KSM, DI, AND API CONCENTRATION RISKS & INDIA

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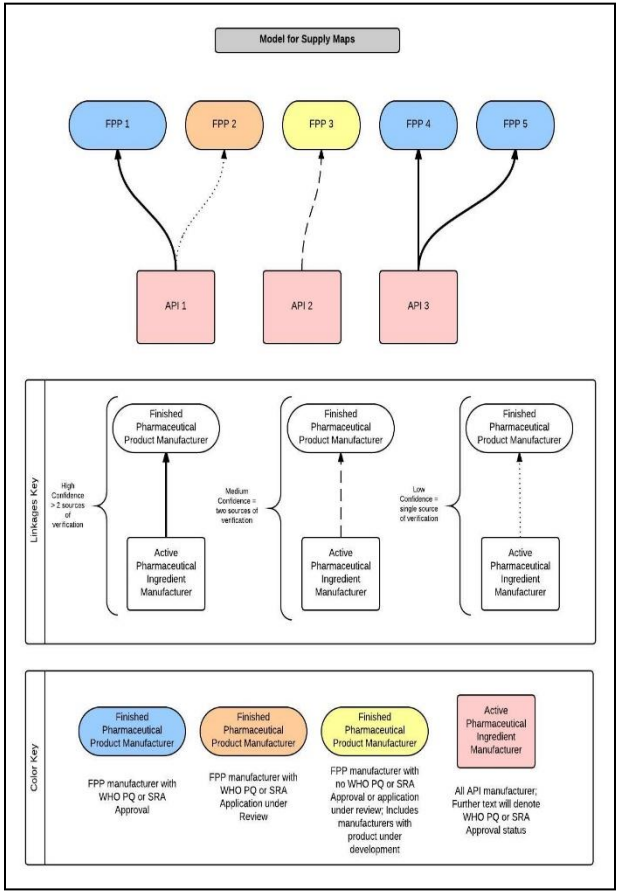
MAPPING UPSTREAM SUPPLY CHAIN, SYSTEMATICALLY



- Recognition that more significant supply risks occur upstream, involving the active pharmaceutical ingredients (APIs) , Drug Intermediates (DI) and Key Starting Materials (KSM)
- Lack of reliable information about API market structure and supply capacity
- 2012-2015-Multi-year API market understanding project (HIV/AIDS, TB, and Malaria) involving visits to prominent FPP, API and KSM producers (mostly in China and India)
- Facilitated understanding of market structure and supply capacity
- Design of interventions to increase resilience in the system based on robust understanding of supply structure and capacity

Source: Yadav et al 2014, unpublished

INDIA'S PHARMA SUPPLY CHAIN & DEPENDENCY

India → Major exporter of finished-dose formulations. US FDA-approved pharma plants ~400

Also, a significant manufacturer of APIs. 3rd or 4th largest API producer by volume

High dependence on China for KSMs, DIs, APIs. China's share in India's API imports | 70–72% (by volume)

Government started Production Linked Incentive (PLI) Scheme in 2020

Goal = Reduce import dependence

Incentive Type | $$ paid on % of incremental sales over 2019–20 baseline

Incentive Rate | 10% (FY23–26), 8% (FY27), 6% (FY28) |

Over 25 KSMs, DI and APIs. Include Penicillin G, 7 – ACA, Clavulanic Acid, 1,1 Cyclohexane Diacetic Acid (CDA), Para amino phenol

CHALLENGES IN PLI SCHEME

Unfavorable Economics Despite Incentive	Economics unfavorable for some products despite incentive
Bias towards Greenfield Plants	New plants prioritized; brownfield upgrades less supported
DVA measurement and thresholds	Documentation-heavy; strict Domestic Value Addition (DVA) requirements (90% fermentation-based, 70% chemical synthesis)