

Regulatory position statement

Permitting the production of phase 1, 2 and 3 clinical trial pharmaceuticals

If you comply with the requirements below, we will not require an operator to have an environmental permit for the production of phase 1, 2 or 3 clinical trial pharmaceuticals where only that activity is undertaken within the installation.

Background

Under the Environmental Permitting Regulations (EPR) we have regulated a number of 'stand-alone' pharmaceutical plants that produce what are known as 'phase 3 pharmaceuticals'. Clinical trials have a number of phases¹. Phase 3 studies are for controlled trials on large patient groups to assess the effectiveness of the drug. Phases 1 and 2 require smaller quantities of the drug and are also covered by this position statement.

Until now we have treated Phase 3 production in the same way as market testing in other sectors, i.e. as falling outside the scope of the exemption for research, development and testing contained in the EPR². However, we acknowledge that:

- this interpretation is arguable
- these activities are relatively small scale, have low emissions to the environment and are well managed.

So, we have decided to adopt a regulatory position whereby these sites are no longer required to have an environmental permit.

1. Clinical trials consist of four phases – the first three occur before a licence is granted and the last is conducted post-licensing. Each phase varies in size, character and focus:

- **Phase 1 determines how a medicine works in humans and helps to predict the dosage range for the medicine. It involves healthy volunteers.**
- **Phase 2 tests efficacy as well as safety among a small group of patients (100–300) with the condition for which the medicine has been developed.**
- **Phase 3 involves a much larger group (1,000–5,000) of these patients and helps to determine if the medicine can be considered both safe and effective.**

2. Schedule 1 paragraph 3(c) exempts activities 'carried on at an installation or mobile plant solely used for research, development and testing of new products and processes'.

Our approach

We will not pursue an application for an environmental permit where the activities carried out within the installation are wholly limited to the production of phase 1, 2 or 3 clinical trial pharmaceuticals.

Enforcement

In not pursuing an application for a permit, we will not normally take enforcement action unless the activity has caused, or is likely to cause, pollution or harm to health. For a more detailed explanation of this enforcement position, please see our [Enforcement and Sanctions](#) statement. This can be found on the '[How we regulate you](#)' page in the Business & Industry section of our web site.

This regulatory position will be reviewed by September 2013.

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