A New Paradigm for MDR-TB Drug Supply

What the World Health Assembly Resolution Will Change

Russian Academy of Medical Sciences
Institute of Medicine
Moscow Forum
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GLC – Symbol of the Old Paradigm

- DOTS-Plus Pilot Phase
- Reservations about Safety of Tx – GLC control
- Significant Doubts about Need for Tx
- Only WHO Quality-Assured Drugs
- Only Limited Quantities of Drugs Available
WHA Resolution – New Paradigm

- “a threat to global health public security”
- less than 3% cases treated per WHO standards
- Urges Member States to achieve “universal access to diagnosis and treatment of MDR/XDR-TB”
WHA 62.15 (May 2009)

• Drug Supply and Quality are a Major Focus
• “inadequate demand” for international Quality-Assured drugs, and
• “inadequate supply (of drugs) through the GLC”
• “are major bottlenecks to treating MDR- and XDR-TB....”
WHA “urges Member States”

- Ensure supply of quality supply of drugs which meet WHO pre-qualification standards “or strict national regulatory authority standards”
- Help ensure that TB meds are sold by prescription, through registered providers
- Prioritize fixed-dose combinations of proven bio-availability
Requests the Director General

• Support states to harmonize national and international drug regulatory standards...

• “thus enabling national pharmaceutical manufacturers to produce material of assured quality to be sold in the local and international markets”

• “to work with countries to develop indicators and to support monitoring and evaluation of the implementation...”
Summary

• The GLC is likely to evolve to monitoring, support, encouragement role

• Brazil, India, other countries in transitions, likely to lead development of new model

• Risks of poor program implementation or poor drug quality are still serious concerns

• Opportunities for national pharmaceuticals

• Need for strong country/regional leadership