

**From:** [REDACTED]  
**Sent:** Thursday, December 24, 2020 10:57 AM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Dear [REDACTED]

Many thanks indeed for sharing the VAERS information – it’s much appreciated,

The slides from [REDACTED] were also very helpful, apologies as I don’t think I replied with a thanks Amanda. On our side, it was very interesting to see there were already 500 recorded pregnancies with the vaccine on the US side. It would be useful to know how you follow them up – the process here is to follow up 9 months after the report to find out outcomes, although updates can be reported at any time.

Many thanks all – and I hope you’re able to enjoy some time off over the break,

[REDACTED]

[REDACTED]  
Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

Direct line: [withheld under s40 of the FOIA]  
Mobile: [withheld under s40 of the FOIA]

**From:** [REDACTED]  
**Sent:** 23 December 2020 16:33  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** FW: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

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Dear [REDACTED]

Pursuant MHRA’s request for information sharing concerning the Pfizer Vaccine AEFI, please find attached the VAERS information sharing.

We hope the information will be helpful.

Kind regards,  
[REDACTED]

**From:** [REDACTED]

**Sent:** Monday, December 21, 2020 11:59 AM

**To:** [REDACTED]

[REDACTED]

**Cc:** [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED]

I am adding my colleagues [REDACTED] and [REDACTED] we are happy to share more information with you. Attached are slides that were presented at a public meeting on Saturday. However, as you can imagine reports are increasing rapidly and there are additional confirmed cases. We are thinking through the best way to keep those who need to know informed and we are happy to share information back to you. We will be back in touch shortly.

Thanks!

[REDACTED]

**From:** [REDACTED]

**Sent:** Monday, December 21, 2020 10:24 AM

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED]

If [REDACTED] wouldn't mind sharing the detail of the individual cases that would be appreciated. We will ensure the details are treated confidentially.

Many thanks,

[REDACTED]

[REDACTED]

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[REDACTED]

Direct line: [withheld under s40 of the FOIA]

Mobile: [withheld under s40 of the FOIA]

**From:** [REDACTED]

**Sent:** 18 December 2020 19:57

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]  
[REDACTED] >

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED]

We agree as well. Thanks for the exchange!

Your summary is correct. I'm cc:ing [REDACTED] at CDC who can provide the most up-to-date details about the individual cases. Obviously, as with the UK cases, not all of this is public so please hold these details confidential.

[REDACTED]

[REDACTED]

**From:** [REDACTED]

**Sent:** Friday, December 18, 2020 1:07 PM

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

H [REDACTED]

We all thought it was very useful to speak with you and colleagues earlier.

Could I please ask on behalf of the team, if you could confirm details [withheld under s40 of the FOIA]

Thanks very much

[REDACTED]

[REDACTED]

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[REDACTED]

Direct line: [withheld under s40 of the FOIA]

Mobile: [withheld under s40 of the FOIA]

**From:** [REDACTED]

**Sent:** 18 December 2020 12:10

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED] I confirm that we will participate. Thanks [REDACTED]

**From:** [REDACTED]

**Sent:** Friday, December 18, 2020 6:42 AM

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

[REDACTED]

I've got the green light for a 1pm/8am meeting. I will set this up now. Please let me know asap if US colleague are unable to join.

[REDACTED]

**From:** [REDACTED]

**Sent:** 18 December 2020 11:35

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED]

I'm working on trying to set up a call for 1pm – I will confirm shortly (this would be 8am US time). We wouldn't be able to make tomorrow, but next week early we are looking to hold a small cluster meeting of key regulators to discuss key updates on assessments and vigilance aspects too, so I'll keep you in the loop about this too.

All the best,

[REDACTED]

**From:** [REDACTED]

**Sent:** 17 December 2020 15:57

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

H [REDACTED]

As you've probably seen in media, there's now at least one case in the US, and not yet in the media there are others here also under investigation. We certainly appreciate whatever further updates you can provide by e-mail, especially as we consider the EUA for the next product (Moderna) which we will likely decide tomorrow.

Maybe it would be a good idea to set up a 30-minute call to further discuss status of potential cases, so we each have as complete information as possible in deciding on next steps? We would also invite

CDC, who may have additional updates. Our preference would be to talk on Saturday, because tomorrow is such a busy day for us working on the Moderna product. If Saturday isn't feasible, I'd like to suggest 7 a.m. or 8 a.m. US time, 1200 or 1300 UK time tomorrow, when we could also carve out some time. Though of course, if those possibilities wouldn't work for your team, we could look for another time.

Thanks!

█

**From:** █

**Sent:** Wednesday, December 16, 2020 1:55 PM

**To:** █

**Cc:** █

█

█

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi █

Thanks for checking and sorry for not clarifying before - this information is not in the public domain so please could you not refer to the additional cases.

Many thanks

█

█

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

█

Direct line: [withheld under s40 of the FOIA]

Mobile: [withheld under s40 of the FOIA]

**From:** █

**Sent:** 16 December 2020 18:28

**To:** █

█

█

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi █

Thank you very much. Would it be okay for us to mention this information about additional anaphylaxis/anaphylactoid reaction reports at our advisory committee meeting tomorrow?

Best wishes,

█

**From:** [REDACTED]

**Sent:** Wednesday, December 16, 2020 1:24 PM

**To:** [REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED]

I've received the following update from our experts:

- Further to the initial three cases which triggered the advice from the MHRA, we have received two more reports of anaphylaxis and three cases reporting "early anaphylaxis" or anaphylactoid reactions. None of these cases are fatal. We are conducting ongoing investigation into these cases, including requests to carry out analytical tests by immunology experts to determine whether an allergic reaction to the vaccine has occurred.
- There is no evidence which indicates a need to strengthen the current warnings on anaphylaxis. The MHRA will continue to review and update our advice on the risk of anaphylaxis with the Pfizer/BioNTech COVID-19 vaccine as more evidence becomes available.

I hope this helps and should we have any further updates I will let you know.

All the best,

[REDACTED]

[REDACTED]

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[REDACTED]

Direct line: [withheld under s40 of the FOIA]

Mobile: [withheld under s40 of the FOIA]

**From:** [REDACTED]

**Sent:** 16 December 2020 16:05

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Thanks!

**From:** [REDACTED]

**Sent:** Wednesday, December 16, 2020 10:50 AM

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED]

We will definitely get a note over to you later today – our vigilance teams are caught up with meetings at the moment but have promised me some material later.

Thanks,

[REDACTED]

[REDACTED]  
Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[REDACTED]  
Direct line: [withheld under s40 of the FOIA]  
Mobile: [withheld under s40 of the FOIA]

**From:** [REDACTED]

**Sent:** 16 December 2020 15:31

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED]

Any updates? We appreciate whatever you or your team can tell us in advance of our public meeting tomorrow morning.

Thanks,

[REDACTED]

**From:** [REDACTED]

**Sent:** Tuesday, December 15, 2020 2:44 PM

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Many thanks!

**From:** [REDACTED]

**Sent:** Tuesday, December 15, 2020 1:12 PM

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Dear [REDACTED]

Thank you for your email – I have sent this on to relevant experts in our vigilance teams and will be in touch as soon as I hear back.

Kind regards,

[REDACTED]

[REDACTED]

Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[REDACTED]

Direct line: [withheld under s40 of the FOIA]

Mobile: [withheld under s40 of the FOIA]

**From:** [REDACTED]

**Sent:** 15 December 2020 15:18

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED]

As you've probably heard, we're going back to our advisory committee on Thursday to talk about the Moderna vaccine. No doubt, since this came up last Thursday, we'll be asked where we stand on these allergic reactions. Do you have any update on what has happened in the UK since last week's reports? As vaccines have been given for additional days, have more immediate-type hypersensitivity reactions been reported?

We'd be happy to discuss by teleconference tomorrow (Wednesday), or maybe it would be simpler, if possible, for you to just provide an email update.

Thanks!

[REDACTED]

**From:** [REDACTED]

**Sent:** Wednesday, December 9, 2020 12:04 PM

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED]

Sorry I am unable to get the right experts on the line in time for this call – we will be in touch once I have a better idea on availability of our technical teams either for a quick call with FDA or for the wider global call.

Best regards,



[REDACTED]  
[REDACTED]  
Head of International and Trade Policy  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

[REDACTED]  
Direct line: [withheld under s40 of the FOIA]  
Mobile: [withheld under s40 of the FOIA]

**From:** [REDACTED]  
**Sent:** 09 December 2020 16:43  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Hi [REDACTED]

From our perspective, the more we can know about this before the advisory committee meeting that starts tomorrow morning US time, the better. If a more global ICMRA call isn't possible before then, we would still greatly appreciate the ability to talk with you about this. We have a lot of meetings today, but if it were possible to talk under our confidentiality agreement at least briefly at 1700 UK time, that would indeed be very helpful.

Here is a link that we can use, in the event that is deemed possible.

**When it's time, join your Webex meeting here.**

Meeting number [REDACTED]

Meeting password: [REDACTED]

[Join meeting](#)

**Tap to join from a mobile device (attendees only)**

**Join by phone**

Thanks,

[REDACTED]

**From:** [REDACTED]

**Sent:** Wednesday, December 9, 2020 10:46 AM

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

[REDACTED]

**Subject:** Re: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Thanks [REDACTED]

[REDACTED] is liaising with the team - the idea is to offer a call to ICMRA main global regulators - but that may not be possible to set up today [REDACTED] will be in contact.

Best regards

[REDACTED]

[REDACTED]

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

[withheld under s40 of the FOIA]

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**From:** [REDACTED]

**Sent:** Wednesday, December 9, 2020 3:35:47 PM

**To:** [REDACTED]

[REDACTED]

**Cc:** [REDACTED]

[REDACTED]

[REDACTED]

**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Dear [REDACTED]

Thank you so much for this information. Our emails crossed. If possible, would you be available for a t-con today?

[REDACTED]

**From:** [REDACTED]

**Sent:** Wednesday, December 9, 2020 10:34 AM

**To:** [REDACTED]

**Cc:** [REDACTED]

[REDACTED]

**Subject:** Re: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

... attached are the 2 reports that have just been uploaded into the EU systems: hope that's helpful in the meantime.

If I can just remind - information shared under our confidentiality agreement.

Thanks

[REDACTED]

[REDACTED]

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

[withheld under s40 of the FOIA]

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**From:** [REDACTED]  
**Sent:** Wednesday, December 9, 2020 12:56 pm  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** Re: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Thanks [REDACTED] - we'll liaise with our vaccines leads - I think the easiest thing will be for them to liaise directly, but we'll think about the best way to do this

Best regards

[REDACTED]

[REDACTED]

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

[withheld under s40 of the FOIA]

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**From:** [REDACTED]  
**Sent:** Wednesday, December 9, 2020 10:03 am  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Dear [REDACTED]

Thank you very much for this information. It would be very helpful if our Office of Vaccines could receive additional details on these adverse events from MHRA under the terms of our mutual confidentiality agreement. I am copying the Director of our Office of Vaccines, Marion Gruber, so that she is aware.

Best Regards,

[REDACTED]

---

[REDACTED] MD, PhD  
Director  
Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
WO71-7232  
Silver Spring, MD 20993  
[withheld under s40 of the FOIA]  
[withheld under s40 of the FOIA]

[REDACTED]



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**From:** [REDACTED]

**Sent:** Wednesday, December 9, 2020 4:57 AM

**To:** [REDACTED]

**Cc:** [REDACTED]

**Subject:** Pfizer Vaccine: 2 serious reactions on the first day of vaccinations

Dear [REDACTED]

In view of the imminent public meetings that you will be holding on the Pfizer vaccine, we thought it important to pass on to you the attached information that has been sent out to NHS health professionals following 2 incidents yesterday (8th December), the first day of the NHS vaccination campaign using the Pfizer vaccine temporarily authorised for unlicensed use on 1 December [withheld under s40 of the FOIA]

I've asked the team to consider what we do to make sure that other regulators are also sighted on these two events and the reinforced advice that we have issued.

Best regards

[REDACTED]

[REDACTED]

Policy Director,  
UK Medicines and Healthcare Products  
Regulatory Agency

[withheld under s40 of the FOIA]

Information sent out:

### **Risk of allergic reactions**

#### **Advice to Healthcare professionals**

This precautionary advice is being issued following two case reports of anaphylactoid reactions associated with administration of Pfizer BioNtech COVID-19 vaccine.

#### **New advice:**

1. Any person with a history of a significant allergic reaction to a vaccine, medicine or food (such as previous history of anaphylactoid reaction or those who have been advised to carry an adrenaline autoinjector) should not receive the Pfizer BioNtech vaccine.
2. Resuscitation facilities should be available at all times for all vaccinations. Vaccination should only be carried out in facilities where resuscitation measures are available.

-

### **Background**

There have been two cases of anaphylactoid reactions in individuals with a strong past history of allergic reactions both of whom carried an adrenaline auto injector. These individuals developed symptoms of anaphylactoid reaction shortly after receiving the vaccine. Both recovered after appropriate treatment. We are seeking further information and will issue further advice following investigation.

Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: [Coronavirus Yellow Card reporting site](#)

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