Memo

| | |
|---|---|
| To: | NICE Appeal Panel |
| From: | [redacted] |
| Office/Location: | London – [redacted] |
| Extension: | [redacted] |
| Date: | September 2016 |
| Matter: | Dinutuximab |

1. This note records the legal advice given to NICE's appeal panel in respect of the Solving Kids Cancers submissions on human rights issues in this appeal.

2. This advice deals with the legal position only. It will be for the Appeal Panel to resolve any relevant factual disputes.

3. As well as considering this advice, the Appeal Panel must take account of the submissions from Solving Kids Cancer and any from the Appraisal Committee. The Appeal Panel should not give additional weight to this particular advice only because it was prepared by their legal advisor.

**The patients as children**

4. Possibly the most significant part of the appellant's argument is that the fact that the patient group in this appraisal are children calls for a different approach to that usually taken by NICE.

5. The fact that the patients are children may have legal significance in three ways. The first is under the UN Convention on the Rights of the Child, ("the UN convention") which the appellant develops. The second, which is mentioned but not developed, is under the Children Act 2004. (The reason this is undeveloped is no doubt that s.11 of the 2004 Act, which imposes obligations to make arrangements to safeguard children, does not extend to NICE[1]. The appellant's paper is imprecise in saying this section applies to "a public health body".

[1]in passing and with respect, contrary to the appellant's paper R ota S v NHS England is not decided on the basis of s.11 of the Children Act and no argument was heard on that point, see para 30. Furthermore s.11 does apply to NHS England so even if S had made observations on it, they would not read across to NICE.

S.11 contains a list. NICE is not on it.). The third is that the age and/or the status of the patients as children may simply be a relevant factor on general public law principles.

6. Dealing with them in order, the UN convention does not have direct effect in UK law. Even a direct breach of the convention would not be unlawful in domestic law, although it may put the UK as a state in breach of its international legal obligations.

7. International law may nevertheless inform the application of domestic law. It is assumed that Parliament intends to act compatibly with the UK's international obligations, so where there are multiple interpretations of a legal provision, some compatible with international obligations and others not, the compatible interpretations should be adopted. Similarly there is a presumption that the Courts will construe case law compatibly with international obligations where they can.

8. None of the legislative provisions that establish NICE make reference to children as a special case. Whether or not that is compatible with the UK's international obligations would not be relevant to the question of whether NICE itself has acted lawfully. The panel should be wary about applying the UN convention directly to NICE when (1) Parliament has had the opportunity to legislate to that effect and has not taken it and (2) that is not the usual position in English law.

9. Therefore the advice on the UN convention is that it does not as such impose any obligations on NICE.

10. S.11 of the Children Act is irrelevant for the reason given above.

11. Finally there is the relevance of the age of the patients on general public law principles. Paragraph 18 of the appellant's legal paper makes a factual assertion that children with cancer typically live longer than adults. Any appraisal must consider all of the relevant characteristics of the patient group in question, as they relate to the judgement on whether a given treatment is acceptably cost effective. Consideration should also be given to whether the same benefit is of demonstrably greater value in a given patient group, although care must be taken not to discriminate on the ground of age, or to take account of non-clinical factors. If in fact children differ materially from adult patients in any relevant way, that should be taken into account. You will have to decide if they do so differ and, if they do, whether it was taken into account. If the effect of NICE's procedures as applied to these children is that a material issue has not been taken into account then that would be a ground to allow the appeal.

12. In deciding what is relevant our advice is that the UN convention is in fact not of great assistance. Article 24(1) seems to us to relate to children's access to available healthcare, and not primarily to decisions as to what should be available. We would agree that the article does require that children should not be disadvantaged in decisions as to what should be

available (it would not be compatible with the article if children's medicines had to demonstrate greater cost effectiveness than adult medicines, for example). That fact may inform your scrutiny of whether all material issues relating to the patient group have been considered in this case and whether NICE's procedures might systematically disadvantage children's treatments, although we do not think it would add greatly, if at all, to obligations of non-discrimination that apply in any event.

13. As to article 3(1) you should note that even if it were to apply directly it would require the best interests of the child to be a primary consideration. It does not rule out other considerations and it does not require paramountcy. You may wish to question the committee and to examine NICE's procedures to see what factors were taken into consideration, and how they were weighted.

14. Finally on this issue, we discuss the arguments made from the ECHR below. In considering those arguments you should consider whether there is anything in the special situation of children that might affect your conclusions on the issues raised.

**Article 2 ECHR**

15. It appears from the FAD that even on the committee's preferred assumptions, Dinutuximab is life extending. Therefore Article 2 is engaged.

16. As to Article 2, universally referred to as the right to life, this is something of a misnomer. There can be no right to life as such, not least because, however much care is taken and whatever level of medical and other resource may be given, eventually every life comes to an end. The right is better considered as a right to have life protected by law. Article 2 is substantially a negative right: outlawing the taking of life. However, it does impose certain positive obligations, notably the obligation to investigate death and to take action to discourage the taking of life.

17. To understand the interaction of article 2 with healthcare it is necessary to distinguish between two different decisions. The first are decisions as to what healthcare a state should provide at all. The second are decisions as to whether a patient should enjoy a health intervention that the state has decided to provide. In a plain English analogy: what is in the shop at all, and can a customer have what he/she sees on the shelf.

18. As to the question of what must be provided in a healthcare system at all, the cases on Article 2 have yet to support an argument that it requires the provision of any particular level of state-funded healthcare for prolonging or protecting life. However our view is that it is at least arguable that Article 2 might extend to require the provision of some truly basic life saving

healthcare[2], but that the healthcare provided in the UK would readily exceed that basic minimum.

19. As to the question of whether a patient should enjoy a life saving healthcare intervention that the state has decided to provide, Article 2 will indeed guarantee that right (provided the intervention is clinically indicated). However that is not the question that arises in a NICE appraisal, and so cases that establish this aspect of Article 2 are not very informative.

20. Solving Kids Cancer refers to the following cases in support of its submission that the decision of the Appraisal Committee not to recommend Dinutuxumab breaches Article 2:

    a. *Scialacqua v Italy* DR 81, 35

    b. *NHS Trust A v M* [2001] fam 348

21. In *Scialacqua*, the European Commission on Human Rights hypothesised an obligation to fund "*treatments that are essential in order to save lives*" but without actually deciding that such an obligation existed. Solving Kids Cancer states that the obligation was assumed but, with respect, the case does not go quite that far. Rather, the Commission decided that even if such an obligation were to be assumed, the complaint made was inadmissible on other grounds. Indeed in *Scialacqua* where the Court ruled that Article 2 "*cannot be interpreted as requiring states to provide financial covering for medicines which are not listed as officially recognised medicines.*" Here the issue is not official recognition, but a judgment on acceptable cost-effectiveness, but the principle may be the same, that the state may decide which treatments it covers (and as to the legal requirements applying to that decision, see below).

22. *NHS Trust A v M* concerned a patient in a persistent vegetative state. Her supervising clinicians wished to discontinue artificial feeding and hydration, arguing this was in her best interests. They sought a declaration they would not be acting unlawfully in so doing. The case confirmed that Article 2 imposes a positive obligation to give life-sustaining treatment in circumstances where, according to responsible medical opinion, such treatment was in the best interests of the patient.

23. However, this is an example of the second type of decision referred to above, i.e. whether a patient should receive a treatment that is generally available within the health service. The

---

[2] in addition to the few direct references there are in case law, there would be an argument by analogy from the obligation to take positive steps to protect citizens from who are at risk of death from criminal acts. It might be argued that the nature of the risk to life should not be determinative, although it must be noted that the scope of the state's obligations even as regards protection from crime is very restricted.

means to treat the patient were available within the NHS. The question was whether her article 2 right would be infringed by having available treatment withdrawn. Therefore the case is not very informative as regards NICE's work, which is to conduct a balancing exercise between the needs of the patients who would benefit from the treatment were it to be recommended, and the needs of all other patients who might otherwise benefit from the resources used to fund the treatment being appraised.

24. *Pentiacova v Moldova* 14462/03 illustrates the Court's approach to this balancing exercise. The European Court of Human Rights had to consider a complaint that Moldova was not sufficiently funding dialysis services, with severe effects on the claimants' lives. It said:

    *the Court considers it necessary to examine the complaints concerning insufficient State financing of haemodialysis and the local authorities' failure to cover the applicants' travelling expenses in the light of the right to respect for private life under Article 8 of the Convention.*

    *Although the object of Article 8 is essentially that of protecting the individual against arbitrary interference by the public authorities, it does not merely compel the State to abstain from such interference since it may also give rise to positive obligations inherent in effective "respect" for private and family life. While the boundaries between the State's positive and negative obligations under this provision do not always lend themselves to precise definition, the applicable principles are similar. In both contexts regard must be had to the fair balance that has to be struck between the competing interests of the individual and the community as a whole, and in both contexts the State enjoys a certain margin of appreciation...*

    *The margin of appreciation referred to above is even wider when, as in the present case, the issues involve an assessment of the priorities in the context of the allocation of limited State resources ... In view of their familiarity with the demands made on the health care system as well as with the funds available to meet those demands, the national authorities are in a better position to carry out this assessment than an international court* (Emphasis supplied)

25. The case is relevant for its illustration of the Court's approach to when a positive obligation to provide a medical treatment might arise. It is clear that the possibility of such a positive obligation is not ruled out. It is also clear that it will rarely arise. The principal obligation is that the state (in this case, NICE) must have struck a fair balance between the competing interests of the individual and the community. Provided it has done so and provided it is within its margin of appreciation (broadly, provided its judgement is reasonable) it will have acted lawfully. Nothing should turn on the fact that *NHS Trust A v M* concerned a known patient and this appeal does not. That is not a relevant distinction. There will be known patients within the NHS hoping for this treatment. Nor does it seem relevant that M was a case of treatment being withdrawn and this appeal concerns treatment that will not be offered, nor that M was an

especially vulnerable person in respect of whom the state may have higher obligations[3]. What is relevant though is that this case concerns a balancing exercise to determine which treatments are to be provided within a resource constrained health system, whereas in *NHS Trust A v M* the treatment was readily available and there was no suggestion resources were at all relevant to the case.

26. It is fair to point out that *Pentiacova* concerned Article 8 (right to respect for private life) not Article 2. Important though Article 8 is, Article 2 must be considered more important still. It would not be impossible that a positive obligation might arise under article 2 that would not arise under article 8. Put another way, when carrying out the fair balancing exercise required, a treatment that is life saving may weight more heavily than one which is not. However we consider the obligation is still to conduct a fair balancing exercise, not to provide the treatment per se.

27. Second, we are not advising that Article 2 is a qualified right, as is Article 8. Article 2 is an absolute right. Rather, the issue is how far does Article 2 extend into a positive obligation to preserve life. Our advice is that it extends as far as requiring a fair balancing exercise between the needs of these patients and the community at large, and that the outcome of that exercise is reasonable.

28. The advice is that Article 2 goes no further than requiring a fair balance to have been struck between the needs of these patients, and the needs of patients at large.

**Article 3 ECHR**

29. Article 3 states that "*no one shall be subjected to…inhumane or degrading treatment or punishment"* and is principally concerned to outlaw the deliberate infliction of suffering. (Again, there is also a positive obligation, not merely to refrain from inflicting suffering, but also to take steps to avoid a person being subjected to ill treatment. But the issue is still avoidance of the positive infliction of ill treatment).

30. Although it is the case that neuroblastoma patients undoubtedly suffer severely, the suffering is caused by their illness, not by the State. The complaint is rather that the State could reduce that suffering but chooses not to. That goes beyond the case law. In Pretty v UK (2002) 35 EHRR 1, Ms Pretty's illness caused her severe suffering, but the Court concluded there was no positive obligation to take steps to reduce that suffering (in her case, by facilitating an assisted suicide, but the argument would also seem to apply to provision of treatment).

[3] In any event we will have to consider the fact that these patients are children, in respect of whom the state may also have additional responsibilities.

31. The remarks of the Court of Appeal in *R v North West Lancashire Health Authority ex parte A [*2000] 1 WLR 977 on this issue are on point. At 996, Auld, LJ states that "*It is plain, in my view, that article 3 was not designed for circumstances of this sort of case where the challenge is as to a health authority's allocation of finite funds between competing demands."* Concurring with this sentiment at 1000, Buxton, LJ said that "*Article 3 of the ECHR addresses positive conduct by public officials of a high degree of seriousness and opprobrium. It has never been applied to merely policy decisions on the allocation of resources, such as the present case is concerned with. That is clear not only from the terms of article 3 itself, and the lack of any suggestion in any of the authorities that it could apply in a case even remotely like the present, but also from the explanation of the reach of article 3 that has been given by the Convention organs.*"

32. It may be possible to make out an argument that if a drug was generally available (i.e. it was recommended that it should be publicly-funded), then deliberate withholding might breach Article 3. If, say, a doctor has a painkilling treatment funded and available which would be clinically suitable for a patient, but does not provide it and instead leaves the patient to suffer, Article 3 might well be breached. But this begs the question of whether the drug is to be generally available, which is the very decision to be made by NICE. (Strictly, it is whether the drug is to be more or less generally available, since NICE neither licenses nor bans drugs). It would be surprising if a decision of a pubic body to focus NHS resources on securing more cost-effective treatment for its population engaged Article 3 rights for those who hoped to enjoy the less cost-effective treatment which could not be provided as a result. The Article 3 argument seems to point to the opposite conclusion. It might be argued that Article 3 could require some sort of process akin to NICE technology appraisals, as the overall intended purpose is to maximise the health benefit from a given budget. If less cost-effective treatments took the place of more cost-effective treatments, that would result in the State failing to reduce suffering to the fullest extent possible, which, it could be argued, might be a breach of Article 3.

33. The advice is that Article 3 is neither engaged or breached in this case.

**Article 8 ECHR**

34. It is necessary to set out Article 8 in full:

    *8(1) Everyone has the right to respect for his private and family life, his home and his correspondence.*

    *8(2) There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the*

*country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.*

35. Article 8 requires respect for private and family life. Although it may not seem obvious, aspects of medical treatment may engage Article 8.

36. Solving Kids Cancer relies on the following cases in support of its submission that the decision of the Appraisal Committee not to recommend Dinutuximab breaches Article 8:

    a. *Bensaid v UK* 2001-I

    b. *Pentiacova v Moldova* (2005) 40 EHRR SE 23

    c. *Tysiac v Poland (2007)* 45 EHRR 42

    d. *Sentges v Netherlands* (2003)

37. With respect to the contrary views expressed by appeals panels in earlier appeals, it remains our advice that Article 8 is typically engaged by NICE appraisals. The scope of Article 8 is wide and at its margins ill defined. However these patients' illness seems clearly to impact on their and their wider families' ability to enjoy family life, not least on the fundamental question of for how long that family life will continue. Although there must clearly be some limits on the ambit of each right, it is not appropriate to take an unduly restrictive approach.

38. In *Bensaid v UK* the matter before the Court was the deportation of an Algerian national, who was a schizophrenic suffering from a psychotic illness which had been treated in the UK while he was resident here. The applicant claimed that proposed expulsion would violate his right to respect for his private life pursuant to Article 8. The Court states that Article 8 encompasses protection for the broader concepts of physical and moral integrity on the basis that they are a vital precondition to the effective enjoyment of private life. It also says that not every act or measure which adversely affects moral or physical integrity will interfere with the rights guaranteed at Article 8. Here, it was decided that a successful case could not be made out but the Court commented that, even if interference with Article 8 had been made out, *"the Court considers that such interference may be regarded as complying with the requirements of the second paragraph of Article 8, namely as a measure "in accordance with the law", pursuing the aims of the protection of economic well-being of the country and the prevention of disorder and crime, as well as being "necessary in a democratic society" for those aims*."

39. *Pentiacova v Moldova* (2005) was referred to above. The Court assumed that Article 8 covered medical treatments for the purposes of an admissibility hearing, but it seems from that case that Article 8 is only likely to be breached where the allegation is denial of access to a

standard of treatment made generally available. It is not likely that Article 8 is engaged where the issue is a general judgment on acceptable cost-effectiveness. (In ruling the complaint manifestly ill-founded and inadmissible, the Court commented that "*the applicants had access to the standard of healthcare offered to the general public*..."). It is also notable that in *Pentiacova* the Court referred to complaints about "*insufficient funding of* [the applicants'] *treatment"* which suggests that the issue was affordability, rather than cost-effectiveness. Affordability is outside NICE's remit. The Court also commented that it was necessary to strike a balance between the needs of individual patients and the community at large, and that, due to lack of resources, there would be many individuals who could not have access to "*a full range of medical treatment, including life saving medical procedures and drugs*". Even so (or perhaps, as a result), the complaint failed.

40. *Tysiac v Poland* (2007) 45 EHRR 42 is a case concerning the denial of access to abortion. Clearly the facts of that case are rather different to this appraisal, but consistently with the advice being given in this paper the Court affirmed that "*the convention does not guarantee as such a right to any specific level of medical care*."

41. Finally there is *Sentges v. Netherlands* (2003), a case in which it was held that Article 8 was only engaged where there was a "*direct and immediate*" link between the measure sought (in that case the provision of a robotic arm to assist a severely disabled person) and the applicant's private life. In that case the Court held there was no such link. On its face, the provision of the robotic arm would seem to have a very direct impact on the applicant's enjoyment of private life, in that it would certainly have enabled him to carry out a wider range of day-to-day tasks for himself, and so enjoy more autonomy and self determination, which are concepts that sit within Article 8. And yet the Court held that Article 8 was not breached. Once again the Court observed that the facilities offered to the applicant met the standard of healthcare generally made available, which appears to be the essential issue protected by the ECHR as the cases stand today.

42. There is also the decision of the English Supreme Court, *R (on the application of McDonald) v Royal Borough of Kensington and Chelsea* [2011] UKSC 33). In that case, the claimant had very limited mobility due to a stroke, among other issues, and a neurogenic bladder issue that necessitated the frequent need to urinate during the night. The applicant had been accessing a commode with the assistance of a publicly-funded carer. The defendant council proposed the use of incontinence pads and special sheeting as an alternative, which would reduce the cost of her care by £22,000 per annum. The claimant relied on a breach of Article 8 among other grounds of claim.

43. In considering the application of Article 8, the Court said

*"…There is no dispute that in principle* [Article 8] *can impose a positive obligation on a state to take measures to provide support and no dispute either that the provision of home-based community care falls within the scope of the article provided the applicant can establish both (i) "a direct and immediate link between the measures sought by an applicant and the latter's private life" – Botta v Italy (1998) 26 EHRR 24 , paras 34 and 35 – and (ii) "a special link between the situation complained of and the particular needs of* [the applicant's] *private life": Sentges v The Netherlands (2003) 7 CCLR 400 , 405.*

*16 Even assuming that these links do exist, however, the clear and consistent jurisprudence of the Strasbourg Court establishes "the wide margin of appreciation enjoyed by states" in striking "the fair balance … between the competing interests of the individual and of the community as a whole" and "in determining the steps to be taken to ensure compliance with the Convention", and indeed that "this margin of appreciation is even wider when … the issues involve an assessment of the priorities in the context of the allocation of limited state resources" – Sentges , at p 405, Pentiacova v Moldova (Application No 14462/03 (unreported) 4 January 2005 , p 13) and Molka v Poland (Application No 56550/00 (unreported) 11 April 2006 , p 17)".* (Emphasis supplied)

44. See also *R (Condliff) v North Staffordshire Primary Care Trust*:

a. *"Private and family life are very broad concepts. There is no doubt that Mr Condliff's state of health is having a seriously adverse effect on his private and family life in the most basic ways, which without bariatric surgery will continue and is likely to become worse. However, harsh as this must seem to Mr Condliff, I do not see that the application of the IFR policy involves a lack of respect for Mr Condliff's private and family life. The policy of allocating scarce medical resources on a basis of the comparative assessment of clinical needs is intentionally non-discriminatory. The statutory function of the PCT is to use the limited resources provided to it for the purposes of the provision of healthcare, i.e. services in connection with the prevention, diagnosis and treatment of illness. To perform that function by allocating those resources strictly according to the PCT's assessment of medical need, i.e. an assessment based on clinical factors, is to do no more than to apply the resources for the purpose for which they are provided without giving preferential treatment to one patient over another on non-medical grounds*." – see paragraph 36;

b. *"The Strasbourg Court has said on many occasions that article 8 is directed primarily at prohibiting positive interference with an individual's private and family life. The court has also recognised that it may give rise to positive obligations, but here the court has proceeded cautiously. There is no universal yardstick for determining the scope of a*

*state's positive obligations under article 8. The Strasbourg Court has been particularly wary of attempts to establish a positive obligation under article 8 in the area of the provision of state benefits, because questions about how much money should be allocated by the state on competing areas of public expenditure, and how the sums allocated to each area should be applied, are essentially matters which lie in the political domain. Such decisions are characteristically made either by politicians who are answerable to the electorate or by bodies appointed by government to make such decisions, including PCTs. Although the Strasbourg Court has recognised that in principle article 8 may be relied on to impose a positive obligation on a state to take measures to provide support for an individual, including medical support, there is no reported case in which the court has upheld such a claim by an individual complaining of the state's non-provision of medical treatment. Attempts have been made, but they have been unsuccessful."* – see paragraphs 40 and 41; and

c. *"…The Strasbourg Court has shown a strong reluctance to entertain complaints of that kind because of the difficult assessments required in the fair administration of a healthcare system with limited resources. The PCT has grappled with the difficult ethical and practical questions involved in setting its IFR policy. In arriving at that policy the PCT has struck what it considers to be a fair balance between the interests of individuals and the community (for example, whether patients who are carers should have priority over others) and a fair balance between different patients with similar health conditions. The case illustrates the balancing exercise referred to in Sentges and Pentiacova . The PCT is entitled to set an IFR policy which reflects what it reasonably considers to be the fairest way of treating such patients."* – see paragraph 47.

45. The appellant correctly focuses on the question of whether NICE's recommendation falls within Article 8(2). in other words: is it (irrelevant material deleted) "*in accordance with the law and … necessary in a democratic society in the interests of … the economic well-being of the country, … for the protection of health …, or for the protection of the rights and freedoms of others*"?

46. The interference will be in accordance with law in as much as NICE is lawfully set up and operating within a properly defined legal framework. The purpose of the interference would seem to be arguably for the economic well being of the country (in as much as general cost-effectiveness in public spending achieves that goal) and arguably for the protection of heath and the protection of the rights of others, again, in as much as maximising health gain from the NHS budget protects the health of the population generally, and tends to protect the population's rights in that regard. (The point is essentially the same as the point made above under Article 3: that inefficient use of NHS resources could be argued to infringe the rights of

those who would have benefited had more efficient use been made). Furthermore, the English Courts and European Court of Human Rights has repeatedly referred to the need to strike a "fair balance" between the needs of an individual and the needs of the community at large (see e.g. *Pentiacova*), indicating that one or more of these permitted objectives was in play. Therefore, the advice is that one or more of these permitted purposes applies.

47. That leaves the remaining question of whether this particular measure is "necessary", bearing in mind both that this is a higher test than "desirable" and that equally, there is a "margin of appreciation" (i.e. a measure of discretion) allowed under the ECHR, particularly on questions of resource allocation by public bodies. The general reluctance of the Courts to scrutinise the resourcing of healthcare provision too critically should be borne in mind.

48. The issue of necessity in this specific case is a question of fact, and so it is for the Appeal Panel to decide in light of the Appellants submissions and the Appraisal Committee's comments on them. There may be a spectrum, from a highly cost-ineffective use of resources likely to divert material sums of money from other treatments, where the Appeal Panel may feel it is more likely to be necessary for use to be constrained, down to a marginally cost-ineffective use unlikely to have any significant effect on budgets, where the Appeal Panel may feel it is harder to establish necessity. The Appeal Panel should be guided but not bound by NICE's usual thresholds for cost-effectiveness, in as much as it would be difficult to argue that it is necessary to manage the availability of a drug below the usual thresholds, but it does not follow without more that it is necessary to manage its availability simply because it is above the threshold. The Appeal Panel needs instead to look at necessity in the round, with the fact that the drug is above the usual threshold (and the degree by which it exceeds the threshold) being one factor to weigh in the balance.

49. It is also legitimate for the Appeal Panel to bear in mind the danger of the cumulative impact of many such arguments (i.e. that this spending is surely too little to matter, and that this other spending is also *de minimis*, and so on, with no account being taken that when added together all of the "small" sums may come to a material sum) and keep in mind the other feasible uses for the funds available to the NHS.

50. Therefore, the advice is that the Appeal Panel must decide if the restrictions contained in this guidance are "necessary", and should allow the appeal if it feels they are not.

**Article 14**

51. Even if none of the substantive rights discussed above are breached by this guidance, Article 14 may nevertheless be in play so long as the guidance is within the "ambit" of any of the substantive rights. In light of the effects of the treatment, the advice is that the guidance does seem to be within the ambit of Article 8, at the least, and probably also Article 2, and so the prohibition on discrimination comes into play.

52. The argument is that as the treatment appraised is for children, a refusal to recommend it amounts to indirect discrimination against children, or on the grounds of age.

53. Discrimination occurs when there is different treatment of individuals in relevantly similar or analogous situations. Direct discrimination is a difference in treatment motivated by a particular characteristic of the individual. Indirect discrimination occurs where the same policy is applied to all, but a certain group is particularly disadvantaged.

54. Certain forms of direct discrimination are always unlawful, for example, treating a person differently because of their race or sex. Other forms of directly discriminatory treatment may not be unlawful per se, but it may still be necessary to look with care at the reasons for them (for example, for a service which is locally commissioned, people living in one area may be able to access the service and people living in a neighbouring area may not, or may have to pay a fee. Discrimination based on address is not per se unlawful, but a court might look carefully at it to see whether it might not nevertheless be unlawful on other grounds).

55. Indirect discrimination is unlawful[4] unless it is objectively justified, i.e., it is a proportionate means of pursuing a legitimate aim.

56. Failure to recommend this treatment clearly affects children more than adults and the appellant is right to say that it must be objectively justified. Whether there is sufficient justification is a question of fact for you. We suggest that the aim that NICE technology appraisals seek to achieve (delivery of acceptable cost effectiveness in NHS treatments) is legitimate. You will want to consider whether the outcome of this appraisal is proportionate to achieve that aim. For that purpose, you should ask whether there would be some other measure that would similarly have delivered a cost effective outcome but have had less of an impact on this patient group, and also whether the impact on these patients is a reasonable price to have paid for the delivery of a cost effective use of public money.

57. The Appeal Panel's attention has also been drawn to section 149 of the Equality Act 2010. This section requires NICE to have due regard to the need to, among other things, eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010 and advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it. In so doing, NICE must have due regard, in particular, to the need to (a) remove or minimise disadvantages suffered by persons who share a relevant protected characteristic that are connected to that characteristic; and (b) take steps to meet the needs of persons who share a relevant protected characteristic that are different from the needs of persons who do not share it. The Appraisal

[4] Assuming it affects a group of people defined by a protected characteristic.

Committee should have had such due regard during the appraisal[5], as must the Appeal Panel itself in this appeal.

58. Therefore the advice is that Article 14 is engaged and the panel should consider whether the recommendations are a proportionate means to achieve a legitimate objective.

59. The Appeal Panel should also ensure that NICE's s.149 Public Sector Equality Duty legislation has been discharged.

**DAC Beachcroft LLP**

[5] in substance. It does not have to have referred to the duty by name