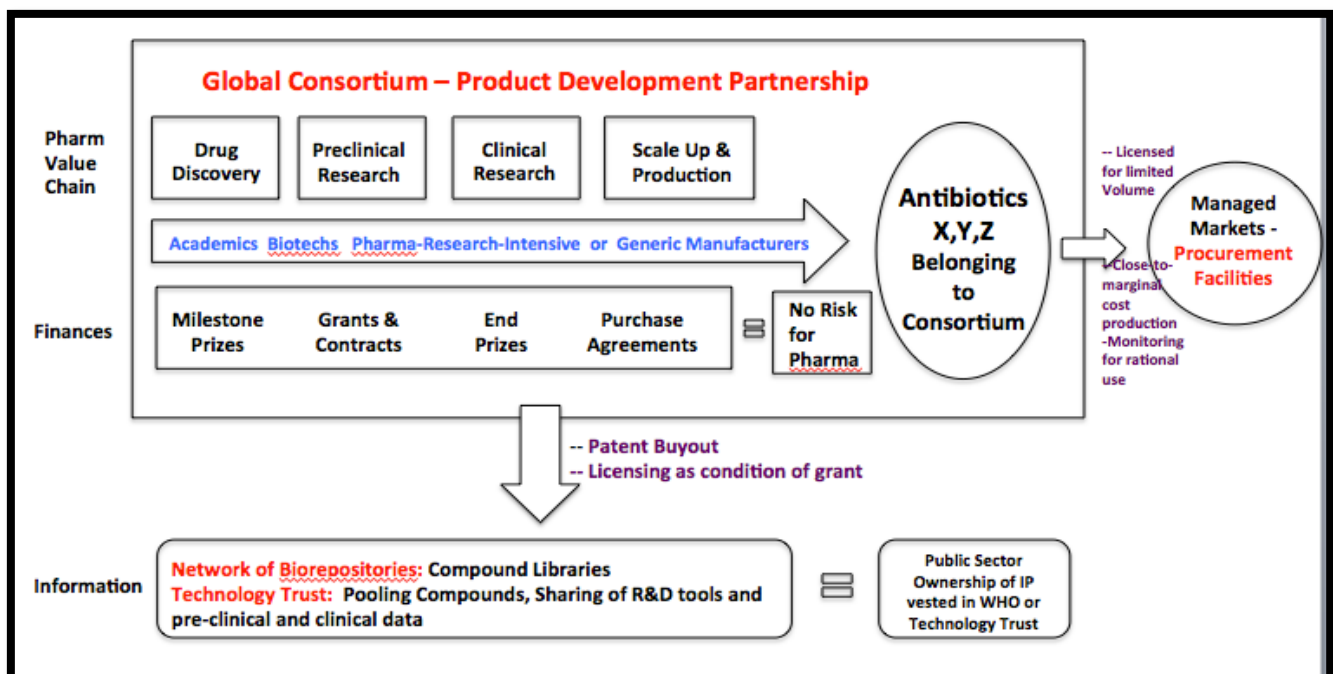


## A Publicly Financed Global Consortium for R&D to Fight Antibiotic Resistance World Health Organization, 13 May 2014

This proposal focuses on creating a global consortium to coordinate pharmaceutical innovation for antibiotics by taking concerted public sector action. Incentives to drive R&D would be applied through a hybrid model of push and pull financing. Various R&D pathways for innovation would be put at play:

- 1) At the drug discovery stage, milestone prizes would give worldwide incentive to new groups from academic scientists to small innovative companies, to create promising, “druggable” leads for novel antibiotics, while guarantying access to novel Intellectual Property Rights (IPR) through subscription of options on new inventions potentially leading to discovery of new classes of antibiotics;
- 2) push mechanisms taking the form of grants for developers (academics, small or large companies) for optimizing the new drugs; or competitive access to contracted services would ensure greater public purchase over the pharmaceutical value chain, both removing the risk and ensuring the certainty of return for antibiotic innovation. Investing across a portfolio of promising drug candidates and approaches also will mitigate the risk of failure;
- 3) end prizes of significant value (c.a. US\$ 2-500 million) would reward proven new molecules, and buy out patent rights on new antibiotic classes within a public sector patent pool. Management of IP rights would ensure that use of the new molecules for human applications;
- 4) public-sector funded clinical trials would assess safety and efficacy of the new antibiotics (alone or in combination to further decrease the risk of resistance);
- 5) purchase agreement with industries for the production of set number of treatments per year, would be used under conditions that preserve the new drugs.



Importantly, the proposed financing model would lower the barriers to entry for small and medium size enterprises, for firms in low- and middle-income countries (LMICs) and academic research centers worldwide. The consortium's primary focus would be on antibiotics' development, but complementary technologies, such as a diagnostic to identify rapidly patients with multi-drug resistant disease for clinical trial recruitment, might fall within its mission.

Enriching a public compound library, particularly with natural products sourced from a network of biorepositories, could provide an innovation platform for discovering new classes of antibiotics. Over a third of small molecule drugs over the past three decades have originated from natural products, and among antibiotics coming to market between 1982 and 2002, over three-quarters of the drugs derived from natural products.<sup>1</sup> Repleting the antibiotic R&D pipeline would help address the scientific bottleneck that has stymied the pharmaceutical industry, which has reported very low yields from high-throughput screening of their proprietary compound libraries. One large multinational company conducted seventy screens (67 HTS, three whole cell) from 1995 to 2001 and identified only five lead compounds. The 7% success rate captures the challenge.<sup>2</sup>

Sharing of knowledge could accelerate the pace of innovation. A technology trust could be put in place to facilitate the licensing and patenting of compounds, sharing of preclinical and clinical data and pooling of R&D tools related to the products. The sharing of clinical data could improve the efficiency and effectiveness of medical product development, and public funding of clinical trials would also justify the availability of the data generated as a public good.<sup>3</sup> Efforts in Europe to implement greater clinical trial data transparency have also met with some industry concerns over the protection of commercial interests, but some companies have taken voluntary steps to allow researchers to access data from their studies.

Public funding through push and pull financing mechanisms would also condition access to the resulting end-products, apportioning supply to countries where the public health need exists and making this access contingent upon plans for the rational use of the novel antibiotic are in place. In a publicly financed pharmaceutical value chain, antibiotic production could take place under purchase agreements, where production could be contracted from qualified drug manufacturers. If much of the upstream work were publicly financed and the intellectual property owned by the public sector, technology transfer should be easier to facilitate. These manufacturers would commit to producing a limited volume of drugs, set centrally by the global consortium's efforts to forecast the antibiotic supply needed for rational use. Through a mechanism like the Green Light Committee and Global Drug Facility, assurances would be provided that plans for and monitoring of the rational use of these novel antibiotics would be in place.

The risks of the antibiotic pipeline could be reduced by strategically applying public support to bottlenecks. Push and pull incentives operate differently, but both might be structured to contribute to delinkage—that is, separating returns on investment from volume-based sales or revenues (Price x Quantity).

---

<sup>1</sup> Pelaez, F. "The Historical Delivery of Antibiotics from Microbial Natural Products—Can History Repeat?" *Biochemical Pharmacology* 71.7 (2006): 981-90.

<sup>2</sup> So AD, Gupta N, Brahmachari SK, Chopra I, Munos B, Nathan C, et al. Towards new business models for R&D for novel antibiotics. *Drug Resistance Updates* 2011; 14(2), 88-94.

<sup>3</sup> Lewis TR, Reichman JH, So AD. The Case for Public Funding and Public Oversight of Clinical Trials. *Economists' Voice*, January 2007.