Plasma Protein Therapeutics : Indian and SAARC Perspective

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Low Usages of Plasma Products in India

**IVIG grams/thousand population**
- **USA**: 57.5
- **Sweden**: 29.3
- **Japan**: 23.6
- **India**: 0.1

**Albumin kgs./million population**
- **Japan**: 534
- **USA**: 367
- **Sweden**: 281
- **India**: 1

**Factor VIII per capita consumption**
- **Sweden**: 5.74
- **USA**: 3.44
- **Japan**: 1.64
- **India**: 0.01

Source: The Marketing Research Bureau, Inc. (MRB), USA.
Why?

- Healthy population
- Affordability
- Availability
- Diagnosis

India does need products
Options...

- **Have own plants**: > 1 billion people
- **Contract Fractionation**: Small/ Medium countries
- **Import**: ...........
Import

- Affordability
- Safety issues
- Erratic supply
- Cross boarder restrictions
- Up gradation of Indian blood banks
- Use of Indian plasma
- Saving foreign exchange
- Self sufficiency

Vulnerable
Transfusion Medicine and Plasma Fractionation are very closely related in India and SAARC.

- Regulatory consideration
- Progress of one is dependent on other
Plasma Fractionation In India

No fully functional commercial facility in India

- Safe and consistent plasma
- Regulatory issues
- Sustainable model
- Governance Deficit
Consistent Supply of Safe Plasma

- Only recovered plasma
- >2700 blood banks (200-8000 unit/month)
- High whole blood usages
- Infrastructural support
- No source plasma
- Lack of training and awareness
## Blood Collection: Demand and Supply

<table>
<thead>
<tr>
<th>Sector</th>
<th>No. of Blood Banks</th>
<th>Annual Blood units collection (in million) 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public</td>
<td>940</td>
<td>4.37</td>
</tr>
<tr>
<td>Voluntary and Trust</td>
<td>376</td>
<td>1.32</td>
</tr>
<tr>
<td>Hospitals</td>
<td>753</td>
<td>1.72</td>
</tr>
<tr>
<td>Private Stand alone</td>
<td>540</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2609</strong></td>
<td><strong>8.01</strong></td>
</tr>
</tbody>
</table>

Population based (1%): For 1.17 Billion population: 11.70 million units/year

8.01 Vs 11.70 Millions Units

3.69 Millions Units
Plasma Availability: Theoretical

1 million units of blood (ave 350 ml)

1 million units of plasma (ave 200 ml)

200,000 liters of Plasma
Componentization: Human Plasma

65% unused.

Liability.

No other use.

Judicious use: Fractionation is the ONLY way.
REGULATORY
Regulatory Issues

- Transfer of Plasma from Blood bank to Fractionating company.
- Change in the Drug and Cosmetic Act.
- Change in Indian Pharmacopeia.
- Upgradation of National Institute of Biologicals.
- Single window clearance
Sustainable Model

- Price sensitivity
- Economy/Size of the project
- Technology based issues
- Trained HR
- Marketing
Plasma Products and Transfusion Medicine in India and SAARC: Historical Perspective
India: Before 1988-89

- Many small plants
- Mainly Albumin and IVIG
- Imported products
- Poor quality of Factors
- Poorly regulated
India : 1988-2000

At blood banking level:

✧ Banning of professional donors
✧ Mandatory testing
✧ Component therapy starts
✧ Regulatory changes
✧ Transfusion Medicine dept

Plasma Products:

✧ National Plasma Fractionation Center, NPFC, Mumbai
✧ First consignment of Factor VIII (1992)
✧ Imported products
India : Post 2000

At blood banking level:

- Modernization of Transfusion Medicine: Product, testing, services and accreditation
- Acceptance of components therapy
- Regulatory changes
- Automation
- Specialized training: DNB

Plasma Products:

- Generation of more plasma
- Beginning of contract fractionation
- Private/public initiative for plasma fractionation
- Regulatory reforms
- National Plasma Fractionation Center, NPFC, Mumbai
## PLASMA FRACTIONATION: SAARC

<table>
<thead>
<tr>
<th></th>
<th>BAN</th>
<th>BHU</th>
<th>IND</th>
<th>MAV</th>
<th>NEP</th>
<th>PAK</th>
<th>SRL</th>
<th>(SAARC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (in million)</td>
<td>133</td>
<td>0.82</td>
<td>1,046</td>
<td>0.28</td>
<td>24</td>
<td>141</td>
<td>19</td>
<td>1,364.1</td>
</tr>
<tr>
<td>Gross National Income (in billion USD)</td>
<td>49</td>
<td>0.5</td>
<td>477</td>
<td>0.59</td>
<td>5.8</td>
<td>60</td>
<td>16</td>
<td>608.89</td>
</tr>
<tr>
<td>Per Capita Income (USD)</td>
<td>360</td>
<td>640</td>
<td>460</td>
<td>2,090</td>
<td>250</td>
<td>420</td>
<td>880</td>
<td>451</td>
</tr>
<tr>
<td>No. Of Blood Banks</td>
<td>44</td>
<td>2</td>
<td>1,549</td>
<td>1</td>
<td>48</td>
<td>NA</td>
<td>57</td>
<td>1,701</td>
</tr>
<tr>
<td>Annual Blood Collection (in thousands)</td>
<td>65</td>
<td>6.2</td>
<td>5,500</td>
<td>2.5</td>
<td>60</td>
<td>NA</td>
<td>150</td>
<td>5,784</td>
</tr>
<tr>
<td>% Whole Blood Usage</td>
<td>98</td>
<td>85</td>
<td>80</td>
<td>90</td>
<td>80</td>
<td>NA</td>
<td>NA</td>
<td>80</td>
</tr>
<tr>
<td>Potential Plasma (in thousand liters)</td>
<td>14</td>
<td>1.2</td>
<td>1,200</td>
<td>0.5</td>
<td>13</td>
<td>NA</td>
<td>30</td>
<td>1,259</td>
</tr>
<tr>
<td>Fractionation Facilities</td>
<td>No</td>
<td>No</td>
<td>?</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>*</td>
</tr>
</tbody>
</table>
INDIA/ SAARC : 2010
PLASMA FRACTIONATION: SAARC

<table>
<thead>
<tr>
<th></th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAARC</td>
<td>1,364.1</td>
</tr>
<tr>
<td>China</td>
<td>1,284.3</td>
</tr>
</tbody>
</table>

Logical Prediction: SAARC needs plasma fractionation capacity of China; 4.16 million liters (presently).
Magnitude of Clotting Disorders

- About 70,000 patients of Hemophilia-A
- About 10,000 patients of Hemophilia-B
- About 100,000 patients of vWD
- Around 1,500 children born every year
- Life expectancy: 19 Vs 62 years global average
- Access to treatment: 15-18%
- Limited treatment options
- HIV/HCV/HBV: Millions infected
Present Treatment Options

- Haemophilia Federation of India (HFI)
  - Factor concentrates
- 56 Centers (Registered patients 11,000)
- 12 Comprehensive Care Centers
- Average cost of treatments: INR 1.5 lakh (~US$ 3000). ~ 3 times of the avg. household income

Difficulties
- Availability
- Metros
Treatment Options

- Mainly Fresh Frozen Plasma (85%) or liquid cryoprecipitate (<15%)

<table>
<thead>
<tr>
<th></th>
<th>US</th>
<th>Europe</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFP</td>
<td>95</td>
<td>100</td>
<td>12</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>30</td>
<td>--</td>
<td>9</td>
</tr>
</tbody>
</table>

Even getting FFP and Cryoppt is complex:

- Less Blood Donation
- Component Therapy: Technology & Financial issues
- Freezing: Blast or Ice-Alcohol bath
- < 6 hrs. protocol
- Storage/Dispensing
## Business Potential of Factor VIII and IX

<table>
<thead>
<tr>
<th>Product</th>
<th>Patients (Million)</th>
<th>I.U./yr (Million)</th>
<th>Plasma*/yr (Million liters)</th>
<th>Potential market# (Million USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F - VIII</td>
<td>70,000</td>
<td>350</td>
<td>1.75</td>
<td>35</td>
</tr>
<tr>
<td>F - IX</td>
<td>10,000</td>
<td>50</td>
<td>0.16</td>
<td>5</td>
</tr>
</tbody>
</table>

Minimum therapy per patient; 5,000 I.U./yr.


# Rate/I.U. = 0.10 USD

5,000 I.U. :: 1.75 Million liters plasma

30,000 I.U. :: 10.5 Million liters plasma
<table>
<thead>
<tr>
<th>Country</th>
<th>Albumin (%)</th>
<th>IVIG (%)</th>
<th>F-VIII (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>31.7</td>
<td>100.8</td>
<td>20.8</td>
</tr>
<tr>
<td>India</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mexico</td>
<td>6.5</td>
<td>37.4</td>
<td>23.5</td>
</tr>
<tr>
<td>USA</td>
<td>195.5</td>
<td>131.3</td>
<td>125.3</td>
</tr>
</tbody>
</table>
Hub for the Region

- Largest among the members, both geographically and economically
- All the other members of SAARC borders India
- One of top five manufacturers of bulk drugs & among the top 20 pharmaceuticals exporters in the world
- Major exporter of Indian pharmaceuticals to member countries
- Better regulatory framework
- Trained HR
Other Technology Platform

- **r_DNA based products**
  - Expensive.
  - IPR issue.
  - Not full range.
  - Better Safety profile.

- **Transgenic Models**
  - Under development.
  - Long gestation.
  - Hold tremendous potential.
Blood is a very scarce resource

Human blood has no substitute

Optimum use of blood components is not just an economic necessity, but a scientific obligation

Componentization and fractionation is the most efficient way to utilize blood

Huge business potential: Domestic and International
Create and set up

- Self sustainable
- Replicable

plasma fractionation model with strong technical, management and strategic inputs for India and SAARC region.
Has the scene changed?
Modern Face of Transfusion Medicine in India

- Blood Acts
- National Blood Transfusion Authority (NBTA)
- National Blood Policy
- Regulatory reforms
- Consolidation of blood bank
- Rational use of blood
- Better safety procedures
- Plasma product development plan
Safe          Affordable      Available

Make plasma products using Indian/ Native Plasma

SAFE SUFFICIENCY
Initiatives of Govt of India

- Create 4 large blood centers
- Set up plasma fractionation center
- Implement quality management system in blood banks
- Increase voluntary blood donation
Plasma Products

Componentization of blood

Centralized Blood Banking

Revenue generation for blood bank

Assured source of consistent safe plasma

Source Plasma

Plasma

Plasma Products

Cells

Patients
Strengthen Plasma Sourcing and Regulatory Support

Contract Fractionation

Fractionation Plant in India
Challenges: Effort and End Point

- Consolidate blood banking scene
- Improve the quality: Donation and quality system
- Increase supply of safe blood
- Generate more blood components, plasma
- Work towards system for “Source Plasma”
- Make more plasma products

Political will and regulatory reforms
Thanks