Nick Hunt — Transcript

Will Jones (Interviewer). Nick Hunt is a retired senior civil servant from the Ministry of Defence who was responsible for the safety and effectiveness of a wide range of explosives.

Nick Hunt. During the last 14 years of my career in the Ministry of Defence, I was in a senior role and I held a personal delegation from the Secretary of State for Defence for the safety of a wide range of explosive items. I was doing exactly what the MHRA is supposed to do for medicines: overseeing manufacturers trials, approving products as safe, investigating safety incidents, taking appropriate action and being subject to senior management review and independent safety audit.

I'm not a medic, but the principles of safety management should surely be the same. The Perseus Group report in April 23 highlighted two things: serious harms caused by the COVID vaccines; and major failings in MHRA safety management not just of the COVID vaccines but of medicines in general.

The COVID inquiry requested that the Perseus Group provide a witness statement, which we did in December of last year, but we were alarmed when public hearings were postponed until 2025.

We think the public needs to hear our evidence now. It's available on the People's Vaccine Inquiry website, detailed and fully evidenced. And I want to just cover a couple of the issues in the next few minutes.

I got involved for two reasons. Firstly, when MHRA approved the COVID vaccines, it was obvious that the amount of testing was woefully inadequate. And secondly, after a couple of Freedom of Information requests, it was obvious to me that MHRA safety management is appalling.

MHRA approved the COVID vaccines based on less than one year of testing compared with the normal 10+ years. They therefore had very little safety data and this would inevitably increase the risk of harms.

In particular, they permitted the manufacturers to swerve a whole range of safety studies: pharmacology, carcinogenicity, pharmacokinetics and genotoxicity. This inadequate testing meant that they had little or no idea about, for example, how much spike protein would be produced in the body, where it would go, what effects it would have, and how long it would persist. Nor about the safety of repeated doses.

And yet they accepted these unknowns, despite knowing that younger age groups were at extremely low risk from COVID and that the so-called vaccines didn't stop infection or transmission. This is abhorrent, coercing younger people to take a medicine of little or no benefit to them, with unknown risk of harm.

And there's another important issue. The public is, in the main, blissfully unaware that all three of the COVID vaccines rolled out in the UK were made using a very different process to the vaccines used in their trials and worse, that the MHRA had no safety data to compare the two. MHRA were flying blind. More unknown risks from inadequate testing.

So what? Well, every day more and more evidence is emerging from around the world pointing to those risks becoming reality. For example, unexplained increases in excess deaths, cardiovascular disease, heart failure, cancers, other long-term sickness and so on. However, the government refuses to release the data which would allow investigation of these issues. They are in complete denial. Worse still, they are ignoring those injured by the COVID vaccines.

The second root cause is how appalling is MHRA safety management. They're allowed to get away with monitoring safety completely differently to any other safety critical sector like aviation, nuclear, oil and gas and defence. To give but three examples: they don't investigate all safety incidents, even just the fatal and serious ones; they don't assess the causation (that's the probability that the medicine caused the reported safety incident); and they've never been subject to an independent safety audit.

In addition, all other sectors manage safety in absolute terms with clear thresholds for actions such as suspension or withdrawal. But not MHRA. They're allowed to get away with monitoring safety in relative terms: does the benefit outweigh the risk which is like sanctioning collateral damage? And is medicine A no worse than other similar medicines, which is just a race to the bottom because they miss safety signals which then get baked into the baseline.

As a result it takes them an average of 11 years to withdraw any medicine on safety grounds.

Baroness Cumberlege's report in 2020 was scathing about MHRA's performance. MHRA was also slower than other national regulators to suspend the AstraZeneca COVID vaccine and they missed other vaccine safety signals for 18 months.

Our written evidence covers not just these issues but much more. For example, we debunked the claims that the COVID vaccines save millions of lives. That's modelling hogwash based on incorrect assumptions about basic immunity, waning of vaccine effectiveness and transmission.

Another claim, serious side effects from the COVID vaccines are rare. Well, actually they're not. They're quite common. For example, in a 2 month period in 2021, September and October, there were 118 fatal reports associated with the COVID vaccines. That's 15 per week and 17,500 serious reports.

I find it staggering that the general public remains largely unaware of all this and reprehensible that the Parliamentarians who are aware because they all saw the Perseus Group report, are - save for a few - in denial.

This isn't just about COVID vaccines, it's about safety management of all medicines.

So what needs to happen next? In our view, there are two simple steps which are essential. The government must direct MHRA to release the NHS, GP and ONS data, segmented by COVID vaccination status, which was provided to the COVID vaccine manufacturers in 2021. It's our data. And the government must commission an independent safety audit of MHRA. The Health and Safety Executive could do that. They are the overarching regulator for all other sectors. Thank you.

Thank you, Nick. So much of what you've told us is shocking. We just take for granted, don't we, that organisations, regulatory bodies like the MHRA are doing their job properly and looking out for us and making sure that the medicines and the drugs that we take are given to us by doctors and by the NHS are safe. And yet we hear from you all of this information that tells us that in fact that isn't the case so often. Why doesn't the MHRA investigate all the yellow cards?

If you just think about the COVID vaccine yellow cards, a good reason is there were so many of them. They were inundated with them. But my observation applied even before the COVID vaccines. There are too many yellow card reports, fatal and serious ones for all medicines. And it's something that June Raine, who's the soon to be departing CEO of the MHRA, admitted in a presentation in 2017 to the Royal College of Physicians that there are just too many yellow cards, they don't have the resources to properly investigate all yellow cards, even just the subset of them that are fatal or serious or relate to children or pregnancy, which you would have thought all of those would have been a priority, but they just don't.

And instead they rely on statistical analysis and the relative assessments that I mentioned.

So how many have they investigated? These yellow card reports?

That was one of the first questions I asked them, and they were unable to answer because they don't have that information at their fingertips. Other people have managed to get slices of information about subsets of yellow cards, and I'll give you one example. Of a sample of 121 yellow cards for the Moderna COVID vaccine that had a fatal outcome, the MHRA followed up only about half with healthcare professionals, of which the majority - it was about 2/3 of that half - went unanswered and MHRA just let that lie and didn't chase chase chase as you would have assumed or hoped they would.

So the medics who put in the reports, they also didn't respond when they were chased?

Correct. I can't remember the percentages but they're quite high. A lot of yellow cards don't have information in them when they're submitted that would be necessary for an investigation. Bizarrely, some are missing the age of the subject or the time between the administration of the medicine and the event, which is quite important and so on. There are bits of information which as well as the individual's medical records which, if you were investigating these, you'd want to know.

Why do you think the doctors themselves don't respond to the MHRA?

I have no idea. I assume that's resource and time pressure. MHRA should be following them up all the time.

And do they assess causation and do they try to work out that basic question? Is it the drug? Is it the medicine causing the adverse event?

Let me read you a statement from which you would conclude that they do. "*The MHRA carefully evaluates reports of serious suspected side effects as soon as they are received to consider whether the medicine or vaccine may have caused the event. Or whether the event was likely to be purely coincidental.*" And that's a good way of describing the process of attributing causation, the likelihood.

However, I asked in a Freedom of Information request for their process for doing that and their records of having done so. And on both counts they said they don't hold that information. So they're misleading the public about a key part of the safety management process.

You said that other sectors manage safety in a different way to the MHRA. In a better way? Can you say why it's better and why do you think the MHRA does manage it differently?

So all the other sectors - defence is just one example but I know something about aviation and nuclear and oil and gas, and transport - they all in common have absolute safety targets. They all have a framework for safety management that is built on absolute measures of safety. There's no such thing as safe or not, it's all a question of degree.

If you take aviation - as members of the public will possibly be aware - that's built on a framework of no accident more than one in a million flying hours. That's an example of an absolute safety target. It gets much more detailed than that, but that's the principle of aviation safety management and all others. MHRA don't have that. They don't predetermine as part of approval what are the safety targets which if breached in practise, would lead to a course of action like suspension pending further investigation or withdrawal or modification or whatever it is.

I mentioned that they do statistical analysis and they measure the safety of one medicine relative to another as part of their assurance of safety. That would be like the nuclear sector saying, well, that nuclear power station is safe because it's no worse than that nuclear power station over there. Forget other nuclear power stations. It's got to be as safe as it absolutely needs to be. That type of aircraft needs to be absolutely safe as it needs to be, not relative to other types of aircraft.

Quite why MHRA is allowed to do it in relative terms actually is completely beyond me. I have a feeling it is to allow more medicines onto the market because I think if they were subject to these absolute safety targets, a lot of them wouldn't make it to the market.

And some might say there's a good reason for that.

It's a difficult one because society has got an ingrained sense that there's a pill for every ill and medicine can cure everything is, I'm afraid that in a lot of cases, medicines actually make things worse or cause other side effects that then need other medicines to deal with the side effects. And you can go on like that.

A huge proportion of hospitalizations in this country are directly the effect of medicines and side effects.

They are. It's 16% I think was the last estimate I saw.

Incredible, isn't it?

It is.

So how long have these things been going on? How long has the MHRA been letting us down in this way?

I'm afraid to say it's decades because you can recall medicine scandals back to Thalidomide in the 60s, I think it was. But in the intervening years there have been other problems, for example those uncovered by Baroness Cumberlege in 2020. They dated back decades. But one thing I think is worth highlighting is MPs on the Health Select Committee in 2004 called out Big Pharma in a scathing report called The Influence of the Pharmaceutical Industry. In fact, all MPs should reread that because things have actually got worse, not better as a result.

In 2014, Patrick Vallance, who at the time was working for GlaxoSmithKline said, and I quote, *"in the future medicines will come to market quicker with less data, with more research being conducted in the post licence phase.*" That is very scary stuff. This isn't just about the COVID vaccines, this is about all medicines.

And like the rest of us, I would have thought MPs would be taking all sorts of medicines of different types and I can't understand for the life of me why they're not bothered about MHRA safety management failings, which we've drawn their attention to for all medicines, not just the vaccines.

So if you're an MP, is your medicine new? Has it only been authorised in the last few years? Having heard MHRA systemic failures, are you quite so confident about taking it?

And I know all medicines have side effects, but then so do aviation, oil, gas, nuclear power and all the rest. They're all regulated very well with robust safety management frameworks. Medicine safety lags well behind, with MHRA operating in a haphazard, unstructured way.

And I think there are two steps MPs should take. Talk to the Patient Safety Commissioner. And that was an action which came out of the Cumberlege report in 2020. The Patient Safety Commissioner herself told me that nine months ago she was starting to engage with other sectors to learn how other high-risk industries manage safety. MPs should be asking her what she's actually learned from other industries.

And secondly, an independent safety audit is absolutely essential, and I mentioned the Health and Safety Executive – they could do that. They're the overarching regulator for all the other sectors and it's beyond me why they're not involved in the regulation of medicines.

Well, thank you, Nick. Let's hope that MPs and others are listening and that someone will do something about it and sort the MHRA out.

Yes.