

Dear Sir Stephen,

PFIZER REPORT OF INCREASED RISK OF HEART CONDITIONS POST COVID VACCINATION

We corresponded in late April 2023 when I drew your attention to the Perseus Group [report](#) which documented concerns about the safety of the Covid vaccines and failings in MHRA's safety management. You provided reassurance (28 April) that commercial pilots and ATCOs are assessed by a medical examiner at regular intervals and told not to fly or control if they feel unwell.

Subsequently, a great deal of further evidence has emerged but I want to draw your attention to one report in particular which has just come to light. It is a [report](#) by Pfizer itself which concludes that there is increased risk of heart-related problems in those who had the Covid vaccine.

I think the implications of Pfizer's report for aviation safety are profound. It is quite common for components in safety critical systems to have variants even just through modification state of the same basic design. If one of the variants is known (or found) to have a higher risk of failure through whatever mechanism then inspection periods (and possibly also the inspection technique) are adjusted accordingly.

Do you agree that it would be best practice for you to review the safety risk assessment which must, I assume, exist to underpin the periodicity and depth of medical examination which the CAA requires of pilots and ATCOs for Class 1, 2 & 3 licences? In particular, should the medical examinations of those who received the Covid vaccination be required more frequently than the current 12 months (or 6 months if over 60)? Also, are the basic ECG and possible follow ups of any ECG abnormalities (1 = Cardiologist review, 2 = Exercise ECG, 3 = 24hr Holter ECG, 4 = Echocardiogram) sufficient for those who had the Covid vaccine.

Also, in light of Pfizer's report, where the increased risk of heart conditions is significant (Hazard Ratios of up to 1.4), is the mitigation "if you feel unwell" before flight or control still sufficient? I would argue that such a significant increase in underlying risk must have implications for the risk of onset of illness during flight or control, not least because of the 'natural' increases in heart rate and blood pressure associated with flying and control – the activity itself puts greater stress on an already damaged heart.

I have copied this to Dr Alison Cave, the MHRA's Chief Safety Officer. In doing so, I would note that MHRA's safety criteria are relative : for Authorisation that 'the benefits outweigh the risks' and for Pharmacovigilance that adverse events are 'no worse than for a similar medicine'. In contrast, all other safety critical sectors are built on absolute tolerability criteria : the level of acceptable risk of death and injury. In other words, the 'benefits' of the Covid vaccine (which are moot anyway) are largely irrelevant to aviation safety - it is the 'risks' which are crucial. Also, that it would be specious to argue that Covid vaccination is no longer offered routinely to those under 65 - this is a 'damage has already been done' issue.

I look forward to your comments.

Yours, Mr N Hunt
12 October 2024

cc Dr Alison Cave, MHRA Chief Safety Officer