考えるのが現実的であるとの声が多く聞かれた。

こういった背景の中で、アジア地域内においては、韓国がアジア諸国の原料血漿を集め、委託生産を行う体制を整えつつある状況にある。

D. 考察

WHO 内における議論は、様々な側面を有しており、理想論と現実論の対立、公共サービスとしての側面と医薬品製造であるとの側面が血漿分画製剤製造にはついて回ることから、WHO 内での議論の収束には時間がかかるものと思量され、今後も定期的な議論のフォローが不可欠であると考えられる。

また、こういった WHO 内での議論に我が国としても産官学が一体となって積極的に取り組むことが重要である。

E. 結論

ASEAN 各国の現状を見る限り、ほとんどの国で血漿分画製剤の自国生産にこぎつけることは難しいと判断せざるを得ない。

その第一の理由はスケールメリットの問題があることである。人口 5,000 万人以下の国での血漿分画製剤の製造は経済的に有利ではないとの専門家の意見もあり、アセアン諸国においては、ブルネイ、カンボジア、ラオス、ミャンマー、シンガポールは自国製造に乗り出すとは考えにくい。

第二に必須医薬品リストに含めるという WHO 専門家会議の結論は欧米諸国及び韓国といった国々の製薬産業を勇気付ける結果となり、必然的に血漿分画製剤を生産する企業のアジア諸国への積極的なアプローチを生むことになり、また、WHO が血漿分画製剤の自国製造の推進から方向転換を行ったという、ASEAN 諸国への誤ったメッセージとなる可能性も排除できず、タイ、マレーシア、フィリピン、インドネシアといった人口の大きな国々の自国製造へのモチベーションを大きく下げる結果となることが予想される。

F. 健康危険情報

（総括研究報告書にまとめて記入）

G. 研究発表

今年度はなし

H. 知的財産権の出願・登録状況

（予定を含む）

今年度はなし

資料１：

血液自給に関する WHO 会議プログラム及び会議結果サマリー

資料２：

アジア諸国血液事業ワークショップサマリー

資料３：

韓国における血漿分画：　国内自給に向けての働きかけ

資料１－１

World Health Organization

Working Group Meeting on Global Report on Safety and Self-Sufficiency in Blood and Blood Products

DRAFT AGENDA

Geneva: 10-14 September 2012

1. Objectives of the meeting
2. Review of the progress of the report developed against the plan agreed during the first meeting;
3. Compilation of each chapter that has been drafted by different group; review the whole report drafted and making necessary adjustment of the contents developed.
4. Identification of gaps, including information gaps and the gaps for further development and revision of the report
5. Development of a final draft report based on the gaps identified during this meeting
6. Any remaining action for finalization of the report
7. Closure

資料１－２

Revised Structure

"Towards Achieving Self-Sufficiency of Safe Blood and Blood Products based on Voluntary Non-Remunerated Donations (VNRBD)"

WHO Global Blood Safety and Self-Sufficiency Report 2012

World Health Organization

Contents

[1] Blood products are defined as any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products

[2] VNRBD also includes donation of plasma and cellular blood components.

Chapter 1: The Context

Key messages:

1. Why now - urgent need to analyse, also several initiatives around the world (Health System Strengthening, Primary Health Initiative and Universal Access) including many initiatives with external aid

2. Dynamism and what's new - things moving rapidly, SS as policy direction before but now this direction have declined/regressed including collection from VNRBD (increasing use of paid donors) moving away from the globally accepted goal. Influence of materialism??? Why slipped off the agenda???

3. Complex nature of system (including beyond health) and interaction of different stakeholders and how to govern the system

4. Now have the Consensus Statement document that elaborate on what it means to be SS as well as the strategies to achieve SS (e.g. Clinical committee on patients needs in the particular health system and NHA/regulatory in ensuring the safety of the supply)

Content:

1. Need for the document- why now? (bring SWOT analysis)
2. Blood and PDMPs need: maternal health, Millennium Development Goals, HIV, Hep B and C, substance of human origin and community- social cohesion and participation, risk to public health, patient and donor safety
3. Blood and health system, increasing need for blood products
4. Safe blood
5. Sufficient blood
6. What is new - after HIV epidemic and government focused on safety issues now focus on self-sufficiency of supply
7. Blood and PDMPs- linkages
8. WHA resolutions and strategy, Oviedo Convention, EC and EU Directives, Consensus statement
9. Beyond health- include trade
10. Economic issues
11. Accountability- who is accountable?- role of government and to govern/steer the health system

12. Access to patients seen as supply issues, safety issues/transfusion outcomes
13. Focus of blood system in the past on product safety/patient and to bring in donor safety as well- to change paradigm, start with studies before new intervention
14. Guiding principles
15. Target audience
16. Methodology
17. Conclusion: introduction to the report outline

Definition- donation vs. donor
WHA resolutions- recommendations as compared to IHR- binding

Content from January 2012 meeting:

Background

- Start with blood transfusion services meeting the needs of patients (based on draft technical report prepared by Cees- care of patients and donors)
- Why now- WHO and other intergovernmental organization promote VNRBD but apparently others factors influencing policy decision and change practice
- Increasing need and age
- Linkages between BCT and plasma for fractionation
- Not only on safety of donors and patients/ blood safety but meeting on the need of health system (how blood contribute and integrate to overall health system)
- Add content to build the case, utilize consensus statement and concept paper for this meeting,
- Part of history and evolution to bring here
- Blood and blood products is one of the most common/critical - 5 million pt receive blood in USA for example, Japan pt who received transfusion is about 1/5 of donors, GDBS- questionon pt receiving transfusion from 66 countries-

Objectives

- To present key issues, challenges and gaps in achieving self-sufficiency of safe blood and blood products based on VNRBD
- To provide an overview of
    - the current global situation on blood safety and self-sufficiency
    - the global demand and supply for Blood Component for Transfusion (BCT)

and Plasma-Derived Medicinal Product (PDMP)

- To share successful stories of countries and regions working towards self-sufficiency based on VNRBD

Target audience

- Policy makers/ decision making bodies in government
- NHAs/ government
- National blood system/programme
- Regulatory bodies
- General public (labelling Japan mandatory- Voluntary or Non-Voluntary, big label, go to parliament)
- General medical practitioner

Scope

- What is new - after HIV epidemic and government focused on safety issues now focus on self-sufficiency of supply
- Safety aspects
- Health system needs
- Beyond health- include trade
- Economic issues
- Ethical principles
- Accountability- who is accountable?
- Access to patients seen as supply issues, safety issues/transfusion outcomes
- Focus of blood system in the past on product safety/patient and to bring in donor safety as well- to change paradigm, start with studies before new intervention

Methodology

(To be developed)

World Health Assembly resolutions and other policy documents

- WHA28.72 Utilization and supply of human blood and blood products (1975)
- WHA56.30 Global health-sector strategy for HIV/AIDS (2003)
- WHA58.13 Blood safety: proposal to establish World Blood Donor Day (2005)

- WHA63.12 Availability, safety and quality of blood products (2010)

- The Melbourne Declaration on 100% Voluntary Non-Remunerated Donation of Blood and Blood Components (June 2009)
- Recommendations of the WHO Global Blood Safety Network
- Consensus Statement on Achieving Self-sufficiency for Safe Blood & Blood Products based on VNRBD (September 2011)

Chapter 2

Evolution of Blood Transfusion: Policies and Practices

Key messages:

1. Blood moved from medical practice (professional/clinical judgement) to medicinal product/pharmaceutical practice- paradigm shift.

2. Evolution of why PDMPs shifted to industry but importance of the linkages between BCT and PDMPs. 'Regulation' of donation process

3. Recognition of different stages of development

Content:

1. Scientific background- what is blood component for transfusion (BCT) and plasma-derived medicinal products (PDMPs) and use, and why the strategies are taken (preserving biological function, contamination etc, testing)
2. Historical perspective- transfusion, evolution of blood service (three stages-I,II,III) and plasma fractionation (country/Gov. and industry- different models existing today and pros and cons), e.g. USA recovered plasma not popular for fractionation) after WWII, major milestones- plastic bags, fractionation, testing
3. Blood system reform, introduce to reduce the risk, increase efficient system- following scandals and adverse events, fear of scandals, patient group, risk is greater when plasma is pooled- VNRBD system and selection/deferral, testing, organization and management, quality culture, regulatory standards, rational use, precautionary principle, risk management, role of government (e.g. when the blood service moved from emergency based to hospital based, government not taking the responsibility for the system- from the provision of blood supply to its regulation to its use. Similarly for PDMPs, government need to take responsibility) lack of clarity of stakeholders

   Examples of adverse events historically

   - Blood scandals- HIV, Hep C (Saldahna, Lancet, 1993)
   - vCJD (risk assessment, emerging infection, inactivation process is not perfect, addressing the issue)
   - Thesis: Mauser, Holland- pt on cryo no infection, but product with HIV with dry heat treatment from paid donors, also in Belgium, Canada, Ludo Muylle
4. Financing mechanism/models of blood service and PDMPs- how it evolved (ad hoc

during medical practice and the need to move into health financing) and how it affect the current system. Comparison of cost of BCTs and PDMPs to number of patients treated???

5. Linking BCTs and PDMPs: Historically plasma is separated but should be interlinked, plasma is no different from other components also important with future development. What happen to plasma can happen to plts and other BCT as precedence has been set. Blood- SOHO, also donation and blood products arise from blood. Both are from same donors etc, need to strengthen link between the different products (incl for RA) as these are going to patients; also raise the issues of different regulatory standards for labile components as compared to plasma sent for fractionation to another countries; influence of GMP; use the example of EU- same standards between plasma for clinical use and for fractionation
6. Paradigm shift- health system and beyond- fragmentation to coordinated services, prevent wastage
7. Policies, systems and practices- global regulatory standards?; countries having control?
8. Impact of technologies
9. Impact of globalization of pharmaceutical industry
10. Increasing population, decreasing donor pools
11. Stakeholders- MoH, PHA, community, universities, RA
12. Future trends, dynamic system etc

Chapter 3

Current situation of global blood supply and safety

Key messages

1. Situation analysis of various elements of self-sufficiency

2. Interpretation of data

3. Synthesis of gaps and challenges
- Purpose- providing the foundation to build the case for SS based on VNRBD
- Identification of issues and gaps and challenges as well as progress, based on Consensus Statement- using GDBS, published articles, regional and country examples

Additional data to be included based on discussion in Sept 2012:

1. Published data on inappropriate use of blood- BCTs and PDMPs
2. Health system needs, demand and use
3. Literature search- identify key words and MeSH terms
4. Each dataset analysed- key messages, interpretation, challenges and gaps
5. Why this report now- focusing on self-sufficiency and VNRBD
6. Data to support that Czech Republic collect 30 litres per 1,000 population –to support I.V.I.G production
7. Public relations shift- Industry in developed countries recruit students (paid system), implication of this practice as now most donation in developing countries are by younger age group. Destroys image for future.

Content from January 2012 meeting:

Overview of Current Global Situation

- Global demand and supply for Blood Component for Transfusion (BCT) and Plasma-Derived Medicinal Product (PDMP)
- GDBS data on VNRBD and SS (incl. trend)
- Indicators (qualitative vs quantitative) for SS (measuring SS)
- Definition: which bench mark to compare with, moving target, separate PDMPs vs BCT, grams vs volume. Czech: collect a lot of plasma but import IVIG from USA- is the country sufficient?

- PDMPs data: Mechanisms need to be explained- can you meet the demand from your own donors, country based need, ?surrogate indicators- progressing towards self-sufficiency, imports/ export of finished products/ intermediate products, contract fractionation but not taking all back as payment method. Example- self-sufficiency ratio, IVIG g/l from Koji- add column on use per 1000 population, type of donors, add no. of donations, factor VIII, albumin/ potential production that can be calculated, need/demand/use, comparison
- WB, Plasma (apheresis and recovered)- globally- volume, units and no, of countries, VNRBD and others
- BCT: components production data and trends, WHO model- surrogate - health coverage, DPT coverage, MM Ratio, LSCS rate, proportion of blood separated into component, group co based on income level and see their median and take as bench mark
- Policy/legal
- Difficulty in assessing self-sufficiency
- Success story Lux- BCT- minimal inventory- if shortages, import from outside, all plasma export, import factors, no more fractionation
- Write to MRB (not peer-reviewed) asking if can use the data, what methodology is used to derive, which companies provide the data or estimates/ extrapolation
- Approach countries to see if the data provided by MRB is accurate
- Data sources (regional/ country data)
- Summary of survey for Sept meeting
- Regional reports
- Trends in country data
- Market data (MRB, etc) on PDMP (incl. trend)- ask Patrick Robert to declare which companies gave the data
- National assessment reports
- Research reports (such as KAP study)
- WHO mission and project reports
- Assessment reports by other WHO programme (MPS, SAM, etc)
- Information from peer-reviewed journals
- Published annual reports
- Data collected by other organizations
- Statement on limitation of data

- Try and ask EMEA to report in aggregated manner, anonymous analysis, if say no, report in the report. Every plasma products licensed in Europe have to give data to EMEA- raw data- include plasma master file, new donors, repeat donors, NAT data, submit risk assessment (annex 14)
- EC, CoE, ABC, WFH- list of products
- FDA/PEI
- Agenda in having many small centres
- To identify others from which to ask data
- GDBS, supplemented by other sources: Global number donors and donation
- No of countries with VNRBD
- Trend of paid donations- both BCT and PDMPs
- Analysis of/figures on the current organizational structure

Chapter 4

Self-sufficiency in safe blood and blood products based on VNRBD: the next paradigm

Additional discussion point in Sept 2012:

- Why
- Correlations of VNRBD and prevalence of infections
- The next paradigm-self-sufficiency based on VNRBD, moving ahead in light of population demography, reducing pool of donors, technologies, globalization
- (take from preamble of Consensus Statement)
- State the goal
- Merging the discussion of SS with VNRBD
- Balance between supply and safety
- Cost is important but not the overriding decision point

Additional points to be added based on Cees' notes on 13-14.09.12

- Check signatories of Oviedo convention (list of countries available)
- WTO: build the case of public health protection.
- To find data on the cost of plasma collection through apheresis : high in VNRBD , low in paid donations. ? Not true in developing countries
- Building on integral HC system
- Include Amsterdam Treaty- self-sufficiency
- Self-sufficiency= through strengthening infrastructure, not just technical
- Apheresis of 6 million litres of plasma to make-up for 6 million litres thrown away recovered plasma (do we have data??). Donor complication are low but not zero e.g. Apheresis incident in France in 2010 to illustrate the point. Precautionary principle, Rio de Janeiro
- Discussion on preference for domestic blood products in relation to donor, patient choice/ informed consent
- Mid 1980-90s, self-sufficiency was a policy direction in many countries. But why this direction change/failed? Root-cause analysis

- Things are changing, several influencing factors. And this should build on to why the report is important today. Is the absence of policy on self-sufficiency contributing to the situation?
- Certain facts- involvement of industry in blood service therefore need to raise the alarm. However, the report is should be non-confrontational in approach, not targeting industry or anti-industry.
- Be clear on the fundamental/non-negotiable: for example, non-commercialization of donation for which policy need to be introduce.
- Stem cells: many countries are re-examining this issue, therefore opportune time.
- Plasma industry is legalized in many countries. Private sector is important part of health system. Possibility of the privatization of health system in future yet maintain the non-commercialization of donation.
- Social change- critical, similar for tobacco.
- Trade issue.
- Models for plasma fractionation- coordinate, collection, fractionate and distribute

  e.g. Fully integrated national system, regulatory aspect- medicine or not, market forces, globalization
- Japan example with labelling, came up following development of Blood Act, to prevent repeat of HIV tragedy. Labelling and use of domestic product- beyond scientific or ethical reason. Agreed by stakeholders, also patient have informed choice. However, faced with criticism of being a closed system, overly regulated, patient not getting optimal treatment- to make Japanese system/market open up.
- Need to build case for labelling such as to improve transparency or traceability. Also shipping of blood products around the world give rise to HIV spread in the past, so labelling can be seen as precautionary measures to limit the spread of disease as per the Rio de Janeiro treaty of taking measures without evidence being available. Labelling can also be seen as a mildest form of regulation as normally pharma companies have to take out the products of lesser quality.
- Labelling is part of the process of informed consent for consumers- not only for product quality but also ethical principle like procuring textile from countries which use child labour.
- Report is as a guide for policy-maker in making decision: build case, give pro and cons for them to choose based on available options and local situation
- Encourage used of domestically used product
- SOHO- not belonging to the individual alone but as the individual belongs to country/society, it can be seen as natural resources

Content from January 2012 meeting

Definition of Voluntary Non-Remunerated Blood Donation (VNRBD1)

"Voluntary Non-Remunerated Blood Donation (VNRBD1)" means that a person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary non-remunerated donation.

This definition has already been endorsed by WHO, the Council of Europe, the International Federation of Red Cross and Red Crescent Societies, the International Society of Blood Transfusion and the International Federation of Blood Donor Associations.

- The HIV epidemic and the outbreak of vCJD have demonstrated that global distributions of plasma-derived medicinal products or intermediates could increase the risk of global spread in case of a new emerging transfusion transmissible disease .
- Voluntary Non-Remunerated Blood Donation is the cornerstone of a safe and sufficient blood supply and is the first line of defence against the transmission of infectious diseases through transfusion. Informed and regular, voluntary, non-remunerated blood donors from low-risk populations have been demonstrated to be at lower risks of HIV and other transfusion-transmissible infections than paid and family/replacement donors.
- Payment for donation of blood (including plasma and cellular components donations) not only threatens blood safety, it also erodes community solidarity and social cohesion which result through the act of voluntary non-remunerated donation and puts an onus on under-privileged populations in need of money. It also compromises the development of a voluntary, non-remunerated blood donor programme. There are concerns that sufficient safe donations and sustainable supply, availability and access to blood and blood products based on VNRBD may be compromised through the presence of parallel systems of paid donations.
- In many countries, systems based on family/replacement donations are currently in use for providing blood for patients. These systems, however, often lead to coercion and place undue burden on patients' families and friends to give blood, also leading to systems of hidden payment. Such systems are unreliable, putting the onus for the provision of blood on the patients' families rather than on the health system. In the long term, family/replacement donation systems will not be able to provide safe, sufficient and sustainable national blood supplies, employing component preparation and apheresis donations, to ensure equitable access for all patients. It will inevitably act as a barrier to enabling national blood systems to develop appropriately alongside the

countries' overall health systems.

- VNRBD, Paid Donation and Family Replacement for whole blood and plasma donation- clarify direct cost and time off work
- Why VNRBD for this now? (The followings need to be strongly argued backed by evidence, development and trend in WE goes away from this direction, also market forces, beyond safety- foundation of blood system)
- Blood, plasma and cellular blood components, and other therapeutic substances derived from the human body, should not be considered a mere 'commodity'. Donated blood that is provided voluntarily by healthy and socially committed people is a precious national resource.

Ethics

- Avoid exploitation- counter blood can regenerate is it still unethical- put in Keown paper, system of VNRBD will be supported by public if equity and access for all requiring transfusion, Not want to live in an environment where human blood are being traded due to ethical reasons- include social cohesion, community participation- ND take from consensus statement

Safety

- Risks-known and unknown, and actions taken mitigating the risks. Meeting report of risk assessment in Toronto, Canada. Risk high- pooling of IVIG, including scandals in the past,
- Donor safety - care of donors better in VNRBD system, patients, products
  - Donor health and safety, HV data. It is not granted the blood donation is innocuous as we wish it to be. PD: potential unsafe practice by the industries, challenge the body. Drop in protein P Strengers paper. Anti-D PH: first do no harm.
  - Also for WB/BCT- frequency of donation, iron depletion,
  - Adverse events in apheresis vs. whole blood. Example of apheresis plt, throwing buffy coat. Plt from apheresis- bacterial contamination and risk vCJD not different from pooled plt.
  - Frequent plateletpheresis also inhibit bone marrow/thrombopoeisis and low plt count, also osteoporosis
  - Known adverse effects of too frequent collecting too much blood/apheresis and immune boosting
  - Similar with anti-D and Hepatitis B and A and tetanus toxoid- immune tolerance after booster
  - No active HV for donors, only when very2 wrong, industry pay to family and quiet. In France, 26 y.o. died during plasmapheresis but as active participating in HV by law,

well studied.

- Formulate in such a way not as criticism to regulators- not only for blood products safety but also for donors safety. Also previous rec not so much based on evidence but on empirical practice, just the past 10 years more studies and need to take this into account (similar to how HV evolved, from pt now moving to donors)
- Maximization of donors: US: 83 litres vs 33 litres in Europe for plasma donations, significant difference. Is it ethical issue or safety issue? Optimizing collection. Reduce discard, reduce false positive, & 6 million plasma discard. How do we reflect these are not evidence based?

Equity

- Where is the equity from FR system? VNRBD will not solve all equity issue. Inequity for access caused by market mechanism of the blood products. If equity is inherent in health system then FR would trigger inequity, hidden market force similar like paid donors
- Security/ Sustainability/Stable Supply- donor base in UK is shrinking over 5 years but as have reduce 15% red cell use, are able to meet the need. But no evidence the other system is better): counterargument paid system is secure and sustainable- but driven by profit and market, if suppose no market then close and go away. No commitment to stay on. FR is a threat. But more fragile, example of paid plasma donors in China is shrinking (Jun Ping to write this section)
- Blood donor in a health system - health promotion, public health benefits to community, counselling, data for health system, care of voluntary donors, HCV burden based on donor data, linkages with other health programmes- maternal and child health
- Give the perspective/ these are the things to be considered when want to make - complicated and complex issue, investment that need to make in health programmes or not address at all- Group decision don't put this in the report
- What's wrong with / why not Paid Donation and Family Replacement (to be integrated in the sections above)
- Distinction: system of VNRBD vs for-profit driven paid system
- Responsibility is not equitably shared within the society of the donations
- Exploitation def, people that in need
- Reference of SOHO for ethical principles, even after regeneration, no free will etc vs conflict of interest
- Plasma (source material) and the act of donation is treated as commodity by industry, therefore ethical discussion doesn't work with example like work and regeneration. Need to bring back plasma and its donation as WB/BCT/SOHO.

Definition of Self-sufficiency of Safe Blood and Blood Products based on Voluntary Non-Remunerated Blood Donation (VNRBD)

"Self-sufficiency of safe blood and blood products based on VNRBD1" means that national

needs of patients for safe blood and blood products, as assessed within the framework of the national health system, are met in a timely manner, that patients have equitable access to transfusion services and blood products, and that these products are obtained from VNRBD of national, and where needed, of regional (such as neighbouring countries) origin.

Recognizing that six blood products will most likely form the drivers for the number of donations of blood, plasma and cellular blood components needed, these should be given priority in policy and strategy development for achieving self-sufficiency based on VNRBD. These six driver products are: 1) whole blood and red blood cells either recovered from whole blood or by apheresis (WB/RBC); 2) platelets either recovered from whole blood or by apheresis (PLT); 3) plasma for transfusion either recovered from whole blood or sourced by apheresis and prepared by any production method (FFP); 4) plasma-derived clotting factor VIII prepared by any production method (pd-FVIII); 5) polyvalent human (H) immune globulin (IgIV or IgSC); and 6) human albumin solutions for transfusion (Alb).

Why SS (The followings need to be strongly argued backed by evidence)

- **Ethics:** Therapeutic substances from human origin should not be commodified, inter-governmental collaboration. (Austria making money from exploitation of people in Hungary vs. surplus plasma), making best use of recovered plasma
- Emphasis on evidence, not only on figures but also on blood system/health system approach that work
- **Safety:** infection risks, spread of infectious agents/global spread of infectious disease-lesson from history of HIV, HCV, vCJD, supply risk, example vaccine- pandemic, co-producing for own population first before supplying others. Mathematical risk assessment required/mandatory. PDMPs from PD even with inactivation process also against unknown/emerging infection, precautionary principles and measures, cannot depend on. Not all regulatory agencies as developed in USA and Health Canada
- **Accountability:** Countries accountable for their own requirement and development, national pride/dignity.
- **Organizational:** How link to SS, support for recovered product. More expensive apheresis. National standards based on local population, also to check compliance in implementation (inspection), what are the missing elements
- The commitment by national governments to the self-sufficiency of safe blood and blood products based on VNRBD, and a coordinated, integrated and collaborative approach to policy development and planning is a pre-requisite to ensure the implementation of a fully effective national blood system.
- **Equity** is not driving ss but ss promote equity: gov to take responsibility, focus on local market and not global market. Global market behaviour -go to who is able to pay more eg IVIG goes to US; albumin goes to/dump in Japan and China. Marketing strategy of manufacturers
- **Sustainability/ Security / (Stable Supply):** and crowding out of national production

system/ prohibitive to national system, example of IVIG shortages in US and impact to Western Europe and Canada and other parts of the world. Threats only based on one source- meet by having backup/contingency plan- similar to food security discussion- make it national goal.

- **Economy (Cost)-** comparison local production/ contract fractionation/ import
- Price
- **Flexibility-** can change quickly, better with commercial system so far, counterproductive is the long term contract (package deal)
- Governmental agencies/NHA need to be aware of these risks. As we are going to demonstrate in the document, supply is a safety issue, therefore NHA accountable for supply as well as safety. Need aggressive and precautionary approach even not proven unsafe, then supply will be markedly reduced for patient. Cannot wait for disaster to happen.
- **Mechanism:** Also have to improve optimal use of blood drive- as can reduce 20-25%. Except in Germany, promoting more use as is driven by the offset of the blood banks, also export to other countries.

Rationale to achieve self Sufficiency based on VNRBD

Governments should be accountable for ensuring a sufficient supply of products from these special resources which are and will remain limited by nature. The availability and safety of the supply, the safety of donors and the appropriate use of blood, plasma and cellular blood donations is and must remain a public affair. The donation of whole blood or its components is an ultimate expression of community and citizen participation in the health system, which also requires effective intersectoral collaboration.

The management of this precious national resource requires a long-term perspective and systematic approach aimed at ensuring continuity, sustainability and security of supply of safe blood and blood products. Universal and timely access to safe blood products of assured quality and efficacy and the appropriate use of such products are essential for quality service provision. This requires a strong foundation based on adequate number of voluntary, non-remunerated blood donors, as the most robust and safe blood systems globally are based on VNRBD.

- Why so (explanation on how SS and VNRBD are inter-linked and integration): myth- VNRBD not able to meet requirement, need to be challenged. If continue buying products, promote commodification of SOHO and worsen/crowding out/inhibit growth of Voluntary system
- No reasons for disconnect these products, plasma also from blood donors/ SOHO. Why would strategy for plasma for fractionation be different from other blood components.
- Why not - what are the other options, why cannot we continue the status quo- co with established VNRBD programme will be threatened (check out the SWOT analysis, bring here and cross-check)