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Reg No: P0013-05

11 November 2020

Dear Sir/Madam,

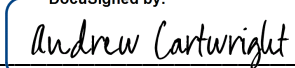
I refer to EPA correspondence dated 19 December 2019 relating to an application from Pfizer Ireland Pharmaceuticals, Ballintaggart, Ringaskiddy, County Cork for an Industrial Emissions licence review.

Irish Water have assessed the IE licence review application and are satisfied to recommend to the Agency the inclusion of the following conditions (overleaf) as part of a revised IE licence for Pfizer Ireland Pharmaceuticals. "Consent" to discharge trade effluent to the IDA pipeline under Section 99E of the EPA Act 1992, as amended, cannot be granted by Irish Water as the proposed trade effluent discharge is to a private drain/outfall pipe in ownership of IDA Ireland rather than the public sewer.

The management of discharges to and from the IDA pipeline, including the discharge from the Irish Water WWTP at Sharnally, requires resolution in terms of asset maintenance and regulations of discharges. Pending resolution of these issues, Irish Water offers the attached recommendation as suggested appropriate conditions to be considered by the EPA. These have regard for protection of assets and environmental quality taking consideration of combined discharges to the IDA pipeline. It should be noted however that review of individual discharge permissions to the IDA pipeline may be required to accommodate any future determination of appropriate standards for the combined discharge from the IDA outfall pipe.

If you have any further queries please do not hesitate to contact us.

Yours sincerely

DocuSigned by:

EBDF6E0E3CDD42C
Andrew Cartwright
Authorised Signatory

IRISH WATER RESPONSE

Irish Water
Colvill House
24/26 Talbot Street
Dublin 1

Name of Facility: Pfizer Ireland Pharmaceuticals **Reg. No:** P0013-05

Location Address: Ballintaggart, Ringaskiddy, County Cork

RECOMMENDED GENERAL CONDITIONS	Condition to be Included (Yes/No)
<p>1. No alteration to, or reconstruction in respect of, the activity, or any part thereof, that would, or is likely to, result in:</p> <p>(1) a material change or increase in:</p> <ul style="list-style-type: none"> i. the nature or quantity of any emission; ii. the abatement/treatment or recovery systems; iii. the range of processes to be carried out; iv. the fuels, raw materials, intermediates, products or wastes generated, or <p>(2) any changes in:</p> <ul style="list-style-type: none"> i. site management, infrastructure or control with adverse environmental significance; <p>shall be carried out or commenced without prior notice to, and without the agreement of, the Agency and/or Irish Water as appropriate.</p>	Yes
<p>2. The licensee shall maintain and implement a Schedule of Environmental Objectives and Targets. The Schedule shall, as a minimum, provide for a review of all operations and processes, including an evaluation of practicable options, for energy and resource efficiency, the use of cleaner technology, cleaner production and the prevention, reduction and minimisation of waste and shall include waste reduction targets, reduction and diversion of storm water runoff from sewer. The Schedule shall include time frames for the achievement of set targets and shall address a five-year period as a minimum. The schedule shall be reviewed annually.</p>	No
<p>3. The licensee shall maintain and implement a detailed programme for maintenance of all plant and equipment based on the instructions issued by the manufacturer/supplier or installer of the equipment.</p>	Yes
<p>4. Silt Traps and Oil Separators</p>	No

<p>The Licensee shall, within six months of date of grant of this licence Install and maintain silt traps and oil separators at the facility/installation:</p> <ul style="list-style-type: none"> ○ Silt traps to ensure that all storm water discharges, other than from roofs, from the facility/installation pass through a silt trap in advance of discharge; ○ An oil separator on the storm water discharge from yard areas. The separator shall be a Class I/Class II full retention/by-pass separator. <<EPA to select as appropriate>> <p>The silt traps and separator shall be in accordance with I.S. EN-858-2: 2003 (separator systems for light liquids).</p>	
<p>5. No specified emission from the installation shall exceed the emission limit values set out in <i>Schedule B: Emission Limits</i>, of this licence. There shall be no other emissions of environmental significance.</p>	Yes
<p>6. Other than the trade effluent authorised to be discharged under this licence, the licensee shall at no time discharge or cause or permit to discharge trade effluent or any other matter unless authorised in writing by Irish Water.</p>	Yes
<p>7. The licensee shall carry out such sampling, analyses, measurements, examinations, maintenance and calibrations as set out below and as in accordance with <i>Schedule C: Control & Monitoring</i>, of this licence.</p> <ul style="list-style-type: none"> ○ Sampling and analysis shall be undertaken by competent staff in accordance with documented operating procedures. ○ Such procedures shall be subject to a programme of Analytical Quality Control using appropriate control standards with evaluation of test responses. ○ Where any analysis is sub-contracted it shall be outsourced to a competent laboratory. 	Yes
<p>8. Monitoring and analysis equipment shall be installed, operated and maintained as necessary, so that all monitoring accurately reflects the emission/discharge.</p>	Yes
<p>9. In the event of any incident which relates to discharges to the IDA pipeline having taken place, the licensee shall notify Irish Water, in the manner prescribed by Irish Water, as soon as practicable after such an incident.</p>	Yes
<p>10. The licensee shall pay to the relevant Water Services Authority such sum as may be determined from time to time, having regard to the variations in the cost of providing drainage and the variation in effluent reception. Payment is to be made on demand.</p>	Yes
<p>11. The licensee shall ensure that any trade effluent generated from canteen activities shall pass through appropriate grease removal equipment prior to discharge.</p>	Yes

<p>12. A summary report of volumes of trade effluent and other matter discharged to the sewer along with monitoring and analysis data as specified in <i>Schedule B: Emissions</i> and <i>Schedule C: Control & Monitoring</i>, of this licence shall be forwarded to Irish Water in a manner and timeframe as may be specified.</p>	Yes
<p>13. The licensee shall undertake a desktop assessment and subsequent screening of trade effluent generated as a result of onsite activities for priority substances, priority hazardous substances and watchlist substances as listed in Tables 11,12 & 13 of S.I. No. 272/2009 – EC Environmental Objectives (Surface Waters) Regulations 2009, as amended. A report on the assessment and screening shall be submitted to Irish Water within twelve months of the date of grant of this licence.</p> <p>The licensee shall ensure that where substances are identified as being present in the trade effluent, measures are taken to reduce, eliminate or phase out their emission as required. The licensee shall also ensure that identified substances are assessed against potential risks to public health and the whole aquatic environment. The environmental assessment shall specifically assess resultant concentrations of substances in the receiving environment against their applicable environmental quality standards (EQS) and environmental objectives established by S.I. No. 272/2009.</p> <p>Subsequent desktop assessments, screenings and reports shall be repeated at intervals commensurate with changes to the characteristics of trade effluent as a result of the use of new raw materials (including cleaning/inactivation chemicals) in manufacturing processes onsite or as requested by Irish Water.</p>	Yes
<p>14. The licensee shall conclude an End User Agreement with Irish Water.</p>	Yes

<div>ADDITIONAL RECOMMENDED CONDITIONS</div> <div>In respect of discharges or emissions to sewers, in accordance with Section 99E of the Environmental Protection Agency Act 1992, as amended.</div> <div>(Specify, if required)</div>

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Limit Values for Process Effluent to IDA Pipeline**Schedule B: Emission Limits**

Emission Point Reference No.: TE1

Emission to (pipeline description): IDA pipeline located downstream of Irish Water's Ringaskiddy WWTP (Shanbally) which outfalls to Dognose Bank, Cork Harbour

Flow Rate (max per day) :**2900 m³/day**

Discharge Point Reference No.	TE1		
Parameter	Emission Limit Values*		
pH	6 - 9 pH units		
Toxicity	10 TU		
	Concentration (mg/l)	Load (kg/day)	Yearly average (BAT -AEL) (mg/l)
COD-Cr	5500	3900	300
Suspended Solids	500	1333	35
Ammonia-Total (as N)	75	200	-
Total Nitrogen	500	1333	-
Total Phosphorus (as P)	60	160	-
Manganese	60	160	-
Zinc	0.5	1.45	0.3
Copper	0.5	1.45	-

Frequency of Monitoring Process Effluent to IDA Pipeline

Schedule C

Emission Point Reference No.: TE1.

Parameter	Monitoring Frequency*	Analysis Method/Technique
Flow Rate	Continuous	On-line flow meter with recorder
pH	Continuous	pH electrode/meter and recorder
Temperature	Continuous	On-line temperature probe
TOC (as NPOC)	Continuous	On-line TOC meter with recorder
COD-Cr	Daily	Standard Method
BOD, 5 days with Inhibition (Carbonaceous BOD)	Monthly	Standard Method
Suspended Solids	Daily	Gravimetric
Ammonia-Total (as N)	Daily	Distillation Titration
Total Phosphorus (as P)	Daily	Standard Method
Manganese	Monthly	Atomic Absorption/ICP
Zinc	Monthly	Atomic Absorption/ICP
Copper	Monthly	Atomic Absorption/ICP
Chromium	Monthly	Atomic Absorption/ICP
Nickel	Monthly	Atomic Absorption/ICP
Adsorbable organically bound halogens	Monthly	Standard Method
Detergents	Monthly	Standard Method
Metals & Organic Compounds	Once off and As Required	Standard Method
Active Pharmaceuticals	As Required	Standard Method
Toxicity	Annually	To be agreed by the Agency

Note 1: All samples excluding those for pH and temperature shall be collected on a 24 hour flow proportional composite sampling basis.

Note 2: Sampling shall take place on alternate week days on a rolling basis to ensure representative samples are obtained for site operations which may vary across the working week.

Control of Emissions to IDA Pipeline

Control Parameter	Monitoring	Key Equipment
Forward feed equalisation (pH)	pH output from equalisation tank	Caustic/Acid Dosing Pumps
Feed Transfer	Flow/feed rate to aeration basins	Forward feed pumps
Dissolved Oxygen	DO in aeration basins	Air blowers
COD Input	COD concentration in equalisation tank	Standard laboratory test
Nutrient content	Nutrient content of forward feed to aeration basin	Standard laboratory test
Mixed Liquor Suspended Solids (MLSS)	MLSS in aeration basins	Standard laboratory test
Sludge Floc Microscopy	Sludge microscopy on aeration basin samples	Standard laboratory test
COD ex clarifier	COD concentration in clarifier overflow	Clarifiers and Standard laboratory test


Description of treatment:

Removal of Fats, Oil and Grease generated as a result of any canteen activities

Control Parameter	Monitoring	Key Equipment ^{Note 1}
Fats, oil and grease removal	Fats, oil and grease content in trade effluent as a result of canteen activities.	Grease removal equipment.

Note 1: Grease removal equipment shall comply with the requirements of European Standards (EN) or Plumbing and Drainage Institute (PDI) standards or as otherwise specified by Irish Water.

Yours sincerely

DocuSigned by:

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Authorised Signatory

Date: 11/11/2020