

Disruptions and Delays: Investigating the factors determining complexity and challenges of Supply Chain in Pharmaceutical Industry: An Empirical Investigation

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Abstract:

Pharmaceutical supply chains experience delays and disruptions affecting access to essential medicines across regions. These challenges are caused by weak forecasting, long procurement cycles, fragmented distribution, poor quality data and shortage of skilled workers. These factors are managed with both forward looking and response-based approaches. Regular stock review, good communication, fast purchasing and close supervision help limit shortages. Response-based strategies like keeping extra stock may instead prove unsustainable over time. Supply chain structure can be adapted to product risk and working with suppliers can improve the ability to manage uncertainty. Flexible systems, real time information and robust internal processes allow quick responses and prevent major supply failures. Similar risks are faced by pharmaceutical firms worldwide when setting up supply networks. Other common problems are product faults, sudden halts in production, slow order handling, late shipments and poor matching of supply and demand. Rather than taking these risks, firms plan to do production in-house near key markets, work with local partners or outsource non-core work to distant locations. Some have gone away from far-off suppliers and are using nearshore or in-house models. Moving production closer reduces delay/improves control. For non-core products, outsourcing to offshore locations is still common but some companies set up offshore centres to manage operations directly. Changing supply chains to cope with delays and risks requires better forecasting tools, better data systems and trained people. Firms work with partners, rely on digital systems and have the right setup for various products. Global medicine supply chains must respond quickly to changes while reducing costs and maintaining product flow constant. Global health needs require clear strategy, simple design and fast action. Study survey was conducted among 218 people from supply chain department of pharmaceutical industry to know the factors that show the complexity and challenges of supply chain in pharmaceutical industry and found that Regulatory Compliance, Cold chain, Long Supply Chains, and Product shelf life are the factors that show the complexity and challenges of supply chain in pharmaceutical industry.

Keywords: Pharmaceutical Industry, Supply Chain Disruptions, Supply Chain Complexity, Lead Time Variability, Demand Uncertainty, Transportation Delays

Introduction

Pharmaceutical companies worldwide are under increasing pressure to meet customer demands promptly, keep steady product availability and lower overall price. The complexities of worldwide business activities in addition to the demand for fast product development has thrust supply chain management (SCM) directly into the centre of firm strategy. Shorter product life cycles, shifting market demand, high production costs and growing shipping costs have never been more difficult to SCM. The Life Science Industry, encompassing pharmaceuticals, biotechnology, and medical

devices, faces unique and complex supply chain challenges. These challenges arise from stringent regulatory environments, global operational complexities, temperature-sensitive products, and rapidly evolving market dynamics. Successfully managing these challenges is critical for ensuring product integrity, compliance, and patient safety. Supply chains within the life science sector must ensure timely delivery of vital healthcare products. However, operational complexities, regulatory pressures, and geopolitical risks significantly affect efficiency, responsiveness, and cost management. Following are the major challenges of SCM in the life science industry:

Regulatory Compliance: Compliance with regulations such as those enforced by the FDA, EMA, and PMDA demands rigorous documentation, traceability, and validation, significantly impacting supply chain flexibility and efficiency.

Cold Chain Logistics: Many life science products require strict temperature controls throughout transit. Breakdowns in the cold chain can lead to significant financial losses and potential patient harm, necessitating sophisticated real-time monitoring and contingency planning.

Globalization and Geopolitical Risks: The global nature of life science supply chains exposes them to geopolitical tensions, trade restrictions, tariffs, and customs delays, leading to unpredictable lead times and increased risks of disruption.

Demand Volatility: Predicting demand accurately is challenging due to unforeseen healthcare crises, varying product lifecycles, and complex clinical and regulatory timelines. Sudden demand shifts can lead to shortages or excess inventory.

Limited Visibility: Fragmented data systems and siloed operations hinder comprehensive visibility across the supply chain, making it difficult to anticipate and rapidly respond to disruptions and demand shifts.

Product Expiry and Inventory Management: Managing inventory with limited shelf-life requires precise coordination to minimize waste and ensure compliance with expiry dates, necessitating robust inventory management systems.

Capacity Constraints: High operational standards and compliance requirements limit production flexibility. Capacity constraints in GMP-certified facilities often lead to bottlenecks, especially during high-demand periods.

Product Diversification and Customization: The emergence of personalized medicine and complex regulatory packaging requirements complicates inventory management, logistics planning, and production processes.

Risk Management and Resilience: Dependence on single-source suppliers, geographic concentration of manufacturing, and limited redundancy in supply chains highlight the need for enhanced resilience and risk mitigation strategies.

Talent Shortages and Technology Gaps: A shortage of skilled professionals with expertise in regulatory compliance and advanced technologies, combined with slow adoption rates of modern technological solutions, hampers innovation and operational efficiency.

Strategic Solutions

To address these challenges, life science organizations should:

- Invest in advanced digital solutions, including AI, blockchain, and integrated data platforms, to enhance visibility and predictive capabilities.

- Strengthen partnerships with CMOs, CROs, suppliers, and logistics providers through collaborative ecosystems and shared data environments. (TMS/eWM)
- Build agile and resilient supply chains by incorporating flexibility, multi-sourcing strategies, and comprehensive scenario planning.
- Embed regulatory compliance and sustainability practices into core supply chain processes to proactively manage compliance and environmental responsibilities. (GTS)
- Implement Configurable Process Scheduling in SAP APO so that Shipping Calendar/Cold Chain Calendar can be accounted for, and Frozen/Refrigerated products will not be shipped over a weekend.

The life science industry must strategically adapt its supply chains to address the complex and evolving challenges inherent in its operations. Embracing digital transformation, collaborative partnerships, and resilient design principles is key to maintaining compliance, efficiency, and patient safety in an increasingly demanding global landscape.

These days businesses rely on supply chains to achieve performance goals. Well managed supply chains enhance delivery velocity, support innovation, bring down excess stock & speed up product launch into rapidly moving markets. Meanwhile, weak supply chains can cause long delays, stock shortage and decrease in customer trust. A supply chain is a network of pathways with numerous actors, tasks and locations instead of one path with one direction. It connects suppliers / internal production teams / shipping groups / retailers / end users. Each group forwards stock and returns data and payments throughout the chain. The network size and shape depend on the number of links and on exactly how firms assign roles and duties to groups (Bilal, Bititci, and Fenta, 2024)

For pharmaceutical supply chains, the firms begin by providing the raw materials, then make the medications, then shift these to storage sites and retailers as drug stores and clinic buyers. Last but not least is the patient that requires the product on schedule to finish treatment. All these steps must be in conformity with safety and health board rules which means supply chains in the sector are riskier and need close control. Drug supply chains get delayed because rules change, systems break, data decelerate or staff do not follow process at each site. Many firms have attempted to reduce this risk by restructuring supply tasks differently. Some bring work back close by, others send non-core tasks far but control with own units and even some do work in teams spread across numerous countries (Huq, Pawar, and Rogers, 2016). All firms in this industry aim to send the correct product at the right place in the appropriate time without squandering or delay. For this, firms need to keep the stock level right, share proper data across all groups and ensure each unit can act quickly if something delays or even changes. That's why firms use planning tools and backups to avoid failure. Supply chains don't operate based on straightforward rules - each phase is dependent on others - and a little fault at one task may lead to a larger issue at an additional task. Many old models fix each part as if it worked alone, which fails during time gaps, sales spike or skipped orders. So, firms now use methods like systems dynamics to demonstrate how each step changes the other ones over time (Sabouhi, Pishvaei, and Jabalameli, 2018). Yaroson (2019) examined System dynamics utilizes neither set numbers nor fixed paths. It builds picture of whole chain with feedback loops, time steps and flow changes. Firms use it to check where delays are coming from, stock moves throughout links and when orders are late filling. This also shows how lead time, information lag and wrong demand numbers can accumulate and stop the chain. Firms which use

system dynamic find they can spot issues early, fix them prior to spreading and test a new procedure before beginning real changes. They can also see how one step - a missed delivery or change of product sales - will impact stock in future week. This lessens waste and keeps service high if the chain is having issues. Numerous issues in drug supply chain stem out of the firms' systems themselves. They might use slow data tools, have data in different files, use rules that do not match up between teams or have staffing gaps. If the order team doesn't speak with the sales team or the stock numbers are different across sites - service breaks. Outside forces also cause trouble for firms, by making raw material shortages, strikes, weather problems, shipping delays, trade laws and customs blocks. These outside factors can't be fixed by the firm, but may be accounted for in case the firm recognizes them earlier and will shift to other options. Others use nearshore plans which keep the cost low but save time and risk. Some still use offshore units but have their very own teams watching work. All of these plans must match a firm product, cost objective and risk.

Firms face length in addition to depth in the chain. One product might require parts of three or more steps. A supplier may depend on a supplier and the firm might not realize that second link exists. So, a problem deep in a chain might come along late and not have an early sign. Such risk requires more tools which give real time views of the entire network and not just the first supplier. Drugs also need special handling. Some must remain cold, others must move fast and most have short life spans. So, firms cannot keep too much stock but mustn't run out. This balance is tough to maintain and is exacerbated by wrong or late data. Firms use two paths to plug these gaps. They build better systems & train their teams to prevent delays. They also keep safety stock; they deal with more than one supplier and have teams that react fast to a delay. Both paths cost money, and firms should select according to time and stock value. Firms check and plan supply work with the SCOR model. It breaks down supply into 5 components - plan, make, source, deliver & return. Each part has steps and a rule. Following this model, firms can track weak points, track key steps and match data across sites. It helps teams plan together and fix issues in view of the network (Paul, Kabir, Ali, and Zhang, 2020).

Firms using SCOR combined with system dynamics might create stronger chains. They see where stock is sluggish, orders are skipped and cost is too high. They correct root causes instead of treating signs. Additionally, they find the proper balance of speed, cost and trust. Supply chains must work in the drug field because delay costs money in addition to health. Patients missing drugs or even getting them late can kill lives. So, firms in this field are obligated to act fast and better plan than some other firms. While markets, trade, health and nature put more risk into the world supply chains must also evolve. They must be much more open, quicker, easier and clear to fix. Firms that act now will remain ready for what happens next. Those who wait might not keep pace (Alkhouri, 2024).

Literature Review

Supply chains in life science are characterized by strict rules, complex tasks and global risks. Such chains must move health products safely and on time. Lags or failures at any point in the chain can stop treatment, increase cost and reduce trust. As firms expand across markets teams must balance cost / speed / safety while handling rules / data and demand.

Akter, Debnath, and Bari (2022) applied A key challenge are rules imposed by health boards like the FDA in the United States, EMA in Europe and PMDA in Japan. These rules demand that each step be proved. Firms must record data, keep clear notes, trace every item and prove every move meets rule. This slows the chain and prevents teams from making snap changes when things break. If data is late or wrong, drugs cannot advance. This makes planning difficult and risk high. Changing global links also require firms in this field. When a raw item comes from one country and that country closes trade, the drug cannot be made. When a ship is unable to reach the port because of war, flood or strike the supply stops. These kinds of risks are more frequent and tougher to plan for. Now it takes many hands to get the drug from plant to patient. Each move - mix, pack, ship, check - approve - must match rule and follow time. One step missed and the drug might not reach user. Firms now want tools that track steps, link teams and warn of a delay. And despite the tools, the chain breaks when teams do not share the same rule or data. To cope with this, firms use more than one source, test all plans, and train teams to act fast. Cost now is also about trust, health and speed. The drug supply chain is complicated and must work every day.

Nguyen et al. (2022) suggested that drug chain must be strong under stress, fast in time and clear in work. Rules will stay. Risk will grow. Firms need chains that see, share, act and fix - before delay becomes harm. Cold chain logistics adds tasks to the supply chain, many items in life science must remain within set temperature ranges starting at the first point through the last. This includes during storage / packing / shipment / handover. If the cold chain breaks the drug might not work. This might waste large stocks and stop patients from receiving the dose at the right time. Firms have to control each step where goods go between hands or places. Each move allows for errors, The chain needs tools that record the whole trip. These tools must inform teams where everything is right now, notify them when something changes and prove items were in range. If one part fails, the entire batch will spoil. Some of these tasks includes real time temperature or time / site watch.

These tools send updates at every stop. If a sensor exhibits spike or drops, the crew will correct it. But loss could still come if teams do not react in time.

Cold chain risk also comes in from outside sources. Power cuts, traffic, ports blocks and missed links might stop the chain from moving on schedule. In such instances goods might stay in incorrect settings for too long. This breaks the cold chain when inside tools work too. So firms need to plan for backup steps. They need spare stock, quicker routes or local stores which keep small loads. The full load might be lost if the team doesn't load items right or misses one alert check. Cold chain rules are different someplace else. This adds another task to the work - each team should check local step and follow it without miss. They must choose cost or risk. More tracking costs more but identifies faults. So, they used data from past trips and determine where to spend and exactly where not to save (Bastani et al., 2021)

Cold chain needs clear plan, strong tools & fast fix. All teams must know their task. They have to be quick when fault comes. The drug chain has no room for delay. When cold chain fails it is not simply cash harm. That is the reason cold chain ought to be strong in all links not in first or even last one. One break and you lose time, stock and trust. Worldwide links in drug supply chain bring reach and risk. As firms expand across borders, they require supply from numerous places. Changed rules or closed borders stop firms from moving goods as planned.

In case one country changes its trade laws, firms might need brand new paper work, pay more to move stocks or wait longer at ports. All these steps slow the chain and add cost. Too long a wait might mean drugs miss use dates or fail completely to reach users on time. Customs checks change too, without a sign. A load moves fast one week then gets stuck the next week. Staff might not know which rule changed and how to solve that stop. Each delay requires time and costs additional. Occasionally the goods have to go back or even move elsewhere which breaks the plan and requires new spend. Political conflict adds unknowns. Whenever two areas stop trade/close borders, firms must change routes or even find new teams. These changes are slow. They take time, cash & new tools. The entire chain may end if the item is rare or if the source is one place. Firms also risk being overly reliant on one nation. A rule change, a port strike or a change in taxes may stop supply. To limit this risk, firms now use more than one source, have teams in most regions and create smaller, local shops near users. These steps cost more but keep goods moving.

Morris (2018) investigated that lead time is now difficult to guess. A task which once took a week may take three. Teams must work with long time gaps and accommodate change. They must not wait for error. They have got to plan for it. This means firms must build fast chains that see far and act before the block. Each delay harms care. That is exactly why teams must consider global risk part of everyday work. They must track news, test new paths and train staff to react once the chain stops. The work is more than sending things fast. It is to send items sure, without miss. That's the new aim in global chains. It's hard today to predict future need since a great deal of changes so fast. Sudden changes in disease pattern or health alerts trigger fast moves. These moves cause supply teams to change plan suddenly.

Drug demand rises when crises impact the public system. A health scare or a new virus can alter what people purchase. In these days, firms might not have time to react. They need stock ready, but they must avoid waste too. A drug's life is unstable and short too. One drug could serve users for years before losing place. New tests could stop plans that were planned far ahead of time. These test steps are governed by rules and not at the firm's pace. Firms which produce drugs have to live with rules at all stages. Stock piles in stores if approval is delayed. A change in the rules quickly can cause abrupt stock jumps. Both shifts break plans even when teams try to be ready.

Yarosan, Breen, Hou, and Sowter (2021) applied Whenever demand is high, firms might run short of items. They might speed up production but still fall behind. Making more takes time and might not exist raw goods. Late stock damages care and trust and raises total cost. Firms hold stock they cannot use when demand drops. Some drugs need to remain cold and some last just a short time. Any unopened drug adds waste to the body. Firms lose money and could lose buyers. Such demand shifts are tough to fix later. Planning tools help, but they cannot see what changes fast. Even new systems can't capture sudden events in full shape. Teams must plan for this with flexible work paths. Some teams hold safety stock for a quick demand increase. Others have more than one maker to help them stay ready. However, all these steps add risk and cost to manage. Selecting the right mix involves skill, time and data. Firms now plan with care sites and rules boards. They ask shops, doctors and public groups what to be expecting. However, no plan can stop all loss from demand shock.

Wang and Jie (2020) addressed risk Drug supply chains must not be anchored on static product sales figures. Teams have to see demand as something that waves. They have to make plans which

change quickly but hold their shape. Change will always break smooth flow in the drug field. Firms with strong links and test plans are ahead. People who treat demand as one set line will back. This is the real rule if firms want to remain in trade. Product expiry remains primarily a challenging task in drug supply chain. Many medications have a short shelf life, so that they can not be stored in stock very long. If firms don't act on time, they must discard unused goods. This creates waste, expense and missed service for the whole system. Firms must manage timing and flow to get stock moved before it goes out of service. Each drug batch has a fixed life from day of manufacturing. The clock begins running when that batch enters storage. Slow stock moves reduce use time before it reaches users. If storage or shipping causes much more delay, the window is simply too small. This makes stock tough to market or utilize. Such an inventory needs systems and steady tracking. Units of stock must have batch number and date connected to them. Firms need to know where each batch sit and just how much time remains. They have to send stock on time left and not on order size.

Bø, Hovi, and Pinchasik (2023) examined Teams need to move if old stock is sitting too much time in a warehouse. They must move it first, plan quick shipment or transfer it to sites which could use it by then. But if stock data are late or teams do not check expiration frequently, this plan fails. The lost stock must then be removed and all that cost add loss. Some supply teams utilize first expiry first out systems to correct this. They always pick stock with the least time to move out first. This works only in case it shows right data at the proper time on the system. Wrong stock may be sent if sites report late or tools break. In many cases expiry waste is caused by incorrect demand plan. If firms order too much and demand falls, stock is unused. If they send too much to low use sites, then local expiry becomes a waste. Stock should match real need to restrict expiry-based loss. A short shelf life also cuts into the stock firms can keep. They cannot store too much lest they expire. But they might store too little to meet rising demand. This makes planning tougher since each batch must balance waste risk with shortage risk. To fix this, firms track batch dates, website use rates and order trends with software. These tools adjust stock live & decrease expiry. Teams also share reports among locations to move soon-expire goods to where they may be used.

Drug firms must treat Expiry as a full risk - not stock loss. Every item wasted is money lost time lost and care missed. Inventory plans must use expired rules not against them. Capacity limits and product complexity slow operations in pharmaceutical supply chains. All these tasks are tough to be flexible with - particularly when demand changes abruptly. Much of this strain is an outcome of capacity limitations in approved sites & the need to manage diverse/custom product lines. In this particular field production should take place on certified sites. These sites follow good manufacturing practise rules that restrict what can be changed during runs. All products require their very own setup / clean down / check / approval prior to production can begin. These steps take time and restrict how fast the website switches from item to item. Whenever demand is high these exact same steps slow output and make it difficult to keep up with them. During high-use times this problem gets worse. A site might run fulltime but not fulfil all orders. It cannot change lines quickly because each change calls for new checks and data. A delay at one site might hold back complete batches and throw stock plans off course. If firms attempt to move orders to another site, they have to check the website has those rules, staff and setups. This takes time and cost more.

Addition of space is no easy fix. The firms cannot open a site quickly. Get rule checks, buy tools, train staff - prove all steps work. So, teams must plan with what they have and find ways to use each site better, not add sites. Simultaneously, firms make more kinds of products. Personalized medicine, targeted care, gene drugs and patient-specific doses make each batch smaller and more individual. These small runs still require full checks just like big ones. With new health rules come new packs, tags and paper. Such rules differ between places, so a group of stock may look and move differently even though the drug inside is the same. Any given product line may require its own pack process / storage type / ship plan. Labels must meet local law and track items with full data. A complete load can stop moving with one mistake. More lines/more steps increase the risk of error. When inventory must be divided by region, label and shelf life it makes inventory planning even more difficult. A firm cannot send one batch to all sites. They must match every stock lot to the correct plan, to the right rule, and at the right time. If they miss, stock could sit idle or expire. Dieser risk increases if products have a short use time or must stay cold.

They scan real time orders with pack flow tied to each order and software shows what can move when. And even with tools, the tools cannot find space when lines are full or slow. The process still must follow checks, staff rules and machine limits.

Teams should design paths to each step. Sites must always be prepared to shift. They also must train staff to run tiny lots and change lines fast. Many packs and rules mean each task takes more skill and care. One wrong tag or form can stop a batch from leaving. Sometimes, firms use outside sites to add space. Such sites might help during peak times or when one site must close. However, working with outside teams adds more steps like ship to and back, extra checks and data gaps.

Katsaliaki, Galetsi, and Kumar (2022) found that firms need strong base plans but space to move and must know when each line will be fully used. See how product mix grows. They have to also plan to switch teams/tools around to accommodate new requirements. The drug field is not returning to one-size plans. Products will get bigger, patient requirements will get different, and more rule sets will split. Chains therefore must match both fixed rules and new shifts. That requires tight plan, right tools, clear steps & quick fix when lines stop. Firms that make those shapes stay ready. The rest of us who do not will get more breaks and longer delays in years to come. Pharmaceutical supply chains today face two major challenges - lack of skilled staff and low adoption of advanced tools. These two issues are closely related and affect how quickly firms adapt to change, handle rules and run safe steady supply systems. Lacking the right people and right tools, firms move slowly, miss key tasks and fall behind in service and cost.

In many drug firms' teams need staffers who know how to comply with health rules, run supply tools, and manage risk. But many now move to other fields or do not train for this work. This leaves an enormous gap which cannot be filled. When teams lose key staff, they lose the ability to keep work safe and smooth. One failed step in a rule task or one stock plan error can stop a whole batch from moving. The people skills gap gets worse with the tools gap. Many supply teams use slow tools, old files, or paper steps to trace goods. These tools are unable to show stock in real time or flag when a delay starts. Strong data prevents teams from acting early. That causes delay, waste and missed service.

Goswami et al. (2024) A number of those gaps could be filled with new tools. AI now tracks need, finds risk and selects best path in digital supply chains. Some firms share records with all teams on a blockchain. Others join different data tools to display orders, stock and tasks in one view. But many teams wait to use these tools or do not know where to start. The low rate of use is related to both cost and skill gaps. Firms might not want to spend or may not have the people to operate new tools well. Moving forward, drug firms must act clearly and strongly. They have to buy new supply tools to see and act faster. AI, smart tags & data links help firms plan & shift before the delay. These also point out when stock sits too long or when tasks get delayed. All contract makers, all research teams and ship firms must see the data. Each part can be a unit when it works together in one system.

Objective

To explore the factors that shows the complexity and challenges of Supply Chain in Pharmaceutical Industry

Methodology

Study survey was conducted among 218 people from supply chain department of pharmaceutical industry to know the factors that show the complexity and challenges of supply chain in pharmaceutical industry. “Random sampling method” and “Factor Analysis” were used to collect and analyse the data.

Findings

Males are 57.3% and 42.7% are female in total study survey population. Among them 32.6% are below 38 years of age, 43.6% are between 38-48 years of age and rest 23.8% are above 48 years of age. 17.9% are working as supply chain analyst, 26.1% as procurement manager, 22.0% as distribution and logistics manager, 13.3% as regulatory compliance specialist, 14.2% as demand planner, and rest 6.4% as supply chain planner in pharmaceutical industry

“Table 1 Demographic Details”

“Variable”	“Respondent”	“Percentage”
Gender		
Male	125	57.3
Female	93	42.7
Total	218	100
Age (years)		
Below 38	71	32.6
38-48	95	43.6
Above 48	52	23.8
Total	218	100
Position		
Supply Chain Analyst	39	17.9
Procurement Manager	57	26.1
Distribution and Logistics Manager	48	22.0
Regulatory Compliance Specialist	29	13.3

Demand Planner	31	14.2
Supply Chain Planner	14	6.4
Total	218	100

“Table 2 KMO and Bartlett's Test”

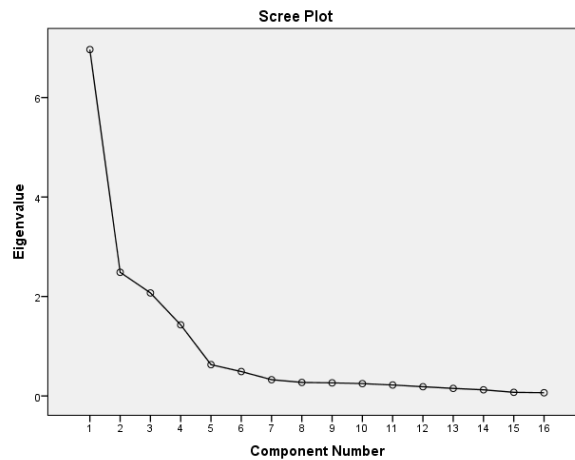
“Kaiser-Meyer-Olkin Measure of Sampling Adequacy”		.874
“Bartlett's Test of Sphericity”	“Approx. Chi-Square”	3144.132
	“df”	120
	“Sig.”	.000

KMO value is 0.874 and the “Barlett’s Test of Sphericity” is significant.

“Table 3 Total Variance Explained”

“Component”	“Initial Eigen values”			“Rotation Sums of Squared Loadings”		
	“Total”	“% of Variance”	“Cumulative %”	“Total”	“% of Variance”	“Cumulative %”
1	6.965	43.528	43.528	3.651	22.817	22.817
2	2.486	15.538	59.066	3.447	21.544	44.361
3	2.071	12.946	72.013	2.980	18.627	62.988
4	1.429	8.932	80.944	2.873	17.956	80.944
5	.630	3.935	84.879			
6	.490	3.065	87.944			
7	.327	2.043	89.987			
8	.272	1.700	91.687			
9	.263	1.644	93.332			
10	.248	1.553	94.884			
11	.220	1.374	96.258			
12	.185	1.157	97.415			
13	.152	.948	98.364			
14	.124	.773	99.137			
15	.073	.458	99.595			
16	.065	.405	100.000			

The “principal component analysis method was applied to extract the factors and it was found that 16 variables form 4 Factors. The factors explained the variance of 22.817%, 21.544%, 18.627% and 17.956% respectively. The total variance explained is 80.944%.



“Table 4 Rotated Component Matrix”

“S. No.”	“Statements”	“Factor Loading”	“Factor Reliability”
	Regulatory Compliance		.952
1	Rules imposed by health boards like the FDA in the United States, EMA in Europe and PMDA in Japan	.876	
2	Conformity with safety and health board rules	.865	
3	Rules change, systems break, slow data process are key challenges	.858	
4	Test steps are governed by rules and not at the firm's pace	.828	
	Cold chain		.938
5	Cold chain logistics adds tasks to the supply chain	.898	
6	If the cold chain breaks the drug might not work	.893	
7	Power cuts, traffic, ports block and missed links might stop the chain from moving on schedule	.874	
8	Cold chain needs clear plan, strong tools & fast fix	.871	
	Long Supply Chains		.893
9	Staff shortages, rule-based bottlenecks, global trade shifts and complex product flows	.909	
10	Supply chain gets more complex and less forgiving	.890	
11	Low adoption of advanced tools	.866	
12	Capacity limits and product complexity slow operations in pharmaceutical supply chains	.643	
	Product shelf life		.860
13	Many medications have a short shelf life, so that they cannot be stored in stock very long	.854	
14	A short shelf life also cuts into the stock firms	.842	
15	Drugs with short shelf life requires precise inventory turnover	.807	
16	Slow-moving stock and demand lead to expired, unsellable products	.738	

Factor “Regulatory Compliance” includes the variables like Rules imposed by health boards like the FDA in the United States, EMA in Europe and PMDA in Japan, Conformity with safety and health board rules, Rules change, systems break, slow data process are key challenges, and Test steps are governed by rules and not at the firm's pace. Factor “Cold chain” consist of variables like

Cold chain logistics adds tasks to the supply chain. If the cold chain breaks the drug might not work, Power cuts, traffic, ports block and missed links might stop the chain from moving on schedule, and Cold chain needs clear plan, strong tools & fast fix. Factor “Long Supply Chains” includes the variables like Staff shortages, rule-based bottlenecks, global trade shifts and complex product flows, Supply chain gets more complex and less forgiving, Low adoption of advanced tools, and Capacity limits and product complexity slow operations in pharmaceutical supply chains. Factor “Product shelf life” includes the variables like many medications have a short shelf life, so that they cannot be stored in stock very long, A short shelf life also cuts into the stock firms, Drugs with short shelf life requires precise inventory turnover, and Slow-moving stock and demand lead to expired, unsellable products.

“Table 5 Reliability Statistics”

“Cronbach's Alpha”	“N of Items”
.905	16

Total four factors namely Regulatory Compliance, Cold chain, Long Supply Chains, and Product shelf life shows 0.905 reliability that includes sixteen variables.

Conclusion

Pharmaceutical supply chains are under pressure from internal gaps and external risks. Staff shortages, rule-based bottlenecks, global trade shifts and complex product flows take time and cost to solve. If not controlled earlier these factors may retard product movement and reduce patient access. Firms now need to view supply management as a strategic task and not a support task. That means having clear plans, digital tools, skilled teams and tried scenarios. Linking teams and sharing data in real time avoids breaks. Planning for risk must become daily work, not a rare step. Every delayed item saves more service and less waste. Every missed step costs time, stock and trust. Firms that act now, build tools and train their people will move faster and are ready. Those who wait might fall behind as the supply chain gets more complex and less forgiving. The study aims to explore the factors that shows the complexity and challenges of Supply Chain in Pharmaceutical Industry and found that Regulatory Compliance, Cold chain, Long Supply Chains, and Product shelf life are the factors that show the complexity and challenges of supply chain in pharmaceutical industry.

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