Site Visit Report

The site visit process is a sample on a particular day of an installation's compliance with some of its licence conditions. Where non-compliance against a particular condition has not been reported, this should not be construed to mean that there is full compliance with that condition of the licence.

Instructions and actions arising from the visit shall be addressed, or where applicable noted, by the licensee in order to ensure compliance, to improve the environmental performance of the installation and to provide clarification on certain issues.

The licensee shall take the actions specified to close out the non-compliances and observations raised in this Site Visit Report.

The licensee may also be requested to provide a response to the Environmental Protection Agency (hereafter referred to as the Agency) in relation to the site visit report findings.

Licensee

Name of Installation	AbbVie Ireland NL B.V.
Licensee	AbbVie Ireland NL B.V.
Licence Register No.	P1087-1
CRO Number	906838
Site Address	Old Bundoran Road, Ballytivnan, Sligo, F91 K735
Site Visit Reference No.	SV22815

Report Detail

Issue Date	03/12/2021
Prepared By	Eimear Kelly

Site Visit Detail

Date Of Inspection	12/11/2021		
Time In	13:30	**Time Out**	14:45
EPA Inspector(s)	Eimear Kelly		
Additional Visitors			
Licensee Personnel and Role	Charlene Rooney, Environmental Health & Safety (EHS) Lead Jodie Fox, EHS Engineer John Gardiner, Facilities Team Lead		

Summary

The Agency carried out this site visit to evaluate the licensee's compliance with the requirements of the Licence.

The licensee was found to be non-compliant with its Licence at the time of the Agency site visit following review of groundwater monitoring documentation. One non-compliance was found in relation to groundwater contamination (incident Ref. No. INCI022104). Observations were raised in relation to labelling of emission points, waste management, planned manufacturing activities and storage of materials.

The issues raised require action to be taken by the licensee as specified in this report.

Site Areas Inspected

- General yard areas
- Boiler emission point Ref. Nos. A1-1 and A1-2
- Diesel generator
- Waste storage area
- Emissions to sewer SE1 composite sampler
- Storm water emission monitoring points Ref. Nos. SW1, SW2 and SW3
- Groundwater monitoring well Ref. Nos. MW1, MW2 and MW3.

Documents Inspected

- Foul and surface water drainage map
- Groundwater monitoring reports, Q2, Q3 and Q4 2021
- Environmental noise monitoring report, 2021
- Storm water monitoring reports, Q4 2021.

1. Health and Safety

		Answer	Condition Number	Non Compliance	Observation
1.1	Was safe and permanent access to sampling/monitoring points provided?	Yes	3.8		Yes

Comment / Action Required

Safe and permanent access to all on-site sampling and monitoring points was provided, however the boiler emission point Ref. Nos. A1-1 and A1-2 were not labelled.

Action required:

Clearly label all monitoring emission points in accordance with the Licence.

2. Site Specific Issues

		Answer	Condition Number	Non Compliance	Observation
2.1	Waste management	Checked	8.5		Yes

Comment / Action Required

Six drums labelled as containing solid hazardous waste material with potential liquid residue were found unbunded in a waste storage yard area.

Action required:

Clearly label and store all waste in areas protected against spillage and leachate runoff, in accordance with Condition 8.4.

		Answer	Condition Number	Non Compliance	Observation
2.2	Planned manufacturing activities	Checked	1.1		Yes

Comment / Action Required

The licensee gave an update in relation to the planned activities for the site. The production of pharmaceutical products including intermediates, has not commenced to date. The Agency had agreed to the clinical trial of Product 1 due to commence in December 2021.

Action required:

Submit a report to the Agency on the clinical trial one month after completion and contact the Agency when the licensee intends to commence the licensable activity which may take place at some point in 2022.

		Answer	Condition Number	Non Compliance	Observation
2.3	New product manufacturing	Checked	1.4		Yes

Comment / Action Required

The licensee communicated that manufacturing of a new product may commence in 2022.

Action required:

Ensure that any condition 1 alterations to the sites activities or any part thereof, shall be notified to the Agency for agreement prior to such activities commencing. This shall be submitted as a licensee return, request for approval, through EDEN.

		Answer	Condition Number	Non Compliance	Observation
2.4	Groundwater monitoring investigation	Checked	6.15.1, 11.4	Yes	

Comment / Action Required

The 2021 groundwater monitoring reports for Q2, Q3 and Q4 were reviewed following the site visit. The reports identified that a number of parameters were elevated at groundwater monitoring wells Nos. MW1, MW2 and MW3 including manganese, iron, conductivity and chloride. The licensee's rational for these elevated paraments is that it's likely related to be poor quality background water.

The licensee failed to notify the Agency as soon as practical following the detection of these parameters at concentrations above the groundwater threshold/limit values. The licensee also failed to arrange and carry out a comprehensive hydrogeological investigation of the site within twelve months of the date of the grant of the Licence.

This is non-compliant with Conditions 6.15.1 and 11.4 of the Licence.

Comment:

The investigation is being dealt with under incident Ref. No. INCI022104.

FOLLOW-UP ACTIONS

The licensee is required to complete the actions outlined in this site visit report within the specified timeframes. Where required, the licensee shall also respond to actions specified in Compliance Investigations and/or submit a response to this site visit report via the EDEN system. The licensee shall maintain a documentary evidence, for review by the Agency, that the prescribed actions were completed within the required timeframe.

(i) Compliance Investigations

The Agency may generate a Compliance Investigation through the EDEN system and issue instructions and actions to the licensee. The licensee will receive notification when an instruction or action is issued and the licensee must respond to the actions within the Compliance Investigation within the specified timeframe.

(ii) Response to Site Visit Report

Where the licensee is requested to (or wishes to) respond to the Agency in relation to this site visit report, the licensee may select the 'Make a Response' link on the actions taken by the licensee to address the issues raised in this site visit report and the target completion dates. This Licensee Public Response provides the licensee with an opportunity to inform both the Agency and the public about the implementing of actions set out in the Agency site visit report. The response must be submitted **within 30 calendar days** of the issue date of this site visit report.

(iii) Publication of Reports

The site visit report will be made available for public viewing via the Agency's Licence Enforcement Access Portal (LEAP), within one day of the issue date. The Site Visit Report and the Licensee Public Response will also be published on the Agency's website, www.epa.ie, 60 calendar days after the site visit report issue date (on the Licence Details Page for the relevant licence).

Please note that licensees are required to comply with the conditions of the licence at all times, and where non-compliance occurs, compliance must be restored within the shortest possible time. These actions will be verified during subsequent Agency visits. Please quote the above Inspection Reference Number in any correspondence in relation this Report.