



Ms. Niamh Connolly
Environmental Licensing Programme,
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Reg No: P1094-01

13 March 2019

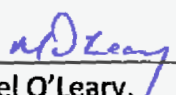
Dear Ms. Connolly,

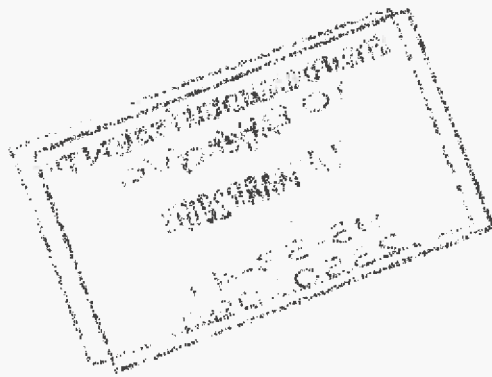
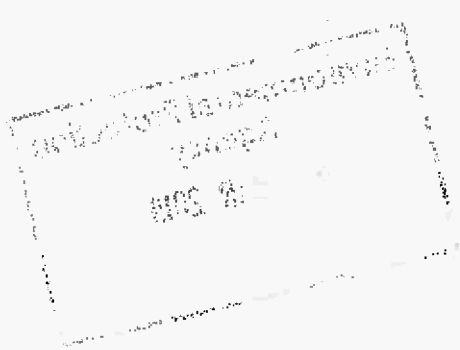
I refer to your correspondence dated 3rd December 2018 relating to an application from Alexion Pharma International Operations Unlimited Company, Monksland Industrial Estate, Monksland, Athlone, Co. Roscommon for an Industrial Emissions licence.

Please find attached Irish Water's consent to discharge to sewer subject to the consent conditions attached.

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

Yours sincerely


Michael O'Leary,
Authorised Signatory



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IRISH WATER RESPONSE

Irish Water
Colvill House
24/26 Talbot Street
Dublin 1



Name of Facility: Alexion Pharma International Operations Unlimited Company

Reg. No: P1094-01

Location Address: Monksland Industrial Estate, Monksland, Athlone, Roscommon, N37 DH79

Consent granted subject to the consent conditions outlined below.	Yes
Consent granted without conditions.	N/A
Consent refused ^{Note 1} .	N/A

Indicate either "Yes" or "No" to the request to include the condition(s) below in the licence as follows:

GENERAL CONSENT 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 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>any changes in:</p> <p>site management, infrastructure or control with adverse environmental significance;</p> <p>shall be carried out or commenced without prior notice to, and without the agreement of, the Agency.</p>	Yes
<p>2. The licensee shall prepare, maintain and implement (text highlighted in black bold for new licence only) / maintain and implement (text highlighted in green bold for reviews) a Schedule of Environmental Objectives and Targets. The Schedule shall, as a minimum, provide for a</p>	No

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.	
3. The licensee shall establish, 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.	Yes
4. Silt Traps and Oil Separators 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: 5. 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>> a. The silt traps and separator shall be in accordance with I.S. EN-858-2: 2003 (separator systems for light liquids).	No
6. 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.	Yes
7. 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 into sewer trade effluent or any other matter unless authorised in writing by Irish Water.	Yes
<ul style="list-style-type: none"> 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. <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
8. Monitoring and analysis equipment shall be installed, operated and maintained as necessary, so that all monitoring accurately reflects the emission/discharge.	Yes
9. In the event of any incident which relates to discharges to sewer having taken place, the licensee shall notify Irish Water and the Local Authority , in the manner prescribed by Irish Water, as soon as	Yes

practicable after such an incident.	
10. The licensee shall pay to Irish Water 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, treatment, monitoring, sampling and analysis costs. Payment is to be made on demand from Irish Water.	Yes
11. The licensee shall ensure that any trade effluent generated from canteen activities shall pass through appropriate grease removal equipment prior to discharge to sewer. <i>Inclusion of note in Schedule C Control of Emissions to sewer</i> Note: Grease removal equipment shall comply with EN or PDI standards or as otherwise specified by Irish Water.	Yes
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: Emission Limits to Sewer</i> and <i>Schedule C: Control & Monitoring</i> , of this licence shall be forwarded to both Irish Water and the Local Authority in a manner and timeframe as may be specified by Irish Water.	Yes
13. The licensee shall conclude an End User Agreement with Irish Water. <i>(End user Agreement to be inserted into the glossary: An agreement between the licensee and Irish Water which provides for the contractual conditions and arrangements (outside the terms and conditions set out in this licence) relating to the acceptance of, and treatment by, Irish Water of the licensee's trade effluent and wastewater.)</i>	Yes

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

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Limit Values for Process Effluent to Sewer

Schedule B: Emission Limits

Emission Point Reference No.: SE1

Emission to: 225mm IW Sewer, Monksland Industrial Estate, Athlone, Co. Roscommon

Volume of Trade effluent emitted:	Maximum in any one day:	86 m ³
	Maximum in any hour:	21 m ³

There are 3 separate monitoring points on site:

Emission Point Code	Monitoring/Sampling Point Code	Description
SE1	M1	Fill Finish Building
SE1	M2	Lab/Admin Building
SE1	M3	Biologics Building

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Discharge Point Reference No.	M1 (Fill Finish Building)	
Parameter	Emission Limit Values*	
Flow	48 m3/day	
Flow	10 m3/hr	
pH	6.0 – 10.0 pH Units	
Temperature	40 Celsius	
Toxicity (Toxicity Units**)	10 TU	
	Concentration (mg/l)	Load (kg/day)
BOD	400	4.8
COD	800	9.6
Total Suspended Solids	100	1.2
Chloride	2,000	24
Sulphates (as SO4)	300	14.4
Fats, Oils and Grease (FOG)	100	1.2
Detergents (as MBAS)	100	1.2
Orthophosphate (as P)	2	0.024

* Note: All samples with the exception of Flow (Continuous), pH (Grab Sample) and Temperature (Grab Sample) shall be taken on a 24-hour flow proportionate composite sampling basis. In this regard, a composite sample for testing purposes shall be defined as any sample extracted from the sampling apparatus between 8.00 am and 12.00 noon on any day for which normal operational activities have been ongoing for the previous 24 hours.

**Note: Toxicity Units (TU) are defined as: $TU = (100/x \text{ Hour EC50})$ where x is the relevant period of exposure and EC50 is expressed as % vol/vol.

M2 (Laboratory and Administration Building)	Discharge Point Reference No.	
	Parameter	
	Emission Limit Values*	
	Flow	3 m3/day
	pH	6.0 – 10.0 pH Units
	Temperature	40° Celsius
	Toxicity (Toxicity Units**)	10 TU
	Concentration (mg/l)	
	Load (kg/day)	
	BOD	400
	COD	800
	Total Suspended Solids	100
	Chloride	1000
	Sulphate	800
	Fats, Oils and Grease (FOG)	100
Detergents (as MBAS)	100	
Orthophosphate (as P)	2	
	0.006	

* Note: If required by Irish Water, all samples with the exception of Flow (Continuous), pH (Grab Sample) and Temperature (Grab Sample) shall be taken on a 24 hour flow proportionate composite sampling basis, otherwise a grab sample shall suffice. In this regard, a composite sample for testing purposes shall be defined as any sample extracted from the sampling apparatus between 8.00 am and 12.00 noon on any day for which normal operational activities have been ongoing for the previous 24 hours.

** Note: Toxicity Units (TU) are defined as: $TU = (100/x \text{ Hour EC50})$ where x is the relevant period of exposure and EC50 is expressed as % vol/vol.

Discharge Point Reference No.	M3 (Biologics Building)	
Parameter	Emission Limit Values*	
Flow	35 m3/d	
Flow	8 m3/hr	
pH	6.0 – 10.0 pH Units	
Temperature	40° Celsius	
Toxicity (Toxicity Units**)	10 TU	
	Concentration (mg/l)	Load (kg/day)
BOD	4,500	158
COD	9,000	315
Total Suspended Solids	100	4
Chloride	4,000	140
Sulphate	300	11
Fats, Oils and Grease (FOG)	100	4
Total Phosphorus (as P)***	250	3.4
Detergents (as MBAS)	100	4
Nitrate (as N)	250	9

* Note: All samples with the exception of Flow (Continuous), pH (Grab Sample) and Temperature (Grab Sample) shall be taken on a 24 hour flow proportionate composite sampling basis. In this regard, a composite sample for testing purposes shall be defined as any sample extracted from the sampling apparatus between 8.00 am and 12.00 noon on any day for which normal operational activities have been ongoing for the previous 24 hours.

** Note: Toxicity Units (TU) are defined as: $TU = (100/x \text{ Hour EC}_{50})$ where x is the relevant period of exposure and EC50 is expressed as % vol/vol.

***Note: The Total Phosphorus Load (kg/day) ELV may be increased from 3.4 kg/day to 8.75 kg/day depending on the performance of the Monksland WWTP and following the written agreement of Irish Water

Frequency of Monitoring Process Effluent to Sewer

Schedule C

Emission Point Reference No.:

SE 1

Discharge Point Reference No.	M1 (Fill Finish Building)	
Parameter	Monitoring Frequency*	Methodology
Flow	Continuous	On line flow meter with recorder
pH	Continuous	On-line pH Probe with Recorder
Temperature	Continuous	On-line Temperature Probe with Recorder
BOD	Monthly	CEN Standards
COD	Monthly	CEN Standards
Total Suspended Solids	Monthly	CEN Standards
Chloride	Quarterly	CEN Standards
Sulphate	Quarterly	CEN Standards
Fats, Oils and Grease (FOG)	Quarterly	CEN Standards
Total Phosphorus (as P)	Quarterly	CEN Standards
Detergents (as MBAS)	Quarterly	CEN Standards
Volatile Organic Compounds/Semi-Volatile Organic Compounds (VOC/SVOCs (according to US EPA Method 542.2 list)**	As Requested	CEN Standards
Active Pharmaceuticals	As Requested	CEN Standards
Toxicity	As Requested	CEN Standards
Respirometry	As Requested	CEN Standards

* Note: 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.

**Note: Analysis shall include those organic solvents in use in the process, which are likely through normal process operations to be present in the wastewater discharge.

Discharge Point Reference No.	M2 (Laboratory and Administration Building)	
Parameter	Monitoring Frequency*	Methodology
Flow	N/A	N/A
pH	As Requested	pH Probe
Temperature	As Requested	Temperature Probe
BOD	As Requested	CEN Standards
COD	As Requested	CEN Standards
Total Suspended Solids	As Requested	CEN Standards
Chloride	As Requested	CEN Standards
Sulphate	As Requested	CEN Standards
Fats, Oils and Grease (FOG)	As Requested	CEN Standards
Total Phosphorus (as P)	As Requested	CEN Standards
Detergents (as MBAS)	As Requested	CEN Standards
Active Pharmaceuticals	As Requested	CEN Standards
Toxicity	As Requested	CEN Standards
Respirometry	As Requested	CEN Standards

* Note: 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.

Discharge Point Reference No.	M3 (Biologics Building)	
Parameter	Monitoring Frequency*	Methodology
Flow	Continuous	On-line flow meter with Recorder
pH	Continuous	On-line pH Probe with Recorder
Temperature	Continuous	On-line Temperature Probe with Recorder
BOD	Monthly	CEN Standards
COD	Monthly	CEN Standards
Total Suspended Solids	Monthly	CEN Standards
Chloride	Monthly	CEN Standards
Sulphate	Quarterly	CEN Standards
Fats, Oils and Grease (FOG)	Quarterly	CEN Standards
Total Phosphorus (as P)	Monthly	CEN Standards
Detergents (as MBAS)	Quarterly	CEN Standards
Volatile Organic Compounds/Semi-Volatile Organic Compounds (VOC/SVOCs)(according to US EPA Method 542.2 list)**	Annually	CEN Standards
Active Pharmaceuticals	As Requested	CEN Standards
Toxicity	As Requested	CEN Standards
Respirometry	As Requested	CEN Standards

*Note: 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.

**Note: Analysis shall include those organic solvents in use in the process, which are likely through normal process operations to be present in the wastewater discharge.

Control of Emissions to Sewer

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.

Signed on behalf of Irish Water

MD Leary

Date 14/3/19

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