REGULATORY PROGRESS

Ann M. Ginsberg
Stakeholders Association Annual Meeting
Berlin, Germany
November 9, 2010

Open Forum Series on Key Issues in TB Drug Development

Goal: *Enhance awareness of key stakeholders (especially, but not only: regulators, Ministries of Health, and NTPs) regarding progress in TB drug development and associated key regulatory issues*

Open Forums on Key Issues in TB Drug Development

- Open Forum 1 – Washington DC; Dec. ‘05
- Open Forum 2 – London, England; Dec. ’06
- Open Forum 3 – Delhi, India; May ’08

- Focus on Africa
- Location: Addis Ababa, Ethiopia
- August 18-19, 2010
- Additional support via unrestricted educational grants from: Astra Zeneca, Aptuit, Bayer, Celgene, GSK, Novartis, Pfizer, PharmaNet, sanofi aventis, Tibotec

SPONSORS:

TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

BILL & MELINDA GATES foundation

Working Group on new TB drugs

TAG
Treatment Action Group

Federal Democratic Republic of Ethiopia
Ministry of Health

EDCTP

Standards of Care for TB Treatment

Panel: Akihiro Seita, WHO/ EMRO; Jeremiah Chakaya, DOTS Expansion WG; Hind Satti, Partners in Health; Tony Moll, Tugela Ferry Hospital; Giorgio Roscigno, FIND Diagnostics

Development of Novel TB Drug Regimens--Defining a Critical Path

Charles Mgone, EDCTP

Advice to Sponsors: meeting regulatory requirements for new TB drug approvals in Africa

Regulators Panel: Apollo Muhairwe (Uganda); Adam Fimbo (Tanzania); Gamal Khalafall Mohamed Ali (Sudan) ; Mandisa Hela (South Africa); Rex Nkhoma (Malawi); Dawit Dikasso (Ethiopia); Vincent Ahonkai (Gates Foundation)

Challenges and Processes for Adoption of New Drugs: The process required to change national TB treatment guidelines in African nations

NTP Panel: Charles Sandy (Zimbabwe); Herman Weyenga (Kenya); Michel Gasana (Rwanda); Kesetebirhan Admasu (Ethiopia); Savior Yevutsey (Ghana); Francis Adatu-Engwau (Uganda); Jeremiah Chakaya (DOTS Expansion WG)

WHO Participation

Haileyesus Ghetahun


Akihiro Seita


Christian Lienhardt

Community Participation

Dorothy Namutamba, ICW East Africa

Francis Apina, TB Alliance Stakeholders Association

2010 Other Regulatory Advances

- CPTR launched – FDA Commissioner, Margaret Hamburg

- Regulatory Guidances issued:
  - EMA – *Addendum to the Note for Guidance on Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections* ***to Specifically Address the Clinical Development of New Agents to Treat Disease due to Mycobacterium tuberculosis;*** adopted by CHMP January 2010
  - FDA – *Draft Guidance for Industry:* ***Non-Inferiority Clinical Trials***; March 2010
  - FDA - *Draft Guidance for Industry:* ***Qualification Process for Drug Development Tools***; October 2010

Thank you