- Not acceptable for setting up of parallel system (PD) as impact on future of blood programme and expose donors to unacceptable procedures and exploited

In-depth analysis of the current situation on SS based on VNRBD

- What is happening on the ground
- How countries are assessing and estimating national needs, already such committee existing to address safety and proper use but not what is the need and projection/prioritization
- Three development stages
  - stepwise progression: from whole blood transfusions towards blood components for transfusion and further towards plasma fractionation, aligned to the state of development of the national health system)
  - It is recognized that the implementation of a policy for self-sufficiency for blood and blood products generally follows a stepwise progression in scope, from whole blood transfusions towards blood components for transfusion and further towards plasma fractionation, aligned to the state of development of the national health system. Achieving self-sufficiency in the supply of blood and blood products from VNRBD and ensuring the security of that supply are important national goals and countries may set different timelines depending on their health system development in the achievement of these goals.
  - Large volumes of plasma recovered from whole blood donations based on VNRBD, mainly in low and middle-income countries, are currently not used and are discarded because of concerns that quality requirements are not being met for plasma for fractionation to manufacture plasma-derived medicinal products.
- What are the challenges and gaps to be address
  - Emerging threats (increasing demand by emerging economy, infections, increasing age population) including commercialization of donation of blood and plasma- will be addressed by governance and optimal use
  - Impact of globalization/ free trade and avoid shake-out/monopoly by few companies

Chapter 5

Working towards self-sufficiency based on VNRBD

Additional discussion point in Sept 2012:

1. Start with summary of chapter 1-4

2. Countries have made steps towards self sufficiency based on VNRBD for 6 driver products: WB, plasma, platelets, FVIII, IVIG, albumin in different level of health development

By different stage: stage 1: Whole blood

Stage 2: Red cells, plasma and platelets

Stage 3: PDMPs

3. Recommendations from Expert Consensus Statement- each strategy: to give country experiences on how to achieve this (highlighting countries example) including labeling. Some country examples

AFRO: South Africa (Fractionation), Uganda, Malawi, Burkina Faso, Namibia, Eritrea???

AMRO: Nicaragua, Brazil (Fractionation), Canada (Chapter 3), Chile, United States (Chapter 3- if Gov really takes responsibility, the likelihood of self-sufficiency is higher), Mexico (Volkow's paper)

EMRO: regional self-sufficiency- Saudi Arabia and GCC countries?, UAE; Iran, Algeria, Tunisia, Morocco

EURO: info/ data Giles Folea, Netherland, France- Donor association anger when LFB bought paid plasma from Czech Republic, UK (chapter 3, contingency planning) open market in EURO, e.g. LUX stop contract fractionation stopped as can't compete with pharma (chapter 3), Scandinavian countries- Finland, Denmark (? How protect market), Austria- bringing people from Hungary for paid plasma (Chapter 3) and issues of transparency on a regular basis, not level playing field

SEARO: Sri Lanka, Thailand; Indonesia,

WPRO: Japan, Australia, Singapore, Hong Kong, New Zealand, Malaysia, Laos FR to VNRBD, Vietnam, China

4. Incremental stepwise process

Content from January 2012 meeting

National

- Ways to achieve SS based on VNRBD (strategies, mechanisms and options) - also refer to

recommendations to NHA

What can countries do/adopt to achieve SS based on VNRBD

- The 'how' and supported by experience: What has been done at country and regional level
- Country Examples for both BCTs and PDMPS (developed and developing countries; Nicaragua (since 1960's), US border issue, discarded plasma in Africa, expansion of commercial plasmapheresis (?), Germany (travel cost issue), China, Netherland/Japan (market force), etc
  - Country examples (Australia/NZ(govt control), Canada (100% SS more fragile, risk-hedge), China (eg in HIV in Henan province, 25 fractionators, allow albumin and FVIII, others import ban), France (mutual recognition, licensing requirement, import regulation), Japan (source plasma-control by Gov. to make it more competitive, labeling and informed consent), Netherlands/Belgium (subsidies,), HK/Singapore/Malaysia (contract fractionation), Thailand (plant construction), US (request company of export limitation), other international/regional organizations (EU/CoE), Luxembourg, NGOs, etc, Regional cooperation: Saudi Arabia, South Africa, Brazil, Norway, Finland and Italy- profile, ask country to write- part of action plan, Ireland
  - Approach countries to write
  - Free movement of people and goods, but Article 152 of EU treaty: Restrictions: Clinical practice and blood donation but with loophole
  - Erosion of system
- Enhancing VNRBD system and eliminating paid donation/family replacement (use WBDD) and also the Strategies to dry out the need and incentives commercial plasma collection
- Need for strengthening blood system, governance, system, mechanism, accountability, organization, nationally coordinated blood and plasma programme (integration)
- Assessing and estimating national needs (detailed tools and guidance will be developed by WHO)
- Quality improvement (particularly plasma)
- Construction of Plant vs. Contract Fractionation (incl. in-depth explanation of contract fractionation)
- Contract fractionation-accepted, where Public-Private partnership worked/ acceptable.
- Governance, coordination, organization, Legislation/Regulations /regulatory mechanism-inspection, ensuring compliance/Incentives to use BCT/PMDP based on VNRBD

- Promotion of Optimal Use of BCT/PMDP
- Missing elements in the system and compliance issues
- Exchange of BCT/PMDP, plasma and intermediates between countries/ governmental cooperation including technology transfer
- Public-private partnership encouraged in blood system but it's the blood donation should be public affair and public institution, but also need info about the supply. For collection: may be delegated to not-for-profit entity but still need to be governed, sustainable, safety issues, etc (against profitability of collecting blood)
- What does it mean to blood chain concept if we only act on blood donation segment- no change in the chain, fx of bld establishment- donor/community interface and clinical interface in terms of demand, regulated by government. Government to decide which part of the interface to be delegated to the private sector, transparent mechanism, create protective coat around blood donation
- Managing the transition/ issues to be addressed in the transition/ Precautions/ preparedness/ Planning the transition / road map
- Put in place to ensure patient access should not be compromised but is it feasible- proper timeline, labelling, careful assessment of pts need, increasing yield, efficiency of the system- testing, inventory
- Access to those not having is bigger issue than worries of reducing access (80% pt with haemophilia have no access to coagulation factors)
- Decision on paid or unpaid system is dependent upon hospital administrators not clinical or patient need. Changing hospital behaviours, not structure
- Products for rare disease/cases
- Trade implications, particularly in relation to WTO rule- existing WHO/WTO guidelines on risks to public health, fair and ethical trade, Not anti trade, demonstrable harm to public health is a loop out FTA. Industry argument: no evidence of unsafe- first study: P Strengers- IVIG
- Incorporate and match with the 12 recommendations (what) to NHA in the Consensus Statement and expanded (why- in rationale and how)
- To include strategies for VNRBD programmes in chapter 5 which also address clinicians role in the clinical interface- appropriate use/ estimation of need and requirement of blood products/ stop asking FR- as a strategy for phasing out FR
- FR system ad hoc, not feasible or sustainable to establish blood compo programme-logistic challenges, also linked to stages of blood system development
- Timeline Melbourne Declaration: strive towards 100% VNRBD by 2020.
- Why country not successful in self-sufficiency- therefore need a global governance

mechanism, despite many resolutions- intro

- New move away from monopoly- Italy, Finland, Middle-east for plasma fractionation
- National control of demand and tremendous advantage in controlling health cost, from industry driven system
- Discussion on open borders- against: threat SS vs. for: dumping of 'waste'- like FVIII
- Threats and market forces- cannot maintain status quo - global governance mechanism
- LFB: need more plasma- EFS increase plasmapheresis, but also buy from Czech Republic

Global Strategies

- Role of WHO (technical guidance, facilitation,,,)
- Need for an international framework, support implementation, global governance mechanism, focusing on regulatory authorities- public accountability and its feasibility

Action plan:

What need to be done	Who	By when
Chapter 4 - 1st draft circulated - Review	PC ND	 21.09.12 25.09.12
Chapter 2 - 1st draft - Update re today discussion	To be decided NAA	??
Chapter 3 - 1st draft agreed by subgroup member - Review	SZ	 21.09.12
Chapter 5 - F/up re country stories for those not participating in Sept 11 meeting - Country profile of those participating in Sept 11 -Content	ND PC PC	 Sept/Oct Oct/Nov
Chapter 1 -Structure -Content	PC	 After Nov 2012
Japanese case study and data from Japan	KJ and SN	19.09.12
Finalize letter to EMA and FDA, attaching Consensus Statement ▪ Antibodies of HIV, HCV and HBsAg- 1st time tested and repeat tested ▪ NAT only positive for HBV, HIV, HCV- 1st time tested and repeat tested ▪ Prevalence in 1st time tested and incidence of repeat done ▪ Broken down by voluntary and compensated/paid donors ▪ Anonymized aggregated	ND	19.09.12

data		
Additional literature searches and update as originally till end 2010 Individual search term- Chapter authors to identify	SZ and YJP to brief SS	
Editorial group meeting after 2nd round of draft	All	2nd week January 2013
Critical review		Jan/Feb
Production		March 2013
Policy-Maker Forum		June 2013

資料２－１

"National Consultative Forum: "Towards achieving sufficient blood supply based on 100% voluntary non-remunerated blood donations in Cambodia"

5 – 6 December 2012, SOFITEL Phnom Penh Phokeethra Hotel, Phnom Penh

Jointly organized by National Blood Transfusion Center (NBTC)/Ministry of Health (MoH), WHO and Nagasaki University in collaboration with US Centre for Disease Control and Prevention (US CDC)

Day 1 – Wednesday 5 December		
7:30 – 8:30	Registration	
Inauguration and Opening Session		
8:30 – 9:30	**Inauguration Address:** ▪ NBTC ▪ Nagasaki University ▪ CDC Atlanta ▪ WHO ▪ Ministry of Health	 Dr Hok Kim Cheng, Director of NBTC Prof Yasushi Miyazaki Dr Anthony Marfin Dr Pieter van Maaren, Representative of Development partners, WHO Representative in Cambodia HE Prof Eng Huot, Secretary of State, MoH
9:30 – 9:50	**Coffee break & Group photo**	
9:50 – 10:50 **(propose 45' presentation and 15' Q & A)**	**Global Strategy on Blood Safety:** ▪ Four WHO strategic directions for achieving 100%	Dr Neelam Dhingra, Coordinator, Blood Transfusion Safety, WHO Headquarters, Geneva.

	voluntary non-remunerated blood donations (VNRBD). ▪ Melbourne declaration. ▪ Global data of Blood Safety (highlighted VNRBD in Asia).	
10:50 – 11:30 (propose 30' presentation and 10' Q & A)	**Recap of the overall National Strategic Plan 2013 -2017:** ▪ Four pillars of NSP 2013 -2017. ▪ Elaborate on the Third pillar : Community Blood donation motivation.	Dr Yos Phanita, Deputy General Director for Health, MoH
11:30 – 12:00 (propose 20' presentation and 10' Q & A)	**Current status of VNRBD in Cambodia:** ▪ Overall results (key indicators) of Blood donations from the past to present. ▪ VNRBD in NBTC vs Provincial Blood Transfusion Centres (PBTCs).	Dr Sek Mardy, Technical Officer for Blood Safety, WHO Cambodia
12:00 – 13:30	**Lunch break**	
13:30 – 13:50 (propose 15' presentation and 5' Q & A)	**"1000 liters of blood donations campaign" by United of Youth Federation of Kandal Province (UYFKP):** ▪ Background: campaign initiative. ▪ Goals. ▪ Activities and plans (How the campaign contributes to achieve 100% VNRBD).	Mr Chhoeun Bunnarith, Director of Health Awareness Program of UYFKP
13:50 – 14:10 (propose 15' presentation and 5' Q & A)	**Mobilisation of VNRBD through ABC Cambodia Radio:** ▪ Goals of ABC Cambodia to contribute to achieving 100% VNRBD. ▪ Activities and plans to reach ABC Cambodia's goal.	Mr Tang Sokhy, ABC Cambodia Radio adviser

14:10 – 14:30 (propose 15' presentation and 5' Q & A)	**Establishing VNRBD role model among students:** ▪ Goals of Phnom Penh International University (PPIU) to contribute to achieving 100% VNRBD. ▪ Activities and plans to reach PPIU's goal.	Ms Tep Kolap, Rector of PPIU
14:30 – 15:15 (propose 30' presentation and 15' Q & A)	**Best practice of Calmette hospital in supporting National Blood Transfusion Services:** ▪ Blood use, blood demand planning. ▪ Plan of conversion Family Replacement Donor to VNRBD to contribute to achieving 100% VNRBD. ▪ Plan to build trust by improving communication of hospital staff to patient and NBTC staff .	HE Dr Chhieng Ra, Director of Calmette Hospital
15:15 – 15:30	**Coffee break**	
15:30 – 16:15 (propose 30' presentation and 15' Q & A)	**"Experience of Japan in achieving 100% VNRBD"**	Prof Yasushi Miyazaki & Dr Yun Fukuyoshi, Nagasaki University, Japan
16:15 – 17:00 (propose 30' presentation and 15' Q & A)	**Experience of Philippines towards achieving 100%VNRBD:** ▪ Brief of the National Blood Program in Philippines. ▪ Current status and how to achieve 100% VNRBD. ▪ How blood safety program sustains.	Dr Christie Monina Nalupta, Director of Blood Services, Philippines Red Cross, Philippines.
Day 2 – Thursday 6 December		
8:30 – 8:45	**Recap day 1**	Dr Ly Vanthy, Deputy director of US CDC Cambodia Office
8:45 – 9:05 (propose 15'	**Public private partnership contributes to achieving 100%**	Okgna Lau Vann, Director of Vital Corporation Co.Ltd

presentation and 5' Q & A)	**VNRBD:** ▪ Demonstration of their success in recruiting VNRBD. ▪ Lesson learned and propose future plan.	
9:05 – 9:50 (propose 30' presentation and 15' Q & A)	**Experience of Vietnam towards achieving 100% VNRBD:** ▪ Brief of the National Blood Program in Vietnam. ▪ Current status and how to achieve 100% VNRBD. ▪ How blood safety program sustains.	Dr. Ngo Manh QUAN, Head of VNRBD promotion Department, National Institutes of Haematology and Blood Transfusion, Vietnam.
9:50 – 10: 05	**Coffee break**	
10:05 – 10:50 (propose 30' presentation and 15' Q & A)	**Experience of Lao PDR towards achieving 100% VNRBD:** ▪ Brief of the National Blood Program in Lao PDR. ▪ Current status and how to achieve 100% VNRBD. ▪ How blood safety program sustains.	Dr Chanthala Suksakhone, Deputy director of National Blood Transfusion Centre, Lao Red Cross, Lao PDR
10:50 – 11:20 (propose 20' presentation and 10' Q & A)	**"KAP survey and IEC"** ▪ Main findings. ▪ Translate from findings to actions. ▪ Available IEC.	Ms Michelle Milette, Volunteer Communication Officer from Australian Red Cross (ARC).
11:20 – 11:45 (propose 15' presentation and 10' Q & A)	**"Planned supports for VNRBD program in Cambodia"**	Ms Emily Tonk, Program Manager – Technical International Humanitarian Blood Projects Australian Red Cross (ARC), Blood Service
11:45 – 12:00	Video show: "The way to reach 100% VNRBD in Cambodia"	
12:00 – 13:30	**Lunch break**	
13:30 – 14:00 (propose 20'	Provide quality donor service and care:	Dr Chhorn Samnang, Deputy director of NBTC

presentation and 10' Q & A)	▪ Donor services. ▪ Donor counseling. ▪ Donor care.	
14:00 – 14:40 (propose 30' presentation and 10' Q & A)	**"Strategic plan year 1 activities in the community and donor motivation"**	Dr Hok Kim Cheng, Director of NBTC
14:40 – 15:40 (propose 60' Q & A and recommendations)	**Plenary discussions and recommendations:** " How to translate the knowledge, lesson learned from the National Consultative Forum into action in order to contribute to achieving 100% VNRBD by 2020"	Dr Hok Kim Cheng, NBTC Dr Neelam Dhingra, WHO Dr Anthony Marfin, US CDC Ms Alyson Pearce, ARC
15:40 – 16:00	**Coffee break**	
16:00 – 17:00	**Closing address:** ▪ NBTC ▪ WHO ▪ US Ambassador ▪ Minister of Health	 Dr Hok Kim Cheng Dr Neelam Dhingra Mr William E. Todd HE Dr Mam Bun Heng

資料２－２

Brief Summary:

The author gave an opening presentation on strategic directions for achieving 100% voluntary non-remunerated blood donations (VNRBD), introduce the action framework, goal and strategic direction for a country to achieve 100% voluntary non-remunerated blood donations. The purpose of this presentation is to set the tone for the two-day consultation.

Other presentations included the introduction of National Strategic Plan 2013-2017; current status of VNRBD in Cambodia; experiences of the recruitment of VNRBD by the United Youth Federation, ABC Cambodia Radio, International Phnom Penh University, Calmette Hospital, Vital Corporation Co. Ltd. Experiences of Japan, Lao PDR, Philippines and Viet Nam were also shared.

270 representatives participated in theforum. They are from Ministry of Health, Phnom Penh Municipality provincial government and health department, national and provincial reference hospitals, Ministry of Education, Universities, Cambodia Red Cross, NGOs, Media and Banks, Mobile companies and private sectors.

There were very good discussions on how to raise awareness of VNRBD in society, how to produce a correct perceptions on blood donations among the population. Initial success has been achieved through the youth organization in one province (Kandal province), through the cooperation with ABC Cambodia Radio and Vital Co. Ltd. A key topic discussed is how to scale up these initial and localized programmes so that the voluntary blood donors programme enjoy wider societal support and the numbers of VNRBD increase more rapidly.

With the recent positive developments, which include the high-level national political commitment and financial and technical support by development partners, Cambodia has great potential to increase the number of voluntary non-remunerated blood donations and eventually achieve the goal of safe and sufficient blood supply based on 100% voluntary donations. The MoH's goal to work towards achieve 100% VNRBD by 2017 was also announced during the closing ceremony.

In addition to the need to strengthen the capacity to engage the community and to educate, recruit, retain blood donors, wider issues need to be addressed to create an enabling environment and ensure a sustainable development of the blood donor programme and national blood transfusion services. These include:

- Develop national coordination mechanism and management in developing a national blood system that is fully integrated into the health-care system with viable and appropriate funding support.
- Strengthening the quality system of NBTC, including developing system to assess donors' suitability to donate blood and provide blood donor counseling.
- Coordination of actions and different partners and multiple donors to cover national priorities that have been identified in the strategic plan and ensure a more harmonized and efficient mode of cooperation that take into account existing systems at country level.

The author had a meeting with officials from the Centers for Disease Control and Prevention (CDC) country and Atlanta offices and discussed the status of the current WHO CDC Co-Ag project, the roles of WHO in future support, with the anticipation of the end of the current Co-Ag by September 2013 and the start of new arrangement and entrance of new partners, including American International Health Alliance (AIHA) and Nagasaki University.

The author also attended the meeting with National Blood Transfusion Centre (NBTC), CDC, Australian Red Cross Blood Service and Nagasaki University to discuss the follow up activities and coordinate a joint operational plan of support for 2012. After the meeting, the author, the director of NBTC and other development partners also visited the NBTC.

Recommendations/Follow-up points:

1. To follow up with each participating organization on the implementation of the recommendations; to request the participating organizations to nominate a key contact point to coordinate donor recruitment activities in their organization and to liaise with NBTC

2. To develop and implement plan:
- to disseminate general information on blood donation, for example the need of blood donations, donation intervals, the message that "blood donations do no harm to one's health",
- to dispel myths and wrong perceptions among the population about the selling of blood, and
- to build the trust of public to the NBTC

3. To scale up the youth blood donor programme based on the Kandal Province and Universities; to develop university student donation programme in the public university with the potential support of Nagasaki University.

4. To increase collaboration between provincial community organizations and youth groups and the PBTCs to increase VNRBD, in particular raising awareness and trust in the communities in the provinces outside Phnom Penh.

資料3

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展望

韓国における血漿分画：　国内自給に向けての働きかけ

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概観

製薬加工における血漿の供給は、韓国内において、収集された全血から取り出された余剰血漿と血漿瀉血からの元血漿より構成されている。不足分は通常、輸入により補われている。2009年における分画のための血漿供給量は、計608,352リットルであり、そのうちの430,267リットルは国内で供給された。ゆえに国内需要の点から見て、国内自給率は、約71%である。

血漿分画製剤の供給に関する基本的政策は、‘血液の国内自給’と‘営利主義の除外’に基づいた、世界保健機構と国際赤十字連合の勧告に従い1978年に政府により構築された。その時より、政府は血漿分画のための公共設備を整備し、1986年の薬事法改訂を経て、韓国赤十字に血漿と血漿製剤の供給の権限を与えた。

この政策により、血漿分画と、輸入の許可、潜在的輸入採血センターの検閲と血漿輸入者の定期的な監査の権限を、韓国赤十字に承諾し実施させてきた。さらに、韓国赤十字は、最終生成物の製造及び血漿分画センターを1991年に設立するという計画を進めてきた。しかしながら、過剰投資争議のため初期の計画は断念し、現在韓国赤十字はほんの2、3の、20%アルブミン溶液、免疫グロブリン分画製剤、クレオプレシピテート（寒冷沈降物）のような中間生成物を製造するために血漿加工している。これらの中間生成物は、薬品会社－グリーンクロス社とSKケミカル社－に購入され、さらに最終生成物として製造されている。

公営政策のおかげで、国内の血漿製品の価格は他の国々と比べ適度に保たれている、そして、国内における電気泳動機器はそれらの競合性を改善させることができた。それに反して、現在の製造連鎖はやや不合理な点がある。この組織的な不合理さが今日までに血漿の国内自給に達するのに実際的な障害となっている。

血漿派生物の分画工程

取り出されたもしくはアフェレーシスされた血漿および冷凍血漿を最終的な生成物にするには、いくつかの段階を通して解凍され、加工処理されなければならない。遠心沈殿法とエタノール析出を通して、凝固因子 IX, 凝固因子 VIII (FVIII)、分画 II (フィブリンシーラントとして使用)、免疫グロブリン (IG)、分画 IV (抗トロンビン)、および分画 V(アルブミンに加工)をそれぞれに分画する。血漿 1 リットルで、0.63 ボトルの (250 単位/ 1 ボトル) 分画 VIII、1.5 ボトル (50ml/ボトル) の免疫グロブリン及び 1.4 ボトル (100ml/ボトル) の 20%アルブミン溶液を産出する。

グリーンクロス社は 12 種類の最終生成物を、一方 SK ケミカルは 2 種類だけ生産している。2009 年度のグリーンクロスの市場占有率は売り上げ全体の約 87%を占めている。医薬品の中でも、破傷風免疫グロブリン、B 型肝炎免疫グロブリン及び水痘ヘルペス免疫グロブリンには、特別な血漿を必要とし、韓国の血液管理法でこれらの血液の有償献血を禁じているので、輸入しなければならない。2009 年の総売り上げは約 1780 億韓国ウォンである (表 1)。

世界と国内市場における最近の変化

世界における分画用血漿の年間の需要は約 25 億リットルであり、その中でアメリカは供給量の約 64%を占め、それは主に営利化された血液システム故である。他の多くの国々は、自発的無償の血漿献血の政策をもつ。

全ての血漿製品の中で、免疫グロブリンの世界的市場占有率おおよそ 43%、一方アルブミン溶液はほんの 13%である。免疫グロブリンの医療適用が着実に拡大しているので、免疫グロブリンの需要は 2012 年までに年々5-8%増えると予測される。反対に、アルブミンの有効性に関する論争が、需要の段階的な減少を引き起こしているのであろう。韓国では顕著な対比が見られる。アルブミンの市場占有率は 35-40%で、免疫グロブリンは 9%以下である。アルブミンの著しい消費は、処方における伝統的な傾向によるもので、またパイオニア的な規定もなく、消費過剰慣習はしばらく続くと思われる。反対に免疫グロブリンの需要は、徐々に増えているようである。凝固因子の需要は、遺伝子組み換え製品が血漿分画製剤に徐々に取って代わっているので、減少傾向にある。

世界的に血漿製品の価格は、この十年の間の不均衡な需要と供給のため、大きく変動してきた。現在の状況は、以前よりは大いに安定したが、輸入血漿の価格が世界市場の状況によりいつ何時にも変動するので、これが国内自給を達成すべきもう一つの理由である。

韓国における供給の見通し

血漿国内自給に関する我々の定義は、主としてアルブミンの需要—すべての血漿製品の中の一番大きな部分を占める—に基礎を置くべきである。それ故に、免疫グロブリンの需要が増加傾向にあるという事実を考慮して、分画に必要な国内血漿需要の合計は 650,000 リットルあたりをさまよっている。輸入すべき特別な血漿 50,000 から 100,000 リットルを引くと、血漿国内自給の

ための実際の目標は、550,000 から 600,000 リットルであろう。

1991 年の血漿フェレーシスの導入後、2009 年には韓国赤十字の血漿採血の数は 465,350 に達した。血漿献血の重要性に対する献血者の意識が普及したのと同様に、献血センターの設立が、この顕著な成長に重要な役割を果たした。しかしながら、輸血用血液の不足はいつも血漿の供給に影響してきたので、韓国赤十字は新鮮な血液製品の必要性を優先すべきである。過去 5 年間における血漿供給を見直すと、血漿国内自給率は 2007 年に 46%という低さに落ちこみ、これは重大な全血の国内不足（表 2）に相互的に関係している。その年において、韓国赤十字の新設製造工場の閉鎖時期の延長にともなう再建が、もう一つの要因であろう。2009 年には献血者の増加によって、血漿国内自給率は 71%まで回復した。2009 年における約 2.57 億の献血を考慮し、1 年間の目標を 600,000 リットルとすると、あと追加血漿 340,000 リットルの採集量で、血漿国内自給に達することとなる。献血者の補充と保持が継続的に増加すれば、これは合理的に達成可能な目標である。

問題と提案

現在の血漿供給連鎖において、いくつかの潜在的脅威として不合理な矛盾点がある。もっとも重要な要因は、血漿および中間生成物の価格が、韓国赤十字と薬品会社の交渉によって決定されていることである。だから採血及び製造にかかる費用の増加はほとんど適正には保証されない。これは、血液センターと血漿分画センターの運営に関して、韓国赤十字の財政問題へと導くであろう。核酸増幅テストの実施または血液の安全性を改善するためのインベントリー・ホールドのようないくつかの要因により血漿アフェレーシスの費用は継続的に増加している。最終生成物の価格設定に一致して、政府による血漿価格の定期的な見直しと価格設定が、この状況を解決するのに必須であると思われる。

現在の二重価格制度は、取り出された血漿とアフェレーシスされた血漿の採取費用の差の結果であり、韓国赤十字の血漿分画センターの稼働率を最適レベルより下になることを余儀なくしている。ゆえに、原材料費の差による中間生成物の二重価格制度の適用は、韓国赤十字の血漿分画センターの効率を強化するために十分検討すべきである。

最後に、我々は血漿製品の公共管理政策における韓国赤十字の元々の役割の創意について考えるべきである。日本では、献血者は血漿国内自給という概念を容易に受け入れ、血漿を寄贈している、それは日本赤十字がよく知られた非営利団体であり、様々な種類の最終生成物を製造しているからである。一方韓国では、一部の人々は血漿を寄贈することに対して、薬品製造利益を上げるために使われるのではと疑問を持っている。故に、理想的な韓国赤十字の役割及び責任と、医薬品産業は、公共利益の最大化するためと、血漿国内自給の目標に達するために議論し問題解決すべきである。

表1. 最近3年における血漿製品の国内市場シェア(億韓国ウォン)

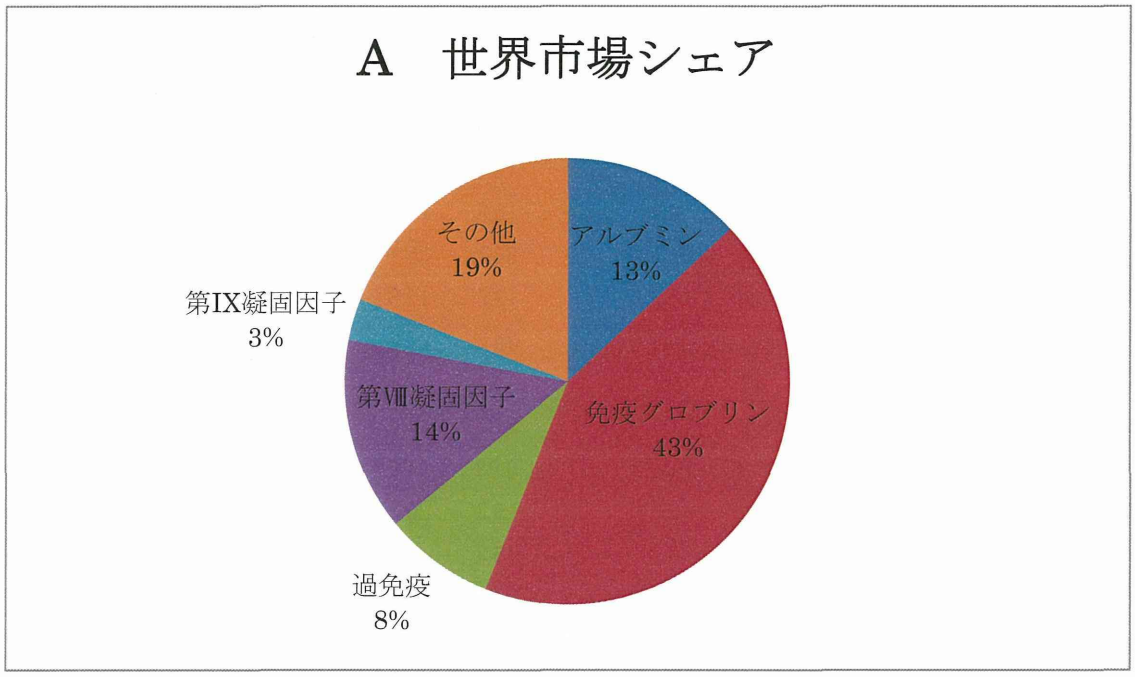
製品名	2007			2008			2009		
	SK	GC	小計	SK	GC	小計	SK	GC	小計
アルブミン	19.6	49.7	69.3	21.4	43.9	65.3	24.8	52.1	76.9
IV免疫グロブリン	2.9	11.2	14.1	3.7	12.4	16.1	4.1	15.5	19.6
破傷風免疫グロブリン	0.8	9.8	10.6	0	10.8	10.8	0	13.1	13.1
B型肝炎免疫グロブリン	0.7	30.4	31.1	0	36.7	36.7	0	42.3	42.3
抗トロンビン	-	11.0	11.0	-	12.6	12.6	-	15.6	15.6
凝固因子VIII	-	33.1	33.1	-	30.2	30.2	-	36.7	36.7
凝固因子IX	-	0.2	0.2	-	0.3	0.3	-	0.5	0.5
水痘ヘルペス免疫グロブリン	-	0.04	0.04	-	0.05	0.05	-	0.04	0.04
ガンマグロブリン	-	0.03	0.03	-	0.03	0.03	-	0.04	0.04
ヒストブリン	-	0.3	0.3	-	0.3	0.3	-	3.5	3.5
フィブリン・シーラント	-	5.4	5.4	-	6.3	6.3	-	9.6	9.6
フィブリノゲン	-	0.03	0.03	-	0.01	0.01	-	0.01	0.01
計	24.0	151.2	175.2	25.1	153.6	178.7	28.9	188.9	217.8

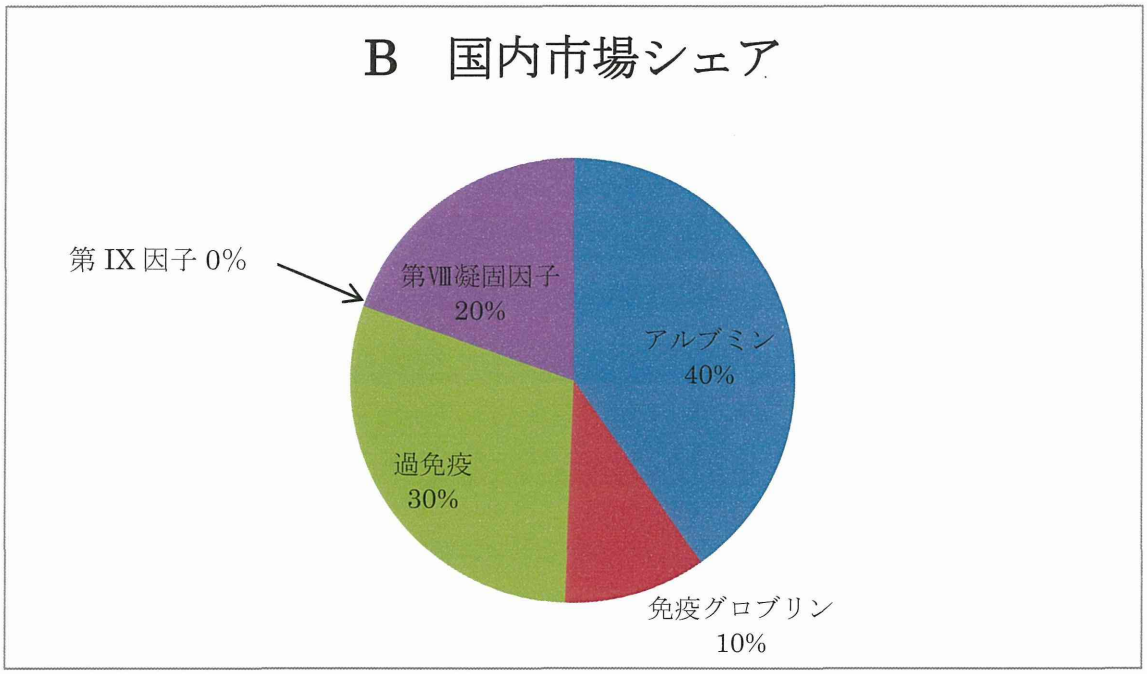
略称: SK、SKケミカル、GC、グリーン・クロス

表2. 最近5年間の国内、輸入血漿供給量の変化

年	国内血漿(L)	輸入血漿(L)	計 (L)	国内自給率(%)
2005	317,329	309,296	626,625	50.6
2006	419,874	210,178	630,052	66.6
2007	300,795	350,526	651,321	46.2
2008	334,259	266,535	600,794	55.6
2009	430,267	178,085	608,352	70.7

図１．血漿製品の（A）世界（B）国内市場シェア





Advancing Transfusion and
Cellular Therapies Worldwide

December 14, 2012

Secretary of the Expert Committee on the Selection and Use of Essential Medicines
World Health Organization
Office of the EML Secretariat
Medicine Access and Rational Use (MAR)
Department of Essential Medicines and Health Products
20 Avenue Appia
CH-1211 Geneva 27

Re: Application for the addition of Whole Blood and Red Blood Cells to the WHO Model Essential Medicines List and the WHO Model Essential Medicines List for children

Dear Sir:

I am writing on behalf of AABB (formerly the American Association of Blood Banks), the American Red Cross, Canadian Blood Services and the International Society of Blood Transfusion to request the addition of Whole Blood and Red Blood Cells to the essential medicines lists (WHO EML and WHO EMLc). Our organizations strongly believe that the placement of important medicines on the EML results in a higher quality of care for patients, better management and use of medicines and more cost-effective use of health resources. The provision of safe, adequate and cost-effective Whole Blood and Red Blood Cells that are appropriately transfused is a key component of the public health infrastructure in every country.

The specific benefits of placement on the EML are included in the Summary Statement of the formal submission for Whole Blood and Red Blood Cells, which is attached. We thank you for your consideration of this request and hope, for the sake of donors and patients, that our request will be endorsed by the WHO Expert Committee.

Sincerely,

Karen L. Shoos, JD
Chief Executive Officer
AABB

On behalf of:

Dr. Richard Benjamin	Dr. Graham Sher	Dr. Peter Flanagan
Chief Medical Officer	Chief Executive Officer	President
American Red Cross	Canadian Blood Services	International Society of Blood Transfusion

American Red Cross

Canadian Blood Services
Société canadienne du sang

ISBT

Application for the inclusion of WHOLE BLOOD and RED BLOOD CELLS in the WHO Model List of Essential Medicines

Submitted by

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American Red Cross
15601Crabbs Branch Way / Rockville, MD 20855-2743

Canadian Blood Services
1800 Alta Vista Drive / Ottawa, ON K1G 4J5

International Society of Blood Transfusion
Central Office / Marnixstraat 317, 1016 TB / Amsterdam, the Netherlands