SUMMARY OF COUNTRY MAPPING EXERCISE

Regional Consultation and Planning Workshop 'Use of TRIPS Flexibilities to Access Affordable ARVs in Asia'

Bangkok 29-31 May 2012

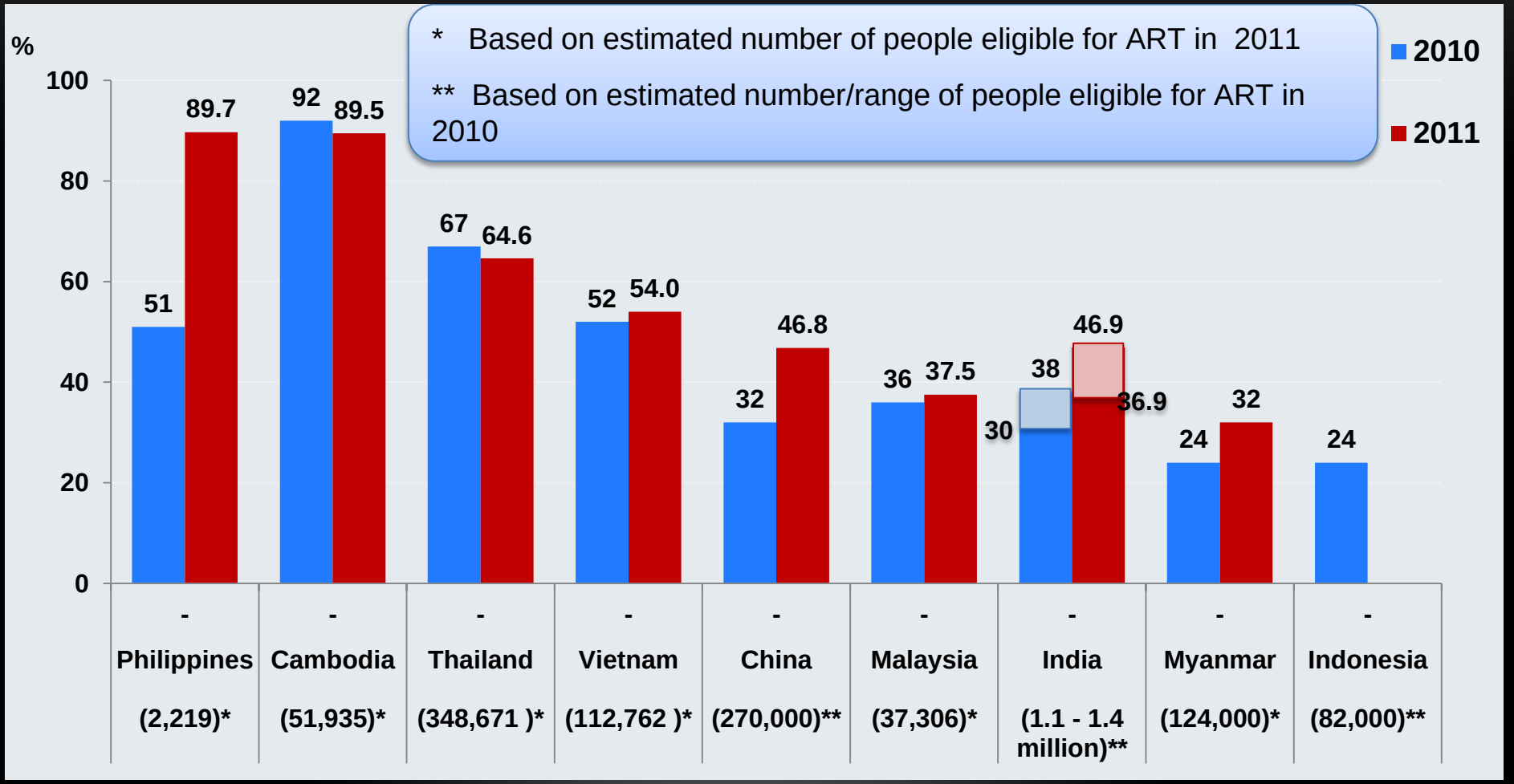
Bob Verbruggen, UNAIDS & Jennifer Ho, Consultant

OBJECTIVES

- Rapid review of current situation, challenges, and opportunities related to access to affordable ARVs
  - (Quasi) complete: Cambodia, China, Myanmar, Philippines and Viet Nam
  - Partial: India, Malaysia, Thailand

- Sections:
  - ART coverage
  - Adoption and implementation of 2010 WHO guidelines on ART
  - Funding for ART and procurement of ARV
  - Legal environment for production, importation and exportation of generic medicines
    - Patent status of key ARVs
    - Challenges and opportunities for the use of TRIPS flexibilities/protection against TRIPS-plus

SECTION I: ART COVERAGE



SECTION II: IMPLEMENTATION OF 2010 WHO GUIDELINES ON ART

STATUS	COUNTRIES
Full adoption, officially endorsed, rollout started	Myanmar, Thailand, Vietnam
Full adoption, awaits official endorsement, rollout has not yet started	China
Partial adoption, officially endorsed, rollout started with plans for full adoption in later dates	Cambodia
No new guidelines, 'unofficial' adoption, rollout has started	Malaysia, Philippines
No new guidelines yet.	India

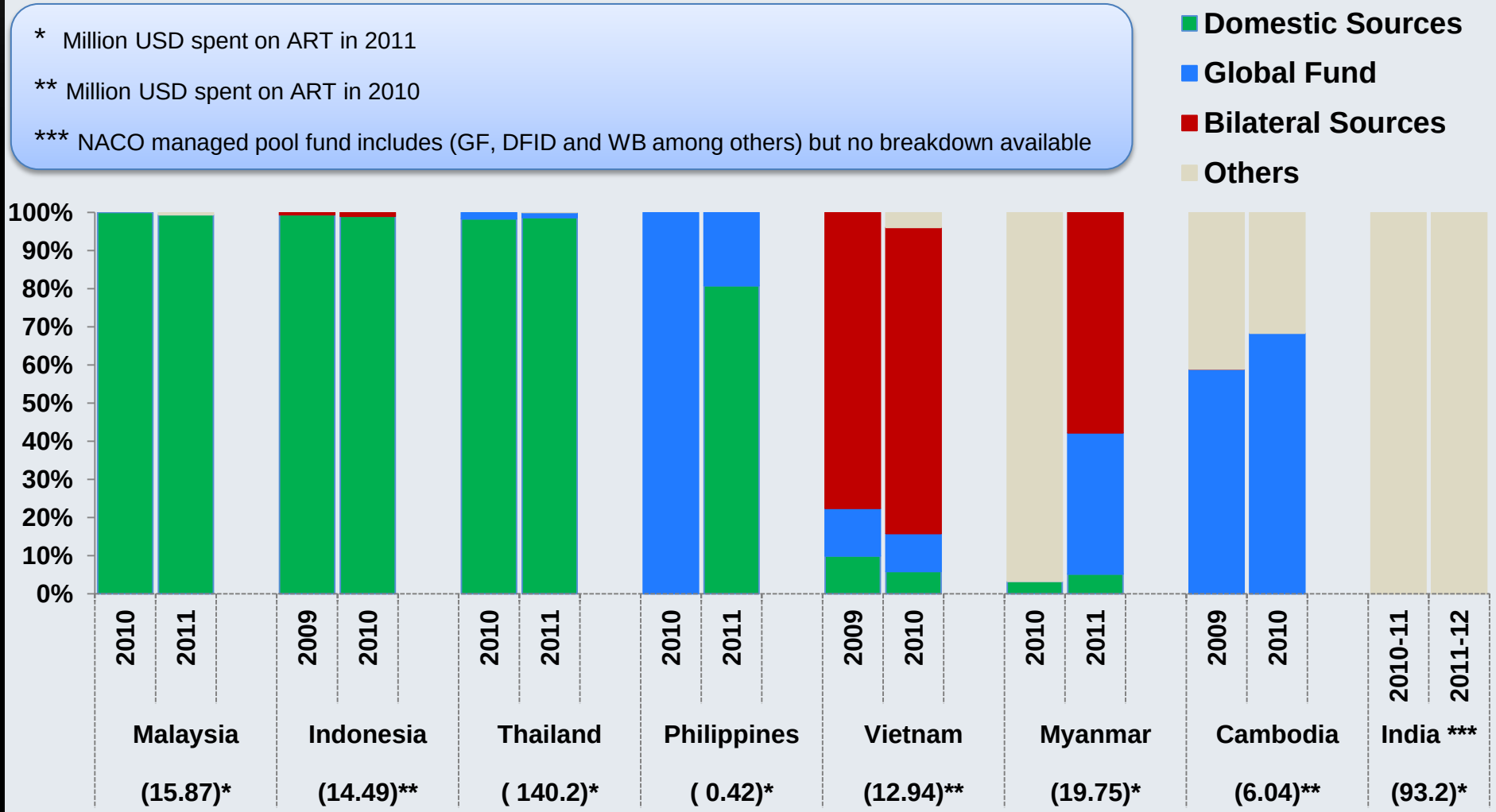
- Challenges to rollouts:
  - Cost (d4T in stock, TDF procurement, increased # of ppl eligible for treatment)
  - Training (e.g. healthcare providers)
  - System capacity (e.g. procurement)

SECTION III: AIDS AND ART PROGRAMME FUNDING SOURCES AND EXPENDITURE

* Million USD spent on ART in 2011

** Million USD spent on ART in 2010

*** NACO managed pool fund includes (GF, DFID and WB among others) but no breakdown available



SECTION IV: ARV PROCUREMENT SOURCES

CATEGORY	COUNTRIES
Domestic production of all currently recommended ARVs available	India
Mainly domestic production, imports only patented second-line ARVs for which there are no compulsory licenses (CLs)	Thailand
Mainly domestic production, imports patented ARVs	China
Some domestic production, imports patented and off-patent ARVs from originators and generics	Malaysia
Some domestic production, imports mainly generic ARVs	Vietnam
No domestic productions, imports both generic and patented ARVs, depends on procurement intermediary for ARVs	Cambodia, Myanmar, and Philippines

SECTION V: ARV PATENT STATUS

- Information extracted from Medicine Patent Pool Patent Database:
  http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/
- Updates received from VN only
  - Suggests that this information is difficult to obtain
- No patents in least developing countries (LDC): Cambodia and Myanmar
- Patents for most recommended first-line ARVs have expired or are about to
  - Exception TDF: patent granted or filed in at least one formulation in four (4) of the six (6) countries
  - Not patented in Malaysia
  - Vietnam is included in the Gilead Science-Medicine Patent Pool Voluntary Licensing Agreement on TDF

SECTION V: ARV PATENT STATUS (CONT.)

- Patents for recommended second-line ARVs have been either filed or granted in at least one formulation in five (5) of the six (6) countries
  - Unknown in Malaysia

- Patents for newest ARVs (e.g. Maraviroc, Raltegravir) have been granted relatively quickly in : China, India, Malaysia, Philippines, Vietnam
  - Patent applications filed in Thailand

- India the only country where ARV patent applications have been actively rejected or opposed
  - China had 1 1/2 (ABC peadiatric formulation – divisional applications pending; AZT+3TC tablet formulation - rejected)
  - Thailand – two (2) successful oppositions (3TC/AZT & ddI)
  - Vietnam – first ever opposition filed

SECTION VI: COUNTRY LEGAL FRAMEWORK

- Patent acts are relatively easily accessible (received copy from all reporting countries; often available on public websites)
- Seven (7) out of eight (8) countries have patent laws
  - Two (2) LDC countries not required to have patent laws by WTO
    - Cambodia's patent law specify no pharmaceutical patents until 2016

SECTION VI: COUNTRY LEGAL FRAMEWORK

- The other six reported patent laws amended to comply with WTO TRIPS agreement and to create legal space for use of TRIPS flexibilities
  - E.g.: CL, parallel importation, patentable subject matter, bolar exception
  - Space/need for further amendments of laws and better use
    - Malaysia (CSO & MOPI): mechanism for pre- and post-grant opposition
    - Philippines: mechanism for importing generic version of patented med
    - Vietnam: patent-registration linkage provision within MoH guidance for drug registration resulted from foreign trade agreements

SECTION VI: COUNTRY LEGAL FRAMEWORK

- Three (3) of five (5) reporting countries + India are engaged/ing in FTA discussions: China, Malaysia, Vietnam
  - In three cases, TRIPS plus provisions are on the table (EU-India and TPP)
    - E.g: data exclusivity and patent-registration linkage
    - Clear stance from Indian Government

- No confirmation regarding Anti-Counterfeit Trade Agreement (ACTA) from any of the countries

SECTION VI: COUNTRY LEGAL FRAMEWORK

- Two (2) LDC counties not required to have patent laws by WTO but they recognise the need to urgently strengthen their legal framework and procurement capacity

- Although not asked, four (4) countries reported interest in and obstacles to strengthening domestic productions (China, Malaysia, Philippines, Vietnam)

> *"Local pharmaceutical companies are gradually becoming stronger in generic drugs manufacturing and legal conditions are supportive, being improved to allow them to access generic drug production technologies" (Vietnam Team)"*

> *"Recent pressure from US government hampers the effort by the Malaysian government to revise its policy and law in IP as effort to promote the growth of generic pharmaceutical industry [in Malaysia] under the Malaysia Economic Transformation Project for Healthcare" (Malaysian Organisation of Pharmaceutical Industries (MOPI))*

KEY POINTS

- Collecting this information has been challenging for all countries
  - Not only patent information but e.g. also procurement information
  - Stakeholders not routinely engaged with each other but when they do, they produce very good responses – illustrating the need for coordination mechanism
- Part of the challenges is the sensitivity of the issues as they relate to 'national interest' – but also under pressure of FTA partners
- Ample examples of good practices (e.g. CLs, local productions) from across the region to learn from and build on
- As access agenda moves into new phase (2015 commitments, less funding, pressure from FTAs), countries need to express willingness and increase capacity to protect their citizens' right to health
  - High-level of awareness of the issue - but transparency and coordination will be prerequisites for appropriate action