Topic:- “Hemophilia market assessment study- MR Methodology”

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Introduction

- Hemophilia is a bleeding problem.
- People with hemophilia do not bleed any faster than normal, but they can bleed for a longer time.
- Their blood does not have enough clotting factor.
- Clotting factor is a protein in blood that controls bleeding.
- The most common type of hemophilia is called hemophilia A. This means the person does not have enough clotting factor VIII (factor eight).
- Hemophilia B is less common. A person with hemophilia B does not have enough factor IX (factor nine).
- The result is the same for people with hemophilia A and B; that is, they bleed for a longer time than normal.
- Bleeding is very hard to control in someone with hemophilia who develops inhibitors. A person with inhibitors faces more bleeding and pain because treatment with factor concentrates does not work.
- Drugs called bypassing agents can be used to work around inhibitors and help blood clot.

Scope of work for the study

Hemophilia market assessment study	
Methodology	**Competitive Intelligence**
Objectives	**Market Dynamics & Intelligence**
Key Information areas	✓Proportion split of various players in the hemophilia market (% shares not the market values as such) ✓Kind of split between government and private players ✓Total number of diagnosed and treated Hemophilia patients in India ✓Distribution channel for hemophilia products ✓Funding of hemophilia products in this country (Specify public vs. private insurance or patient/cash funding) ✓Current usage of brands (% shares) ✓Willingness to try any new brand, drivers and barriers impacting product uptake ✓New competitor launches occurring in the next two years ✓Process to get hemophilia products onto the reimbursed market (i.e. Competitive Tender, Health Technology Assessment, etc.) ✓Key Opinion Leaders ✓Cost/ unit meaning procurement rates at which the hospitals are procuring these brands
Sample Size	**Total: (n= 70)** Channel Partners (n=20), Government and Private Institutions (n=40), Patients (n=10)
Timing	**5 weeks**

Scope of work for the study

Hemophilia market assessment study- Breakdown of Interviews

Field Interviews

Respondent Category	Total
Government & Private Institutes	40
Channel Partners	20
Patient	10
Total	70

EPIDEMIOLOGY OF HAEMOPHILIA IN INDIA

• Haemophilia is a lifelong bleeding disorder that prevents blood from clotting properly. The severity of a person's haemophilia depends on the amount of clotting factor that is missing
• In India, incidence of Haemophilia is about 1 in 10,000 male births
• Around 1/3rd of the new cases are caused by genetic mutation of the gene in mother or child, with no previous history of Haemophilia in the family
• The diagnosis of the disorder is either determined by presentation of the symptoms like prolonged bleeding, unexplained bleeding and so on, or on the basis of previous family history
• There is no predominant age group which is affected by Haemophilia. It is usually inherited since birth and remains with the patient, life long
• Factor utilisation in India is estimated to be 35%-40%
• Undiagnosed patients, spontaneous or sudden bleeding caused by an injury, non availability of the treatment centres and high cost of therapy are the major challenges in the management of the disorder

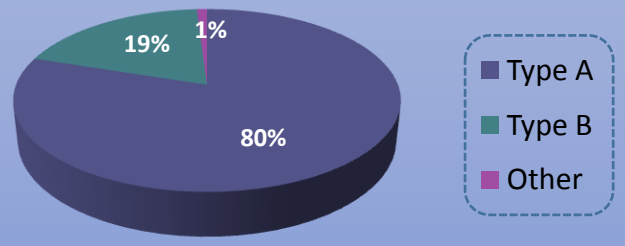
"It is estimated that there are more than 1 lakh patients of Haemophilia in India but only 10%-15% of the patients are diagnosed and registered with HFI. In case of injury to undiagnosed Haemophilic patient, management and treatment of patient becomes very critical as clinicians are not able to diagnose the problem first hand and the treatment delays significantly" – ***Hemophilia Federation of India***

Prevalence, 2013

125,000

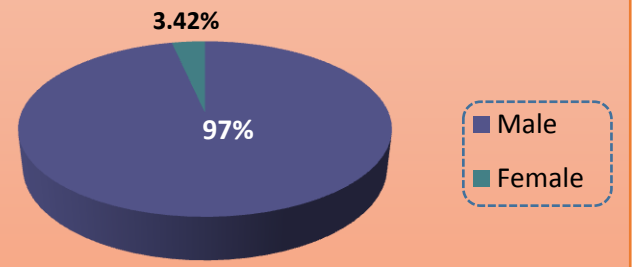
Statistics	Value
Incidence	1/10,000
Diagnosis	18,000 (14%)

By Type



Females are usually only carriers of Hemophilia and are unlikely to be affected by the condition.
Only 4-5 female patients of bleeding disorder (Von-Willebrand Disease) were identified in the year 2013

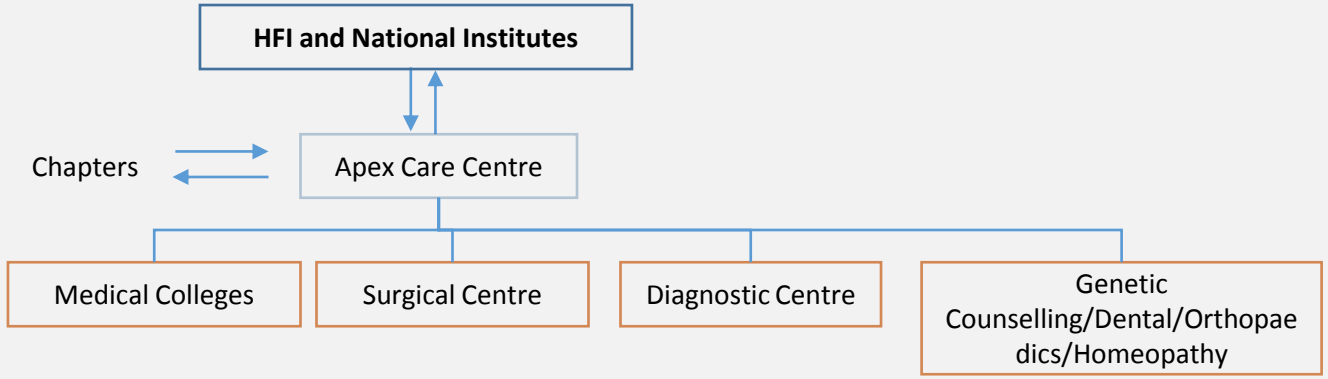
Bleeding disorder ratio by gender



Source: Haemophilia Federation of India

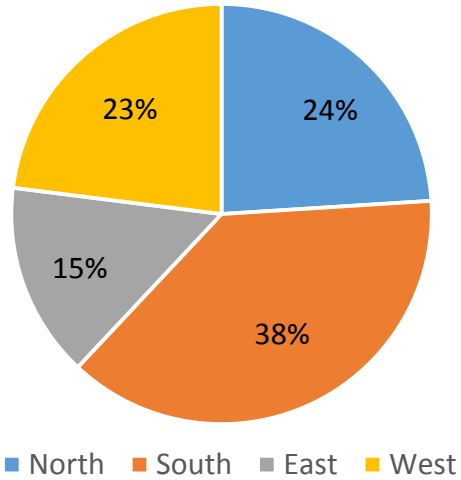
EPIDEMIOLOGY OF HEMOPHILIA IN INDIA (CONT'D)

• It is estimated that there are around 125,000 patients with Haemophilia, out of which only 18,000 are diagnosed and registered patients
• Haemophilia Federation of India maintains the national registry for the Haemophilia patients. This registry is comprehensive and consists upto 98% of the diagnosed patients in India
- HFI has developed a robust web application as per the guidelines of advisory board and IT regulations
- All HFI chapters are equipped and trained for management of web application
- HFI has about 10 methods of collecting data in an efficient manner by being in contact with various state governments, organisations and NGOs



Source: Haemophilia Federation of India

Zone-wise Distribution



Organisation	% of Patients
ESIC	3%-5%
Railways	5%-6%
Defence	2%
CGHS	1%-2%
Other	90% (approx)

DIAGNOSIS & TREATMENT CHANNEL

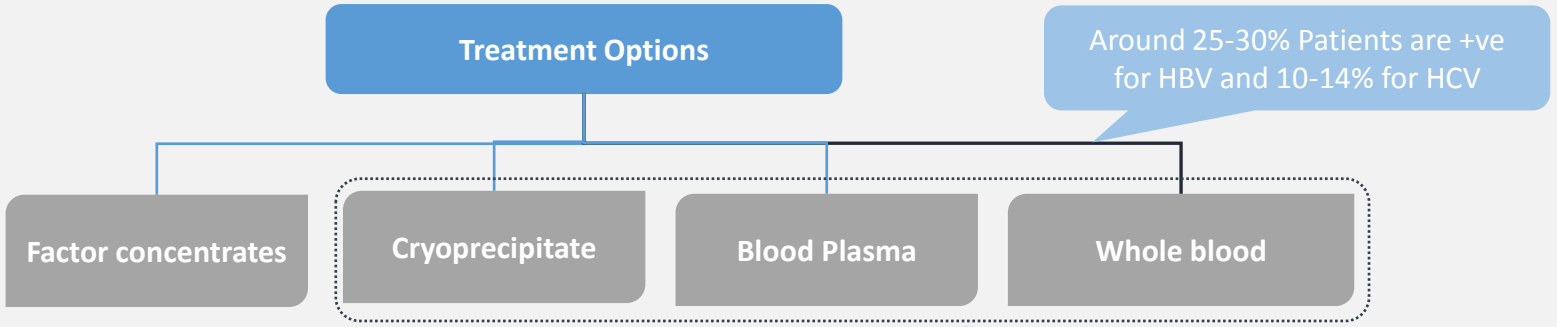
Diagnostic tests

Diagnosis of Hemophilia includes screening tests and clotting factor tests. Screening tests are blood tests that show if the blood is clotting properly. Clotting factor tests, also called factor assays, are required to diagnose a bleeding disorder

- **Complete Blood Count** (CBC) - *CBC and Hemoglobin count*
- **Activated Partial Thromboplastin Time (APTT) Test** - *Clotting factors (VIII, IX, XI and XII)*
- **Prothrombin Time (PT) Test** - *Clotting ability of factors*
- **Fibrinogen Test** - *Ability to form blood clot*
- **Chorionic Villus Sampling (CVS) or Fetal blood sampling** (18 or more weeks) – *If mother is a known carrier, testing can be done in prenatal stage*
- **Inhibitor Assay** – *Haemophilia patients to find out inhibitors development*

Treatment Options:

- Haemophilia is treated by replacing the missing clotting factor in the blood. This is done by injecting a product that contains the needed factor into a vein



Due to the high cost of AHF, most patients in India may be required to take infusions of unsafe, wet blood products such as **Fresh Frozen Plasma (FFP)** or lyophilized cryoprecipitate. This necessity exposes patients to blood borne infections like HIV/AIDS and Hepatitis

- **Of the total patient receiving factor concentrates almost 98% cases seek treatment on need basis, and a maximum of 1 % to 2% patients take prophylactic therapy, which is also determined by the socio economic status of the patient**

SEVERITY OF HEMOPHILIA

Severity: The level of severity depends on the amount of clotting factor that is missing from a person's blood

-**NORMAL = 50% - 150%** of the normal activity of clotting factor VIII (8) or IX (9) in the blood

-- **MILD HEMOPHILIA** 5% - 30% of normal clotting factor activity

- Might bleed for a long time after surgery or a very bad injury
- Might never have a bleeding problem
- Do not bleed often
- Do not bleed unless injured

- **MODERATE HEMOPHILIA** 1% - 5% of normal clotting factor activity

- Might bleed for a long time after surgery, a bad injury, or dental work
- Might bleed about once a month
- Rarely bleed for no clear reason

- **SEVERE HEMOPHILIA** less than 1% of normal clotting factor activity

- Bleed often into the muscles or joints
- Might bleed one or two times per week
- Might bleed for no clear reason

Correlation of severity with International units per mL of whole blood

Level	Percentage of normal factor activity	Number of international units (IU) per millilitre (ml) of whole blood	% of Haemophilia patients
Normal range	50% - 150%	0.50 – 1.5 IU	-
Mild Haemophilia	5% - 30%	0.05 - 0.40 IU	35-40%
Moderate Haemophilia	1% - 5%	0.01 - 0.05 IU	20 %
Severe Haemophilia	less than 1%	less than 0.01 IU	40-45%

Source: Haemophilia Federation of India and LSCPL primary interviews

MARKET ANALYSIS

Clotting factors

- The overall market for clotting factors comprising of anti-haemophilic factors, blood plasma products and cryoprecipitate was estimated to be INR 1,480 million in year 2013
- The market share for clotting factors was estimated to be around 52% in 2013 and is expected to grow with a rate of 7% by 2015 reaching up to INR 943 million
- Clotting factors are primarily used for management of Hemophilia, moreover they also have utility in other conditions such as Surgeries, trauma, burns, oncology and so on

- **Key growth drivers for clotting factors market are as:**

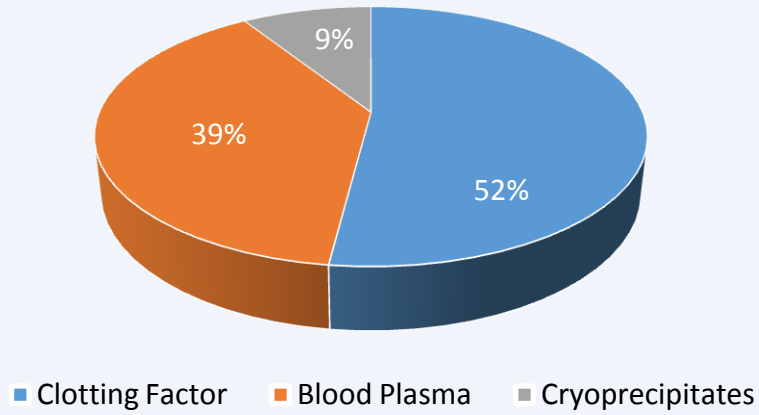
- Increasing numbers of hemophilic A and B cases and certain surgeries

- Increased life expectancy for hemophilia patients translates to longer usage period hence more consumption of clotting factors

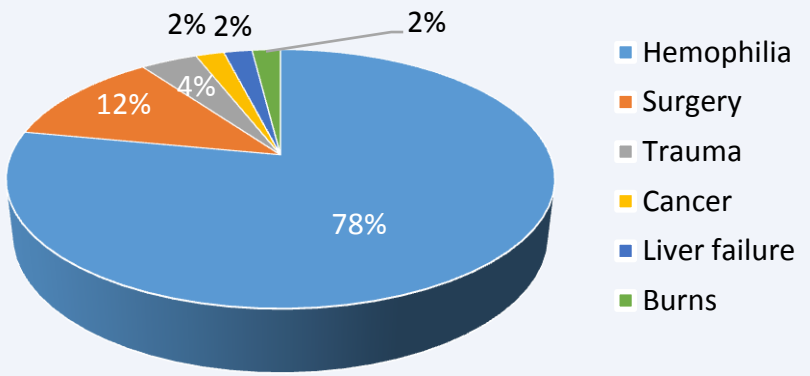
- Growing awareness of the condition hence an increasing number of new patients are registering for treatment at hospitals and other healthcare institutions

- Rising income levels: Increasing expenditure is also responsible for higher utilization of recombinant and plasma derived coagulation factors

2013 Sales INR 1,480 million



Clotting factor usage

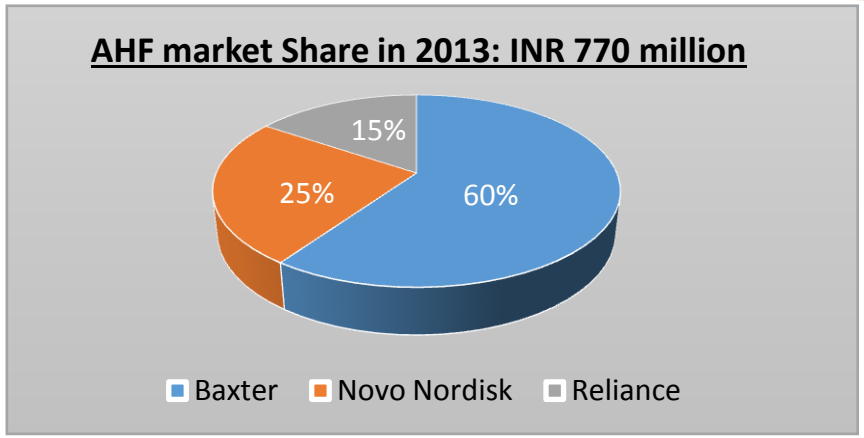


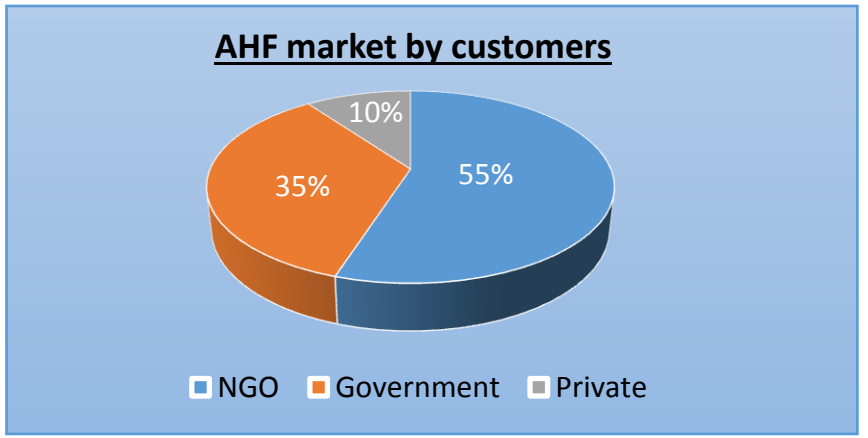
Source: LSCPL primary interviews

MARKET ANALYSIS : HEMOPHILIA

• In India, major companies which are active in Anti Hemophilia Factor segment are Baxter and Novo Nordisk
• Reliance is also present in the segment with a Factor VIII product "Hemorel". Hemorel is an imported product and have supply and shortage issues due to on and off import of the product .

Category	Brands	Factor	MRP in INR	Strength	Company	% Share in AHF sales
Non-recombinant	Hemophilium	Factor VIII	4,190	250 units	Baxter	40%
Non-recombinant	Hemonine	Factor IX	13,150	600 units		20%
Recombinant	Feiba	Factor VIII inhibitor bypassing activity	25,000	500 units		8%
Recombinant	Recombinate	Non plasma factor VIII	29,500	1000 units		32%
Recombinant	Novo Seven	Factor VII	86,900/43,400	2mg/1mg	Novo Nordisk	100%
Non-recombinant	Hemorel	Factor VIII	3,800	250 units	Reliance	100%





Source: LSCPL primary interviews

MARKET ANALYSIS: PRESCRIBER AND COST ANALYSIS

Category of clinicians treating Hemophilia

Hematologist	Pediatrician	Consulting Physician	General Surgeon
75%	20%	5%	1-2% (In case a patient undergoes surgery)

Cost comparison of Hemophilia factor treatment:

- Depending on the condition, haemophiliacs need factor 7, 8 or 9. Factor 8 is the most commonly needed AHF
- The cost of AHF varies from the type of injury and episode to episode. For instance, a simple injury may be treated by 2,000-2,500 units of AHF for a 50 kg body weight, but severe injury like intracranial injury can call for 30,000 units of AHF which will cost around INR 2 lakh

Factor	Per unit cost (In INR)	Average number of required units
Factor VIII	12	2,500
Factor IX	18	4,000
Factor VII	43,400	1-2 mg

Income wise distribution of patients

- As Haemophilia is a low volume high value disease, irrespective of income slab, majority of the patients seek assistance from government/reimbursement organisations or HFI
- None of the insurance companies operating in India covers the expenses of the disorder due to high cost of treatment and its uncertain nature

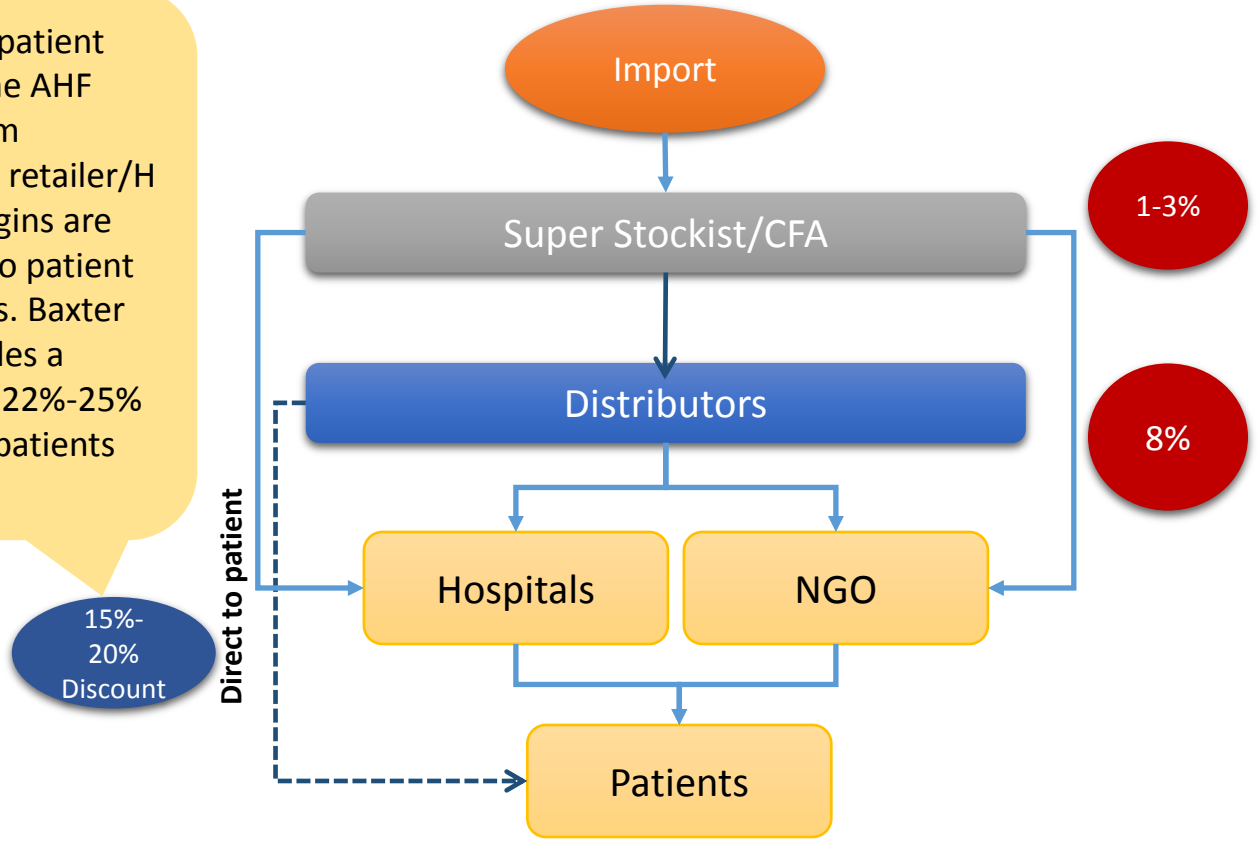
Income Level*	% of patients
High Income (above INR 5 lac)	10%
Middle Income (INR 2-5 lac)	40-45%
Low Income (Upto INR 2 lac)	30%
BPL	15%

** Income slabs as per HFI's definition as stated in the PIL. Realistically, only a portion of High income group patients can afford therapy and adhere to the complete regimen of the therapy.*

DISTRIBUTION CHANNEL

- All the available AHF products in India are imported
- AHF being very costly product, various NGO's and Hospitals are actively providing the therapy either free-of-cost or at affordable/subsidised prices to the patients . Hemophilia Society is one such example which procures AHF directly from the company at discounted prices and provides the same to the customer at economical rates or for free (depending on the patient affordability)
- Companies operating in the AHF segment provide drugs at a subsidized rates to the NGOs and health institutes

In case the patient purchase the AHF directly from dstributors, retailer/Hospital margins are passed on to patient as discounts. Baxter India provides a discount of 22%-25% on MRP to patients and NGOs

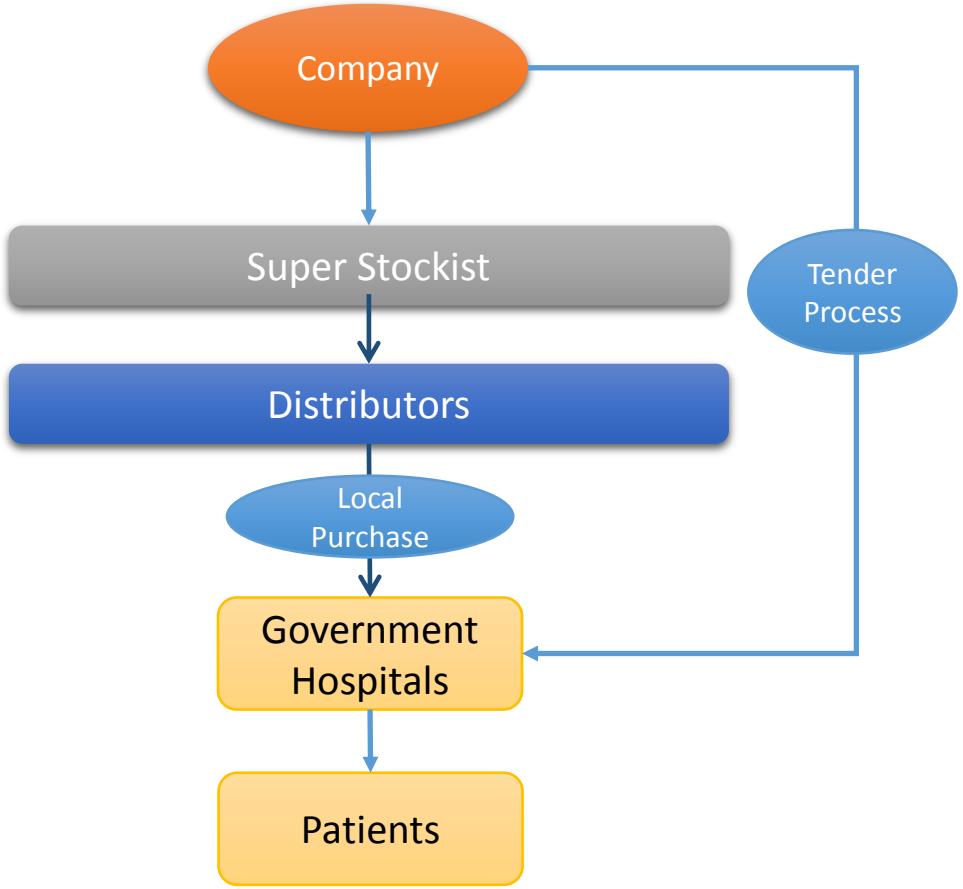


DISTRIBUTION CHANNEL (Cont'd)

Government distribution process:

- Certain NGOs and public hospitals are active in procurement and distribution of AHF product for instance Delhi government set up Hemophilia centers in three of its hospitals. Hemophilia Society of India and Hemophilia Federation of India are also actively working in providing support to patient population
- Under government Hemophilia aid program, patients under BPL are provided with free medicines for the management of the disorder, whereas patients within income group of INR 2-5 lakh have to bear 30-50% of the product cost

- In India, there are selected government institutes which offer treatment and management of Hemophilia for instance SGPGI, Lucknow; Lok Nayak Jai Prakash Hospital, Delhi and so on
- Karnataka government was the first in India to provide the free AHF drugs to BPL patients
- Government institutes procure the AHF usually through tender process and in case of supply issues, procure it through local purchase as well
- Liasioning agents are involved in the tender procurement of the target products
- Irregular supply and non availability of the AHF drugs are the major areas of concern in government organisations



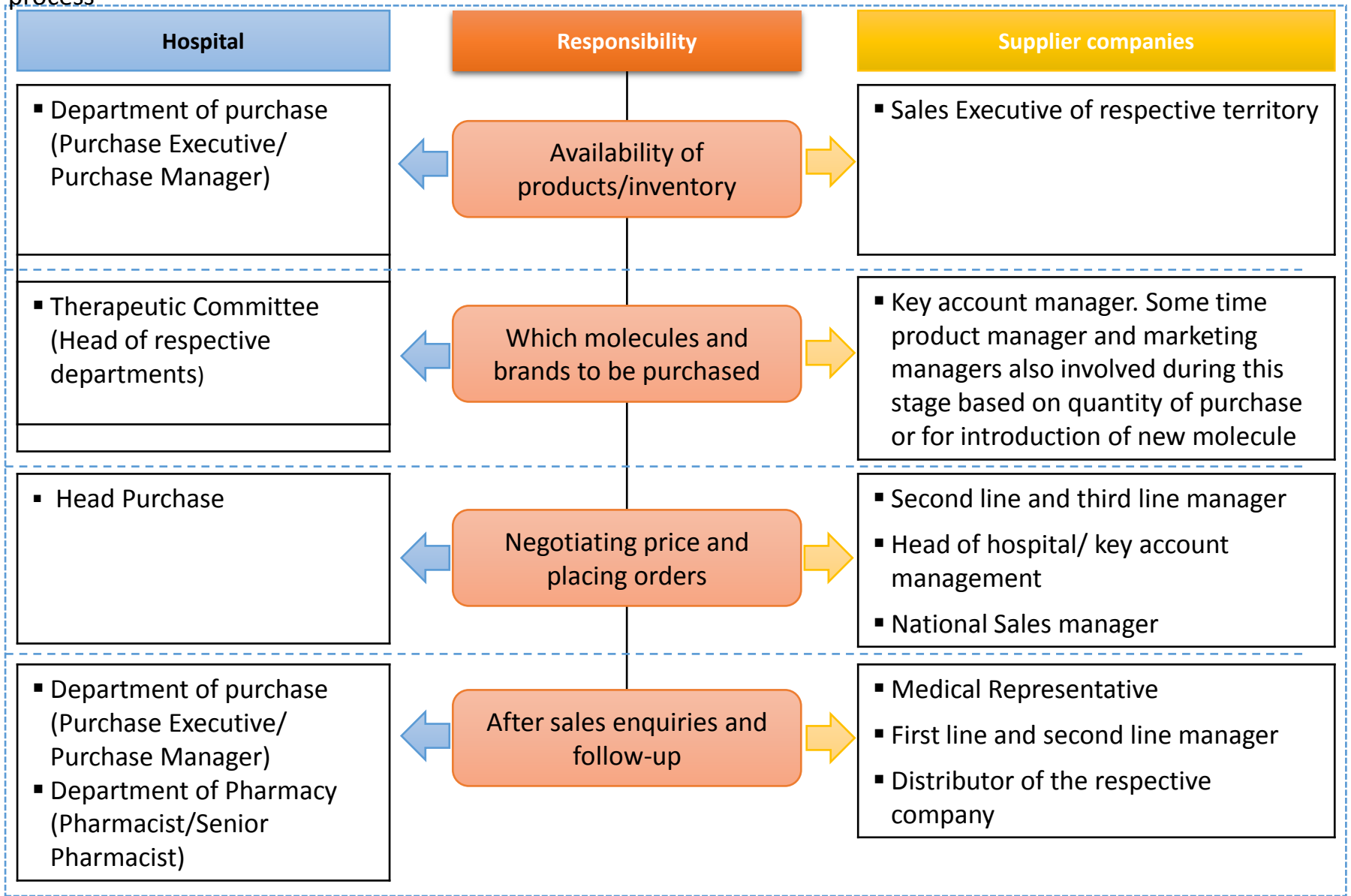
LEADING HEMOPHILIA CENTERS

- **New Delhi**
  - Lok Nayak Jai Prakash Hospital, Delhi Gate
  - Deen Dayal Upadhyae Hospital, Hari Nagar
  - Guru Teg Bahadur Hospital, Dilshad Garden
- **West Bengal**
  - Kolkata Medica College
- **Bihar**
  - Patna Medical College and Hospital (PMCH)
- **Karnataka**
  - Bowring & Lady Corzon Hospital, Bengaluru
  - Victoria Hospital, Bengaluru
  - KC General Hospital, Bengaluru
  - Wenlock Government Hospital, Manglore
  - KR Hospital, Mysore
  - District Hospital, Hassan
  - District Hospial, Dharwad
  - CG Hospital, Davangere
- **Tamil Nadu**
  - For Pediatric patients: Institute for Child Health & Hospital for Children, Chennai
  - General Hospital, Department of Hemophilia, Chennai
- **Puducherry**
  - JIPMER Hospital
  - Government Hospital
- **Uttar Pradesh**
  - SGPGI and Medical College, Lucknow
  - Medical College, Jhansi
  - Medical College, Allahbad
  - Medical College, Meerut
  - Medical College, Kanpur
- **Jammu & Kashmir**
  - Medical College, Jammu
  - Medical College, Kashmir

- Victoria Hospital does not maintain stock of AHF for the last 2-3 years. This is mainly attributed to paucity of funds and internal logistical issues
- If a patients seeks treatment at this centre, he/she is asked to procure the factor/drug from the open market or Haemophilia Chapter, Bangalore

DECISION MAKING : PRIVATE HOSPTIALS

- Following are the key points of contact between the supplying company and the hospital during the procurement process



DECISION MAKING : GOVERNMENT HOSPTIALS

PROCUREMENT PROCESS FLOWCHART

Calling upon tenders

- Purchase Officer calls for total requirements from various government hospital pharmacies to generate schedule copy for e-tender
- Chairperson/Dean of Central Purchasing Authority invites medicine tenders after finalizing details of medicine e-tender with Superintendent of Pharmacy, subject experts, and also after accounts department has also thoroughly scrutinized it
- Tenders are advertised through newspapers and government portals
- Tender comprises two parts:
  a) Technical bid
  b) Commercial bid

- After tenders are invited, based on sample verification, detailed statements of technical observations are prepared by Superintendent of Pharmacy, along with recommendations from subject expert doctors

Analysis of commercial bid

- Products that fulfill competent committee's technical requirements are qualified to be entered for bidding
- Closely assisted by Superintendent of Pharmacy and Chief Accountant, Chairperson finalizes tender winner on the basis of commercial bid
- Usually, supplier that has submitted the lowest bid is selected as long as all quality and efficacy parameters are at par

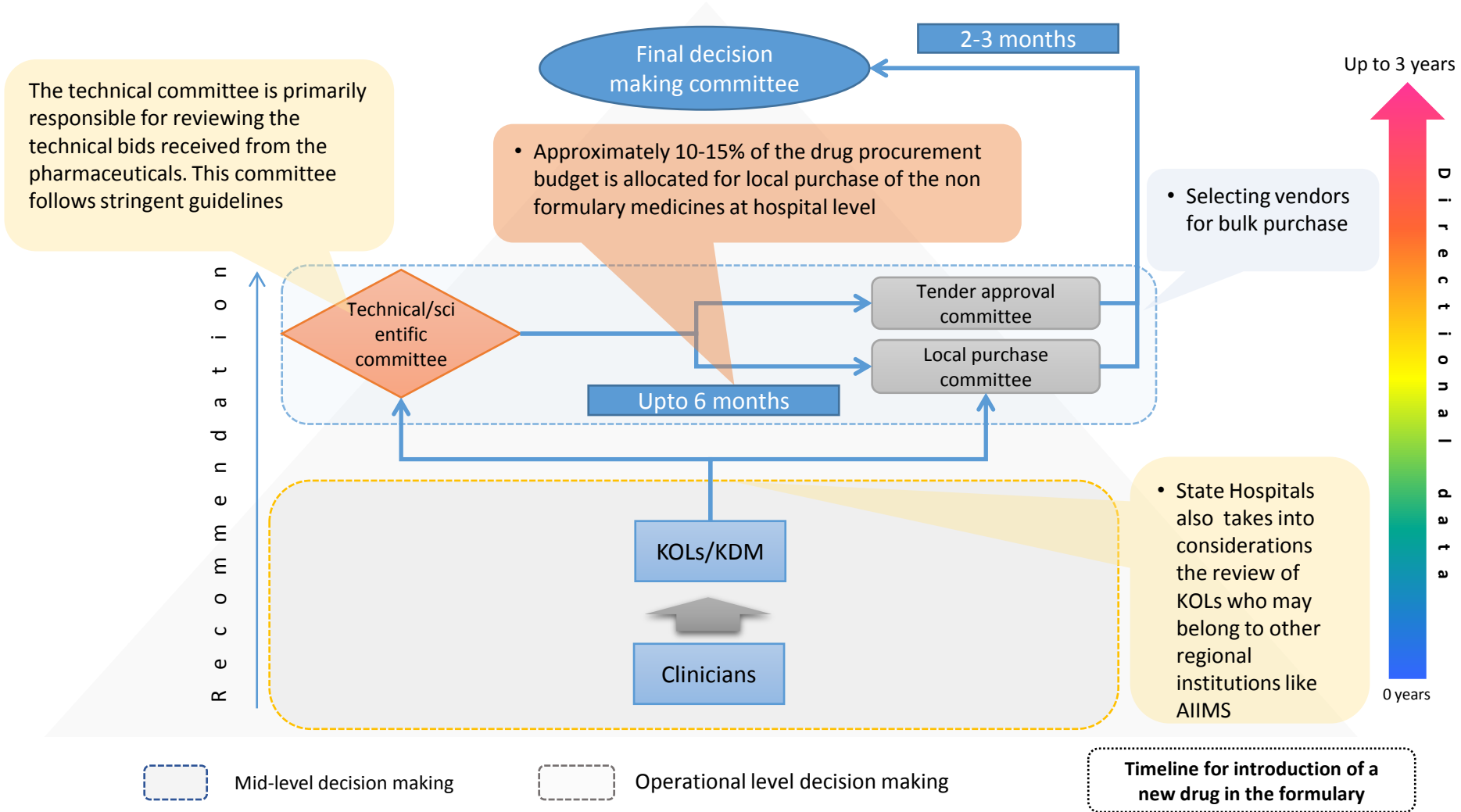
Execution of contract

- After tender is assigned to the company, Assistant Purchase Manager executes and circulates rate circular to all hospital pharmacies

- Documents required to attach with tenders for imported products are embedded

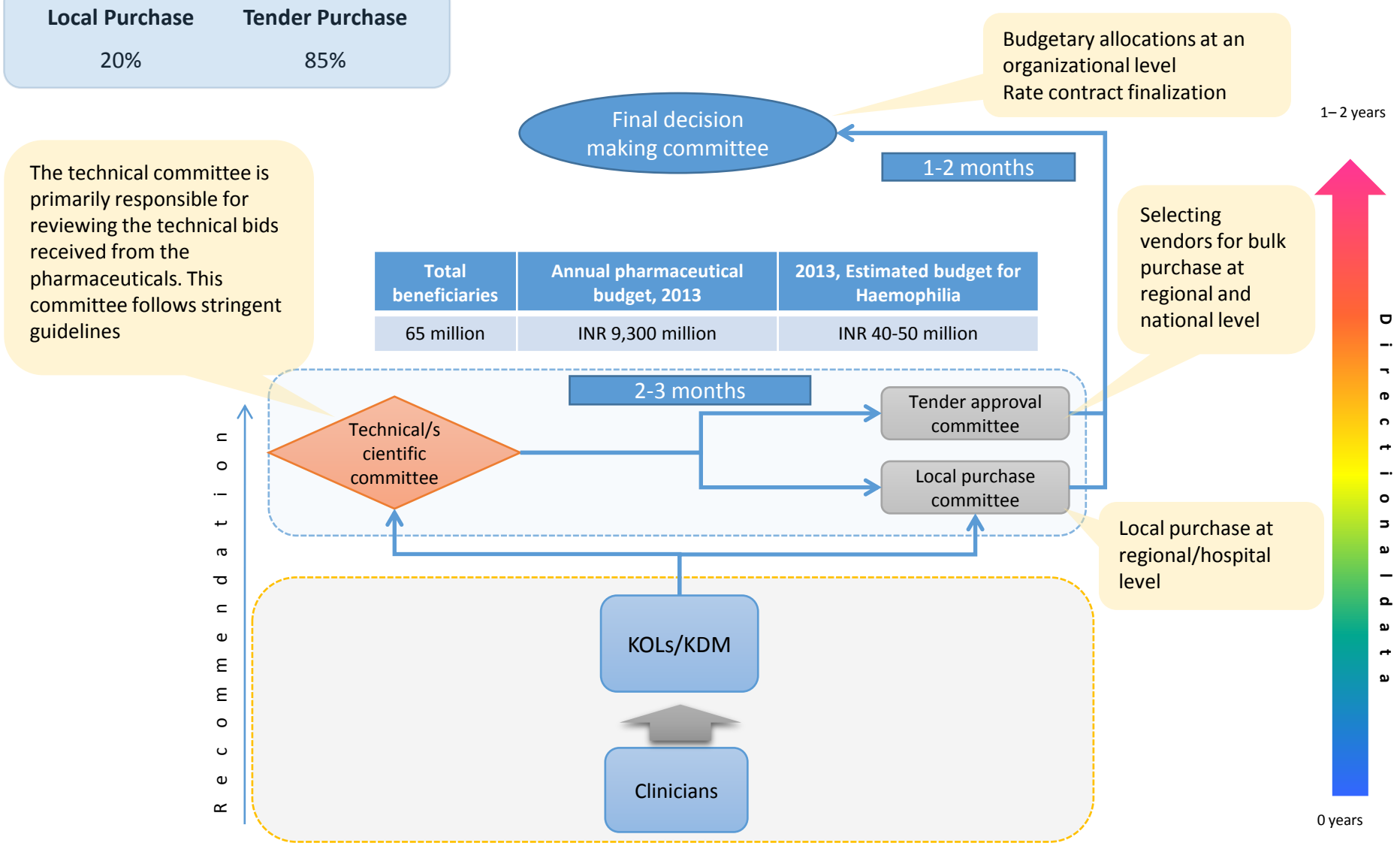
DECISION MAKING : GOVERNMENT HOSPTIALS (CONT'D)

- Till early 2000 haemophilia was not included in the health budget. Lately many of the state government have recognised centres for the treatment and management of haemophilia in the respective regions
- Minimum criteria for inclusion of a new drug in the hospital formulary is minimum 3 years of market standing, although the rules are amended in case, if the drug is clinically proven globally and is beneficial for the large mass of patient pool
- In case of Hemophilia, listing and procurement of the drug may take from 6 months-1 year
- Baxter is a unanimous choice due to consistency in availability and good efficacy



DECISION MAKING : ESIC

Local Purchase	Tender Purchase
20%	85%



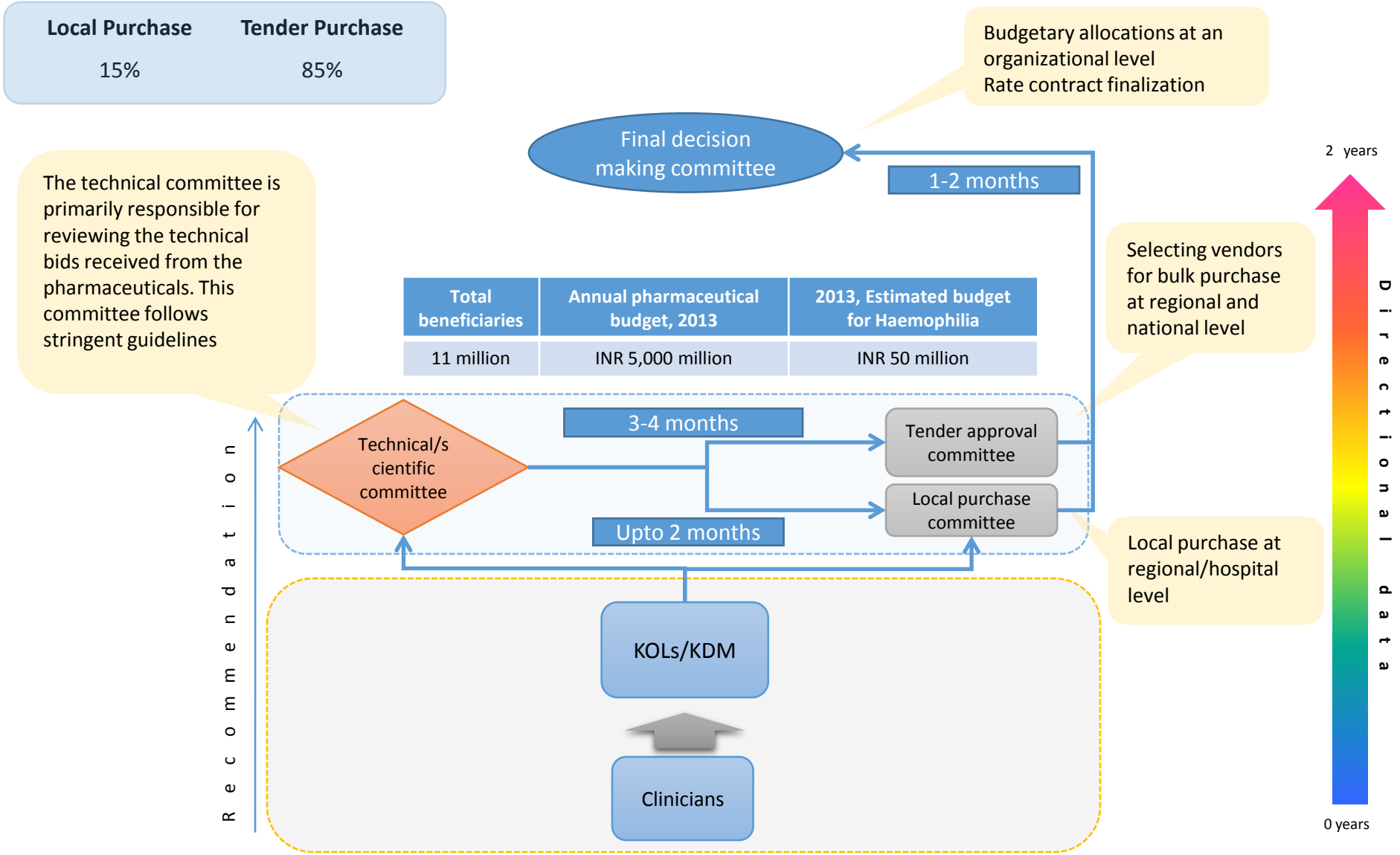
Mid-level decision making

Operational level decision making

Timeline for introduction of a new drug in the formulary

DECISION MAKING : RAILWAYS

Local Purchase	Tender Purchase
15%	85%



Mid-level decision making

Operational level decision making

Timeline for introduction of a new drug in the formulary

DECISION MAKING : DEFENSE

Local Purchase	Tender Purchase
40%	60%

- Updation and revision of formulary, and listing of new molecule takes 4-5 years
- All of the individual units rely heavily on local purchase for drugs and supplies, thus it is a recommended way for new molecule/brand for entering into the defence medical institutes

The technical committee is primarily responsible for reviewing the technical bids received from the pharmaceuticals. This committee follows stringent guidelines

Final decision making committee

Budgetary allocations at an organizational level
Rate contract finalization

Total beneficiaries	Annual pharmaceutical budget, 2013	2013, estimated budget for Haemophilia
1.5 million	INR 5,500 million	INR 20-25 million

The Directorate General of Armed Forces Medical Services (DGAFMS) is the controlling authority of AFMS. One of its primary functions is provisioning, procurement and storage of expandable (drugs and consumables) and non-expandable (equipment's) stores required for medical treatment

Upto 36 months

Technical/s cientific committee

Tender approval committee

Local purchase committee

Upto 6 months

KOLs/KDM

Clinicians

Recommendation

Selecting vendors for bulk purchase at regional and national level

Local purchase at regional/hospital level
Local purchase plays an important role in defense supplies
Hospital level tenders issued at each command center

Up to 5 years

Directional data

0 years

Mid-level decision making

Operational level decision making

Timeline for introduction of a new drug in the formulary

DECISION MAKING : LISTING GUIDELINE OVERVIEW

Key guidelines for tender listing and local purchase of drugs in Indian reimbursed organisation:

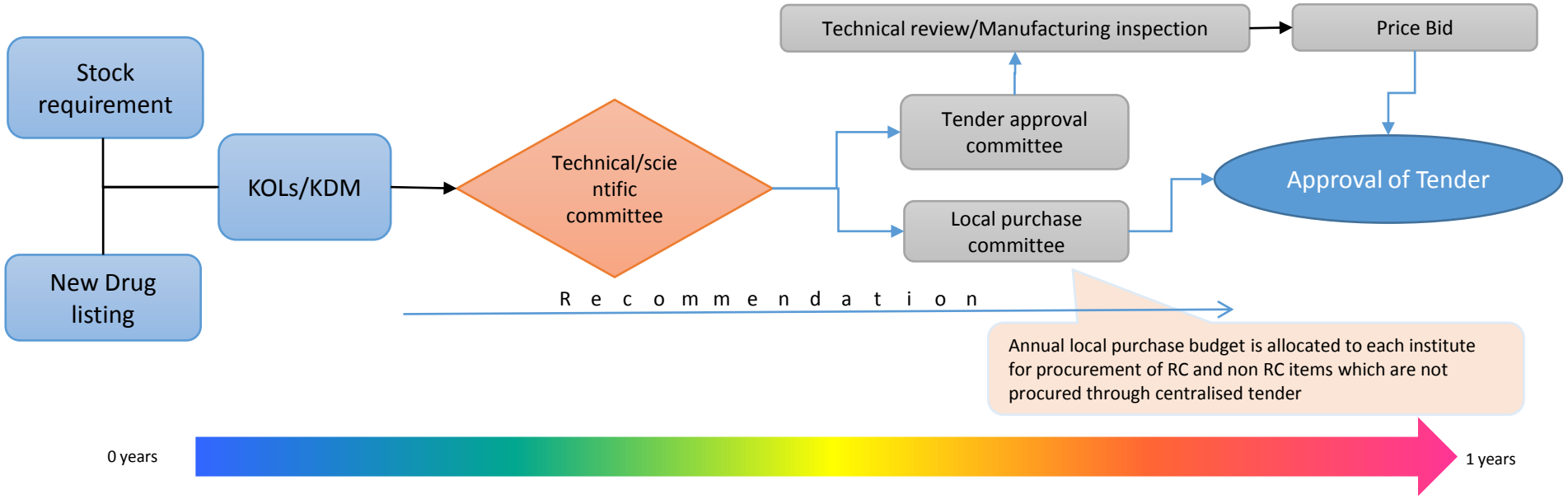
- For introduction of new molecule in the presence of already available molecules of the same cadre, listing of the brand require minimum 3-5 years of standing in Indian market. Moreover this criteria is overruled in case of patented and exclusive drugs
- The firms will have to get registered with local and national drug control organisation
- Certificate of approval from Drug Controller General of India
- The firms must possess a valid Good Manufacturing Practices (GMP) certification and DGQA certificate for the quoted items or Valid import License
- Certificate for individual drug by state/central authority and have an annual turnover of more than INR 200-500 million for the last 3-5 years
- Every government reimbursement organisation maintains a list of commonly used medicines which are generally covered under the formulary and rate contract of the organisation. In case of non formulary items, each institute under the organisation is allocated with a certain budget for the procurement of the required drugs locally

Organisation	Number of Hospitals	Haemophilia treatment centre
ESIC	34 Model Institutes, 117 Hospitals	34 Model Institutes
Railways	125 Hospitals	All headquarter units
Defence	11	All Centre
CGHS	254 Dispensaries, 47 empanelled hospitals	Hospitals under central government

List of Key Decision Makers in reimbursed institutes

List of KDM

DECISION MAKING : STATE GOVERNMENT



Tamilnadu Medical Services Corporation

- The Tamil Nadu Medical Services Corporation Limited is engaged in the procurement, storage and supply of drugs and medicines to the various Government Hospitals, Primary Health Centres and through them to the Health sub-centres throughout Tamil Nadu.
- Treatment and management of Haemophilia is available across all medical colleges in Tamil Nadu
- Drugs and factors for the treatment and management of Haemophilia are made available by TNMSC to all the listed centres through 25 warehouse and stores spread all across Tamil Nadu
- Procurement of AHF is done through tender process only
- TNMSC maintains 4 months physical stocks in its warehouses and 2 months stocks in pipeline for all the drugs
- TNMSC finalize the drug list every year by getting the requirements from the medical institutions these requirements are placed in the Drug Committee Meeting convened in the month of November every year
- The supply of selected drugs are allowed to be distributed to the hospitals as per the clearance of CDL, Kausuli. In addition to this, samples of the drug are drawn from the warehouses randomly and sent to the laboratories for analysis

DECISION MAKING : STATE GOVERNMENT (CONT'D)

Karnataka State Drug Logistics & Warehouse Society (KSDL&WS)

- Karnataka State Drug Logistics & Warehouse Society is responsible for the procurement of the drugs and medical supplies to the government institutes across 27 districts of the state
- Karnataka state government has 14 warehouses for drug and supplies storage
- KSDL&WS implement the logistical drugs and warehouse management to ensure the drugs of assured quantity are made available at all levels, up to the sub-center
- KSDL&WS also ensures to economize expenditure on drugs through pooled procurement system and helped to optimize accountability
- In the state capital, for treatment and management of Haemophilia, only KC General Hospital, maintains the stock of AHF which are provided for free to BPL patients and at subsidized rates for non BPL patients
- Victoria Hospital, Bangalore does not maintain any stock of the AHF from past 2-3 years
- Government medical institute face the issue of supply shortage in case of Haemophilia factors for instance KC General Hospital currently have factor XI (Hemonine) and Factor VIII inhibitor (Feiba); Factor VIII is out of stock and it generally takes around 2-3 months for the stock update in the hospitals
- Though the drugs for treatment and management of Hemophilia are included in the state government budget, the main factor for the non availability/shortage of the AHF in the hospitals of Bangalore could be attributed to low volume high cost treatment and lack of financial resources

DECISION MAKING : STATE GOVERNMENT (CONT'D)

Andhra Pradesh Drug Control Administration

- The Drugs Control Administration in the State offers services to the citizen as well as to manufactures and distributors of drugs
- Dr Batti Lala Meena is a Director General Drugs and Copyrights
- Management and treatment of Haemophilia is available in all the government teaching institute across state of Andhra Pradesh
- State government primarily procure the Haemophilia drugs (Factor VIII) from Baxter India trough tender process only
- Haemophilia Federation of India has 7 chapters in the state of Andhra Pradesh, out of which only 2 chapters i.e. Hyderabad and Vijayawada, are fully active and operational chapters

Organisation	Identified patients	2013, Procurement value (in INR million)	2013, Procurement by local chapter of HFI (in INR million)
TNMSC	1,400	61	20
KSDL&WS	1,500	7.5	15-18
APDCA	2,900	13	18-20

- Government institutes generally face issues with supply shortage which is governed by internal logistic and financial scarcity
  - TNMSC allocated INR 95 million in FY 2013 for the procurement of Haemophilia drugs and have only consumed INR 40 million till December 2013
- Many of the state governments like Government of Karnataka do not even allocate sufficient amount for the procurement of Haemophilia drugs considering the patient populations
  - In many cases patients are returned from the government medical institutes due to non availability of drugs or asked to procure the drug/factor from the open market

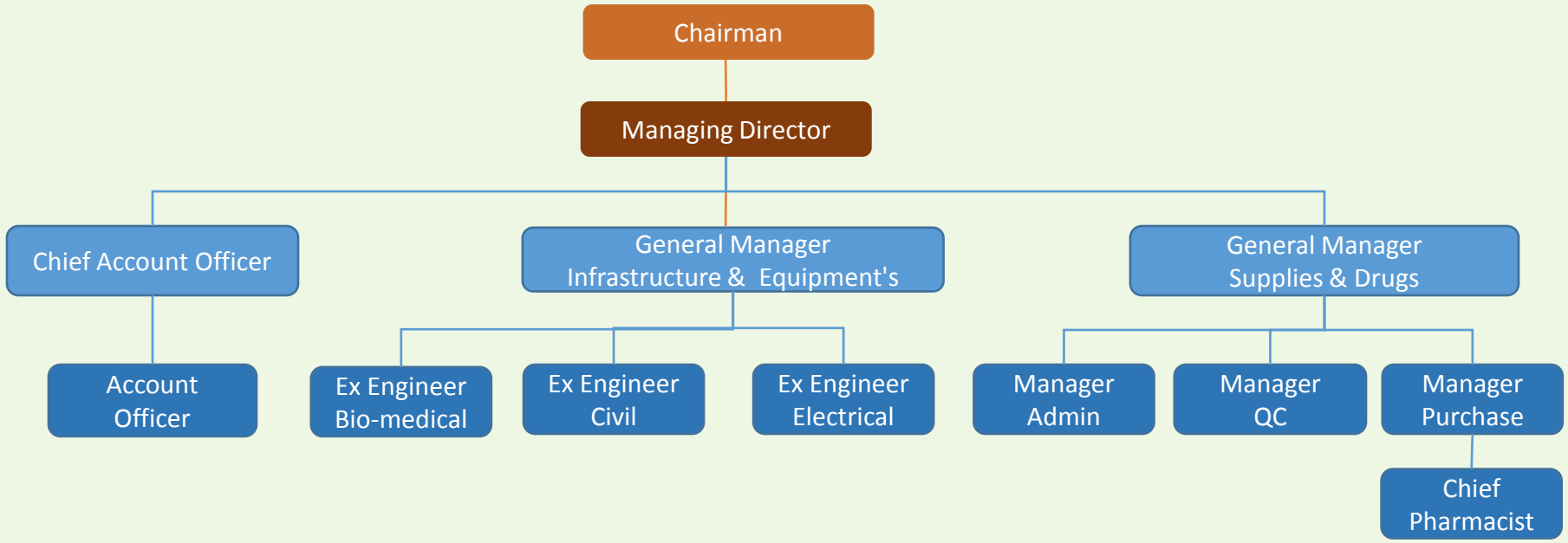
DECISION MAKING : STATE GOVERNMENT (CONT'D)

Overview of Drug procurement committee in State*

Board of Directors

- Secretary, Health & Family Welfare (Chariman)
- Secretary, Finance Department
- Director Medical Education
- Director Medical Health Services
- Director of Drug Control
- Managing Director (Drug Corporation)

Organogram



*-Designations and hierarchy are subjected to change as per the nomenclature and nature of the organisation

UNMET NEEDS AND ATTITUDE ASSESSMENT TOWARDS NEW PRODUCT

	Willingness to try	Not willing to try	Not sure
CGHS	↑↑↑ •If the product provides economical benefit •Clinical edge over the current treatment		↑↑ •Newer brands that are costly may have clinical edge.
ESIC	↑↑ •If the product is available at lower costs thus can be used for longer duration of therapy	↑↑↑ •Costly brands	
Railway	↑↑ •If the product provides the benefit over the available brands		
AFMSD	↑↑ •If the product provides the benefit over the available brands and have proven clinical advantage over the available treatment		
State Government	↑ •It will be based on the cost economic outcome of the product	↑↑ •If the product is costlier than the current available product	

Degree of response

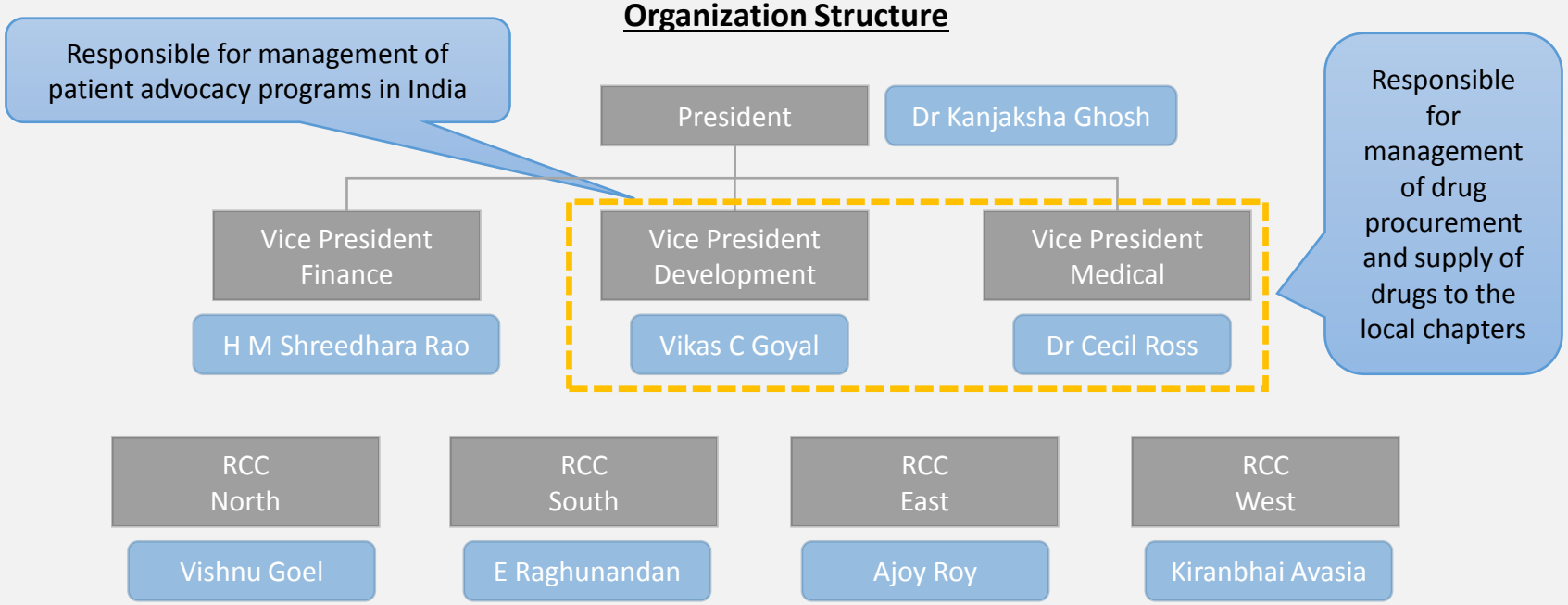
↑ **Low** ↑↑ **Moderate** ↑↑↑ **High**

HEMOPHILIA SUPPORT ORGANISATIONS

Hemophilia Federation of India:

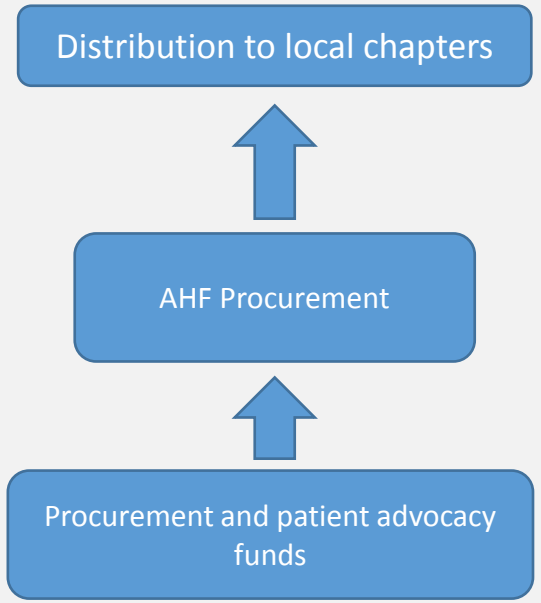
- HFI was established in 1983 it is a self-help NGO run by Persons with Haemophilia themselves. HFI represent India as National Member Organization at the World Federation of Haemophilia based in Canada. It also work in close collaboration with World Health Organization (WHO) and National Aids Control Organization
- HFI operates in India through 72 chapters (48 affiliated and 24 non-affiliated chapters) across the country
- In year 2013, HFI focused on activation of inactive or partially active chapter across India. For this an executive team was formulated which visited the chapters to understand and resolve their practical issues and challenges
- HFI in collaboration with AIIMS, NIIH-Mumbai and St. Johns Medical College has initiated the inhibitor screening program to have a periodic checking of inhibitor at least after 50 exposure days
- Procure AHF products majorly from **Baxter India and Novo Nordisk** and provide to patients on economical rates or for free to economically challenges patients

Organization Structure



HEMOPHILIA SUPPORT ORGANISATIONS

AHF Procurement Procedure for HFI



Procurement Agreement

- HFI currently is only procuring products from Baxter India
- Haemophilia Federation of India gets into MoU (undertaking) with the pharmaceutical company. This agreement entails details of minimum quantity that HFI commits to procure within the stipulated duration of the agreement
- On the basis of the commitment Baxter India in turn provides 30% of the unit for free of cost

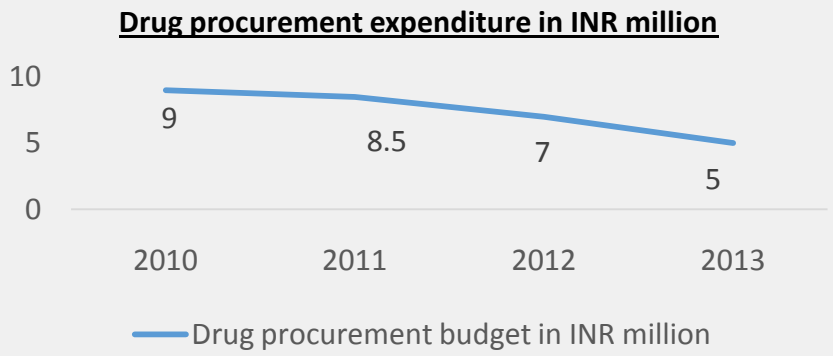
Distribution

- Indentation for all chapters across India is carried out at Delhi office, however delivery is made by local distributors to various chapters on need basis
- Since all chapters are locally based out of hospitals, the factors are stored in the cold storage facilities of those respective hospitals

Fund Raising

HFI is currently managing the funds through donations, fund raising activities and support from international organisations

HFI AHF Procurement trend: Delhi Chapter



- Procurement of factor VIII and IX by HFI is consistently been declining for the last 3-4 years
- Maximum procurement achieved was around INR 9 million in 2010
- Reasons for decline are:
  - Paucity of funds
  - Availability of factors in government institutes
  - Non supportive behaviour of Pharmaceutical companies

HEMOPHILIA SUPPORT ORGANISATIONS (CONT'D)

- HFI provide total quality care, education and treatment at affordable cost, psychosocial support and economic rehabilitation to the patient. On 17 April,2013 HFI organised a walk from Janpath to Boat Club, Delhi and distributed haemophilia awareness and education material
- Provide training through CME, Workshops and training seminar for the clinicians and paramedical professionals to keep them updated and maintain competency level
- Two international Haemophilia Training Centres at CMC Vellore and KEM Hospital Mumbai
- HFI maintains national haemophilia registry which is fully functional and approved by the Institutional Ethical Review Board of St. John's Medical College & Hospital, Bangalore

- **Associations:**

  - Baxter India
  - Novo Nordisk
  - HANS Foundation
  - ONGC (Oil and Natural Gas Corporation)
  - SAIL (Steel Authority of India)
  - CANON
  - Give India
  - Nestle India

- **Patient Advocacy Programs:**

  - Medical assistance to children and person with Haemophilia
  - Carrier detection test for unmarried women and pre-natal diagnosis for female haemophiliacs
  - Financial support to haemophiliac families
  - Provide Anti-Haemophilic factors to patients for free or subsidized rates
  - Education and awareness campaigns
  - Educations support to Haemophilia children's
  - Providing alternative treatment support to patients

- HFI does not receive any kind of financial aid from government of India rather certain government undertakings like ONCG, BHEL and so on provide assistance to HFI in organizing camps and advocacy program for Hemophilia
- HFI is consistently making efforts for the rights of patients and has filed PIL in state high courts for approval and establishment of Hemophilia centers across every state in the country

HEMOPHILIA SUPPORT ORGANISATIONS (CONT'D)

HFI Anti Haemophilia Factors procurement and supply rates

Factor	Procurement rate (Per unit in INR)	Price to Patient (Per unit in INR)*
VIII	10	0 to 12
IX	18	0 to 20

** Price to patient depends on the payer capacity*

Availability of Haemophilia treatment post intervention of HFI

Complete treatment

- Jammu &Kashmir
- Uttar Pradesh
- Uttarakhand
- Tamil Nadu
- Gujarat
- Goa
- Rajasthan
- Haryana
- Delhi
- Bihar
- Assam

Partial treatment

- Jharkhand
- Maharashtra
- Karnataka
- Andhra Pradesh
- Kerala

PIL/Lobbying in progress

- Punjab
- West Bengal
- Orissa

PIL to be filed

- Chhattisgarh
- Nagaland
- Mizoram
- Tripura
- Arunachal Pradesh
- Meghalaya
- Manipur

As the state government and central government is taking initiatives for establishment of treatment and management centres for Haemophilia, the over all market for AHF is likely to see an expansion due to increase in budgetary allocations for the procurement of drugs, in near future

HEMOPHILIA SUPPORT ORGANISATIONS (CONT'D)

Hemophilia patients welfare society:

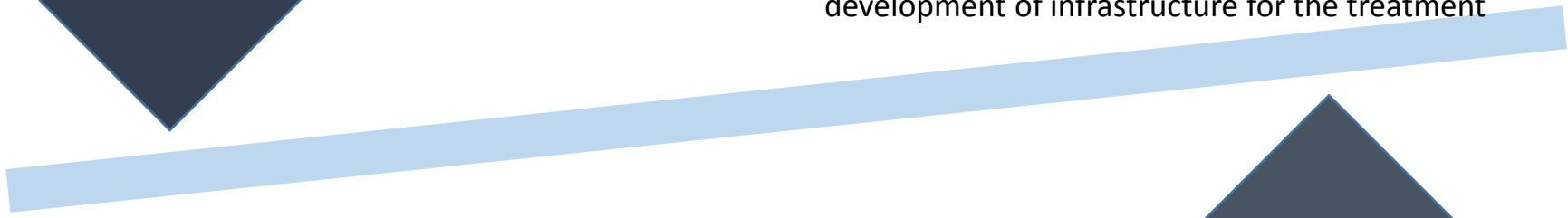
- It is a non-profit organisation based out of Lucknow which works for the welfare of people suffering with a genetic disorder haemophilia
- Provide education and information about Haemophilia care, to make treatment available at affordable cost
- Provide AHF at subsidised cost
- Provide support by locating undiagnosed person, provide carrier detection test and prenatal diagnosis
- After intervention of UP High Court, society has brought about INR 135 lakhs in year 2012 from state government

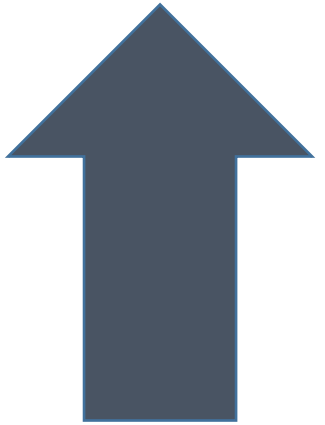
Government support

- The central government will provide financial assistance under the National Rural Health Mission (NRHM) to state governments to help haemophilia patients
- State governments were invited by the centre to submit proposals for treatment of haemophilia cases in their respective programme implementation plans for consideration of assistance
- Indian Railways provide discounts to Haemophilia patients on travelling

Barriers and Enablers

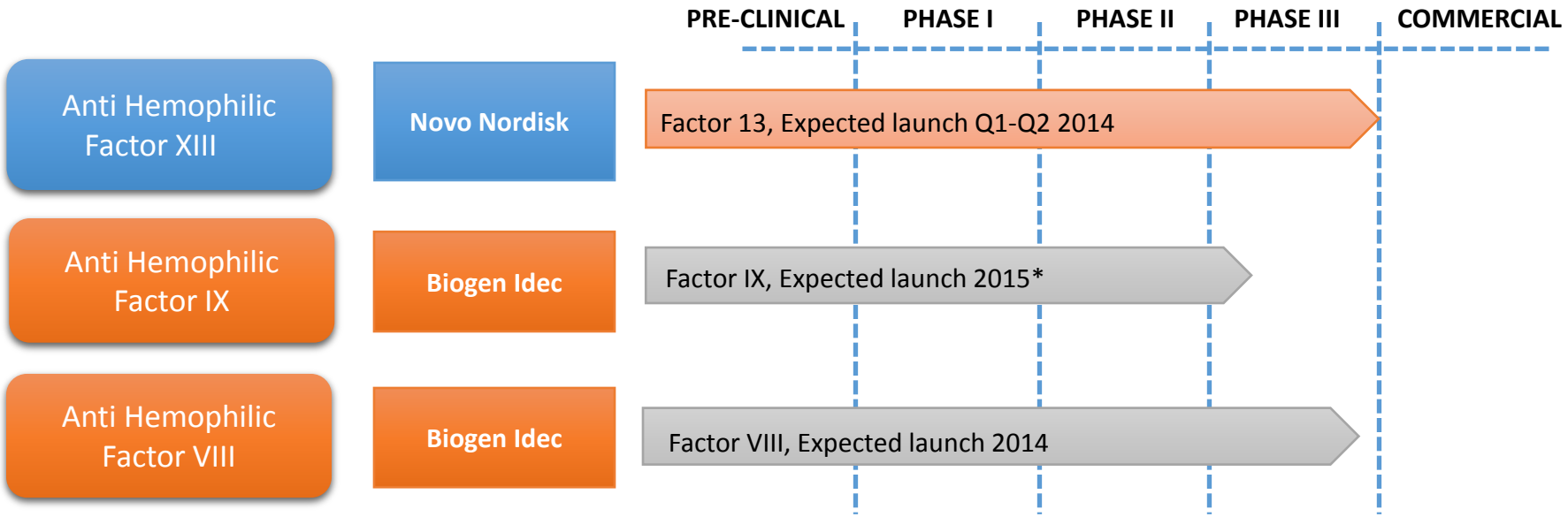
- Better diagnosis and improved treatment options
- Improved standard of care
- Increased numbers of Hemophilia Treatment Centers
- Improved safety of AHF; Recombinant AHF
- Development of Inhibitors
- Initiative by state and central government for development of infrastructure for the treatment





- High cost of therapy
- Poor patient compliance and adherence to the treatment
- Limited options for the patients with inhibitors, available options pose major economic challenge
- Lack of awareness and knowledge
- Non-availability of the AHF in remote areas
- Lack of early treatment and prophylaxis options
- Storage and administration of clotting agents
- Approach to Hemophilia Treatment Centre is difficult for the patients from remote areas and for those with lack of transportation, and with crippling physical disabilities

PIPELINE ANALYSIS



Other AHF brands which are currently not available in India are as follows:

- Xyntha (Factor VIII) – **Pfizer**
- BeneFIX (Factor IX) – **Pfizer**
- Helixate FS (Factor VIII) – **Bayer**
- Kogenate FS (Factor VIII) – **Bayer**

*-Expected global launch

Source: LSCPL primary interviews and other secondary sources

ANNEXURE

Hemophilia Comprehensive Care included in the 12th Five Year Plan:

- Govt. of India has included hemophilia care in 12th five year plan which will provide comprehensive care services including diagnosis and management of hemophilia in 120 medical colleges throughout the country
- Central government under the NRHM has approved INR 32.4 million for treatment of Hemophilia in the state of Haryana

  - State government has designated general hospitals of Gurgaon, Karnal, Ambala, Hisar, and Rohtak where the treatment of Hemophilia would be available
- Central government under NRHM allocated INR 11 million and INR 32.4 million for Hemophilia treatment to government of Jharkhand and government of Maharashtra, respectively
- Rashtriya Bal Swasthaya Karyakram (RBSK) under NRHM provides facility for early detection and treatment of Haemophilia
- It is considered as a great achievement of HFI which had been lobbying with the Govt. for last two years
- From 23rd to 24th February 2013, HFI organized a National Hemophilia Care Meet at Hotel Ashoka, Bangalore. The meet was sponsored by **Novo Nordisk** and was jointly organized by HFI, CMC & Saint John's. Approx. 120 participants including medical experts

Hemophilia Annual General Body Meeting:

- Annual General Body Meeting 2013 was held on September 28th & 30th 2013 ad Vishwa Yuvak Kendra, New Delhi. More then 150 patients, their families and doctors were present on this 2 day event which consist of trainings, presentations and awards were given to patients

ANNEXURE

Salient features of HFI report filed for Public Interest Litigation

- For the Dept. Health, Govt. of NCT of Delhi:
- An AHF facility to be set up in 3 hospitals, namely Lok Nayak, DDU and GTB hospital.
- All BPL (below poverty line) families will be provided free AHF
- In emergency cases of emergency, free treatment to all Haemophilia patients in the designated hospitals.
- Graded payment system in respect of APL (above poverty line) patients with minimum 3 years domicile in Delhi:
  - Family income up to Rs. 200,000 per annum – 20% cost of AHF
  - Family income up to Rs. 250,000 per annum – 50% of cost of AHF
  - Family income above Rs. 500,000 per annum - full cost of AHF to be borne by the patient
- Central Government hospitals functioning in Delhi to provide AHF free to BPL category and to patients in emergency.
- Monthly clinics to be started shortly in Safdarjang and Kalawati hospital.

ANNEXURE

Split of Patients on the basis of On Demand (OD) vs Prophylactic therapy vs Severity of Haemophilia (n=10)

Severity	Therapy	% of patients
Mild	OD	30%
Moderate	OD	20%
Severe	OD	50%

THANK YOU