WITNESS STATEMENT OF PERSEUS GROUP

"In the future, medicines will come to market quicker with less data, with more research being conducted in the post-license phase."

Sir Patrick Vallance (2014)

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I, NICK HUNT, will say as follows: -

INTRODUCTION

1. I make this statement on behalf of the Perseus Group.
2. The evidence presented is true to the best of my knowledge and belief.
3. The Perseus Group is a small multidisciplinary team of experts from various fields including medicine, pharmaceutical manufacture and regulation, and safety management. The Group, formed in September 2022, comprises individuals with shared concerns about the safety of the Covid-19 vaccine and medicines in general and MHRA's remit to keep patients safe. For simplicity, we/our in this statement refers to the Perseus Group.
4. This statement covers our concerns about Covid-19 vaccine safety, MHRA's authorisation of the Covid-19 vaccines, its post-Authorisation surveillance and lessons we believe can be learned from best practice safety management in other safety critical sectors.
5. I hold an Engineering Degree (BSc(Eng)) and a Masters in Business Administration (MBA). I retired in 2017 as a Senior Civil Servant in the Ministry of Defence. During my employment, I also held the following qualifications: Chartered Engineer (CEng), Registered Project Practitioner (RPP) with the Association for Project Management, internal MOD safety qualifications relating to explosive items and airworthiness, and registration with the Office of Government Commerce (OGC) as a Gateway Reviewer of high risk programmes and projects led by other Government Departments.
6. From 2004, I was personally responsible, through formal delegation flowed down from the Secretary of State for Defence, for the safety and effectiveness of a

wide range of explosive items used by the UK Armed Forces. My role included approving products for Service use, monitoring in-service safety and effectiveness and, when necessary, taking decisions about limiting, modifying or suspending use of individual products in the light of safety issues. My role was, therefore, analogous to the Medicines and Healthcare products Regulatory Agency (MHRA) for medicines.

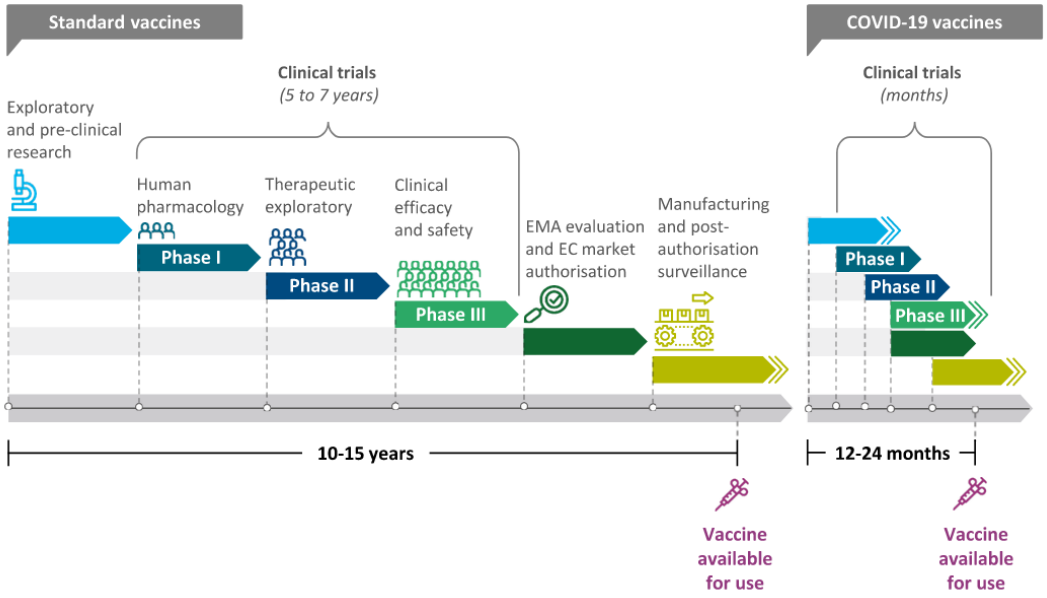
7. In April 2023, we published a report[1] titled "Safe And Effective?". Our purpose was to bring to the attention of politicians and policy makers evidence of serious shortcomings in MHRA's regulation and safety management of the Covid-19 vaccines and, indeed, medicines in general. We sent the report to all MPs and Peers. We also sent the report to, *inter alia*, MHRA, the Patient Safety Commissioner (PSC), the Joint Committee on Vaccination and Immunisation (JCVI), the Commission on Human Medicines (CHM), Chief Medical Officer (England), Government Chief Scientific Adviser, DHSC Chief Scientific Adviser, UK Health Security Agency (UKHSA), UK Vaccine Task Force, NHS Commercial Medicines Director and the General Medical Council.

8. We gave evidence to the All Party Parliamentary Group on Covid-19 Vaccine Damage. Specifically:
    a. we attended its meeting on 5 June 2023 and assisted the Chair with formulation of questions to Maria Caulfield, Parliamentary Under Secretary of State at the Department of Health and Social Care who attended the latter part of the meeting; and
    b. we gave a presentation[2] about our report to its meeting on 3 July 2023. At the end of the meeting, the Chair asked us to provide a list of the key questions[3] which we thought MPs should be asking.

VACCINE SAFETY

9. <u>Increased Risks from Short Clinical Trials</u> We were extremely alarmed by the short duration of the Covid-19 vaccine trials prior to Authorisation - less than a year compared with the normal 10 to 15 years[4].

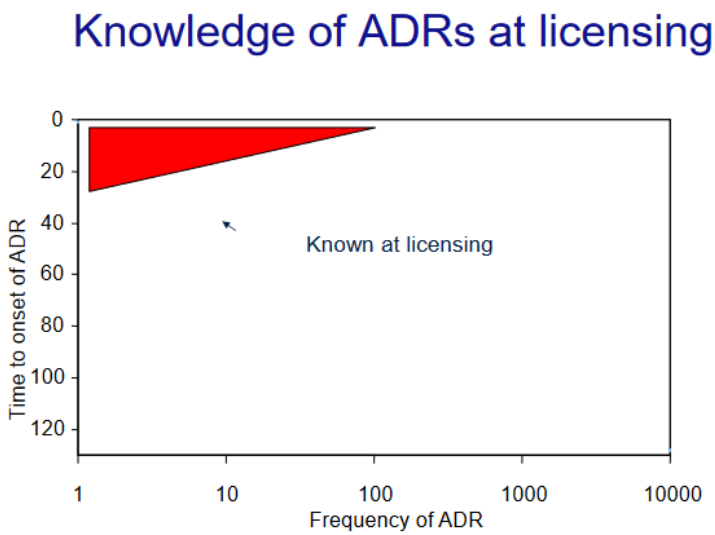
Figure 1 – Standard vaccine development process and timeline vs COVID-19 vaccine development



10. This severely limited the amount of safety and effectiveness data available for assessment by MHRA and other national regulators.
11. The Pfizer, AstraZeneca and Moderna clinical trials started around March/April 2020. From October 2020, MHRA conducted 'rolling reviews' of relevant data from each company and consulted the Commission on Human Medicines, leading to Temporary Authorisation in late 2020/early 2021.
12. We do not believe that lessons were learned from the Pandemrix Swine-Flu vaccine approved in 2009[5]. The parallels to the Covid-19 vaccines are uncanny: much shorter than normal trials, indemnity for the manufacturer (GlaxoSmithKline) and emergency authorisation[6]: *"Vaccines, as with all pharmaceutical products, are subject to extensive clinical trials. However, it is recognised that during a pandemic the trials may not be as rigorous as they would otherwise be, because of the demand to safeguard lives. Completing mass trials can take months or even years. For that reason, the European Union intervened and licensed Pandemrix for use within the EU, including the UK, without the completion of the normal rigorous trials."* Unforeseen safety issues followed, notably narcolepsy, a type of brain injury which took an extended period to be formally acknowledged. Pandemrix was withdrawn in March 2011.
13. Even after normal length clinical trials, there remains significant post-authorisation safety risk and uncertainty about effectiveness. This is due to the

widely accepted limitations of clinical trials - for example, so far unidentified adverse events, no long term safety data, lack of evidence relating to special populations and at-risk groups, and interactions with other medicines.

14. Indeed, in a presentation[7] (Slide 16) to the Royal College of Physicians on 1 June 2017, Dame June Raine, then MHRA's Director of Vigilance and Risk Management Division, illustrated the limited knowledge about Adverse Events at the point of Authorisation.



15. '*Known at licensing*' is pointing to the small red triangle top left, the common adverse events which occur relatively quickly and are therefore identified during clinical trials. The predominant white area represents rarer adverse events and any which take longer to manifest, neither of which are found in clinical trials. This is the situation with 'normal' length trials. The much shorter Covid-19 vaccine trials would only have shrunk the top left area and exacerbated the safety risks.
16. There were other specific problems as follows.
17. <u>Key Testing Omitted</u> We found evidence from Pfizer and Moderna submissions to the US Securities & Exchange Commission in mid 2020 that they regarded their mRNA products as Gene Therapies[8] (para 8.7) not traditional vaccines.
18. We are aware of ongoing debate about this. For example, the World Health Organisation (WHO) had highlighted the need for separate regulations for mRNA vaccines in December 2019 in a consultation report[9] which concluded: *"The consultation also recognized that development of RNA-based vaccines requires WHO action…It was clear that the scientific evidence for these vaccines is limited*

and more data will most likely become available in coming years." The WHO established meetings in autumn 2020 to draft new regulations and a first draft was published in December 2020[10], just as the Covid-19 vaccines were first gaining approvals.

19. In any case, international regulators designated the products as vaccines meaning that few, if any, pharmacology, pharmacokinetic, biodistribution, carcinogenicity and pharmacodynamic studies had to be conducted :
    a. the European Medicines Agency's (EMA) Pfizer Covid-19 vaccine Assessment Report[11] (page 45) stated:
        i. *"No safety pharmacology studies were conducted with BNT162b2"*
        ii. *"No pharmacodynamics drug interaction studies were conducted with BNT162b2"*
        iii. *"No traditional pharmacokinetic or biodistribution studies have been performed with the vaccine candidate BNT162b2."*
    b. the EMA's Moderna Covid-19 vaccine Assessment Report[12] (page 43) shows that there was no such testing on humans.
20. For example, the lack of pharmacokinetic testing meant that there was little or no evidence of the distribution of mRNA in the human body, the quantity of spike protein produced or indeed its persistence. Subsequently, spike protein has been shown to
    a. be distributed in various organs and blood vessel walls throughout the body and in heart muscle cells;
    b. negatively affect the integrity of the human blood-brain barrier[13]; and
    c. persist for longer than originally thought.
21. These potential safety issues only emerged during vaccine rollout to the population.
22. We can only assume that MHRA briefed Ministers about the omission of these key tests and about the consequential safety risks.
23. <u>Vaccine Ingredients</u>. MHRA appears not to have identified (or discounted without investigation) that some of the ingredients were novel or known to be toxic and/or harmful.
24. For example :
    a. Pfizer's lipid ingredients ALC-0159 and ALC-0315 had not previously been included in any licensed drug before[14] (page 14) and had undisclosed quality control standards.

b. ALC-0315 is a type of man-made molecule called a cationic lipid, which can be toxic because it can trigger a process that leads to inflammation and cell death. This was reported[15] in 2018 as a major challenge for using cationic lipids in different applications;
c. ALC-0159 contains PEG (Polyethylene glycol) which is known[16] (Section 3) to cause anaphylaxis which can be life-threatening;
d. the lipid nanoparticle technology used in the mRNA vaccines had been previously found[17] to be toxic when multiple doses were given, in attempts to make it work for conventional gene therapy; and
e. the adenovirus vector used in the AstraZeneca vaccine was known since 2007 to cause platelet activation which can lead to blood clots.
f. mRNA within cells can alter the cell's 'signature' making it appear foreign to the immune system and increasing the risk of autoimmune disorders.

25. Taking manufacturers' assessments at face value. In January 2022, after a US court case, Pfizer was forced to release its clinical trials documents at a rate of 55,000 pages every 30 days[18].
26. We found some concerning data where results were, *prima facie*, worse in the vaccine group than in the placebo group :
    a. the US Food & Drug Administration (FDA) reported[19] (page 23) "*From Dose 1 through the March 13, 2021 data cutoff date, there were a total of 38 deaths, 21 in the COMIRNATY* (Pfizer vaccine) *group and 17 in the placebo group. None of the deaths were considered related to vaccination.*";
    b. Pfizer reported[20] (Table S4 on page 11) four cases of cardiac arrest in the vaccine group compared to one in the placebo group; and
    c. Pfizer stated in its 6 month follow up report that the number of deaths from any cause was higher in the 'vaccine' group : 15 deaths, compared to 14 in the placebo group[21] ('Adverse Events 3rd para) and [22] (Table S4 on page 11). Pfizer stated that "*none of these deaths were considered to be related to BNT162b2 by the investigators"*
27. We understand that MHRA received all of the available clinical trials data prior to Authorisation but it is not known to what extent it probed the manufacturers' 'sentencing' as unrelated to the vaccine. FOI 23/056 requested release of MHRA's Requests for Further Information (RFI) letters to the manufacturers but

MHRA refused citing FOI Exemptions Section 41, Section 43 and Section 38. We therefore remain concerned that MHRA took manufacturers' assessments of causation at face value.

28. Unblinding. Phase 3 clinical trials do not generate long term safety data prior to Authorisation. So post-Authorisation medium term 'follow-up' trials of vaccinated and unvaccinated individuals is extremely important in order to start to establish the longer term safety profile.
29. However, Pfizer/BioNTech started unblinding (giving the vaccine to the placebo group) its trial on 14 December 2020[23] (page 17, 3rd para) less than 2 weeks after UK Temporary Authorisation. Moderna started unblinding its trial on 13 April 2021. We could not establish a clear date for AstraZeneca but unblinding was allowed to happen as the placebo group started to get vaccinated.
30. Unblinding may have been reasonable for any trials participants at high risk from Covid-19, but the majority were in good health and the removal of the control group was in contravention of advice from the International Coalition of Medicines Regulatory Authorities of which the MHRA is a member[24].
31. The decision to eliminate the control group before the follow-up trials were completed has made assessment of mid- to long-term adverse events almost impossible. We can only assume that MHRA briefed Ministers about the consequential safety risk.
32. Scaling up production. Pfizer's clinical trials used a Covid-19 vaccine manufactured using 'Process 1'. However, the product authorised by MHRA was manufactured using a different cheaper, higher volume, higher yield 'Process 2'. Pfizer was required[25] (bottom of page 46) to provide evidence of comparative safety and immunogenicity but this was not expected to be available before February 2021. Therefore, at the point of Temporary Authorisation (2 December 2020) MHRA had no evidence of the comparative safety and immunogenicity between the two. It confirmed this in reply to FOI 23/510[26] (page 5). The lack of comparative safety and immunogenicity data remains the case because the requirement for Pfizer to produce those data was deleted by the EMA in September 2022.
33. The position is the same with Moderna. Its clinical trials used product manufactured using a process which it called "Scale A". The product authorised and rolled out was manufactured using a different process called "Scale B". No

comparative safety and immunogenicity data were available at the point of Authorisation.

34. Likewise AstraZeneca. Its clinical trials used product manufactured by its Process 2 & 3. However, the product which was approved and rolled-out was manufactured using Process 4. There was limited characterisation comparison but even that suffered from issues with acceptance criteria and incomplete data. More importantly, there were no formal comparative safety and immunogenicity data.
35. It can only be assumed that MHRA briefed Ministers about the consequential safety risks of approving the roll-out of a product with no data to compare its safety and immunogenicity with the (different) product used in each manufacturer's clinical trials.
36. The full implications of this remain unclear but there is evidence of problems with RNA integrity, DNA contamination and batch inconsistency.
37. There were early press reports indicating potential batch issues: for example:
    a. in January 2021, there was a report[27] of 23 Norwegian care home residents dying within days of Pfizer Covid-19 vaccination;
    b. in August 2021, CNN reported that two people died in Japan days after receiving doses from a batch of Moderna Covid-19 vaccine suspended due to particulate contamination; and
    c. in December 2021, there was a report[28] that one batch of Pfizer's Covid-19 vaccine resulted in the hospitalisation of 120 children in Vietnam.
38. In early 2021, leaked emails from the EMA included documents which revealed a significant drop in the RNA integrity of the Pfizer-BioNTech vaccine in commercial vaccine batches (around 55%) compared to clinical trial batches (around 78%). This was known by key regulators, including the MHRA, just a few weeks before Temporary Authorisation was granted on 2 December 2020. The EMA classified this drop in quality as a 'product related impurity' and simply lowered the acceptance criterion of the commercial batches rolled out to the general public to 50%.
39. In 2023, independent testing[29] of surplus vials of Pfizer's Covid-19 vaccine revealed contamination with residual DNA fragments which were not completely removed during the Process 2 manufacturing process.

40. DNA contamination was already of concern to regulators prior to Covid-19. In 2010, the US FDA issued guidance to manufacturers[30] (page 37): "*Residual DNA might be a risk to your final product because of oncogenic and/or infectivity potential. There are several potential mechanisms by which residual DNA could be oncogenic, including the integration and expression of encoded oncogenes or insertional mutagenesis following DNA integration. Residual DNA also might be capable of transmitting viral infections if retroviral proviruses, integrated copies of DNA viruses, or extrachromosomal genomes are present*.".
41. In June 2022, research[31] by Sasha Latypova, a retired pharmaceutical R&D executive, was published showing significant batch variation in the rate of reported serious adverse events and deaths from the Pfizer Covid-19 vaccine compared with the 'flu vaccine.
42. In March 2023, a Danish study[32] found that some batches were associated with a much higher reporting rate of adverse reaction and death. The Paul-Ehrlich-Institut, Germany's equivalent of MHRA, countered the report's findings, highlighting the lack of segmentation (eg the interval between vaccination and adverse event or the age and gender of the vaccinated persons) and confounders (eg batches are not all 100% used and are available for different lengths of time). These are reasonable observations but it has failed to publish any corresponding 'improved' analysis of its own. It is also worth noting that MHRA does not actually have data for age, time from vaccination to death/injury and vaccine batch for all fatal/serious adverse event reports (see para 75 below).
43. UK batch testing is done by LGC Ltd which is MHRA's Official Medicines Control Laboratory (OMCL) certified by MHRA's National Institute for Biological Standards & Control (NISBC). LGC's batch testing of the Covid-19 vaccines is limited to 'potency & identity' (basically checking the amount of active ingredients) and, for Pfizer & Moderna only, testing against specification of RNA encapsulation, RNA content, and RNA integrity; not DNA contamination.
44. MHRA's reply to FOI 23/796[33] stated that, despite reports of DNA contamination in the Pfizer Covid-19 vaccine, it *"currently has no intentions to test for the presence of fragmented DNA and SV40 enhancer*". We think this is negligent.
45. Finishing. The vaccines are presented in multidose vials. The process of thawing, diluting and mixing Pfizer vaccines is carried out in vaccination centres, which poses a risk of inadequate mixing leading potentially to both over- and

under-dosing. This risk is particularly significant when 'finishing' is done by volunteer vaccinators instead of trained healthcare professionals. Good Manufacturing Practice, the regulatory handbook covering drug manufacture, legally mandates 'finishing' to be carried out in a facility licensed to manufacture pharmaceutical products, to minimise the risk of potentially dangerous errors. Many of the vaccination centres, hastily constructed for the Covid-19 vaccine rollout, did not have the required licences and would not have been eligible for one.

46. Assessment of Benefit The impetus for early Authorisation, despite the inevitable increase in safety risks from much shorter than normal trials and key testing being omitted, was attributed to the perceived public health benefit of Covid-19 vaccination[34]. However, it was already known at the time that:
    a. the average age of death from Covid-19 was the same as, if not higher than, the average age of death from all causes; and
    b. the risk to younger age groups from Covid-19 is very small. For example: only 6 healthy children died of Covid-19 in England between March 2020 and March 2021, less than the number of children dying of influenza every winter
47. Indeed, Kate Bingham, head of the UK Vaccine Task Force, said[35] in October 2020: "P*eople keep talking about 'time to vaccinate the whole population', but that is misguided*", "*There's going to be no vaccination of people under 18. It's an adult-only vaccine, for people over 50, focusing on health workers and care home workers and the vulnerable*." The Secretary of State for Health confirmed this in the Commons on 10 November 2020 (Hansard, Column 748): *"The vaccine will not be used for children. It has not been tested on children. The reason is that the likelihood of children having significant detriment if they catch covid-19 is very, very low. This is an adult vaccine for the adult population."*
48. This is supported by looking at the Number Needed to Vaccinate (NNV) which quantifies the balance between health benefit and risk from the disease. It is not known what was MHRA's assessment of 'Number Needed to Vaccinate' (NNV), by age group, in December 2020 or even if one existed. However, in January 2023, the Government published data[36] (Table 3) that had been provided to JCVI in October 2022, giving the estimated number of people, segmented by age and risk, who needed to be vaccinated (NNV) to prevent a single hospitalisation or

intensive care admission. For older age groups, the numbers were in the thousands or tens of thousands. However, for healthy younger cohorts, the numbers were in the hundreds of thousands.

Table 3: NNV for prevention of hospitalisation for different programmes

	Programme			
Age	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
5 to 11	34200			
12 to 15	31400			
16 to 19	11200	76000	73500	
20 to 29	13300	17600	40900	
30 to 39	9900	15300	35900	
40 to 49	10000	9600	20600	
50 to 59	3000	3000	8000	
60 to 69	1200	1000	3600	
70+	300	500	800	
In a risk group	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
20 to 29	2400	3400	7500	7500
30 to 39	1600	3100	7800	7800
40 to 49	2200	2500	6000	6000
50 to 59	800	1200	3100	3100
No risk group	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
20 to 29	19900	33900	168200	
30 to 39	21700	53800	210400	
40 to 49	21700	44900	92500	
50 to 59	10900	15800	43600	

49. These NNV data just confirm that the vaccine reduces a younger person's chance of hospitalisation from Covid-19 by a tiny percentage because Absolute Risk Reduction is the reciprocal of NNV - which, as already stated, was already known in mid 2020.
50. No data were presented for NNV to prevent a death.
51. We therefore believe that MHRA failed to take proper account of the very different balance of benefit and risk across the age ranges. The Temporary Authorisation simply licensed the Covid-19 vaccination for all individuals aged 16 and over and left deployment decisions to the JCVI.
52. Notwithstanding the heightened safety risks from the much shorter than normal trials, low benefit to younger age groups and no evidence of the effect on transmission, the Covid-19 vaccines were authorised in Dec 20/Jan 21, specifically: the Pfizer, AstraZeneca and Moderna Covid-19 vaccines were provided with Authorisation letters from the MHRA on 2 December 2020; 30 December 2020 and 8 January 2021, respectively, under Regulation 174 of the human medicines regulations (HMR) 2012.
53. Despite the omission of key tests, MHRA misleadingly claimed[37] (3rd para from the bottom) that "*no corners were cut*". It attributed the speed of Authorisation to

'rolling review' – "*assessing packages of data as they became available from ongoing studies on a staggered basis."*

54. We acknowledge that a rolling review process is faster than waiting for the whole dataset. However, it simply does not obviate the underlying issue that the much shorter than normal clinical trials of the Covid-19 vaccines generated correspondingly less safety and effectiveness data.

55. Audit Trail for Temporary Authorisation We believe that the audit trail for Temporary Authorisation is confused.

56. On 7 November 2020, Professor Van Tam, then Deputy Chief Medical Officer for England, wrote[38] to Dame June Raine, Chief Executive of the MHRA, seeking her views about the suitability of the Pfizer Covid-19 vaccine for Temporary Authorisation under Regulation 174 of the Human Medicines Regulations (HMR) 2012. Professor Van Tam wrote similarly on 24 November 2020 regarding the AstraZeneca vaccine[39]; and 24 December 2020 regarding the Moderna Covid-19 vaccine[40].

57. Dame June Raine did not reply to Prof Van Tam. Instead, Lord Bethell, one of the Health Ministers, intervened[41] and instructed MHRA to draft a reply for him to send to Prof Van Tam which he did on 1 December 2020 (Pfizer)[42]; 29 December 2020 (AstraZeneca)[43]; and 7 January 2021 (Moderna)[44], respectively. In each letter, Lord Bethell said "*I have decided to approve*" (that Covid-19 vaccine). This is contrary to the Human Medicines Regulations (2012), Part 1, Section 6 which defines the Licensing Authority as the Secretary of State for Health (except in Northern Ireland).

58. Why did Dame June Raine not reply to Prof Van Tam ? Why did Lord Bethell intervene ? What advice did Dame June Raine provide to Lord Bethell to underpin the latter's reply to Prof Van Tam ?

59. We found other evidence of confusion between Ministers and MHRA about legal accountability for medicine authorisation:

    a. at the Covid-19 Vaccine Damage APPG on 5 June 2023, Maria Caulfield was asked why the AstraZeneca Covid-19 vaccine was still authorised despite withdrawal on safety grounds in other countries. She replied *"It is for the MHRA to determine to suspend a licence. I will ask the MHRA to confirm why we did not suspend the licence for the AstraZeneca Covid-19 vaccination when other countries did. The Government cannot suspend a*

licence. Rather, the Government (through the licensing minister) follows the MHRA's recommendation."[45] (Question 13); and

b. in reply to FOI 22/1002, MHRA stated that "*All the Covid vaccines and therapeutics authorisation decisions were taken by the Licensing Minister and were not delegated.*"[46] Yet the Licensing Minister is the Secretary of State, not Lord Bethell.

60. We believe that this apparent confusion between Ministers and MHRA about responsibility and accountability is unacceptable in relation to safety.

VACCINE PHARMACOVIGILANCE

61. General. Given residual post-Authorisation risks, medicine Regulators employ a range of Pharmacovigilance techniques including monitoring, investigation and statistical analysis of spontaneous reporting of adverse events and post-Authorisation (Phase 4) studies, supplemented by, *inter alia*, ecological (population-level) analysis, audit, enforcement and regulations about advertising.

62. This is no different in principle to other safety critical sectors but we found that MHRA's implementation has serious shortcomings and does not follow some key elements of best practice in other sectors.

63. Statistical Analysis of Yellow Cards. Contrary to popular belief and the impression given in its public statements, MHRA's safety monitoring of medicines does not rely on investigating individual Yellow Card reports and assessing causation. Instead, MHRA relies on a form of statistical analysis called 'disproportionality analysis'. This involves weekly mining of the database of all Yellow Card reports for all medicines looking for statistically significant differences in the frequencies of different types of side-effect between the drug of interest and other drugs. All major medicine regulators use disproportionality analysis but they use different algorithms and signal detection thresholds, so they perform differently.

64. There is a fundamental problem with this approach: it is a relative assessment of safety (is this medicine more or less safe than other similar medicines?) whereas other safety critical sectors assess safety in absolute terms. This is explained in more detail at para 100.

65. The problem is that if MHRA misses any safety signals (and it does), they get incrementally baked into the baseline. Newer drugs can then have more adverse events and still be considered acceptably safe by MHRA because the older ones

have safety issues undetected by its statistical analysis. It seems like a race to the bottom.

66. Missed Safety Signals. There is evidence of MHRA missing safety signals.

67. At the beginning of March 2021, nine weeks after the AstraZeneca Covid-19 vaccine rollout began, national regulators in Austria, Denmark, Norway, Iceland and Germany, started to report a potential link between blood clots and the Covid-19 vaccines. Denmark suspended use of the AstraZeneca Covid-19 vaccine on 11 March 2021, after they had vaccinated 734,000 people. Other countries rapidly followed suit[47]. On 11 March, MHRA said[48] that it could see no evidence of a linkage, despite associated Yellow Card reports as early as 7 February, and it did not publish safety advice until 7 April 2021[49]. By then, 24 million people had been vaccinated in the UK without MHRA's pharmacovigilance system confirming the problem.

68. Later, MHRA became concerned about the effect on its disproportionality analysis of the very large proportion of COVID-19 vaccine reports in its Yellow Card database - by then over 80% of all vaccine-related Yellow Cards.

69. It undertook some analysis which reported[50] in June 2022. Specifically, MHRA was concerned that:

    a. "*With the majority of the vaccine dataset now comprised of reports for COVID-19 vaccines, these have the potential to unduly influence the disproportionality statistics for other vaccines.*"

    b. "*If the safety/reporting profile for the COVID-19 vaccines differs significantly from other vaccines then this will impact disproportionality statistics and either mask potential signals or result in more false positive signals.*"

    c. "*Additionally, there are potential issues with the large volume of COVID-19 vaccine reports impacting the disproportionality analyses for the COVID-19 vaccines themselves*."

70. MHRA's report concluded that the high number of Covid-19 vaccine Yellow Cards was indeed suppressing signal detection for other vaccines, leading to safety signals being missed. So the MHRA decided to:

    a. remove Covid-19 vaccine Yellow Cards from disproportionality analysis of other vaccines; and

b. assess Covid-19 vaccines against other drugs (rather than other vaccines) and to change the statistical method used.

71. It is not clear from its report what specifically happened to trigger its concern or when that was. The report refers repeatedly to 8 February 2022 in terms of a YC database snapshot so presumably MHRA realised that there might be a problem just before then. We can only assume that MHRA reported the issue to Ministers as soon as they became aware of it.

72. In 2013, MHRA's reply to FOI 13/186[51] showed that it took an average of 11 years from Authorisation to withdraw medicines on safety grounds. This would be unacceptable in any other safety critical sector such as aviation, nuclear or defence. FOI 23/361 sought up-to-date data but MHRA refused on grounds of cost (Section 12 Exemption).

73. The safety issues highlighted by the Cumberlege Report with Primodos, pelvic mesh and sodium valproate had persisted for years, even decades, before they were formally recognised by MHRA.

74. MHRA would, presumably, acknowledge that its Disproportionality Analysis (above) is not perfect and would argue that its Pharmacovigilance has other strands. However, these have shortcomings, too.

75. Investigating fatal/serious YC reports. MHRA says it does a weekly review of all new fatal/serious YC reports but this can, at best, only be cursory and superficial because there are too many to review properly. For example:

    a. in September-October 2021, there were 118 fatal reports (15 per week) and 17,500 serious reports (>2000 per week) associated with the Covid-19 vaccines;

    b. the average to 25 October 2023 was 17 fatal reports per week. 35% of those were individuals less than 60yrs old.

76. MHRA acknowledges the 'low level of completeness' of YC reports[52] (slide 4). Many YC reports are missing key data such as age[53], time from vaccination to death/injury[54] (Question 2), vaccine batch data[55] and medical records which are surely crucial to any preliminary assessment of a new fatal or serious YC report.

77. MHRA confirmed in reply to FOI 23/400[56] that it does not hold records about the number of causation assessments it has made, what the assessments were, nor does it have a written process for assessment of causation.

78. In reality, MHRA does not follow up a fatal/serious YC to obtain missing key data until it is triggered to do so by its Disproportionality Analysis (above) or it receives a Coroner's report citing the medicine as the cause of death.

79. We would simply note that:

    a. following up fata/serious YC reports must be important because MHRA knows that its statistical analysis misses safety signals and is just a relative assessment between medicines; and

    b. other safety critical sectors do investigate all reported safety incidents.

80. In any case, we found evidence that MHRA's follow-up of YCs is haphazard. For example:

    a. in reply to FOI 23/379[57] MHRA stated that of 121 YCs for the Moderna vaccine with a fatal outcome, it followed up 65 with healthcare professionals, of which 42 went unanswered meaning that they could not be properly investigated. The antithesis of rigorous follow-up;

    b. MHRA does not have this sort of information at its fingertips. Due to limitations of the YC database, that FOI required time-consuming manual extraction of data from each individual YC; and

    c. FOI 23/641 asked, in relation to a 2 month sample of Yellow Cards (September-October 2021), how many fatal/serious ones included the individual's age, vaccine batch, time between vaccination and fatal/serious event, and the individual's medical records. MHRA refused on the grounds of excessive burden due to limitations of the YC database;

    d. Analysis of MHRA's downloadable interactive Drug Analysis Profiles (iDAPs) reveals that, as at 25 October 2023, for the Pfizer, AstraZeneca and Moderna Covid-19 vaccines combined, 16% of all fatal YC reports (qty2508) still had no age recorded.

81. All of this shows that MHRA:

    a. has no routine management information about YC follow-up: how many YCs are missing key data and how many requests to reporters for further information are outstanding; and

    b. cannot properly interrogate the YC database for trends which might indicate safety issues with a medicine - for example, age, batch-related issues and temporal association.

82. We believe that MHRA should:
    a. routinely obtain data missing from all new fatal/serious YC reports and those associated with children & pregnancy, not wait until some time in the future when its statistical analysis finds a potential safety signal or it happens to receive a Coroner's report;
    b. make the IT and process changes necessary to have real-time management information about follow-up and investigation of YC reports and rapid searching for trends; and
    c. have a written process covering the follow-up and investigation of individual YC reports. It does not currently have one[58] (bottom of page 2). Likewise for assessing causation (consisting of things like: who does the assessment, what medical qualifications they must have, what data are required, causation criteria, 3rd party sign off and what to do with the assessment).
83. On 29 July 2023, I emailed[59] the Secretary of State for Health (copy to the PSC, Baroness Cumberlege and my MP) expressing concern that MHRA does not properly investigate serious/fatal Yellow Card reports and that its statistical analysis is poor. I received a reply from DHSC but it ignored those points.
84. Wider public data Another element of MHRA's Pharmacovigilance is supposed to be review of wider public data for potential safety signals. However, we found some important sources where MHRA is completely passive - just waiting to be sent information (which does not usually happen):
    a. Regulation 28 reports. The Chief Coroner collects and publishes individual Coroner's Regulation 28 'Reports to Prevent Future Deaths (RPFDs) many of which include a medicine as the cause of death. On 19 January 2023, MHRA confirmed in reply to FOI 22/1113[60] that it had not received any Regulation 28 reports citing Covid-19 vaccines as the cause of death, being unaware that two such reports[61,62] had previously been published by the Chief Coroner;
    b. Coroners Inquests MHRA's reply to FOI 22/1113 also confirmed that MHRA "*does not hold information on Coroner's Inquests unless they are reported to us, which is not always the case. Therefore we are not able to provide a number for how many Inquests found a COVID-19 vaccine responsible for a death.*";

c. Post-mortems MHRA's reply to FOI 22/1113 also confirmed that MHRA "*does not hold information on post mortems unless they are provided in relation to a Yellow Card report.*"; and

d. Vaccine Damage Payment Scheme (VDPS). MHRA is not involved in the VDPS process[63] (page 2) – another source of safety signals.

85. There are also wider population-level data. We found many examples which individually might be rejected as circumstantial, "correlation does not equal causation" or "confounding factors". However, collectively they strongly indicate potential signals of a serious level of death and serious injury from the Covid-19 vaccines which we believe should have triggered close scrutiny by MHRA.

86. UK national population-level data includes the Office for Health Improvement and Disparities (part of DHSC) which produces excess mortality graphics. England saw increases in excess deaths after Covid-19 vaccine rollout started, especially in the 25-49 and 50-64 age groups, and for cardiac and ischaemic heart deaths[64]. This has continued. An analysis[65] published in the Lancet on 1 December 2023, co-authored by Imperial College, the ONS and DHSC, stated that:

a. "*in the year to June 2023, excess deaths were 11% higher than expected for 25-49 year olds, 15% higher for 50–64 year olds and 9% higher for over 65 year olds*";

b. "*this is driven by: all cardiovascular diseases (+12%), heart failure (+20%), ischaemic heart diseases (+15%), liver diseases (+19%), acute respiratory infections (+14%), and diabetes (+13%)*"; and

c. "*the greatest numbers of excess deaths in the acute phase of the pandemic were in older adults. The pattern now is one of persisting excess deaths which are most prominent in middle-aged and younger adults*."

87. NHS data showed a marked increase in ambulance calls in England for life threatening conditions[66] (Section 4.2) coinciding with the start of Covid-19 vaccinations.

88. Public Health Scotland data shows that compared with 2018-19 there was an increase in cardiovascular incidents in early 2020 (presumably due to Covid-19) but then a further increase coinciding with Covid-19 vaccination from Dec 20[67].

89. The Office for National Statistics (ONS) publishes employment data. In 2020, there was a rise in the number of people not working due to long-term sickness (presumably partly due to Covid-19). However, the numbers started to rise again in mid 2021[68] which coincides with the Covid-19 vaccines being rolled out to the working age population. One would have expected an effective Covid-19 vaccine to have reversed the trend but by the end of 2022, the number was about 25% higher than the 2014-2019 level.

90. There is a plethora of national data from around the world, as well as research reports. Here is a very small selection:

    a. in August 2021, a study of 40 US hospitals clearly showed an increase in incidence of myocarditis and pericarditis coinciding with the roll-out of the Pfizer, Moderna and Janssen Covid-19 vaccines[69]. It observed that this was primarily in younger males within a few days after the second vaccination, and at a higher incidence rate than acknowledged by the US authorities at the time;

    b. in November 2021, a US study of cardiology patients observed a post Covid-19 vaccination increase in biomarkers associated with the risk of heart attack. It predicted an increased risk of heart attack within 5 years from 11% to 25%[70];

    c. in April 2022, an Israeli paper showed a 25% increase in acute coronary syndrome and cardiac arrest calls in 16-39 year olds in Israel associated with the first and second doses of Pfizer Covid-19 vaccine but not with Covid-19 infection[71]; and

    d. there was a significant rise in US disability data for people aged over 16[72] coinciding with Covid-19 vaccination.

91. We are aware of an argument that these harms were entirely attributable to the Delta wave and 'long Covid'. We disagree: not everywhere had significant Covid-19 infections before Omicron. Indeed, there is a very important control group – Australia.

92. Covid-19 vaccine roll-out in Australia started on 22 February 2021. There were very few Covid-19 cases prior to December 2021[73] but its hospitals started to be overwhelmed before that:

    a. in April 2021 Queensland doctors called this a "*ticking time bomb*" and described a "*flood of patients.*"[74];

b. in the year to June 2021, despite the low Covid-19 case rate, South Australia saw 25,800 extra ambulance calls (mostly cardiac) compared to previous years - about double the increase seen in the preceding two years;

c. a Freedom of Information request[75] showed that prior to Covid-19 South Australia normally saw an average of about 1,100 cardiac presentations per month for 15-44 year olds. There was a notable rise to just over 1,200 per month from February 2021 when vaccine rollout started. It rose again when Covid-19 hit in December 2021 which suggests that both Covid-19 and Covid-19 vaccination contributed to increased cardiac issues in younger age groups;

d. by October 2021, despite it being spring in Australia, there were press reports of ambulances being unable to drop off patients in hospitals that were at full capacity. Mark McGowan, Premier of Western Australia, said: "*Our hospitals are under enormous pressure. This has been something no-one has ever seen before. Why it is, is hard to know."* [76]; and

e. overall in 2021, compared with 2015-19, there was elevated excess mortality after Covid-19 vaccination roll-out but before any significant Covid-19[77].

93. Another control group is Singapore which is one of the most Covid-19 vaccinated nations (91.5%). Vaccine roll-out started only 1-2 months after the UK but it had minimal Covid-19 until Omicron in September 2021. Nevertheless, it saw cardiovascular deaths increase by 9% in 2021, compared with 14% in England[78] (Table 3). The explanation is probably multifactorial but Covid-19 vaccination starting around the same time in both countries but Covid-19 not hitting Singapore until much later would clearly help to unravel the relative contributions of Covid-19 and the vaccines.

94. We also found population level data that shows that

a. the more doses given, the higher the Covid-19 rates[79] (Figure 2, page 21); and

b. repeated injections switch the immune response into a different antibody type (IgG4). This antibody allows 'tolerance', thus preventing an immune response to foods, for example. The result of this switch in IgG subclass is that the spike protein is ignored, thus increasing the risk of infection[80].

95. On 5 January 2022, in reply to FOI CSC 82243[81], MHRA said that it did not hold information about the duration of hospitalisation for those where the primary diagnosis was Covid, segmented by vaccination status and age. We regard that as an obvious population-level indicator of Covid-19 vaccine safety and effectiveness, as well as informing the known risk of Vaccine-Associated Enhanced Disease (VAED) - the risk that a vaccinated individual is sicker when infected with a later variant compared with the unvaccinated. MHRA referred me to UKHSA which confirmed that it did not hold the information either.
96. Overall, MHRA appears to have ignored a wide range of alarming population-level data in UK and overseas about:
    a. significant numbers of serious reactions, hospitalizations, and deaths from Covid-19 vaccines;
    b. a rise in hospitalisations and ambulance calls for heart attacks and other serious conditions coincident with Covid-19 vaccination roll-out;
    c. rise in long-term sickness and disability some of which is potentially linked to repeated Covid-19 vaccination; and
    d. Covid-19 vaccination in the absence of Covid-19 (Australia, Singapore).
97. MHRA Proactive Vigilance Strategy. In February 2021 (which was, notably, after initial Authorisation) the MHRA published its Proactive Vigilance strategy[82] for the Covid-19 vaccines. However, we found evidence of it not being followed through.
98. The MHRA's Yellow Card Vaccine Monitor (YCVM) programme was a proactive programme, working closely with the NHS, where a large number of Covid-19 vaccinees would be invited to register (before vaccination and therefore before the onset of any side-effects) for individual follow-up at set intervals to ask about any subsequent adverse reactions or other health issues. Just under 30,000 people were registered. In December 2022, in reply to FOI 22/1083, MHRA released a report[83] dated 26 August 2021 which showed (Table 3), worryingly, that 53% had reported at least one adverse event. MHRA also confirmed under that FOI that this was the MHRA's last report about this surveillance programme. We conclude that it discontinued the YCVM programme after only 6 months.
99. MHRA's Clinical Practice Research Datalink (CPRD) bibliography lists peer-reviewed research and reports that have used anonymised population-level data provided by MHRA from NHS datasets for, *inter alia*, ICU, A&E, inpatients,

outpatients, cancer registration, and pregnancy, including Covid-19 vaccination status. However, it is apparent that the MHRA is either not conducting population-level data analysis relating to the Covid-19 vaccines (or is not publishing the results) because:

a. none of the datasets provided by the MHRA's CPRD division for research include any NHS data after June 2021;
b. by January 2023, MHRA's CPRD Bibliography contained only two population-level studies relating to the Covid-19 vaccines, both relating to thrombocytopenia (low blood platelet count), one from February 2022 and one from October 2022. So after 2 years, only one type of adverse event had been subject to MHRA's promised ecological analysis; and
c. to date, MHRA's CPRD database shows that no new research studies have been approved by MHRA/CPRD since July 2022.

100. The following paragraphs describe elements of 'best practice' safety management in other safety critical sectors which MHRA does not follow.

101. Safety Risk assessment. In other safety-critical sectors there is a clear, documented process for assessing the absolute safety risk and tolerability of harms from use of products, and use of the ALARP principle - reducing safety risks to 'As Low As Reasonably Practicable'. The implementation varies by sector but they are, in principle, all the same : the design/development process, safety approval process and the monitoring of post-approval use are all managed and regulated against absolute, quantified safety targets and risk assessments.

102. In Defence, this is explained in Section 2.8 of 'An Introduction to System Safety Management in the MOD'[84]. Figure 4 (page 15) is a simple illustration of the tolerability of safety risk and Figure 9 (page 33) of Safety Risk Classification:

Figure 4: Risk as a Combination of Severity and Probability

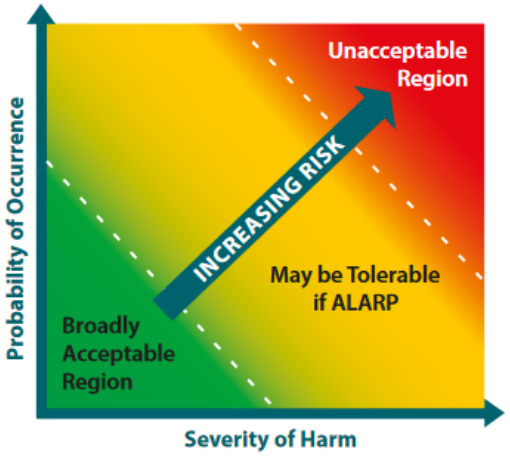
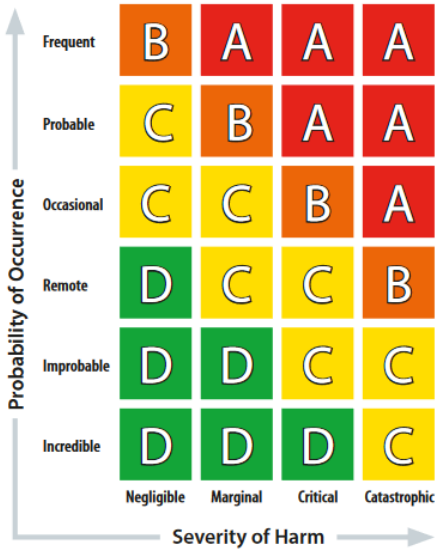


Figure 9: A Risk Classification Matrix



103. Unlike MHRA, other safety critical sectors also have safety management systems which include tolerability of risk. Picking a few examples :
    a. the Civil Aviation Authority's 'Principles and Guidelines for the Spaceflight Regulator in assessing ALARP and Acceptable Risk'[85]. Figure 2 (page 4) illustrates 'tolerability of risk';
    b. in aviation, there are absolute safety targets such as the number of fatal incidents per million flying hours;
    c. in nuclear, there are absolute safety targets relating to exposure to nuclear core damage and ionising radiation dose; and
    d. the Food Standards Agency's safety management system is underpinned by absolute safety risk assessment.
104. As well as influencing licensing decisions, the 'tolerability of risk' framework also describes, *inter alia,* clear thresholds for timely action and escalation of decision-making if safety risks increase. In this regard, product-related safety risks are categorised according to probability and safety impact. For example, in MOD, Class A risks have to be notified to Ministers; Class D risks are managed at

junior level (individuals whose competence is routinely assessed for the purposes of safety delegation).

105. In contrast, MHRA confirms that it does not define an absolute 'tolerable rate' for the safety of medicines[86]. Instead, it defines "acceptably safe" in relative terms": "*For a medicine to be considered safe, the expected benefits of the medicine will be greater than the risk of suffering harmful reactions.*" and without defining that balance for any medicine. Furthermore, as already evidenced, MHRA's primary surveillance method is Disproportionality Analysis which is a relative measure of safety, not absolute.

106. MHRA might argue that Patient Information Leaflets (PILs) accompany all medicines and list possible adverse events in terms of frequency (eg 1 in 10, 1 in 100 etc). However, those frequencies are not MHRA's thresholds for suspending or withdrawing a medicine. Rather, from inspection of evolving versions of the Covid-19 vaccine PILs, MHRA simply updated the PILs as adverse events accumulated:
    a. adding new adverse events under the appropriate frequency category;
    b. moving types of adverse event between frequency categories;
    c. adding new frequency categories (eg the 1 in 10,000 category first appeared months after Temporary Authorisation); and
    d. it also fails to provide any quantified risk by age. For example, in relation to myocarditis, it simply states: *"myocarditis is more common in younger age groups"*, from which it is impossible for healthy young adults to know how much more common.

107. We also note that the original PILs for the Covid-19 vaccines did not even mention the risk of death. This was added later (AstraZeneca 18 April 2021; Moderna 15 September 2023) but not actually quantified: MHRA just introduced the possibility as "*fatal cases have been seen*" or "*some cases had a fatal outcome*". It is still not mentioned in the Pfizer PIL despite at least one Coroner citing that vaccine as the cause of death. This is the antithesis of informed consent.

108. Overall, it is unclear what safety risk criteria eventually lead MHRA to suspend/withdraw a medicine.

109. **We believe that this issue of MHRA's safety management being, essentially, relative and not built on the absolute tolerable level of risk of**

harm or death goes to the heart of the matter. Even without the Covid-19 vaccines, the volume of YC reports (many of which omit key information) is too large for MHRA to investigate them properly or assess causation. MHRA relies instead on statistical analysis which misses some safety signals, and it has no absolute thresholds for either risk or benefit which would trigger action. MHRA must also be keenly aware of the pharmaceutical industry's significant financial investment in any medicine so is, presumably, cautious about the 'burden of proof' when considering safety action.

110. There is a further problem which underlines the point. It seems more common in the pharmaceutical sector than other safety critical sectors that the safety risks turn out to be higher, and/or the benefits lower, than assessed at the point of approval. I am not being accusative; rather, it arises from the greater complexity of the human body, the variability of every person's health baseline and their reaction to a medicine, compounded by the complexity of interactions between medicines and the widely accepted limitations of clinical trials. This emphasises the need for robust safety management of medicines at which, on the evidence, MHRA is failing.
111. Independent Safety Audit. Unlike other sectors, there is no independent Safety Audit of MHRA. Instead MHRA relies on Quality Audit[87]. The two are very different: quality audit is about compliance; safety audit is about risk.
112. Organisational separation. Unlike other sectors, there is no separation between those responsible for a) Regulation (rule-making, audit and enforcement) and b) those undertaking safety management. MHRA tries to fulfil both functions. Put another way, MHRA is the safety manager for the NHS which buys and dispenses medicines, yet it is also the Regulator trying to hold itself to account.
113. Delegation. Unlike other sectors, MHRA has no process for delegation to competent, suitably qualified and experienced individuals of the responsibility for products' safety and effectiveness[88]. Instead, safety decisions are made by groups not individuals (which raises the risk of 'groupthink' and procrastination: "let's wait for more data") and there is no written process for escalating higher safety risks up the management chain, ultimately to the Secretary of State who is legally accountable under the HMR 2012. Neither did we find any evidence of graded classification of product safety risks to inform routine senior management product safety reviews within MHRA.

OVER-PROMOTION

114. Using the word "Safe". The MHRA is also responsible for the monitoring of, and the enforcement of laws governing, the advertising of medicines in the UK, which are outlined in its own guidelines to these laws: "The Blue Guide".
115. MHRA's 'Blue Guide' says *"Advertising which states or implies that a product is "safe" is unacceptable. All medicines have the potential for side-effects and no medicine is completely risk- free…".* However, the Government, DHSC, MHRA, UKHSA, NHS, media and celebrities have all frequently used, unqualified, the word "safe" in relation to the Covid-19 vaccines. We are not aware of any action being taken.
116. Presentation about Risk Reduction. Relative Risk Reduction (RRR) compares the number of vaccinated people getting ill with the number of unvaccinated people getting ill. Absolute Risk Reduction (ARR) is a measure of how much vaccination reduces an individual's baseline risk of getting ill if infected.
117. Vaccine manufacturers (and others) focused on promoting the Relative Risk Reduction of the Covid-19 vaccines (which they claimed from their original clinical trials was c95% but which later proved wildly over-optimistic), rather than the Absolute Risk Reduction (which was about 0.88% across all age groups). Younger age groups were at even lower risk from the Alpha/Delta variants to start with, and a <1% reduction in an individual's risk due to Covid-19 vaccination would hardly have been very persuasive, hence the promotion of the RRR figure.
118. The Association of the British Pharmaceutical Industry (ABPI), the pharmaceutical industry's regulator, in its Code of Practice prohibits the use of relative risk reductions without also discussing the absolute risk reduction. The industry self-regulatory body, the Prescription Medicines Code of Practice Authority (PMCPA), has upheld several complaints about this. Government officials and agencies (including the MHRA itself) are also guilty of this misrepresentation. MHRA appears to have taken no action.
119. A complaint filed by parents' action group 'UsForThem' against Pfizer was upheld[89] by the ABPI in relation to safety claims made by its CEO. The MHRA is not known to have taken any enforcement action in this instance.
120. Manufacturers' Claims.
    a. Pfizer's claims about safety and effectiveness are difficult to understand given that the number of deaths in the vaccine and placebo arms were in

step with each other for the first 20 weeks of its clinical trial (27 July - 11 December 2020 - around the point of Temporary Authorisation), and at a time of high Covid-19 prevalence. This is on top of the unchallenged assessment (paras 25-26 above) that all of the deaths in the 'vaccine' arm of the clinical trials were unrelated to the vaccine;

b. on 3 February 2021, AstraZeneca issued a press release[90] claiming "*100% protection against severe disease, hospitalisation and death*". However, this was based on few data: only two severe Covid-19 hospitalisations and one death in the placebo arm[91] ('Findings'). AstraZeneca's claim was repeated widely but we do not believe that so few data provide adequate evidence for claiming 100% effectiveness, nor was it borne out in practice; and

c. all the manufacturers claimed effectiveness of >90% in reducing the risk of hospitalisation. However, in practice, effectiveness has proved to be much lower and has waned quickly (in a few months).

121. Effect on Transmission. The case for Covid-19 vaccination of younger age groups was, in large part, based on reduction of Covid-19 transmission with emotional advertising: "*protect your loved ones*". However, the evidence that Covid-19 vaccines reduce transmission was flimsy at best:

a. the Covid-19 vaccines trials did not include assessment of effect on transmission, so there was no evidence when roll-out started;

b. in May 2021 PHE's (later UKHSA) 'COVID-19 vaccine surveillance report Week 19'[92] (Table 1) contained partial data about vaccine effect on transmission with the caveat *'Low Confidence - little evidence is available at present and results are inconclusive';*

c. on 9 September 2021 (Week 36) the corresponding report no longer included the table referred to above. Instead it included alternative data[93] (Table 4) which, ironically, showed that, for some age groups, there was a higher rate of Covid-19 infection (per 100K people) in those vaccinated compared with the unvaccinated. In subsequent Weekly Reports the differential increased more and more in favour of the unvaccinated; and

d. on 22 October 2021 Boris Johnson confirmed[94] that Covid-19 vaccination does not protect the individual from infection or from transmitting it to others.

122. Yet vaccine effect on transmission remained a key argument for vaccinating children as well as mandating Covid-19 vaccination for Care Home workers (Commons Debate July 2021) and NHS staff (October 2021).

123. Millions of Lives Saved? Some people claim that the Covid-19 vaccines saved millions of lives. One notable source for this claim is 'Global impact of the first year of COVID-19 vaccination: a mathematical modelling study' (Watson et al. (2022)) published in the Lancet[95]:

> *"Based on official reported COVID-19 deaths, we estimated that vaccinations prevented 14·4 million (95% credible interval [CrI] 13·7–15·9) deaths from COVID-19 in 185 countries and territories between Dec 8, 2020, and Dec 8, 2021. This estimate rose to 19·8 million (95% CrI 19·1–20·4) deaths from COVID-19 averted when we used excess deaths as an estimate of the true extent of the pandemic, …"*

124. However, the modelling was based on assumptions[96] which are known in the literature to be wrong. The most obvious ones are :

    a. infection-derived immunity : assumed to last 1yr (para 1.2.1) but is actually robust and much longer-lasting;
    b. vaccine effectiveness against infection: no account was taken of waning (Table 1);
    c. vaccine effectiveness against transmission: assumed as 50% reduction due to vaccination (1.2.2). However, as evidenced at para 120 above, early UK Government estimates were lower than this and were 'low confidence', 'little evidence' and 'inconclusive'; and by September 2021 the Government had given up claiming any benefit at all. In fact, by then Government data showed that, in some age groups, rates of Covid-19 infection were actually higher among vaccinated individuals than the unvaccinated.

125. There are many other such studies but they all feature unrealistic assumptions about, variously, pre-existing immunity from related coronaviruses, post-infection immunity from Covid-19, and vaccine effectiveness against infection and transmission. Also, they are also based on comparison against modelling the counterfactual (future infections in the absence of vaccination) which has proved highly inaccurate throughout.

126. One such study ("Evaluation of Effectiveness of Global COVID-19 Vaccination Campaign", September 2022) exemplifies the problem. It claimed that Covid-19 vaccination averted >1.5 million deaths in 12 countries, However, in an Appendix[97] (page 5) dealing with sensitivity analysis, it stated: "*As such, we saw virtually no difference between the model simulations with 50% transmission reduction and what happened in all vaccinated countries ……. Thus, the difference in deaths averted for the 2 scenarios appears as ≈0%."*

127. It also stated (bottom of page 5): "*... with the 20% transmission reduction in 2 countries, Mexico and Columbia, the herd immunity threshold was crossed and the disease rapidly became extinct. This indicates that a 20% reduction in the transmission rate is probably too large to be reasonable …*" That last sentence is particularly telling - they dismissed a sensitivity simply because it contradicted their preconception that the Covid-19 vaccines must, surely, have been necessary.

128. Nor do the 'millions of lives saved' models explain:
    a. the significant and sustained excess deaths since July 2021 (more than in the whole of 2020); and
    b. why those excess deaths are skewed towards the young when the risk from Covid-19 is skewed towards the old

129. An alternative hypothesis which fits those issues is that it was the emergence of the less pathogenic variants which slowed the rate of accumulation of death and serious illness, not the vaccines.

130. <u>Mortality higher in the unvaccinated?</u> ONS' vaccine mortality surveillance report for England is often cited to justify that Covid-19 vaccination is beneficial. In particular, it concludes that the age-standardised mortality rate is lower in the vaccinated than the unvaccinated. However, independent analysis[98] casts serious doubt on this. Among other things, the ONS analysis:
    a. underestimates the number of unvaccinated individuals which inflates the mortality rate for the unvaccinated and deflates it for the vaccinated.
    b. presents a non-Covid death rate for the unvaccinated about 50% higher than for the vaccinated. This is implausible.
    c. presents a non-Covid death rate for the vaccinated which are lower than historical (pre-2020) norms. This, too, is implausible

131. Serious Adverse Events are "very rare"? Some people try to justify Covid-19 vaccine safety on the grounds that serious adverse events are very rare. However,
    a. by February 2022, over 80% of all vaccine-related Yellow Card reports related to the Covid-19 vaccines (the YC system started in 1964);
    b. in September 2022, an independent reanalysis of the original Pfizer and Moderna clinical trials data found that as many as 1 in 800 suffered a serious adverse event following vaccination[99];
    c. in the US Vaccine Adverse Events Reporting System (VAERS), there have been more deaths reported in 2021 and 2022 related to Covid-19 vaccines than all reported vaccine deaths in the past 30 years combined[100] (para 3.1); and
    d. in reply to FOI 23/641, MHRA said that in just one 2 month period (1 September - 31 October 2021), it received over 22,000 Yellow Card reports associated with COVID-19 vaccines of which
        i. 118 (1 in 186) included a fatal outcome; and
        ii. 17,500 (80%) were considered serious.

    In that period, there were 1.86 million vaccinations, so ignoring under-reporting, 1 in 15,762 resulted in a report of a death and 1 in 106 resulted in a report of a serious adverse event. Obviously, they are just reports of potential association but those are staggeringly high rates and worthy of full investigation. However, for the reasons evidenced above, this is not something MHRA can or does do.

LACK OF TRANSPARENCY

132. Post-Authorisation Safety Studies (PASS). PASS studies were agreed over two years ago with Pfizer[101], AstraZeneca[102] and Moderna[103], including delivery of Interim/Progress and Final Reports, and were a condition of authorisation of the Covid-19 vaccines.
133. The PASS studies - which Pharmaceutical companies are almost always required to do for any new medicine - use real data from the NHS and other national healthcare systems to anonymously match vaccinated and unvaccinated individuals by age, gender and Covid infection status. This allows detailed investigation of the relative incidence of Adverse Events of Special Interest (AESI; including death) between vaccinated and unvaccinated individuals.

134. As they use real data from healthcare records, those PASS studies will be much more informative about Covid-19 vaccine safety than:
    a. the Yellow Card system where MHRA just compares the relative frequency of (passively) reported Covid-19 vaccine adverse events to those for other medicines, a process which has already been evidenced to miss safety signals; and
    b. the ONS analysis of excess deaths which founders (among other things) on
        i. the 'denominator problem': not knowing with certainty the number of unvaccinated people.
        ii. 'healthy vaccinee bias' : the observation that the unvaccinated are, on average, less healthy (all causes) and so more likely to die. The PASS matching process removes this bias.
135. Of the thirteen interim/progress PASS reports due to date, only 2 have been published: AstraZeneca's 'Interim Report 1' and one Pfizer 'Progress Report' which did not contain any results. However, I obtained the companies' PASS interim reports[104] via an FOI request. The reports are concerning.
136. NHS data for 2020 and 2021 were included in the companies' first interim reports but not for 2022 and 2023. Those later data were unavailable due to, firstly, "*CPRD server capacity issues*" (page 72 of Pfizer's second report dated September 2022) and then "*a quality issue with the CPRD data availability*" (page 74 of its third report) which wasn't resolved in time for its fourth (dated September 2023). Negligence, incompetence, sinister?
137. There are conflicting results between national datasets for the same AESI.
138. There are some AESIs where incidence rates are higher in the vaccinated, in particular:
    a. AstraZeneca's 'Interim Report 1'[105] dated 21 April 2022 presents rates of Adverse Effects of Special Interest (AESI) per 10,000 people which are very often higher in the vaccinated, sometimes significantly. This is shown graphically in the 'Figure 5' graphs which follow Table 11.1.
    b. Pfizer's fourth interim report[106] (dated September 2023 but which used U.K. data for 2020-21 only), includes some worrying results (page 159):
        i. Arrhythmia: "*Rates were comparable between vaccinated and non-vaccinated. In the tails of the survival curves (after 100 days),*

the curves flattened in most data sources except in CPRD where the risk increased."

ii. Heart failure: "*The incidence of heart failure was uncommon any time after the start of follow-up and increased with age, as expected, in all data sources. Rates were comparable between vaccinated and non-vaccinated individuals. In the tails of the survival curves (after 100 days), the curves flattened in most data sources except in CPRD where the risk increased.*"

iii. Acute coronary artery disease: "*From day 100-150 onwards the incidence was much lower, and the curves flattened in all databases except in CPRD where there was an increase in the cumulative incidence, especially in the vaccinated cohort.*"

139. We believe that the interim PASS reports present a loud safety signal which would surely have rung alarm bells in MHRA. We also hope that MHRA has solved the problems with UK data availability for the companies' final PASS reports due later this year.

140. Covid-19 Vaccine Benefit/Risk EWG minutes. In August 2020, the Government established a Covid-19 Vaccine Benefit Risk Expert Working Group (EWG). It met frequently and has often been cited in public reassurance about the safety of the Covid-19 vaccines: for example, in reply to a Petition for a House of Commons Debate[107]; here[108] in relation to pregnancy, breastfeeding, children, thrombo-embolic events, menstrual disorders, myocarditis, pericarditis, and Guillain-Barré Syndrome; and in answer to a Parliamentary Question[109].

141. On 15 December 2021, the MHRA said it planned to publish the EWG minutes. Specifically, in reply to FOI 21/1252, MHRA: *"The COVID-19 Vaccines Benefit Risk Expert Working Group (VBR EWG) has held 68 meetings since it was formed in August 2020, several topics are discussed at each meeting including discussions on different potential side effects. We intend to publish the minutes of the consultations with the Commission on Human Medicines (CHM). As we plan to publish the data, we consider that your request is covered by Section 22 of the Freedom of Information Act (information intended for future publication) and the information you have asked for is therefore exempt from disclosure.".*

142. However, this was later contradicted and publication was declined:

a. on 11 April 2022 in reply to FOI 22/592[110]; and

b. on 5 June 2023 in answer to a Parliamentary Question[111].

143. However, on 20 October 2023, in reply to FOI 23/695, MHRA returned to withholding publication under a Section 22 Exemption (information intended for future publication) despite nearly 2 years having passed since first applying that Exemption to FOI 21/1252 (above). That has been appealed (result pending).

144. We believe that this long standing failure to publish minutes of great public interest is a gross breach of MHRA's public assurances about transparency and the principle of 'informed consent'.

145. Freedom of Information. We have found it extremely difficult to obtain information from MHRA, frequently having to resort to requesting an Internal Review and/or complaints to the Information Commissioner. We are not alone. In August 2023, the Information Commissioner issued 'Practice Recommendations' to MHRA about "*its declining trend in performance in terms of the time limits for complying with information requests. It has also consistently failed to carry out internal reviews within the recommended timeframes.*" MHRA is also very tardy in publishing previous FOIs.

OTHER ISSUES

146. Legal and Ethical Considerations re Experimental Trials on Humans The Helsinki Declaration states that '*All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.'*

147. The Helsinki Declaration was brought into UK Law by The Medicines for Human Use (Clinical Trials) Regulations (Part 2, para 6: "Clinical trials shall be conducted in accordance with the principles of the Declaration of Helsinki.")

148. MHRA recently approved Moderna's 'NextCove' clinical trial[112].of a Covid-19 booster. The clinical trial uses healthy individuals aged 12 yrs and above to "*evaluate mRNA-1283.222, one of Moderna's bivalent COVID-19 investigational vaccines that may protect people from getting sick if they come into contact with the virus that causes COVID-19*."

149. We believe that the trial contravenes the Helsinki Declaration, and is not therefore compliant with UK Law, because

a. it was abundantly clear, *ab initio*, that younger age groups are at very low risk from Covid and would derive correspondingly low benefit from any Covid booster; and
b. Moderna stated in the Patient Information Leaflet for the NextCove booster trial that it is "*still researching the product and we do not know if it is effective and safe to use. We do not know if it will prevent SARS-CoV-2 infection or reduce the severity of COVID-19 illness.*"

150. Although MHRA defers to the Health Research Authority (HRA) on the ethical aspects of clinical trials, MHRA remains ultimately responsible for authorising clinical trials, and the Secretary of State for Health is legally accountable. It is not known if MHRA challenged the HRA in relation to the Helsinki Declaration given the negligible risk to children from Covid-19. However, we do know that MHRA "*does not hold a quantitative assessment of the foreseeable benefits to the younger individuals involved in the trial and those affected by the condition under investigation*"[113] (page 5).

151. Black Triangle. The Human Medicines Regulations state that "*The licensing authority may establish a list of medicinal products that are subject to additional monitoring.*" and "*the summary of product characteristics and the package leaflet must include a symbol and statement as follows: "▼ This medicinal product is subject to additional monitoring"*. The Covid-19 vaccines were not designated as such until months after Temporary Authorisation : Moderna (1 April 2021); AstraZeneca (7 July 2021); and Pfizer (14 July 2021). It is not clear why the Covid-19 vaccines were not designated as worthy of additional monitoring *ab initio*, or, if they were, why that status was not included in the Patient Information Leaflet as required by the Human Medicines Regulations.

152. Manpower. MHRA faced additional challenges due to Brexit, which required them to regulate all UK medicines, a task previously covered by the EMA. Unfortunately, in 2021 (associated with MHRA's reversion from Trading Fund to being funded directly by DHSC), MHRA had to make 300 (20%) redundancies due to funding cuts. To make matters worse, as at August 2022, its vacancy rate was a further 20% below the new baseline[114]. We believe that this would have severely compromised MHRA's safety management of the Covid-19 vaccines (and indeed all medicines).

153. However, we found evidence that no assessment was made of the safety implications of the manpower shortage. In reply to a Parliamentary Question (UIN 49097, 14 September 2021) DHSC confirmed that "*The Department has not made a specific assessment of the MHRA's staffing levels.*" Also, in reply to FOI 23/585[115], MHRA confirmed that it had not made any assessment of the impact on safety management as part of its Operational Transformation Programme (OTP) under which the manpower cuts were made.
154. Conflicts of Interest. The MHRA's regulation of medicines is primarily funded by fees from the pharmaceutical industry, in line with Treasury guidance. It is unclear why the MHRA's medical device regulation is funded differently, with a larger proportion of funding coming from taxpayers and only a small portion from fees. It is also worth noting that all UK regulators have different cost recovery regimes. The MHRA is not unique in facing concerns over industry funding. Similar concerns have been raised [116] regarding the funding of the FDA, EMA and TGA (the Australian medicine regulator).
155. In 2017, the MHRA received over £980,000 from the Bill and Melinda Gates Foundation which is heavily invested in vaccines. MHRA states that such donations are accepted for specific projects/programmes.
156. The key question is whether taxpayer funding of the MHRA's licensing and monitoring activities would improve safety management, particularly given the fundamental failings that have already been discussed.
157. The MHRA competes with the pharmaceutical industry for talented staff, and it is not uncommon for individuals to work in both sectors during their careers. To mitigate any potential conflicts of interest, stronger disclosure systems could be implemented to reduce the risk of biased decision-making.

SUMMARY

158. The much shorter than normal clinical trials left significant residual safety risks because key tests were omitted.
159. There was inadequate critical assessment of the manufacturers' trials data.
160. The vaccines rolled-out were manufactured using different processes to the products used in the clinical trials. There was (and remains) no evidence comparing the safety and immunogenicity of the two.
161. The audit trail for Temporary Authorisation is confused.

162. Insufficient regard was paid to younger age groups' very low risk from Covid-19. In particular, we believe that the vaccination of children was never justifiable given the absence of medium/long term safety data and flimsy evidence about the effect of vaccination on transmission.
163. Deficiencies in MHRA's pharmacovigilance hampered its identification of safety signals from the thousands of reports of adverse events which manifested post-Licensing.
164. MHRA seems oblivious to potential safety signals from population-level data, including official UK data and 'control groups' such as Australia and Singapore.
165. The significant and sustained excess deaths since July 2021 (more than in the whole of 2020) remain unexplained.
166. Safety and effectiveness of the Covid-19 vaccines and effect on transmission were overestimated and over-promoted.
167. Claims that the vaccines saved millions of lives are based on seriously flawed assumptions.
168. Deaths and serious harms from the Covid-19 vaccines have been far from rare.
169. There has been a lack of transparency regarding key safety documents.
170. We believe that involving children in clinical trials of Covid-19 boosters is unlawful.
171. MHRA does not follow some key elements of best practice safety management in other safety critical sectors.
172. MHRA had serious manpower shortages.

CONSEQUENTIAL QUESTIONS

173. The Perseus Group believes that the evidence in its Witness Statement leaves many unanswered questions.
174. Licensing:
    a. Why did MHRA regulate the mRNA products as vaccines when the manufacturers themselves (Biontech and Moderna in SEC submissions in 2020) regarded them as gene therapies which require a wider range of testing? Who decided this and when?
    b. What advice did MHRA give Ministers about the safety risks associated with the much shorter than normal trials and the key testing which was omitted?

c. Under what authority did Lord Bethell approve the Covid-19 vaccines when the Secretary of State for Health is defined as the Licensing Minister in the Human Medicines Regulations?
d. What is MHRA's assessment of where the synthetic mRNA goes in the body and for how long it persists? When did MHRA make this assessment? What is the evidence relied upon?
e. Did MHRA verify manufacturers' claims that all death/serious harms during their trials were not attributable to the Covid-19 vaccines?
f. What advice did MHRA give Ministers about the safety risks of approving the roll-out of products with no data to compare their safety and immunogenicity with the (different) products used in the clinical trials?
g. What was MHRA's assessment of 'Number Needed to Vaccinate' (NNV), by age group, in December 2020?
h. What had changed since the public statements in autumn 2020 that this was an "adult vaccine" because children were at negligible risk from Covid-19?
i. What evidence did MHRA consider in relation to the effect of Covid-19 vaccination on transmission?
j. What is MHRA's quantitative benefit/risk assessment in relation to licensing Covid-19 vaccination of children, pregnant women and those of reproductive age?
k. Why has MHRA got no plans to investigate DNA contamination found in the mRNA vaccines?

175. Pharmacovigilance:
a. Why does MHRA define safety in relative terms ("benefits outweigh risks") and rely on a method (Disproportionality Analysis) which is a relative measure of safety when other sectors manage safety in absolute terms?
b. Why was MHRA slower than other national regulators to react to safety issues with the AstraZeneca Covid-19 vaccine? Why did MHRA subsequently give it Conditional Marketing Approval despite the safety issues which led to it no longer being in use in the UK? Why has MHRA (on behalf of the Licensing Minister) not withdrawn the license for the AstraZeneca Covid-19 vaccine? Does MHRA still regard it as safe (ie "benefits outweigh the risks")?

c. Why does MHRA wait to obtain missing key data from YC reports until triggered by its Disproportionality Analysis or a Coroner?
d. Why does MHRA not have a process describing how it follows up individual YCs and assesses causation?
e. What (and when) specifically led MHRA to realise there might be a problem which led to its report about missed safety signals in June 2022? When did MHRA brief Ministers about the issue? Were the changes to its statistical methods successful going forward? What retrospective action did MHRA take regarding the safety signals which had been missed? Are there other instances of missed signals?
f. What improvements would MHRA make to its IT to facilitate routine extraction of management information and trends relating to YC reports? How beneficial would they be?
g. Why does MHRA not routinely trawl Regulation 28 reports, Coroners Inquests and Post Mortem data for potential safety signals rather than just wait to be sent information? Alternatively, why are Coroners not required to send to MHRA copies of any Inquest or Post Mortem results where a medicine was thought to have contributed to a death?
h. What wider population level data did MHRA review as part of its Covid-19 vaccine pharmacovigilance? In particular, did MHRA investigate the potential safety signals from comparisons between the relative timings of Covid-19 infection and vaccination in UK and Australia/Singapore?
i. Has MHRA investigated the potential signals that some vaccine batches might be responsible for proportionately more harms?
j. Has MHRA investigated reports of linkage between Covid-19 infection rates and the number of Covid-19 vaccinations/boosters?
k. What is MHRA's latest view about the risk of Vaccine Associated Enhanced Disease?
l. Why did MHRA apparently stop its Yellow Card Vaccine Monitor programme in August 2021 only 6 months after it was announced?
m. Why does MHRA's CPRD database only list two reports for one adverse event related to Covid-19 vaccines and only include NHS datasets for research purposes up to mid 2021?
n. Why has MHRA not published manufacturers' PASS interim reports?

o. Why has MHRA still not published minutes of the Covid-19 Vaccine Benefit/Risk Expert Working Group?
p. Why did MHRA approve Covid-19 vaccine booster trials involving children, which is, *prima facie*, contrary to the Helsinki Declaration?
q. Why did the first versions of the Covid-19 vaccine Patient Information Leaflets not mention the risk of death? What prompted its later inclusion?
r. Why did Patient Information Leaflets not carry the 'Black Triangle' designation until months after the Covid-19 vaccines were first authorised?

176. Systemic:
    a. Why did neither MHRA nor DHSC assess the safety implications of MHRA's manpower reductions in 2021 and shortages in 2022?
    b. Why does MHRA not define a threshold of safety and/or the balance between benefit and risk which would lead to the withdrawal of any medicine?
    c. Does the MHRA think that any of the following would improve its safety management:
        i. adopting the principle of absolute tolerable level of risk and product safety risk classification used in other safety critical sectors?
        ii. independent safety audit?
        iii. organisational separation so that MHRA is not the safety manager for the NHS which buys and dispenses medicines as well as the Regulator trying to hold itself to account?
        iv. personal safety delegations to individuals responsible for signing off drug licences (linked to product safety risk classification)?

CONCLUSIONS

177. There have been many attempts over the years to improve MHRA's safety management of medicines, and several previous Inquiries. The evidence in this Witness Statement is that they have not succeeded.
178. We believe that the situation will continue to get worse if not addressed. This is exemplified by a quote in 2014 from Sir Patrick Vallance, then working for GlaxoSmithKline. At the time, based on concerns about, *inter alia*, the increasing

time and cost of medicine development and clinical trials, and the pharmaceutical industry's problems with getting return on investment, Sir Patrick Vallance said: *"In the future, medicines will come to market quicker with less data, with more research being conducted in the post-license phase."* [117] (bottom of page 3).

179. How prescient.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: _____

Dated: _____

Endnotes

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