Intervention by **Zakir Thomas**[1] (India) before the UN Secretary General's High Level Panel

It is almost a no brainer to say that the traditional model of drug discovery for antibiotics is not working. Closing down of infectious diseases R&D by research based pharma in the recent years show the limitations of market driven mechanisms deliver for antibiotics.

Therefore, new models of research like Open Source Drug Discovery (OSDD) of India, ANDI of Africa need be supported and replicated. There is probably no alterative to public investment in R&D for antimicrobials.

There is good news on the tropical infectious diseases or the neglected diseases front, even as we hear the bad news of pharma closing down infection R&D. The latest GFinder survey reports that there are 485 compounds ready to be taken to the development phase, 117 for TB in the pipeline.

Here is the challenge. The delinkage is working at the research phase, but as TB shows it is not translating into development phase.

Some of the solutions for facilitating the development phase, I will discuss tomorrow in the delinkage panel.

Regulatory Capacity Building

For TB there are two drugs in the most advanced phase, Bedaquilin of Janssen Pharmaceuticals and Delamanid of Otsuk Phara. US FDA has given conditional marketing approval to Janssen's Bedaquilin based on Phase II trials while Phase III is ongoing. EMA has done it for Delamanid. Developing world regulators are not this proactive.

OSDD which I was the project director took one combination therapy of TB in collaboration with TB Alliance for clinical trial. This was an eye opener. The regulatory agencies are underprepared to handle complexities of such trials. Regulatory capacity building is a key requirement to get new drugs into the developing world markets.

Clinical Trial Capacity

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Facilities to conduct such trails are almost non existent, particularly in cases like TB which require BSL3 compliant patient care.

Unclear regulatory pathways and unclear access to market drive the innovator companies away from the developing world markets.

Need of New Diagnostics

We have also, probably underestimated the extent of the resistance. 4 out of 5 patients screened for TB were resistant to Pyrazinamide and so PaMZ trial is facing an uncertain future. This shows how critical is the need for affordable diagnostics which can detect drug resistance.

Now some specific comments on AMR.

1. The important role of pharmacist who dispenses medicine at the medical shop need be underlined. She is the most important link who is the most undertrained in the chain. We should incorporate this into their training.
2. Indiscriminate use of antibiotics for animal use should be stopped as it gets into the food chain.
3. Curb the combination spree. A large number of combinations which were available in the market was recently banned in India.
4. Stop manufacturers of API from dumping antibiotics into the environment.