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Attachment A.1

Non-Technical Summary

A.1: Non-Technical Summary

1 Introduction

AbbVie Ireland NL B.V (AbbVie Operation, Sligo / AbbVie) operates a pharmaceutical manufacturing facility at Manorhamilton Road on the outskirts of Sligo town.

AbbVie have global expertise and are proven pharmaceutical leaders in the industry. Work is focussed on a number of fully integrated therapeutic areas including: antiviral, oncology, and cardiovascular/renal.

Established in 2002, AbbVie Operations, Sligo is licensed, state-of-the-art, high containment facility for the manufacture of a wide range of pharmaceuticals. The highly sophisticated technology o site in combination with the depth of expertise that exists within the workforce helps AbbVie develop and deliver products and processes from small scale clinical trial supply to larger commercial manufacturing. The quality control labs are equipped with the latest design technology for chemical and microbiological analytical testing to meet customers' needs.

AbbVie is fully committed to ensuring their manufacturing facility operates to the highest safety and environmental standards possible.

AbbVie is applying to the EPA for a review of the plant's Industrial Emissions (IE) Licence (Reg No.P0642-02) to include for the operation of a new VOC (Volatile Organic Compound) abatement system in the form of a new thermal oxidiser on site and also to update a number of existing licence conditions that are either obsolete or out-dated.

The new thermal oxidiser is being installed to abate off-gases from processing activities. Currently these off-gases are treated in either the existing thermal oxidisers and/or the cryogenic condenser. However, the existing thermal oxidiser was not designed to treat off-gases from chlorinated solvents (e.g. Dichloromethane) which will be used in the manufacturing process increasingly in the production of new pharmaceutical products.

1.1 General Information

1.1.1 Hours of Operation

Active Pharmaceutical Ingredients (API) Building operates 24 hours a day, 7 days a week.

Drug Product Building operates 24 hours a day, 5 days a week.

1.1.2 Class of Activity

The class and nature of the Industrial Emissions Directive (2010/75/EU) activity carried out in accordance with the First Schedule to the Environmental Protection Agency Act 1992 (as amended) is '5.16 The production of pharmaceutical products including intermediates'. The equivalent Industrial Emissions Directive category is 4.5.

1.1.3 Environmental Impact Statement & Planning

The introduction of the new thermal oxidiser will have an insignificant environmental impact on the local environment and hence an Environmental Impact Statement (EIS) has not been prepared in support of the application. The environmental impacts of development on site since the original EIS was issued in 2001 have been reviewed and information relating to this is included as part of Attachment B.

A full planning history including planner's reports and final decisions has been included in the application part of Section B.

Sligo County Council have confirmed the introduction of the thermal oxidiser is considered exempted development under Schedule 2, Part I, Class 21 of the Planning and Development

Regulations (2001) as amended. A Section 5 Exemption has been granted on this regard (Ref. ED 170).

1.1.4 Best Available Techniques (BAT)

Under the new Industrial Emissions Directive, the emissions limits and equivalent control parameters for licensed facilities should be based on the principles of Best Available Techniques (BAT). A review has been completed of BAT associated with the new thermal oxidiser and all associated equipment proposed for the VOC abatement system at the AbbVie site.

The Best Available Techniques Reference Documents (BREFS) that have been the focus of the review are;

- Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector
- Organic Fine Chemicals
- General Principles of Monitoring
- Energy Efficiency

The BAT review tables which are included as part of Section I.8 of the main application, outline whether a particular conclusion is relevant to the new VOC abatement plant and how it is implemented.

1.1.5 Seveso

The quantities of chemicals stored on site are below applicable thresholds of the EC (Control of Major Accident Hazards involving Dangerous Substances) Regulations 2006 and The Chemicals Act (Control of Major Accident Hazards involving Dangerous Substances) Regulations 2015. These regulations do not apply to the facility.

1.2 Description of the Installation and its Activities

The facility will manufacture a number of API's for medical applications. API's are the pure drug substances in a very concentrated form. These must then be diluted to the correct strength, by the addition of inert ingredients, and turned into the standard forms, which can be taken by the patient, such as tablets or capsules. This operation is called secondary manufacturing or drug product formulation.

The API building will be multi-purpose and will manufacture multiple products. The active pharmaceutical ingredients will be manufactured using standard chemical synthesis methods and standard types of equipment of proven design. The facility will be designed to operate in batch mode. There will also be a Drug Product building, which will produce tablets, using standard equipment for blending, milling, and tablet making. The facility will also include a number of supporting utilities and services.

The site consists of four main buildings and a number of ancillary facilities. These are:

- Utility building (Building 70)
- Bulk Pharmaceutical building (Building 40)
- Drug Product building (Building 20)
- Administration and laboratory (Building 10)

The ancillary facilities as follows:

- Tank farm
- Tank unloading/loading bay
- Process water storage tank

- Sprinkler pump house and storage tank
- Emergency generator
- Air emissions abatement equipment
- Aqueous waste treatment system
- Drum store
- Security building.

1.2.1 Pharmaceutical Production Methods

Bulk Pharmaceutical building

The production processes will be operated in batch mode and the equipment used to manufacture the products and intermediates will be glass-lined or stainless steel and of standard design for the industry. The following are brief descriptions of typical production processes involved in the manufacture of active pharmaceutical ingredients, not all of which are required for each product.

- Reactions

  Appropriate solvents will be weighed into a chemical reaction vessel, called a reactor. Specified quantities of raw materials will be added and heated to the required temperature range before a reactant is added at the required flow rate. Reaction conditions such as pressure, time, addition rate and temperature will be set for each product and in-process testing and sampling will be done.

- Crystallisation

  Crystallisation will be carried out on some products.

- Separation

  Separations will be required. These may be liquid – liquid separation of, for example, an aqueous and an organic solvent, using a phase splitter, or solid-liquid separation using a filter or centrifugation.

- Distillation

  A variety of distillations may be required, either at atmospheric pressure or under vacuum, in order to purify material, separate materials, or recover solvents for disposal.

- Drying

  Drying will be carried out in filter dryers or blender/dryers (with or without vacuum).

- De-Lumping /Sizing

  De-lumping, that is grinding down of material to a uniform size, will be carried out using mills under specified operating conditions.

Drug Product building

The operations to be undertaken in the Drug Product building include the following:

- Blending

  Blending is the addition and mixing of powder raw materials with different properties. The objective is to have, on completion of the blending step, a final product that is homogenous (uniform). To achieve this, a number of pre-blending steps are necessary.

- Compression into tablets

  Tablets are formed, under pressure in a tablet press, from the blended powder.

- Tablet Coating

  Tablets are coated using the tablet coater.

1.3 Raw Materials, Auxiliary Materials, Finished Products

Pharmaceutical active ingredients are made from very complex chemical molecules. It takes a series of chemical synthesis steps to transform the initial raw materials into the complete molecule required. Only a few of the steps required for each product will be undertaken in the Bulk Pharmaceutical building. The raw material for the Drug Product building will be the active ingredient. The finished products will be tablets of the drug.

A range of other materials will be used in the Bulk Pharmaceutical building. These will include common organic solvents such as Dichloromethane, Methanol, Ethyl acetate, Toluene, Formaldehyde and Acetone, inorganic salts such as Potassium Carbonate, Sodium Bicarbonate and Sodium Hydroxide and organic and inorganic acids such as Formic acid, and Hydrochloric Acid. Organic solvents and water will be used to clean equipment in the Bulk Pharmaceutical building.

In the Drug Product building inactive powders, called excipients, will be added to the active pharmaceutical ingredient to dilute it to the required level of concentration and to form the base of the tablet. Hot water, purified water and detergents will be used to clean the equipment in the Drug Product building.

Various chemicals will be used in the water purification process and in the treatment of water for the boilers and cooling towers. The facility maintenance staff will use oils and lubricants.

The full list of the materials to be used and the annual quantities are provided in the tables in Section G of this application.

1.4 Energy & Resources

AbbVie achieved accreditation to ISO 15001:2001 in 2013. Energy Audits are carried out annually and the recommendations from these reports will be incorporated into the facility's Environmental Management Plan.

Electricity for the site is sourced from the 38kV ESB Sub Station located at the existing Abbott Ireland site in Ballytivnan. The average energy use on-site is approximately 8000 MWH per year.

Fuel used on-site includes Kerosene and LPG for the boilers and thermal oxidiser.

Table 1.4: Energy usage on site in recent years

Energy Type	2013	2014
Kerosene (m^3)	969	1,134
LPG(m^3)	987	468
Electricity (MWHrs)	9,439	10,737

The water demand for the site is approximately 230 m^3/day. This is sourced from the Sligo County Council public supply main which runs near the site.

1.5 Sources of Emissions from the Installation,

There will be emissions to the air, surface water and sewer and also emissions of noise and waste from the facility.

1.5.1 Emissions to Air

Emissions to air will come from the thermal oxidiser, cryogenic condenser, scrubber, boilers and from dust exhaust systems. Very low levels of emissions to air will come from the laboratory fume hoods and the vents from the bulk tanks.

1.5.2 Emissions to Surface Waters

The site storm water drainage system will collect rain water run-off from roofs, the car park, site roads and the goods delivery area concrete yards, and will discharge into the stream which runs along the eastern boundary of the site.

Areas of the site where a spillage might occur, such as the tanker-unloading bay and the drum store, will be bunded and have a localised sump to contain any rainwater. These areas will be isolated from the storm water drainage system. Any water collected in these sumps will be sampled regularly and tested. If the results are in compliance with emission limit values, the contents of the sump can be discharged to the storm water system. Alternatively the contents can be treated or undergo further treatment on site.

The bulk tanks will be bunded, which will contain the contents of a tank in the event of a leak. The diesel tank will also be bunded. These bunds will be isolated from the storm water drainage system and any rain water which collects in the bunds will be sampled and tested and dealt with as described above for the tanker bay and drum store bund.

An oil/water interceptor will be installed on the storm water drainage system to remove any oil, which may enter it from trucks and cars on the site roads or car park.

The storm water drainage system will drain to retention pond prior to discharge to the receiving water body. The quality of the water leaving the pond will be monitored continuously by measuring the pH and total organic content. In the event of a high level alarm the sluice valve on the outlet from the pond will be closed and the contaminated water will be retained for further testing and treatment or disposal by an alternative means if necessary.

In the unlikely occurrence of a fire, the water used to fight the fire may come in contact with potential pollutants. In order to minimise the environmental impact from the firewater, the facility has been designed so that the firewater drains to the retention pond. The outlet of this retention pond closes upon activation of the firewater deluge systems.

1.5.3 Emissions to Sewer

There are a number of sources of liquid waste at the facility. Sanitary wastewater will be generated in the kitchens, toilet areas and showers. Certain utility equipment including the water treatment and purification systems, the boilers and the cooling towers will also generate wastewater. Finally the manufacturing processes will give rise to solvent and aqueous waste streams. The two waste streams will be collected via separate drainage system and will be stored separately.

The solvent waste will be treated in the aqueous waste solvent stripper to reduce the water content. It will then be stored in a bulk tank and taken off site by road tanker for recovery or disposal. The solvent waste is not discharged to sewer.

1.5.4 Emissions to Ground

There are no emissions to ground from the facility.

1.5.5 Noise Emissions

There is audible plant noise from the external pumps of the tank farms, the extraction fans of the buildings and the compressed air of pneumatic lines. Other noise sources include the cooling towers air compressors, boilers and thermal oxidiser. Baseline noise monitoring was carried out during the preparation of the EIS at 3 no. locations around the site for a maximum of 60 minutes. Noise levels were generally low, though there was some local traffic and activity noise; i.e. no noise issues prior to site development. Noise monitoring is carried out annually at 4 no. boundary

locations as well as 3 no. locations off-site. Results of the 2014 noise monitoring which was submitted in the site's AER for 2014 show that the noise limits, as set in the site's current Industrial Emissions Licence, were fully complied with.

Note: There will be no anticipated odour emissions from the facility.

1.6 Abatement Systems

There are a number of abatement systems in place across the site. These are outlined below.

1.6.1 Thermal Oxidiser

AbbVie treat these gaseous waste streams by passing them through either a Thermal Oxidiser plant or through a Cryogenic Direct Contact abatement unit prior to release to atmosphere, in order to ensure compliance with their Industrial Emissions Licence requirements.

The existing Thermal Oxidiser plant was installed in 2002, has been fully operational to date and is due for replacement. Thermal Oxidiser technology has improved and become more efficient in the last 10 years and AbbVie is in the process of replacing the existing Thermal Oxidiser plant with a new Thermal Oxidiser unit.

The new Thermal Oxidiser installation will consist of the following external equipment:

- An LPG-fired Thermal Oxidiser (similar to a cylindrical boiler)
- A Heat Recovery unit to capture any waste heat and re-cycle this to the facility
- A Scrubber unit and Quench Tank to provide a further level of waste gas cleaning and cooling
- A Plume Eliminator to remove any visible exhaust plumes being emitted, particularly in cold weather
- An Exhaust stack, the height of which will be 10m
- Thermal Oxidiser Control panel
- Miscellaneous piping and associated pumps

1.6.2 Cryogenic Condenser

This system will be used as a back-up to the new TO. This piece of equipment is not suitable for the abatement of Volatile Organic Compounds which is why the TO will be the main abatement unit used on-site.

1.6.3 Dust Extraction with HEPA Filters

There are 3 HEPA filters in place at the facility to extract dust containing active pharmaceutical ingredients from production areas.

1.6.4 Solvent Treatment

An aqueous waste solvent stripper is located on site. The purpose of this is to remove concentrated solvent material from aqueous streams. The concentrated solvent material is taken off-site for disposal via road tanker.

1.7 Environmental Conditions of the Site of the Installation.

An on-site stream flows through the southern part of the site. This is a small tributary of the Bellanurly Willsborough stream. This stream is located 0.5km to the north of the site and it enters Sligo Estuary/Bay 1.6km to the west of the site. The current status of the Bellanurly Willsborough stream under the Water Framework Directive is "Good". Its biological water quality classification is Q4, indicating that the waters are satisfactory and unpolluted.

The latest Bi-annual Groundwater Monitoring report submitted with this application provides detailed information on the current conditions of the site. In summary, the groundwater monitoring results at the site show elevated concentrations of conductivity, chloride, sulphate, iron and manganese. Historically, slightly elevated concentrations of COD, orthophosphate, ammonia and sulphate have been seen in groundwater results. This poor groundwater quality is most likely related to both agricultural activities up-gradient of the site (e.g. fertiliser application, lands spreading) and possibly a leaking foul sewer on site or in the vicinity of the site as evidenced by the elevated conductivity and chloride at MW-2 and MW-4. Full details of the methods, analysis and results are contained in the attached Baseline Report.

Emissions to air comply with the Air Quality Standards.

Noise emissions comply with the licence limits.

1.8 Nature and Quantity of the Existing and Proposed Emissions

The following tables summarise the licence emissions from the site.

Table 1.8.1: *Boiler Emission Limit Values (A1-1, A1-2)*

Parameter	Emission Limit Value (mg/m^3)
Sulphur Oxides (as SO_2)	70
Nitrogen Oxides (as NO_2)	180
Carbon Monoxide	100

Table 1.8.2: *Thermal Oxidiser Emission Limit Values (A2-1(a))*

Parameter	Emission Limit Value (mg/m^3)
Oxides of Sulphur (as SO_2)	70
Nitrogen of Oxides (as NO_2)	200
Carbon Monoxide	300
Total Organic Carbon (as C)	20
2-Methoxyethanol and Dimethlyformamide	2 (at mass flows >0.001kg/h)
TA Luft Class I Organics	20 (at mass flow >0.1kg/hr)
TA Luft Class II Organics	100 (at mass flow >0.5 kg/hr)

Table 1.8.3: ***New Thermal Oxidiser Emission Limit Values (A2-1(c))***

Parameter	Emission Limit Value (mg/m^3)
Oxides of Sulphur (as SO_2)	70
Nitrogen of Oxides (as NO_2)	200
Carbon Monoxide	300

Total Organic Carbon (as C)	20
Chlorides (as HCl)	10
Dioxins/Furans	0.1ng/m^3 (6-8 Hour Sample)

Table 1.8.4: *Cryogenic Condenser Emission Limit Values (A2-1(b))*

Parameter	Emission Limit Value (mg/m^3)
TA Luft Class I Organics	20 (at mass flow >0.1kg/hr)
TA Luft Class II Organics	100 (at mass flow >0.5 kg/hr)

Table 1.8.5: *Process Scrubber Emission Limit Values A2-2*

Parameter	Emission Limit Value (mg/m^3)
Chlorides (as HCl)	10
Formic Acid	10

Table 1.8.6: *Dust Extraction Emission Limit Values (A2-2 – A2-5)*

Parameter	Emission Limit Value (mg/m^3)
Total Dust	1
Dust (as Active Pharmaceutical Ingredients	0.15 (at mass flow > 1g/hr)

Table 1.8.7: *Sewer Emission Limit Values (SE 1)*

Parameter	Emission Limit Value (mg/m^3)
Temperature	25°C (max)
pH	6-9
Toxicity	10 TU
	mg/l
BOD	450
COD	1300
Suspended Solids	350

Parameter	Emission Limit Value (mg/m^3)
Ammonia (as N)	25
Total Phosphorus	10
Sulphate	1500
Chlorides	8000
Detergents (as MBAS)	20
Fats, Oils, Grease	10

1.9 Existing Environment and Impact on the Facility

1.9.1 Impact on Air Emission

Existing air quality at the site was established during the preparation of the EIS by measuring ambient concentrations of sulphur dioxide, nitrogen dioxide and smoke. All values were well within relevant air quality standards, indicating a satisfactory air quality in the area i.e. no source of contamination prior to site development.

The EPA manages the national ambient air quality network. The Air Framework Directive deals with each EU member state in terms of "Zones". The Air Quality Standards Regulations 2011 state "The Agency shall establish zones and agglomerations throughout the territory of the State for the purpose of air quality assessment and air quality management". The zones and agglomerations are defined as follows:

Zone A: Dublin Conurbation

Zone B: Cork Conurbation

Zone C: Other large cities and towns comprising Galway, Limerick, Waterford, Clonmel, Kilkenny, Sligo, Drogheda, Wexford, Athlone, Ennis, Bray, Naas, Carlow, Tralee, Dundalk, Navan, Letterkenny, Celbridge, Newbridge, Mullingar, Balbriggan

Zone D: Rural Ireland, i.e. the remainder of the State excluding Zones A, B and C.

In accordance with the above information, background concentrations were taken for Zone C (which includes Sligo) from the EPA document – "Air Quality in Ireland 2013, Key Indicators of Ambient Air Quality" when carrying out air quality impact assessments as part of the thermal oxidiser installation.

Air dispersion modelling (Report No: IE0311237-22-RP-0001) was carried out for this licence review application to assess the impact from the introduction of the new thermal oxidiser. The modelling indicated that the emissions have no significant effect on the environment and do not breach statutory Air Quality Standards. Report is included in Attachment I.1.

1.9.2 Impact on Surface Waters

All surface water from the facility is discharged into a small stream that passes through the property entering at the western boundary and generally flows from east to west until it reaches the eastern boundary of premises where it turns south along the boundary. It then flows westwards and shortly afterwards discharges to the estuary at Cartron. It flows through culverts under the Ballytivnan Road and also another business premises. There is some evidence to suggest that its source is a spring in a nearby field east of the proposed development but the flow is added to by drainage ditches in the locality.

Source of Surface Water;

Surface water discharge will originate from the roofs of buildings, hard paved areas (cars and truck parks) and internal circulation roads. The maximum rate of surface water emissions is no more than 0.62 m^3/s.

Uncontaminated surface water run-off typically has a BOD of 5 -10 mg/l and a suspended solids concentration of 10-15 mg/l. These concentrations increase to about 20mg/l and 30mg/l respectively at times during the year and particularly in early autumn when the heavier rains flush decaying vegetation such as grass clippings and leaves from the land. Uncontaminated surface water is normally discharged directly to the nearest surface water drainage system as it does not cause contamination. It is standard modern good practice to exclude surface water from municipal foul drainage systems.

The receiving waters affected by the site include:

1. Sligo Harbour
2. Doonally River
3. Stream

The stream acts as the receiving waters for surface water emissions. Prior to any discharge the surface water will pass through the retention pond which allows for monitoring of the discharge. The surface water emission point reference is known as SW1.

1. Sligo Harbour

Sligo Harbour is part of Sligo Bay and is effectively the estuary of the Garavogue River. It approximates to an east-west rectangle with a length of about 6km and a width of about 2km. Almost 90% of the estuary dries out at low water on spring tides leaving a well-defined river channel along the northern side. The navigation channel was dredged in 1985 to give a depth of 2.7m (chart datum) at low water spring tide. The amplitudes of the tides are about 3.3m for mean spring and 1.5m for mean neap. The main entrance of the estuary is between Deadman's Point and Coney Island.

The bay and estuary form an important amenity being used for angling, bathing at a number of beaches, boating, shell-fisheries and navigation. Cummeen Strand is internationally important because of its significant goose population. Sligo Bay has not been designated a sensitive area.

2. Doonally River

Doonally River flows along the northern and north-western part of AbbVie's property and a short distance later then discharges to the estuary at Cartron. It is an important river with a substantial ecological interest. The river was sampled and analysed by Forbairt in 1997 and is deemed to be in good condition.

The location of the site in relation to the Doonally River is such that the possibility of drainage from the site reaching it is remote.

3. Stream

A small stream passes through the property entering at the eastern boundary and generally flowing from east to west until it reaches the eastern boundary of AbbVie's existing premises where it turns south along the boundary. It then flows westwards and shortly afterwards discharges to the estuary Cartron. It flows through culverts under the Ballytivnan Road and also at a nearby field east of the proposed development but the flow is added to by drainage ditches in the locality. The stream was sampled and analysed by Forbairt in 1997 and is deemed to be in good condition.

The capacity of this stream is determined by a culvert which passes under Ballytivnan Road and another culvert downstream of this.

Impact on Receiving Waters from AbbVie;

As stated previously, the stream which runs along the eastern boundary of the property is the receiving waters for surface water emissions. The stream due to its size to has very low, or zero, amenity value.

There is a small chance that Lampreys, that are important fish species which are listed on Annex II of the Habitats Directive, could occur in the small stream. The most likely of these to occur is the Brook Lamprey (Lampetra planeri) as it is non-migratory and occurs in small streams, particularly in the limestone regions of Ireland. As the River Lamprey and Sea Lamprey are migratory species, living part of their lives in the sea, it is very unlikely that they would be found in the small stream within the property owing to the culverted lower section.

Owing to the calcareous nature of the area, consideration must be given to the possibility of the occurrence of the freshwater crayfish (Austropotamobius pallipes) in the small stream within the property or in the Doonally River. This species is protected under the Wildlife Act, 1976 and is also listed on Annex II of the Habitats Directive. Crayfish have been recorded from the Garvoge River in Sligo Town and at another site in the vicinity of Lough Gill . While the water quality and habitat of the small stream appear suitable, the fact that it is relatively short in length and not connected to a larger river system may lower the likelihood of its occurrence.

There will be no waste water discharge to the stream. The only discharge to this stream is from the single emission point (SW1) - the uncontaminated surface water. This will have minimal adverse impact on the stream.

The proposed works around the new thermal oxidiser increase the impermeable area of the site by approx. 1-2 % of the site area. The original surface water drainage system was originally designed to allow for future expansion. The sites surface water would continue to drain to the retention pond via a hydrocarbon interceptor before discharging to the on-site stream via a flow control device.

The mitigation measures as a result of the installation would follow the same strategy as previously. Measures included control of surface water runoff, the use of hydrocarbon interceptor, bunded tanks/ drum storage, adherence to the facilities Environmental Management Programme, loading/unloading of the chemicals in bunded areas and regular testing of bunds, drains, lines and also continuous surface water monitoring.

It is deemed that the proposed thermal oxidiser installation will have negligible impact on the surface waters.

1.9.3 Impact on Sewer

The proposed installation will generate additional process wastewater due blow down from the new scrubber. The additional process wastewater volumes would be approximately 2m^3/day. AbbVie's licence limit is 300m^3/day. The average daily discharge is approximately 191m^3/day, therefore even with the proposed increases, the daily discharges would still be well below the limit. Monitoring as per the licence would continue as before. Any emissions will be treated along with the rest of the sites effluent to comply with the emission limit values as set out in the licence before release to the public sewer.

It was deemed that the proposed installation would have imperceptible residual impact on the environment.

1.9.4 Impact on Groundwater

All new tanks associated with the new thermal oxidiser skid are bunded and hence there will be no impact on groundwater.

1.9.5 Noise Emissions

The new thermal oxidiser is replacing an existing thermal oxidiser. Predicted calculations indicate that there will be negligible impact from the new installation.

AbbVie has never had any noise complaints or recorded any exceedance of the noise emission limit values during any of the annual noise surveys.

1.10 Proposed Technology

1.10.1 New Thermal Oxidiser

The principle of direct fired technology is relatively straight forward; the gases are fired into a combustion chamber and then held at the required temperature for the specified period of time, the size/volume of the chamber being directly proportional to the required operating temperature and residence time. As the chamber can be lined with a refractory brick or similar refractory coating, there are no technical limitations to achieving operating temperatures greater than 1100°C.

Although this solves the problem of the halogenated VOCs, the higher temperatures can cause an increase in thermal nitrogen oxides (NOx) for which there are licence limits set at 200mg/m^3. To ensure continued compliance with the licence, additional flue gas treatment in the form of Selective Non-Catalytic Reduction (SNCR) technology will be employed as part of the abatement plant. With SNCR, a reducing agent, commonly an aqueous solution of urea is added to the flue gas which has been cooled to between 950°C-1100°C leading to a reduction in NOx through chemical reaction. This technology can reduce NOx levels by approximately 60-70%.

After the combustion processes, flue gas will be cooled in a quench system, before scrubbing of the flue gas to remove HCI. The flue gas will exit the quench/scrubber at a temperature of approx. 50°C where it will be reheated to approx. 150°C in a plume eliminator heat exchanger.

The flue gas will then exit the exhaust stack at approx. 150°C via a continuous emission monitoring system (CEMS). The system shall be designed to eliminate as far as practical any visual plume under normal operating conditions.

A new steam boiler has been installed to recover heat from the exhaust gas stream from the new thermal oxidiser and used to generate steam for use on site.

Table 1.9 provides detail on the volumetric flow rates and solvent loadings to be treated in the new thermal oxidiser.

Table 1.9 Total Unit Design Rates

	Max Nitrogen Flow (Nm^3/hr)	Max Solvent Rate (kg/hr)
DCM (Dichloromethane)	1000	88.6
THF (Tetrahydrofuran)		86.4
Ethyl Acetate		9.7
Methanol		2.0
DMF		0.0
Acetone		5.7
IPA		0.6
MTBE		3.4
Ethanol		0.4
MIBK		0.4
Heptane		2.2
Total	**1000**	**199.5**

1.11 Summary and Quantity of Waste

AbbVie maintains records of waste generated on-site. The quantity and nature of wastes produced at the site are reported in the AER which is submitted annually as per the conditions of AbbVie's Industrial Emissions Licence.

1.11.1 Non-Hazardous Waste

Non-hazardous waste is collected from the site by Barna Waste and Galway Metal.

Total 2014: 84 Tonnes

1.11.2 Hazardous Waste

Hazardous waste is collected from the site and taken to Indaver Ireland in Dublin or directly to the disposal facility abroad. Records for hazardous waste shipments sent off-site including waste contractor documentation, TFS (Transfrontier Shipment) forms WTF (Waste Transfer Forms) are held on site and are available for viewing as required.

Total 2014: 2630 Tonnes

1.12 Waste Management and Policy

The Environmental Management Plan has a series of objectives and targets to minimise waste generation and maximise the recovery of waste generated. The implementation of the plan is monitored, to ensure these objectives and targets are achieved.

All waste is segregated by waste type in a manner to prevent release and is clearly labelled. Aqueous waste and laboratory waste collected from around the site is stored in a dedicated hazardous waste storage area until ready for off-site shipment. This is a locked caged area. Hazardous waste generated from manufacturing buildings B20 and B40 and the laboratory areas are collected by the Total Waste Management (TWM) vendor or warehouse personnel. Waste is transported to a locked shipping container, located separate from the warehouse areas, where it is sorted and stored securely while awaiting offsite shipment. Hazardous waste of drug products or containers of Active Pharmaceutical Ingredients (API) are never stored outside of a secure location. All waste shipped off-site shall be packaged to meet all applicable requirements and in a manner to prevent any release during transportation. No Hazardous waste shall leave the AbbVie site unless both the driver and the transport vehicle are fully compliant with the above requirements.

Food waste is managed in accordance with the Waste Management (Food Waste) Regulations 2009.

1.13 Operation of new Thermal Oxidiser

1.13.1 Plant Automation

The existing Delta-V DCS (Version 11.3) system has been the sole automation platform associated with the running of the existing Thermal Oxidiser Unit, Cryogenic Abatement Unit and vent header system to date. A system integrator is tasked with the integration of the new vent header system control requirements needed for an efficient supply to the new Thermal Oxidiser.

The thermal oxidiser will have a number of operational modes that will be controlled by the thermal oxidiser PLC / SCADA control system. For the VOC abatement & vent header system to begin its automated start-up sequence, a number of criteria will need to be fulfilled e.g. all utility streams required for the operation of the thermal oxidiser need to be within recommended ranges / set points.

1.13.2 System Performance

When the new thermal oxidiser system is in operation, it is expected that the performance requirements documented in the Functional Specification are achieved.

1.13.3 System Failure

If any of the new equipment should fail, specific indication alarms are activated to inform the operational or maintenance personnel that the equipment has failed.

1.13.4 Safety & Training

Any personnel working on at site must follow all of the site safety procedures. There are standard operating procedures in place for the operation of the abatement equipment.

1.13.5 Stoppage

In the event of a production stoppage, the CEMS continue to operate. In the case of the thermal oxidiser, an appropriate warm up period will apply to ensure the unit is at operational temperature to recommence emissions abatement. The thermal oxidiser PLC will communicate to the sites DCS that it is available.

In the event of the new DTO not being available (unplanned shutdown / maintenance), the vent header will be manually configured to an alternative abatement system i.e. the cryogenic condenser.

1.14 Measures to be taken on and following Permanent Cessation of Activities

A Closure Plan has been prepared that details the measures to be undertaken at the site in order to prevent possible environmental damage as a result of the cessation activities at the site under normal operating conditions. It also details remedial and corrective actions that may have to be carried out should environmental pollution occur at the site.

The scope of this plan addresses the key issues, which would occur in an orderly shutdown of all or part the site activities; i.e. well planned and well financed. It is envisaged that a complete shutdown would take place on a phased basis over an estimated time period of 9-12 months.

The scope of the plan includes the following major activities:

- Setting up a management structure to oversee the Closure Plan;
- Cessation of all production activities;
- Removal of all remaining raw materials, intermediates and final products from the site;
- Cleaning and decontamination of all equipment and buildings;
- Shutting down of all environmental and utility systems;
- Completion of report on all aspects of the site within 60 days of completion of plan activities;
- Maintaining an on-going security and environmental monitoring service.

1.15 Measures planned to Monitor Emissions into the Environment.

1.15.1 Emissions to Atmosphere

The existing main atmospheric emission points for the thermal oxidiser and the cryogenic condenser are provided with Continuous Emissions Monitoring Systems (CEMS), which have been approved by an approved certification body. The new TO emission point is also equipped with an approved CEMS.

The boilers emissions are monitored annually and bi-annually for the licence parameters as per the licence.

Dust emissions from all licenced emission points are monitored by manual gravimetric methods annually.

1.15.2 Emission to Sewer

There is continuous monitoring of Flow, pH and TOC of the process wastewater prior to discharge to the sewer as per the licence.

1.15.3 Emissions to Surface Water

The storm water drainage system will drain to retention pond prior to discharge to the receiving water body. The quality of the water leaving the pond will be monitored continuously by measuring the pH and total organic content. In the event of a high level alarm the sluice valve on the outlet from the pond will be closed and the contaminated water will be retained for further testing and treatment or disposal by an alternative means if necessary. There are daily visual inspections as well as weekly COD sampling.

1.15.4 Groundwater Monitoring

Groundwater is monitored annually via a network of four wells located around the site.

1.15.5 Noise Monitoring

The site currently carries out annual noise surveys at the boundary and noise sensitive locations.

1.16 Measures to Comply with an Environmental Quality Standard

AbbVie has an EMS accredited to ISO 14001 in place to enable a systematic and documented approach to environmental performance and improvement. The EMS provides a structured process for the achievement of continual improvement. A copy of the accreditation certificate issued by Certification Europe Ltd. is included as attachment C.2 of this Licence Review application.

1.17 Measures to comply with Council Directive 80/68/EEC and 2006/118/EC

The following containment measures ensure compliance with the Council Directive 80/68/EEC and 2006/118/EC in relation to the protection of groundwater.

- Over ground pipelines and transfer lines
- Double contained piping used on the process waste lines from the Bulk Pharmaceutical building, Drug product building and the Laboratory areas
- Minimisation of tank filling losses by conservation vents
- Overfilling protection on bulk storage tanks
- Secondary containment of relief valve or bursting disc discharges from synthesis vessels to a Catch pot.
- Vent collection and ducting from reactors to central abatement systems
- Closed transfer systems from reactors to filters/dryers
- Bunding of external tanks
- Retention pond to hold contaminated water in the event of a fire or accidental spillage
- All the environmental monitoring and abatement equipment will be alarmed either locally or back to the DCS system, therefore an early warning system is in place in case of an environmental incident. Automatic shutdown systems will also be configured.

1.18 Main Alternatives to the Proposed Technology

A direct fired thermal oxidiser is the best technology for the proposed use.

Alternative technologies such as cryogenics, catalyst replacement and regenerative thermal oxidation were evaluated as part of the project.

Jacobs Engineering carried out a VOC Abatement System Concept Study examining the suitability of each technology. It was concluded that thermal oxidation would be the technology of choice as it has proven to be robust and reliable and is utilised in the majority of API manufacturing sites in Ireland.

PM Group subsequently produced a report “Thermal Oxidiser Technology Assessment” (IE0311237-41-RP-0001) to assess which type of thermal oxidiser would meet AbbVie’s requirements. This is included in Attachment of this application.

Attachment B.1

Certificate of Incorporation for AbbVie Ireland NL B.V.

Uittreksel Handelsregister
Kamer van Koophandel

KvK-nummer 55023177

Rechtspersoon

RSIN	851533504
Rechtsvorm	Besloten Vennootschap
Statutaire naam	AbbVie Ireland NL B.V.
Statutaire zetel	Zwolle
Eerste inschrijving handelsregister	02-04-2012
Datum akte van oprichting	30-03-2012
Datum akte laatste statutenwijziging	01-07-2012
Geplaatst kapitaal	EUR 240.930.000,00
Gestort kapitaal	EUR 240.930.000,00
Deponering jaarstuk	De jaarrekening over boekjaar 2012 is gedeponeerd op 19-12-2013.

Onderneming

Handelsnaam	AbbVie Ireland NL B.V.
Startdatum onderneming	30-03-2012 (datum registratie: 02-04-2012)
Activiteiten	SBI-code: 2120 - Vervaardiging van farmaceutische producten (geen grondstoffen) SBI-code: 46461 - Groothandel in farmaceutische producten
Werkzame personen	0

Vestiging

Vestigingsnummer	000024724262
Handelsnaam	AbbVie Ireland NL B.V.
Bezoekadres	Meeuwenlaan 4, 8011BZ Zwolle
Telefoonnummer	0384256500
Datum vestiging	30-03-2012 (datum registratie: 02-04-2012)
Activiteiten	SBI-code: 2120 - Vervaardiging van farmaceutische producten (geen grondstoffen) SBI-code: 46461 - Groothandel in farmaceutische producten Het verwerven van de onderneming met merkproducten van Abbott Ireland; het aankopen, verkopen, importeren, exporteren, produceren en distribueren, en de commerciële toepassing van farmaceutische, ziekenhuis, voeding gerelateerde, chemische, diagnostische, medische en aanverwante producten; het verwerven, verkopen, exporteren en beschikbaar stellen van licenties; houdstermaatschappij.
Werkzame personen	0

Enig aandeelhouder

Naam	AbbVie Ltd
Bezoekadres	Clarendon House 2, Church Street, Hamilton HM 11, Bermuda
Ingeschreven in	Registrar of Companies The Islands of Bermuda, Bermuda onder nummer 35511

Uittreksel Handelsregister
Kamer van Koophandel

KvK-nummer 55023177

Enig aandeelhouder sedert	01-07-2012 (datum registratie: 04-07-2012)

Bestuurders

Naam	Chase, William Joseph
Geboortedatum en -plaats	01-12-1967, Southfield, Michigan, Verenigde Staten van Amerika
Datum in functie	01-01-2013 (datum registratie: 10-07-2013)
Titel	Directeur
Bevoegdheid	Alleen/zelfstandig bevoegd
Naam	McEwen, Sean Paul
Geboortedatum en -plaats	15-06-1975, Letterkenny, Donegal, Ierland
Datum in functie	01-01-2013 (datum registratie: 10-07-2013)
Titel	Directeur
Bevoegdheid	Alleen/zelfstandig bevoegd
Naam	Egan, James Patrick
Geboortedatum en -plaats	26-01-1963, Roscommon, Ierland
Datum in functie	01-01-2013 (datum registratie: 10-07-2013)
Titel	Directeur
Bevoegdheid	Alleen/zelfstandig bevoegd
Naam	Benes, Russell John
Geboortedatum en -plaats	17-11-1976, Illinois, Verenigde Staten van Amerika
Datum in functie	07-07-2014 (datum registratie: 23-07-2014)
Titel	Directeur
Bevoegdheid	Alleen/zelfstandig bevoegd

Uittreksel is vervaardigd op 23-07-2014 om 14.12 uur.
Voor uittreksel

mw. Hankie van Baasbank, Raad van Bestuur

The Netherlands Chamber of Commerce Commercial Register extract

Commercial Register No. 55023177

Legal entity

RSIN	851533504
Legal form	Private Limited Liability Company (Besloten Vennootschap)
Statutory name	AbbVie Ireland NL B.V.
Corporate seat	Zwolle
First entry in Commercial Register	02-04-2012
Date of deed of incorporation	30-03-2012
Date of deed of last amendment to the Articles of Association	01-07-2012
Issued capital	EUR 240.930.000,00
Paid-up capital	EUR 240.930.000,00
Filing of the annual accounts	The annual accounts for the financial year 2012 were filed on 19-12-2013.

Company

Trade name	AbbVie Ireland NL B.V.
Company start date	30-03-2012 (registration date: 02-04-2012)
Activities	SBI-code: 2120 - Manufacture of pharmaceutical preparations SBI-code: 46461 - Wholesale of pharmaceutical goods
Employees	0

Establishment

Establishment number	000024724262
Trade name	AbbVie Ireland NL B.V.
Visiting address	Meeuwenlaan 4, 8011BZ Zwolle
Telephone number	+310384256500
Date of incorporation	30-03-2012 (registration date: 02-04-2012)
Activities	SBI-code: 2120 - Manufacture of pharmaceutical preparations SBI-code: 46461 - Wholesale of pharmaceutical goods For further information on activities, see Dutch extract.
Employees	0

Sole shareholder

Name	AbbVie Ltd
Visiting address	Clarendon House 2, Church Street, Hamilton HM 11, Bermuda
Registered in	Registrar of Companies The Islands of Bermuda, Bermuda under number 35511
Sole shareholder since	01-07-2012 (registration date: 04-07-2012)

Board members

The Netherlands Chamber of Commerce Commercial Register extract

Commercial Register No. 55023177

Name	Chase, William Joseph
Date and place of birth	01-12-1967, Southfield, Michigan, United States of America
Date of entry into office	01-01-2013 (registration date: 10-07-2013)
Title	Director
Powers	Solely/independently authorised
Name	McEwen, Sean Paul
Date and place of birth	15-06-1975, Letterkenny, Donegal, Ireland
Date of entry into office	01-01-2013 (registration date: 10-07-2013)
Title	Director
Powers	Solely/independently authorised
Name	Egan, James Patrick
Date and place of birth	26-01-1963, Roscommon, Ireland
Date of entry into office	01-01-2013 (registration date: 10-07-2013)
Title	Director
Powers	Solely/independently authorised
Name	Benes, Russell John
Date and place of birth	17-11-1976, Illinois, United States of America
Date of entry into office	07-07-2014 (registration date: 23-07-2014)
Title	Director
Powers	Solely/independently authorised

Extract was made on 23-07-2014 at 14.12 hours.
For extract

mw. Hankie van Baasbank, Raad van Bestuur

Attachment B.2

Site Location Map

IE0311237-22-DR-0001

NOTES

1. THIS DRAWING IS TO BE READ IN CONJUNCTION WITH ALL RELEVANT ARCHITECTS AND ENGINEERS DRAWINGS AND SPECIFICATIONS.
2. DO NOT SCALE, USE FIGURED DIMENSIONS ONLY.
3. ANY DISCREPANCIES TO BE REPORTED TO THE ARCHITECT.
4. ALL DIMENSIONS ARE IN MILLIMETERS.
5. ALL LEVELS ARE IN METRES RELATIVE TO ORDNANCE SURVEY DATUM AT MALIN HEAD.

LEGEND

SITE BOUNDARY

PROPERTY BOUNDARY

RATHBRAGHAN

LOCATION OF NEW THERMAL OXIDISER

FORMAL ISSUE
20150902.163821 – MCMABY

ISSUE	DESCRIPTION	DRN	ORIG	AUTH CHK	APP	DATE
A	PRELIMINARY	BM	CR	CR	MD	02/09/15

CLIENT ABBVIE IRELAND NL B.V. - MANORHAMILTON ROAD

PROJECT VOC ABATEMENT

TITLE INDUSTRIAL EMISSIONS LICENCE REVIEW APPLICATION SITE PLAN

CLIENT REF.	CLIENT DRG No.
PROJECT No. IE0311237	
A0 SCALE 1:1250	DRG No. IE0311237-22-DR-0001

THIS DRAWING WAS CREATED USING: AutoCAD

IE0311237_22_DR_0001

Attachment B.6 (i)

Section 5 exemption from Sligo County Council

COMHAIRLE CHONTAE SHLIGIGH
ÁRAS AN CHONTAE COIS ABHAINN SLIGEACH

SLIGO COUNTY COUNCIL
COUNTY HALL RIVERSIDE SLIGO

T +353 71 911 1111
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E info@sligococo.ie
W www.sligococo.ie

REGISTERED POST

13th December 2013

File Ref: ED 170

PM Rec'd. Original to File No:
Date: 16 DEC 2013
Copy to:
Action:

AbbVie Ireland N L B.V.
c/o Paul Heade – PM Group
Killakee House
Belgard Square
Tallaght
Dublin 24

Re: Application for exemption in accordance with Section 5 of the Planning and Development Act 2000 (as amended) in respect of installation of new thermal oxidiser plant at Manorhamilton Road, Co. Sligo

---

I enclose herewith a declaration in accordance with Section 5 of the Planning and Development Act, 2000 (as amended) in respect of the following:

Name & Address of Applicant:	AbbVie Ireland N L B.V., Manorhamilton Road, Sligo
Declaration Requested for:	Installation of new thermal oxidiser plant
Location:	Manorhamilton Road, Sligo
File Reference:	ED 170
Application Received:	4th December 2013

Where a Declaration is issued under this Section, any persons may, on payment to An Bord Pleanala of such fee as may be prescribed, refer a declaration for review to the Board within four weeks of the date of issuing of the declaration by Sligo County Council.

Signed on behalf of Sligo County Council

Kevin Colreavy
ADMINISTRATIVE OFFICER
PLANNING SECTION

sligo.ie

SLIGO COUNTY COUNCIL
(Comhairle Chontae Shligigh)

MANAGER'S ORDER

P523/13
ED/170

APPLICATION FOR DECLARATION OF EXEMPTED DEVELOPMENT PURSUANT TO SECTION 5 OF THE PLANNING & DEVELOPMENT ACT 2000 (AS AMENDED)

Name & Address of Applicant:	AbbVie Ireland N L B.V., Manorhamilton Road, Sligo
Declaration Requested for:	Installation of new thermal oxidiser plant
Location:	Manorhamilton Road, Sligo

Having regard to:

i. The details submitted under Exemption Certificate ED/170 received on 4th December 2013.
ii. Any submissions and observations received.
iii. The provisions of the Planning and Development Acts and Regulations.

The Planning Authority considers that:

i. Installation of new thermal oxidiser plant is development and is exempted development.

Reasons and Considerations:

i. Sections 2, 3 and 4 of the Planning and Development Act 2000, as amended.
ii. Articles 6 and 9 and Schedule 2 of the Planning and Development Regulations 2001, as amended.

Order: **Pursuant to Section 5 of the Planning & Development Act 2000, Sligo County Council hereby decides that the said installation of new thermal oxidiser plant is development and is exempted development.**

Director of Services

13/12/13
Date

To whom this function has been delegated in accordance with the provisions of Section 154 of the Local Government Act, 2001, by Order No. 7/13 dated the 9th May 2013

Attachment B.6 (ii)

Planning History and Environmental Impact Review

1 Planning History & Environmental Impact Review

The following review provides a summary of how the planning and development of the site since the original pharmaceutical manufacturing facility planning application considered the environmental impacts of additional development throughout the evolution of the site.

The review primarily deals with planning associated with major development works on site which had the potential for environmental impact.

This review deals with the environmental impact of the subjects that are within the functional remit of the Environmental Protection Agency, namely, Air, Water, Ground, Noise and Waste.

A letter from Sligo County Council has been provided (Attachment B.6) confirming that the planning authority did not deem that an Environmental Impact Assessment was required for any of the subsequent planning applications since the original planning application for the site.

2 Planning Application 01481, PL01/481 (Granted 04/09/2001)

Abbott Ireland chose the site specifically to manufacture active pharmaceutical ingredients and drug products. The site for the then new pharmaceutical manufacturing facility straddled the boundary between Sligo County Council and Sligo Borough Council (formerly called Sligo Corporation). Initial planning permission was obtained from both local authorities in September 2001. The planning applications were accompanied by an Environmental Impact Statement (EIS). The EIS described the existing environment at the site of the facility, the likely impact the facility would have on the environment, the mitigation measures which would be taken and any residual impacts. These descriptions covered a wide range of environmental topics such as human beings, flora and fauna, air and noise, soil and water, climatic factors and landscape, material assets and cultural heritage.

A copy of the EIS has been provided with this licence review application. The reader is referred to the EIS and its non-technical summary for a detailed description of the existing environment and the environmental effects of the original development.

2.1 Integrated Pollution Control (IPC) Licence

Abbott Ireland applied for an IPC Licence in 2002. The original IPC licence (Reg. 643) set out the conditions with which the Abbott Ireland Pharmaceutical Operations facility must comply, in order to operate the facility. The licence set limits on emissions from the facility to air and to the sewer, on the noise emissions and on the quantities of waste, which the facility could generate. Permission to use the existing thermal oxidiser was granted under this licence

Other conditions related to the management of the facility, the maintenance of equipment, the monitoring of emissions and the reporting of environmental data to the EPA.

3 Planning Application 041528, (Granted 24/02/2005)

As part of Abbott Ireland's on-going commitment to the development and growth of the site, Abbott initiated a new project (Project Apollo) to increase the manufacturing capacity of this facility. This involved a number of works site wide and included for;

- 2 No. additional manufacturing cells were added to the existing vacant space within the sites Bulk Pharmaceutical Building (Building 40).
- 4 No. new bulk storage tanks were added to the tank farm
- Drum Store Expansion
- New VOC Abatement Plant (Cryogenic Condenser)

Planning permission for the Project Apollo was obtained in 24/02/2005. An EIS was not required to accompany the planning application as the proposed activities were not covered by EC (Environmental Impact Assessment) Regulations, 1989-2001. A copy of the planners report, planning decision along with the applicant's environmental report has been provided with this licence review application.

3.1 IPPC Licence Review

Abbott was issued with a new IPPC licence (Ref No.P0643-02) in 2005 after a review which accounted for a number of changes on site due to project Apollo. This review provided for the addition of two contained manufacturing cells in the existing Bulk Pharmaceutical Building for the manufacture of two new Active Pharmaceutical Ingredients, the addition of a Kilo Laboratory, the introduction of a cryogenic condenser abatement system for the treatment of gaseous exhaust streams containing dichloromethane, additional tanks in the tank farm area and an expansion to the drum storage area. The existing utilities on site were adequate to supply the new proposed equipment.

The key changes in terms of environmental impact included;

3.1.1 Air Impacts

One of the main environmental impact concerns of the project was the installation of a new air abatement system at the facility primarily for the treatment of dichloromethane air emissions but also to act as a back-up to the existing on-site thermal oxidiser. In accordance with EU Directive IPPC 96/61/EC (now superseded by the Industrial Emissions Directive 2010/75/EU) and the introduction of the Protection of the Environment Act 2003, Abbott used the concept of Best Available Techniques (BAT) in deciding on a suitable air abatement technology.

The vent from the new air emission abatement system (Cryogenic Condenser) was routed to the existing emission point A2-1 through which the existing TO currently vented to atmosphere. Detailed air dispersion modelling was conducted by the facility to assess impact of these new emissions on the environment.

Other minor emissions related to the works included;

- The hydrogen vent from the new hydrogenation reactor vessel introduced a new minor emission point to the site. There would be low levels of fugitive emissions from this vent.
- There would be fugitive emissions points from two out of the four new tanks in the tank farm area. These fugitive emissions would not contain any chlorinated solvents.
- The vents from the other two new tanks at the farm tank, would contain fresh and contaminated dichloromethane, and would be routed to the new air emission abatement system for treatment.

3.1.2 Emissions to Surface Water

There was no impact on emissions to surface water as a result of the new works.

3.1.3 Emissions to sewer

There will was increase in the volumes of effluent emitted to sewer as a result of the introduction of the new API's to the plant. The aqueous waste streams would continue to be tested in accordance with Condition 6.7 of the licence to ensure they are suitable for release to sewer.

3.1.4 Protection of Groundwater

All the new tanks would be bunded to contain the contents of the tank in the event of a leak. The bunds were built in accordance with EPA guidelines.

3.1.5 Noise Emissions

There would be no impact on noise emissions as a result of the introduction of the new operations at the facility. All external equipment was designed so that noise was minimised. Noise was also monitored and verified during the construction and commissioning phase of the project.

3.1.6 Waste Emissions

Waste solvent containing dichloromethane (chlorinated waste) would be stored in one of the new tank farm tanks. This would be a dedicated waste tank for this type of waste solvent. This solvent would be transferred off-site for disposal in accordance with current waste legislation.

Waste solvent, not containing dichloromethane (non-chlorinated waste) from the two new processes would be stored in one of the existing tank farms tank. Again, this solvent would be transferred off-site for disposal in accordance with current waste legislation.

4 Planning Application 1270012 (Granted 19/04/2012)

4.1 Planning

This planning application related to significant works site wide including alterations and extensions to 3 No. buildings on the existing Abbott Ireland Pharmaceutical Campus as follows:

(a) 2 No. 3 storey extensions to the existing Administration / Laboratory Building approximately 1661m^2 in area (height 15.6m) located to the east and west of this facility and alterations to the existing south facade;

(b) 2 No. single storey extensions approximately 2072m^2 in area (height 13.5m) to the existing Production / Tableting Building with internal mezzanines, located to the east and west of this facility

(c) An extension to the existing single storey high bay Warehouse (including relocated docks) to the west of the existing 3 storey Manufacturing Building approximately 380m^2 in area (height 16.6 m);

(d) The proposed works also include an inter-building 2 storey link approximately 787m^2 in area (height 13.5 m) directly located to the west of a proposed link currently subject to planning (planning reference number PL 11/411);

(e) Alterations to building facades to include roof mounted equipment, external stairs and miscellaneous single storey porches to all buildings;

(f) Ancillary works include 42 no additional car spaces and revisions to roads and services, including pipe bridges, bunded tanks with canopy over and revised landscaping.

Supplemental environmental reports to the parent EIS accompanied this planning application.

The reports were produced by AWN Consulting & Environmental Impact Services. These reports are included with the Environmental Impact Statement and Environmental Reports submission supporting the application. The environmental reports assessed any potential environmental effects arising from the subject alterations and expansion development, as follows:

- Landscape & Visual Impact Assessment
- Noise Assessment
- Air Quality and Climate Assessment
- Soils, Geology and Hydrogeology Assessment
- Hydrology Assessment
- Traffic Impact Assessment

An Appropriate Assessment Screening report was also prepared which assessed potential ecological impacts with particular focus on EU designated ecological sites.

The conclusions found that the proposed development would pose no significant environmental effect and EIS would not be required to be lodged with the planning application. Additional EIA was considered not applicable by Sligo County Council.

4.1.1 Air Impacts

There was no new air emission points required as part of the proposed expansion. Monitoring would continue as per the IPPC licence. In terms of impact from traffic, the operational impact of the expansion was assessed using the UK DRMB Screening Model. The impact was deemed negligible.

4.1.2 Emissions to Surface Water

The proposed works increased the impermeable area of the site by approximately 0.2 hectares i.e. 5.8 %. The original surface water drainage system was originally designed to allow for future

expansion. The sites surface water would continue to drain to the retention pond via a hydrocarbon interceptor before discharging to the on-site stream via a flow control device. The mitigation measures as a result of the development would follow the same strategy as previously. Measures included control of surface water runoff, the use of hydrocarbon interceptor, bunded tanks/ drum storage, adherence to the facilities Environmental Management Programme, loading/unloading of the chemicals in bunded areas and regular testing of bunds, drains, lines and also continuous surface water monitoring.

It was deemed that the proposed expansion would have imperceptible residual impact on the environment.

4.1.3 Emissions to sewer

The proposed expansion would generate additional domestic and process wastewater. The additional process wastewater volumes would be approximately 45m^3/day and a maximum of 180m^3/week. Abbotts IPPC limit at the time was 230m^3/day, therefore even with the proposed increases, the daily discharges would still be well below the limit. Monitoring as per the IPPC licence would continue as before.

It was deemed that the proposed expansion would have imperceptible residual impact on the environment.

4.1.4 Protection of Groundwater

There were no operational impacts from the expansion. Mitigation measures to protect ground and groundwater would follow the same strategy as before i.e. control of surface water runoff, the use of hydrocarbon interceptor, bunded tanks/ drum storage, adherence to the facilities Environmental Management Programme, loading/unloading of the chemicals in bunded areas and regular testing of bunds, drains, lines and also continuous surface water monitoring.

4.1.5 Noise Emissions

The noise levels at the noise sensitive locations in the vicinity of the site were predicted to remain unchanged as a result of the expansion.

5 Installation of New Thermal Oxidiser

5.1 Planning Requirements

The following key points are noted regarding the new Thermal Oxidiser installation:

- The proposed installation consists of external plant and equipment
- There is no requirement for a building as part of the works.
- The height of the highest point of the installation will be less than 15m (the exhaust stack)
- The location of the installation is the rear of the AbbVie facility and not easily visible from the public road or houses.
- There will be a requirement to excavate part of the mound to the rear of the facility and provide either a retaining wall or re-slope the mound. The removed material will be used elsewhere on the AbbVie site.
- Once the new Thermal Oxidiser installation is operational, the existing Thermal Oxidiser will be decommissioned and removed.

The Planning and Development Regulations 2001, allows for certain exempted developments under Schedule 2, Part 1 Class 21 as follows;

- The installation or erection by way of addition or replacement of plant or machinery, or structures of the nature of plant or machinery
- Any works for the provision within the curtilage of an industrial building of a hard surface to be used for the purposes of, or in connection with the industrial process carried on in the building

Conditions and Limitations of the Planning and Development Regulations 2001;

- Any such development shall not materially alter the external appearance of the premises of the undertaking.
- The height of any plant or machinery, or any structure in the nature of plant or machinery, shall not exceed 15 metres above ground level or the height of the plant, machinery or structure replaced, whichever is the greater.

In this regard, an application was made to Sligo County Council seeking an exemption in accordance with Section 5 of the Planning and Development Act 2000 (as amended) in respect of the installation of the new thermal oxidiser. Sligo County

5.2 Environmental Impact Considerations

AbbVie Ireland and PM Group are engaging with the EPA regarding a review of the sites Industrial Emissions Licence (Ref No.P0643-02).

The impact of the new thermal oxidiser on the existing EIS was assessed. The original EIS for the facility, which was submitted with the original planning application, stated that the pharmaceutical manufacturing plant would be flexible in nature. This would permit the company to manufacture new products apart from those specified in the EIS.

The introduction of the new thermal oxidiser will allow the AbbVie greater flexibility in the production of new drug products that require the use of chlorinated solvents in the manufacturing process as up to now only the Cryogenic Condenser could treat chlorinated waste gas streams. It is considered that there will be an improved environmental impact as a result of this proposed replacement due to improvements in the design of these units and age / performance of the equipment.

All technology and equipment associated with the new Thermal Oxidiser has been chosen based on Best Available Technique (BAT) concepts. A comprehensive BAT review will be included as per the requirements of *Section I.8 Environmental Considerations, Alternatives and BAT* of the licence review application.

An Appropriate Assessment Screening report which assesses potential ecological impacts with particular focus on EU designated ecological sites is also submitted with the licence review application (Attachment B.6)

5.2.1 Impact on Air Emissions

PM Group have carried out air dispersion modelling to ensure that atmospheric emissions from the new Thermal Oxidiser do not result in a contravention of applicable European and Irish Air Quality Standards (AQSs). Results from the air dispersion modelling assessment conclude that atmospheric emissions from the proposed thermal oxidiser will not result in ground level concentrations which exceed the relevant AQSs for the protection of human health, vegetation and the environment.

5.2.2 Impact on Surface Water

The proposed works increased the impermeable area of the site by approx. 1-2 % of the site area. The original surface water drainage system was originally designed to allow for future expansion. The sites surface water would continue to drain to the retention pond via a hydrocarbon interceptor before discharging to the on-site stream via a flow control device. The mitigation measures as a result of the installation would follow the same strategy as previously. Measures included control of surface water runoff, the use of hydrocarbon interceptor, bunded tanks/ drum storage, adherence to the facilities Environmental Management Programme, loading/unloading of the chemicals in bunded areas and regular testing of bunds, drains, lines and also continuous surface water monitoring.

It is deemed that the proposed thermal oxidiser installation would have negligible impact on the surface waters.

5.2.3 Impact on Sewer

The proposed installation will generate additional process wastewater due to blow down from the new scrubber. The additional process wastewater volumes would be approximately 2m^3/day. AbbVie's licence limit is 300m^3/day. The average daily discharge is approximately 191m^3/day, therefore even with the proposed increases, the daily discharges would still be well below the limit. Monitoring as per the licence would continue as before. Any emissions will be treated along with the rest of the sites effluent to comply with the emission limit values as set out in the licence before release to the public sewer.

It was deemed that the proposed installation would have imperceptible residual impact on the environment.

5.2.4 Impact on Groundwater

All new tanks associated with the new thermal oxidiser skid are bunded and hence there will be no impact on groundwater.

5.2.5 Noise Emissions

The new thermal oxidiser is replacing an existing thermal oxidiser. Predicted calculations indicate that there will be negligible impact from the new installation.

AbbVie has never had any noise complaints or recorded any exceedance of the noise emission limit values during any of the annual noise surveys.

5.3 Conclusion

AbbVie and PM Group put forward that the new thermal oxidiser will have no significant environmental effects and hence does not require additional Environmental Impact Assessment in addition to the extensive reporting that has been done on this subject over the development of the site.

Attachment B.6 (iii)

Planning Granted Table

Planning Authority Letter of Exemption for EIA

Final Decisions for Previous Planning Granted

Planners Reports for Previous Planning Granted