Submission No 1

Grainne Oglesby

From: Licensing Staff
Sent: 25 April 2018 08:05
To: Grainne Oglesby
Subject: FW: P1073-01
Attachments: cover letter for Shire Pharmaceuticals Emissions Licence.docx; Shire Pharmaceuticals - EPA Licence.docx

Sub for you

From: Lisa.Maguire@hse.ie [mailto:Lisa.Maguire@hse.ie]
Sent: 24 April 2018 16:42
To: Licensing Staff <licensing@epa.ie>
Subject: P1073-01

Hi
Please find enclosed submission report from the Health Service Executive on IE licence P1073-01, Shire Pharmaceuticals.

Kind Regards,
Lisa Maguire

Environmental Health Officer
Co. Clinic,
Navan
Co. Meath
046 - 9098754

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Dublin North East
Environmental Health Service
Co. Clinic
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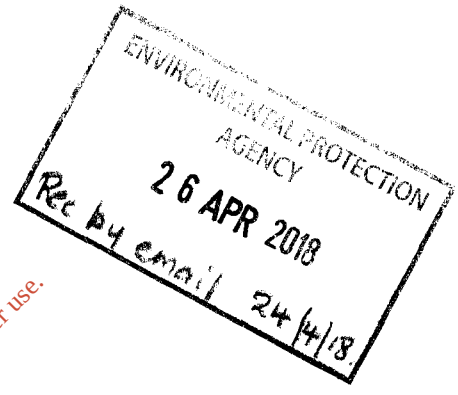
Mr. Patrick Doyle
Environmental Licensing Programme
Environmental Protection Agency Headquarters
PO Box 3000
Johnstown Castle Estate
Co. Wexford



24th April 2018

Re: Review of an Industrial Emissions Licence

Class and Nature of Activity:

5.16 Production of Pharmaceutical Products including intermediates.

Production, for the purposes of the activities mentioned in paragraph 5.12 to 5.17, means the production on an industrial scale by chemical or biological processing of substances or groups of substances mentioned in any of those paragraphs. The regulations do not define what is meant by 'industrial scale' however the proposed facility will be an industrial use.

Applicant: Shire Pharmaceuticals Ireland Limited

Reference No: P1073-01

EHIS Ref No: 0740

Dear Mr. Doyle,

Details of the review of the licence were circulated to the following Health Service Stakeholders on 23rd March 2018:

- Emergency Planning – Brendan Lawlor
- Assistant National Director for Health Protection – Kevin Kelleher / Marie Woods

- CHO – Pat Bennett
- Estates – Helen Maher, Estates Manager, Environmental Services.

The Environmental Health Service response to the application is in the attached consultation report.

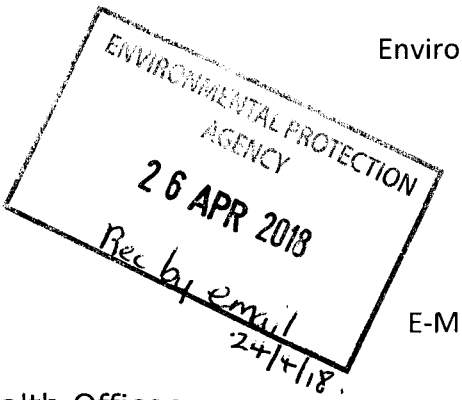
If you have any queries regarding the report the initial contact is Ms. Elish O'Reilly, Principal Environmental Health Officer, County Clinic, Navan, Co. Meath.

Yours Sincerely,

Elish O' Reilly

Elish O'Reilly
Principal Environmental Health Officer

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive



Dublin North East
Environmental Health Service
Co. Clinic
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Phone: 046 9098754
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Ms. Elish O'Reilly
Principal Environmental Health Officer
Co. Clinic
Navan
Co. Meath

20th April 2018

Re: Application for an Industrial Emissions Licence

Class and Nature of Activity:
The classes and nature of the industrial emissions directive activities in accordance with the First Schedule to the EPA Act of 1992 are:

5.16 Production of Pharmaceutical Products including intermediates.

Production, for the purposes of the activities mentioned in paragraph 5.12 to 5.17, means the production on an industrial scale by chemical or biological processing of substances or groups of substances mentioned in any of those paragraphs. The regulations do not define what is meant by 'industrial scale' however the proposed facility will be an industrial use.

Applicant: Shire Pharmaceuticals Ireland Limited

Location of facility: Piercetown, Dunboyne, Co. Meath, A86 HD21.

Reference No: P1073-01

EHIS Ref No: 0740

Dear Elish,

Shire Pharmaceuticals are applying to the EPA for an Industrial Emissions Licence for a new multi-product biopharmaceutical facility in Piercetown, Craddockstown and Ballymagillin Townslands, Dunboyne, County Meath. Planning permission was granted by Meath County Council on 19th October 2017, (Planning Reference RA 170887). The facility will also be regulated by the Health Products Regulatory Agency (HPRA).

The following are observations made whilst reviewing the said application, the EIAR and related documents in conjunction with EPA guidance documents and associated legislation. This report only focuses on the operational impacts of the development.

Description of project:
This facility is designed to manufacture four of Shire's existing Rare Disease products. However the facility has been designed in such a way to allow for the addition of other products during the life of the project. It consists of a Biopharmaceutical Production Building with related external plant and equipment, including boiler stacks 26 m high. A single storey Warehouse Facility with roof mounted plant and equipment and associated docking and yard areas. A laboratory and administration building including roof mounted plant and equipment. A permanent car park for 362 cars, a bunded tank farm, water and waste water, pipe bridges, cooling towers, gas storage facilities, emergency generators, a waste recycling compound and structures, items of plant and equipment and their associated yards, internal roads and services, fencing, exterior lighting, landscaping and landscape berms, and underground water attenuation tank and building mounted and ground mounted signage.

The facility intends to commence production in 2019 and will operate 7 days per week, 24 hours per day and is expected to employ 345 people onsite. An Environmental Management System will be in place at the facility to manage and control potential impacts from the facility on the environment

Site Location:
The site is primarily a greenfield site of approximately 50 ha, situated around 2.5 km north-west of Dunboyne and approximately 16 km to the north-west of Dublin City Centre. The site is bounded by the N3 to the west. The Fairyhouse and Trim junctions are located to the north of the site and Kilsaran concrete plant bounds the site to the south. The rest of the site is surrounded by agricultural lands with some low density rural residential landholdings throughout the area.

The nearest water courses are the Pinkeen Stream (a tributary of the Tolka River)400m to the northeast and the River Tolka, which is 400m to the southwest, downgradient of the facility. The Tolka River has a 'poor' status and is classed by Inland Fisheries Ireland *as 'under significant pressure from pollution.'*

The GSI classifies the bedrock aquifer as a Locally Important Aquifer, which is Moderately Productive only in Local Zones. It also describes the site as having a Low Vulnerability status. Groundwater is used by the local

community as a source of water supply. The Dunboyne public water supply is also sourced from groundwater in the area and there is a groundwater Source Protection Zone located approximately 1.2 km to the south west of the site. Chemical analysis of the groundwater carried out by the applicant indicates that the groundwater quality of the aquifer at present is very good and shows no evidence of industrial activity. There are no areas of conservation in the immediate vicinity of the site.

Human Beings:
The site notice advising of the licence application has been erected at three locations along the front of the Shire site. Notification of the Licence review application was also placed in the Irish Examiner on 15th March 2018. I could not find any mention of public consultation carried out in the EIAR. There is a requirement on the applicant to consult the public about their proposals and they should identify, assess and evaluate any concerns or issues the public may have in relation to the development.

No specific human health risk assessment has been carried out to estimate the potential human health effects related to potential emissions arising from the proposed development. There is an increased requirement in the EIA Directive 2014/52/EU to assess potential significant impacts on population and human health. It is however acknowledged that emission impacts were assessed in specific individual chapters and that in particular air emissions shall comply with air quality standards.

It is stated within the EIAR that the impacts on human beings are largely positive. "*The proposed development will have a positive long term impact on the immediate hinterland, the Town of Dunboyne and County Meath through continued expanded employment and the associated economic and social benefits.*"

Noise:
It is stated in the EIAR that the primary sources of noise from the operation of the facility are

1. Building Services and Factory Process Plant including cooling towers, air handling units, condenser units and rooftop mounted fans and exhaust units;
2. Two Emergency Diesel Generators and;
3. Additional vehicular traffic on public roads.

For noise assessment purposes it was assumed that all items of plant will operate continuously 24/7, although it is expected that the generators will only run occasionally, for example, when grid power fails and intermittently during daytime hours for testing purposes.

An environmental noise survey was conducted to quantify the existing noise environment in the vicinity of the site. The survey was conducted in accordance with *ISO 1996: 2007: Acoustics — Description, measurement and assessment of environmental noise.* Four noise monitoring locations surrounding the site were selected for the noise survey; these were in close proximity to the nearest noise sensitive receptors which were also identified. Reference has been made to the EPA's Guidance Note for Noise: *'Licence Applications, Surveys and Assessments in Relation to Scheduled Activities'* which sets out a procedure for applying appropriate operational noise limits from this type of facility at the nearest noise sensitive receptors taking account of the background noise environment. The results of the noise survey placed the noise levels above the criteria for a low background noise area and so the following noise limits will apply, Daytime 55dB, Eveningtime 50dB, nighttime 45dB.

Noise modelling was carried out using the Brüel & Kjær Predictor Type 7810 proprietary noise calculation package and calculations were based on *'ISO 9613: 1996: Acoustics – Attenuation of sound outdoors – Part 2: General method of calculation'.* All proposed plant items associated with the operation of the facility were included and noise levels were predicted at a total of 14 noise sensitive receptors. All predicted operational noise levels (which are worst case scenarios) are stated to be below the acceptable noise limits, including when the generators are running. No noise mitigation measures are required. It is stated that annual noise monitoring is proposed at 3 no. noise sensitive locations on an annual basis.

The additional traffic generated during the operational phase will primarily relate to the employee and personnel vehicle movements between shift changes. The peak hours for operational traffic are expected to occur between 07:30 and 08:30 in the morning and 17:00 and 18:00 in the evening with the bulk of the traffic accessing the site from the R147 and then onto the M3 Motorway. It is stated the potential for noise impact along this route is minimal since there are no noise sensitive receivers located along the route. There are no specific guidelines or limits relating to traffic related sources along the local or surrounding roads. In order to assess the potential noise impact from any changes in road traffic, the assessment guidance of 3dB change was used to quantify the likely impacts. The impact assessment has concluded that this development will not result in any perceptible noise impact and that predicted noise levels associated with the day to day operations of the site will be well within the proposed criteria applicable to a site of this nature.

The proposed development will adopt and implement a Mobility Management Plan which will lower the potential traffic impacts. Some of

the measures include the promotion of car sharing, car pools and the promotion of public transport, cycling and walking for travel to work. Shire will also run a shuttle bus service between the site and M3 Parkway Railway Station during peak commuting hours to encourage staff travel by rail. Bicycle parking is also provided at the site however there are no direct cycle routes or footpaths to the site itself.

It is stated that the proposed development will not give rise to any significant levels of vibration in the receiving environment during its operation.

Air:
There is the potential for a number of emissions to the atmosphere during the operational phase of the development, in particular, boiler related air emissions from the two chimney stacks on site. Additional traffic generated due to the opening of the proposed development may also lead to the release of air pollutants. However it is stated the increase in traffic associated with the proposed development during the operational phase is not of the required magnitude to cause any significant impacts at nearby sensitive receptors according to TII guidance.

Air dispersion modelling was carried out to assess the concentrations of Nitrogen Dioxide (NO2) predicted to arise from the facility and the consequent impact on human health. The United States EPA's regulatory model AERMOD (Version 16216r) was used. Information on the physical environment, design details for all emission points on-site and a full year of meteorological data were all inputted into the model which then predicted ambient concentrations at various receptors for each hour of the meteorological year. The modelling covered an area of approximately 10 km2 with the site at the centre. It is stated this study adopted a worst-case approach which lead to an over-estimation of the actual levels that will arise, in keeping with good EIA practice.

The potential impact of NO2 emissions from the proposed facility on air quality were assessed in line with EU Directive 2008/50/EC and the EU (Air Quality Standards) Regulations 2011. The NO2 modelling results indicate that the ambient ground level concentrations are below the relevant air quality standards for NO2, even for worst case off-site receptors. It is stated in the EIAR *"with regards to the emissions from the boilers, provided each stack is built to a height of 27.3 m above local ground level respectively, the air impact assessment outlined above has demonstrated that mitigation measures are not required."*

Surface Water:
A Stage 1 Flood Risk Assessment was undertaken in line with '*The Planning System and Flood Risk Management (FRM) Guidelines for*

Planning Authorities' produced by the DoEHLG. The results of that assessment were that there is no significant risk of flooding at the site. Whilst flooding does occur along the Tolka River (1:100 year event) it is stated that the proposed attenuation measures will ensure that the rate of flow from the vicinity is sufficient to handle the 1:100 year flood event. As such, there will be no predicted significant impact from a flood event.

There will be no direct discharges of contaminated water to surface water during the operational phase. All proposed buildings will be served by a new surface water drainage network. The roofing will have rainwater harvesting and collection for greywater site uses. The roof system and the facility yard system will collect to a substantial underground rainwater attenuation tank to the front of the site. This attenuation tank has been appropriately sized to take into account the total area of impermeable surfaces, the volume required for the 100 year rainfall event, plus a 10% allowance for climate change. The proposed attenuation system will be equipped with a flow control chamber which will limit the surface water discharge to greenfield run-off rate in accordance with Sustainable Urban Drainage Systems (SuDS). Outflow from the attenuation system will link to the existing roadside surface water drainage ditch/swale to the front of the site. The surface water drainage system will be monitored as required by the EPA.

It is stated in the EIAR that surface water impacts could only occur due to accidental leakages from cars in the car park areas or accidental leakage from the bunded areas or effluent treatment system and chemicals during refuelling or transport.

Stringent controls and procedures will be put in place to prevent and minimize spills. Fuel and chemical storage tanks will be stored above ground within bunds with impervious bases. The design of all bunds will conform to standard bunding specifications - BS8007:1987. Drainage from the bunded area(s) shall be inspected and properly managed. All process materials, product and chemicals will be delivered to the site in tamper proof and/or lockable containers or tankers, which are approved for transport use. Any chemicals, oils, herbicides required for site maintenance will be stored in suitable contained areas.

Car parking shall be impermeable paving with a connection to existing drainage ditches. Swales shall be provided for attenuation during high rainfall. A petrol/oil interceptor will be located to the north of the attenuation tank. This will prevent discharge of oils/fuels which may potentially be present in surface water run-off from the car park and main building areas. Filter drains will also be installed on sections of the proposed surrounding swale preventing discharge of oils, fuels etc. within surface water run-off. Regular inspection and maintenance of oil interceptors will be undertaken.

Groundwater:
The proposed water demand for the development will be up to a maximum of 685m3 per day. Drinking water will be supplied via the public water main. Consultation with Irish Water has been undertaken and agreement has been made that there is sufficient capacity of the public water supply system to provide the required volume of water.

It is also proposed that a groundwater supply be developed on site as a secondary water source if required. The Dunboyne public water supply is sourced from groundwater and there is a groundwater Source Protection Zone located approximately 1.2 km to the south west of the site. Also numerous local residents have boreholes and private wells as their source of water.

Groundwater quality data assessed during the EIA process indicates that the groundwater quality of the aquifer at present is very good and shows no evidence of impact from human activity. All wells within 2k of the site were identified, however this was done through a desktop survey of the GSI well database which, as acknowledged by the applicant, may not be a fully comprehensive list. To assess the impact of utilising a borehole on site a 72-hour constant rate combined pumping test was undertaken in June 2016. The tests were undertaken at two trial well locations from which water for the facility would be extracted. A review of yields has shown that the aquifer is capable of supplying 400m3 per day if required. Monitoring of surrounding wells during pumping showed no impact on the water table outside the site area.

It is stated in the EIAR there will be no direct discharges of contaminated water to groundwater or soil during the operation of the facility. The only impact that could occur is due to accidental leakages from vehicles in the car park areas or accidental leakage from the bunded diesel storage tanks and/ or chemical releases during refuelling or transport. The operation of an Environmental Management Plan and implementation of control measures will minimise the likelihood of any spill or leaks at the site. Fuel and chemical storage tanks will be fully bunded, above ground in designated areas with an impervious loading area. Bunding will be to a volume in compliance with EPA standards. Drainage from the bunded areas will be to an interceptor and inspected and properly managed. All tanks, bunding and transfer pipelines will be tested regularly to confirm integrity. It is proposed that routine groundwater monitoring will be undertaken at two separate points.

Waste:

Solid Waste
The process is expected to generate three main categories of waste – biowaste, hazardous and non-hazardous waste.

1. Non-hazardous waste will be segregated for recycling/recovery/disposal and area waste stations will be located throughout the facility. Other wastes that will be generated on site in smaller quantities will include textiles (rags), cleaning products, aerosols, paints and furniture.

2. Hazardous waste will be segregated at source and will be packaged, labelled and transferred to the designated waste storage areas by Shire personnel. Waste management companies, as authorised by Shire, will be responsible for the transfer of waste off site to authorised recovery/disposal facilities.

3. All biowaste will be treated to deactivated it on site

    - All process generated biowaste plastics will be sent through a shredder and granulator to be reduced to plastic nuggets. The plastic nuggets will then be exposed to saturated plant steam to inactivate all viable cell matter. This treatment renders all the single-use process waste safe for recycling or sanitary disposal.

    - All process generated biowaste from the laboratory will be treated by autoclave to ensure it is deactivated. This allows it to be treated as general waste.

The deactivation of all bio-hazardous waste reduces the volume of solid waste material and also the cost of disposing of bio-hazardous waste material.

There shall be on-site segregation of all waste materials into appropriate categories. The main waste materials shall be stored in appropriately labelled bins or other suitable receptacles in the designated waste storage areas. Bins will be clearly identified with the approved waste type to ensure there is no cross contamination of waste materials. This will be checked by Shire's Operations and Management Technician.

Liquid Waste
The production process is also expected to generate four liquid waste streams, each of which will undergo different treatment prior to disposal.

1. Waste from the cell containing areas containing genetically modified organisms is collected in a dedicated closed collection system and pumped to a continuous thermal biowaste inactivation skid. The inactivated waste is then pumped to the site waste neutralization system.
2. Process waste which does not contain GMOs is collected in an open collection system and pumped to the site waste neutralization system.
3. A separate open waste collection system is provided for any process waste which cannot be handled by the local municipality and needs to be trucked offsite for disposal (e.g. high phosphate waste).
4. The fourth waste collection system recovers clear blowdown from the WFI stills and clean steam generators and HVAC cooling coil condensate and returns it to the site waste facility to be used as cooling tower make-up.

All waste types generated on site will be managed according to Shire's Waste Management Procedure which will comply with Irish and European waste management legislation. A dedicated Environmental Health and Safety Department will be responsible for overseeing the implementation of the Waste Management Procedure. The EHS department will also ensure that all waste contractors used by the facility and all recovery/disposal outlets, are suitable for use, appropriately authorised and audited as required. Records and copies of relevant documentation of all waste leaving the site shall be maintained on file. Waste management during the operational phase of the proposed development will follow the priorities of the waste hierarchy and avoid significant volumes of waste being sent unnecessarily to landfill.

Wastewater

Wastewater i.e. domestic effluent and trade effluent (post-treatment) will be discharged to the public sewer. (As described above all trade effluent shall be subject to flow balancing and pH neutralisation to ensure there are no impacts on the sewer). Shire has estimated that 550 m3/day will be discharged during the operation of this biopharmaceutical plant. Irish Water has advised that the receiving wastewater system will have the capacity to accept the proposed discharge. A new rising main sewer will be constructed from the site and will discharge to the sewer near Blanchardstown which eventually discharges to the Ringsend Wastewater Treatment Plant. Wastewater to be discharged is relatively low strength and has similar characteristics to domestic wastewater. The loading associated with the proposed discharge, as a percentage of Ringsend WWTP is insignificant when compared with the overall plant loading.

Emergency Response Procedures:
An on-site emergency preparedness plan will be generated and maintained, which details the required response of Shire's Emergency Response Team in the event of an incident on site. The emergency preparedness plan will include arrangements for contacting the emergency services and those people in the surrounding environment that might be affected.

Decommissioning & Closure
I could not locate a decommissioning plan for the facility.

Conclusions:

1. The Environmental Health Service recommends that meaningful public consultation is carried out with regards to this proposal. Any concerns the public may have in relation to the development must be addressed by the applicant.

2. Directive 2014/52/EU has an increased requirement to assess potential significant impacts on population and human health. In light of this and in conjunction with the requirements of the Healthy Ireland Initiative, The Environmental Health Service recommends that an assessment of the entire project is carried out to identify and explore opportunities for any possible health gain or benefit from the operation of the facility. These should be fully considered and implemented by the applicant. The implementation of the mobility management plan is a good example of this.

3. The Environmental Health Service recommends that a formal complaints procedure is implemented to resolve any possible issues or community concerns in relation to traffic, noise, air or water complaints. In particular when investigating noise complaints the Environmental Health Service considers that the methodology in *BS4142 Method for Rating Industrial Noise Affecting Mixed Residential and Industrial Areas* would be appropriate when assessing nuisance from noise impact of the operation. It is this department's opinion that adherence to specified noise limit values on site does not always protect sensitive receptors from noise nuisance. The Environmental Health Service also recommends that the annual noise monitoring carried out should be compared with the predicted results as outlined in the EIAR.

4. The air impact assessment carried out clearly states that each chimney stack should be built to a height of 27.3m. The description elsewhere throughout the EIAR states the chimney stacks are a

height of 26m. Please ensure the height requirements of the air impact assessment are complied with.

5. A Decommissioning Management Plan should be prepared for the facility. An Environmental Liability Risk Assessment should also be carried out to ensure there are no residual impacts arising from the closure of the facility.

Lisa Maguire

Lisa Maguire
Environmental Health Officer