International Logistics Criteria of Medicinal Products for Human Use: How Do They Relate to Cargo Logistics Providers?

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Abstract This study explores the logistics criteria of medicinal products with logistics outsourcing. It examines the subjective decisions of the managers at medicinal product firms with regard to the outsourcing of logistics work to cargo logistics providers. The research targets outsourcing logistics decision makers from firms that manufacture medicinal products for human use in Taiwan. The empirical evidence supports five key logistics criteria factors: documentation, equipment, technology, certification, and training. The four key logistics outsourcing decision factors examined are quality, freight, service, and delivery. A significant relationship between the logistics criteria of the cargo logistics providers and the outsourcing logistics decisions of the medicinal products firms is also identified. The study provides an empirical validation of the two-factor construct to develop survey scales for international logistics criteria and client decisions with the establishment of a standard questionnaire, which uses 47 successful questionnaires and follows the Delphi method. Factor analysis was used on 40 criteria between the medicinal products firms and cargo logistics providers. The Pearson's coefficients on the correlations applied the two factors of logistics criteria and outsourcing decisions.

Keywords International logistics criteria · Client outsourcing decision · Medicinal products for human use · Cargo logistics providers

1 Introduction

The global COVID-19 coronavirus outbreak has seriously hampered the delivery of medicinal products by cargo logistics enterprises. Global logistics companies are essential service providers as they enable medicinal product enterprises to outsource the on-time delivery of their products. In the past decade, Taiwan's medicinal products industry has increased its competitive advantages in terms of production through

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outsourcing its deliveries to external cargo logistics providers. The outsourcing of a company's logistics functions represents an effective allocation of their resources and reconfigured its supplier network to build long-term partnerships. Organizations have traditionally focused their attention on controlling their own costs to increase profitability by concentrating on improving the business processes that the organization controls independently (Ergun et al. 2007). The medicinal products transportation process in different regions has required giving special consideration to the aspects of long-range transportation by trucks, ships, and air cargo. There has been a need to control the temperature, humidity, and other factors during the transportation process. The outsourcing of key logistics activities has been one of the most important trends in medicinal companies, and the logistics service criteria affect the outsourcing firm's logistics perception, consequent behavior, and partnership selection (Meng 2014). The logistics criteria and outsourcing decision factors have led to a growing body of research to define their essential characteristics. Du et al. (2005) pointed out that product customization has been recognized as an effective means to meet individual client's needs, and customers can be actively involved in the product customization. Logistics outsourcing controls a firm's differentiation choices on logistics customization and enables executives to pursue improved efficiency. There are many implications for service value of logistics outsourcing in terms of the customization of services (Remko 2000). Fugate et al. (2006) stated that an effective supply chain flow requires the creation of synergistic relationships between the supply and distribution partners in order to maximize service and provide a profit. These decisions are largely determined by the political and organizational factors associated with the regional autonomy, geographical factors, climate, travel distances, infrastructure, roads, and electricity supply in which the population is distributed. Logistical outsourcing issues are included in the strategic agenda because they can have a positive influence on company performance (Tracey 2006). Although logistics studies have become a key component of research work, they have invariably lacked a focus on organizations' logistics decisions in respect of medicinal products for human use.

2 Logistics on Medicinal Products for Human Use

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) sets out medicinal products specifications for good distribution practices (GDP), which continue the thrust of the good manufacturing practices (GMP) established in the scheme. A manufacturer of medicinal products for human use is required to comply with the local legislation. This legislation specifies the application of GMP for medicinal products exclusively intended for export. A manufacturing license, the GMP certificate, is issued, which signifies that laboratory control of the pharmaceutical products has been conducted (Tomić et al. 2010). The quality of international pharmaceutical products continues to improve, and the quality control regime spans the entire process from production to sales; that is, the drug quality management covers the entire life cycle of the drugs and includes stringent requirements for the procedures. The

quality control of international pharmaceutical companies has continued to improve. The drug quality management process covers the entire life cycle of drugs, and since the GDP came into being, it has extended to drug distribution. Over 130 countries have adopted the GDP specifications. These specifications cover the management required by the wholesale distributors in respect of risk management, inspection, storage, and transport. The distribution processes under GDP are consistent with quality assurance principles (Meng et al. 2019). Thus, logistics providers are to be able to meet the needs of their medicinal clients by acting as their geographical partner to propagate the spread and range of their clients' service criteria. Through factor and correlation analysis, this study designs valuable criteria to align with the needs of their outsourcing medicinal companies to enable them to perform some or all of the logistics activities. These will evolve into tailor-made services to meet the diverse needs of their clients. Chikumba (2009) indicated that medicinal products logistics operators need to get additional spatial information, understand the needs of the health facilities, and take into account environmental factors in order to monitor the flow of medicinal products at each health facility. Central logistics models are primarily coordinated by arranging for the products to be received first at their central medical stores and then distributed to intermediate stores and ultimately to the final service points. In a decentralized system the intermediate stores are responsible for receiving, storing, and distributing the end products, and they are also responsible for procurement of the production inputs. The active pharmaceutical ingredient (API) specifications need to comply with the GDP regulations, which comprise procurement, importation, storage, supply, distribution, export activity, processing, packing, reverse logistics, and warehousing, as well as the rules for contract agents, brokers, traders, and others involved in the supply chain that are not the original manufacturers' suppliers (APIC 2017). APIs are the parts of any drug that are used in the formulation of the finished product to produce the intended effects of the drug. Based on the drug GMP, the definition of API refers to the components of a drug by reference to its physical and chemical properties, its biological treatment, the technology used in manufacturing to produce the necessary pharmacologically effective active chemical ingredient. The active chemical ingredients commonly used are drugs manufactured in the production of biotechnology products.

With medicinal products for human use, international logistics providers play an important part in aligning GDP and GMP to ensure the stability of the quality during the transport or storage of the products. They need to monitor the temperature and humidity to ensure they meet the requirements of the national health authority, and to do so, they need to develop customized criteria for pharmaceutical logistics (Meng et al. 2019). For cargo logistics providers involved with medicinal products, the main functions concern the degree of centralization and the number of storage points through which the product will pass before being delivered to the recipient. Roy et al. (2009) argued that the drug supply available must not only meet with the requirements of the population and the estimated demand for the pharmaceutical items, but it also scientifically meet the quantity and quality of the medicinal products demanded. The overall API logistics links are not allowed to have errors that could compromise the quality of the drugs during transportation. Accordingly, a strict set

of comprehensive service standards for drug delivery have been set up to reduce the incidence of risks and accidents in order to maintain a consistent quality of the drugs and to ensure there are no adverse effects on any of the key factors in the delivery process.

3 Delphi Method and Questionnaire Design

The data for this study were collected from a survey. To determine the questionnaire items, it was crucial to ensure their content validity and survey instrumentation accuracy. A standard questionnaire using the Delphi method was established. The questions were based on expert opinions and suggestions from pharmaceutical industry representatives, academics, and those with advanced knowledge in related fields. The first Delphi step involved experts and professors determining the number of experts required for each group. They decided on one from international ocean freight transportation, one from international air freight transportation, one professor from a university, and one product executive from a pharmaceutical company to provide guidance on the principals of good distribution practices in respect of active substances for medicinal products for human use. The Meng et al. (2019) studies on medicinal criteria were divided into a total of 40 measures of logistics criteria and client decision-making, as shown in Table 1.

The research target for this study is the actual outsourcing logistics decision makers in respect of medicinal products for human use in Taiwan. The results of the pretest of all 40 items were very good, so the survey was distributed to 60 logistics outsourcing decision makers and was carried out during June to September 2019. A total of 52 successful questionnaires were returned, but five of these were discarded because of incomplete information. Accordingly, there were 47 usable responses for an overall response rate of 78.3%. Statistical analyses and factor analysis were conducted using SPSS. First, factor analysis was used to investigate any separate underlying factors and to reduce redundancy. Next, Pearson correlations were used to assess the bivariate relationships. The Cronbach's α values were statistically determined to provide a summary measure of the inter-correlations that existed. In this study, the Cronbach's α values, which are depicted in Tables 2 and 3, show that the factor dimension attributes with respect to the logistics criteria and outsourcing decisions are all greater than or equal to 0.6. This shows that each dimension achieved reliability.

4 Empirical Results

To simplify the analysis structure, this study conducted two factor analyses of the forty items in the logistics criteria and outsourcing decisions lists. This study adopted the principal components to extract the factors whose Eigenvalue was greater than 1

Table 1 Measurements of international logistics criteria and client decisions

Measurements of logistics criteria	Measurements of outsourcing decisions
1. Self-check	1. Medicinal products for human use distribution regulations
2. Personnel service	2. Drug delivery processes files need to be saved properly and could date back
3. Premises and equipment	3. GDP/GMP specifications in respect of compliance document management
4. Complaints	4. Delivery documents are immediately returned
5. Containers and labels	5. Sufficient manpower
6. Organization and management	6. Temperatures in warehouses are periodically calibrated
7. Vehicles and equipment	7. Workplace environment is clean
8. Sending and receiving	8. Drug distribution has excellent specifications (GDP) (blue-chip vendors)
9. Repackaging and relabeling	9. Provide written procedures for processing jobs under abnormal conditions
10. Product returns	10. Has dangerous goods expertise
11. Contract activities	11. Has expertise in highly potent and toxic drugs
12. Transport	12. Emerging market delivery route planning
13. Recalls	13. Capacity for risk assessment for transport
14. Self-audit	14. Drug storage conditions reflect GMP/GDP knowledge
15. Self-inspection	15. Reverse logistics capacity; able to handle rejection and recalls of pharmaceutical products
16. Information transfer	16. Workers receive the necessary GMP/GDP training regularly
17. Shipping	17. Acquired Partners in Protection (PIP) certification
18. File management	18. Obtained United States Business Coalition against Terrorism (C-TPAT) certification
19. Quality systems	19. Obtained Authorized Economic Operator (AEO) certification
20. Final provisions	20. Transportation vehicles cleaning procedures

and then used the varimax of orthogonal rotation to obtain the rotated coefficients. Finally, factors four and five were extracted. The accumulated variance explained was 72.13% in respect of the logistics criteria and 68.42% for the outsourcing decision; the analysis results of the individual factors of the logistics criteria and outsourcing decisions are illustrated in Tables 2 and 3, respectively.

Factor analysis was conducted to classify the identified client's outsourcing decisions into several critical dimensions. The results identify equipment as the most important dimension of the logistics criteria, whereas quality is the most important dimension of the outsourcing decisions.

Table 2 Factor analysis of logistics criteria

Factor dimensions of logistics criteria	Factor loading	Cronbach's α	Eigenvalue	Explanation rate (accumulated)
DOCUMENTS - File management - Contract activities - Self-inspection - Self-audit	**0.59** **0.74** **0.58** **0.66**	**0.72**	**3.68**	**23.82% (23.82%)**
EQUIPMENT - Premises and equipment - Containers and labels - Vehicles and equipment - Repackaging and relabeling - Shipping - Transport	**0.66** **0.54** **0.69** **0.71** **0.48** **0.51**	**0.77** **0.71**	**2.91** **2.48**	**16.2% (41.18%)** **17.44% (57.46%)**
TECHNOLOGY - Sending and receiving - Information transfer - Self-check - Final provisions	**0.58** **0.76** **0.59** **0.53**	**0.61**	**2.98**	**11.63% (74.41%)**
CERTIFICATION - Recalls - Product returns	**0.78** **0.71**	**0.67**	**2.43**	**9.19% (71.21%)**
TRAINING - Personnel service - Organization and management - Quality systems - Complaints	**0.69** **0.46** **0.44** **0.68** **0.54**			

In order to understand the relationships between the factors of the logistics criteria and outsourcing decision indicators, the study used Pearson's correlation analysis. The results are shown in Table 4.

The empirical results show that there are significant relationships between the factors of the logistics criteria and outsourcing decisions. The detailed analyses and corresponding relationships are stated below.

1. A significant relationship exists between "Documents" and "Quality" as well as "Documents" and "Delivery."
2. A significant relationship exists among "Equipment," "Technology," and "Certification" and among "Quality," "Freight," "Service," and "Delivery."
3. There are significant relationships between "Training" and "Quality" and "Service" and "Delivery."

Table 3 Factor analysis of outsourcing decisions

Factor dimensions of outsourcing decisions	Factor loading	Cronbach's α	Eigenvalue	Explanation rate (accumulated)
QUALITY - Temperatures in warehouses are periodically calibrated - Drug delivery processes files need to be saved properly and could date back - Medicinal products for human use distribution regulations - Sufficient manpower - Workplace environment is clean	**0.69** **0.77** **0.74** **0.64** **0.58** **0.71**	**0.71**	**7.94**	**37.54%** **(37.54%)**
FREIGHT - Transportation vehicles cleaning procedures - Provide written procedures for processing jobs under abnormal conditions - Workers receive the necessary GMP/GDP training regularly - Low cost provider - Acquired Partners in Protection (PIP) Certification	**0.59** **0.57** **0.73** **0.58** **0.54**	**0.73** **0.87**	**2.41** **1.68**	**16.77%** **(54.45%)**
SERVICE - GDP/GMP specification of compliance document management - Drug storage conditions reflect GMP/GDP knowledge - Expertise in highly potent and toxic drugs - Obtained Authorized Economic Operator (AEO) certification - Has dangerous goods expertise - Obtained United States Business Coalition against Terrorism (C-TPAT) certification	**0.69** **0.58** **0.48** **0.57** **0.81** **0.78** **0.58**	**0.61**	**1.62**	**13.41%** **(75.86%)**

(continued)

Table 3 (continued)

Factor dimensions of outsourcing decisions	Factor loading	Cronbach's α	Eigenvalue	Explanation rate (accumulated)
DELIVERY - Delivery documents are immediately returned - Drug distribution has excellent specifications (GDP) (blue-chip vendors) - Reverse logistics capacity; able to handle rejection and recalls of pharmaceutical products - Emerging market delivery route planning	**0.54** **0.69** **0.43** **0.58**			**8.36% (72.18%)**

Table 4 Pearson's coefficients on logistics criteria and outsourcing decisions

		Logistics criteria				
Outsourcing decision	Factors	Documents	Equipment	Technology	Certification	Training
	Quality	0.24^{**}	0.18^{**}	0.59^{**}	0.35^{**}	0.25^{*}
	Freight	0.18	0.27^{**}	0.64^{**}	0.31^{**}	0.06
	Service	0.04	0.36^{**}	0.57^{**}	0.48^{**}	0.31^{*}
	Delivery	0.53^{**}	0.56^{**}	0.48^{**}	0.28^{**}	0.27^{**}

**Significance level $p < 0.01$; Significance level $^{*}p < 0.05$

4. "Equipment,"Technology,"and "Certification" in operations are potential logistics factors to connect with the outsourcing decisions. The results showed that the logistics criteria have a significant relationship with the outsourcing decisions.

5 Conclusions

This study conceptually defined the domain factors and, using the Delphi method, designed 40 survey items to empirically validate and explore the relationships between the service criteria and outsourcing decisions on the medicinal products examined. The results align with those of Gouveia et al. (2015), who surveyed European participants with respect to GMP guidelines in which quality, security, and effectiveness at exceptional levels are applicable to the manufacturing of health products. By providing positive logistics criteria to the client, the potential negative service failure associated with the logistics decision is reduced. This suggests that cargo logistics providers should place their emphasis on the documents, equipment, technology, certification, and training factors. The logistics criteria are the matters that drive the clients' outsourcing intentions. Understanding the behavioral intention

on outsourcing is the main factor to influence clients' decisions (Meng et al. 2010). This study demonstrated that equipment is the most important criterion and that firms should take it into account when developing their strategy. The study also presented the strategic management that is necessary regarding the decision factors of quality, freight, service, and delivery. In summary, this study identified the essential factors that need to be comprehensively evaluated to provide an understanding of the logistics criteria and outsourcing decisions. We expect that it can be used as a reference for strategic planning carried out by cargo logistics providers. The results revealed that the proposed two factors have psychometric properties that are desirable to clients when they make decisions, and that these factors can improve efficiency and core competency.

References

APIC (2017) Active pharmaceutical ingredients committee: how to do document: GDP for API. European Chemical Industry Council

Chikumba PA (2009) Application of geographic information system (GIS) in drug logistics management information system (LMIS) at district level in Malawi: opportunities and challenges. In: International conference on e-infrastructure and e-services for developing countries, e-infrastructures and e-services on developing countries, pp 105–115

Du X, Jiao J, Tseng MM (2005) Understanding customer satisfaction in product customization. Int J Adv Manuf Technol 31:396–406

Ergun O, Kuyzu G, Savelsbergh M (2007) Shipper collaboration. Comput Oper Res 34:1551–1560

Fugate B, Sahin F, Mentzer JT (2006) Supply chain management coordination mechanisms. J Bus Logist 27:129–162

Gouveia BG, Rijo P, Gonçalo TS, Reis CP (2015) Good manufacturing practices for medicinal products for human use. J Pharm Bioallied Sci 7:87–96

Meng SM (2014) Logistics image of outsourcing clients in the wireless telecommunications industry: how is it related to the service value of air cargo logistics provider? Int J Asian Soc Sci 4:940–955

Meng SM, Liang GS, Lin K, Chen SY (2010) Criteria for services of air cargo logistics providers: How do they relate to client satisfaction? J Air Transp Manag 16:284–286

Meng SM, Yang HY, Dai J (2019) International logistics criteria on medicinal products for human use. Int J Asian Soc Sci 9:148–168

Remko IVH (2000) The role of third-party logistics providers in mass customization. Int J Logist Manag 11:37–46

Roy C, Das JK, Jha HK, Bhattacharya V, Shivdasani JP, Nandan D (2009) Logistics and supply management system of drugs at different levels in Darbhanga District of Bihar. Indian J Public Health 53:147–150

Tomić S, Filipović SA, Ilić MA (2010) Good manufacturing practice: the role of local manufacturers and competent authorities. J Artic Arch Ind Hyg Toxicol 61:425–436

Tracey M (2006) The role of logistics in strategic management. Int J Integr Supply Manag 2:356–382