1. Background

Alkermes Pharma Ireland Limited (hereafter referred to as APIL) P0100-02 is an installation that produces finished and semi-finished pharmaceutical products (controlled release formulation), but no chemical synthesis occurs on-site. The products vary with markets and they currently produce about nine products in tablet form.

The installation is licensed under:

Class 12.2.1: The surface treatment of substances, objects or products using organic solvents, in particular for dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning or impregnating, with a consumption capacity of more than 150 kg per hour or more than 200 tonnes per year of the First Schedule to the EPA Act 1992 as amended.

The installation was first licensed to Elan Corporation plc. in 1997 (Licence Reg No. 100). The licence was subsequently revised on 19/04/2002 (Licence Reg. No. 603 (P0100-02)) and the revised licence was transferred to APIL (P0100-02) on 14/09/2011. Eight Technical Amendments (A, B, C, D, E, F, G and H) have previously been completed in relation to this licence Reg. No. P0100-02. The licence was amended for the purposes of Section 82A (11) of the EPA Acts 1992, as amended on the 18th December 2013. That amendment gave effect to the requirements of Directive 2010/75/EU (Industrial Emissions Directive).

2. Technical Amendment request

On the 01 June 2016, the Agency received a request for a Technical Amendment of IE licence P0100-02. The request relates to:
- Inclusion of three new emission points (NV1.07, NV1.08 and NV1.09) for particulates and API emissions only, due to the introduction of proprietary drug manufacturing at the installation;
- Removal of 10 redundant emission points (2.01 to 2.04, 2.06 to 2.09 and 3.05 to 3.06 inclusive);
- Replace the nomenclature for catalytic thermal oxidiser with Regenerative thermal oxidiser;
- Amend Condition 3.2.2 of the licence reference to '10% oxygen for thermal oxidisers' with 'no correction for oxygen for thermal oxidisers'.

<table>
<thead>
<tr>
<th>TO:</th>
<th>Director</th>
</tr>
</thead>
<tbody>
<tr>
<td>FROM:</td>
<td>Jennifer Cope Environmental Licensing Programme</td>
</tr>
<tr>
<td>DATE:</td>
<td>3 October 2016</td>
</tr>
<tr>
<td>RE:</td>
<td>Technical Amendment to Industrial Emissions Licence Register Number: P0100-02, held by Alkermes Pharma Ireland Limited, Monksland Industrial Estate, Athlone, County Roscommon.</td>
</tr>
</tbody>
</table>
3. Consultation with the Office of Environmental Enforcement (OEE)

I have consulted with the OEE inspector, Helen Boyce, in relation to this technical amendment request. The OEE confirmed that the proposed changes cannot be accommodated under the existing licence.

4. Assessment

The licensee requests the inclusion of three new emission points (NV1.07, NV1.08 and NV1.09) for particulates and API emissions only, due to the introduction of proprietary drug manufacturing at the installation and the removal of 10 redundant emission points, which would reduce the net mass emissions to air from the installation.

Impact of air emissions on the receiving environment

APIL had an air quality assessment (AQIA) (November 2015) completed on their behalf by PM Group. The air emission points considered included the three proposed emission points NV1.07, NV1.08 and NV1.09. The model used was AERMOD (Version 7.7), input parameters included meteorological data from Gurteen met station (2010-2014), topography, building effects and emission characteristics. The background concentrations for the area have been taken for Zone C (which includes Athlone) from the EPA 2014, *Air Quality in Ireland 2013, Key Indicators of Ambient Air Quality*.

The requested amendment does not permit any net increase in mass emissions to air from the installation. The 2015 model results, including background, indicates that the predicted environmental concentrations did not exceed the air quality standards for PM$_{10}$ and PM$_{2.5}$ and the derived environmental assessment levels for active pharmaceutical ingredients (API's). The API results are based on a highly conservative approach assuming a frequency of operation of 8,760 hours as opposed to actual batch and manufacturing campaign time periods, which for some API's is much lower. The API weighing and dispensing activities occur in dedicated isolators with double HEPA filtration on the outlets and hence emissions of API particles are not expected. The flow rates of the isolators are much lower than the emission points they feed into and hence constitute only a small percentage of the volumetric flow. The APIs are only a small constituent of the actual particles extracted at various stages of the manufacturing process.

On the basis of the air quality impact assessment completed on behalf of APIL and the above assessment, I am satisfied that a technical amendment of the IE licence under Section 96(1)(c) of the EPA Act 1992 as amended is appropriate to accommodate the new emission points and removal of the redundant emission points.

I recommend the following:

- **Schedule B.1 Emissions to Air** be amended to include emission points NV1.07, NV1.08 and NV1.09 the emission limit values for particulates and API to read 1 mg/Nm$^3$ and 0.15 mg/Nm$^3$ respectively and include the maximum flow rate to 3,000 m$^3$/hour for NV1.07 and 6,000 m$^3$/hour for NV1.08 and NV1.09.

- the redundant emission points 2.01 to 2.04, 2.06 to 2.09, 3.05 and 3.06 be deleted from **Schedule 1 (i) Emissions to Air** and **Schedule 1 (ii) Monitoring of Emissions to Atmosphere**.

- **Schedule 1 (ii) Emissions to Atmosphere: Abatement/Treatment Control** be amended to include emissions points NV1.49, NV1.50, NV1.51, 4.04, B9.33, NV1.07, NV1.08, NV1.09.
Schedule 1 (iii) Monitoring of Emissions to Atmosphere be amended to include quarterly monitoring of particulates for the new emission points NV1.07, NV1.08 and NV 1.09.

Schedule 1 (iii) Monitoring of Emissions to Atmosphere be amended to delete Note 1 for emission point NV1.06 as it is no longer required and amend the monitoring frequency in the table to quarterly and renumber Note 2 to Note 1 accordingly.

The licensee requests that the name for emission point NV3.00 to amended from 'catalytic thermal oxidiser' to Regenerative thermal oxidiser in the Schedule 1(i). According to the AER for 2015 the catalytic thermal oxidiser shut down in October 2015. The Office of Environmental Enforcement approved (LR016704) the relocation of emission point NV3.00 and the installation of a regenerative thermal oxidiser (RTO) to replace the catalytic thermal oxidiser on 26 June 2015. The licensee clarified that the minimum discharge height above ground has been amended from 13 m to 27 m and the maximum flowrate from 35,700 m$^3$ to 30,000 m$^3$/hour. Note 1 for elv on the table for NV3.00 and NV5.00 is out of date and no longer required. I recommend that Schedule 1(i) be changed to reflect these amendments. The new RTO does not require correction for oxygen as it does not introduce oxygen for combustion purposes. Therefore, I recommend that condition 3.22 of the licence be amended to remove '10% oxygen for thermal oxidisers' and replace with 'no correction for oxygen for thermal oxidisers'. This will not impact on the permitted mass emission.

5. Appropriate Assessment

Table 3.0 lists the European Sites assessed, their associated qualifying interests and conservation objectives.

A screening for Appropriate Assessment was undertaken to assess, in view of best scientific knowledge and the conservation objectives of the site, if the activity, individually or in combination with other plans or projects is likely to have a significant effect on any European Site. In this context, particular attention was paid to the European Site(s) specified in Table 3.0 below.

Table 3.0: List of European Sites assessed, their associated qualifying interests and conservation objectives.

<table>
<thead>
<tr>
<th>European Site (site code)</th>
<th>Distance/Direction from installation</th>
<th>Qualifying interests (* denotes a priority habitat)</th>
<th>Conservation objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>River Shannon Callows SAC (site code 000216)</td>
<td>1.85 km east of the installation</td>
<td><strong>Habitats:</strong> Molinia meadows on calcareous, peaty or clayey-silt-laden soils (Molinion caeruleae), Lowland hay meadows (Alopecurus pratensis, Sanguisorba officinalis), Limestone pavement*, Alluvial forests with Alnus glutinosa and Fraxinus excelsior (Alno-Padion, Alnion incanae, Salicion albae)*</td>
<td>As per NPWS (2015) Conservation objectives for River Shannon Callows SAC (site code 000216). Generic Version 4.0. Department of Arts, Heritage and the Gaeltacht (13/02/2015).</td>
</tr>
<tr>
<td>Middle Shannon Callows SPA (site code 004096)</td>
<td>1.85 km east of the installation</td>
<td><strong>Species:</strong> Whooper Swan (<em>Cygnus Cygnus</em>), Wigeon (<em>Anas Penelope</em>), Corncrake (<em>Crex crex</em>), Golden Plover (<em>Pluvialis apricaria</em>), Lapwing (<em>Vanellus vanellus</em>), Black-tailed Godwit (<em>Limosa limosa</em>), Black-headed Gull (<em>Chroicocephalus ridibundus</em>)</td>
<td>As per NPWS (2015) Conservation objectives for Middle Shannon Callows SPA (site code 004096). Generic Version 4.0. Department of Arts, Heritage and the Gaeltacht (13/02/2015).</td>
</tr>
<tr>
<td>Site Description</td>
<td>Distance from Installation</td>
<td>Habitats</td>
<td>Reference</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Castlesampson Esker SAC (site code 001625)</td>
<td>5.54 km west of the installation</td>
<td><strong>Habitats:</strong> Turloughs*, Orchid-rich calcareous grassland*</td>
<td>NPWS (2015) Conservation objectives for Castlesampson Esker SAC [001625]. Generic Version 4.0. Department of Arts, Heritage and the Gaeltacht</td>
</tr>
<tr>
<td>Ballynamona Bog and Corkip Lough SAC (site code 002339)</td>
<td>6.09 km north west of the installation</td>
<td><strong>Habitats:</strong> Turloughs*, Raised bog (active)<em>, Degraded raised bogs, Rhynchosporion depressions, Bog woodland</em></td>
<td>NPWS (2015) Conservation objectives for Ballynamona Bog and Corkip Lough SAC [002339]. Generic Version 4.0. Department of Arts, Heritage and the Gaeltacht</td>
</tr>
<tr>
<td>Crosswood Bog SAC (site code 002337)</td>
<td>6.75 km east of the installation</td>
<td><strong>Habitats:</strong> Raised bog (active)*, Degraded raised bogs</td>
<td>NPWS (2016) Conservation Objectives: Crosswood Bog SAC 002337. Version 1. National Parks and Wildlife Service, Department of Arts, Heritage and the Gaeltacht</td>
</tr>
<tr>
<td>Carn Park Bog SAC (site code 002336)</td>
<td>9.52 km northeast of the installation</td>
<td><strong>Habitats:</strong> Raised bog (active)*, Degraded raised bogs.</td>
<td>NPWS (2015) Conservation Objectives: Carn Park Bog SAC 002336, Version 1. National Parks and Wildlife Service, Department of Arts, Heritage and the Gaeltacht</td>
</tr>
<tr>
<td>Mongan Bog SAC (site code 000580)</td>
<td>9.75 km south of the installation</td>
<td><strong>Habitats:</strong> Raised bog (active)*, Degraded raised bogs, Rhynchosporion depressions</td>
<td>NPWS (2016) Conservation Objectives: Mongan Bog SAC 000580, Version 1. National Parks and Wildlife Service, Department of Arts, Heritage and the Gaeltacht</td>
</tr>
<tr>
<td>Fin Lough SAC (site code 000576)</td>
<td>11.20 km south of the installation</td>
<td><strong>Habitats:</strong> Alkaline Fens <strong>Species:</strong> Geyer's whorl snail <em>(Vertigo geyeri)</em></td>
<td>NPWS (2015) Conservation objectives for Fin Lough (Offaly) SAC [000576]. Generic Version 4.0. Department of Arts, Heritage and the Gaeltacht</td>
</tr>
<tr>
<td>Killeglan Grassland SAC (site code 002214)</td>
<td>13.92 km west of the installation</td>
<td><strong>Habitats:</strong> Orchid-rich calcareous grassland*</td>
<td>NPWS (2015) Conservation objectives for Killeglan Grassland SAC [002214]. Generic Version 4.0. Department of Arts, Heritage and the Gaeltacht</td>
</tr>
</tbody>
</table>

The activity is not directly connected with or necessary to the management of any European Site and the Agency considered, for the reasons set out below, that it can be excluded, on the basis of objective information, that the activity, individually or in combination with other plans or projects, will have a significant effect on any European Site and accordingly determined that an Appropriate Assessment of the activity was not required.

This determination is based on the following reasons:
- The installation is not located within any European site;
• The proposed changes do not substantially change the nature or extent of the operations and emissions at the installation from what was considered during the last review (P0100-02);
• Air dispersion modelling conducted for the licence review application (P0100-02), technical amendment B and E and for this technical amendment has demonstrated that the impact of air emissions from the installation on qualifying interests of any European site is negligible;
• As outlined in section 4. above, ten redundant emission points (2.01 to 3.06) are to be removed from the licence. There will be no overall net increase in emissions from the installation.
• While there is potential for accidents and unplanned releases from the installation, it is considered that the conditions of the licence in relation to bunding and the protection of surface water and groundwater, are sufficient to ensure that accidental emissions from the activity will not impact on the qualifying interests of any of the European sites identified above, particularly in light of the nature of the potential accidental emissions, and the distance and hydrological connectivity between the installation and any European site. The licence specifies accident prevention and emergency response requirements.

The Agency is satisfied that no reasonable doubt remains as to the absence of adverse effects on the integrity of those European sites specified.

6. Recommendation
This memo recommends that the requested changes be accommodated by a Technical Amendment of Licence P0100-02 (held by Alkermes Pharma Ireland Limited), in accordance with Section 96(1) (c) of the EPA Acts 1992 as amended.

I recommend that the licence amendment be approved as set out in the attached Recommended Technical Amendment. The making of the amendment will not result in the relevant requirements of Section 83(5) of the EPA Acts 1992 as amended ceasing to be satisfied.

Signed,

[Signature]

Jennifer Cope
Environmental Licensing Programme