

This Memo has been cleared for submission to the board by:  
Frank Clinton, Programme Manager

Signed: *Gráinne O'Leary* Date: *20/1/11*



OFF

**LICENSING &  
RESOURCE USE**

**LICENSING UNIT MEMORANDUM**

**TO:** Directors

**FROM:** Gavin Clabby

**DATE:** 20<sup>th</sup> January 2011

**RE:** Request for the transfer of IPPC licence, Reg. No. P0395-02, from AHP manufacturing B.V. trading as Wyeth Nutritionals Ireland to Pfizer Ireland Pharmaceuticals CRO No. 490938, formerly known as Pfizer New PIP Holdings.

**Background**

Licence Reg. No. P0395-02 was granted to AHP Manufacturing B.V. on the 23<sup>rd</sup> January 2004. AHP Manufacturing B.V. and Pfizer Ireland Pharmaceuticals, applied to the Agency on 16<sup>th</sup> December 2010, to transfer the licence to Pfizer Ireland Pharmaceuticals. This transfer of licence shall allow Pfizer Ireland Pharmaceuticals to operate the installation, currently operating at Askeaton, County Limerick under licence Reg. No. P0395-02.

The Agency is informed that Pfizer Ireland Pharmaceuticals (hereafter PIP) is an unlimited liability company incorporated under the laws of Ireland and registered in the Companies Registration Office (Registered Number 490938). PIP is an indirect wholly-owned subsidiary of C.P. Pharmaceuticals International C.V. (hereafter C.P.), a limited partnership organised under the laws of the Netherlands, with its seat in Rotterdam, the Netherlands. CP is represented by its general partners, Pfizer manufacturing LLC (hereafter PM), organised under the laws of the State of Delaware. CP and PM jointly act, each in its capacity, as general partner for, and on behalf of, CP.

CP operates a holding function and owns a large number of affiliates and subsidiaries in a number of different companies. CP's ultimate parent company is Pfizer Inc. (New York, USA).

**Assessment**


The application was assessed under Section 94 of the Environmental Protection Agency Acts 1992 to 2007. It is deemed to comply with the requirements of Section 94 of the Environmental Protection Agency Acts 1992 to 2007, as follows:

- The application complies with Section 94(2) having been jointly made by the current licensee and the proposed transferee.
- The application was accompanied by the appropriate fee, in accordance with Article 7(a) of the EPA (Licensing Fees) Regulations 1994 to 2008.
- The applicants have a fully detailed and costed Residual Management Plan.
- The applicants have a fully detailed and costed Environmental Liability Risk Assessment.

- Information in relation to the status of the proposed transferee as a 'Fit and Proper Person' has been provided and, based on a review of the information; the applicant has no relevant convictions, has sufficient technical experience and support (the existing site management structure will remain in place following the transfer).
- In relation to Financial Provision, a Parental Guarantee is to be provided for PIP. This guarantee must be agreed with the Office of Environmental Enforcement.
- The transferee or any relevant person has not had an application for a licence refused.
- The proposed transferee has stated in writing that they accept all liabilities, requirements and obligations provided for in or arising under the licence regardless of how and in respect of what period, including a period prior to the transfer of a licence, that may arise' in accordance with S.94 (6).

### **Recommendation**

It is recommended that the transfer of IPPC licence Reg. No. P0395-02 from AHP Manufacturing B.V., trading as Wyeth Nutritionals Ireland to Pfizer Ireland Pharmaceuticals CRO No. 490938, be approved under Section 94 of the Environmental Protection Agency Acts, 1992 to 2007.

  
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Gavin Clabby  
Inspector, OCLR