your ref AH/LW/3022/001
our ref 12 April 2016

dpg
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Dear Sir/Madam

Judicial Review - Letter Before Claim

1. **To:** NHS England

2. **The Claimant:** National Aids Trust (NAT)

3. **Reference Details:** AH/LW/3022/001

4. **Details of the Matter being Challenged:**

   The decision[1], dated 21 March 2016, to prevent the inclusion of Pre Exposure Prophylaxis for HIV (PrEP) for consideration in competition with other specialised commissioning treatments as part of the annual CPAG prioritisation process.

5. **The Issue:**

5.1. **Summary of Factual Background**

[1] https://www.england.nhs.uk/2016/03/prep/

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Our understanding of the factual background to this proposed claim is as follows:

The Claimant

5.1.1. NAT is an independent charity that works to achieve effective HIV prevention; early diagnosis of HIV; equitable access to treatment, care and support for people living with HIV; enhanced understanding of HIV and those living with it; and the eradication of HIV-related stigma and discrimination. It is committed to partnership working and works in a collaborative and productive manner with a range of partner organisations in pursuit of its aims.

What is PrEP?

5.1.2. PrEP[2] involves HIV negative people taking an anti-retroviral (ARV) drug (eg; Truvada) to avoid getting HIV. Multiple studies around the world have shown PrEP to be effective in reducing the risk of contracting HIV.

5.1.3. Most trials of PrEP and the US CDC Guidelines involve taking PrEP daily. The results of the 'Pre-Exposure Option for reducing HIV in the UK: Immediate or Deferred' (PrOUD) trial[3], released in 2015, were unequivocal in demonstrating its efficacy; one HIV infection was stopped for every 13 gay men who took PrEP.

5.1.4. A French study[4] (Ipergay) has also looked at the efficacy of PrEP when taken 'on demand', in other words not daily but only before and after sexual intercourse. that

5.1.5. Both studies found that PrEP was 86% effective – i.e. it stopped 17 out of every 20 HIV infections that would have happened without PrEP. The effect was so pronounced that, before both trials had been completed, those on the placebo arm were offered PrEP immediately because results already showed the significant protective benefit of such intermittent PrEP.

5.1.6. Studies with heterosexual men and women show that PrEP works well in people who are able to take it consistently. For example, an African

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[2] As opposed to Post-Exposure Prophylaxis, which is a means of preventing transmission after having been exposed to the virus and is available from sexual health clinics or A&E departments. It is a 4 week course of ARV medication and should be taken as soon as possible (but no later than 72 hours) after the individual has been potentially exposed to HIV, to optimise efficacy.

[3] http://www.proud.mrc.ac.uk/

[4] http://www.ipergay.fr/

study showed that it was 75% effective – i.e. it stopped 15 out of every 20 HIV infections that would have happened without PrEP[5].

5.1.7. PrEP was licensed in the US in 2012 and the US Centre for Disease Control (CDC) has now published clinical guidelines for PrEP[6]. Notably, 'recommended indications' are given for prescribing PrEP, based on risk of infection. As a consequence, in the US over 30,000 people, mostly gay men, are now taking PrEP. In at least two programmes offering PrEP to gay men at high risk of HIV, there have been no infections at all when many would have been expected if PrEP wasn't provided.

Why is PrEP Needed?

5.1.8. It is estimated that a record number (2800) of gay men in the UK acquired HIV in 2014 – about 8 gay men contracting HIV every day[7]. 1 in 17 gay men aged 15-59 are now living with HIV, rising to 1 in 8 in London. This compares to 1 in 360 of the UK population as a whole.

5.1.9. While condoms, testing, and treating HIV-positive people are just about containing the HIV epidemic at its current level, infection rates in gay men are not decreasing, and more and more gay men are living with HIV every year. A recent study showed that PrEP could make all the difference and, when compared to other HIV prevention measures, had the most powerful single effect[8].

5.1.10. Whilst infections amongst heterosexual men and women are occurring at a lower rate, there are also heterosexuals who are at high risk of HIV acquisition and who could benefit from PrEP, for example, HIV negative people in a relationship with someone known to be HIV positive and still infectious since their viral load is as yet not suppressed.

5.1.11. PrEP will save money, by preventing future HIV infections, so long as PrEP is provided to people at high risk of infection. For each individual who acquires HIV, the personal impact is considerable. In addition, the cost to the NHS is very high – one person's treatment over their lifetime costs around £360,000[9].

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[5] Baeten JM et al. Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women. New England Journal of Medicine 367: 399-410, 2012

[6] http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf

[7] Public Health England HIV in the UK – Situation Report 2015 – Incidence, prevalence and prevention.

[8] Punyacharoensin N et al. Effect of pre-exposure prophylaxis and combination HIV prevention for men who have sex with men in the UK: a mathematical modelling study. The Lancet HIV 3: e94-e104, 2016.

[9] Nakagawa F et al. Projected Lifetime Healthcare Costs Associated with HIV Infection. PLOS One 10(4): e0125018, 2015

5.1.12. Two cost-effectiveness models for PrEP in the UK have been developed. The first model[10] showed that daily PrEP use in gay men would be cost saving (ie; immediately reduce costs overall) if it was taken by gay men who had sex without a condom with five or more partners in a three-month period. It would be cost-effective (ie; not immediately cost-saving but it would become so in the long run) if taken by gay men who had sex without a condom with three or more partners or who had had a sexually transmitted infection in the last three months. If drug prices were to fall by 50% (as they may do when the drugs come off patent in 2018), or everyone took intermittent PrEP as in Ipergay, then PrEP would be cost-saving for all these groups.

5.1.13. The second model[11] showed that PrEP would be cost saving when given to gay men with an HIV incidence of 5% a year. In other words, it would save money if given to a group of gay men where, without taking PrEP, one in every 20 would have acquired HIV within a year. This is roughly similar to HIV incidence in gay men attending STI clinics who have had condomless sex as receptive partners in the last year. Importantly, the model only assumed that PrEP was 64% effective – this figure was used as a conservative estimate of PrEP's effectiveness although it was actually 86% in the PROUD study. If PrEP is assumed to be 86% effective, it is more likely to be cost-saving.

CPAG

5.1.14. According to its website[12], NHS England's Clinical Priorities Advisory Group (CPAG):

> "*...makes recommendations to NHS England's Directly Commissioned Services Committee on the commissioning of services where there could be a substantial change in service provision. Its scope includes all directly commissioned services of NHS England. It calls on the expertise of its members to make recommendations on NHS England's approach to commissioning services, treatments and technologies. It considers which of these should be prioritised for investment. This is achieved by following the principles and criteria of the decision-making framework. This framework supports a systematic approach to decision making, focused on patients' needs and based on clearly defined evaluation criteria.*

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[10] Cambiano V et al. Is pre-exposure prophylaxis for HIV prevention cost-effective in men who have sex with men who engage in condomless sex in the UK? BASHH Spring conference, Glasgow, 2015.
[11] Ong K-J et al. Will HIV PrEP given to high-risk MSM in England be cost-effective? Preliminary results of a static decision analytical model. Public Health England Conference, Coventry, 2015.
[12] https://www.england.nhs.uk/commissioning/cpag/

As and when appropriate, CPAG engages with other NHS commissioners and stakeholders, such as clinical commissioning groups (CCGs), and calls on sources of sound evidence from outside the NHS, professional bodies, and other relevant organisations. It is important to note that CPAG is not a decision-making body. Instead, it makes formal recommendations to the NHS England Board about the commissioning of services in those circumstances where there could be a substantial change in service provision. Its scope includes all services directly commissioned by NHS England, that is specialised services, health and justice services, armed forces health, secondary care dental services, and wider primary care.

Taking an evidence-based and systematic approach, CPAG will make recommendations as to the appropriate use of resources based on the clinical and cost effectiveness of both new and existing treatments / services.

CPAG will deliver its objectives by considering, in particular:

- *Recommendations from the individual Clinical Reference Groups (CRGs) and single operating teams covering NHS England's direct commissioning responsibilities;*
- *Detailed information about available financial resources.*

CPAG reports to the Direct Commissioning Committee, and as such is required to demonstrate that the process to reach the recommendation has:

- *the support of the clinical body as represented by the national CRG;*
- *been developed with public and patient engagement to a level proportionate with the impact of the decision;*
- *included consideration of the public sector equality duty;*
- *been informed by clarity of the evidence base;*
- *considered consistency with the other commissioning policies of NHS England;*
- *an identified financial resource to deliver implementation.*

Communications Between the Parties and other Relevant Organisations

5.1.15. The Defendant, through its HIV Clinical Reference Group, set up a PrEP policy writing group in September 2014, tasked with developing a plan for the Defendant to commission PrEP[13]. The group developed well-formulated proposals to seek funding for PrEP through the CPAG recommendation process. As part of this work i) a detailed evidence

[13] NAT's Director of Strategy, Yusef Azad, was part of the group

review was completed, along with ii) a detailed policy proposition, and these were then subject to stakeholder testing. Copies of both documents were published on the Defendant's website and are **enclosed**.

5.1.16. The Defendant then issued a Specialised Services Circular on 24 April 2015 "*to clarify the current commissioning position*". This confirmed that "*NHS England is the responsible commissioner for all antiretroviral drugs (ARVs), including where they are used in HIV prevention either in preventing mother to child transmission or as post exposure prophylaxis following sexual or occupational exposure to HIV infection.*"[14]

5.1.17. The Defendant's policy proposition states:

"NHS England proposes to routinely commission [PrEP] for the treatment of adults at high risk of HIV acquisition in accordance with the criteria outlined in this document."

5.1.18. In essence, the plan was for PrEP to be provided based on certain eligibility criteria (aimed at maximising effectiveness and cost-efficiency), which would render an estimated 8-12,000 gay men, and a further 1,000 heterosexual people, eligible for the treatment, and would have an estimated take-up rate of 50%. The Defendant would fund the cost of the medication, whilst local authorities would fund the cost of the PrEP clinic service, excluding the cost of the medication. .

The Decision and Subsequent Communications

5.1.19. After developing these documents, the HIV CRG's work was nearly complete, and all that remained was for the Defendant to put it out for public consultation (for a minimum of 30 days to allow further, wider views to be obtained) and subsequent submission to CPAG, who would consider the proposal under its terms of reference and decision-making criteria.

5.1.20. The launch of the public consultation was delayed, however, and the cause of the delay was unclear to those who had been involved in the process thus far. Questions were raised in Parliament and by constituency MPs, and the Defendant's promise to put the proposal

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14 http://www.bashh.org/documents/SSC1516%20Position%20regarding%20PrEP%20April%202015.pdf

through its prioritisation process was repeated in both the House of Lords and the House of Commons[15].

5.1.21. On 21 March 2016, with no prior warning or consultation, and no communications in this respect having been made to the HIV CRG or its members (as far as NAT is aware), the Defendant issued a press release[16] informing the public that it would not be "*including PrEP for consideration in competition with specialised commissioning treatments as part of the annual CPAG prioritisation process*" because "*local authorities are the responsible commissioner for HIV prevention services"* and doing so "*could present risk of legal challenge from proponents of other 'candidate' treatments and interventions that could be displaced by PrEP if NHS England were to commission it.*"

5.1.22. The rationale for this sudden change of position is not explained in terms. However, the Defendant suggests that it considers that it does not have the "responsibility" for commissioning HIV prevention services, because, in its view, local authorities are responsible for doing so under the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013[17].

5.1.23. But this purported division of responsibility is illogical and artificial (as well as being wrong in law, see further below). The Defendant's own Circular clearly set out the legal responsibility it considers that it has for commissioning "*all antiretroviral drugs (ARVs) including where they are used in HIV prevention...*"[18] Accordingly, the Defendant already commissions funding for other forms of HIV prevention[19], and in July 2015 approved funding for a 'Treatment as Prevention' (TasP) programme to help reduce transmissions from persons known to be HIV

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[15] http://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2016-01-12/22187/ & http://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Lords/2016-02-09/HL6026/

[16] https://www.england.nhs.uk/2016/03/prep/

[17] On the same day, the Defendant wrote to relevant bodies in Yorkshire and the Humber to inform them that funding for dispensing Post-Exposure Prophylaxis (PEP) would be restricted to NHS funded services only (eg; A&E departments, HIV Treatment Centres, sexual assault referral centres and NHS contractors). PEP would not be funded for dispensing by services commissioned through local authorities and delivered by independent contractors, because the Defendant "*would not expect them to be involved in the dispensing of ARVs*"[17]. A copy of the letter is **enclosed**.

[18] See http://www.bashh.org/documents/SSC1516%20Position%20regarding%20PrEP%20April%202015.pdf and quoted at 5.1.16 above

[19] For example, ARVs to prevent mother to child transmission and post-exposure prophylaxis

positive[20], and has put 'targeted prevention' at the core of its 5 Year Forward View.[21]

5.1.24. Instead, a pilot is proposed, which will benefit only 500 people, and will somehow only cost £2m. It is unclear why it is permissible to fund the pilot and not the PrEP proposal that had been worked up.

5.1.25. The decision caused significant consternation among the HIV and public health community[22], and in Parliament, and on 29 March 2016 NAT wrote to the Defendant to query the decision and raise its concerns.

5.1.26. Given the tight timescale imposed by the late stage at which the decision under challenge was made, a response was requested by 1 April 2016, and one duly arrived, offering a meeting between the parties, to take place on 12 April 2016. NAT responded by explaining that because of the very late announcement of the Defendant's decision, which had left very little time before commencement of the CPAG decision-making process, the meeting would need to take place sooner. The Defendant refused to bring the meeting forward, assuring NAT that resolution of the dispute would not be prejudiced by the delay.

5.1.27. The meeting was attended by Yusef Azad (NAT's Director of Strategy), Ian Green (Chief Executive of the Terrence Higgins Trust), Dr Jonathan Fielden (the Defendant's National Director of Specialised Commissioning), John Stewart (the Defendant's Strategy and Policy Director for Specialised Commissioning) and Claire Foreman (Senior Programme of Care Manager for Blood and Infection, Specialised Commissioning). The Defendant's representatives made it clear at the meeting that they were not willing to reconsider the decision.

5.1.28. NAT's intention remains to resolve this matter outside litigation with the Defendant if at all possible. However, in light of the extremely tight timeframes involved through no fault of our client, we are issuing this pre-action correspondence today. It remains our client's intention to continue the ongoing discussions with the Defendant alongside serving this formal correspondence and it is hoped that the issue of proceedings will be unnecessary.

If any part of this summary of the factual background is disputed or is believed to be inaccurate, please identify in your response to this letter each part of the factual

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[20] https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/10/f03pc-tasp-oct15.pdf

[21] https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf

[22] See for example http://www.adph.org.uk/wp-content/uploads/2016/03/ADPH-Press-Release-Provision-of-PrEP-and-PEP.pdf

background that is disputed, please explain why it is disputed and please provide full details of the basis for this alternative factual account including copies of any reports or relevant contemporaneous records upon which it is based.

5.2. **Relevant Law**

5.2.1 NHS England is the operating name of the NHS Commissioning Board, which was established by s1H National Health Service Act 2006 (the Act).

5.2.2 s2 of the Act empowers the Defendant to do "*anything which is calculated to facilitate, or is conducive or incidental to, the discharge of any function conferred*" on it by the Act.

5.2.3 s1H of the Act confers on the Defendant "*the function of arranging for the provision of services for the purposes of the health service in England*" in accordance with the Act, "*for the purpose of discharging*" the duty (shared with the Secretary of State) under s1(1) of the Act to "*continue the promotion in England of a comprehensive health service designed to secure improvement… in the prevention, diagnosis and treatment of physical and mental illness*", but only in relation to parts of the health service not "*provided in pursuance of the public health functions of the Secretary of State or local authorities*".

5.2.4 The public health functions of the Secretary of State and local authorities are set out at s2B. A local authority "*must take such steps as it considers appropriate for improving the health of the people in its area*", while the Secretary of State "*may take such steps as [he] considers appropriate for improving the health of the people of England*". The steps that "*may be taken*" include "*providing services or facilities for the prevention, diagnosis and treatment of illness.*"

5.2.5 Under Regulation 6 of the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013, "*each local authority shall provide, or shall make arrangements to secure the provision of, open access sexual health services in its area… by exercising its functions under section 2B of the Act for preventing the spread of sexually transmitted infections".*

5.2.6 Under s7A of the Act, the Secretary of State may arrange for, *inter alia*, the Defendant, to exercise any of his public health functions[23].

[23] An annual agreement is reached between the Secretary of State and the Defendant, under which a range of public health services are provided, notably immunisation and screening programmes (https://www.england.nhs.uk/commissioning/pub-hlth-res/). The Commissioning Intentions for 2016/17 have been agreed and are set out in this document - https://www.england.nhs.uk/commissioning/wp-

5.2.7 By s3B, the Secretary of State may by regulations require the Defendant to provide certain prescribed services. Under the 2012 Regulations[24], Sch 4 para 17, the Defendant must provide (to such extent as it considers necessary to meet all reasonable requirements) "*Adult specialist services for patients infected with HIV.*"

5.2.9 Under s 13C of the Act, the Defendant has a duty to act "with a view to securing that health services are provided in a way which promotes the NHS Constitution".

5.2.10 By s13G of the Act, the Defendant "*must, in the exercise of its functions, have regard to the need to— (a) reduce inequalities between patients with respect to their ability to access health services, and (b) reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services.*"

5.2.11 Under s13H of the Act the Defendant is under a duty to "*promote the involvement of patients, and their carers and representatives (if any), in decisions which relate to the prevention or diagnosis of illness in the patients, or their care or treatment.*"

5.2.12 Under s 13Q, the Defendant is under a duty, in respect of its commissioning arrangements, to "*make arrangements to secure that individuals to whom the services are being or may be provided are involved (whether by being consulted or provided with information or in other ways) …in the development and consideration of proposals by the Board for changes in the commissioning arrangements where the implementation of the proposals would have an impact on the manner in which the services are delivered to the individuals or the range of health services available to them*". It has published its arrangements on public involvement.[25]

5.2.13 Section 149, Equality Act 2010 places public bodies such as the Defendant under a duty to have due regard to the need to promote equality of opportunity for people who share protected characteristics (which include race, sexual orientation and gender), and that having due regard may include treating people who share a protected characteristic more favourably than others.

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content/uploads/sites/12/2016/02/ph-commissioning-intentions-1617.pdf. Neither PrEP nor PEP are included.

[24] National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012/2996

[25] https://www.england.nhs.uk/wp-content/uploads/2015/11/ppp-policy-statement.pdf

5.2.14 Section 19, Equality Act 2010 prohibits indirect discrimination through the application of a provision, criterion or practice that – although applied to all - disadvantages people who share a protected characteristic, and which cannot be shown to be a proportionate means of achieving a legitimate aim.

5.3. Grounds of Challenge

Error of Law

5.3.1. The Defendant appears, on the face of its Decision, to have misconstrued its legal powers under the Act to commission PrEP. The Defendant has a broad power to arrange for the provision of services which will discharge its duty to promote a comprehensive health service including the "prevention" of illness (s 1H). Its power under s 2 is to do "anything" calculated to facilitate the discharge of this function.

5.3.2. Although the Defendant's duty under s 1H does not extend to that part of the health service provided pursuant to the "public health functions" of the Secretary of State and local authorities, it nonetheless retains a broad power to arrange for prevention services otherwise. Moreover, the Defendant has a specific duty to provide adult specialised services for those infected with HIV.

5.3.3. Accordingly, the Defendant has lawfully, in pursuance of its broad powers to do so, commissioned antiretroviral drug (ARVs) for HIV prevention. The Defendant (correctly) considers itself to have the power to commission ARVs for PEP, for those previously *exposed* to HIV but not yet infected (or diagnosed as such), and for TasP, designed to use treatment as prevention, and for use in preventing mother to child transmission[26], where the purpose is prevention for the unborn child (the last of these is understood to be via a s 7A agreement).There can be no rational distinction between these forms of treatment and PrEP so as to empower the Defendant to commission some but not others.

5.3.4. Neither the Secretary of State nor local authorities are currently providing PrEP so as to preclude the Defendant from doing so. Local authorities appear to have no intention of doing so[27]. It follows that, if the provision of PrEP does not fall within the services which are currently being provided in pursuance of local authorities' public health functions, the Defendant has the power to provide PrEP and its purported reason for its decision is wrong in law.

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26 http://www.bashh.org/documents/SSC1516%20Position%20regarding%20PrEP%20April%202015.pdf

27 http://www.local.gov.uk/web/guest/media-releases/-/journal_content/56/10180/7758943/NEWS

5.3.5. In summary, the Defendant plainly has the power to commission PrEP as it initially intended. Its decision to the contrary therefore appears to be based on a misdirection as to the scope of its legal powers.

Fettering of Discretion / Irrelevant Consideration

5.3.6. In light of the above, the Defendant plainly has a discretion as to whether or not to commission PrEP which it was intending to exercise once CPAG had make its recommendations.

5.3.7. By its decision not to allow PrEP to go for consideration by CPAG, the Defendant stated there is a risk of legal challenge from proponents of other treatments that may miss out as a consequence.

5.3.8. However, this is unlawful. The Defendant's discretion is to be exercised in accordance with the outcome of the CPAG process which will assess PrEP (and other treatments under consideration) against clearly identified criteria. Instead, the Defendant appears to have prevented itself from proper consideration of PrEP for fear of as yet undisclosed legal challenges.

5.3.9. If the Defendant's perception is that such legal challenges will be based on an argument that the Defendant is not the responsible commissioner for such treatment, then this is an irrelevant consideration because it is wrong as a matter of law (as above). Public bodies cannot make decisions based on fear of groundless litigation.

Reasons

5.3.10. Under the NHS Constitution, the Defendant has pledged to "*make decisions in a clear and transparent way, so that patients and the public can understand how services are planned and delivered.*" By ss 13H and s 13Q, the Board is required to enable the public including interested stakeholders to be properly informed and involved in its decisions.

5.3.11. Yet, in its recent decision, the Defendant has failed adequately to explain the reasons for its sudden change of position i.e. from considering itself the responsible commissioner all ARVs for HIV including their use in prevention, to considering that it is not responsible for HIV prevention at all.

5.3.12. The current decision, premised as it is on a risk of undisclosed legal challenges, is opaque and leaves parties such as NAT in the dark as to the basis of its decision. This makes the decision unlawful.

Breach of Equality Duties / Potential Discrimination

5.3.13. The Defendant does not appear to have assessed the impact of its decision on people who share certain protected characteristics.

5.3.14. It is clear that there are a number of potential impacts which are highly material to decisions around PrEP. Those eligible for PrEP are likely to be predominantly men who have sex with men (MSM) and people of Black African ethnic origin, so the decision not to permit it to proceed to CPAG consideration has the potential for a disproportionate impact in terms both of gender and sexual orientation by comparison with other treatments being progressed to CPAG.

5.3.15. Further, in determining that it should continue commissioning other HIV ARV treatments but not PrEP, there are other detailed equalities impacts to be assessed (such as the impacts on men as a group at risk of contracting HIV and gay men in particular). As the Defendant is aware from the research undertaken, PrEP is the preventative treatment most likely to be taken by MSM. It does not appear that any of these matters have yet been considered by the Defendant.

5.3.16. The apparent failure of the Defendant to comply with its duty under s149 2010 Act (the Public Sector Equality Duty ("PSED")) or the duty in s13G of the Act to reduce health inequalities constitutes a clear error of law. Further, the decision is likely to constitute unlawful indirect discrimination on grounds of gender and/or sexual orientation under s 19 of the 2010 Act which is precisely what compliance with the PSED is intended to prevent.

Legitimate Expectation

5.3.17. For 18 months the Defendant worked with clinicians and representative bodies, drawing up detailed documents to put to consultation, and working up a detailed proposal for funding PrEP. As recently as February 2016 Parliament was assured that "*the PrEP clinical policy proposition is one of many going through NHS England's 2016/17 prioritisation round.*"[28]

5.3.18. All this gave rise to a legitimate expectation on the part of the Claimant that PrEP would be considered in accordance with its agreed process: a 30 day consultation round and then consideration by CPAG following which the Board would receive the CPAG's recommendations.

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[28] http://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Lords/2016-02-09/HL6026/

5.3.19. Rather than putting the proposal forward for consultation as agreed, and then it entering the prioritisation round, at which cost-effectiveness and clinical efficacy would be considered in a transparent and fair manner, PrEP was shelved on the basis of sparse and opaque reasoning. This is a breach of the process which NAT was entitled to expect the Defendant to follow in light of its clear and consistent representations to this effect, and is accordingly unfair and unlawful.

Failure to Consult / Procedural Unfairness

5.3.20. The Defendant's stated intention was to undertake a public consultation exercise prior to PrEP proceeding for consideration by CPAG. We understand that this consultation would have been intended to give effect to the Defendant's published s 13Q arrangements for such an important potential change to commissioned services. Yet the Defendant made a pre-emptive decision to withdraw PrEP from consideration by CPAG without this public consultation and without consulting with patients or their representatives before making the decision under challenge. That failure breaches its public involvement obligations both under ss 13Q and s13H of the Act.

In your response please refer to each numbered point in turn and confirm whether the ground is conceded or disputed and, if it is disputed, please provide full details of the basis on which it is disputed.

6. **Details of the Action that the Defendant is Expected to Take:**

6.1. Withdraw/reconsider its decision not to put PrEP forward for consideration by CPAG;

6.2. As part of 6.1, agreement that PrEP should be subject to at least a 30-day consultation by 1st May 2016 so as to enable it to proceed to be consideration in the current CPAG round in June 2016.

6.3. The Defendants are also invited to agree to the grant of a protective costs order (PCO) in the event that they refuse the action required above in recognition of the general public importance of the issues raised by this claim, the Claimant's low financial resources as a relatively small campaigning organisation and their inability to otherwise proceed with the claim. Further evidence can be provided as to the Claimant's financial resources if necessary. However, it is clear that they would be unable to proceed with the case in the absence of a Protective Costs Order, and that any funds to cover inter-partes costs liability will be reliant on fundraising alone. The Claimant is intending to

fundraise what it can to cover this. They propose that this be capped at £5,000.00.

6.4. If you do not agree to the grant of a PCO on the above terms, then we ask that you do agree to the Claimant making a PCO application on a no-costs basis and for the costs up to the date of the determination of that application to be borne by each party for themselves.

7. **Details of the Legal Advisors Dealing with this Claim:** Deighton Pierce Glynn, Suite 201 QC 30, 30 Queen Charlotte Street, Bristol, BS1 4HJ, reference AH/LW/3022/001.

8. **Details of any Interested Parties:** Secretary of State for Health; Local Government Association;

9. **Documents and information that you should provide with your response:**

You are asked to provide the following information in your response in accordance with the judicial review pre-action protocol.

You are reminded that in responding to this letter you must comply with your duty of candour.

This duty requires due diligence in: (a) investigating what material is relevant to this claim; and, (b) disclosing that material where it is relevant or assists the Claimant, including on some as yet unpleaded ground. A failure to comply with the duty of candour when providing your response to this letter may result in costs sanctions.

The duty of candour is reinforced by paragraphs 6 and 16(d) of the Judicial Review Pre-Action Protocol which provide that you must enclose any relevant documentation requested by the Claimant with your response and that where you ignore this requirement the court may impose sanctions, for example costs sanctions.

Accordingly, in your response, you are asked to confirm that you have investigated what material is relevant to this claim and to disclose that material in or with your response. In addition, we would ask you to ensure that copies of the following documents are provided with your response in compliance with your pre-action disclosure duties:

9.1. Any documents (both internal and external) explaining the reasoning behind this decision, and any evidence on which it is based, including in particular:

9.1.1. Details of the legal challenges referred to in the decision;

9.1.2. A copy of any available Equality Impact Assessment considered as part of the decision and

9.1.3. Any advisory submission, recommendation or report to the Defendant, or the individual relevant decision maker, which preceded the decision.

9.2. Details of any communications with external bodies in relation to this decision or in respect of the risks associated with proceeding to commission PrEP.

10. **Details of any other Documents that are Considered Relevant and Necessary:**

None other than those identified above.

11. **Alternative Dispute Resolution (ADR):**

We have welcomed the Defendant's agreement to meet our client on 12 April 2016 and discuss the matter.

However, in the absence of an agreement following that meeting to accede to the action set out at paragraphs 6.1-2 above, we do not consider that this matter is suitable for an alternative form of resolution because it concerns important public policy and the change requested is very straightforward and urgent.

If your authority is minded to propose ADR, please provide full details of the form of ADR that is being proposed, contact details of any external ADR provider that is being proposed, details of the outcome of your enquiries into that provider's availability, details of the likely timescales involved, details of the likely costs of mediation and how your authority proposes those costs be met and details of any concessions your authority is prepared to make pending the outcome of the ADR referral.

12. **Address for Reply and Service of Court Documents:** Deighton Pierce Glynn, Suite 201 QC 30, 30 Queen Charlotte Street, Bristol, BS1 4HJ, reference AH/LW/3022/001.

13. **Proposed Reply Date:** By 4.00pm on Thursday, 14 April 2016.

14. We have shortened the timescale because of the very limited time available between now and commencement of the CPAG decision-making process. Because the meeting was delayed until 12 April 2016, there is little further time remaining to allow for response.

15. If you need more time please confirm that the CPAG decision-making process will be delayed so that allowing you further time does not prejudice the Claimant.

16. We hereby give notice that we intend to issue proceedings forthwith following the expiry of time for response. As above, this does not preclude any ongoing discussions continuing in parallel but we do not consider that our client can allow its formal legal position to be prejudiced by holding off the issue of proceedings any further after this time.

Yours faithfully

DPG

DEIGHTON PIERCE GLYNN

cc: Government Legal Department (by fax and DX)
Department of Health (Richmond House) (by fax and post)
Local Government Association (by fax and post)