Neutral Citation No [2013] NIQB 101 | *Ref:* **TRE9009**

*Judgment: approved by the Court for handing down (subject to editorial corrections)** | *Delivered:* **11/10/2013**

IN THE HIGH COURT OF JUSTICE IN NORTHERN IRELAND

_____

QUEEN'S BENCH DIVISION (JUDICIAL REVIEW)

_____

JR65's Application [2013] NIQB 101

IN THE MATTER OF AN APPLICATION BY JR65 FOR JUDICIAL REVIEW

AND

IN THE MATTER OF DECISIONS OF THE DEPARTMENT AND MINISTER FOR HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY

_____

TREACY J

Introduction

1. By this application the applicant seeks to challenge a policy maintained by the Department of Health, Social Services and Public Safety ("the Department") by which there is a lifetime ban on males who have had sex with other males ("MSM") donating blood. The applicant also challenges a decision by the Minister with responsibility for the Department made on 22 September 2011 not to alter this ban and/or the ongoing failure of the Minister to do so and adopt a position consonant with that which now applies throughout the rest of the United Kingdom (where MSM are subject to a one year 'deferral period').

Background

2. Since 1985, the UK has had in place legislation and procedures applying to the donation of blood for transfusion whereby certain categories of persons are required automatically to refrain from donating blood on account of their meeting certain criteria, including criteria relating to their sexual or other behaviour. Since 1985, men who have engaged in male-to-male sexual relations are subject to a permanent deferral from donating blood.

3. From 2005, the list of relevant criteria has been set down in Blood Safety and Quality Regulations 2005 which transpose the corresponding list in Commission Directive 2004/33/EC. Pursuant to these Regulations and the 2004 Directive, categories of persons may either be temporarily or permanently deferred from donating blood. In the 2004 Directive in relation to "permanent deferral" the category "sexual behaviour" is defined as "persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood."

4. The list of behavioural deferrals, both temporary and permanent, applying in Northern Ireland is found in Table 4 of the April 2011 report of the Advisory Committee on the Safety of Blood, Tissues and Organs. Together with a number of other categories of persons, there is a requirement of permanent deferral applying to men who have had male-to-male sexual relations.

5. In 2011 the Advisory Committee on the safety of Blood, Tissues and Organs (SaBTO) completed a review of the Donor Selection Criteria which are used to ensure the safety of the blood stock for *inter alia* transfusion in the UK. SaBTO is an independent agency which advises the health ministers and health departments in all parts of the UK on issues relating to the safety of blood, tissues and organs in the UK. It is composed of expert medical/scientific personnel. In preparing to advise the relevant persons on the issue of donor selection criteria it commissioned an expert committee to give detailed scientific consideration of the relevant facts.

6. This review considered the appropriate eligibility criteria for various donor types including men who have had anal or oral sex with another man (MSM), and commercial sex workers in particular. The outcome of this process was that it was recommended that the previous policy of permanent deferral applying to MSM donors be replaced by a temporary 12 month deferral period. This recommendation was accepted in England, Scotland and Wales and came into force in November 2011 however Northern Ireland did not follow suit.

7. On 8 September 2011, the UK Department of Health announced a permanent deferral will no longer apply to MSM, who will be permitted to donate blood, should they wish, provided that they have not had male to male sexual relations during the 12 month period prior to such donation (and provided they are not so deferred, either temporarily or permanently, for some other reason). This change in policy, applying in England, Wales and Scotland, was from 7 November 2011, the decision to change those applicable policies being taken by each of the Health Ministers acting on behalf of each of the jurisdictions.

8. This followed what has been referred to as a "recommendation" to each of the devolved administrations by the Advisory Committee to change the policy from a lifetime ban to a one-year deferral period for MSM.

9. The Applicant is a gay man who has previously engaged in homosexual conduct with other men. After living as an active homosexual for a period he experienced a religious conversion and would now no longer consider himself a homosexual, but as 'someone who struggles with homosexuality'.

10. He gave blood when he was a teenager, before he had had intercourse with another man. He considered giving blood on another occasion despite knowing that he did not meet the eligibility criteria, but ultimately elected not to do so. He heard that the ban was lifted in the rest of the UK and looked forward to it being lifted in Northern Ireland also and was disappointed when this did not happen.

11. The applicant feels that the act of giving blood is socially responsible and also a practical demonstration of his faith and he is frustrated that he is prohibited from doing so. Further the Applicant considers that the continuation of the policy of permanent deferral of potential MSM donors sends out a message of rejection to members of the male homosexual community.

12. The applicant accepts that by reason of matters set out in his second affidavit, he would not presently be entitled to give blood in Northern Ireland even if the lifetime ban was lifted.

13. The applicant is concerned that the Minister's membership of the DUP, who adopt a very firm moral stance against homosexuals, may have prejudiced his consideration of the issue and prevented him from considering the matter fairly.

Relief Sought

14. The applicant seeks:

    (i) An order of certiorari to quash the lifetime ban and/or the decision of the Minister of 22nd September 2011 whereby the lifetime ban was upheld;

    (ii) A declaration that the lifetime ban is unlawful, ultra vires and of no force or effect;

    (iii) A declaration that, as the competent authority for the purposes of Directive 2002/98/EC and designated by the Blood Safety and Quality

Regulations 2005 ("the 2005 Regulations"), the Secretary of State for Health is responsible for the determination of the appropriate deferral periods in Northern Ireland and, accordingly, the maintenance (or otherwise) of the lifetime ban;

(iv) In the alternative, an order of mandamus requiring the Minister and the Department forthwith to lift the lifetime ban and align the blood donation policy in Northern Ireland with that employed in England, Scotland and Wales.

15. The grounds relied upon are:

(i) That the ban/decision are *Wednesbury* unreasonable because:

(a) The maintenance of the current lifetime ban fails to give any or adequate weight to the latest expert medical and scientific evidence, including that set out by the Advisory Committee on the Safety of Blood, Tissues and Organs ('the Advisory Committee'), which recently reviewed the policy pertaining to the current lifetime ban and concluded that there was no additional risk attaching to a 12 month deferral period, as opposed to the previous lifetime ban;

(b) The maintenance of the current lifetime ban is unsupported by evidence. Indeed, the evidence suggests that a lesser deferral period would be safer, given that there is a lesser risk of non-compliance.

(c) The maintenance of the current lifetime ban is illogical having regard to the acknowledged fact that Northern Ireland, when required to, calls upon the blood supply of Great Britain where the lifetime ban has now been lifted.

(d) The maintenance of the current lifetime ban is further illogical in that an individual who has had and continues to have heterosexual relations with a vast number of partners remains freely eligible to donate blood, whilst a male individual who has had homosexual relations with only one partner is precluded from blood donation, which is irrational in that the risk of HIV infection is far greater in relation to the heterosexual individual in such circumstances.

(e) The maintenance of the current lifetime ban fails to give any or adequate regard to the common legal framework for blood safety

throughout the United Kingdom, pursuant to the 2005 Regulations, which apply throughout the four jurisdictions, such that it is irrational that the policy should be applied inconsistently throughout the United Kingdom.

(ii) The Minister's decision and the lifetime ban are contrary to directly effective EU law and/or the general enforceable principles of EU law and/or the relevant transposing provisions of domestic law in that:

(a) Article 4.1 of the European Directive 2002/98/EC provides for designation of a competent authority to implement the requirements of the Directive as to blood safety. By regulation 2(1) of the 2005 Regulations, the competent authority with the responsibility for determining policy is the Secretary of State for Health in England. The Northern Ireland Minister has acted in a field in which, by virtue of the provisions of the Directive and the 2005 Regulations, he has no authority to act.

(b) The lifetime ban, and its maintenance, are contrary to the EU principles of non-discrimination and proportionality; and/or the EU principle of protection of fundamental human rights, including the right not to be discriminated against on grounds of sexual orientation, the said rights having effect as general principles of EU law by virtue of Article 6(3) of the Treaty of European Union.

(c) The lifetime ban, and its maintenance, is further contrary to Article 21 of the Charter of Fundamental Rights of the European Union, having effect by virtue of the Article 6(1) of the Treaty of European Union.

(iii) In the alternative, the Minister has misdirected himself as to his ability to set policy in this area for the reasons set out at paragraph (i)(a) above.

(iv) The Minister's decision was unlawful pursuant to section 28A(10) of the Northern Ireland Act 1998 (as amended) by virtue of his having failed to secure Executive approval for the decision, contrary to the requirements of the Ministerial Code and by section 20(3) and/or section 20(4) of the 1998 Act as (i) the decision was a controversial decision and/or (ii) the decision was in respect of a cross-cutting matter.

(v) The Minister's decision was taken without any or adequate consultation;

(vi) The Minister's decision is infected by apparent bias;

(vii) The Minister has failed to give appropriate reasons for his decision.

Relevant Reports

The Advisory Committee on the Safety of Blood, Tissues and Organs (the "Advisory Committee" or "SaBTO") – Donor Selection Criteria Review – April 2011 (the "Advisory Committee Report")

16. The Advisory Committee established a Steering Group to review the current criteria for exclusion from blood donation based on sexual behaviour:

> "…The Terms of Reference for the Steering Group… includes reviewing deferral criteria related to sexual behaviour which has the potential to put transfusion recipients at increased risk of TTIs [transfusion transmitted infections] and the appropriateness of existing deferral criteria in the light of technological advances, specifically:
>
> 1. The appropriateness of continuing lifetime exclusion of men who have had sex with men (MSM)…" [pp8 and 9]

17. The below table refers to the behavioural deferrals for blood donation in the United Kingdom as at the date of the Advisory Committee Report (pp34 and 35 of the Advisory Committee Report):

	Behavioural Risk	**Duration**
1	Sex with a sex worker	1 Year
2	Accepting money or drugs for sex	Permanent
3	Sex with an intra-venous drug user (IVDU)	At least 1 year after last sexual contact
4	Sex with anyone who may ever have had sex in parts of the world where HIV/AIDS is common	At least 1 year after last sexual contact
5	Sex with anyone infected with HIV, Hepatitis B or C	At least 1 year after last sexual contact

6	Females who have sex with a man who had sex with a man	At least 1 year after last sexual contact
7	Anyone who thinks they may be HIV positive	1 Year
8	Men who have ever had oral or anal sex with a man (MSM)	Permanent

18. The relevant parts of the Executive Summary in the Advisory Committee Report are set out below:

> "Since 1985, men who have ever had oral or anal sex with another man (MSM) have been permanently deferred from donating blood in the UK. Similarly, individuals who have ever accepted money or drugs in exchange for sex are permanently deferred from donating blood. In 2006, a review of the permanent deferral of MSM found that there were insufficient data regarding compliance to determine the impact of any changes. Recently, data has become available on the level of compliance with the current donor deferral criteria. These data, together with advances in the testing and processing of donated blood, changes in the epidemiology of sexually transmitted infections (STIs) and improved scientific knowledge have prompted a review of donor deferral on the basis of sexual behaviour…
>
> The review noted that process improvements and automation have significantly reduced the chance of errors in blood testing such that the modelled risk of a HIV infectious donation being released into the blood supply is 1 per 4.4 million donations. The introduction of either a 12 month or a 5 year deferral would not significantly affect this figure if the number of non-compliant individuals remained unchanged. Under the current permanent deferral, it was shown that 11 % of MSM had donated blood since becoming ineligible, although the majority of non-compliers had not had a risk exposure (ie oral or anal sex with a man) within the 12 months prior to donation. Upon investigation, non-compliers were shown to be supportive of a change to a 12 month deferral…

> In the UK population as a whole, where risk factors were reported for new diagnoses of blood borne viruses, heterosexual sex was the most commonly reported risk factor for both acute Hepatitis B infection (63%) and human immunodeficiency virus (54%) during 2009…" [emphasis added] [p7]

19. Under the heading of 'Background and Process', the Advisory Committee Report makes reference to a number of incremental improvements in the ability to detect infection in donors and reduce the potential for transfusion transmission:

> "...There have been a number of incremental improvements in the ability to detect infection in donors and reduce the potential for transfusion transmission. These improvements are the result of scientific and technological advances in donation testing, notably i) Reduction of the window period through the introduction of nucleic acid technology (NAT) testing; ii) Effective use of Information Technology to reduce the number of human errors in the testing laboratory environment and product release errors; iii) Introduction of automated sample handling and tracking systems to reduce testing errors; iv) increased information surrounding compliance with the current deferral…" [p8]

20. At p18 of the Advisory Committee Report, reference is made to the trends in the new diagnoses of HIV in Northern Ireland:

> "There were 79 new diagnoses of HIV in Northern Ireland in 2010. The highest ever annual figure of 91 new diagnoses of HIV was recorded in 2008. Previously, there were around 60 new cases annually in Northern Ireland. The trend in the number of new HIV cases is increasing in Northern Ireland, the UK and Europe, although compared with the rest of the UK, Northern Ireland had the largest proportional increase – around 300% - of new HIV diagnoses between 2000 and 2009. HIV/AIDS prevalence remains lower in Northern Ireland."

21. Regarding the reduction of the risk of transfusion transmitted HIV, the Advisory Committee Report provides:

> "The risk of transfusion transmitted HIV has been reduced by improved screening using 4th generation EIA assays that detect HIV antibody/antigen. In addition, early HIV infection can be detected by p24 antigen specific assays however these have lower sensitivity compared to HIV NAT testing of mini-pools which was introduced in the early 2000s. Individuals in the early stage of HIV infection (window infections) without detectable HIV antibody/antigen may transmit infection, however HIV NAT testing reduces the window period to nine days". [p19]

22. In relation to "Advances in donation testing and handling", the Advisory Committee Report states:

> "Great improvements in donation testing have been implemented since the last review of blood donor selection in relation to sexual behaviour." [p40]

23. Under the heading "4.6 Transfusion risk from new/currently unknown infections", the Advisory Committee Report refers to the lifetime ban on all MSM donating blood which was put in place in the 1980s to prevent the risk of HIV contamination as no rapid test was available at that time:

> "…When HIV was first discovered in the 1980s it was predominantly associated with homosexual men and as no rapid test was available all MSM were excluded from donating blood. Concern has been expressed by some commentators that a new sexually-transmitted infection could emerge in a similar way and that any change to MSM deferrals should take this into account." [p22]

24. Under the heading, "Background and Process", the Advisory Committee Report, also, recognised that equality issues were engaged:

> "In addition to these technological advances and quality control there have been significant social, cultural and legal changes since 2001, which need to be considered when reviewing blood donor selection. The Equality Act 2010 prohibits discrimination on grounds of sexual orientation, but includes a provision which permits blood donor deferral if the refusal is a reasonable judgement made on the basis of available data." [p8]

Briefing Paper provided to the Minister from the Health Protection Branch of the Department – 1 July 2011 (the "Briefing Paper")

25. The first page of the Briefing Paper suggests the Department of Health in London wanted a United Kingdom wide approach:

> "Timescale: Urgent – DH would like to make a UK agreed announcement before 19th July 2011.
>
> …
>
> Recommendation(s): That you consider SaBTO's recommendations and based on their advice agree to a UK-wide response in a change in policy from a lifetime to a 12 month deferral period for men who have sex with men."

26. The Briefing Paper provides that in 2009 in the United Kingdom, heterosexual sex was the most commonly reported risk factor for Hepatitis B and HIV:

> "12. In the UK population in 2009, where risk factors were reported for new diagnoses of blood-borne viruses, heterosexual sex was the most commonly reported risk factor for both acute Hepatitis B infection (63%) and HIV (54%). The intravenous drug user population had the highest risk of Hepatitis C virus (> 90% of new diagnoses)." [para 12]

27. The Briefing Paper goes on to refer to the key determining factor for permanent deferral on the basis of sexual activity:

> "…The key determining factor for permanent deferral on the basis of sexual activity is that it would include persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood. DH has received legal advice that there is no bar on the face of the legislation which would prevent those currently subject to a permanent deferral criteria – such as MSM – from being moved to a relevant temporary deferral group if their sexual behaviour is no longer considered to be high risk. This would permit the application of a 12 month deferral period for MSM." [para15]

Draft Official Report (Hansard) from meeting of the Committee for Health, Social Services and Public Safety (the "Health Committee") which took place on 26 October 2011 on the issue of the lifetime ban (the "Hansard Report")

28. In reliance on para22 of his first affidavit dated 18 November 2011, the applicant says the Advisory Committee was set up to advise the Devolved Administrations as well as Ministers of the United Kingdom Government and, therefore, it is the expert body within the United Kingdom which is best placed to provide advice on questions of blood safety. In his evidence to the Health Committee, the Minister referred to the Advisory Committee as advising the four United Kingdom Health Ministers:

> "…The Advisory Committee on the Safety of Blood, Tissues and Organs … advises the four UK Health Ministers on how to ensure the safety of blood, cells, tissues and organs for transfusion and transplantation…". [p17]

29. Consideration was given to the HIV rates in England, Scotland and Wales and to the fact that, at times, blood donated in England, Scotland and Wales is imported into Northern Ireland. In this regard, Mr Matthew McDermott of the Rainbow Project stated:

> "[The Minister] has said that blood will be taken from England, Scotland and Wales under the system that they will implement… There are higher incidences of HIV in England, Scotland and Wales than in Northern Ireland. Therefore, in order for the Minister's argument to be consistent with the lifetime ban on the grounds of safety,

> he would have to apply the ban to blood from England, Scotland and Wales as well. However, that is not the case." [p5]

30. Mr McDermott, later, referred, in more detail, to the figures for HIV rates in England, Scotland and Wales compared with Northern Ireland:

> "…424 people access HIV specialist care in Northern Ireland, less than half of whom are men who have sex with men; in England the figure is 1.23 people per thousand; in Scotland 0.59 people per thousand; and it is 0.40 per thousand in Wales. Taking those figures together, 1.12 people per thousand of the population in England, Scotland and Wales are in that category, in Northern Ireland, the figure is 0.24 per thousand. There is a much greater risk in England, Scotland and Wales, although, as the experts say, it is still insignificant, and the system that they have put in place is more than robust. The argument that the ban is on safety grounds does not stack up if you are going to take blood from England, Scotland and Wales. In theory, the system there will be much more unsafe." [p9]

31. In terms of the prevalence of HIV in Northern Ireland, the Minister said:

> "…The trend in the number of new HIV cases is increasing in Northern Ireland, the UK and Europe, although compared with the rest of the UK, Northern Ireland had the largest proportional increase – around 300% - of new HIV diagnoses between 2000 and 2009. HIV/AIDS prevalence remains lower in Northern Ireland." [p18]

32. In relation to blood imported into Northern Ireland from the rest of the UK, the Minister said:

> "It is normally fewer than 100 units a year. So, last year, for example, I think that we received two lots of 40 units. Blood was provided at the time of the bus crash, because it was thought that there might have been considerably higher requirement as it transpired, this year we did not need additional blood. It happens primarily when a

> major incident takes place... However, there could be a major incident, in which case we would be very glad to receive blood from either the UK or the Republic of Ireland." [p34]

33. The Minister then confirmed the Department did not request that blood from the rest of the United Kingdom does not come from MSM:

> "The Chairperson: Do you request that such blood is not derived from the MSM community?
>
> Mr Poots: No." [p34]

34. In relation to the risk, the Minister said:

> "The Chairperson: So whatever the risk is, it is safe enough. The very low risk is low enough.
>
> Mr Poots: If you are looking at the relative risks involved, they are diminished greatly by the small amounts we receive." [p35]

35. Regarding the position in Northern Ireland in respect of blood donation by MSM, the Minister indicated he had not made a final decision. He then went on to say, at that stage, they did not intend to change anything and were taking advice on the matter:

> "…I want to make it clear at the outset that I have not made the final decision on blood donation by men who have had sex with men and that I will consider carefully all the relevant issues…
>
> My first duty today is to provide reassurance to the public, recipients of blood donations and, indeed, the Committee on the robustness of the arrangements to maintain the safety and integrity of the blood supply in Northern Ireland. Appropriate donor selection, including compliance with deferral criteria, and accurate donation testing form the twin pillars that ensure the safety of our blood supply. That is the most important point for me in relation to this issue. As Minister, I will consider all the relevant evidence. I must also take into account the issue of wider public confidence…

...

The Department of Health announced on Thursday 8 September that England, Scotland and Wales were changing their blood donations policy for MSM and that the change would be implemented at blood donation sessions on 7 November 2011. Until 7 November, the permanent exclusion will continue to apply. I have not made any decision to change that at this point.

As the Committee is aware, SaBTO has considered advice from its review group on the issue of donations from men who have sex with men. SaBTO concluded that there was no longer a reason to maintain the lifetime ban on donations from men who have had sex with men. The details are set out in the briefing note, which was sent to the Committee. I have asked my officials to clarify a number of important issues around the circumstances and context of Northern Ireland in relation to the procedure for decision-making. I also intend to seek further information from SaBTO on the relative risks arising from potential donations. Until that work is complete, I am not in a position to finalise my views on those issues and to consider what response to the analysis of the SaBTO review group would be most appropriate in all circumstances.

…

In conclusion, I am sure that the Committee will understand that, given the complexity of the issue, I have asked for further advice and will be seeking further meetings to inform my decision. I will take whatever time is necessary to consider all aspects before reaching a final decision…[pp17 - 19]

…

There was perhaps an urgency in the question about what we were doing. At this stage, we do not intend to change anything. We will take all advice on this matter. As I indicated, there are things that have come to light even since then that would lead us to ask further questions." [p24]

36. The Minister was asked what further advice he was seeking and as part of his response the Minister said:

> "So, there is a range of things that I have to do before reaching a conclusion. We have to ask SaBTO a series of questions. Those questions are not about MSM but about people in general who give blood. For example, currently, people who have had sex with a prostitute can give blood after a year, as can people who have had sex in Africa. We want to pose questions about those issues, because I have concerns about them…" [p22]

37. Consideration was, also, given to the risk involved if a 12 month deferral period was introduced. The Committee Chairperson stated the Briefing Paper provided to the Minister by the Health Protection Branch of the Department indicated:

> "…if the 12-month referral were introduced, the risk would be 0.228 per million donations. The current risk is 0.227 per million donations, so that would be a rise of 0.001 per million donations…" [emphasis added] [p24]

38. The increase in risk referred to above appears to have been based on compliance rates with the reduced deferral period remaining the same as with the lifetime ban. The Chairperson then went on refer to the effect on the risk if there was enhanced compliance with a 12 month deferral period:

> "…The paper goes on to state that, if there is enhanced compliance with having a 12-month ban instead of the lifetime ban, the risk could be reduced... If the lifetime ban were scrapped and a 12-month deferral put in place, it could actually reduce the risk of infection considerably – probably by one third – if the figures in your paper are anything to go by." [emphasis added][p25]

39. Earlier in the meeting, in relation to the introduction of a lesser deferral period, the Chairperson, also, stated:

> "Even the figures from the Department show that compliance rates would be much enhanced if we were to go down that route." [p8]

40. In the Health Committee meeting, the Minister was asked the question, "Have you had any advice on your powers where blood safety is concerned?" In response, the Minister said:

> "There are a number of views on that, and we are looking at all the legal perspectives on it". [p21]

41. Later, the Minister was, again, asked about this power:

> "…Am I right in thinking that you have the power to not just follow GB standards but to actually go for a higher level of public protection than that which exists in the rest of the United Kingdom? Do you have the power to do that?
>
> Mr Poots: It is certainly something that I am investigating. I will be raising with SaBTO my concern about some of the other categories that are currently giving blood." [p32]

Position of the Northern Ireland Blood Transfusion Service

42. In her email dated 9 June 2011 Dr Reaney, Senior Medical Officer in the Department, confirmed to an individual in the Department that in relation to the suggested changes to the lifetime ban on blood donation by MSM, the Northern Ireland Blood Transfusion Service had:

> "no particular issues about this change…"
>
> and it was
>
> "well linked into the UK work…and will be ready to implement the change from the beginning of September [2011]."

Relevant material in relation to whether the Minister made a decision in September 2011

43. A letter dated 8 September 2011 from Dr Elizabeth Mitchell, Deputy Chief Medical Officer to Dr Kieran Morris, Chief Executive of the Northern Ireland Blood Transfusion Service refers to the recommendations made by the Advisory Committee and states:

> "…It is the responsibility of each Health Minister to consider the recommendations provided by advisory committees such as SaBTO, and take the final decision on the policy implications for their country.

> Today… the Department of Health, London, is announcing that the lifetime blood donation ban is lifted for men who have had sex with men… The change of policy will apply in England, Scotland and Wales. In Northern Ireland the Minister for Health, Social Services and Public Safety is considering whether the lifetime deferral should be changed…"

44. An internal email dated 15 September 2011 from the Minister's Special Advisor stated:

> "Following the Minister's decision to keep the ban on blood donation by men who have sex with men, attached is a revised answer to AQO 331/11-15." [emphasis added]

45. In a note from the Department's file dated 20 September 2011 under the heading, "Minister's decision to keep the lifetime ban on blood donations by men who have had sex with men (MSM)", a note for the Department's file provides:

> "At the Minister's briefing session for oral questions… the Minister advised that…he had decided to keep the lifetime ban on blood donations by men who have had sex with men…" [emphasis added]

46. In an extract from the Northern Ireland Assembly Written Answers Booklet dated 23 September 2011 the Minister was asked a question by an MLA (AQO 331/11-15), namely whether he would consider lifting the lifetime ban on homosexual men donating blood. He gave the following answer in the Assembly:

> "I take the view that the current position in Northern Ireland should not be altered.
>
> The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) has confirmed that the risk of HIV infection would, although by a small margin, increase as a result of a relaxation in the present lifetime deferral.
>
> Safety must be my primary concern and I want to ensure the maximum public confidence." [emphasis added]

47. In the Attorney General's pre-action response dated 29 November 2011 under the heading 'Absence of decision', it states:

> "Absence of decision

> The Minister has not made any decision to refuse to lift the lifetime ban on men who have had sex with men from giving blood. His answer to the Assembly question asked by Mr Kinahan MLA as to whether he would consider lifting the ban was, "I take the view that the current position in Northern Ireland should not be altered…" This is no more than an expression of current opinion and the Minister, in his appearance before the Committee for Health, Social Services and Public Safety ("the Committee") on 26 October 2011, said that he had not made a final decision on the issue. The Minister also said that he was awaiting further advice from the UK Government Advisory Committee on the Safety of Blood, Tissues and Organs ("SaBTO") on the relative risks arising from potential donations and he continues to await further information on this to inform his decision. Given that no substantive decision has been taken on this matter, there is simply, pending the Minister's further consideration, a continuation of existing policy and any challenge now falls foul of the requirements in RSC Order 53 rule 4.
>
> The Minister's position on this issue was also made clear in the letter issued on 8 September by the Deputy Chief Medical Officer to the NI Blood Transfusion Service…which states that "The official line to take is: The change of policy will apply in England, Scotland and Wales. In Northern Ireland the Minister of Health, Social Services and Public Safety is considering whether the lifetime deferral should be changed.""

Legal Context

The Treaty on the functioning of the European Union

48. Under Title XIV, 'Public Health', Article 168(1) provides:

> "1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.
>
> Union…"

49. Article 168(4) provides the European Parliament and the Council shall contribute to the achievement of the objectives by adopting measures as described below:

> 4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:
>
> (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures…"

Background to the relevant Directives

50. There are two European Directives which regulate the collection, testing, processing, storage and distribution etc of human blood and blood components:

    (i) European Directive 2002/98/EC of the Parliament and Council (setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC) (the "2002 Directive"); and

    (ii) Commission Directive 2004/33/EC (implementing the 2002 Directive as regards certain technical requirements for blood and blood components) (the "2004 Directive").

51. Recital 3 of the 2002 Directive explains that the 2002 and 2004 Directives follow on from Directive 2001/83/EC relating to medicinal products for human use (the "2001 Directive"). The 2001 Directive regulated the quality, safety and efficacy requirements of proprietary industrially prepared medicinal products derived from human blood or plasma but it specifically excluded human whole blood, plasma and blood cells for the purposes of transfusion.

The 2002 Directive

52. The first three recitals of the Directive, so far as material, state as follows:

> "Whereas

> (1) The extent to which human blood is used therapeutically demands that the quality and safety of whole blood and blood components be ensured in order to prevent in particular the transmission of diseases.
>
> (2) .... all precautionary measures during their collection, processing, distribution and use need to be taken making appropriate use of scientific progress in the detection and inactivation and elimination of transfusion transmissible pathogenic agents
>
> (3) ... It is essential ... that whatever the intended purpose, Community provisions should ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States, bearing in mind the freedom of movement of citizens within Community territory. The establishment of high standards of quality and safety, therefore, will help to reassure the public that human blood and blood components which are derived from donations in another member State nonetheless meet the same requirements as those in their own countries."

53. The purpose of the 2002 Directive is described in the Recitals as follows:

> "(5) In order to ensure that there is an equivalent level of safety and quality of blood components, whatever their intended purpose, technical requirements for the collection and testing of all blood and blood components including starting materials for medicinal products should be established by this Directive."

54. Recital 22 provides:

> "According to Article 152(5) of the Treaty, the provisions of this Directive cannot affect national provisions on the donations of blood. Article 152(4)(a) of the Treaty states that Member States cannot be prevented from maintaining or introducing more stringent protective measures as regards standards of quality and safety of blood and blood components."

55. Recital 24 provides:

> "Blood and blood components used for therapeutic purposes or for use in medical devices should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation and that any risk of transmission of infectious diseases is minimised; each and every blood donation should be tested in accordance with rules which provide assurances that all necessary measures have been taken to safeguard the health of individuals who are the recipients of blood and blood components."

56. Its objective is also set out expressly in Article 1, which provides:

> "This Directive lays down standards of quality and safety of human blood and of blood components, in order to ensure a high level of human health protection."

57. The definitions in Article 3 provide:

> (e) 'blood establishment' shall mean any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion.
>
> (j) 'Deferral' shall mean suspension of the eligibility of an individual to donate blood or blood components such suspension being either permanent or temporary.

58. Article 4(1) refers to the designation of the competent authority which will implement the Directive:

> "1. Member States shall designate the competent authority or authorities responsible for implementing the requirements of this Directive."

59. Article 4(2) provides:

> "2. This Directive shall not prevent a Member State from maintaining or introducing in its territory more stringent protective measures which comply with the provisions of the Treaty."

60. Article 5 covers 'Designation, authorisation, accreditation or licensing of blood establishments'. In particular, Article 5.3 states the competent authority is responsible for licensing and regulating the blood establishment:

> "3. The competent authority, having verified whether the blood establishment complies with the requirements set out in this Directive, shall indicate to the blood establishment which activities it may undertake and which conditions apply." [emphasis added]

61. In relation to eligibility of donors, Article 18 provides:

> "1. Blood establishments shall ensure that there are evaluation procedures in place for all donors of blood and blood components and that the criteria for donation referred to in Article 29(d) are met…"

62. Article 29(d), under the heading, 'Technical requirements and their adaptation to technical and scientific progress' provides:

> "…The following technical requirements and their adaptation to technical and scientific progress shall be decided in accordance with the procedure referred to in Article 28(2):
>
> …
>
> (d) requirements concerning the suitability of blood and plasma donors and the screening of donated blood including
>
> — permanent deferral criteria and possible exemption thereto
>
> — temporary deferral criteria…" [emphasis added]

The 2004 Directive

63. The 2004 Directive establishes the relevant blood donation eligibility criteria where its requirements are in accordance with the advice of the Committee of the Commission established under Article 28 of Directive 2002/98/EC.

64. The 2004 Directive imposes obligations on Member States to ensure blood establishments provide prospective donors with certain prescribed information and to obtain information from those donors.

65. The recitals to the 2004 Directive so far as material state:

> "Whereas
>
> Directive 2002/98/EC lays down standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and for their processing, storage and distribution when for transfusion so as to ensure a high level of human health protection
>
> ...Directive 2002/98/EC calls for the establishment of specific technical requirements.
>
> This Directive lays down those technical requirements which take account of Council Recommendation 98/463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood..., "

66. Article 4 of the 2004 Directive relates to the eligibility of donors:

> "Blood establishments shall ensure that donors of whole blood and blood components comply with the eligibility criteria set out in Annex III."

67. Annex III sets out the eligibility criteria for donors of whole blood and blood components.

68. Part 2 of Annex III sets out the deferral criteria for donors of whole blood and blood components. Part 2.1 identifies classes of donor who should be the subject of a "permanent deferral." Part 2.2 identifies classes which should be the subject of a "temporary deferral."

69. In Part 2.1, in relation to "sexual behaviour", permanent deferral includes:

> "Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood."

70. In Part 2.2, temporary deferral refers include:

> "Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood."

71. The applicable deferral period for persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood is defined, as follows:

> "Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests."

72. In relation to acceptance criteria for donors of whole blood and blood components, paragraph 1 of Annex III provides:

> "Under exceptional circumstances, individual donations from donors who do not comply with the following criteria may be authorised by a qualified healthcare professional in the blood establishment. All such cases must be clearly documented and subject to the quality management provisions in Articles 11, 12, and 13 of Directive 2002/98/EC."

Blood Safety and Quality Regulations 2005 ("the 2005 Regulations")

73. The explanatory note provides that the 2005 Regulations implement, in the UK, the 2002 Directive setting out the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and the 2004 Directive which contains certain technical requirements relating to blood standards.

74. The 2005 Regulations impose safety and quality requirements on human blood collection and storage. The requirements apply to blood transfusion services in England, Scotland, Wales and Northern Ireland. Regulation 2(1) provides:

> "2.—(1) <u>The Secretary of State is designated the competent authority for the purpose of the Directive…"</u>

75. Regulation 7(1)(c) provides:

> "7.—(1) A blood establishment shall—
>
> …

(c) ensure that all testing and processes of the blood establishment which are referred to in Parts 2 to 5 of the Schedule are validated…"

76. Regulation 7(2)(d) provides that a blood establishment shall, in relation to the donation of blood:

"(d) apply eligibility criteria for all donors of blood and blood components in accordance with Part 3 of the Schedule…"

77. Part 3, para 2.1 of the Schedule transposes the requirements of Annex III, paragraph 2 of the 2004 Directive, which provides *inter alia* for the permanent deferral of "[p]ersons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood."

78. Regulation 7(3) places an obligation on blood establishments to ensure each donation of blood and blood components are tested in conformity with Regulation 7(7):

"(3) A blood establishment shall ensure that, in relation to the blood and blood components which it collects, processes, stores or distributes—

(a) each donation of blood and blood components (including blood and blood components which are imported into the European Community) is tested in conformity with—

(i) the basic testing requirements for whole blood and apheresis donations, specified in paragraph (7)…"

79. Regulation 7(7) provides:

"(7) The basic testing requirements with which blood establishments must ensure compliance pursuant to paragraph (3)(a)(i) are—

(a) testing to establish ABO Group, except in respect of plasma intended only for fractionation;

(b) testing to establish Rh D Group, except in respect of plasma intended only for fractionation; and

(c) testing for the following infections of donors—

(i) Hepatitis B (HBs-Ag);

(ii) Hepatitis C (Anti-HCV);

(iii) HIV 1 and 2 (Anti-HIV 1 and 2)."

Northern Ireland Act 1998

80. Para 38 of Schedule 3 refers to reserved matters and includes:

> "Technical standards and requirements in relation to products in pursuance of an obligation under Community law but not standards and requirements in relation to food, agricultural or horticultural produce, fish or fish products, seeds, animal feeding stuffs, fertilisers or pesticides." [emphasis added]

81. Section 20 of the Northern Ireland Act 1998 refers to the Executive Committee. Sections 20(3) and (4) provide:

> "(3) The Committee shall have the functions set out in paragraphs 19 and 20 of Strand One of the Belfast Agreement.
>
> (4) The Committee shall also have the function of discussing and agreeing upon—
>
> (a) significant or controversial matters that are clearly outside the scope of the agreed programme referred to in paragraph 20 of Strand One of that Agreement;
>
> (b) significant or controversial matters that the First Minister and deputy First Minister acting jointly have determined to be matters that should be considered by the Executive Committee."

82. Article 24(1) provides the Minister or Northern Ireland department must not act in a way incompatible with Convention rights or Community law:

> "(1) A Minister or Northern Ireland department has no power to make, confirm or approve any subordinate

legislation, or to do any act, so far as the legislation or act—

(a) is incompatible with any of the Convention rights;

(b) is incompatible with Community law;

…"

83. Section 28 includes various provisions in relation to the Ministerial Code. In particular, Section 28A(10) provides:

> "(10) Without prejudice to the operation of section 24, a Minister or junior Minister has no Ministerial authority to take any decision in contravention of a provision of the Ministerial Code made under subsection (5)."

Ministerial Code

84. Para 2.4 of the Ministerial Code provides, *inter alia*, that:

> "Any matter which:-
>
> (i) cuts across the responsibilities of two or more Ministers;
>
> ...
>
> (v) is significant or controversial and is clearly outside the scope of the agreed programme referred to in paragraph 20 of Strand One of the Agreement;
>
> ...
>
> shall be brought to the attention of the Executive Committee by the responsible Minister to be considered by the Committee.
>
> Regarding (i), Ministers should, in particular, note that:-
>
> • the responsibilities of the First Minister and deputy First Minister include standards in public life, machinery of government (including the Ministerial Code), public appointments policy, EU issues, economic policy, human rights, and equality. Matters under

consideration by Northern Ireland Ministers may often cut across these responsibilities..." [emphasis added]

EU Charter of Fundamental Rights (the "EU Charter")

85. Article 21 (Non-discrimination) of the EU Charter provides:

> "(1) Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited."

Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007 (the "Lisbon Treaty 2007")

86. Pursuant to the Lisbon Treaty 2007, Article 6 in the Treaty on the European Union was replaced by the following:

> "6(1) The Union recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union of 7 December 2000, as adapted at Strasbourg, on 12 December 2007, which shall have the same legal value as the Treaties…"

87. Article 52(1) refers to the scope of guaranteed rights:

> "1. Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others."

Arguments

Applicant

88. The applicant argues that the Minister disregarded relevant evidence, ie the expectation that the reduced deferral period would increase compliance thereby reducing risk, in arriving at his decision. It is argued that the Minister further failed to consider relevant expert evidence suggesting that there is no material increase in risk to health under the reduced deferral period.

89. The applicant contends that the Minister did make a decision which is reviewable by this court in September 2011 and even if no decision was made the continuing policy is reviewable.

90. The applicant argues that the decision is unsupported by relevant evidence, that it is illogical on the basis that blood is imported from the UK and further illogical as other at risk groups are subject to a temporary deferral period only.

91. The applicant argues that the current policy is not based on risky behaviour in any reasonable way.

92. The applicant argues that the Minister is not competent to make any decisions regarding the implementation of the Directives and that this authority rests solely with the Secretary of State.

93. The applicant further argues for the non-competence of the Minister on the basis that the matters at hand are reserved as per para 38 of Schedule 3 of the Northern Ireland Act 1998.

94. The applicant argues that the current policy is discriminatory on the basis of sexual orientation and gender. The designation of MSM as a high risk has a disproportionate effect on gay men and is therefore indirectly discriminatory. This discriminatory treatment must be justified as legitimate and proportionate which the respondent has failed to do.

95. The applicant argues that the current policy is contrary to the EU principles of non-discrimination and proportionality and also contrary to A21 of the EU charter of fundamental rights.

96. The applicant argues that the decision is *Wednesbury* unreasonable.

97. The applicant argues that the decision is cross cutting and controversial and accordingly should have been brought to the attention of the Executive Committee.

98. The applicant argues that the decision is infected by apparent bias.

Respondent

99. The respondent argues that the decision in relation to the deferral period is not reserved to the Secretary of State and that he is empowered to make such a decision.

100. The respondent argues that MSM donors are at a higher risk of acquiring infectious diseases and therefore may be put in the high risk/permanent deferral category.

101. The respondent argues that no final decision has been made and the issue is subject to ongoing consideration and as such any challenge is premature.

102. The respondent argues that there was a range of reasonable responses available to him and he has not acted outside of these reasonable responses and therefore the issue is not *Wednesbury* unreasonable.

103. The respondent argues that the challenge is out of time as the policy is 25 years old.

104. The respondent argues that the fulfilment of Member State obligations may be entrusted to other bodies under the constitutional arrangements of that Member State.

105. The respondent argues that he is not taking any action in relation to technical standards or in the alternative that the matter at hand does not relate to the technical standard of a product.

106. The respondent argues that he is not prevented by the Directive from introducing more stringent measures.

107. The respondent argues that the position of other Member States may be relevant when assessing the proportionality of a measure.

108. The respondent argues that he must comply with EU obligations by ensuring the lawful interpretation and application of the eligibility criteria.

109. The respondent argues that he is competent to apply higher standards and the divergence between the position in Northern Ireland and in England, Scotland and Wales is not on its own discriminatory.

110. The respondent argues that the general principal of non-discrimination does not require all parts of the UK to adopt the same standards, only the same minimum standards.

111. There is no requirement on a Member State when observing the principle of proportionality to have to choose the least restrictive measure and therefore an outright ban may be permissible. The Respondent argues he is entitled to apply the precautionary principle when dealing with public health.

112. The respondent argues that the SaBTO report is not a sufficient basis for concluding that there is no additional risk to patients if a 12 month deferral period were to be implemented. The respondent notes that the SaBTO report itself notes an increase in risk level if compliance rates stay the same.

113. The respondent argues that the data presented does not constitute overwhelming evidence.

114. The respondent argues that pending a definitive decision the maintenance of the status quo is not unreasonable.

115. The respondent argues that the policy is not discriminatory on the basis of sexual orientation but makes provision for legitimate differences in treatment based on behaviour. Further, the fact that it has a disproportionate effect on gay men is inevitable.

116. The respondent argues that charter rights may be limited if such limitation if justified and proportionate and if it genuinely meets the objectives of general interest recognised by the EU.

117. The respondent argues that the absence of legislation prohibiting discrimination in any field touching giving blood renders this point non-justiciable.

118. The respondent argues that since no decision has been made there is no basis for claims that the decision is contrary to the Ministerial Code.

119. The respondent argues as there is no decision made, there can be no decision infected with apparent bias. Further it is argued that the Ministers' theological

observations do not sound on the public safety evaluation that the Minister must engage in.

Notice Party

120. The Notice Party argues that the decision in relation to the appropriate deferral period in Northern Ireland is not reserved to the Secretary of State.

121. The Notice Party argues that the DHSSPS is entitled to give directions to NIBTS and that NIBTS is obliged to carry out those directions.

122. The Notice Party argues that the directives did not mandate a change of structure of internal institutions, nor do they require a single centralized decision maker in relation to eligibility criteria within the Member State.

Discussion

Was a Decision Made?

123. In September 2011 the Minister was presented with information relating to the appropriateness of maintaining the policy of permanent deferral as it relates to men who have engaged in anal or oral sex with another man who wish to donate blood. Prior to this new information the policy was well settled and consistently applied and supported by medical opinion. There was no active reason to reconsider the policy or to diverge from it. When this new information was presented the continuation of the policy was called into question. It became a live issue. The path ahead diverged and the Minister was required by the passage of time to choose one path or the other – whether to maintain the status quo or to change the existing policy.

124. At this fork in the road the Minister chose one of the options, namely to maintain the status quo. That is, he decided that the information now available did not persuade him to take the option of changing the policy. The Minister maintains that he is seeking further information before making a final decision on the issue. What this means in effect is that the Minister has rejected the persuasiveness of the currently available evidence, but at some time in the future he may receive further information which is more persuasive at which point he will again, find himself at a decision point, another fork in the road. However, this does not change the fact that at the relevant point the Minister clearly chose between two competing options, which is, plainly, a decision.

125. The Minister at the time appears to have considered that he had made a decision (see the remarks set out at para 43 *et seq* above).

Wednesbury Unreasonable/Irrationality

126. Upon reviewing the EU and domestic legislation, as well as the events, discussions and exchanges of information, it seems that up to two decisions must be answered by a Member State in relation to eligibility criteria and deferral periods for donors or classes of donors. For present purposes I shall ask these questions in the context of MSM donors.

127. The first decision is whether MSM donors should be considered as ***'Persons whose sexual behaviour puts them at a high risk of acquiring severe infectious diseases that can be transmitted by blood'*** **[2004 Directive Annex III 2.1]** or whether they should be considered as ***'Persons whose behaviour or activity puts them at risk of acquiring infectious diseases that may be transmitted by blood'.*** **[2004 Directive Annex III 2.2.2]**

128. If the question above is answered by the latter statement, the relevant deferral period must be decided upon. This deferral period is to be ***'that which is defined by the nature of the disease and by the availability of an appropriate test'***. **[2004 Directive Annex III 2.2.2]**

129. In continuing the lifetime deferral policy, the Minister has decided that MSM are in the first category (high risk). In this he has deviated from the position taken in England, Scotland and Wales.

130. Is this an unreasonable decision? Was it beyond the range of responses, open to a reasonable decision maker, to decide that MSM donors should remain in the high risk category and thus should be permanently deferred from donating? This decision was made against the recommendation of the Secretary of state who recommended that the SaBTO report should be followed. This was a de facto communication that MSM donors were now considered by the Secretary of State, and the medical community in the UK to be in the lower 'risk' category because if the SaBTO report proceeded on the basis that MSM donors remained at high risk it would not be open to the Secretary of State/Competent Authority to recommend a temporary deferral period as the high risk category mandates permanent deferral.

131. It is clear from the SaBTO report that anal/oral male homosexual acts do increase the risk of acquiring blood borne disease. For example, in relation to HIV the report notes at page 68 in Appendix 5:

> 'UAPMP data from 2008 for previously undiagnosed HIV infections ... shows that the prevalence was higher in MSM (3.1%; 291/9473) compared with heterosexual attendees (0.35%; 322/92,694)'

132. Later on the same page it continues to note that the Gay Mens Sexual Health Survey notes the prevalence of HIV between 8.6% and 13.7% which are much higher percentages than in the other populations which were tested.

133. There is no assistance in the directives regarding when 'risk' becomes 'high risk'. This would seem to be left to each Member State to decide.

134. The lower risk category plainly allows the member state to define risk in terms of the likelihood of passing a disease to the end recipient of the blood, as the deferral period is set by *inter alia* the capacity to test for the disease. In the UK the decision arrived at is that MSM donors are in the second category and that the applicable deferral period is 12 months. The attendant risk from these criteria is accepted in Scotland, Wales and England. The SaBTO report concludes that the additional risk from this new policy is very minimal and it is equivalent to maintaining the life time ban.

135. In September 2011 the options open to the Minister were to:

(a) Continue to maintain the position that MSM donors, by virtue of their behaviour are in the high risk category. In this scenario no additional analysis of risks passed to the blood recipient is necessary as permanent deferral is mandated; or

(b) Accept the alternative analysis in which MSM donors are placed in the less risky category and based on that to assume a temporary deferral period in relation to such donors of at least 12 months.

136. Given these two options, and considering the reported difference in infection rates above, there are two reasonable responses and the one selected by the Minister is not Wednesbury unreasonable on these grounds.

137. However consideration does not end there. I must further consider whether it was, within the range of responses, open to a reasonable decision maker to choose this position over the other, in circumstances were blood is in fact imported from other parts of the UK where the categorization of MSM donors is in the lower risk group and such donations are therefore NOT subject to the permanent deferral criteria.

138. The Minister has decided that MSM behaviour creates such a high risk of infection to the donor that such donors must be permanently deferred with the result that such blood cannot enter the Northern Ireland Blood Stock. Importing blood from other places which do accept MSM donors, even in limited quantities, leaves the door open for MSM blood to do just that. There is clearly a defect in reason here. If there is a *genuine* concern about the safety of MSM donated blood such that the blood stock must be protected absolutely from such blood then the security of that blood must actually be maintained absolutely. Applying a different standard to imported blood defeats the whole purpose of permanent deferral of MSM donors. As appears from para 33 above when blood is imported from the rest of the UK the authorities in NI do not request that such blood is not derived from the MSM community.

139. In relation to the Minister's submission that the Directive contemplates using blood from permanent deferral categories in 'exceptional circumstances' the affidavit evidence of Dr Reaney suggests that while blood is imported in small quantities and fairly rarely, the circumstances in which it is important are not 'exceptional' and are instead imported as a 'contingency supply' which 'may or may not' be used. I do not believe that this falls within the 'exceptional circumstances' envisaged by the Directive.

140. For these reasons I conclude the decision was Wednesbury irrational.

Discrimination

141. Had the decision been rational, it would be unlikely that it would have been discriminatory. As above there is a factual, statistical difference in the risk presented by persons who have engaged in male homosexual intercourse and other groups and a decision maker is entitled to take such facts into account in reaching a decision. For example, if the male homosexual intercourse was non-consensual, and the sexual orientation of the proposed donor was heterosexual, that individual would be subject to the same permanent deferral under the current policy. Also, at all points in the evidence gathering and analysing process the focus has been on the risk attaching to the behaviour. That male homosexual intercourse occurs mostly between men who are homosexual is unavoidable.

142. In light of the above findings it is not necessary to reach any conclusion on the ground of *apparent bias.*

The Minister's Competence under EU Law

143. NIBTS is a Special Agency established by The Northern Ireland Blood Transfusion Service (Special Agency) (Establishment and Constitution) Order (Northern Ireland) 1994. The relationship between the Minster and Special Agencies is defined in the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990 as follows:

> Directions as to functions of special agency
>
> 4. (1) The Department may direct a special agency to exercise on its behalf such functions with respect to the administration of such health and social care as are specified in the directions.
>
> (2) The Department may give directions to a special agency with respect to the exercise of any functions exercisable by virtue of paragraph (1).

144. NIBTS was licensed as a blood establishment for the purposes of the 2005 Regulations in 2007. Its role as a Special Agency and its role as a blood establishment are different and concurrent.

145. Under the scheme in the 2002 and 2004 Directives the relevant parties with obligations are the Competent Authority (The Secretary of State) and the blood establishment. The 2002 Directive, ***specifically*** states that:

> The Competent Authority, having verified whether the blood establishment complies with the requirements set out in this Directive, shall indicate to the blood establishment *which activities it may undertake and which conditions apply*.

146. In terms of who may give directions in relation to the activities a blood establishment may undertake and what conditions apply it is clear from the specific terms of the Directive that this responsibility is reserved solely for the competent authority. Further, the Minister is empowered only to give directions to NIBTS (a) in its function as a special agency, not in its function as a blood establishment; and (b) in relation to functions which NIBTS exercises on his behalf. Neither of these criteria is met in this instance and thus the Minister was not empowered to give any directions in relation to the implementation or interpretation of the Directives.

147. The Minister was further deprived of competence in this matter as technical standards remain a reserved matter under para38 of Schedule 3 of the 1998 Act set out at para 82 above. Article 29 of the 2002 Directive relates to "Technical requirements and their adaptation to technical and scientific progress". At para(d) of this article the following is included as a technical requirement:

> Requirements concerning the suitability of blood and plasma donors and the screening of donated blood including
>
> - Permanent deferral criteria and possible exemption thereto;
>
> - Temporary deferral criteria.

148. Therefore all decisions relating to these criteria are necessarily technical criteria. The contention that blood is not a product for the purposes of the S.38 of Schedule 3, this is clearly not the case (see A & Others v The National Blood Authority ("the *Blood Transfusion* case") [2001] EWHC QB 446).

Breach of the Ministerial Code etc

149. As a decision was made by the Minister, contrary to the submissions of the Respondent, it is appropriate to consider the arguments in relation to breaches of the Ministerial Code. Section 28A of the Northern Ireland Act 1998 provides, so far as material:

> "28A Ministerial Code
>
> (1) Without prejudice to the operation of section 24, a Minister or junior Minister shall act in accordance with the provisions of the Ministerial Code.
>
> (5) The Ministerial Code must include provision for requiring ministers or junior ministers to bring to the attention of the Executive Committee any matter that ought by virtue of section 20(3) or (4) to be considered by the Committee.
>
> (6) The Ministerial Code must include provision for a procedure to enable any Minister ... to ask the Executive Committee to determine whether any decision that he is proposing to take or has taken

relates to a matter that ought by virtue of section 20(3) or (4) to be considered by the Committee.

(10) Without prejudice to the operation of section 24 a Minister... has no ministerial authority to take any decision in contravention of a provision of the Ministerial Code made under subsection 5."

Paragraph 2.4 of the Ministerial Code provides:

"Any matter which:-

(i) cuts across the responsibilities of two or more Ministers;

...

(v) is significant or controversial and is clearly outside the scope of the agreed programme referred to in paragraph 20 of Strand One of the Agreement;

...

shall be brought to the attention of the Executive Committee by the responsible Minister to be considered by the Committee.

Regarding (i), Ministers should, in particular, note that:-

- the responsibilities of the First Minister and deputy First Minister include standards in public life, machinery of government (including the Ministerial Code), public appointments policy, EU issues, economic policy, human rights, and equality. Matters under consideration by Northern Ireland Ministers may often cut across these responsibilities..." [emphasis added]

150. The issue at hand is both controversial (it has generated much publicity and public debate, and views on the issue are highly polarised) and cross-cutting (it is acknowledged in the SaBTO report that it touches on equality issues, it further deals with the implementation of EU Directives) and as such the Minister had no authority to act without bringing it to the attention of the Executive Committee (see section 28A(10) of the 1998 Act and the Ministerial Code set out above).

Conclusion

151. To summarise:

(i) as the competent authority for the purposes of Directive 2002/98/EC and designated by the Blood Safety and Quality Regulations 2005 the Secretary of State for Health is responsible for the determination of the appropriate deferral periods in Northern Ireland and whether to maintain or not the impugned lifetime ban. Accordingly the Minister was not empowered to give any directions in relation to the implementation or interpretation of the Directives;

(ii) Para 38 of Schedule 3 to the Northern Ireland Act 1998 provides that technical standards and requirements in relation to products in pursuance of an obligation under Community law are reserved matters. Under para (d) of Art 29 of the 2002 Directive deferral criteria are included as a technical requirement. By virtue of Section 24(1) of the 1998 Act the Minister has no power to act incompatibly with Community law;

(iii) the lifetime ban is both controversial (it has generated much publicity and public debate, and views on the issue are highly polarised) and cross-cutting (it is acknowledged in the SaBTO report that it touches on equality issues, it further deals with the implementation of EU Directives) and as such the Minister had no authority to act without bringing them to the attention of the Executive Committee which he failed to do. In doing so the Minister breached the Ministerial Code and by virtue of Section 28A(10) of the 1998 Act he had no legal authority to take a decision in breach of the Ministerial Code;

(iv) for the reasons set out at paras 126-140 above the decision of the Minister was irrational.

[153] Accordingly, the application for judicial review is allowed.