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Systematic Review

Decision Criteria for Partial Nationalization of Pharmaceutical Supply Chain: A Scoping Review

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Abstract: (1) Background: Any disturbance in the pharmaceutical supply chain (PSC) can disrupt the supply of medicines and affect the efficiency of health systems. Due to shortages in the global pharma supply chain over the past few years and the complex nature of free trade and its limitations when confronted by a major global health and humanitarian crisis, many countries have taken steps to mitigate the risks of disruption, including, for example, recommending the adoption of a plus one diversification approach, increasing safety stock, and nationalizing the medical supply chains. (2) Objective: To scope findings in the academic literature related to decision criteria to guide national policy decisions for the "Partial Nationalization of Pharmaceutical Supply Chain" (PNPSC) from the viewpoints of the three main stakeholders: industry, payers (government and health insurance), and patients. (3) Methods: These consist of a scoping review of the peer-reviewed literature. (4) Results: A total of 115 studies were included. For local manufacturing decisions, five criteria and 15 sub-criteria were identified. Weighting, decision-making, risk assessment, and forecasting were the main data analysis tools applied; (5) Conclusions: The findings could serve as a baseline for constructing PNPSC frameworks after careful adaptation to the local context.

Keywords: PSC; pharmaceutical supply chain; healthcare; reshoring; nationalization; local production; API; active pharmaceutical ingredient; pharmaceuticals; drugs; medicines

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1. Introduction

1.1. Characterization, Relevance, and Complexity of the PSC

According to the IQVIA Institute, drug spending worldwide in 2021 was estimated at USD $1.5 trillion. Eleven (11) markets—USA, Japan, Germany, France, Italy, Spain, UK, Brazil, Canada, South Korea, and Australia—together spent USD $618 billion on medical drugs in terms of hospital and retail sales, amounting to around half of all global medicine expenditure. The global active pharmaceutical ingredient (API) market was valued at USD $300.7 billion in 2021. The API market is segmented on the basis of the molecule, type, type of manufacturer, synthesis, chemical synthesis, type of drug, usage, potency, and therapeutic application (IQVIA 2022).

Figure 1 is a graphic representation of the PSC showing the different inputs resulting in the manufacture of pharmaceutical specialties distributed in consumer markets.

The pharmaceutical industry plays a significant role in providing medicines and saving human lives. The operation of PSC is a crucial element, and any disturbance affecting

supply chains could disrupt the supply of medicines and undermine the efficiency of health systems.

Pharmaceutical companies' supply networks are highly complex, involving the coordination of large numbers of diverse products, markets, processes, and intermediaries in the network, as well as ensuring the timely delivery of products to the right place and to the right customers.

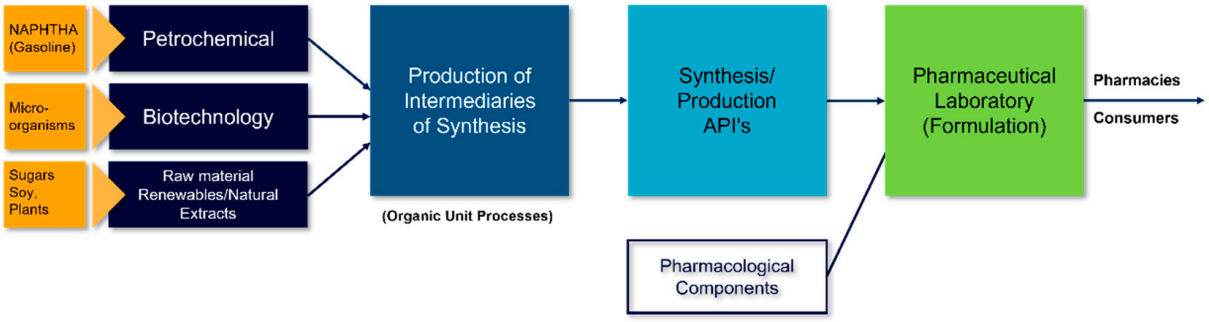

Figure 1. Generic graphic representation of the PSC.

These companies face a substantial range of risks that Milind and Sriram (2020) described as " . . . disruptions that occur along the pharmaceutical supply chain, hindering the regular supply of products . . . mainly caused by a shortage of raw materials, product quality issues, short product life cycles, or sustainable supplier failure . . . irregularities that may generate lead time loss, late deliveries, backorders, production losses and supply shortages leading to uncertainty in the volume of sales and income".

The pharmaceutical industry is also hampered by fluctuations in demand and uncertainties in the PSC, especially those on the demand side related to quantities and reimbursement prices. PSCs overwhelmingly depend on the rules set by private or public health systems, which not only impact pharma companies' production and investment decisions, but also play a key role in the criteria used by public health managers when deciding to incorporate a pharmaceutical product into the health system. Stakeholders' decisions are also directly affected by the complexity and risks of PSC operations.

On the supply side, pharma companies need to be able to satisfy the increasing demand for medicines while operating highly complex supply chain structures involving multiple variables and actors.

On the demand side, a range of political entities and institutions, often as "intermediate payers", are involved as stakeholders responsible for decision-making on resource and budget allocations in the healthcare sector. Meanwhile, patients—a third important category of stakeholders in the PSC—need good access to innovative and affordable drugs produced by suppliers (Milind and Sriram 2020).

Production fragmentation in the pharma area and other industries increases the systemic risks in supply-chain networks caused by extreme events. Supply and demand uncertainties in the pharmaceutical industry negatively affect its commercial sustainability in both local and non-local markets, and any disruptions in supply chains can seriously undermine the availability of pharmaceutical products in the industry's target markets.

1.2. Recent Disruptions in the PSC and Actions to Mitigate Them

Even before and after the COVID-19 pandemic, the global pharma supply chain has faced shortages in the supply of pharmaceuticals. This is the case for many products that have been listed on the US Food and Drug Administration (FDA) Shortages Webpage (n.d.): https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm, accessed on 11 November 2022.

In addition to supply shortages, the COVID-19 pandemic exposed the complex nature of free trade and its limitations when confronted by a major global health and humanitarian

crisis. The risks of drug supply shortages and disruptions have been suffered by many developing countries traditionally dependent on external suppliers. The inability to meet the growing demand for antiviral agents, for example, caused an unprecedented global shortage of pharmaceutical ingredients, which resulted in higher prices.

In recent years, an estimated 80% of all the inputs for medical drug production worldwide were sourced from China and India, while India itself also sourced many ingredients from China according to (Zhu et al. 2020). The lockdown of many Chinese and Indian pharmaceutical producers during the pandemic reduced the supply of key medicines precisely when demand was reaching an all-time high. While China remains a significant supplier of APIs to generic drug manufacturers worldwide, the outbreak of the virus there impeded Chinese pharma factories from working at full capacity to supply the vastly increased demand.

To reduce the impact of the lack of strategic medicines for their populations, during the pandemic, some national authorities took deliberate steps to block exports of what they considered to be essential drug-related items. Fearing internal shortages, India, for example, was reported to have stopped exporting at least 26 active drug ingredients normally manufactured there (Rahaman 2021). After the pandemic, this led to a major shift in the Indian Government's approach to critical medicines production by its decision to promote domestic manufacturing of key starting materials (KSM)/intermediates and APIs, develop its own local sources of materials, and adopt alternative strategies aimed at reducing its dependency on other countries. Meanwhile, the United States FDA, in its turn, belatedly realized that the portfolio of suppliers of many key ingredients to the American market was indeed dependent on this narrow group of Chinese and Indian raw material suppliers.

Given that the COVID-19 pandemic exposed the vulnerable modern supply chain logistics to a major disruption in the entire healthcare sector, pharma companies are now, in the post-pandemic era, increasingly aware of the urgent need to build resilient supply chains to weather not only the new strains of the virus, but also to prepare for future events.

To mitigate the negative fallout and to protect supply chain operations, several recommendations have been proposed by experts, such as Tang (2006) and Zhu et al. (2020). These include the possibility of pursuing a plus-one diversification approach (i.e., avoidance of dependence on a single supplier), increasing emergency stock, nationalizing medical supply chains, and so on. The main thrust of these and other measures is to seek to alleviate the problems still arising from the crisis and boost the resiliency of pharma companies to withstand potential shortages in the longer term.

In the context of this scenario, this scoping review seeks to identify the parameters that must be adopted in a decision of last resort to nationalize production in the event of the inadequacy of the strategies so far proposed for mitigating supply chain disruptions.

1.3. The Option of PSC Partial Nationalization

Zhu et al. (2020) have pointed to the need for countries to "shockproof" themselves by reshoring the production of essential medical goods. The "reshoring" approach has gained traction in the USA, India, and other countries, not only to ensure a stable supply of key ingredients, but also to bolster ailing economies.

While it is possible for health authorities to encourage the nationalization of off-patent pharmaceuticals (OPPs), providing API and OPP meet the requisite quality criteria, this does not apply to patented pharmaceuticals. OPPs represent between 60% and 80% of the size of the pharmaceutical market in most emerging markets (IQVIA 2022).

OPPs are the products that are similar to the innovator product following the expiration of the patent. It is important to remember that the nationalization option stimulated by industrial policy is applicable only to products with expired patents.

Given the high costs involved in PSC verticalization, a country's limited budget for investment, and aspects related to comparative advantages, future attempts by some countries to "shockproof" themselves by nationalizing their pharmaceutical supply chain could well turn out to be partial and confined to a few select APIs.

1.4. A Framework to Support a National Strategy for the Selection of Products to Be Nationalized

From the standpoint of microeconomics theory, the make-or-buy/vertical integration decision of a firm is the central issue in transaction cost economics. This theory, developed by Williamson (1981), shows how trading partners protect themselves from hazards associated with exchange relationships. The integration of activities by a company is a way to safeguard economic rents, and the institutional arrangements are chosen according to the level of investment protection and lowest transaction cost. There are numerous accounts in the literature describing the efforts and techniques adopted by individual pharmaceutical companies to select drugs to be prioritized from a portfolio of products. Such decision-making processes often depend solely upon the priorities of an individual organization (Hilbert and Blome 2015; Shelanski and Klein 1995; Aurentz et al. 2011).

However, we were unable to identify any of the literature referring to methods of prioritization or vertical integration decisions from a 'collective interest' viewpoint. This was the gap in the literature regarding this topic of investigation that required a scoping review—a method used to summarize a range of evidence to understand broadly what is known about a phenomenon.

The objective of this paper is to scope the three main stakeholders from their PSC perspectives advocated in the academic literature relating to the prospective criteria for the PNPSC. The stakeholders are: industry; payers—government and health insurance; and patients.

The identified criteria will be useful to construct a coherent decision-making framework applicable to production decisions in the context of shortage risks, strategic positioning, and pandemic preparedness while considering limited healthcare budgets and the need to minimize environmental impacts.

This paper aims to promote a pragmatic approach to industrial policy and point to new areas for policy interventions in the pharmaceutical sector.

The paper is structured as follows. Section 2 contains the proposed methodology for a scoping review, while Section 3 presents the results presenting the key concepts obtained from the literature and responses to the questions raised in the scoping survey. Section 4 focuses on discussion, and Section 5 sets out our conclusions.

2. Methodology

To facilitate a structured and transparent approach to identifying the criteria for the selection of the products to be nationalized, and contribute to the policy debates, we adopted the method of scoping review for this study.

This study was conducted and written according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations (Page et al. 2021). Our work focused on the six phases required for a scoping review: (1) identifying the research question(s); (2) researching relevant studies; (3) selecting studies; (4) mapping, extracting, and tabulating the data; (5) analyzing the data; and (6) presenting the results. The definition of 'scoping' reviews is presented below.

2.1. Scoping Review

Scoping reviews are a knowledge synthesis method used to summarize a range of evidence to understand broadly what is known about a phenomenon. They differ from systematic reviews in their broad approach to a topic, their purposive sampling frame, and their identification of gaps in the literature (Whittemore et al. 2014).

2.2. Identifying the Research Question

The following four research questions originated with the University of São Paulo team of researchers and collaborators.

- According to the scientific reference literature, what are the current methods employed for analyzing a product (in any sector) and deciding to manufacture it locally?

- What are the criteria and methods practiced by industry and institutions in the health, pharmaceuticals, medical drugs, areas, etc., for selecting pharmaceuticals and APIs for local manufacturing of these products?
- What are the criteria used by public health managers in the pharmaceutical sector when deciding to incorporate a product into the health system?
- Which are the data analysis tools used to support the above methods?

2.3. Search Strategy

With support from experienced researchers, we constructed a comprehensive search strategy for identifying published papers that met the inclusion criteria.

Structured search strategies were used in database searches (MedLine, Embase, Google Scholar, and IEEE Xplore) and constructed using PubMed MeSH terms and boolean operators, as described in Figure 2.

MedLine and Embase: (Health resource OR Health technology assessment OR HTA OR Health technologies assessment OR Healthcare technologies assessment) AND (Resource allocation OR Resource allocations OR Resource designation OR allocation efficiency OR Resources allocation OR Decision-making OR Decision-making OR Health priority OR Priority setting OR Health policies OR Healthcare policy OR Healthcare policies OR Complexity management OR Portfolio management OR Product data management OR production complexity OR criteria) AND (API OR active pharmaceutical ingredients OR active principle OR finished pharmaceutical product OR finished pharmaceutical products OR active substance OR active constituent OR bulk active OR pharma product OR pharmaceutical products OR pharmaceuticals OR orphan drug OR orphan drugs)
IEEE Xplorer: (Portfolio OR Resource allocation* OR production OR criteria OR pipeline OR Manufacture) AND active pharmaceutical ingredients OR active principle finished pharmaceutical product OR finished pharmaceutical products active substance OR active constituent OR bulk active OR pharma product OR pharmaceutical products OR pharmaceuticals)
Google Scholar: Health technology assessment, Health priority resource allocation "active pharmaceutical ingredients"

Figure 2. PNPSC Search Strategy.

2.4. Selection Criteria

Inclusion and exclusion criteria were developed at the outset of the review. The inclusion criteria covered (a) primary and secondary studies, as well as (b) articles that directly answered the research questions ('systematic review') or that would assist a broader understanding of what is known about a phenomenon ('scoping review').

Papers addressing the following subjects were included: decision-making about investments in the production of and the payment (reimbursement) arrangements for pharmaceuticals in particular countries. Congressional abstracts, letters, editorials, unavailable full-text, and studies presenting subjects in (Figure 3) were excluded.

2.5. Study Selection

The electronic databases were monitored for the peer-reviewed literature, using filters for English, Spanish, and Portuguese language articles, but none for publication dates. The lack of studies in Spanish and Portuguese selected in our scoping review is due to the non-compliance of such studies to the pre-established inclusion criteria. The studies nevertheless underwent the same selection process as those in English.

Reference lists of relevant papers and conference abstracts were manually searched, results were imported into the Reference Manager Zotero^{TM}, and duplicate citations were removed. A detailed breakdown of citations identified from the various information sources is presented in Figure 3 (Zotero n.d.).

The titles and abstracts that appeared to meet the inclusion/exclusion criteria, or where there was any uncertainty, were screened for relevance and duplication. The full-text articles were then downloaded in Zotero and then screened.

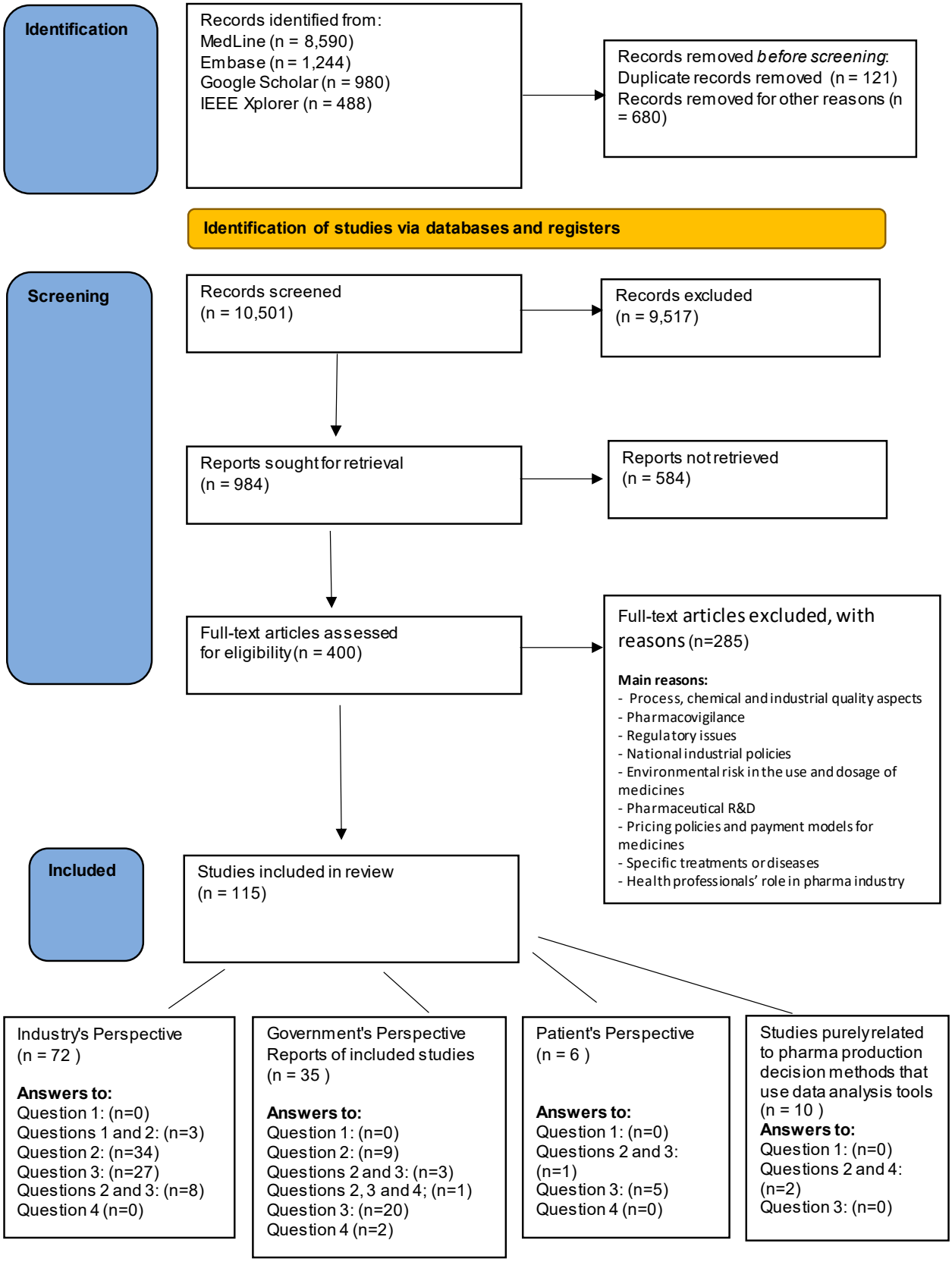

Figure 3. PRISMA flowchart of the PNPSC study selection process.

2.6. Charting, Extracting, and Tabulating the Data

The researchers charted key data from the papers selected for inclusion in the scoping study using a data charting form that involved sifting through and sorting data according to key aspects or concepts.

The key aspects or concepts were identified a priori and recorded under the following headings: articles evaluated "Yes" or "No", were selected, or excluded; reason for selection or exclusion; main findings; and conclusion.

2.7. Data Extraction and Synthesis

The data were analyzed qualitatively using a general inductive approach. Three researchers carefully examined extracted data (raw text from the tables) to familiarize themselves with the content and potential themes.

Initial coding categories representing 'meaning units' (themes) were then created. The themes (industry perspective; government perspective; patient perspective), were created to represent the views of the main PSC with influence on the production, consumption, or reimbursement decisions of the PNPSC, as well as the choice of analytical tools (decision models) used to analyze PSC data. Subthemes were added as they emerged during the selection procedure.

Each article was also classified according to topic areas (e.g., "Perspective") and categories within each area (e.g., "Key Concept"). The synthesis was conducted using a cascading process, and the lists of areas and categories were updated as more articles were reviewed.

Papers were first checked by a researcher to determine applicability to the research questions, perspectives, and categories. Subsequently, all articles were fully reviewed a second time to check alignment with the respective research question (Questions 1–4).

The registered protocol is available at Zenodo (Supplementary Materials). Consulting stakeholders and experts who might propose additional references and/or insights not found in the literature are optional in scoping reviews (Levac et al. 2010), but in the case of the present review, the authors decided not to consult them.

3. Results

By October 2021, a total of 11,302 potentially eligible peer-reviewed article listings were identified in the electronic databases. Of these, 121 duplicates were identified and automatically eliminated, and 680 titles were manually eliminated, including congress abstracts, letters, and editorials. 10,501 articles were finally evaluated by title, of which 984 were selected by title, 400 by abstract, and 115 by full text. The selected 115 were each analyzed regarding the theme of PNPSC in terms of the three main perspectives and their respective initial key concepts identified in the literature, as represented in Figure 4:

Perspective	Key Concepts
Industry Perspective	Industry and Enterprise; Strategy; Volume and Scale; Portfolio and Prioritization; Pricing and Price; Value; Environment and Hazard; Active Pharma Ingredient (API), Production and Manufacturing; Supply; Risk, Future and Trends; Research, Unmet need, Development, and Innovation; Investment; Patents & Intellectual Property; Competitivity.
Government Perspective	Essential Medicines; Shortage; Crises and Emergencies; Funding and Subsidies; Costs; Plan and Prioritization; Criteria and Decision.
Patient Perspective	Patient; Affordable; Reimbursement and Payment.

Figure 4. Key concepts related to the PNPSC identified in the literature review.

Figure 3 shows the PRISMA flow chart of the review process and the number of articles at each stage.

3.1. Analysis and Data Synthesis

Table 1 presents the responses to the questions identified in the scoping survey in line with the various criteria and sub-criteria.

3.1.1. What Are the Current Methods Employed in the Scientific Reference Literature for Analyzing and Deciding on the Local Manufacture of a Product (From Any Sector)?

Three journal articles addressed methods for analyzing and deciding on the local manufacture of a product in any sector. The main concern highlighted related to economic (supply side) factors or criteria, with the two main sub-criteria identified as "Minimization of raw material and manufacturing costs" and "Maximizing return on investment, profit maximization, and product portfolio optimization".

3.1.2. What Are the Criteria of the Methods Used by Industry and Institutions (Health, Pharmaceuticals, Drugs, or Inputs Areas) for Selecting Pharmaceuticals and APIs for Local Manufacturing?

The selection of pharmaceuticals and APIs for local manufacturing involves a wide range of factors or criteria including economic (supply side), economic (demand for API), technical feasibility, environmental impact, and strategic vision.

Ten sub-criteria were identified under this scope in 44 journal articles as being relevant to the decisions of pharmaceutical firms to pursue local manufacturing or not. (Table 1, Question 2 column, highlighted in grey).

3.1.3. What Criteria Are Used by Public Health Pharmaceutical Sector Managers to Incorporate a Product into the Health System?

63 journal articles carried relevant references to the criteria employed by public health practitioners. We selected the scope of four decision factors or criteria: economic (supply side); economic (demand for API); environmental impact; and strategic vision. Concern with "Technical feasibility" was referred to only in the case of vaccine manufacturing.

Among the factors or criteria affecting decisions, 12 sub-criteria were identified as being adopted by public health managers. The major concerns were with the projected impact on payers' budgets in the short/medium term. Other relevant sub-criteria were value assessment of the drug-related to its health gain, affordability and availability, patient preferences, criteria for the subsidization of medicines, environmental risk caused by emissions and waste generation, avoidance of supply interruption risks, risks of shortages, ensuring access to essential and disease-related medicines, and, finally, innovation incentives/scientific spillover (Table 1).

Table 1. Partial nationalization of the pharmaceutical supply chain (PNPSC)—summary of findings scope or criteria, sub-criteria, and addressed questions.

Scope/Criteria	Sub Criteria	Question 1	Question 2	Question 3	Question 4
Economic (Supply side)	Raw Material Costs/Manufacturing Costs	(Hilbert and Blome 2015)	(Plotkin et al. 2017); (Crawford et al. 2012); (Jayasundara et al. 2019); (Malone et al. 2001); (Ten Ham et al. 2021)		
	Quantity/Target Population size/economies of scale/economies of scope		(Foroutan et al. 2018); (Suwanthawornkul et al. 2018); (Berdud et al. 2020); (Hupcey and Ekins 2007)		
	Return on Investment/Profit maximization/Product portfolio optimization	(Balestra 2017); (Bujar et al. 2017)	(Årdal et al. 2018); (Balestra 2017); (Vennemann et al. 2019); (Keyhani et al. 2005); (Moreno and Epstein 2019); (Aurentz et al. 2011); (Lee Mendoza 2019); (Robinson and Howell 2014); (Ronco et al. 2021)	(Verghese et al. 2019); (Garattini and Padula 2018)	
	Industrial Competitivity		(Costantino 2021); (Mahajan et al. 2020); (Cherian et al. 2021)	(Xu et al. 2020); (de Vet et al. 2021)	
Economic (Demand for API)	Projected Impact on payers' budget (BIA) in short and medium terms		(Vieira 2020)	(Angelis et al. 2020)	
	VALUE ASSESSMENT of the drug-related to its HEALTH GAIN (Health benefits of using the pharmaceutical including improved quality of life, survival, clinical surrogate endpoints, and/or safety)		(Aurentz et al. 2011); (Vennemann et al. 2019); (Leong et al. 2013); (Kreiner 1995); (Antoñanzas et al. 2016); (Camejo et al. 2014); (Lee Mendoza 2019); (Vogler et al. 2017); (Brixner et al. 2018)	(Angelis et al. 2018) (Angelis et al. 2020); (Jakab et al. 2020); (Gonçalves 2020); (Leong et al. 2013); (Kreiner 1995); (Nicod 2017); (Sorenson et al. 2017); (Aranda-Reneo et al. 2021); (Frutos Pérez-Surio et al. 2019); (Pauwels et al. 2016); (Leong et al. 2013); (Kreiner 1995); (Vogler et al. 2018); (Antoñanzas et al. 2016); (Benzi and Ceci 1998); (Simoens 2010); (Rizzardo et al. 2019); (Dionne et al. 2015); (Chambers et al. 2014); (Mitchell 2021); (Bae et al. 2018); (Drake et al. 2016); (Bastani et al. 2019); (Jönsson 2004)	
	Affordability and Availability			(Gong et al. 2016)	
	Patient preferences			(Young et al. 2017); (Cook et al. 2019); (Hoos et al. 2015)	
	Criteria for the subsidization of medicines			(Pace et al. 2015); (Afsharmanesh et al. 2020)	
	Disease related			(Kramer et al. 2021); (Vreman et al. 2019)	

Table 1. *Cont.*

Scope/Criteria	Sub Criteria	Question 1	Question 2	Question 3	Question 4
Technical feasibility	API Quality Assurance		(Farghaly et al. 2021); (Ganzer et al. 2005); (Brixner et al. 2018)		
	Production Process/Technical feasibility/Manufacturing Complexity		(Panzitta et al. 2015); (Lugovoi et al. 2021); (Ougier et al. 2021)	(Kameda 2014)	
Environmental impact	Environmental risk caused by Emissions and Waste generation during Level I upstream process		(Pålsson et al. 2019); (Renteria Gamiz 2019); (Segawa et al. 2016); (Sarasati and Dachyar 2021); (Kar et al. 2018); (Li et al. 2020); (Ougier et al. 2021)	(Kar et al. 2018); (Forster 2014); (Costantino 2021); (Abbott 2004); (Duong et al. 2019); (Reidenberg 2007); (Nyakatawa 2015); (Zarei et al. 2020); (Moosivand et al. 2021); (Shukar et al. 2021); (Cogan et al. 2018); (Tucker et al. 2020); (Ventola 2011); (Jackson and Faith 2013)	
Strategic vision	Avoid supply interruption risks/Shortage risk/guarantee access to essential medicines		(Bonvillian 2021); (Hilbert and Blome 2015); (Panzitta et al. 2017); (Milind and Sriram 2020); (Moktadir et al. 2018); (Zhu et al. 2020); (Shukar et al. 2021); (Cogan et al. 2018); (Guharoy and Noviasky 2021)	(Costantino 2021); (Abbott 2004); (Duong et al. 2019); (Reidenberg 2007); (Nyakatawa 2015); (Zarei et al. 2020); (Moosivand et al. 2021); (Shukar et al. 2021); (Cogan et al. 2018); (Tucker et al. 2020); (Ventola 2011); (Jackson and Faith 2013); (Broccoli et al. 2018)	
	Innovation incentives/scientific spillover		(Ahn 2017); (Jakab et al. 2020); (Botwright et al. 2020)	(Verghese et al. 2019); (Angelis et al. 2020); (Hughes 2012); (Chalkidou 2010); (Garrison and Towse 2019); (Messori 2016a); (Castillo-Laborde and Silva-Illanes 2014); (Messori 2016b); (Moreno and Epstein 2019); (Camejo et al. 2014); (Zelei et al. 2021); (De Pinho Campos et al. 2011)	
Methods and Techniques	Weighting Methods				(Islei et al. 1991); (Németh et al. 2019)
	Risk Assessment				(Milind and Sriram 2020); (Moktadir et al. 2018)
	Demand Forecasting				(Sekhri 2006)
	Decision method/modeling				(Thokala et al. 2016); (López-Cuadrado et al. 2020); (Vernon and Hughen 2006); (Chen and Hung 2010); (Moktadir et al. 2018); (Hasan et al. 2019); (Carlsson 1979); (Ogorodova et al. 2016); (Hafner et al. 2017); (Justo et al. 2019)

3.1.4. What Are the Methods That Use Data Analysis Tools for Questions 1 to 3?

We chose eight journal articles that tackled the issues concerning the adoption of methods and techniques applicable to the modeling of attributes responding to the various criteria: weighting; decision-making; risk assessment; and forecasting.

See Table 1: "Partial Nationalization of Pharmaceutical Supply Chain (PNPSC)—Summary of findings scope, criteria, and addressed questions", after the References Section.

References for the papers classified in each area, category, and subcategory are presented in Table 1.

Given that articles may be linked to multiple categories, the total number of articles (115) was less than the sum of the counts of the individual scope/criteria categories (123).

Table 2 contains the description criteria and sub-criteria scoped as a result of the present study, and Table 3 describes methods and techniques identified in the scoping review to analyze related data (Tables 2 and 3).

Table 2. Partial nationalization of pharmaceutical supply chain (PNPSC)—scope or criteria, sub-criteria, and description.

Criteria/Scope	Sub Criteria	Description
Economic (API Supply)	Raw Material Costs/Manufacturing Costs	Consider internal factors such as raw material costs, the number and complexity of intermediate steps, and the efficiency with which the overall process converts those materials into the API.
	Quantity/Target Population size/economies of scale	Refer to the phenomenon where the average costs per unit of output decrease with the increase in the scale or magnitude of the output (quantity) being produced by a firm.
	Return on Investment/Profit maximization/Product portfolio optimization	Criteria that rank projects according to the financial present value of future cash flow, after discounting the initial investment;
	Industrial Competitivity	External factors that impact profits, total costs, and customer value creation as Regulatory environment; prices of final products imports; R&D expenditure; Exports of final products; Raw Material Cost (RM); Salary and Wages (SW); skilled labor; Advertising and Marketing (AM) Cost; Capital Usage Cost (CUC) Cost of utilities compared to manufacturing counterparts: water, electricity, sharing of common effluent treatment plants; local financial or political stability, domestic demand satisfied by offshore plants, intellectual property rights protection, human and environmental rights protection; level of automation. Testing facilities may be provided at a reasonable cost.
Economic Demand for API	Projected Impact on payers' budget (BIA) in short and medium terms	Budget impact assessment of patient populations' medicine consumption. Drug-related direct consumption. The analysis should estimate the annual financial impact over a minimum timeframe of 5 years.
	VALUE ASSESSMENT of the drug-related to its HEALTH GAIN (Health benefits of using the pharmaceutical including improved quality of life, survival, clinical surrogate endpoints, and/or safety)	Related to the decision-making opportunity cost of a drug to set government (insurer) payment or reimbursement thresholds. A measurement of reimbursement and commercial co-payment attractiveness is needed. Medicines that are more effective than existing comparators can get a higher price. Willingness to pay is based on clinical, economic value, and societal considerations which can affect government and Insurance reimbursement decisions. Reimbursement decisions depend on value definitions. Value in healthcare can be defined as "health outcomes per dollar achieved'. Patient or consumer behaviors are affected by (and correspondingly respond to) the price and price change of any healthcare product or service. Price elasticity of demand is critical.

Table 2. *Cont.*

Criteria/Scope	Sub Criteria	Description
	Affordability and Availability	Criteria related to availability and affordability are the two main criteria to assess whether patients can receive timely, adequate, and efficient treatment. Affordability is measured as the ability of residents to afford a treatment course based on the daily wages of the lowest-paid unskilled government worker.
	Patient preferences	These criteria move the discussion from cost to aligning on the clinical value for patients. Patient preferences can be used to inform decision-making across the product lifecycle across the four domains: Treatment satisfaction (7 attributes), Symptom bother (8), Treatment administration (5), and Impact on daily life (5). Patients have a role to play alongside all other stakeholders in determining intended outcomes and priorities, acceptable uncertainty, as well as the benefit/risk and value of a medicine. Their recommendations and conclusions may be different from those of regulators, payers, academic researchers, other health care professionals (HCPs), and industry, making it even more important that these opinions are well understood by all those making decisions.
	Criteria for the subsidization of medicines	Criteria for prioritizing and increasing the legitimacy of pharmaceutical subsidization (or funding of medicines) processes and making them more acceptable to a wider range of stakeholders.
	Disease-related	Criteria for value assessment of Orphan drugs for rare diseases; Antibiotics for infectious diseases. Drugs for neglected diseases and unmet needs. Measures of the impact of available treatments and drugs on a life-threatening or chronically debilitating need to be assessed.
Technical feasibility	API Quality Assurance	Criteria that consider product and manufacturer quality assurance: Product quality assurance: the equivalence standards of the drug to the innovator standard; Manufacturer quality assurance criteria: quality standards of the manufacturing process and whether manufacturing is done within or outside the local market. Processes to manage safety concerns or adverse events of the product;
	Production Process/Technical feasibility/Manufacturing Complexity	Criteria consider the manufacturing complexity in terms of batch-to-batch reproducibility/process, equipment, and quality system. Focuses on manufacturing active pharmaceutical ingredients (APIs) that have lost patent protection.
Environmental impact	Environmental risk caused by Emissions and Waste generation during Level I upstream process	Criteria that consider the environmental risk posed by the individual API manufacturing in Level 1 - Cradle to gate API phase of production stages: Production of API, including extraction, processing, production, and transportation of raw materials. The following attributional processes are part of the production system and are classified as upstream processes: • Production of raw materials and chemicals used as inputs to the core process. The production includes extraction, transport, and refinement of resources; • Production of solvent and catalysts used in the core process; • Generation of energy used in the upstream processes; • Transports between upstream processes; • Treatment of waste generated in the upstream process; Risks: • Manufacturing and storage of the API (including all intermediate stages); • Solvent and catalyst use and disposal; • Solvent recovery and incineration; • Generation of energy used in the core process; • Transports to and between core process steps; • Treatment of waste generated in the core process.

Table 2. *Cont.*

Criteria/Scope	Sub Criteria	Description
Strategic	Avoid supply interruption risks and shortage risks, guaranteeing access to essential medicines	Criteria that consider the risk of unavailability/shortage of essential drugs used as lifesaving interventions or for high-acuity conditions, and drugs without an available substitute in the market. Essential Medicines are those that satisfy the priority health care needs of the population (WHO). They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. The supply of essential medicines is a "public goods" problem in the sense that the private market does not adequately address it.
	Innovation incentives/scientific spillover	Criteria consider strategic vision regarding stimulating the valuation of medicines to promote "the dynamic efficiency" of a drug. Industrial Policies (pricing and reimbursement) have been designed to boost innovation and, at the same time, ensure that taxpayers' money is spent efficiently.

Table 3. Partial nationalization of the pharmaceutical supply chain (PNPSC)—methods and techniques identified in the scoping review.

Criteria/Scope	Sub Criteria	Description
Methods and Techniques	Weighting Methods	Weight techniques for obtaining scores of criteria and sub criteria.
	Risk Assessment	Method to select the relevant risks associated with Pharmaceutical Supply Chains (PSCs). Risk is represented in terms of an uncertain event which could probably lead to unfavorable outcomes such as late delivery, financial burdens, business loss, etc.
	Demand Forecasting	Demand forecasting serves four functions critical to the effective delivery of medicines and supplies: 1. Allows manufacturers to plan capacity for existing products, ensuring sufficient supply to meet demand. 2. Provide manufacturers with information about new market potential, permitting them to efficiently allocate resources for developing, producing, and commercializing new products. 3. Enable health systems in developing countries to build capacity to deliver products, matched to the scale and mix of products required. 4. Allows donors to efficiently allocate their resources by ensuring optimal prices and adequate supplies of products.
	Decision Model	Problem-solving

4. Discussion

Several countries, such as India (Cherian et al. 2021), the United States (The White House 2021), and Brazil (Fairbanks 2022), have appointed their industrial policy managers for the local production of APIs and verticalization of the chain based on the National Ministry of Health essential drug lists. The criteria presented in this article, combined with the weights assigned to them to reflect national priorities and qualitative/quantitative attributes, could serve to develop models to amend the lists. Using the criteria in mathematical or artificial intelligence (AI) models will allow a bolder selection of products to be produced locally. Ideally, these three highly populated countries with high local demand should aim toward a common strategy to avoid global oversupply leading to falling prices, as well as to boost the economic sustainability of pharma firms by offering improved investment prospects in product lines.

Our scoping review serves as a contribution to complement Cherian's article "India's Road to Independence in Manufacturing Active Pharmaceutical Ingredients: Focus on Essential Medicines" (Cherian et al. 2021).

The findings of this article can be incorporated into multicriteria decision-making models, such as the analytic network process (ANP) developed by Thomas L. SAATY, from the University of Pittsburgh (Saaty 2008).

4.1. Policy Implications

Framework development helps national entities responsible for health care avoid taking investment decisions solely based on stakeholder consultation and political criteria. As pointed out by Chang and Andreoni (2020), industrial policy is back at the center stage of economic debate, while the world is undergoing dramatic transformations, with the rise of the global value chain (Chang and Andreoni 2020).

This contribution brings a pragmatic approach to industrial policy and points to new areas for policy intervention in the pharmaceutical sector.

4.2. Future Recommendations

Our further studies will aim to select attributes to allow the quantification of each criterion where an attribute is defined as a "quantitative or qualitative measure of performance associated with a particular criterion" (Belton and Stewart 2002) or a "descriptor of performance or impact requiring ordering of preference" (Keeney 1992).

The identified criteria will be useful for constructing a future coherent decision-making framework that can be applied to production decisions on the risks of pharmaceuticals shortages, the need for strategic positioning, and pandemic preparedness, notwithstanding limited healthcare budgets and the need to minimize environmental impacts. Meanwhile, a universal overarching framework can be defined as "a set of principles, guidelines, and tools to guide decision making in selecting, organizing, understanding, summarizing, quantifying, and communicating the evidence relevant to benefit-risk decisions . . . while methodologies are tools for assisting the conduct of a scientific assessment." (Leong et al. 2013).

A framework will incorporate the criteria and attributes in mathematical modeling and be useful for providing documentation for a structured discussion.

The criteria identified in this scoping review point towards the construction of a general model for specifying the list of items to be verticalized. Sub-criteria can be included to finetune this study in the event of specific interest emerging in drug APIs based on synthetic, biological, or botanical materials.

The answer to the fourth question raised by the literature review reveals that the proposed algorithm must comprise: (1) a calibration model, attributing weights to the criteria according to the national interests of the three main stakeholders; (2) a predictive model to estimate the epidemiological situation over a five-year time horizon—the investment maturation time; and (3) an optimization model to make it possible to link the outcomes of 1 and 2 to attributes and variables that reflect the criteria and sub-criteria.

4.3. Limitations

We are aware that the scoping review is limited by the fact that the findings presented in Figure 4 and Tables 1–3 have not been tested or discussed with stakeholders' representatives. Although this is not methodologically required for a scoping study, the tests and discussions could at some stage be conducted to validate the criteria in real-world multicriteria industrial policy decision-making.

5. Conclusions

Transaction cost economics theory does not explain or support industrial and health policy decisions regarding the verticalization of the production of strategic goods, such as pharmaceuticals. The five criteria and their respective sub-criteria mapped along this

scoping review indicate that multicriteria decision-making theory seems to fit better to decision problems that address collective interests.

This was the first effort to scope findings in the academic literature related to decision criteria to guide national policy decisions for the PNPSC from the viewpoints of the three main stakeholders: industry, payers (government and health insurance), and patients.

Drug shortages constitute a major public health crisis. This paper presents the first comprehensive review of the available literature on PNPSC-related aspects, which provides a set of criteria on which to build a framework for a shared understanding of the national strategies that can be adopted.

Stakeholders, such as industry, health systems, and patients, can benefit from the planning of private and public investments to bring about the nationalization of the supply chain for a selection of drugs needed to deal with epidemics while maintaining an innovative and competitive environment conducive to avoiding drug shortages that negatively affect the delivery of health care. While not all countries can afford to "nationalize the supply chain", it is a valid strategy for countries or groups of countries with certain levels of population, income, technological development, and innovation capacity.

Although the criteria may be adjusted over time, a dependable list of criteria will undoubtedly help establish consistent decision-making, accountability, and transparency in the pharmaceutical market. In this spirit, it is hoped that the present paper will serve as a tool to aid communication between stakeholders.

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