

India and Second-Line ART

Evaluating the Way Forward

INP+ Dissemination Workshop

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Current Scenario: National ART Programme

- Number of PLHIV on first-line ARVs: 62, 731
- Number of deaths since April 2004: 4907
- Five-year targets set by NACO:
 - 2007: 100,000
 - 2008: 125,000
 - 2009: 150,000
 - 2010: 184,000
 - 2011: 300,000

How does India compare to other countries in providing second-line ART?

- India is providing no second-line HIV drugs.
- Compare to:
 - Brazil: LPV/r, ATV, TDF and ENF.
 - Thailand: ABC, ddl, LPV/r, SQV/r
 - South Africa: LPV/r and ddl.

How much will it cost?

- According to GFATM, NACO believes it will cost \$3m in the first year, \$7m in the second year, and \$70m in later years.
- Discussion paper finding: tentatively, it will cost \$2m in the first year, \$3m in the second year, and \$7m in the fifth year.
- The total 5 year cost to provide second-line ART is \$19m.

Who Will Pay?

- In the first two years, Clinton Foundation/UNITAID will cover the cost of providing second-line ART.
- In the next three years, NACO's cost is estimated to be \$14m.
- GFATM funds exist to cover this cost, but a submission must be made to request that this include second-line ART.
- The NACP-3 five year proposed budget for ART is 1334 crores (\$302.6m) and the overall HIV proposed budget is \$2.6b.

How many people need second-line ART?

- There are no formal estimates.
- Raw data obtained from 38 ART centres shows that 900 PLHIV need second-line ART.
- There is a need to quantify % people needing ARVs, and measure drug resistance - these numbers are needed to accurately project needs of people requiring treatment.

What will the new ART guidelines recommend for second-line ART?

NRTI:

- 1st TDF/ABC
- 2nd ddI/ABC
- 3rd TDF/AZT

PI:

- 1st LPV/r
- 2nd ATV/r
- 3rd SQV/r
- 4th IND/r

Where does NACO buy its drugs from now?

- NACO buys its drugs primarily from Indian generic companies.
- A comparison of NACO's procurement prices to global lowest prices demonstrates that NACO/HSCC are negotiating best prices.

Why is second-line ART more expensive?

- Second-line ART is more expensive than first-line ART. There are four reasons for this:
 - Lack of competition leading to high prices (patents contribute to this problem)
 - Low demand volume
 - Dosage-related issues
 - Chemical complexity of second-line ART

Are prices likely to drop?

- The answer is yes. More competition, more certainty with demand volume. Even dosage issues and chemical complexity is being addressed.
- Experience with first-line ART shows that prices come down.

What can NACO do about the cost?

- NACO should recommend to Ministry of Chemicals and Fertilizers that they waive duties and taxes of Active Pharmaceutical Ingredient and intermediates required to make second-line HIV drugs. This adds a modest amount to the price of the drug.

What can NACO do to use GFATM funds to purchase second-line ART?

- ABC and ddi - Indian generic manufacturers
- IDV, TDF and LPV/r capsules - needs approval. There is precedent for such approval from GFATM for other countries.
- SQV and NFV - cannot be purchased at this time.
- LPV/r tablet and ATV must be purchased from the originator

Government Use

- NACO should be ready to use 'government use' provisions under law to provide ARVs to PLHIV in India.
- The law allows NACO to start purchasing key drugs even while the patent application is pending.
- Many other countries have issued government use licenses.

Procurement and Supply

- Transparency - NACO and HSCC should make available on the website:
 - Procurement plan
 - Suppliers to ART programme
 - Processes used to select procurement agency and select suppliers/drugs
 - Prices of drugs purchased
 - Quality control

Procurement and Supply, cont.

- Civil Society Involvement - In the Philippines, civil society participation in monitoring procurement is mandated by law
 - PLHIV should be involved in monitoring procurement in India, institutionally and otherwise
 - Most information is public and should be made available upon request

Programme Review

- Revised National Tuberculosis Control Programme experience - 2nd line drugs to be introduced
- From its inception, RNTCP has used a process of external programme review
- Uses experts with actual programme-building experience to offer implementation strategy and review
- ART programme could benefit from such a process, not in 5 years, but like RNTCP from early stages - PLHIV participation.

Key Recommendations

- NACO should immediately accept CHAI/UNITAID's offer to fund first two years of second-line ART, and start PLHIV on treatment by 1 May 2007.
- INP+ will provide the list of network members requiring 2nd line.
- NACO/donors to reimburse those who paid out-of-pocket.
- NACO/donors to support INP+ in the Positive Fund.