

REGIONALIZING PHARMACEUTICAL PRODUCTION AND INNOVATION

Social Protection and Health: South-South and Triangular
Cooperation to Enhance Capacity to Produce and Deliver
Vaccines

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Regionalization and Local Production

- Paper co-authored with Padmashree Gehl Sampath
 - Combines economic/industrial policy expertise and legal expertise
 - A South-North collaboration
- We start with the premise that a regional approach to localization of R&D and production capacity a useful idea
 - The COVID-19 pandemic one of recent developments confirming importance of securing supply chains
 - Strategic use of trade relations and fragmentation

From Abstract Concept to the Reality of Implementation

- The idea of regional approach to industrial development long-standing
 - Consider the Andean approach of 1970s
- Although regional approach to manufacturing and distribution of vaccines widely discussed, there has been limited analysis of what precisely this would look like from a regional organizational standpoint
- Our paper sets out 5 conceptual approaches and discusses potential advantages and disadvantages

Private-Sector Decision-Making

1. Private sector decision-making with incentives within host region
 - a. Most decision-making in the pharmaceutical sector, including for vaccines, made by privately held enterprises
 - b. National and regional authorities can establish incentive framework while allowing “market” forces to determine direction of investment and assume risks
 - c. On regional level, important for governments to agree on maximum level of incentives to preclude destructive competition for investment (e.g., OECD minimum corporate tax)

Geographically Concentrated Hub(s)

2. Geographically concentrated regional hub(s)
 - a. Gathering production resources at a single location creates opportunities for integrated network of infrastructure, support resources, reducing transport inefficiencies, etc.
 - b. Indian examples of Pharma cities, e.g., combining proximity of API manufacturing to basic resource inputs, waste processing, energy, etc.
 - c. May envision series of hubs within region, in principle focusing on different types of products
 - d. Numerous questions to be addressed, including choice of location, responsibility for governance, taxation, etc.

Distributed Supply Chain

3. Distribute responsibility for stages of production to designated countries within the region
 - a. Allocate to different countries within region responsibility for producing different products, or
 - b. Allocate production at stages in accordance with capacity – a predetermined supply chain
 - i. May provide opportunity for least developed countries and region (e.g., packaging)
 - c. Create risk of “weak link” undermining system
 - i. Could be addressed by redundancy and/or external backups

South-South Collaboration and Flying Geese

4. Global South collaboration in investment in R&D and production
 - a. Integrated supply chains based on LMIC cooperation
 - b. Incorporate technical cooperation and training
 - c. Geographic separation may increase risk of supply chain disruptions
5. Promote development of regional champions that may trigger greater demand for products and processes throughout region
 - a. May not alleviate concerns over supply chain security, including political risk

Regional Approach to Drug Regulation

- Various efforts underway
- European Union has most developed model with EMA
- Evolution the starting with autonomous national authorities, promulgation of harmonized/approximated standards, mutual recognition systems, leading to centralization of approvals
- Residual national responsibilities retained
- Particularly important for accelerating access to vaccines

Governance

- Regional integration efforts historically fraught
 - Ceding elements of national autonomy
- Current regional arrangements, leaving aside EU, do not invest regional authorities with substantial powers to make industrial policy decisions on behalf of members
- Decision-making by consensus may avoid disputes, but consensus difficult to achieve
- Regionalization of local production may require negotiation of specific international agreements that establish authority beyond that granted under existing regional constitutional structures

Key Points

- The abstract benefits of regionalization of local production leave many questions regarding how that regionalization will be organized
- The “constitutional” issues involving decision-making, especially with non-consensus decisions, need to be addressed
- There are many stakeholders within the process, including existing manufacturers, investors, patient groups, etc., whose interests will be affected