Plasma Protein Therapeutics Association

Date: July 14, 2015
Reference No.: FDAA15007 **VIA EMAIL**

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

SUBJECT: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry [Docket No. FDA—2015—D—1211]

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) thanks FDA for the opportunity to participate in the guidance development process and is pleased to provide these comments on the draft guidance entitled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" ("draft guidance").[1] PPTA understands that the draft guidance "provides blood establishments that collect blood or blood components, including Source Plasma, with revised donor deferral recommendations for individuals at increased risk for transmitting human immunodeficiency virus (HIV) infection" and, when finalized, is intended to supersede the memorandum to blood establishments entitled "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products" dated April 23, 1992 ("1992 memo").[2]

About PPTA

PPTA is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies, collectively referred to as plasma protein therapies. Plasma protein therapies are used in the treatment of a number of rare diseases. These diseases are often genetic, chronic, life-threatening conditions that require patients to receive regular infusions or injections of plasma protein therapies for the duration of their lives. These therapies include clotting therapies for individuals with bleeding disorders, immunoglobulins to treat a complex of diseases in persons with immune deficiencies, therapies for individuals who have alpha-1 anti-trypsin deficiency, which typically manifests as adult-onset emphysema and substantially limits life expectancy, and albumin, which is used in emergency-room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these medically needed, life-sustaining therapies.

General comments

PPTA supports FDA's use of science-based decision-making in determining changes in the Agency's blood and plasma donor eligibility criteria for men who have sex with men (MSM). PPTA applauds the U.S. Department of Health and Human Services (HHS) for undertaking studies that provided data for consideration. PPTA respects the reduction of the lifetime deferral to 12 months for MSM, as recommended by the HHS Advisory Committee on Blood and Tissue

[1] *See* FR Notice, 80 Fed. Reg. 27973 (May 15, 2015)
[2] *See id*. at 27974

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Safety and Availability, providing the change in policy is accompanied by a robust monitoring system to evaluate the impact of the change. PPTA appreciates the most recent update by the Agency on the FDA/NHLBI-sponsored Transfusion-Transmissible Infections Monitoring System (TTIMS) at the May 13, 2015, FDA Blood Products Advisory Committee meeting and looks forward to continued engagement with regulators and patient stakeholders during the implementation process. PPTA understands that the base period for TTIMS, according to the Fed Biz Opps solicitation, will be September 21, 2015 – September 20, 2016.[3] PPTA urges FDA to meet this timeline and, at the least, ensure that the base period is begun prior to finalization of the draft guidance, which PPTA understands will occur this calendar year.[4]

[3] *See* https://www.fbo.gov/index?s=opportunity&mode=form&id=fafd8ba758edea829e220be43026f89e&tab=core&tabmode=list&= accessed July 7, 2015

[4] *See* http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/UCM338498.pdf accessed July 7, 2015

Specific comments

Page	Section	Language	Comments/Recommendations
5	II.C.2.	In addition, the study found that potential donors might have benefited from shorter donor education materials and the ability to answer "I don't know" to questions that currently accept only "yes" or "no" responses.	PPTA wishes to point out that the study was conducted with the AABB DHQ materials, not the PPTA materials. PPTA's educational materials are designed different from the AABB materials. PPTA incorporates a "Risk Poster." The poster is designed using Information Mapping®. We note that FDA has not carried the study suggestions into its recommendations. **Recommendation** We request that prior to FDA's recommending these suggestions that it evaluates the educational materials incorporated in the PPTA DHQ.
7	II.D.	Change to a one-year deferral is also supported by other evidence, including the experience in countries that have already changed their policies to a one-year deferral (Argentina, Australia, Brazil, Hungary, Japan, Sweden and United Kingdom).	As PPTA has discussed with FDA, including at liaison meetings, Association member companies supply a global market, and other countries continue to maintain more restrictive deferral criteria[5] that global manufacturers must evaluate and address. **Recommendation** We request that FDA acknowledge in the final guidance that in addition to the noted countries that have adopted the one-year deferral period numerous other countries have other deferral times, including indefinite and permanent deferrals. We further request that FDA note that manufacturers of blood components, including Source Plasma, that market either the component for manufacturing use or the final fractionated products, may be unable to implement FDA's less restrictive recommended deferral time period.

[5] Attachment 1

8	II.F.	In addition to the behavioral deferrals noted for MSM, [commercial sex work] and [injection drug use], the 1992 memo addressed several other deferrals that had been recommended in order to reduce the risk of HIV transmission through the blood supply … . For most of these deferrals, directly applicable data are not available at this time to support a change in the existing deferral policies.	PPTA respectfully asks why FDA has added tattoos and ear and body piercings as additional risk factors for HIV transmission when there has been no new evidence or sufficient applicable data to support a change to the 1992 memo to add these deferrals. **Recommendation** We request FDA remove tattoos and ear and body piercing as additional risk factors unless FDA provides directly applicable data to support the change in existing deferral policies to reduce the risk of HIV transmission.
9 * 11	II.F. * III.B	In the case of the deferral for persons with hemophilia or related clotting disorders who have received clotting factor concentrates, the rationale for deferral has changed from prevention of HIV transmission to that of ensuring that donors are not harmed by the use of large bore needles used during the donation process. While 21 CFR 640.3(c)(3) currently requires deferral for receipt of any derivative of human blood which the FDA has advised is a possible source of viral hepatitis, given the enhanced safety measures now used in the manufacture of clotting factor concentrates, FDA does not consider the receipt of FDA-licensed clotting factor concentrates to be a risk factor for hepatitis. Further, FDA has not recommended a deferral for the receipt of other FDA-licensed plasma-derivatives because of HIV or hepatitis risk, and we intend to consider revisions to the current regulations. [citation omitted] We recommend that you defer indefinitely an individual with hemophilia or related clotting factor deficiencies requiring treatment with clotting factor concentrates for reasons of donor safety, rather than based upon the risk of HIV infection.	PPTA looks forward to continued work with FDA to address implementation of this policy change in its DHQ. Regarding the deferral of individuals with hemophilia or related clotting factor deficiencies, PPTA considers it appropriate to ask donors once and only once if they have hemophilia or another clotting disorder since these conditions are inherited and known to the donor at the time he presents for his first donation. With respect to deferring individuals who have received other plasma derivatives, FDA notes that it "intends to consider revision to the current regulations." **Recommendation** In light of this stated intent, we request that FDA develop a pathway using 21 CFR 640.120 to allow for immediate removal of the requirement to defer prospective donors who have received plasma derivatives.

9	III.A.1.	We recommend that donors be provided donor education material before each donation explaining the risk of HIV transmission by blood and blood products, certain behaviors associated with the risk of HIV infection, and the signs and symptoms associated with HIV infection, so that donors can self-defer.[6]	The 1992 memo currently lists HIV associated clinical signs and symptoms, on which the signs or symptoms of HIV/AIDS in the PPTA DHQ are based. The Centers for Disease Control and Prevention (CDC) currently list four symptoms (no signs) of HIV infection:[7] fever, enlarged lymph nodes, sore throat, and rash. However, this list may not be valuable, as CDC recognizes, because the symptoms are common and may be caused by other illnesses. With current testing for HIV, inclusion of such nonspecific symptoms as a surrogate for HIV infection is obsolete and confusing. **Recommendation** Accordingly, PPTA respectfully requests that FDA not recommend that signs/symptoms be included in donor education materials. Should FDA still feel this relevant, it should provide a rationale for the benefit of including this information in the educational material and point to the CDC recommendations in the guidance document as the relevant signs and symptoms to present.
9	III.A.3.	We recommend that the updated DHQ include the following elements to assess donors for risk:	**Recommendation** PPTA respectfully suggests that FDA list the elements in order of potential risk.
10	III.A.3.i.	A history ever of a positive[4] test for HIV. * [4] In this context, "positive" includes positive test results on an HIV diagnostic assay and repeatedly reactive or reactive results on antibody or NAT blood donor screening assays, respectively.	PPTA respectfully requests that FDA clarify footnote 4. Industry does not perform diagnostic assay testing or confirm results under this category. Any such reports of a diagnostic positive test result would be hearsay unless accompanied by laboratory reports. FDA needs to clarify the documentation required to defer a donor because of a report of a diagnostic test result. The threshold for diagnostic testing should be clearly stated and separately the requirements for interpretation of blood donor screening assays should be clearly stated.

[6] Further, the draft guidance does not provide a specific list of recommended signs and symptoms associated with HIV for inclusion in the donor education materials. We invite comments and the submission of data on what specific signs and symptoms associated with HIV infection would be most appropriate for inclusion in the education material in the blood donor setting. 80 Fed. Reg. at 27974

[7] http://www.cdc.gov/hiv/basics/whatishiv.html accessed July 2, 2015

			Recommendation Accordingly, PPTA respectfully requests that FDA revise the language as follows: A history ever of a positive[4] test for HIV. * [4] In this context, "positive" includes: (1) positive test results on an HIV diagnostic assay [FDA to clarify documentation required here] or (2) for blood donor screening assays either a confirmatory positive antibody result or a NAT positive result.
10	III.A.3.iv.	A history in the past 12 months of sex with a person with a positive test for HIV, a history of exchanging sex for money or drugs, or a history of non-prescription injection drug use,	**Recommendation** For clarity, PPTA respectfully suggests that FDA revise this section, to mirror section III.C.1, as follows: A history of sex during the past 12 months with any of the following individuals: a person who has a positive test for HIV; a person with a history of exchanging sex for money or drugs; or a person with a history of non-prescription injection drug use.
10 * 11 * 12	III.A.3. * III.B. * III.C.	v. A history in the past 12 months of receiving a transfusion of Whole Blood or blood components such as packed red blood cells, platelets, or plasma, vi. A history in the past 12 months of contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or mucous membrane, vii. A history in the past 12 months of a tattoo, ear or body piercing, * 5. Defer for 12 months from the most recent transfusion any individual who has a history of receiving a transfusion of Whole Blood or blood components. 6. Defer for 12 months from the most recent exposure,	PPTA respectfully suggests that FDA take a risk-based approach and reduce the deferral time period to four months given the fact that the current window periods have been considerably reduced for HIV, HBV, and HCV because of NAT testing of blood and plasma donations for these viruses. This would be consistent with current EU requirements,[8] e.g. four months for tattoos and piercings. Additionally, with today's automated donor management systems, an across-the-board, defined deferral period that is independent of the actual risk is not warranted from a compliance perspective. The deferral periods should be based on risk, not on a one-size-fits-all category. **Recommendation** PPTA respectfully suggests the deferral period for these secondary

[8] *See* 2004/33/EC Annex III

		any individual who has a history of contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or mucous membranes. 7. Defer for 12 months from the most recent tattoo, ear or body piercing, an individual who has a history of tattoo, ear or body piercing. However, individuals who have undergone tattooing within 12 months of donation are eligible to donate if the tattoo was applied by a state regulated entity with sterile needles and non-reused ink. Individuals who have undergone ear or body piercing within 12 months of donation are eligible to donate if the piercing was done with single-use equipment. * 2. Donors deferred because of a history of receiving a transfusion of Whole Blood or blood components such as packed red blood cells, platelets, or plasma during the past 12 months may be eligible to donate if 12 months have passed since their last transfusion and they meet all other donor eligibility criteria. 3. Donors deferred because of a history of contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or mucous membranes during the past 12 months may be eligible to donate if 12 months have passed since their last exposure and they meet all other donor eligibility criteria. 4. Donors deferred because of a history of tattoo, ear or body piercing in the past 12 months may be eligible to donate if 12 months have passed since their last tattoo, ear or body piercing and they meet all other donor eligibility criteria.	risks be reduced to 4 months based on reduction of the window period using current NAT assays. In addition, PPTA reiterates our request to remove tattoos, ear or body piercings from the list of HIV risk factors.
10 * 11	III.A.3.x. * III.B.10.	For female donors: a history in the past 12 months of sex with a man who has had sex with another man. *	These sections are confusing in that they do not recognize the 12-month deferral for MSM. PPTA respectfully recommends that FDA change the language to:

		Defer for 12 months from the most recent contact, a female who has had sex during the past 12 months with a man who has had sex with another man.	**Recommendation** For female donors: a history in the past 12 months of sex with a man with a history in the past 12 months of sex with another man. * Defer for 12 months from the most recent contact, a female who has had sex during past 12 months with a man who has had sex with another man during the past 12 months.
10	III.A.3.	Note: In the context of the donor history questionnaire, male or female gender is taken to be self-identified and self-reported. In instances where a donor has asserted a change in gender identification, medical directors may exercise discretion with regard to donor eligibility.	PPTA respectfully requests that FDA lift the burden of decision from industry and take a position on donor gender identification. Either gender is not important and all references to gender should be removed from the donor history questionnaire or gender is important and FDA needs to proactively address gender concerns.[9] Specific scenarios and appropriate actions need to be addressed by FDA. For example, what if the self-identified gender does not match the sex stated on the donor's identification card? What if a donor refuses to assign a gender to them self? What if the donor considers their gender fluid and changes gender self-reporting in the course of a frequent donation program? With the change in donor hemoglobin levels in the final rule, what hemoglobin cut-off is acceptable for a donor who reports a gender that is not consistent with the sex they were assigned at birth? Is a center out of compliance if it accepts that a donor is a female and allows donation with a hemoglobin value below 13.0 g/dL for someone who was assigned male at birth?

[9] Definitions of terminology

- **Gender identity:** A person's internal, deeply-felt sense of being male, female, or something other or in-between, regardless of the sex they were assigned at birth. Everyone has a gender identity.
- **Gender expression:** An individual's characteristics and behaviors (such as appearance, dress, mannerisms, speech patterns, and social interactions) that may be perceived as masculine or feminine.
- **Sexual orientation:** A person's physical or emotional attraction to people of the same and/or other gender. Straight, gay, lesbian, and bisexual are some ways to describe sexual orientation. It is important to note that sexual orientation is distinct from gender identity and expression. Transgender people can be gay, lesbian, bisexual, or straight, just like non-transgender people.
- **Sex assigned at birth –** self explanatory

			Recommendation At a minimum, PPTA encourages FDA to indicate in the guidance a requirement for donors to respond to a donor history questionnaire based on the sex they were assigned at birth. This will ensure that donors who may become pregnant are asked screening questions appropriately. At present, some transgender men (assigned female at birth) can become pregnant, but sex reassignment surgery cannot yet enable transgender women (assigned male at birth) to become pregnant. Screening based on sex assigned at birth, rather than gender identity or expression, would also minimize the potential eligibility concerns described above in relation to gender-nonconforming donors.
11	III.B.	1. Defer indefinitely an individual who has ever had a positive test for HIV. 2. Defer indefinitely an individual who has ever exchanged sex for money or drugs. 3. Defer indefinitely an individual who has ever engaged in non-prescription injection drug use.	PPTA respectfully requests that FDA clarify the use of "indefinitely." Is FDA recommending that industry indefinitely or permanently defer individuals who test positive for HIV? This has two distinctly different meanings and may require changes to existing BECS. In addition, the terminology is inconsistent with "Guidance for Industry—Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry" **Recommendation** PPTA recommends that FDA is consistent with their terminology as it relates to individuals with a positive test for HIV.
13	III.C.6.	Male donors previously deferred because of a history of sex with another man, even one time, since 1977, may be eligible to donate provided that they have not had sex with another man during the past 12 months and they meet all other donor eligibility criteria[.]	PPTA respectfully asks that FDA confirm that individuals remain permanently deferred until such time that they present if that is what FDA intends. In terms of "may be eligible" to donate, what is FDA's position on a donor who was deferred because he provided false information on his sexual history at a previous donation? Because the donor provided unreliable information, he was permanently deferred. Are those donors to be considered for reinstatement?

			Recommendation PPTA suggests FDA provide clarity in the guidance indicating the individual should remain deferred until such time they present at the collection site and are evaluated for acceptance at that time.
13	III.D.2.	If you distributed blood or blood components collected from a donor who should have been deferred according to the recommendations in section III.B. of this guidance, we recommend that you notify consignees of all blood and blood components. We recommend that the consignee retrieve and quarantine the in-date blood and blood components collected from the donor. We do not recommend retrieval and quarantine of plasma pooled for further manufacturing into products that are manufactured under processes that include validated viral clearance steps, which have been shown to be robust in the clearance of lipid-enveloped viruses.	PPTA notes that FDA has not indicated a lookback time period. **Recommendation** PPTA respectfully requests that FDA not recommend any retrieval of unpooled units beyond PPTA's voluntary 60-day inventory hold standard based on existing viral inactivation/removal methods.
18	IV.1.	Revision of your donor education materials, DHQ and accompanying materials must be submitted to FDA as a prior approval supplement (PAS) under 21 CFR 601.12(b). Revision of a previously accepted DHQ and accompanying materials must be reported as a major change if you are revising the FDA accepted DHQ and accompanying materials to implement these new recommendations. Report such a change to FDA as a [PAS].	PPTA believes that the PAS requirement is unacceptable. PPTA requests that FDA work with the AABB Interorganizational task force to develop interim acceptable questions and other materials that can be used until the respective DHQs are accepted via FDA guidance. If FDA continues down the path of requiring a PAS, then FDA needs to send a clear message to the impacted donor community that they will not be able to donate at the time of final guidance issuance because of the licensing procedures. A PAS cannot even be prepared until after the final guidance is issued and interpreted. **Recommendation** PPTA respectfully recommends no more than a CBE-30 submission and preferably a CBE, as long as the changes are not less restrictive than the final guidance.

Conclusion

PPTA appreciates the opportunity to comment on the draft guidance and looks forward to continued work with FDA on revising the donor deferral recommendations for individuals at increased risk for transmitting HIV infection. PPTA welcomes from FDA any questions regarding these comments.

Thank you for your consideration.

Respectfully submitted,

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Plasma Protein Therapeutics Association

Attachment

Plasma Protein Therapeutics Association

July 2015

Country	MSM donor deferral policy	Notes
Argentina	**12 months**	• Contributing reason for change from lifetime deferral: Harmonizing policy for risky sexual behavior
Australia	12 months	• Individual states and territories all had their own version of indefinite deferral • 1996-2000: Rolling introduction of 12-month deferral • Contributing reason for change from indefinite deferral: Harmonizing policy for risky sexual behavior
Brazil	12 months	• Contributing reason for change from lifetime deferral: Harmonizing policy for risky sexual behavior
Czech Republic	12 months	• 2008: Lifetime deferral[i] • Contributing reason for change from lifetime deferral: Harmonizing policy for risky sexual behavior
Finland	12 months[ii]	• Contributing reason for change from lifetime deferral (2013): Risk analysis
Hungary	12 months	• Contributing reason for change from lifetime deferral: Harmonizing policy for risky sexual behavior
Japan	12 months[iii]	
Sweden	12 months	• 2008: National Board of Health and Welfare proposed that MSM should become eligible to donate blood, but only after 6-month quarantine period after sexual intercourse • From March 1, 2010: MSM were supposed to be allowed to donate blood, after 1 year of abstaining from sex, but blood banks rejected law, causing law to be delayed • Law was finally adopted and allows gay man to donate blood if he did not have any sexual contact in past 12 months with another man; *however, corresponding plasma is not allowed to be used for production of pharmaceutical products*[iv] • Contributing reason for change from lifetime deferral: Harmonizing policy for risky sexual behavior
UK (England, Wales, Scotland)	12 months	• 1985: Lifetime deferral • Contributing reason for change from lifetime deferral (September 2011): Harmonizing policy for risky sexual behavior • Due to theoretical risk of vCJD transmission posed by UK plasma, plasma is sourced from plasma collection centers in USA, primarily from Life Resources Inc., which is wholly owned by UK Department of Health.[v]

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Canada	**5 years**	• 1983: Lifetime deferral suggested; response criticized, suggestion withdrawn • 1985: Lifetime deferral mandated • 2012: 5-year deferral suggested • Contributing reason for change from lifetime deferral (2013): Risk analysis, and extensive consultation with scientific experts and with patient and community groups
New Zealand	5 years	• 1998: 10-year deferral • Contributing reason for change from 10-year deferral (2008): Implemented single sample NAT for HIV, HBV, HCV
Austria	**Lifetime**	• According to paragraph 5 of the BSV (Blutspendeverordung), people that have constant risk behavior for infection with sexually transmitted diseases, especially HIV and HBV, are permanently deferred[vi]
Belgium	Lifetime[vii]	
China	Lifetime[viii]	
Croatia	Lifetime[ix]	
Denmark	Lifetime	
France	Lifetime	• In June 2012, French Minister of Social Affairs and Health, Marisol Touraine, announced that she would like to remove permanent deferral for men and replace it with criterion related to risk practices[x] • In April 2015, the Court of Justice of the European Union declared[xi] that the Tribunal administrative de Strasbourg will have to determine whether, in France, in the case of a man who has had sexual relations with another man, there is a high risk of acquiring severe infectious diseases that can be transmitted by blood. For the purposes of that examination, the Tribunal administrative de Strasbourg, will have to take account of the epidemiological situation in France[xii]
Germany	Lifetime	• Not only MSM are deferred: Any person whose sexual practices involve clearly increased risk, compared with general population: heterosexual persons with high-risk sexual practices, sexual intercourse with frequently changing partners, male and female prostitutes[xiii]
Hong Kong	Lifetime	
Iceland	Lifetime	
Ireland	Lifetime[xiv]	
Israel	Lifetime[xv]	
Lebanon	Lifetime[xvi]	
Netherlands	Lifetime	
Northern Ireland	Lifetime[xvii]	
Norway	Lifetime	
Slovenia	Lifetime	
Switzerland	Lifetime	
Turkey	Lifetime[xviii]	

USA	Lifetime	• 1983 • Draft guidance dated May 2015; comments due July 14: 12 months
Chile	**No specific policy**[xix]	• Assessment of risky sexual behavior, regardless of orientation (2013)
Italy	No specific policy	• Assessment of risky sexual behavior, regardless of orientation
Mexico	No specific policy[xx]	• Changed from lifetime deferral • Assessment of risky sexual behavior, regardless of orientation (2012)
Poland	No specific policy	• Assessment of risky sexual behavior, regardless of orientation
Portugal	No specific policy[xxi]	• Assessment of risky sexual behavior, regardless of orientation (2010)
Russia	No specific policy	• Assessment of risky sexual behavior, regardless of orientation
South Africa	No specific policy[xxii]	• 2001: 5-year deferral instituted by new national blood service • 2006: 6-month deferral instituted • Assessment of risky sexual behavior, regardless of orientation (2014)
Spain	No specific policy	• Assessment of risky sexual behavior, regardless of orientation
Thailand	No specific policy[xxiii]	• Assessment of risky sexual behavior, regardless of orientation

Source (unless otherwise noted): Wilson K, Atkinson K, Keelan J. Three decades of MSM donor deferral policies. What have we learned? Int J Infect Dis. 2014 Jan;18:1-3. doi: 10.1016/j.ijid.2013.09.016. Epub 2013 Oct 30.

[i] Decree of Ministry of Health of 15 April 2008 – Decree No. 143/ 2008 Coll., Article 1 of Part B of Annex 3

[ii] Finnish Red Cross Blood Service. Ban on donation of blood imposed following male-to-male sexual contact to become temporary. December 13, 2013. http://www.veripalvelu.fi/news/2728

[iii] Seed CR, Kiely P, Law M, Keller AJ. No evidence of a significantly increased risk of transfusion-transmitted human immunodeficiency virus infection in Australia subsequent to implementing a 12-month deferral for men who have had sex with men. Transfusion. 2010 Dec;50(12):2722-30. doi: 10.1111/j.1537-2995.2010.02793.x

[iv] The Swedish National Board of Health and Welfare (Socialstyrelsen)

[v] Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)

[vi] Blutspendeverordnug (Blood Donation Decree)

[vii] Avis du CSH relatif à la sécurisation maximale de la collecte et de la transfusion sanguine (CSH 8094)

(Validé par le Collège Transitoire en date du 18.02.2005) (Opinion of CSH on the maximum security of the collection and Blood Transfusion (HSC 8094) (Validated by the Transitional College dated 18.02.2005)) [French]
[viii] Yang Y. China says lesbians may donate blood, but not gay men. Latitude News. http://www.latitudenews.com/story/china-says-lesbians-may-donate-blood-but-not-gay-men/ accessed October 20, 2014
[ix] PRAVILNIK O KRVI I KRVNIM SASTOJCIMA (ORDINANCE The blood and blood components) [Croatian]
[x] Decree of January 12, 2009, defines selection criteria for blood donor
[xi] http://curia.europa.eu/juris/document/document.jsf?text=&docid=164021&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=348629 accessed July 1, 2015
[xii] http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2009/10/WC500004016.doc accessed July 1, 2015
[xiii] Richtlinien zur Gewinnung von Blut und Blutbestandteilen und zur Anwendung von Blutprodukten (Hämotherapie) - Erläuterungen zum Blutspende-Ausschluss von Männern, die Sexualverkehr mit Männern haben (Guidelines for collection of blood and blood components and the use of blood products (hemotherapy) – Annotation on deferral of MSM)
[xiv] Irish Blood Transfusion Service. Exclusion of Men who have Sex with Men from Blood Donation. November 7, 2011. https://www.giveblood.ie/Become_a_Donor/Keeping_Blood_Safe/Safety/MSM.html
[xv] Kalman A. Health Ministry to reconsider blood donations by gay men. The Times of Israel. March 24, 2013. http://www.timesofisrael.com/health-ministry-to-review-homosexual-blood-donations/
[xvi] Donner Sang Compter. Preparing yourself to Give Blood. http://www.dsclebanon.org/en/facts/1/ accessed October 20, 2014
[xvii] BBC News. Health Minister Poots stands by ban on gay blood donors. June 17, 2012. http://www.bbc.com/news/uk-northern-ireland-18476308
[xviii] Radikal (Radical). 'Erkek erkeğe birlikte oldunuz mu?' ('Have you had MSM?') [Turkish]. December 19, 2011. http://www.radikal.com.tr/turkiye/erkek_erkege_birlikte_oldunuz_mu-1072945
[xix] The Santiago Times. Gays and lesbians in Chile now allowed to donate blood. April 25, 2013. http://santiagotimes.cl/gays-and-lesbians-in-chile-now-allowed-to-donate-blood/
[xx] Consejo Nacional para Prevenir la Discriminación (National Council to Prevent Discrimiation) (CONAPRED). Celebra Conapred entrada en vigor de norma de donación de sangre, libre de discriminación (Celebrate Conapred entry into force of standard blood donation, free from discrimination) [Spanish]. http://www.conapred.org.mx/index.php?contenido=noticias&id=3334&id_opcion=108&op=214 accessed October 20, 2014
[xxi] Resolução da Assembleia da República n.º 39/2010 Recomenda ao Governo a adopção de medidas que visem combater a actual discriminação dos homossexuais e bissexuais nos serviços de recolha de sangue (Assembly Resolution No. 39/2010 Republic Urges the Government to adopt measures to combat the current discrimination against homosexuals and bisexual men in the service of collecting blood) [Portuguese]
[xxii] South African National Blood Service (SANBS). Change in Donor Acceptance Criteria. Blood Beat. June to August 2014. 6-8
[xxiii] Thai Red Cross Society. Blood Donor Criteria. January 1, 2013. http://english.redcross.or.th/article/1114