2nd August 2021

The Secretary of State for Health and Social Care
C/O The Government Legal Department
102 Petty France
London SW1H 9GL

The Medicines and Healthcare Products Regulatory Agency
151 Buckingham Palace Road
London SW1W 9SZ

Dear Sirs,

Proposed claim for Judicial Review
LETTER BEFORE CLAIM PURSUANT TO THE
PRE-ACTION PROTOCOL FOR JUDICIAL REVIEW

Authorisation for Temporary Supply of COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection (BNT162b2 RNA)

We are instructed on behalf of relevant children whose identity will be divulged to you within the next 21 days. This is a letter before claim in accordance with the Judicial Review pre action protocol under the Court's Civil Procedure Rules (CPR). We intend principally to set out (a) a clear summary of the facts and the legal basis for the claim and (b) details of the information that our client is seeking and why it is considered relevant.

1. Proposed claim for judicial review

1. This claim is brought against the Secretary of State for Health and Social Care, care of The Government Legal Department, and/or alternatively the Medicines and Healthcare Products Regulatory Agency (MHRA).

2. The claim relates to emergency authorisations by the Secretary of State, acting as the licensing authority and on the advice of the MHRA, of the COVID-19 mRNA Vaccine BNT162b2 (BNT162b2 RNA) ('the Vaccine'). The Secretary of State is sued as the licensing authority, acting on the advice of the MHRA, for the Vaccine.

2. The Claimants

3. The identity of relevant children, who are aged between 12-15 years and 16-17 years, and litigation friends will be divulged to you within the next 21 days.

3. The Defendant's reference details

4. Please advise. The Secretary of State is asked to say if he considers that the MHRA would be the correct Defendant in its own right; and, similarly, the MHRA is asked to state its view as to whether it or the Secretary of State is the correct Defendant.

4. The details of the Claimants' legal advisers

5. Jackson Osborne Solicitors, 20 Little Britain, London EC4 (ref: JRMHRA22101)

5 The details of the matter being challenged

6. We challenge the following:

(1) The decision of the Secretary of State on 2nd December 2020, acting on the advice of the MHRA, to grant temporary use authorisation for the Vaccine in children of 16 and 17 years' of age, a decision which is challenged more than three months after it was made in the light of the advice given by the Joint Committee of Vaccines and Immunology ('the JCVI') on 15 July 2021 relied upon below; and/or alternatively

(2) The decision of the Secretary of State on 4th June 2021, acting on the advice of the MHRA, to grant temporary use authorisation for the Vaccine in children aged between 12-15 years old (the "Vaccine"); and/or alternatively

(3) The decision of the Secretary of State not to revoke the temporary use authorisation of the Vaccine for both age groups in the light of the said advice of the JCVI; and his continuing failure to do so.

In respect of each of the above, we assume that the Secretary of State remains the licensing authority pursuant to the Human Medicine Regulations 2012 (as amended) ('the 2012 Regulations'). Alternatively, the challenges are brought directly against the MHRA.

6. The details of any Interested Parties

7. We do not consider that there are any other interested parties.

7. The Issue

A. The Essential Basis of the Application

8. This proposed application for judicial review relates to the authorisation by the MHRA to allow the administration and supply of the Vaccine to individuals aged 12 years or over. The Secretary of State is sued as the licensing authority, acting on the advice of the MHRA, for the Vaccine.

9. The authorisation was given pursuant to Regulation 174 of the 2012 Regulations.

10. The authorisation remains valid until or unless expressly withdrawn by the MHRA or the Secretary of State acting with or without advice from the MHRA and thus remains extant and potentially active.

11. Additionally, the authorisation of 4th June 2021 has confirmed the authorisation for the vaccine to be applied to and provided for all individuals over the age of 12, which includes the cohort of individuals aged 16 and 17 years. Authorisation for 16- and 17-year-olds was first given alongside the authorisation for adults on 2nd December 2020.[1] The MHRA have not published their reasons for the decision. However, their chief executive did announce their conclusion that 'the benefits of this vaccine outweigh any risk', by which she must have meant any risk *to the child*.

12. On 9th July 2021, the authorisation was confirmed by the Secretary of State for all individuals over the age of 12 years.[2]

13. By 15th July 2021, the Joint Committee on Vaccination and Immunisation ("JCVI") reported that the adverse effects of the vaccine on the cohort of younger individuals meant that risks of the vaccine appeared to outweigh the benefits of the same in this cohort of youngsters. This was confirmed by a press release dated 19th July 2021.[3]

14. Moreover, the JCVI statement published at the same time made clear that until more data becomes available there should be no vaccines administered to the under 18s, stating that "*the health benefits of universal vaccination in children and young persons below the age of 18 years do not outweigh the potential risks*".[4]

15. To this end the JCVI is correctly following the principles laid down by the Medicines and Devices Act 2021 which allows the 'appropriate authority'- in this case the

[1] https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19
[2] https://www.gov.uk/government/news/the-mhra-concludes-positive-safety-profile-for-pfizerbiontech-vaccine-in-12-to-15-year-olds
[3] https://www.gov.uk/government/news/jcvi-issues-advice-on-covid-19-vaccination-of-children-and-young-people
[4] https://www.gov.uk/government/publications/covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-jcvi-statement/jvci-statement-on-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-15-july-2021

MHRA and the Secretary of State for Health, to make regulations "only if the authority considers that the benefits of doing so outweigh the risks" (Section 2 (4)).

16. Moreover, the Health Protection (Vaccination) Regulations 2009 require the Secretary of State for Health in England to ensure, so far as is reasonably practicable, that the recommendations of the JCVI are implemented in circumstances such as these where those recommendations, among others, are made by the full JCVI and relate to a new provision for vaccination under a national vaccination programme.

17. The concern for the Claimants herein is that the authorisation granted to employ the vaccine for all young persons of 12 upwards has been neither withdrawn nor suspended. The somewhat capricious approach of this government throughout the pandemic, whereby announcements regarding public health issues are made, then resiled from, means that any indications of intent from the Secretary of State cannot be relied upon with any confidence. Thus, unless the authorisation for the use of the vaccine for all individuals under the age of 18 years is specifically withdrawn, it can, without further data, be implemented. It is clear from the temporary authorisation that confirmation of 'efficacy and safety' had not been reached for the 12- to 15-year cohort as study C4591001 required a follow up by October 2021, whilst overall the efficacy and safety of the vaccine required a Clinical study by December 2023 (also from study C4591001).

18. Further concerns that the court will be asked to address relate to the suggestion that 'vulnerable' 12- to 15-year-olds will still be vaccinated and that, despite little advantage to any under 18s and potential risk, the cohort 12 to 17 will be 'offered' the vaccine to protect any person in the household who may have immune suppression. No attempt has been made by the MHRA to determine any evidential basis for which children are particularly vulnerable *to Covid 19*, rather than in general terms. Thus, the potential risk to a young healthy person is being subordinated to an older, ill person without providing the data or evidence that the vaccination of a young healthy individual can be protective of an older, ill person who has most likely already been vaccinated anyway

B. The Broad Grounds

19. We propose to bring the application on the following grounds.

20. **Illegality**: most specifically that the MHRA/ Secretary of State based the authorisation for the under 18s without proper regard to relevant evidence; moreover that no adequate reasons were given for the decision to authorise these vaccines; that no reasonable decision maker could have made such a decision based upon the paucity of data; and the knowing failure to have available data that clearly indicated that the benefits outweighed the risks to the health of such young persons.

21. **Irrationality**: the actual merits of the authorisation and maintaining this will be considered.

22. The Claimants have a **legitimate expectation**, in view of the advice of the JCVI, in the absence of reliable data and on the basis that the risks outweigh the benefits to the individuals under the age of 18, that the legislation cited above and the guidelines will be followed and that any authorisations for the under 18s will now be withdrawn.

23. These grounds are expanded below.

C. Timing of this Application

24. The authorisation of the Vaccine for 12 to 15 year olds was given on the 4th June 2021. Although the authorisation for the 16 and 17 year olds was given in December 2020 (and thus outside the three month period for bring this application for the slightly older cohort), it is only as a result of the Government's own published papers and admissions that the Claimants can seek, with confidence, the remedy that they are entitled to, namely the withdrawal of the authorisations for all under 18s.

25. It is now abundantly clear that the welter of evidence supports the position that these authorisations constitute breaches of the Medicines for Human Use (Clinical Trials) Regulations 2004 by reason of clear failure to comply with Good Clinical Practice. Moreover, there has been clear breach of the Medicines and Medical Devices Act as cited above.

26. In the application itself, full particulars will be provided, but suffice it to say and <u>first</u>, the Defendant has accepted that young persons are not or are minimally at risk from Covid 19 and there is no or insufficient evidence of any <u>benefit</u> to children from the vaccination. Vaccination would thus have only limited impact at best and any more than trivial risk must be considered disproportionate. In particular:

(1) Both authorisations (the December 2020 authorisation insofar as it applied to 16- and 17-year-olds) were made on the basis of no more than one clinical trial, which was itself conducted by the manufacturer of the Vaccine, Pfizer, in which only 1,131 children were given the drug (a further 1,129 were given a placebo). This trial concluded that as many as 0.1 % - one child in one thousand – suffered a 'life threatening event' as a side effect of the Vaccine. To put this in perspective the risk of a child or teenager (in any one year) under 20 dying within 28 days of a positive PCR test for SARS-Cov-2 is one in 500,000, or one in two million for a healthy child (risks acknowledged and relied upon by the JCVI in making its recommendation, based upon around 30 children dying within 28 days of a positive PCR tests between March 2020 and March 2021). There is no greater risk from the virus for 16-17 year-olds than 12-15 year-olds; and there is no evidence that 16-17 year olds are any less at risk of side-effects from the Vaccine than younger teenagers. The Vaccine has been given authorisation under an exemption from the usual trial protocols for vaccines or other medications, it was developed only in 2020 and its long-term effects cannot, by definition, be known.

(2) This compares with deaths for under 20s from all causes in 2019 being 3,905 deaths, though this is just 1,506 if infants in the first year of life are excluded. (There is an elevated risk of mortality in the first year of life, due to a range of causes including birth trauma, birth defects, and greater susceptibility to infectious disease). Thus, the percentage of the tiny number of children over 1 year old who died within 28 days of a positive PCR test, around 30 out of 1,506, is around 2%. It is not known how many of those actually died from the disease as opposed to having the disease noted on their death certificate.

(3) Young persons who are asymptomatic are not 'super-spreaders' and would not spread the virus which makes vaccinating healthy youngsters sharing a household or having access to a household with a vulnerable person (almost certainly vaccinated) irrational.

(4) There is increasing evidence that youngsters rarely transmit the virus.

(5) By its own publication on 22 July 2020 and subsequent confirmatory studies, there is low level of transmission between pupils and teachers.

(6) It is unprecedented to suggest that an asymptomatic spread of a respiratory virus can be even a theoretical hypothesis; and the MHRA has cited no evidence to support this hypothesis.

(7) The lateral flow testing cannot reliably detect the presence of Covid 19 and even the PCR testing is subject to serious flaws by finding false positives to the extent of 50% according to the findings of the Office for National Statistics in December 2020.

27. Secondly, there is a growing body of evidence, which was barely acknowledged in the December decision and not referred to in the announcement of the June decision (regarding 12-15-year-olds, about which no reasons have been published) that there is a serious known risk of harm, in addition to the risk of harm from long-term effects which cannot be known. The 2012 Regulations provide (regulation 58 (4) (b)) that the licensing authority may only grant the application to license the product for use by weighing the positive therapeutic effects against the risks to the health of the patients or of the public. In this case, the JCVI has now confirmed its opinion that the risks outweigh the benefits and thus the authorisations have been given and maintained without due regard to the evidence which clearly supports that opinion. In the UK alone, as of May 2021, 370 deaths have been recorded as a suspected reaction to the Pfizer vaccination whilst 7 deaths in the under 18s have been recorded as suspected reactions. Given the very limited number of children and young people who have been vaccinated, that is a disturbingly high number relative to the risk of death from the virus, which is close to non-existent. Moreover, the deaths do not account for the thousands of adverse reactions which have been tabulated by the 'yellow card' system.

28. The MHRA fails to address any risks or harms and further fails to identify precisely, or at all, the benefit which outweighs such risks and harms.

29. There is, in summary, no real evidence upon which the government and the regulatory body could have ever relied, that the perceived benefit of authorisation for the use of vaccinations in the under 18s outweighed the risks; and it would be irrational, unreasonable and thus unlawful for this authorisation to be allowed to remain extant.

30. In *Chester v Afshar* [2004] UKHL 41 and *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, the House of Lords and Supreme Court established the primacy of 'patient autonomy' in respect of medical treatment and the necessity of full information before informed consent to treatment could be given. In this respect it is clear that the patient information leaflet ('PIL') provides information as to side effects from the Vaccine but, as with all medicines, there the patient is provided with remarks of rarity of such effects and the general tenor does not go to any real risk/ benefit to

the patient of a certain age. It notes only that the vaccine is not recommended for children under the age of 12. That, in itself, is an issue to be considered by the court; the question will be raised as to the evidence that informs the development of risks for an 11-year-old as opposed to a 12-year-old; and for a 17-year-old as opposed to an 18-year-old. What data has been relied upon to reach such arbitrary cut-off points?

D. Proportionality and Convention principles and international humanitarian law

31. The temporary authorisation of new medication, which does not engage the normal processes and safeguards of full marketing authorisation under the 2012 Regulations, is a decision which entails the risk to life of any person who may, as a result of that decision, take the medication. Article 2 of the European Convention on Human Rights is thus engaged and the MHRA (and the Secretary of State insofar as he adopts the MHRA's recommendation), as the public body with responsibility for that authorisation, must make a decision that evaluates the risk to life.

32. The European Court of Human Rights ('the Strasbourg Court) has found that Article 2 was engaged in the following cases:

(1) The administration of drugs to a disabled child despite his mother's opposition (*Glass v. the United Kingdom* (2003) Application no. 61827/00)); and

(2) The death of a patient after a heart attack caused by the administration of a drug (*Altuğ and Others v Turkey* (2015) 32086/07 (official translation in French))

33. Moreover, a state cannot be required to allow access to unauthorised medication even where conventional forms of medical treatment appear insufficient (*Hristozov v Bulgaria* (2013) 47039/11 and 358/12).

34. Article 8 is also engaged in circumstances where medication is being authorised for teenagers who may wrongly be assumed to have *Gillick* competence and/or who may not (or whose parents may not) have sufficient information to be able to consent to the treatment.

35. The intensity of review required is considerable where fundamental rights are at stake: *Pham v Secretary of State for the Home Department* [2015] UKSC 19, *per* Lord Reed at para 113:

> "there are a number of authorities in which a finding of unreasonableness was based on a lack of proportionality between ends and means. ... There are also authorities which make it clear that reasonableness review, like

> proportionality, involves considerations of weight and balance, with the intensity of the scrutiny and the weight to be given to any primary decision-maker's view depending on the context. The variable intensity of reasonableness review has been made particularly clear in authorities, such as *R v Secretary of State for the Home Department, Ex p Bugdaycay* [1987] AC 514, R v Secretary of State for the Home Department, Ex p Brind [1991] 1 AC 696, and R v Ministry of Defence, Ex p Smith [1996] QB 517, concerned with the exercise of discretion in contexts where fundamental rights are at stake. The rigorous approach which is required in such contexts involves elements which have their counterparts in an assessment of proportionality, such as that an interference with a fundamental right should be justified as pursuing an important public interest, and that there should be a searching review of the primary decision-maker's evaluation of the evidence."

36. And *per* Lord Sumption at para 106:

> There is in reality a sliding scale, in which the cogency of the justification required for interfering with a right will be proportionate to its perceived importance and the extent of the interference. [5]

37. The domestic courts are in a better position to assess local needs and conditions and they may apply a stricter standard than the European Court of Human Rights ('the Strasbourg Court') when considering whether measures are proportionate or whether less restrictive means might obtain the desired outcome, an objective question based on the merits, not whether the decision maker has considered each less restrictive measure (*Belfast City Council v Miss Behavin' Limited* [2007] UKHL 19, per Baroness Hale at para 31)

38. In this case, a particular intensity of review must be applied given that Article 2 is engaged.

39. The World Medical Association, in the Helsinki Declaration first made in 1964 and amended since,[6] included the following declaration, which can reasonably be assumed to reflect international humanitarian law:

> While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

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[5] See also See *R (on the application of Daly) v Secretary of State for the Home Department* [2001] UKHL 26 at [26]–[27], *per* Lord Steyn; *R (on the application of Yogathas) v Secretary of State for the Home Department* [2002] UKHL 36 at [9], *per* Lord Bingham of Cornhill; *R (on the application of Razgar) v Secretary of State for the Home Department* [2004] UKHL 27 at [16], per Lord Bingham of Cornhill

[6] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

40. The Universal Declaration on Bioethics and Human Rights 2005 (‘the 2005 Declaration’) was a declaration by the International Bioethics Committee) of the United Nations Education, Science and Organisation (‘UNESCO’) that was declaratory of international humanitarian law. Article 7(a) provides that:

> “*authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law”*.

41. The above paragraphs are repeated as to the fact that the Vaccine is not in the “best interests” of children until established to be of benefit according to an individual’s health requirements supported by medical evidence.

42. Article 7(b) further states:

> “*research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual’s human rights. Refusal of such persons to take part in research should be respected”*.

43. In respect of the above authoritative declarations of international humanitarian law, there is a 'strong presumption' that legislation should be interpreted in a way that is compatible with the United Kingdom's international obligations. The presumption of compatibility applies in relation to international treaty obligations whether or not they have been incorporated into domestic law. Underlying these presumptions is the idea that it is an important principle of public policy to respect the comity of nations and to obey an instrument binding under public international law.

44. In *Salomon v Customs and Excise Comrs*,(4) Diplock LJ held that:

> "… there is a *prima facie* presumption that Parliament does not intend to act in breach of [public] international law, including therein specific treaty obligations; and if one of the meanings that can reasonably be attributed to the legislation is consonant with the treaty obligations and another or others are not, the meaning which is so consonant is to be preferred."

E. Drawing the above points together:

45. The putative Claimants challenge the authorisations on four grounds:

(1) The decision to authorise the Vaccine to 16- and 17-year-olds in December 2020 was irrational and a disproportionate interference with the Article 2 and 8 rights of young people in that age category.

(2) The decision to authorise the Vaccine to 12-15-year-olds in June 2021 was irrational and a disproportionate interference with the Article 2 and 8 rights of young people in that age category;

(3) The MHRA, which has an ongoing duty to review its decisions in the light of further evidence and advice, irrationally failed to review and withdraw its two authorisations on being advised by the JCVI that the risks to children under 18 – including 16- and 17-year-olds and including the risk of death – outweigh the advantages of the Vaccine to them; and

(4) The failure to review and remove the authorisation in circumstances where there is no, alternatively insufficient, evidence that the Vaccine can prevent the transmission of SARS-CoV-2; and so the condition precedent for its authorisation under s 174 of the 2012 Regulations no longer applies.

46. In respect of (1), and as acknowledged above, this pre-action letter is sent over three months after the decision to authorise for 16-17 year olds, the Secretary of State and the MHRA have an ongoing duty to review the authorisation of medication in the light of evidence and advice not available to them when the initial decision was made. This duty is particularly intense where the approval was under the temporary use exemption only and based on incomplete trial data from a very short period of time with a small sample of participants.

47. Moreover, the duty of review became stark, when, on 19 July 2021, the JCVI directly contradicted the finding of the Chief Executive of the MHRA, who said on 3 June 2021 that the advantages of taking the Vaccine for children aged 12-15 outweighed the disadvantages. This finding had also been made in the authorisation of the Vaccine for adults and 16-17 year-olds in December 2020. Not only did the JCVI contradict the advice in relation to 12-15-year-olds, but they also expressly found that the disadvantages of the Vaccine <u>for all under 18 year-olds</u> outweighed any advantages.

48. This letter seeks to set out, above but not exhaustively, the MHRA's unreasonable failures to take into account relevant considerations and evidence, their lack of reasoning and their other failings that are relevant to one or more of the above grounds.

49. It is an important consideration that looking at any benefit, so far as it applied to other age groups, is irrelevant. It is long established that rights of the individual under Article 8 of the Convention may not be subsumed to consideration of benefit to the wider community save, in terms, in cases of serious and imminent danger.

50. Article 7 of the 2005 Declaration (cited above) establishes that, as a matter of ethical principle and law, there is an obligation to protect children before adults. To submit them to risk of harm in order to avoid risk of harm to older age groups, and indeed the very elderly and/or those nearing end of their life because of co-morbidities, is a fundamental breach of ethics and in breach of Article 7 quoted above.

F. Regulation 174

51. Regulation 174 is not satisfied in the absence of a public health crisis affecting children or of evidence of a material reduction in transmission.

52. Both authorisations were for temporary supply under reg. 174 of the 2012 Regulations, a provision to address the spread of pathogens is to deal with a public health emergency.

53. The Claimants make two points on this issue.

(1) Not only is there no evidence that there is a public health emergency concerning the spread of pathogens to children and teenagers under 18, there clearly is no such emergency. Deaths of 1 in 500,000 even including those with serious pre-existing conditions (amongst whom the odds are substantially higher, leaving the actual risk for healthy children substantially lower) could not possibly constitute such an emergency when the risk of death for any person between 1 and 20 in any given year is around 1 in 10,000.

(2) There is no evidence that the Vaccine would have any effect on the *transmission*, as has been set out above. The statutory basis for authorisation is limited to where medication (including vaccination) is necessary to prevent or severely reduce the *spread* of pathogens. Where vaccinating children will have no such effect on the spread and where (given the lack of severe effect of the virus on them) it is not necessary to protect them from the spread, the conditions precedent to reg. 174 of the 2012 Regulations are not met.

G. Conclusion

54. The authorisation of the Vaccine to 16-17-year-olds and then to 12-15-year-olds was made in the absence of any or any adequate reasoning, failed to evaluate the evidence of any possible benefit while also failing to account for or weigh in the balance the harms, failed to account for the absence of evidence of any material effect on transmission of the virus and was unreasonable and irrational. The authorisations failed to take adequate account of the risk to life of children or of their bodily integrity and were disproportionate breaches of Convention rights and international humanitarian law.

55. The Secretary of State should review the authorisations in the light of the JCVI recommendations and revoke them; and failure to do so would breach his ongoing duty to review the efficacy and risks of treatment that has only an emergency, temporary authorisation.

56. Finally, the absence of any evidence that the Vaccine materially reduces transmission of the virus renders the condition precedent in reg. 174 of the Regulations unmet and voids the legal basis for authorisation.

57. On all the above bases and for all the above reasons which are set out in short form in this letter, the Claimants demand the action set forth in this letter, failing which the matter will be taken to the Court for judicial review

8. The details of the action that the defendant is expected to take

58. Withdraw the authorisation of the Vaccine for children and teenagers under 18.

9. ADR proposals

59. We are willing to consider reasonable offers of ADR.

10. The details of any information sought

60. None at this stage, save information in the documents requested below.

11. The details of any documents that are considered relevant and necessary

61. All the raw data upon which the MHRA based its impugned decisions in December 2020 and June 2021.

12. The address for reply and service of court documents

62. Jackson Osborne Solicitors, 20 Little Britain, London EC4

Our ref JRMHRA22101

13. Proposed reply date

63. We refer you to our answer above in respect of documentation. On receipt of that documentation, we reserve the right to add to the submissions we have made in this letter.

64. We request that you provide a reply to this letter within 14 days.

Please acknowledge receipt of this letter by return.

Yours faithfully

JACKSON OSBORNE