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[REDACTED]

MHRA

10 South Colonnade
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United Kingdom

www.gov.uk/mhra

6th February 2024

Dear [REDACTED],

FOI 24/081 – The Yellow Card Scheme and definition of hypersensitivity

Thank you for your email dated January 9th 2024 where you asked for information on the following:

- *Can you please tell me if UCB are legally obliged to report to you? And if so, what have they reported.*
- *Also, on the iDAP recording of reactions, can you tell me any more info about the immune system disorders? I would like to know where if at all, hypersensitivity fits into these recorded reactions.*

As outlined in our previous response, there is a legal obligation for pharmaceutical companies to report serious adverse event reports to their drugs. UCB Pharma is one of these pharmaceutical companies.

Between 2009 and 30th January 2024, UCB Pharma had submitted 2032 UK spontaneous Adverse Drug Reaction (ADR) reports to the MHRA. If you would like more detailed breakdowns of this data, please submit a further FOI request outlining the specific areas in which you require more detail.

It is important to note that the number of reports received from pharmaceutical companies do not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different medicinal products. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

When viewing the iDAPs, the Immune System Disorder row can be expanded to see the conditions grouped within this term by clicking the plus button on the left hand side. This will bring up a list of subgroups including Allergic Conditions, click the plus button next to this to display further subgroups, including Allergic Conditions NEC. Click the plus button next to Allergic Conditions NEC to bring up individual reaction terms. Hypersensitivity can be found here, as shown in the screenshot below:



<input checked="" type="checkbox"/> Immune system disorders
<input checked="" type="checkbox"/> Allergic conditions
<input checked="" type="checkbox"/> Allergic conditions NEC
Allergic oedema
Allergy to animal
Allergy to arthropod sting
Hypersensitivity
Serum sickness
Type IV hypersensitivity reaction

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance

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