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*Judgment: approved by the Court for handing down*
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**IN HER MAJESTY'S COURT OF APPEAL IN NORTHERN IRELAND**

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**ON APPEAL FROM THE HIGH COURT OF JUSTICE IN NORTHERN IRELAND**

**QUEEN'S BENCH DIVISION (JUDICIAL REVIEW)**

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**IN THE MATTER OF AN APPLICATION BY JR 65 FOR JUDICIAL REVIEW**

**Before: Morgan LCJ, Gillen LJ and Weir LJ**

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**MORGAN LCJ**

[1] The respondent in this appeal judicially reviewed the Department of Health, Social Services and Public Safety ("the Department") in respect of the maintenance by it of a lifetime ban on males who have had sex with other males ("MSM") donating blood. He also challenged the decision by the Minister with responsibility for the Department ("the Minister") not to alter the ban so as to 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.

[2] In his judgment dated 11 October 2013 Treacy J allowed the application for judicial review after concluding:

(i) As the competent authority for the purposes of Directive 2002/98/EEC and as designated by the Blood Safety and Quality Regulations 2005 (the 2005 Regulations) the Secretary of State for Health ("the Secretary of State") 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) Paragraph 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 Article 29 (d) 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 crosscutting (it is acknowledged in the Advisory Committee on the Safety of Blood, Tissues and Organs ("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 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) The decision of the Minister was irrational.

[3] This court remitted to Treacy J the contention on behalf of the respondent that the Minister's decision was infected with apparent bias. In a judgment delivered on 8 January 2015 the learned trial judge so held. The Minister and the Department now appeal against the findings made against them and the Secretary Of State as Notice Party submits that he was not responsible for the determination of the appropriate deferral periods in Northern Ireland. The respondent cross appeals against the failure of the learned trial judge to deal with his claim that the imposition of a lifetime deferral for MSM is disproportionate and in breach of EU law. The Attorney General appeared with Ms Gray for the appellants, Dr McGleenan QC and Mr McLaughlin appeared on behalf of the Secretary of State and Mr Scoffield QC and Mr Atchison appeared for the respondent. We are grateful to all counsel for their helpful written and oral submissions.

**Background**

[4] Following the emergence of HIV, MSM were permanently deferred from donating blood in the UK in 1985. Individuals who had ever accepted money or drugs in exchange for sex were also permanently deferred from donating blood. These deferrals were because of the high risk of serious blood-borne infections, such as HIV, hepatitis B and hepatitis C viruses and syphilis among these groups.

[5] The UK Blood Services use a number of strategies to maintain safe supplies of blood and blood components. These combine deferral from donation from groups that are known to have increased prevalence and incidence of specific transfusion transmitted infections (TTIs) with testing for selected TTIs. A number of such current deferral criteria relate to specific sexual behaviours. A major review of blood donor

deferral criteria in relation to sexual behaviour took place in 2001, when the available evidence did not support a change to the lifetime deferral for MSM. Since then the combination of donor deferral and improvements in testing, particularly the introduction of highly sensitive and specific nucleic acid tests, has dramatically reduced the number of TTIs. There has not been a confirmed case of blood-borne viral transmission since 2005. Further, active global surveillance mechanisms are much improved and help to identify emerging new threats to the blood supply and enable appropriate risk reduction measures to be implemented.

[6] (SaBTO advises the four UK Health Departments on blood donor deferral. It established a Blood Donor Selection Steering Group (the Steering Group) to examine in particular the evidence in relation to the donation of blood by MSM and commercial sex workers. The Steering Group reported in April 2011. It concluded that the evidence supported a change from a lifetime ban to a 12 month deferral period for men after their last oral or anal sex with another man, even if a condom or other protected method was used and recommended accordingly. The research examined in particular the risk of HIV infectious donations being released into the blood supply. It was not disputed that the risks of other blood borne infections were no higher in MSM. Taking into account the average of 64,000 donations of blood per annum in Northern Ireland the estimated increase in risk assuming the same level of compliance by donors was 1 infection every 15,500 years. The Steering Group further concluded that communications should include a focus on the importance of ensuring compliance with this and other deferral policies. It noted the results of a study which suggested that a shorter deferral period would lead to increased compliance thereby further reducing the risk below that which presently applies. It also took the view that the lifetime deferral for commercial sex workers should be replaced by a 12 month deferral period.

[7] SaBTO considered the recommendation from the Steering Group at its meeting on 3 May 2011. Dr Liz Reaney, Senior Medical Officer in the Department of Health, Social Services and Public Safety, was present at that meeting as an observer. SaBTO agreed that the available evidence supported the introduction of a 12 month deferral period for men after their last oral or anal sex with another man, even if a condom or other protective was used and recommended a change in the deferral period to the four UK Health Departments. It considered that there was a lack of robust data on compliance and a relative paucity of data on blood borne infection rates in commercial sex workers and this was insufficient to justify the recommendation to remove the lifetime ban on such proposed donors.

[8] Work then began on a submission to the Minister to approve SaBTO's recommendation in this jurisdiction. The submission was based on a similar submission by the Department of Health in London to the Secretary of State. Dr Reaney confirmed that she recommended acceptance of the SaBTO advice. She liaised with Dr Joanne Murdoch who was the medical director of the Northern Ireland Blood Transfusion Service ("the NIBTS") which is responsible for organising

the donation of blood for transfusion and the maintenance of the blood bank. By virtue of the Northern Ireland Blood Transfusion Service (Special Agencies) (Establishment of Constitution) Order (Northern Ireland) 1994 the NIBTS was established as a special agency to which the Minister could give direction by virtue of the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990. NIBTS had been working closely with its counterparts in the other parts of the United Kingdom to ensure that the change in policy arising from the SaBTO recommendations could be implemented across the UK in a coordinated way.

[9] Welsh, English and Scottish officials advised UK colleagues on 1 July, 5 July and 7 July 2011 respectively that their Ministers had agreed the proposed policy change. On 1 July 2011 a submission for the Minister was prepared within the Department and approved by the Deputy Chief Medical Officer on that date, by the Chief Medical Officer on 7 July and by the Permanent Secretary on 8 July 2011. The change of policy was announced by the health ministers in England, Scotland and Wales on 8 September 2011 and the new policy was implemented by the relevant blood transfusion services in those countries on 7 November 2011.

**The Minister's Response**

[10] The appellant's evidence is silent on what happened between 8 July 2011 and 8 September 2011. On the same date that the change of policy was announced in the other jurisdictions Mr Kinahan MLA tabled a question for the Minister asking "whether he would consider lifting the ban on homosexual men and bisexual men donating blood". A note on the file made by Mr Camplisson of the Health Protection Branch indicated that at the Minister's briefing session for oral questions which was held at noon on Thursday, 15 September 2011 the Minister advised that, having discussed this matter with the Attorney General, he had decided to keep the lifetime ban on blood donations by MSM. On foot of that decision a draft answer for the oral question was prepared together with supplementary questions to assist the Minister.

[11] The oral question was not reached on 19 September 2011 and on the following day the Department issued the following written answer to Mr Kinahan:

> "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."

[12] On 26 October 2011 the Minister appeared before the Assembly's Committee for Health, Social Services and Public Safety (the Committee). At the outset he

indicated that he had not made a final decision on blood donations by MSM and that he would carefully consider all the relevant issues including the views of the Committee on the issue. He had not made any decision to change the policy at that point. He noted there were 79 new diagnoses of HIV in Northern Ireland in 2010. The highest ever annual figure of 91 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 was 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 remained lower in Northern Ireland than in the rest of the United Kingdom. He stated that with the exception of Italy and Spain all EU countries operated a lifetime deferral for MSM. The Council of Europe's European Committee on Blood Transfusion was reviewing European practice. The USA and Canada continue to operate a lifetime deferral for MSM but Australia and New Zealand had reduced their MSM deferrals in recent years to one year and five years respectively. He indicated that he was taking a precautionary approach. He accepted that small amounts of blood were imported from the rest of the UK each year.

[13] The judicial review proceedings were issued on 18 November 2011. A reply to the respondent's pre-action protocol letter was received from the Office of the Attorney General on 29 November 2011. In that response it was submitted that the Minister had not made any decision to refuse to lift the lifetime ban on MSM. It was suggested that his answer to the Assembly question was no more than an expression of current opinion and that his appearance before the Committee on 26 October 2011 had made it clear that he had not made a final decision. It is accepted now, however, in the affidavit of Mr McCormick, Permanent Secretary, sworn on 21 September 2012 that the Minister had decided not to follow the recommendation from SaBTO in his Assembly answer but that on further reflection he adopted the view that there should be further consideration and investigation of the issue and that while that consideration continued the deferral period for MSM should not change.

**The Regulatory Regime**

[14] Much of the relevant European legislation and the implementing Regulations have been set out in the decision of the learned trial judge and it is not necessary for us to repeat it here. It is however, helpful to look at the general architecture of those provisions. Directive 2001/83/EC (the 2001 Directive) was made pursuant to Article 95 TEC, which provided for the adoption of legislation necessary to enable the completion of the internal market through harmonisation. The Directive established a community code relating to medicinal products for human use. "Medicinal product" was defined as including any substance or combination of substances presented as having properties for treating or preventing disease in human beings. Substance was defined so as to include any matter which may be human including human blood and human products. Article 3 of the Directive provided that it did not

apply to whole blood, plasma or blood cells of human origin except for plasma prepared by a method involving an industrial process.

[15] Directive 2002/98/EC (the 2002 Directive) was made pursuant to Article 154 (4) (a) TEC, which was intended to ensure a high level of human health protection by setting high standards of quality and safety of blood and blood derivatives. Such measures did not prevent any Member State from maintaining or introducing more stringent protection measures. Recital 3 of the 2002 Directive noted that the quality, safety, and efficacy requirements of proprietary industrially prepared medicinal products derived from human blood or plasma were ensured through the 2001 Directive. The specific exclusion of whole blood, plasma and blood cells of human origin from the 2001 Directive had, however, led to a situation whereby their quality and safety, insofar as they are intended for transfusion and not processed as such, were not subject to any binding Community legislation. It was essential, therefore, that whatever the intended purpose, Community provisions ensured that blood and its components were of comparable quality and safety throughout the blood transfusion services in Member States, bearing in mind the freedom of movement of citizens within Community territory. The establishment of high standards of quality and safety, therefore, helped to reassure the public that human blood and blood components which were derived from donations in another Member State nonetheless met the same requirements as those in their own country.

[16] Article 29(d) of the 2002 Directive provided that technical requirements concerning the suitability of blood and plasma donors and the screening of donated blood including permanent and temporary deferral criteria be referred to a relevant committee. That led to Directive 2004/33/EC (the 2004 Directive) setting out the technical requirements for blood and blood components. In particular Annex 3 of the 2004 Directive provided for permanent deferral from blood donation for persons whose sexual behaviour put them at high risk of acquiring severe infectious diseases that can be transmitted by blood whereas those whose behaviour or activity placed them at risk of acquiring infectious diseases that may be transmitted by blood were subject to deferral after cessation of the risk behaviour for a period determined by the disease in question.

[17] The Directives have been implemented in domestic legislation by the 2005 Regulations. Regulation 2 designates the Secretary of State as the competent authority for the purposes of the 2002 Directive. The Secretary of State is given power by Regulation 4 to grant authorisations to blood establishments to collect and test blood and to process, store and distribute blood and blood components when they are intended to be used for transfusion. Regulation 5 gives the Secretary of State power to revoke or suspend that authorisation if the establishment fails in any material respect to comply with the requirements of the Regulations. These powers apply, of course, to NIBTS.

[18] The eligibility criteria for donors of blood as set out in Annex 3 of the 2004 Directive are enacted verbatim in Part 3 of the Schedule to the Regulations. By virtue of Regulation 7(2)(d) a blood establishment must in relation to the donation of blood apply eligibility criteria for all donors of blood and blood components in accordance with Part 3 of the Schedule. It is common case that if the permanent deferral for MSM presently operated by NIBTS is not in compliance with the eligibility criteria set out in Part 3 of the Schedule the Secretary of State is entitled to revoke or suspend the authorisation presently enjoyed by NIBTS.

**Standing**

[19] The core of the respondent's challenges in the judicial review application were the contentions first that the Secretary of State, not the Minister, was the only person entitled to make the decision as to the appropriate deferral period for MSM and that, in any event, the lifetime ban for MSM was contrary to the EU principle of proportionality and the protection of fundamental rights. In his grounding affidavit the respondent indicated the background against which he had sexual contact with a number of men. He stated that his last sexual contact with another man was within the last 12 months but that prior to April 2011 he not had sexual contact with another man for about 18 months. He said that he gave blood while a sixth former at his school and wished to do so again.

[20] In a second affidavit the respondent commented upon a psychiatric report within his medical notes and records which stated that he had been paid for having sex with men in the past. He said that on one occasion when he was feeling very isolated and depressed he was approached by an older man who asked him for sex and offered him money. He agreed. He acknowledged that as a result he was subject to a permanent deferral on the basis that he fell within the definition of a commercial sex worker. He noted that although the Steering Group had recommended a 12 month deferral for commercial sex workers SaBTO did not accept this recommendation for the reasons set out at paragraph 7 above.

[21] When the application for leave to issue judicial review proceedings was considered by the learned trial judge there was considerable debate about the respondent's standing to pursue his application. The Order 53 Statement included claims based upon the Convention. As a result of the submissions on standing the learned trial judge refused leave on those grounds on the basis that the respondent was not a victim for the purposes of the Human Rights Act 1998. He accepted, however, that the respondent had standing to pursue his other claims. There was no application to set aside the grant of leave and the issue of standing was not raised again in the substantive hearing.

[22] The Notice of Appeal was filed on behalf of the Attorney General in December 2013. The Notice did not raise any issue about the standing of the respondent. An amended Notice of Appeal was lodged in February 2015 and

similarly did not raise the issue. The case was listed for hearing on 12 October 2015 and in a supplemental skeleton argument lodged one week beforehand an application to amend the Notice of Appeal to renew the argument on standing was made.

[23] The Attorney General submitted that the respondent had no interest in the outcome of these proceedings. He had accepted money for sex and was subject to an entirely independent and freestanding permanent deferral. As a result he was ineligible to donate blood. The Attorney accepted, however, that the respondent had in his favour a decision of the judge that the appropriate decision maker was the Secretary of State. That was an issue of some constitutional importance in which the respondent might be said to have some proper interest but he had no such interest in respect of the deferral of MSM because of his ineligibility.

[24] Mr Scoffield pointed out that this was an issue which had previously been pursued vigorously by the Attorney General. On a number of occasions prior to the leave hearing representations had been made to the Legal Services Commission seeking to have the respondent's legal aid certificate revoked on the basis of his lack of standing. That application was successful for a time. It was, therefore, surprising that the explanation for the omission of the issue in the Notice of Appeal was oversight. Standing should take into account the role of the court which was to preserve and protect the rule of law. The issue of whether the Minister acted in breach of EU law engaged section 24 of the Northern Ireland Act 1998 and was just as much a constitutional issue as the issue around who was the decision maker. The respondent is a gay man who had given blood before and wishes to do so again. Although he is ineligible to donate blood by virtue of his permanent deferral as a sex worker it is material that the Steering Group recommended that the deferral period for sex workers should also be 12 months. This is likely to be revisited in the future. The deferral period for blood donation engages the fundamental rights of all MSM.

[25] Section 18 (4) of the Judicature (Northern Ireland) Act 1978 provides that an applicant for judicial review must have a sufficient interest in the matter to which the application relates. This requirement is then repeated in Order 53 Rule 3(5) of the Court of Judicature Rules. The leading decision on the approach to standing in this jurisdiction is Re D's Application [2003] NICA 14. Carswell LCJ noted that in recent years the courts have tended to take a more liberal attitude to matters of standing and tentatively suggested the following propositions:

(i) Standing is a relative concept, to be deployed according to the potency of the public interest content of the case;

(ii) Accordingly, the greater the amount of public importance that is involved in the issue brought before the court, the more ready it may be to hold that the applicant has the necessary standing;

(iii) The modern cases show that the focus of the courts is more upon the existence of a default or abuse on the part of a public authority than the involvement of a personal right or interest on the part of the applicant;

(iv) The absence of another responsible challenger is frequently a significant factor, so that a matter of public interest or concern is not left unexamined.

[26] We consider that the guidance in Re D remains helpful today. The European Court of Justice (ECJ), as we shall see, has ruled that the life time ban on blood donation by MSM engages fundamental rights of European law. The position in Northern Ireland differs from that in the rest of the United Kingdom in that MSM are subject to a lifetime deferral and there has been no consideration of those fundamental rights. The contention is that the Minister has acted incompatibly with European law and therefore beyond his constitutional remit as defined by section 24 of the Northern Ireland Act 1998. There is a clear public interest at stake involving the justification of differential treatment of a significant section of the community by a public authority on the basis that they are male homosexuals engaging in sexual activity. Although there may well be another challenger this application has had a full hearing both in this court and at first instance. Where a point of constitutional significance affecting fundamental aspects of EU law is at stake the likelihood of a later challenger is not of great weight. There is no dispute that the respondent would have had standing to pursue all of the issues in the absence of his having accepted money in the past. We are satisfied that Re D provides strong support for the respondent's position that he continues to have standing on the core issues in this case.

[27] The Supreme Court examined the modern law of standing in Axa and others v The Lord Advocate and others [2011] UKSC 46. Although the case was particularly concerned with the law of Scotland Lord Reed set out the appropriate approach to standing at paragraph 170:

> "170. For the reasons I have explained, such an approach cannot be based upon the concept of rights, and must instead be based upon the concept of interests. A requirement that the applicant demonstrate an interest in the matter complained of will not however operate satisfactorily if it is applied in the same way in all contexts. In some contexts, it is appropriate to require an applicant for judicial review to demonstrate that he has a particular interest in the matter complained of: the type of interest which is relevant, and therefore required in order to have standing, will depend upon the particular context. In other situations, such as where the excess or misuse of power affects the public generally, insistence upon a

> particular interest could prevent the matter being brought before the court, and that in turn might disable the court from performing its function to protect the rule of law. I say "might", because the protection of the rule of law does not require that every allegation of unlawful conduct by a public authority must be examined by a court, any more than it requires that every allegation of criminal conduct must be prosecuted. Even in a context of that kind, there must be considerations which lead the court to treat the applicant as having an interest which is sufficient to justify his bringing the application before the court. What is to be regarded as sufficient interest to justify a particular applicant's bringing a particular application before the court, and thus as conferring standing, depends therefore upon the context, and in particular upon what will best serve the purposes of judicial review in that context."

[28] In Re Loughlin's (Jason) Application [2015] NIQB 33 the Divisional Court took the view that Re D and Axa both recognised that in determining standing it was necessary to examine the context. The context included the identification of the public interest involved and the connection, if any, of the applicant to it. The Attorney submitted that the context in this case was that the respondent was a cross-appellant on the issue of proportionality so that his position was not as strong as his standing on the issue of who was the decision maker because in the latter case he had a judgment to defend. It was further submitted that in any event he could not benefit from any change to the deferral period for MSM because he was subject to permanent deferral for other reasons as discussed.

[29] We are satisfied that the respondent has standing on all issues. The matters set out at paragraph 26 above are part of the context. Although the Attorney accepted that a proportionality assessment should have been conducted by the Minister and that he was now willing to do so it became clear as the argument developed that there is a controversial issue on the interpretation of the proportionality requirement in the application of the 2002 and 2004 Directives. That further supports the position of the respondent. We do not consider that the respondent can be deprived of standing because of his previous acceptance of money for sex. Accordingly we refuse leave to amend the Notice of Appeal.

**Léger**

[30] Subsequent to the decision of the learned trial judge the ECJ delivered judgment in Case C-528 Léger v Ministre des Affaires Sociales, de la Sante et des Droits des femmes on 29 April 2015. That was a case in which a French national

challenged the decision of a blood establishment to refuse his blood donation on the ground that he was permanently deferred as a man who had had sexual relations with another man under the French implementation of the 2004 Directive. The ECJ was asked for a preliminary ruling on whether the sexual behaviour justified a permanent deferral from blood donation or merely a temporary deferral for a period determined after cessation of the risk behaviour.

[31] The Court examined the scheme of the 2004 Directive and concluded at paragraph 38:

> "Accordingly, the general scheme and purpose of the Directive mean that it is necessary to adopt the interpretation according to which the permanent deferral from blood donation provided for in point 2.1 of Annex III to that Directive concerns persons whose sexual behaviour puts them at a "high risk" of acquiring severe infectious diseases that can be transmitted by blood, while temporary deferral from blood donation concerns a lower risk."

[32] The Court observed that the wording of Annex III did not precisely determine the categories of persons concerned by the deferral provisions leaving a margin of appreciation to the Member States. It considered, however, that the issue of whether MSM were high risk and therefore subject to permanent deferral had to be considered taking into account the need to respect the fundamental rights guaranteed by EU law. Article 21(1) of the Charter of Fundamental Rights of the European Union ("the Charter") prohibited any discrimination based on sexual orientation. The criteria adopted in France determined the deferral from blood donation on the basis of the homosexuality of the male donors who, on account of the fact that they have had homosexual sexual relations, were treated less favourably than male heterosexual persons.

[33] At paragraph 52 the Court said that Article 52(1) of the Charter stated that any limitation on the exercise of the rights and freedoms recognised by it must be provided for by law and respect the essence of those rights and freedoms. In addition, that Article provided that, 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 EU or the need to protect the rights and freedoms of others.

[34] The essence of the Court's decision is contained in paragraphs 63 to 65:

> "63. It is for the referring court to ascertain whether, in such a situation and in compliance with the principle of proportionality, there are effective

> techniques for detecting HIV in order to avoid transmission to recipients of such a virus, the tests requiring to be performed according to the most recent scientific and technical procedures, pursuant to recital 29 in the preamble to Directive 2002/98.
>
> 64. In particular, it is for the referring court to verify whether scientific or technical progress in the field of science or health, taking account in particular of the cost of systematic quarantining of blood donations from men who have had sexual relations with other men or the cost of the systematic screening for HIV of all blood donations, allows a high level of health protection for recipients to be ensured without the resulting burden being excessive as compared with the objectives of protecting health.
>
> 65. On the other hand, even if, with the current state of scientific knowledge there is no technique satisfying the conditions laid down at [63] and [64] of the present judgment, a permanent deferral from blood donation for the whole group of men who have had sexual relations with other men is proportionate only if there are no less onerous methods of ensuring a high level of health protection for recipients."

**Proportionality**

[35] The respondent submitted that the permanent deferral from blood donation on the basis of the homosexuality of the male donors because of the fact that they have had sexual relations with other men treated them less favourably than male heterosexual persons. Article 21 (1) of the Charter prohibits discrimination based on sexual orientation. Article 52 of the Charter, dealing with proportionality, provides that limitations on such rights can only be made if they are necessary to genuinely meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others.

[36] The approach to proportionality in EU law has been helpfully considered by the Supreme Court in R (Lumsdon) v Legal Services Board [2015] UKSC 41. At paragraph 37 of the decision the court recognised that proportionality as a ground of review of national measures frequently applied where there was an interference with the fundamental freedoms guaranteed by the EU Treaties. In those circumstances proportionality generally functioned as a means of preventing disguised discrimination and unnecessary barriers to market integration. Where the integration of the internal market or the related social values were at stake the

principle was applied strictly. That was explained in Gebhard v Consiglio dell' Ordine degli Avvocati e Prosecutori di Milano Case C-55/94:

> "national measures liable to hinder or make less attractive the exercise of fundamental freedoms guaranteed by the Treaty must fulfil four conditions: they must be applied in a non-discriminatory manner; they must be justified by imperative requirements in the general interest; they must be suitable for securing the attainment of the objective which they pursue; and they must not go beyond what is necessary in order to attain it." (para 37)

[37] It follows, therefore, that if fundamental rights are engaged the national measures restricting the donation of blood by MSM must be no more onerous than is required to achieve the legitimate aim, which in this case is the maintenance of a high level of human health protection. It was common case that Member States have a margin of appreciation in determining the level of protection which they wish to afford to public health. Accordingly it was submitted that the approach to proportionality should reflect that in Commission of the European Communities v Italian Republic (Trailers) Case C-110/05. That was a case in which the issue concerned the prohibition of the use of trailers by certain vehicles. As a result that affected the level of imports of such trailers. The court was satisfied that it was for the Member State to determine the standard of road safety that it wished to secure and the fact that one Member State imposed less strict rules than another was a reflection of the competence of the Member State to determine such standards. The margin of appreciation available to Member States in that area did not undermine the objective of integrating the internal market.

[38] Commission v Italian Republic was, therefore, a case in which the Court found that fundamental rights were not in issue. The approach to proportionality is dependent upon the context. We recognise that the context includes the maintenance of the high level of protection which the Member State wishes to afford public health. In light of Léger it also includes the fundamental rights of MSM.

[39] It was submitted by the appellant that there was no fundamental right engaged in this case because the difference in treatment was not based on sexual orientation but on conduct. Further, it was submitted that Annex III of the 2004 Directive distinguished between sexual behaviour that gave rise to high risk and that which gave rise to risk. Once it was established that the sexual behaviour gave rise to high risk the terms of Annex III required that a permanent deferral followed. Accordingly it was contended that the ECJ had erred in considering the question of fundamental rights and in concluding that this was discriminatory on the grounds of sexual orientation since not all gay men were permanently deferred.

[40] I do not accept those submissions. The suggestion that national measures implementing EU law should not take into account fundamental rights is unsupported by any authority and appears to be plainly wrong. It is contradicted by paragraph 50 of Supreme Court's decision in Lumsdon. The analysis of the ECJ in Léger comparing the position of gay men who have sex with heterosexual men who have sex appears entirely valid. We were invited to refer a question to the ECJ which would effectively have asked the court to reverse its decision on those issues. I do not consider that there is any basis upon which we should do so.

[41] The final general issue I wish to deal with is the submission that the application of a permanent deferral by the NIBTS was a more stringent protective measure which was authorised by Article 4 of the 2002 Directive. Accordingly the maintenance of the permanent deferral went beyond EU law and the Charter did not apply.

[42] That issue was addressed in Lumsdon where the Supreme Court approved the observations of Advocate General Sharpston as to what fell within the scope of EU law in Bartsch v Bosch und Siemens Case C-427/06:

> "For that to be the case, the provision of national law at issue must in general fall into one of three categories. It must implement EC law (irrespective of the degree of the discretion the Member State enjoys and whether the national measure goes beyond what is strictly necessary for implementation). It must invoke some permitted derogation under EC law. Or it must otherwise fall within the scope of Community law because some specific substantive rule of EC law is applicable to the situation."

The maintenance of the permanent deferral for MSM plainly implemented EU law and it follows, therefore, that the Charter applied.

[43] The starting point for the proportionality assessment is that the permanent deferral of MSM secures a high standard of health protection. No deferral system can be foolproof because of the risk of non-compliance. The Steering Group estimated that the permanent deferral of MSM in England and Wales in 2005/2007 gave rise to a risk of HIV infectious donations of 1 in 4.41 million. Assuming the same level of compliance it was estimated that a deferral period of 12 months would have given rise to a risk of such infection of 1 in 4.38 million donations. Applying that to the Northern Ireland context the additional risk of infection is 1 in 15,500 years. To suggest that such an increased risk is infinitesimal is to overestimate it.

[44] In his letter of 19 September 2011 to Mr Kinahan the Minister indicated that he was maintaining the permanent deferral criterion on the grounds of safety and

public confidence. In light of the minute increase in risk assuming the same compliance level it is clear that a high standard of health protection would still be maintained by a 12 month deferral period. If the study suggesting increased compliance as a result of a 12 month deferral period turned out to be correct the standard of health protection would actually be increased by the reduction in the deferral period. In any event it is clear that any proportionality assessment balancing the fundamental rights of MSM against the assessed increase in risk alone must inevitably conclude that the deferral period should be reduced to 12 months.

[45] In the course of his meeting with the Committee on 26 October 2011 the Minister raised a number of further issues upon which the respondent relied on the proportionality issue. First, it was pointed out and indeed was common case that there was a higher prevalence of HIV in MSM. The Minister noted that the increase in incidence of HIV was over 300% between 2000 and 2011. That was the highest rate of increase in the UK during that period. That statistic needs to be seen in context. The numbers in Northern Ireland are comparatively small. There were only 19 HIV diagnoses in this jurisdiction in 2000. The 2011 figure is 82 diagnoses. The total number of people receiving treatment for HIV in Northern Ireland in 2011 was 552. This represents 0.3 per 1000 of population. The comparable figure for the United Kingdom is 1 per 1000. In certain parts of London the incidence of HIV is five times the national average. It is apparent, therefore, that the incidence of HIV in this jurisdiction is markedly lower than in the rest of the United Kingdom and the risk of HIV infection through blood donation is correspondingly lower than in the rest of the United Kingdom.

[46] In the course of his discussion with the Committee the Minister indicated that he was aware that the Council of Europe's Committee of Ministers was examining the possibility of a common approach to the Directives dealing with blood donation. A Technical Memorandum (the Memorandum) was prepared for the Committee of Ministers dated 17 April 2012 and considered at a meeting on 13 June 2012. The appellant relied on this material in relation to the proportionality issue. The Memorandum noted that a significant number of countries in the EU maintained a permanent deferral for MSM. The only exceptions were Spain which has had a six month deferral period since 2000 and Italy which has a four month deferral period for MSM. Latvia also prescribes a temporary deferral period and subsequent to the judgment in Léger we were advised that France now has a 12 month deferral period in place of the previous permanent deferral for MSM.

[47] The Memorandum discussed the extent of HIV incidence and prevalence in various EU states. The conclusion was that there were strong regional differences in the categorisation of affected persons. It was noted that there had been an increase in HIV prevalence among MSM in the period from 2004 to 2010. It was also noted that there had been considerable improvement in testing techniques. The Memorandum also examined approaches outside Europe and found that there was no consistency in how deferrals for sexual risk behaviours were applied. The conclusion was that

neither permanent deferral nor temporary deferral or individual risk assessment for each donor with respect to sexual risk behaviour seemed to be clearly superior to the other. The majority of those involved in the preparation of the Memorandum favoured no change in the current practice of permanent deferral of MSM.

[48] Having considered the Memorandum the Committee of Ministers adopted a resolution on 27 March 2013 recommending inter alia that state parties should collect, evaluate and publish epidemiological data to facilitate risk analysis and should decide on a temporary deferral policy for a given risky sexual behaviour only when having demonstrated that the sexual behaviour does not put the donees at high risk of acquiring severe infectious diseases that can be transmitted by blood. It is apparent, therefore, that the resolution recognised that different solutions may be appropriate in different Member States, which is consistent with the finding of diversity in the Memorandum. It is also apparent that the question for each was whether donees were protected from a high risk of acquiring severe infectious diseases that could be transmitted by blood.

[49] In his presentation to the Committee the Minister indicated that SaBTO was the advisory body on this issue for the United Kingdom and this was confirmed by Dr Reaney. In her affidavit she also indicated that decisions on blood safety and quality taken by the United Kingdom are not affected by any of the reports or recommendations from the Council of Europe. She compared the list of references from the Memorandum with that of the SaBTO Steering Group report. She found that the majority of technical references were different. The Council of Europe report mostly used sources relating to the specific epidemiology of disease in a wide range of different countries. Consistent with its remit the SaBTO report examined the epidemiology of disease in the United Kingdom and a number of studies conducted in the UK.

[50] The Minister noted that Northern Ireland was largely self-sufficient in blood although he accepted that from time to time contingency blood supplies had to be imported from Great Britain. Dr Reaney indicated that the number of units of blood imported in this way constituted less than 0.3% of the total number issued. In his presentation to the Committee the Minister indicated that the quantities imported were so low that any risks were greatly diminished. He had not requested that blood from MSM should not be provided.

[51] The Minister also informed the Committee that he was concerned about the deferral period for other sexual behaviour. He wished to take a precautionary approach and noted that Article 2 of the 2002 Directive permitted Member States to adopt more stringent criteria which comply with the provisions of the Treaty. In particular he noted the temporary deferral periods in relation to those with multiple sexual partners and indeed for those who had sex with persons they believed were infected with HIV. He indicated his wished to discuss this with SaBTO and to establish the position of the Minister of Health in the Republic of Ireland where a

permanent deferral was in place. Despite this there is no evidence in the papers that any such discussion had taken place either with SaBTO or with his counterpart in the Republic of Ireland in the two-year period leading up to the judgment at first instance. Nor is there any suggestion that the Department engaged with the authors of the Technical Memorandum. That suggests that this issue was not perceived as having a high priority.

[52] The appellant invited us not to determine the issue of proportionality but to allow the Minister, if he was the decision maker, a period of 12 months to make the proportionality assessment. There are a number of reasons why I am unable to accept that invitation. First, it is clear from the decision in Léger that this court is under a duty to make the necessary findings and carry out the proportionality assessment absent some compelling countervailing reason. That reflects the allocation of responsibilities between the legislature which is responsible for bringing forward legislation, the Executive which acts within the law and the court which applies the law. In this case that unsurprisingly imposes an obligation to protect fundamental rights. The court must be careful not to trespass on the proper territory of the other arms of government but must also faithfully honour the obligations which have been allocated to it under our legislative and constitutional arrangements. Secondly, we have had the benefit of full argument on the issue and I consider that we are, therefore, in a position to make that assessment. Thirdly, it is apparent from the appellant's submissions that there is a difference of view as to the proportionality approach. It was argued on behalf of the appellant that the fundamental rights of MSM were not engaged. If we were to adopt the course suggested by the appellant it seems likely that this would simply prolong the litigation probably resulting in yet further appeals. Fourthly, this judicial review application was issued more than four years ago. It concerns the fundamental rights of a section of the public. Reflection on the issue does not appear to have had a high priority. Further delay in my view would be inexcusable.

[53] The permanent deferral from blood donation is designed to contribute to the general objective of ensuring a high quality of human health protection. Léger indicates that a fundamental right is in issue. In those circumstances the national measure must not exceed what is appropriate and necessary in order to attain the objective. Where there are several appropriate measures the least onerous must be selected. This applies also where the Member State is considering a more stringent requirement since that requirement must be in accordance with the principles of the Treaty.

[54] For the reasons given at paragraph 43 above the increase in risk from the introduction of a 12 month deferral period for MSM would not diminish the high quality of human health protection in Northern Ireland. That finding is not in any way undermined by the material from the Council of Europe and that conclusion is supported by the evidence submitted by the Department from Dr Reaney. There has been no material to call into question the reliability of the findings made by the

SaBTO steering group. The maintenance of a permanent deferral for MSM exceeds what is necessary to maintain a high quality of human health protection in Northern Ireland and is disproportionate because of its impact on MSM. It is plain that the decision of the NIBTS to maintain a permanent deferral for MSM was a reflection of the decision of the Minister to retain the status quo while he considered the position. I accept that he was entitled to a period of reflection but as a matter of EU law the maintenance by him of a permanent deferral for a period of years after receiving the SaBTO advice was unlawful, although in fairness to him he received no advice from the Department on how he should approach proportionality.

**The decision maker**

[55] By virtue of section 4 of the Northern Ireland Act 1998 (the 1998 Act) a transferred matter means any matter which is not an excepted or reserved matter. General matters of public health are neither excepted nor reserved matters and consequently fall to be dealt with as transferred matters. By virtue of section 23 (2) of the 1998 Act the prerogative and other executive powers in respect of transferred matters are exercisable by any Minister or Northern Ireland department.

[56] As the learned trial judge noted NIBTS is a special agency established by the Northern Ireland Blood Transfusion Service (Special Agency) (Establishment and Constitution) Order (Northern Ireland) 1994. The Department's powers in relation to NIBTS are set out in Article 4 of the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990:

> "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)."

[57] It appears that the only direction issued on foot of these powers was the Functions of the Northern Ireland Blood Transfusion Service (Special Agencies) (No 1) Direction (Northern Ireland) 1995 which provides *inter alia* that NIBTS shall ensure that all hospitals and other clinical units in Northern Ireland are provided with adequate supplies of blood and blood products and that these comply with all current national standards of safety and efficacy. At the time of this direction NIBTS, in common with other blood transfusion agencies, operated a permanent deferral for MSM. In the absence of any further direction that has remained the position.

[58] NIBTS was granted an authorisation as a blood establishment for the collection and testing of blood and the processing, storage and distribution of blood

and blood components intended for transfusion by the Secretary of State pursuant to Regulation 4 of the 2005 Regulations. That accorded with Article 5 (1) of the 2002 Directive which required the competent authority to be the authorising body. Regulation 7(2)(d) of the 2005 Regulations requires a blood establishment to apply eligibility criteria for all donors of blood and blood components in accordance with Part 3 of the Schedule to the Regulations. That part of the Schedule replicates the content of Annex 3 of the 2004 Directive. Where a blood establishment has failed in any material respect to comply with the requirements of the Regulations the Secretary of State is empowered by Regulation 5(1)(a) to suspend or revoke the authorisation of the establishment. Part 3 of the Schedule to the 2005 Regulations must, of course, be interpreted in accordance with Annex 3 to the 2004 Directive. I have concluded that the maintenance of a permanent deferral for MSM is disproportionate and contrary to EU law. It follows that I would hold that NIBTS is acting contrary to the Regulations in maintaining that deferral period and that the Secretary of State's power to revoke or suspend its authorisation is now engaged.

[59] The learned trial judge concluded that the Secretary of State, as the competent authority, was the only person who could give direction to NIBTS on deferral criteria. He relied first upon Article 5 of the 2002 Directive which provides as follows:

> "Article 5
> Designation, authorisation, accreditation or licensing of blood establishments
>
> 1. Member States shall ensure that activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution when intended for transfusion, are undertaken only by the blood establishments which have been designated, authorised, accredited or licensed by the competent authority for that purpose.
>
> 2. For the purpose of paragraph 1, the blood establishment shall submit the information listed in Annex I to the competent authority.
>
> 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.

> 4. No substantial change in activities shall be undertaken by the blood establishment without prior written approval by the competent authority.
>
> 5. The competent authority may suspend or revoke the designation, authorisation, accreditation or licence of a blood establishment if inspection or control measures demonstrate that the blood establishment does not comply with the requirements of this Directive."

The judge concluded that the power in Article 5(3) to indicate what activities the blood establishment may undertake and what conditions applied was reserved to the competent authority. That must include the particular deferral criteria to be applied. The Minister had no authority in that area. Although the Minister could give direction as to the functions of a special agency he could not give direction to a blood establishment on matters arising from the Directive.

[60] We have come to a different view about the scope of Article 5. The purpose of the Article is set out in Article 5 (1) and concerns the designation, authorisation, accreditation and licensing of blood establishments by the competent authority. The information to be provided by the proposed blood establishment is set out in Annex 1 of the 2002 Directive. That information includes location, customers, documentation, personnel details, hygiene provisions, premises and equipment and operating procedures. It does not include any information in relation to the deferral criteria operated by the establishment. If the purpose of the Article was to give direction on the deferral criteria the provision of such information would have been essential.

[61] Secondly, Article 5(3) plainly contemplates two activities. The first is verification that the blood establishment complies with the requirements set out in the Directive. The second is an indication of the activities that the establishment may undertake and the conditions applying to it. The language indicates that the requirements of the Directive are separate from the activities that are authorised. Deferral criteria fall within the requirements of the Directive. The nature of the activities that might be authorised can be seen from the 1995 Direction where issues of assessment of need, education, advice, counselling and research were all included.

[62] Thirdly, the obligation to ensure that the technical criteria for the donation of blood are met is imposed by Article 18 of the 2002 Directive on blood establishments. The 2002 Directive enables the competent authority to ensure the implementation of the requirements of the Directive by authorised blood establishments on the basis of the exercise of the power of revocation or suspension. The Directive does not contain any provision giving a power of direction to the blood establishment by the competent authority. Fourthly, Article 4(2) of the Directive enables Member States to

maintain or introduce more stringent protective measures which comply with the provisions of the Treaty. That discretion is not given to the competent authority. This provision supports the view that the Minister in exercise of his powers to secure a high standard of public health can, in the implementation of the Directive, introduce such measures as long as they comply with the provisions of the Treaty. We have concluded, therefore, that Article 5(3) of the 2002 Directive does not give the competent authority power to give direction on the deferral criteria nor does it remove from the Minister his entitlement to give direction to NIBTS.

[63] The second basis upon which the learned trial judge concluded that the Minister was deprived of jurisdiction to give a direction to NIBTS about blood deferral periods was that the fixing of such periods was a reserved matter. As previously indicated Schedule 3 of the 1998 Act set out the list of reserved matters. Paragraph 38 of that Schedule provided as follows:

> "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."

The judge noted that Article 29 of the 2002 Directive was entitled "Technical requirements and their adaptation to technical and scientific progress". The Article then provided for a list of technical requirements and their adaptation to technical and scientific progress to be determined in including at (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."

[64] The learned trial judge concluded that in light of the introductory words in Article 29 the requirements set out at (d) must be technical requirements. He rejected the submission that blood was not a product for the purposes of paragraph 38 of Schedule 3 relying on A and others v The National Blood Authority [2001] EWHC QB 446 where it was conceded in a consumer case that blood was a product. On that basis he found that paragraph 38 of Schedule 3 deprived the Minister of competence to take decisions in relation to the deferral periods.

[65] We have received extensive submissions on the issue of whether blood is a product for the purposes of Schedule 3 of the 1998 Act. Dr McGleenan drew our attention to the 2001 Directive dealing with a Community code in respect of medicinal products for human use. That Directive was made under Article 95 of the EC Treaty which provides for harmonisation of community law. It specifically excludes whole blood, plasma or blood cells from its remit. If it were intended to establish technical standards in relation to blood as a product one would have expected to find it in this Directive. Unlike the 2001 Directive the 2002 Directive is made under Article 152 (4) (a) EC Treaty dealing with human health protection. It is not prescriptive and enables Member States to impose more stringent protective measures. Paragraph 38 of Schedule 3 is concerned with fixed standards for products established by Community law.

[66] Mr Scoffield submitted that Article 29 of the 2002 Directive was concerned with technical standards. He relied upon recital 5 of the 2002 Directive which recorded that technical requirements for the collection and testing of blood and blood components including starting materials for medicinal products should be established by the 2002 Directive and the 2001 Directive should be amended accordingly. The fact that the 2002 Directive had amended the 2001 Directive demonstrated that each was concerned with technical standards in relation to products.

[67] We have not found it necessary to determine the issue of whether blood is a product for the purpose of paragraph 38 of Schedule 3 of the 1998 Act. We accept that Article 29 of the 2002 Directive sets technical standards but the technical standards set by Article 29 (d) of the 2002 Directive are standards in relation to blood donors and not standards in relation to products. We are satisfied, therefore, that the technical standards contained within the 2002 Directive in relation to blood donors do not fall within paragraph 38 of Schedule 3 of the 1998 Act. This was not a reserved matter and the Minister had competence to act in accordance with the Ministerial Code as required by section 28A of the 1998 Act.

[68] There is no real dispute that the decision made by the Minister contained in his letter of 19 September 2011 was controversial and probably also significant in that it represented a departure from the principle of parity with the rest of the United Kingdom. By virtue of the Ministerial Code the Minister was required to bring the matter to the attention of the Executive Committee. His failure to do so meant that he had no Ministerial authority to take that decision by virtue of section 28A(10) of the 1998 Act.

[69] Thereafter the Minister reconsidered his decision as he explained when he appeared before the Health Committee on 26 October 2011. These proceedings were issued on 18 November 2011. We do not consider that the requirement in the Ministerial Code to refer significant or controversial matters to the Executive Committee prevents a Minister seeking advice and gathering information prior to

doing so. We consider, therefore, that there was no further breach of the Ministerial Code during the period of reflection prior to the issue of these judicial review proceedings.

**Bias and irrationality**

[70] The conclusions that we have reached on the earlier matters are sufficient to deal with the substantive issues in this case but we consider that we should deal with the findings of irrationality and bias made against the Minister. In his consideration of the submissions on irrationality the learned trial judge noted that the SaBTO report stated that anal/oral male homosexual acts increase the risk of acquiring blood-borne disease. Annex III of the 2002 Directive distinguishes between persons whose sexual behaviour puts them at high risk of acquiring blood borne infection and those whose activity puts them at risk. As the learned trial judge noted, there is no assistance as to the circumstances governing when a risk becomes a high risk. In light of the reported difference in infection rates for MSM he concluded that it was reasonable for the decision maker either to continue to maintain the permanent deferral of MSM donors or to introduce a temporary deferral period of at least 12 months.

[71] Having so concluded, however, he then went on to consider whether the Minister's decision remained rational in light of the fact that blood was imported, albeit in limited quantities, from Great Britain where MSM donors are now categorised as lower risk. He concluded that if there was a genuine concern about the safety of MSM donated blood the Minister would have protected the blood stock absolutely. He noted that no request had been made that imported blood should not be derived from the MSM community. He concluded that the Minister's decision was on that account irrational.

[72] We agree with the learned trial judge that it was not irrational for the Minister, on the materials and advice provided to him, to conclude that MSM donors were persons whose sexual behaviour put them at high risk of acquiring severe infectious diseases and consequently that a permanent deferral should be maintained. Indeed that was the case that was argued on his behalf by the Attorney General in this appeal. It is common case, however, that a permanent deferral does not offer absolute protection because some MSM donors get through the screening system and there are in any event risks from other persons. In accepting limited quantities of blood from Great Britain the Minister accepted the risk that some of that limited quantity might contain blood from an MSM donor. He was entitled to take the view that any such risks were small having regard to the testing system in place. We do not consider that acceptance of that small risk rendered irrational the Minister's conclusion that MSM donors should be considered as persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases. The point that the Minister and the Attorney General have made in this appeal is that once the high risk condition in Annex III is reached permanent deferral

automatically follows. The Minister had spoken to the Attorney General prior to taking his decision in September 2011 and appears to have been acting in accordance with advice. We cannot characterise his approach as irrational. We, therefore, allow the Minister's appeal on this point.

[73] In his original extensive judgment the learned trial judge did not deal with the allegation of apparent bias made against the Minister. The matter was remitted to him by this Court and he delivered his judgment on the issue in January 2015. Mr Scoffield applied to the learned trial judge to introduce two additional pieces of evidence in support of that claim and the judge acceded to that application. The first was a BBC news report dated 25 September 2001 entitled "Gay Blood Donor Comments Furore":

> "A claim that homosexual blood donors could pass on the HIV virus has provoked uproar in the Northern Ireland Assembly. Lagan Valley DUP representative Edward Poots attacked the Northern Ireland Human Rights Commission because it said the ban on homosexuals giving blood could be discriminatory.
>
> Mr Poots said: 'It is a human right for people receiving blood to know that they are getting clean blood and blood that has not been contaminated by the HIV virus.'
>
> The DUP member made the comment during a debate on an Ulster Unionist motion criticising the Commission for alleged failure to address the concerns of both unionists and nationalists in Northern Ireland."

The only risk in this statement is that the Minister may have been predisposed to believe that MSM were more likely to contract the HIV virus because of their sexual behaviour. In fact it is common case that the risk of infection in MSM is higher than in the general population.

[74] The second piece of evidence is a transcript from the debate in the Northern Ireland Assembly on 5 November 2013 when the Minister discussed the learned trial judge's decision:

> "The question is this: will I appeal it? I am very reluctant to appeal it. Number one, it gives the larger parties in the Executive considerably more power. Number two, it refers a lot of governance back to the

national Parliament and, as a unionist, should I be that concerned about that? Number three, do I believe that I would get fairness in the Court of Appeal or would there be a circling of the wagons? I am concerned that that may not be the case.

People have made suggestions about my own moral views and so forth, and, although there has been no bias found — because there is no bias to find — it is interesting to see that just last week in England Sir James Munby outlined that secularism rules in courts now and there is no place for religious beliefs. He had to be rebuked by the former Archbishop of Canterbury George Carey who said that we are now living in:

'An age when all faiths are equal - except Christianity'.

When I was at the Department of the Environment, I was asked a question by a BBC journalist as to whether I was fit to be a Minister and a Christian. What a shameful, despicable question, particularly when there are people in this Government who have engaged in terrorism and have been convicted of terrorist activities. It is alright for them to be in Government, but, if you embrace Christian values, you should not be there. That was the substance of the question.

**4.45 pm**

There is a continual battering of Christian principles, and I have to say this: shame on the courts, for going down the route of constantly attacking Christian principles, Christian ethics and Christian morals, on which this society was based and which have given us a very good foundation. It is a shame that George Carey had to respond in the way that he did to a judge in GB who made such a statement. It appears that our judges are rushing headlong in behind them.

Therefore, I am not sure that I would get a fair hearing ..."

[75] The respondent submitted that this passage made it clear that the Minister did not believe that he would get a fair hearing on the appeal because of his Christian principles. We accept that interpretation. It is important to note, however, that his specific criticisms relate to comments by a judge in England and Wales, the response by the Archbishop of Canterbury and a BBC journalist. The passage referring to a continual battering of Christian principles and attacking the courts for going down the route of constantly attacking Christian principles ethics and morals is, therefore, set in a wider landscape than the issues arising from this particular case. We agree, however, that these comments form part of the background which the fair-minded and informed observer should take into account.

[76] Almost immediately after this contribution in the course of the same debate the Minister complained about the court's ruling on an adoption issue while the legislation was being considered by the Assembly and continued:

> "And as to this issue of blood safety, I was well within my rights to ask why we should rush into this, if every country in Europe except two, every country in North America and most of the western world maintains a lifetime ban? Why do we have four groups from the MSM lobby on the advisory group?"

That again is part of the background because it supports the Minister's contention that his decision was made on a precautionary basis of maintaining the status quo with a view to securing a high standard of public health.

[77] The learned trial judge concluded that he should ascertain all the circumstances which have a bearing on the suggestion of apparent bias and then applied the test in Porter v Magill [2002] 2 AC 357 by asking whether those circumstances would lead a fair-minded and informed observer to conclude that there was a real possibility of bias. The first circumstance that he took into account was that the decision of the Minister was irrational. He relied on that finding to infer the real possibility of some undisclosed agenda. For the reasons earlier indicated we do not agree with his conclusion on rationality.

[78] Secondly, he noted that the Minister's decision was against the advice of his senior officials and without any consultation with the Assembly Health Committee or other interested parties. The judge made the point that the Minister is only entitled to reject the advice and recommendations of his officials on rational grounds. Thirdly, the reply to the pre-action correspondence made by the Attorney General's office denied that the Minister had made a decision on the maintenance of a permanent deferral. It is now common case that he did make a decision by 19 September 2011 but the Minister's position by the time that he reached the Committee was that he had reflected and was still considering the position. The

judge considered that the pre-action correspondence gave rise to a very troubling lack of candour and an attempt to conceal the fact that he had made a decision.

[79] Fourthly, he took into account the suggestions by politicians from other parties that the Minister had been prejudiced in his decision-making. Fifthly, the learned trial judge inferred that the Minister's comments to the Committee indicated that he interpreted the court's judgment as an assault on Christian principles and morals. Since the court's decision did not touch at all upon Christian principles or morals the inference was that the Minister regarded his impugned decision as an expression of his Christian beliefs and morals. Lastly, the learned trial judge noted the Minister's previous opposition to gay rights legislation and took into account the 2001 BBC article.

[80] In addition to those circumstances Mr Scoffield also placed reliance on the fact that the maintenance of a permanent deferral for MSM donors was inconsistent with a temporary deferral for other groups such as those with multiple partners or those who have had sexual encounters with persons they believed to have HIV. The respondent relied upon this not just on the question of apparent bias but also on the issue of irrationality. We do not accept that this circumstance is material. There was no material before the Minister advising him about a change to any other deferral criterion. In his appearance before the Committee the Minister indicated that he had concerns about other categories of blood donors. The essence of the Minister's position was that he was retaining the status quo in the interests of maintaining a high level of human health protection while further assessment such as that conducted by the Council of Europe was completed.

[81] We agree that the test set out in Porter v Magill is the correct starting point in determining whether a decision is affected by apparent bias. Porter v Magill was a case in which the complaint was that the local government auditor was investigator, prosecutor and judge in respect of the matter in issue. The context in this case is different. The Minister is making a public interest decision about the protection of human health. There is no judicial or quasi-judicial determination. The decision on the deferral period is administrative and contains a policy decision on the question of the degree of protection of human health.

[82] The manner in which the Porter v Magill test should be applied in administrative decisions has been considered in some detail in the context of planning decisions by councillors in R (Lewis) v Redcar and Cleveland Borough Council [2008] EWCA Civ 746. That was a case in which a challenge was made to the decision of a majority group of councillors, shortly before an election, to proceed with an indication that it was minded to grant planning permission for a major leisure development linked with housing on an open land site in the ownership of the authority. The court drew a distinction between a predisposition to the grant of planning permission and a predetermination in respect of the application. The essence of its approach is set out in paragraph 71 of the judgment:

> "It is for the court to assess whether committee members did make the decision with closed minds or that the circumstances did give rise to such a real risk of closed minds that the decision ought not in the public interest to be upheld. The importance of appearances is, in my judgment, generally more limited in this context than in a judicial context. The appearance created by a member of a judicial tribunal also appearing as an advocate before that tribunal (*Lawal v Northern Spirit Ltd [2003] ICR 856*) may make his judicial decisions unacceptable, but the appearance created by a councillor voting for a planning project he has long supported is, on analysis, to be viewed in a very different way."

In this case the Minister has expressed a predisposition about the risk to public health from blood donation by MSM in his 2001 contribution to the assembly. The question for the court is whether it is satisfied that there was predetermination or such a real risk of a closed mind that the decision was not one that should be upheld in the public interest.

[83] A similar context has also been considered in this jurisdiction by Weatherup J in Re Cullen's Application [2005] NIQB 9. That was a case in which there was a challenge by a coursing club to a decision by the Minister to refuse a licence to take hares by means of nets for the purposes of hare coursing and the making by the Minister of an Order prohibiting the taking of Irish hares at any time during the subsequent 12 month period. The challenge was based among other things on the fact that the Minister had been a member and employee of the League Against Cruel Sports which had a clear anti-coursing stance and that she had held various positions in that group which had been criticised by the Advertising Standards Agency for misrepresenting the effect of coursing on hare populations. She had contributed to a debate in the House of Commons on 26 November 2002 on hare coursing in which she stated "in racing terms, I have some form on this issue."

[84] Weatherup J stated that the court must apply the Porter v Magill test at paragraph 18 of his judgment. That paragraph was referred to by the learned trial judge. The learned trial judge did not refer to the manner in which the test was to be applied which was set out at paragraphs 23 and 24 of the decision:

> "[23] The two stage test for apparent bias as defined in Porter v Magill above involves, first of all, identifying the circumstances that are said to give rise to bias, and secondly, asking whether a fair-minded and informed observer having considered the given

> facts would conclude that there was a real possibility that the decision maker was biased. The approach of the fair-minded and informed observer will depend on the context. In the political arena it will be recognised that political figures adopt positions on political issues that may be party political positions or may be personal political positions. Such a political figure, if he or she obtained ministerial office, may be called upon to make decisions in areas where they have adopted a public political position, whether as a party position or a personal position. Indeed political figures will have been elected for the purpose of advancing a political position. In those circumstances the political figure may well be predisposed to a particular position that bears on the matter for decision. The fair minded and informed observer will be aware that the political decision maker will have been elected because of a public position on many issues and may well be predisposed to a particular outcome.
>
> [24] On the other hand ministerial decision makers must make the decision in accordance with the legislative or other provisions governing the particular decision. While it is legitimate for the Minister to be predisposed to a particular outcome it would be illegitimate for the Minister to have predetermined that outcome. Wade and Forsythe on Administrative Law (9th ed.) at page 472 state that attempts to represent government policy as objectionable on grounds of natural justice "are usually complaints of predetermination, alleging that the effective decision was taken in advance, thus rendering the hearing futile and the result a foregone conclusion."

[85] Turning then to the circumstances upon which the respondent relies as demonstrating apparent bias the first in time is the newspaper report of 25 September 2001 referred to at paragraph 73 above. For the reasons given in that paragraph it does not appear that a great deal turns on the report. Next there is a newspaper report in the Belfast Telegraph of 4 May 2007 dealing principally with funding for gay and bisexual groups by the Office of the First Minister and Deputy First Minister. At the end of the article it was noted that Mr Poots, then Culture Minister, faced controversy and criticism from two Free Presbyterian Church ministers over grant aid to the annual Belfast Gay Pride festival. Mr Poots signalled

that he would not intervene on the matter and would not have a direct input on such grant issues. That contradicts the suggestion of the use of Ministerial power to disadvantage the gay community. The article asserts that the Minister had strongly opposed recent gay rights legislation but does not indicate what the legislation was or what the nature of his opposition was.

[86] The next article upon which the respondent relies is a BBC report dated 19 February 2008 entitled "Poots hits out at gay rugby team". The substance of the article indicates that the Minister objected to what he called an apartheid in sport and he considered the setting up of an all homosexual rugby team as exclusive rather than inclusive. The article indicates that the founders of the rugby team said that they welcomed anyone to join the club. The article did not suggest that the Minister espoused any difference in treatment on the grounds of sexual orientation in the playing of the sport.

[87] The next relevant item is the submission made to the Minister dated 1 July 2011. The judge correctly noted that the advice recommended that the Minister consider the SaBTO recommendations and based on their advice agree to a UK wide response in a change of policy from a lifetime to a 12 month deferral period for MSM. It is also relevant to note, however, that the advice noted that the permanent deferral for MSM had been introduced in 1985 because of the high risk of serious blood-borne infections such as HIV.

[88] The submission suggested that there had been significant social, cultural and legal changes since 2001 when the deferral criteria were last reviewed and referred in particular to the Equality Act 2010 which permitted blood donor deferral provided the refusal was reasonable because of an assessment of risk based on available data. The Act does not, of course, apply to Northern Ireland. The review noted that a change in the deferral criteria would produce a small increase in risk if compliance remained at current levels but could be reduced if compliance increased.

[89] The submission stated that 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. It noted that legal advice indicated there was no bar on the face of the legislation to a change in the deferral period. The advice went on to note that if the recommendations were accepted the UK would be the first country in Europe to remove the lifetime deferral specifically for MSM. With the exception of Italy and Spain all other EU countries operated a lifetime deferral for MSM. The European Committee on Blood Transfusions of the Council of Europe was reviewing European practice with a view to establishing a harmonised approach to sexual behaviour deferrals. The US and Canada continue to operate a lifetime deferral for MSM but Australia and New Zealand had reduced their deferral periods.

[90] It is, therefore, part of the circumstances that need to be taken into account that the submission advised the Minister about the increased risk of MSM acquiring HIV, the extent of the maintenance of permanent deferral throughout Europe, the maintenance of a lifetime deferral in the US and Canada and the wider European review of practice. The next circumstance to be taken into account is that the Minister spoke to the Attorney General. The Attorney's advice has not by convention been disclosed but it suggests some level of care on the part of the Minister. The matters referred to earlier in this paragraph provided a proper basis for the Minister to reflect on whether a permanent deferral should be maintained. It is important to recognise that the advice to the Minister did not address in any material way the need to recognise the fundamental rights of MSM and the issue of whether the Minister's decision was rational or biased needs to be seen in that context.

[91] We agree with the learned trial judge that the contention in the pre-action protocol letter that the Minister had not made a decision is troubling. We are entirely satisfied that the Minister initially made a decision to maintain the permanent deferral of MSM. By the time he came to the Assembly Health Committee he had changed his position and was maintaining the permanent deferral so that he could reflect on whether he should alter the deferral period. In his submissions the Attorney General submitted that the Minister had taken no final decision at any stage but was merely reflecting on how he should proceed. That was consistent with the pre-action protocol letter from the Attorney's office dated 29 November 2011. It was not, however, consistent with the assertion at paragraph 25 of the affidavit of the Minister's Permanent Secretary who acknowledged that the Minister had initially decided not to follow SaBTO. There appears to be some conflict between the approach of the Attorney and the affidavits sworn on behalf of the Minister. Against that background we cannot conclude that the lack of candour on this issue should be visited on the Minister.

[92] We frankly pay little attention to the unparticularised allegations by political opponents that the Minister was prejudiced. Such comments are regrettably not uncommon in the political arena. The final relevant circumstance concerned the comments by the Minister in the Assembly after the judgment at first instance in November 2013. The learned trial judge concluded that the Minister's complaint of a continual battering of Christian principles in connection with the judgment could only arise if the Minister regarded his challenged decision as a manifestation of the expression of his religious beliefs. We do not read the remarks in that way. In the middle of the passage set out at paragraph [74] above there is a complaint by the Minister that he was questioned as to whether he was fit to hold his position because he was a Christian. The quoted passage finishes with an assertion by the Minister that he was not sure that he would get a fair hearing. Those passages in our view point towards the proposition that the Minister's complaint was that because he was a Christian he was unlikely to get a fair hearing. That did not in any way involved a suggestion that his decision had been determined by his Christian principles and indeed in the further passage we have set out at paragraph 75 he returns to the

reasons for his maintenance of the permanent deferral to secure the safety of blood recipients.

[93] Having analysed all the relevant circumstances in this matter we have concluded that there is no basis for the conclusion that the Minister's decision in this case was predetermined by his Christian beliefs and there is ample evidence to indicate that the Minister approached the decision-making by evaluating the competing factors before adopting on a precautionary basis the status quo. We do not consider that the fair-minded and informed observer could conclude that there was a real risk of apparent bias.

**Conclusion**

[94] For the reasons given we refuse leave to the appellant to amend the Notice of Appeal on the issue of standing, we allow the appeal of the appellant and Notice Party on the correct decision maker, we allow the appeal of the appellant on irrationality and apparent bias and I would allow the cross-appeal of the respondent on the basis that the maintenance of a permanent deferral for MSM was disproportionate and contrary to EU law.

**GILLEN LJ**

[95] I have had the benefit of reading in draft the judgment of Morgan LCJ in this matter.

[96] For the reasons he has given, I concur with the decisions to:

- refuse leave to the appellant to amend the Notice of Appeal on the issue of standing,
- allow the appeal of the appellant and notice party on the correct decision-maker and
- allow the appeal of the appellant on the issue of rationality and apparent bias.

[97] However I depart from the decision of Morgan LCJ in allowing the cross-appeal of the respondent on the basis that the maintenance of a permanent deferral for MSM was disproportionate and contrary to EU law.

[98] Before setting out my reasons for this departure I respectfully adopt a number of the principles set out in the judgment of Morgan LCJ namely:

- Lumsdon's case is clear authority for the proposition that proportionality is a ground of review of national measures frequently applied where there is an interference with the fundamental freedoms guaranteed by EU treaties.

- It follows that if fundamental rights are engaged the national measures restricting the donation of blood by MSM must be no more onerous than is required to achieve a legitimate aim, which in this case is a maintenance of the high level of human health protection.
- Member States have a margin of appreciation in determining the level of protection which they wish to afford to public health. However the approach to proportionality is dependent upon the context and in light of the case of Léger, this includes the fundamental rights of MSM.
- The suggestion that national measures implementing EU law should not take into account fundamental rights is insupportable.
- The maintenance of the permanent deferral for MSM plainly implemented EU law and the Charter clearly applies.

[99] I turn now to some general observations about the role of the courts in the post Human Rights Act 1998 landscape. In this era the traditional deference to the legislature or executive on matters of public interest has to be balanced against the compelling need for the judiciary to protect fundamental rights. The role of the courts in protecting such rights has been part of our constitution long before the Human Rights Act but is now even more firmly entrenched by the Act and is enforceable throughout the UK.

[100] The key component is to demarcate the judicial role reflecting appropriate deference to the legislature and the executive on the one hand and an act of participation in upholding a rights based democracy on the other i.e. to delineate separate spheres for judicial and legislative decision-making. Judges are not made into legislators by the Human Rights Act.

[101] As Lord Hope's famous dictum in R v DPP ex parte Kebilene [2000] 1 Cr App Rep 275 asserts at p. 380-381, courts should recognise "an area of judgment within which the judiciary will defer on democratic grounds to the considered opinion of the elected body". Judges need to recognise the latitude or the discretionary area of judgment which must be given to official decision-makers.

[102] Judicial review is conceptually a claim to review the lawfulness of an enactment or a decision, action or failure to act in relation to the exercise of a public function. Claims frequently involve several interrelated potential targets. They may be connected "vertically" (e.g. an enactment and a decision made under it) or "horizontally" (e.g. a decision and its later implementation). They are likely to be sequential. The plaintiff's timing dilemma will be whether to challenge early and risk criticism for prematurity, or later and risk being found to have fatally delayed (See Fordham "Judicial Review Handbook" 6th Edition at [5.3]).

[103] Equally so, the principles governing judicial review dictate that the courts must not cross the clear boundary between what is administration, whether it be good or bad administration, and what is an unlawful performance of the statutory

duty by a body or person charged with performance of that duty. Measured restraint by the court is a strong theme of judicial review. An example of restraint occurs typically on public health issues which require the evaluation of complex scientific evidence. In such cases courts may and should be slow to interfere with the decision which a responsible decision maker has reached after a consultation with expert advisers (see R v Secretary of State for Health, ex p Eastside Cheese Company [1999] EuLR 968 and 978g).

[104] One protection from over intrusion by the court is that judicial review is generally conducted by approaching the question from the decision maker's point of view. That includes considering the position as at the time when the decision maker acted, the circumstances in which the action was taken and the material that was available at the time (see Fordham "Judicial Review Handbook, 6th Edition at 13.70). Courts must not stray beyond their proper constitutional competence and usurp the prerogatives of the executive on public health matters for which the Minister is ultimately accountable to the electorate. As Lord Radcliffe famously said in Edwards v Barrstow [1956] AC 14 at 13-89 "the court is not a second opinion … their duty is no more than to examine those facts with a decent respect for the tribunal."

[105] In R (Age (UK)) v Secretary of State for Business, Innovation and Skills [2009] EWHC 2336 (Admin) [2010] ICR 260 at [41] Blake J said:

> "Governments must be free to govern …. But … judges must also judge, which they can do in this field by applying well-established principles of proportionality and in so doing apply an appropriate intensity of inquiry whilst ensuring that they do not stray beyond their proper constitutional competence and usurp the prerogatives of the executive on sensitive social issues for which it is ultimately accountable to the electorate."

[106] Lord Reed said in AXA General Insurance Ltd v HM Advocate [2012] UKSC 46:

> "Although the courts must decide whether, in their judgment, the requirement of proportionality is satisfied, there is at the same time nothing in the Convention or in the domestic legislation giving effect to the Convention rights, which requires the courts to substitute their own views for those of public authorities on all matters of policy, judgment and discretion."

[107] There is no doubt that there are circumstances where judicial intervention can act to obviate in advance a proven risk of injustice or breach of fundamental rights. In R (On the Application of the Refugee Legal Centre) v Secretary of State for the Home Department [2004] EWCA Civ. 1481, the court was considering a challenge to the legality of the detained fast track asylum seeker system in the narrower sense of the system up until the Secretary of State for Home Department's decision.

[108] At [7] Sedley LJ said:

> "We accept that no system can be risk free. But the risk of unfairness must be reduced to an acceptable level. Potential unfairness is susceptible to one of two forms of control which the law provides. One has access, retrospectively, to judicial review if due process has been violated. The other, of which this case has been put forward as an example, is appropriate relief, following judicial intervention to obviate in advance a proven risk of injustice which goes beyond aberrant interviews or decisions and inheres in the system itself. In other words it will not necessarily be an answer, where a system is inherently unfair, that judicial review can be sought to correct its effects."

[109] Thus in the present case, the court has to consider whether or not a fundamental right has been rendered illusory by the actions of the Minister. If such a fundamental right cannot be claimed or insisted upon, it is not simply an imperfect fundamental right but one that is not worthy of such a description. However the court's vigilance in reviewing any interference with such a right must be calibrated to the nature and degree of interference considered appropriate. A discretionary public law power has to be exercised in a manner that is not arbitrary or partial and the court will be vigilant in its scrutiny to ensure that that does not become inevitable in advance even of a decision.

[110] The fact of the matter is however that in this instance the Minister has a very wide discretion in the field of public health in the context of devolved/regional governance.

[111] The scheme of devolution in Northern Ireland adumbrates that competence in all areas has been devolved (i.e. it is a "transferred matter") unless it is an "excepted matter" or a "reserved matter". Section 4 of the Northern Ireland Act 1998 makes this eminently clear as does Section 6.

[112] Executive authority in Northern Ireland is exercised by the Northern Ireland Ministers or Northern Ireland Departments.

[113] The impugned decision in the instant case comes within the ambit of the protection of public health and is therefore a transferred matter i.e. health. The Minister is making a decision pursuant to the broad powers conferred on the Department by Section 2 and Section 3 of the Health and Social Care Reform (Northern Ireland) Act 2009. In short, as Morgan LCJ has said at paragraph [67] "we are satisfied that the technical standards contained within the 2002 Directive in relation to blood donors does not fall within paragraph 38 of Schedule 3 of the 1998 Act. This was not a reserved matter and the Minister had competence to act in accordance with the Ministerial Code as required by Section 28A of the 1998 Act".

[114] The fact of the matter is that the Minister has not yet made a decision on this matter. As is pointed as at [13] of the judgment of Morgan LCJ , it is now accepted in the affidavit of Mr McCormick, Permanent Secretary, sworn on 21 September 2012 that the Minister had made a decision not to follow the recommendation from SaBTO in his Assembly answer but that on further reflection he adopted the view that there should be further consideration and investigation of the issue . While that consideration continued the deferral period for MSM should not change. Strictly speaking therefore I consider that an initial decision was made – which in theory could be subject to a judicial review – but that the reality of the matter is that the situation has now changed and the Minister's approach is that he should give further consideration and investigation to the issue before coming to a decision.

[115] In R v Hammersmith and Fulham London Borough Council [2012] 1 WLR 1057 at [18] the Court of Appeal allowed argument as to the lawfulness of a fresh decision for essentially pragmatic reasons stating:

> "Judicial review claimed can be something of a moving target … where the first decision is succeeded by a new decision … the court may take the pragmatic view that it will adjudicate upon the real dispute between parties without requiring distinct and separate applications for judicial review."

[116] I am satisfied therefore that we are dealing with a situation where a decision has not been made by the Minister.

[117] I do not consider that this court can come to a conclusion that the outcome of that decision has been prejudged or is inevitable once the test of proportionality has been applied. That would be to usurp the function delegated by Parliament to the Minister.

[118] Doubtless it can be plausibly argued that there is existing cogent evidence in favour of a change from permanent deferral to temporary deferral, viz:

(i) With mathematical assurance, Morgan LCJ has indicated at [43] that the Steering Group analysis points to an additional risk of infection in only one in 15,500 years by changing from permanent deferral to temporary deferral.

(ii) Incidence of HIV in this jurisdiction is markedly lower than in the rest of the UK and the risk of HIV infection through blood donation is correspondingly lower than in the rest of the UK.

(iii) The technical memorandum produced by the Council of Europe's Committee of Ministers examining the possibility of a common approach to the Directives dealing with blood donation recommended that State parties should collect, evaluate and publish epidemiological data to facilitate risk analysis and should decide on a temporary deferral policy for risky sexual behaviour only when having demonstrated that the sexual behaviour does not put the donors at high risk of acquiring severe infection diseases that can be transmitted by blood. The resolution recognised that different solutions may be appropriate in different Member States.

(iv) SaBTO is the advisory body on the issue for the United Kingdom. As Dr Reaney has acknowledged, decisions on blood safety and quality taken by the United Kingdom are not affected by any of the reports or recommendations from the Council of Europe. Comparing the list of references from the memorandum with that of the SaBTO Steering Group Report, Dr Reaney observed that the majority of technical references were different, the Council of Europe Report mostly using resources relating to specific epidemiology of a disease in a wide range of different countries. The SaBTO report examined the epidemiology of disease in the United Kingdom and a number of studies conducted in the UK.

[119] However notwithstanding this strong evidence, the Minister, presumably as a careful custodian of the health of the people of Northern Ireland, is in my view entitled to weigh up a number of considerations, including the above, before coming to a decision. Thus for example the Minister can at least plausibly argue that he wishes to take the following additional steps:

(i) To adopt a precautionary approach and to discuss with SaBTO the issue of temporary deferral periods in relation to those with multiple sexual partners and indeed for those who have had sex with persons they believe are infected with HIV. How would SaBTO deal with this?

(ii) He may wish to discuss further with SaBTO the findings of the Committee of Ministers notwithstanding that they may have relied on different technical references. A careful Minister may be entitled to explore why it is that SaBTO, relying on new case sources, comes to a different *technical* decision from outside technical references in the wider European context. It may well

> be that the answer is simply that the epidemiology of disease is different in the UK but it is a matter that this court should be slow to reject as a reasonable ground for investigation. The fact of the matter is that the vast majority of Member States, including our neighbour the Republic of Ireland, have adopted a different approach from that recommended by SaBTO. I consider that the Minister is entitled to explore why this should be so with for example our nearest neighbour the Republic of Ireland which in theory one would have thought should be relying on similar studies to that conducted in the UK. Have they obtained different studies? Have they come to a reasoned conclusion contrary to SaBTO which the Minister is entitled to take into account?

[120] I consider that we as judges are not in a position to make the assessment which the Minister is tasked to perform. We have neither the expertise nor all the necessary material before us to determine at this time whether the eventual decision made is a proportionate one. The Minister must be given an opportunity to exercise his own discretion and make a choice. The question is not whether the Minister comes to a correct solution or a conclusion which meets with the approval of the court. The question is whether the court considers that his discretion was properly exercised and he has acted proportionately.

[121] It is of course ultimately the role and duty of the court – as Léger makes clear - to make the necessary findings and carry out the proportionality assessment. The doctrine of proportionality may require the reviewing court to assess the balance which the decision maker has struck, not merely whether it is within the range of rational or reasonable decisions, and may require attention to be directed to the relevant weight accorded to interests and considerations. However, in the instant case, on what material is the assessment to be made? The decision has not yet been made and the Minister has not yet carried out his own proportionality assessment. Leger is not authority for the proposition that the court can usurp the role of the Minister to carry out his own assessment and make a decision which then of course is subject to the scrutiny of this court.

[122] Obviously if the Minister continued to refuse to make a decision or delayed inordinately wholly different considerations would apply. However the fact that the judicial review was instituted four years ago, and the decision has not yet been made, is not in my view a powerful factor. The judicial review has called into question whether the Minister or the Secretary of State is the person who should make the decision and until this was resolved – particularly in light of the decision of Treacy J – it is difficult to see how the Minister could have progressed to make a decision to alter the status quo.

[123] In all the circumstances therefore I have come to the conclusion that it would reflect an inappropriate deference to the role of the Minister under the terms of the 1998 Act if this court were to determine *at this time* that the decision of the NIBTS to

maintain a status quo is a matter that he is not entitled to do as a matter of EU law. It is a decision that he has not yet made and he should be afforded the opportunity to do so before this court should intervene. I would therefore dismiss the cross-appeal of the respondent that the maintenance of a permanent deferral of MSM was disproportionate and contrary to EU law on the basis that a decision to that effect has not yet been made.

**WEIR LJ**

[124] I too agree with the orders proposed by Morgan LCJ with one exception, that which proposes to declare that the maintenance of a permanent deferral from blood donation by MSM is disproportionate and contrary to EU law.

[125] I gratefully adopt the analysis of the principles to be derived from the decisions in Léger and Lumsdon between paragraphs [35] and [42] and the conclusions derived from them. However I would also draw attention to the terms of the concluding paragraph of Léger:

> "69. Having regard to the foregoing considerations, the answer to the question referred is that point 2.1 of Annex III to Directive 2004/33 must be interpreted as meaning that the criterion for permanent deferral from blood donation in that provision relating to sexual behaviour covers the situation in which a Member State, *having regard to the prevailing situation there*, provides for a permanent contraindication to blood donation for men who have had sexual relations with other men *where it is established, on the basis of current medical, scientific and epidemiological knowledge and data*, that such sexual behaviour puts those persons at a *high risk* of acquiring severe infectious diseases and that, with due to regard to the principle of proportionality, there are no effective techniques for detecting those infectious diseases or, in the absence of such techniques, any less onerous methods that such a counter indication for ensuring a high level of health protection of the recipients. It is for the referring court to determine whether, in the Member State concerned, those conditions are met."*(emphasis in italics supplied here and hereafter)*

[126] At paragraph [6] the conclusions of the SaBTO Donor Selection Steering Group Report of 14 April 2011 are described and at [7] the conclusion of SaBTO that the available evidence supported the introduction of a 12 month deferral in place of the permanent deferral for MSM donations. This conclusion was, as we have seen,

adopted by SaBTO at its meeting on 3 May 2011 and the respective Departments of Health in Wales, Scotland and England recommended its acceptance to their Ministers. The recommendations were accepted and implemented by their respective blood transfusion services with effect from 7 November 2011. A similar recommendation by the Northern Ireland Department to its Minister was not accepted, leading in turn to the initiation of the present proceedings.

[127] However, as noted at paragraph [46], at the same time that the SaBTO Steering Group was deliberating the subordinate ad-hoc group of the European Committee on Blood Transfusion of the Council of Europe was also at work. The SaBTO Steering Group noted that this work was in progress at paragraph 6.1 of its report and that the outcome of that review was expected in 2011. The report of the review entitled "Risk Behaviours Having an Impact on Blood Donor Management" ("the Memorandum") was in fact not published until April 2012. By that time England, Scotland and Wales had already altered the deferment period for MSM so that the European conclusions could not have been taken into account in arriving at their decisions.

[128] While SaBTO is the advisory body that is looked to in the United Kingdom on the issue of blood safety it would seem surprising if research that extended European-wide and beyond on the same issue were not, if available, to be taken into consideration by those advising a Minister on the deferral question. This is not the place nor am I remotely qualified to embark upon an evaluation of the relevance of the contents of the Memorandum to such consideration. However on its face there appear to be a number of matters arising from it that might well merit consideration by those suitably qualified of which the following are some examples:

- The Council of Europe data contained in the Memorandum demonstrated strong regional differences in disease incidence and prevalence.

- Similarly, there was considerable variation in the trends discerned in the donor populations of individual Member States for which data was available.

- The data examined is now all of some vintage, relating to the period between 2000 or earlier and 2010.

- Regardless of the type of deferral policy in place, whether time-limited or permanent, it is evident that MSM do in fact donate blood.

- There is a scale of different risk magnitudes in sexual behaviour. The working group believed that MSM and Commercial Sex Workers put them at the upper end of an "imaginary scale" of risk.

- It is presently not always possible to sharply discriminate between "high risk" and "risk" of acquiring transfusion transmitted infection with respect to sexual behaviour.

- Based on the data, none of the deferral policies currently in use seems to be clearly superior.

- More studies are needed to further investigate the effect of a change in donor deferral policies.

- Modelling studies show that HIV transmission risk might increase if MSM were allowed to donate, although this may only be a marginal increase *if adequate deferral periods are applied and adhered to*. However the spread of emergent infections is augmented by certain aspects of sexual behaviour that, in Europe, are generally more common among MSM than among heterosexuals.

- Donor deferral criteria alone are not sufficient to guarantee blood safety.

- There is a limit to ensuring blood safety through testing and processing alone. This has reinforced the importance and the necessity of a donor selection process based on scientific evidence and transparency for the donor. This requires that sexual risk behaviours, as defined by epidemiological studies, must be clearly addressed in donor questionnaires to prevent "at risk" persons from donating blood.

- The possibility of newly emerging infections must be taken into consideration when determining deferral periods.

- The working group favoured the development of uniform European criteria for a Donor Health Questionnaire in order to a have a comparably efficient donor selection protocol in all European countries.

- Considering that residual risk is strongly influenced by adherence to donor deferral criteria it must be noted that MSM donate and account for 0.7-2.5% of all male donors *in countries with permanent deferral in place*. It is therefore necessary not only to address deferral periods, but also to take measures to increase donor understanding and adherence.

- In order not to compromise patient safety, the majority of the working group favoured no change in the current practice of permanent deferral of MSM, Commercial Sex Workers and other persons with high risk sexual behaviour *until new evidence is available*.

[129] A common theme in both the SaBTO and the Memorandum is that compliance with any deferral period remains a "key issue". Neither report provides reliable guidance as to existing levels of compliance nor, importantly, as to likely levels of future compliance if a permanent deferral were to be replaced with some lesser period. It is said at para 9.3 of SaBTO that a study commissioned by the English Health Promotion Agency to look at blood donor compliance employed qualitative research with a sample of 30 "compliers" and "non-compliers" with the current MSM donor exclusion. This appears to this non-statistician a very small sample from which to make statistically reliable predictions about the likely future compliance behaviour of the MSM population and it also seems unsurprising and less than conclusive that:

> "Almost all qualitative interview participants (all currently compliant with the lifetime MSM exclusion) maintained that they would comply with a five year and a twelve month MSM deferral, particularly if provided with sufficient information on the rationale for the exclusion".

[130] In summary, it may be seen from the contents of the two reports that compliance with whatever deferral period is fixed is a "key issue" in ensuring blood safety, that the data considered is now of some vintage and is variable and inconsistent as between Member States and, certainly in the case of the UK, regions within those Member States and that there is little if anything to support the hope that a departure from permanent deferral would maintain or enhance the incomplete level of compliance with the present permanent deferral regime.

[131] In my view this court does not at present have available to it the materials required to perform the exercise mandated by the concluding paragraph of Léger. Coming to this matter in 2016, it has no information about the "prevailing situation" to which it can have regard nor is it equipped with "current medical, scientific and epidemiological knowledge and data" such as it would require to enable it to decide "with due regard to the principle of proportionality", which is I entirely accept applicable, whether there are less onerous methods than a permanent contra indication for blood donation by MSM.

[132] I consider that, now that his competence to decide this question has been resolved, the Minister, whose identify has in fact changed during the long period occupied by these proceedings, ought to be afforded a reasonable opportunity to assess the matter in the light of all the relevant data and other research material both previously existing and which has come into being since 2011, to take advice on it from appropriate medical, scientific and legal advisors and then reach and promulgate an informed, proportionate decision. I express the hope that, especially in view of the controversy that has surrounded this matter for now some five years, he and his Department will apply themselves to that task without delay. For my

part, until he has been allowed a reasonable time in which to carry out his task or, in default of his doing so, until this court has available to it the requisite and up-to-date information mandated by Léger, I would not feel able to declare that the maintenance of the present permanent deferral in this jurisdiction for MSM is disproportionate and contrary to EU law. Accordingly as matters presently stand I would refuse the cross-appeal of the respondent.