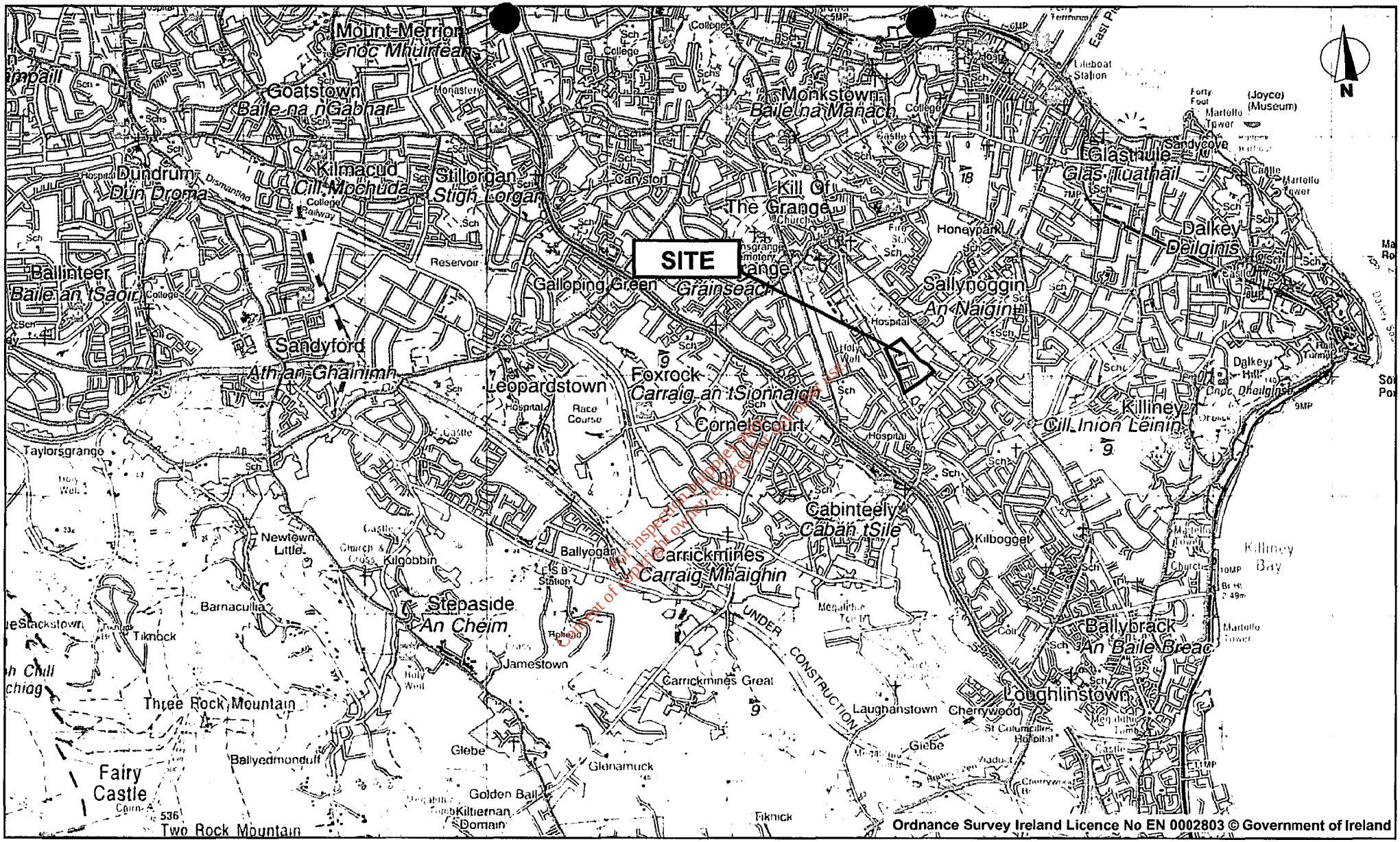

ARUP

Pfizer

Pfizer Aseptic Production Plant

Site Location (OS Discovery Sheet 50)

Figure 1