
India strengths in ARVs to fight Global AIDS Epidemic

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Global AIDS Epidemic

1. AIDS has killed more than 25 million people since 1981.
2. A total of 40 million infected as of now and 5 million people are newly infected in 2005.
3. Sub-Saharan Africa - the worst hit with more than 25 million infected and an estimated 2.4 million deaths in 2005, in this region.
4. Growing infection and deaths in Asia.

It is an extraordinary global health challenge.....also an extraordinary subject.....

Global Treatment Forecast

Year	Adults and children on ARV	Adult On ARV	Adult Unmet Need	Child On ART	Child Unmet Need	
2006	1,700,000	1,600,000	4,800,000	110,000	610,000	
2007	2,400,000	2,200,000	4,800,000	180,000	610,000	
2008	3,100,000	2,800,000	4,700,000	260,000	610,000	
2009	3,900,000	3,600,000	4,600,000	360,000	590,000	
2010	4,900,000	4,400,000	4,500,000	470,000	570,000	

Source - UNAIDS

An extraordinary existing and anticipated gap in treatment cover age...

1. There has been good progress in last two years in some countries like Brazil, Argentina and Cuba with coverage reaching 80%.
2. Progress is very slow in sub-Saharan Africa, poor countries in LA and Central America and Asia.
3. As of mid 2005, only one in ten Africans who need ARVs, actually receive ARVs

An extraordinary gap in treatment coverage in
Africa...

Global ARV need Forecast

Year	Total ARV	First Line	Toxicity	Second Line	TB ARVs
2006	3,027,506	2,690,408	78,015	43,966	215,117
2007	4,810,317	4,330,761	101,515	98,582	279,459
2008	6,615,521	5,999,434	111,560	197,011	307,516
2009	8,281,746	7,584,852	116,615	256,891	323,388
2010	9,760,567	8,861,775	121,834	452,135	324,823
2011	11,198,156	10,005,795	135,557	703,808	352,996
2012	12,392,503	10,827,875	139,000	1,064,118	361,509
2013	13,346,625	10,912,778	141,144	1,922,825	369,879
2014	14,085,401	10,789,279	142,608	2,774,005	379,509
2015	14,653,204	10,155,714	144,247	3,966,500	386,742

An extraordinary need for ARVs ...

Source - UNAIDS



India Responds...

1. Development of Generic drugs and FDCs
2. Manufacturing of APIs and Formulations
3. Regulatory Filings
4. Reaching out globally to serve the markets needs

1. India companies are some of the first companies in the world to have developed Generic ARVs
2. Indian companies have invested heavily in R&D for Generic ARVs , Single dose drugs and FDCs.
3. Indian R&D infrastructure and talented scientists facilitate faster development time, therefore, quick to serve the market thus providing better access.
4. Most of the Indian Companies who are focused on ARVs have developed some of the second line drugs

Effective Development capabilities...

1. Indian companies with a strategic focus on ARVs , have set up huge formulation manufacturing capacities, probably, that can meet the global demand.
2. Some Indian Companies for eg., Aurobindo Pharma have invested heavily in API manufacturing capacities thus providing reliable supply of API for global needs.
3. Manufacturing plant approvals by USFDA, WHO pre -qualification project.

Huge manufacturing facilities with an ability to further scale up....



Regulatory Filings and Approvals

1. Highest number (12) of USFDA approved Generic ARVs are from one Indian company i.e, Aurobindo Pharma.
2. Highest number of Generic ARV manufacturing companies, including Aurobindo Pharma, who have WHO pre-qualified ARVs.
3. Most Indian manufactured ARVs are registered in most of the countries in Africa.

Most approvals from Stringent Regulatory authorities...



Reaching out to serve.....

1. Indian companies supply most of the generic ARVs under Global Fund projects in most of Africa and Rest of the World.
2. Some Indian Companies like Aurobindo are major suppliers of ARV APIs to many customers globally.
3. Indian Companies are in better position serve PEPFAR needs globally as most Generic ARV USFDA approvals belong to Indian Companies.

High width and depth of coverage..



In summary ..

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1. Very good R&D infrastructure and resources to develop Generic ARVs and very good portfolio of products already developed.
 1. Large API manufacturing capacities with an ability to scale -up.
 2. Huge Formulation mfg. Capacity.
 3. Highest number of Product and Plant approvals from Stringent regulatory bodies like USFDA and WHO.
 4. Very good penetration and registrations in Africa and other third world countries ..

An excellent response to an extraordinary global health challenge e...

Further increase in momentum to serve unmet need of quality and affordable ARVs for Africa region....



Aurobindo's Strategic Focus on ARVs

1. Aurobindo, in line with its mission “quality and affordable pharmaceuticals to all” have invested heavily in ARV development and manufacturing, treating ARV as a Strategic Therapy Area to take on the extraordinary global health challenge.
2. Has the largest basket of ARV APIs, among the Indian Companies, with large API mfg. capacities.
3. Has the largest number (12) of Generic ARVs approved by USFDA or WHO Pre -qualification project. These products include First line drugs and Ped. Formulations.



Aurobindo's Strategic Focus on ARVs

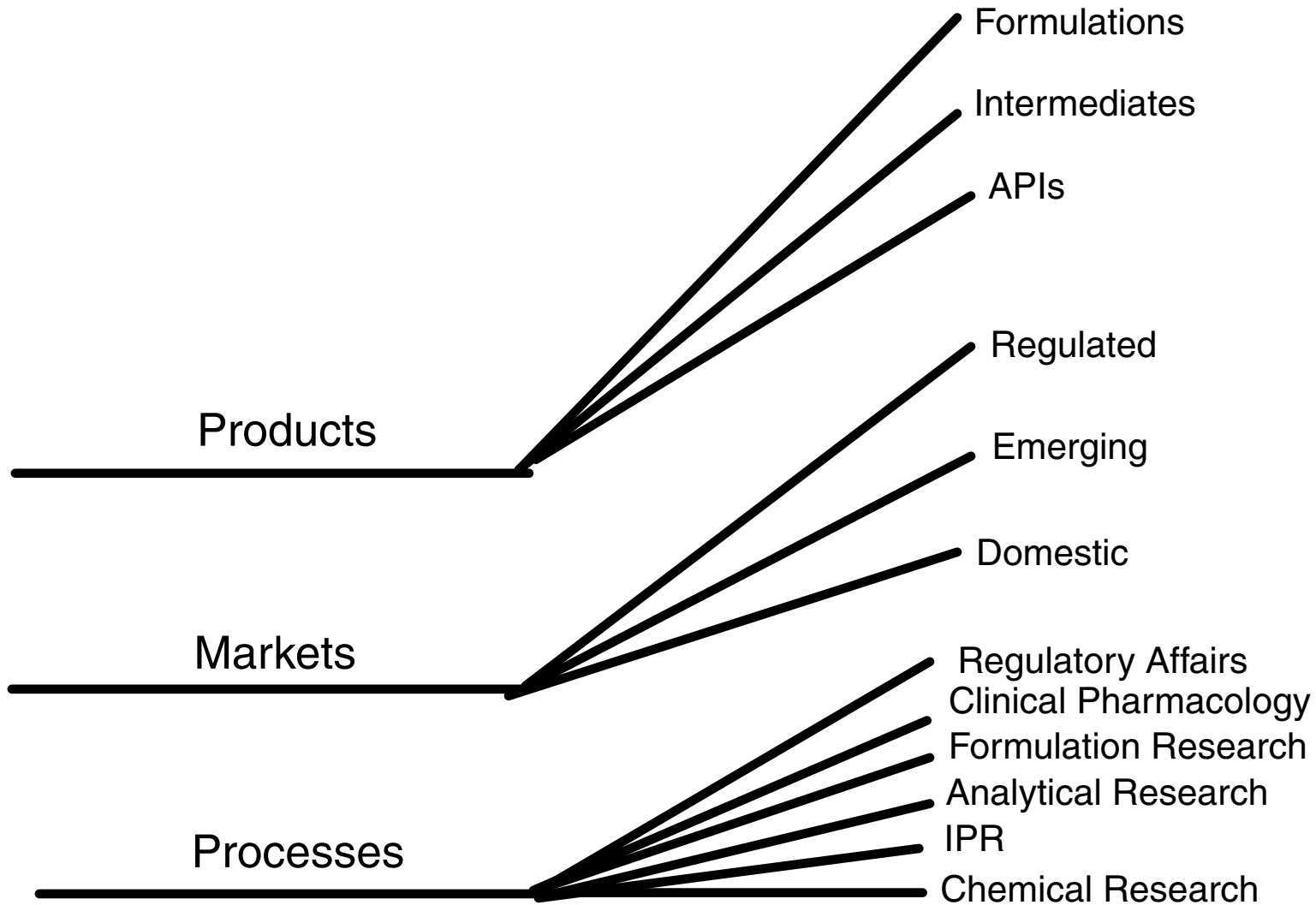
1. Huge formulation capacities for ARV products and these facilities are approved by USFDA, MCC, WHO Pre-qualification project.
2. Registration of ARVs in most countries of Africa.

- A vertically integrated pharmaceutical powerhouse
- Headquartered in Hyderabad, India
 - Over 120 APIs and formulations. Exports to over 100 countries. More than 60% of sale goes to emerging global markets
 - One of India's top 5 pharmaceutical companies. Among the top 3 exporters in the industry
- Subsidiaries in strategic pharmaceutical markets like USA, China, Brazil
- One of the top 4 global producers of key anti - infectives
- Strategic Presence in anti - infectives , ARVs, CVS, CNS,

Ranks in the top 100 in Forbes Magazine's
Asia's 100 best growth companies



Vertically Integrated all the way



Aurobindo R&D Strengths



More than 500 Talented Scientists

16,000 Sq. mts . R&D facilities

- In-house R&D capabilities to deal with complex chemistry and get speedy audit/approvals
- Demonstrated quality of skills, dossiers, filings and production capabilities



R&D Lab..
Most
modern





Manufacturing Facilities – state-of-the-art



- 92 API manufacturing blocks/modules
- 37 blocks/modules for Formulations
- USFDA, MHRA, ANVISA, Health Canada, WHO approved.

Our Manufacturing Strengths..



- Regulatory compliant facilities
- Cost effective operating structure
- Mammoth capacities
- Track record of reliability
- Vertically integrated
- Skilled workforce

All Facilities cGMP compliant



- Total Area around 4,000,000 sq.mtrs
- Plant area 936,000 sq mtrs.
- Built-up area 304,000 sq mtrs.
- Manufacturing area 145,000 sq mtrs.

cGMP Compliant Facilities . . .





Cost Efficient and Mega Infrastructure



Thank You