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Health innovation, IPRs and access to essential drugs: experiences of and emerging options for the IBSA countries

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Tuesday, April 13th 2010
IBSA Academic Forum
Brasília, Brazil

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Overview of presentation

- **State of play in South Africa**
  - Medicines for HIV/AIDS
  - Medicines generally
- **Placing IP within context of current concerns**
  - Drug regulatory processes
  - Procurement and supply chain management
  - Domestic industrial policy
- **Identifying future action**
  - Implications of developments in other IBSA countries
  - Proactive agenda

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State of play in South Africa

- **Medicines for HIV/AIDS**
  - First generation ARVs
    - Off-patent, patents not enforced, or “non-voluntary” licences granted
  - Second generation ARVs
    - In general: not patented, patents not enforced, or licences granted
    - Notable exception: lopinavir/r
  - Latest drugs
    - Handful of licensees or exclusive co-marketing agreements
  - Other HIV-related medicines
- **Medicines generally**
  - “Transparent” pricing mechanism with some price controls
  - TRIPs+ legal framework insufficient for ensuring access

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IP within context of current concerns

- **Drug regulatory processes**
  - Regulatory backlogs
  - Inability/unwillingness to align with national health priorities
  - Particular concern about FDCs without innovator references
- **Procurement and supply chain management**
  - Centralisation of procurement: health vs. treasury
  - SCM concerns: added costs; potential for corruption; delays
  - “Fiscal federalism”: conditional grant vs. equitable share
- **Domestic industrial policy**
  - Undue focus on preferential procurement
  - Limited attention to sustainability of supply

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Identifying future action

- **Implications of developments in IBSA countries**
  - Proposed EU-India FTA
    - In context of Patents (Amendment) Act, 2005 – already TRIPs+
    - Additional TRIPs+ provisions sought
  - Narrowing pipeline of generic antiretrovirals in India
    - Pre-1995 drugs
    - Mailbox applications and patent oppositions
    - Products patented post-2005
- **Proactive agenda**
  - Aligning patent legislation in favour of access
  - Creating conditions for API production: IBSA or beyond
  - Technical co-operation: drug regulation and manufacturing

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