

Mr Mark Durrington
Ipsen Biopharm Ltd
Ash Road
Wrexham Industrial Estate
Wrexham
LL13 9UK

Our ref: PAN-002089
Your ref: -
Date: 23 November 2017

Dear Mr Durrington,

We need more information about your application.

Application reference: PAN-002089
Operator: Ipsen Biopharm Ltd
**Facility: Wrexham Pharmaceutical Works, Ash Road, Wrexham
Industrial Estate Wrexham LL139UF**

Thank you for your application received on 13 November 2017. I need to ask you for some more information before I can decide that your application is duly made. The information required is summarised below:

Incomplete application forms

Not all of the questions included in the application forms have been answered. Please can you complete the following questions:

Form F1 Question 2, 3, 6, 7D

Unclear answers to questions

Some of the answers on the applications forms are not clear, or do not satisfy the question requirements. Please review the submitted answers to the following questions:

Application Form C2

- Qu 2B The non-technical summary that's been included is unclear.
The non-technical summary should outline the changes you wish to make to your installation. As per the pre-application advice submitted to yourselves on 25 October 2017 the technical summary should include a description of the variation within the context of the site's process/activities. The summary should also make reference to impacts on production capacity, and any inclusion of new processes (with regard to your present environmental permit). Please include a description of what changes to emissions will result from the proposals (including any abatement or control measures). Further guidance is available on our website;
https://naturalresources.wales/media/678690/part-c2_guidance_final.pdf
This information is needed to confirm whether the variation you have applied for is correct.
- Qu 5 In the non-technical text that has been submitted it's reported that the minor technical variation will not require any new emission points. The application's site map shows approximately 14 aerial emission points (A18-A31) that aren't included in the current permit for this site. Can you please explain this change.
Additionally, the site plan with your application does not have a green outline to define the installation boundary. Please confirm the Installation's boundary

Qu 6 and whether your application intends to vary this from the previous permit. Without a clear non-technical summary to describe the intended changes to the permit, and their impacts, it is not possible to confirm whether an Environmental Risk Assessment is required.

Application Form C3

Qu 2 Table 2 The non-technical text that you've submitted reports that no new emission points are to be added as part of this variation however the emission point references included here are not present in your current permit. Each record here should include a unique emission point reference and location description, which should be labelled and identifiable on your site plan. Please submit a record of each emission point this variation is expected to impact (including any changes to emissions through an existing emission point in your current permit).

Further guidance is available on our website;

https://naturalresources.wales/media/678696/part-c3_guidance_final.pdf

Apx 2 Qu 2 It is not clear, from the document you've used to answer this question, what benchmark emission levels your emissions have been screened against, or what technical guidance note has been used to assess your releases. It is also unclear how the technical details included in the file "Unit 9 _12.doc" correspond to the process details noted in "Ipsen Process Description.doc".

Application Form F1

Qu 2 The OPRA score you've submitted as part of this variation varies significantly from the OPRA score we have on file. Please confirm the current OPRA score, and submit a new OPRA file to reflect this.

Qu 7D The Operator's declaration has not been signed. Please see the note on this below.

Guidance is available on our website as to how to complete each section of our forms and is available at;

<https://naturalresources.wales/permits-and-permissions/installations/apply-to-vary-change-a-permit-for-installations/?lang=en>

Declaration by a Relevant Person

Unfortunately the submitted application is not valid as the declaration is not complete.

Please make sure a relevant person completes this and send it back to us. In the case of a company, a relevant person would be a director, manager, company secretary or any similar officer or employee listed on current appointments in Companies House. A Delegation of Authority from a relevant person would permit another business employee to sign on the relevant person's behalf. Further advice on this is available on our website;

https://naturalresources.wales/media/678703/part-f1_guidance_final.pdf

Please reply within 10 working days from the date of this letter. If we don't hear from you, we must return your application and fee.

When we receive the missing items we'll continue to check the details in your application. If there's enough there for us to begin the process of deciding whether or not we can grant your application we say the application is 'duly made' and we'll let you know this by letter.

If you email or write to us please quote the application reference PAN-002089 on any correspondence and send it to the relevant address below. If you have any questions please phone me on 0300 065 3474 or email Chris.Roscoe@naturalresourceswales.gov.uk.

Yours sincerely



Chris Roscoe
Senior Permitting Officer

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Chris.Roscoe@naturalresourceswales.gov.uk

Canolfan Trwyddedu Cymru (Caerdydd), Cyfoeth Naturiol Cymru, Tŷ Cambria, 29 Heol Casnewydd, Caerdydd. CF24 0TP
Wales Permitting Centre (Cardiff), Natural Resources Wales, Cambria House, 29 Newport Road, Cardiff. CF24 0TP

Gwefan/Website www.cyfoethnaturiolcymru.gov.uk
www.naturalresourceswales.gov.uk

Croesewir gohebiaeth yn y Gymraeg a'r Saesneg
Correspondence welcomed in Welsh and English