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## Loss and Damage Analysis in International Transport of Pharmaceutical Products

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**Abstract:**

**Purpose:** The purpose of the article is to investigate the main causes and factors of loss or damage of pharmaceutical cargoes in international transport, and brief analysis of trade flows and transport trends in pharmaceuticals provides a background for consideration.

**Design/Methodology/Approach:** Claims data derived from surveyor company and handled by insurance brokers have been scrutinized. The study sample consisted of 2168 cases examined between 2015 and 2020, and of reports drawn up at the end by a surveyor, that have been systematically analysed every six months to identify the dominant types of damage and the main causes that contributed to the loss or damage of pharmaceuticals.

**Findings:** The research clearly shows that between 2015 and 2019 trade in pharmaceuticals grew from USD 502 billion to USD 636 billion in 2019, i.e., by 26.7%. In parallel with the increase in global trade, the global pharmaceutical transport and logistics market is also developing and is expected to grow at a CAGR of 4.1% in the period of 2019-2024. Despite advancements in cooling technology and logistics, there are still loss and damage plaguing the industry. The prevailing causes for the frequency of losses have been divided into six categories: 1) refrigerating equipment breakdown or malfunction, 2) unsuitability of packaging and preparation of cargo for transit, 3) delays not only to the destination, but also during transport, 4) human failure, 5) careless handling, 6) Acts of God. However as far as value of loss and damage is concerned, it is the refrigerating equipment breakdown or malfunction that resulted in more than half of the claims.

**Practical Implications:** The research findings and proposed recommendations can be used by risk management professionals, as understanding factors responsible for cargo loss and damage is a prerequisite for effective risk management throughout the entire transport chain.

**Originality/Value:** Given the scarcity of information on the reasons for the loss and damage of pharmaceutical cargoes, each study in this field can be considered valuable.

**Keywords:** Pharmaceuticals, cold chain, cargo loss and damage, breaking cold chain integrity, pharmaceutical trade.

**JEL classification:** M21, L99, L83, C38.

**Paper Type:** Research article.

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## 1. Introduction

The COVID-19 pandemic has affected many economies and industry sectors around the world but has also drawn attention to the pharmaceutical market and the international trade and transport of this commodity. Under the name "pharmaceuticals" are a variety of substances that are produced by or used in the pharmaceutical industry, incl. medicaments, antibiotics, blood, toxins, vaccines, hormones are just a few of them.

The picture of pharmaceutical transport and logistics market is very complex and described as "one of the most regulated, expensive, and fragile cargo markets in the world today" (Shanley, 2018b). Unforeseen events which may occur at any stage of the pharmaceutical supply chain can result in the loss or damage of cargo causing financial losses for companies (exporters, importers, carriers etc.). More importantly, however, they can have a negative impact on product quality, and the risk is more than the loss of cargo - it can also endanger the health and well-being of patients. Moreover, the total loss of a shipment of pharmaceuticals i.e., a lack of delivery, means that valuable medicines may not reach the patients who need them.

Therefore, the purpose of this article is to investigate the main causes and factors of loss or damage of pharmaceutical cargoes in international transport. Understanding these factors is a prerequisite for effective risk management throughout the entire transport chain.

## 2. Global Trade and Transport of Pharmaceutical Products

In 2019, pharmaceutical products were the world's 7<sup>th</sup> most traded commodity and represented 3.51% of total world trade by value. According to data of UN COMTRADE, between 2015 and 2019 trade in this commodity grew from USD 502 billion to 636 billion in 2019, i.e., by 26.7%. In 2019 the trade in pharmaceuticals represented 3.51% of total world trade, and Table 1 below lists the largest pharmaceutical exporting and importing countries in 2019.

**Table 1.** Top 10 exporting and importing countries in pharmaceutical products in 2019

Export		Import	
Country	Share (%)	Country	Share (%)
Germany	14,4	United States	20,5
Switzerland	12,7	Germany	8,54
United States	9,73	Belgium	5,77
Ireland	9,68	Switzerland	4,88
Belgium	7,31	China	4,39
France	5,68	Italy	4,3
Italy	5,39	UK	4,19

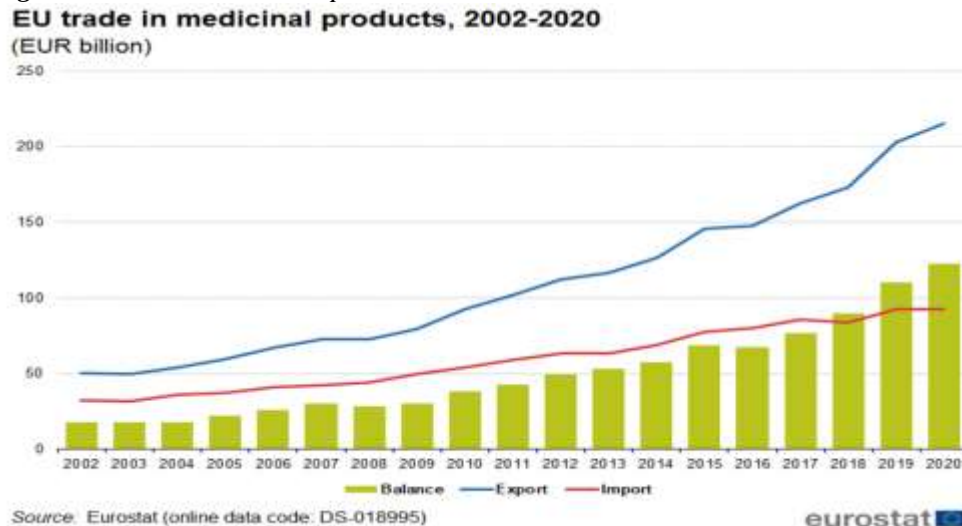
<b>Netherlands</b>	4,75	France	4,05
<b>UK</b>	4,29	Netherlands	3,92
<b>India</b>	2,77	Japan	3,59

*Source: Own elaboration based on UN COMTRADE data.*

For years, Germany has been the unquestionable leader in the pharmaceutical trade, ranking first among exporters and second among importers, representing 14.4% (USD 91,5 billion) and 8,54% (USD 54,3 billion) of global trade respectively. Another important player in this market is Switzerland (12.7% share in global trade), and the United States representing 20,5% of global imports (USD 131 billion). It is clearly visible that this market is highly concentrated since as much as 77% of global export and 52% global imports in pharmaceuticals come from European continent.

Figure 1 shows that exports and imports of pharmaceutical products outside the EU increased almost every year between 2002 and 2020, reaching EUR 215 billion and EUR 93 billion respectively in 2020. (Eurostat, 2021).

**Figure 1. Extra-EU trade in pharmaceuticals in 2002-2020.**



*Source: Eurostat (2021).*

In parallel with the increase in global trade, the global pharmaceutical logistics market is also developing. According to the 2020 Biopharma Cold Chain Sourcebook, this market is expected to grow at a CAGR of 4.1% in the forecast period of 2019-2024. Globally, spending on pharmaceutical cold-chain logistics (packaging, transport, storage etc.) has been rising steadily since 2018, and it is projected to grow by another 25% over the next three years, reaching USD 21.3 billion in 2024. (Pharmaceutical Commerce, 2020). However, according to the International Air Transport Association (IATA), the global pharmaceuticals logistics market was valued even more at USD 64 billion in 2017 (IATA, 2018).

Pharmaceutical transport typically combines different modes. The more valuable, temperature-sensitive, and time-sensitive product, the more likely will be transported by air, which is prized for its speed and flexibility. Other pharmaceuticals are usually transported by sea, and a fierce competition between ocean lines and air carriers over medicament shipments has recently been observed. A stunning 43% of pharmaceuticals transported by air consists of products with a value above USD 150 per kg, incl. vaccines and hormones, whereas medicaments with values of less than USD 15 per kg are usually shipped by sea (Seabury, 2013). In turn, road transport is mainly used to connect with both air and sea freight, while rail remains insignificant.

Air cargoes share of global pharmaceutical product transport has declined from 17% in 2000, to 11% in 2011, according to IATA, however newer data are not available. It is certain, however, that shipowners, using new technological and organizational solutions, take over a large part of the cargo, mainly because of cost competitiveness, as maritime transport is up to 80% less expensive than air transport.

Pharmaceutical air transport is dominated by European countries and the United States (together almost 60% of all air freight), although emerging economies in Asia have increased their market share. European trade routes have in recent years seen a mode shift towards air transport, while many North American trade lanes, especially with India, have shifted towards maritime transport (Seabury, 2013).

So far, most of the growth in pharmaceutical marine transport has been in relatively low value, high-volume products such as solid-dose tablets, generic pharmaceuticals, and excipients (Shanley, 2018b). The IATA noted that in 2012, 3.5 million mt of pharmaceuticals were still shipped by sea, compared to 0.5 million mt by air. (IATA, 2014), however, in terms of value of this air freight, it was around \$213 billion against the \$56 billion value of ocean freight. It is interesting that among the strong supporters of sea transport are the largest drug producers, such as AstraZeneca, which increased the percentage of products shipped by sea from 5% in 2012 to almost 70% in 2017 (Guisbert-Williams, 2017).

According to Seabury (2013), who in 2012, did the research (interviews) among freight forwarders, most (about 80%) pharmaceuticals are shipped as general cargo, primarily those which do not require specific treatments and may be transported in standard range of temperature (15-25 Celsius degrees). While around 20% of shipments require temperature control in the transport chain, more than 75% of them require only passive cooling solutions, and just 5% require active cooling solutions. Of temperature-sensitive products shipped, 51% were ambient, 31% were refrigerated, 17% were frozen, and 32% should not be allowed to freeze (Sykes, 2018).

However, the latest shipments of Covid-19 vaccines have certainly radically changed this profile, since the two Covid-19 vaccines that are based on the mRNA platform

require ultra-low temperature, with the Pfizer-BioNTech vaccine needing to be maintained between  $-80^{\circ}\text{C}$  and  $-60^{\circ}\text{C}$  and the Moderna vaccine at  $-25^{\circ}\text{C}$  and  $-15^{\circ}\text{C}$ .

The unprecedented demand for vaccines has set new standards for ultra-cold chain, and has increased requirements for shipping container manufacturers, logistics operators, and specialized shipping and airline companies (Shelley, 2021) and foster the introduction of new type of container. Tower Cold Chain has launched a new container for the transport of pharmaceutical products that require an internal temperature range of  $-80^{\circ}\text{C}$  to  $-60^{\circ}\text{C}$ , and Envirotainer introduced the CryoSure container that can maintain temperatures of  $-70^{\circ}\text{C}$  (Brett, 2021).

### 3. Study Design and Results

There is little data on the loss and damage of pharmaceutical cargoes, especially those that can be attributed to maritime transport. The only information on these losses that is available comes from the air carriers, and very little from the pharmaceutical sector. Moreover, these data are often out of date, incomplete or inconsistent.

In 2014, IMS Health, an American company that provided information for healthcare industry (from 2017 known as IQVIA), revealed that the top 10 pharmaceutical companies lost an average of USD 16 billion each year due to transportation problems, the resulting temperature excursions, and delays. For the entire pharmaceutical industry, losses exceeded USD 35 billion (Basta, 2020).

According to the International Air Transport Association (IATA), 20% of temperature-sensitive medicines are impacted due to temperature excursions during transport, and over 50% of temperature excursion occur while products where in a custody of airlines and airports. Annual product losses range between 2.5 – 12.5 billion USD, that was unacceptable high considering the market value of 300 billion USD (IATA, 2018).

Some sources state, that of all the modes of global transport of pharmaceuticals, air transport was identified as the most potentially risky, accounting for 80% of all reported temperature deviations. It is also reported that in maritime transport there is only 1% of temperature variation, while in road transport it is slightly higher at 18% of all excursions (Shanley, 2018a). However, it is forgotten that it is air transport that transports the most drugs requiring refrigeration, hence such good results of sea transport are not relevant here.

In a very recent study, 2019 Biopharma cold chain logistics survey, almost half (44.6%) of respondents reported many incidents with deviations from the desired temperature, and 16% admitted that temperature fluctuations occur on monthly basis. Moreover, the reported deviation is not a matter of one degree or two, 37% reported temperature excursion up to 4 Celsius degrees and 21% between 4 and 8 degrees (Pelican Bio-Thermal, 2019).

Therefore, to achieve the goal formulated in the introduction, claims data derived from a leading cargo surveyor offering expertise in the field of cargo losses/damages was examined, as well as claims handled by the two largest companies operating in the Polish brokerage market.

The study sample consisted of 2168 cases (claims) examined between 2015 and 2020, and of reports drawn up at the end by a surveyor, indicating the factors behind the occurrence of loss of or damage to pharmaceutical cargoes. All these claims have been systematically analysed every six months to identify the dominant types of damage and the main causes that contributed to the loss or damage of pharmaceuticals<sup>2</sup>.

Most of the incidents (92%) concerned losses in international air and sea transport. 43% of these losses, considering the frequency of damage, were attributable to maritime transport, 53% to air transport and the rest to land transport. However, when it comes to the value of claims, as much as 87% were attributed to air transport.

Majority of losses (68%) concerned temperature-sensitive pharmaceuticals and occurred because of breaking the cold chain integrity. It means that a continuity in satisfying the expected cargo requirements such as temperature, air composition, humidity etc., has not been ensured across the entire cold chain (Klopott, 2019)

As this study revealed, a variety of reasons can compromise the integrity of the cold chain ranging from technical (machinery breakdown), organisational (improper planning), human (errors in shipping documents) to extraordinary (severe weather conditions), listing the more prevailing ones.

The main causes that contributed to the analysed losses or damage to pharmaceuticals have been divided into six main categories:

1. Refrigerating equipment breakdown or malfunction (cooling machinery is working, but not correctly).
2. Unsuitability of packaging and preparation of cargo for transit (e.g., substandard packaging which cannot withstand low temperatures or high humidity or cannot ensure sufficient protection to the cargo).
3. Delays not only to the final destination, but also during transport (excessive time laps between changing transport modes or between storage and loading on the ship, aircraft or land conveyance without connection to a power source).
4. Human failure (e.g., errors and omissions in transport documents or shipment instructions, incorrect setting of temperature and other parameters, mistaken units of measurement, failure to connect the transport unit to power source).

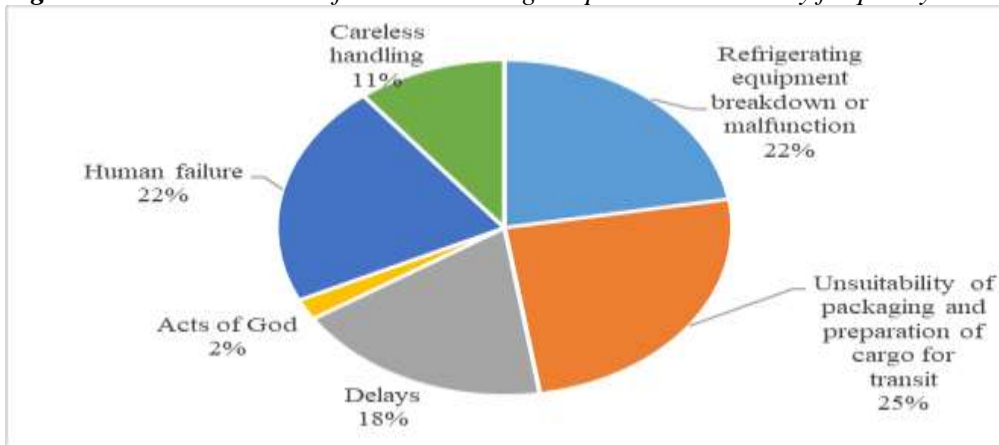
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<sup>2</sup> This is part of a larger study by the author on the loss and damage of perishables and temperature-sensitive cargoes.

5. Careless handling (during loading, discharge, manipulation in the warehouse or place of storage; careless handling during the stacking/unstacking of cargo in a transport unit; improper stacking/stowage in a transport unit that does not comply with good practices).
6. Acts of God (which means hazards out of human control (e.g., heavy weather, storms, earthquake) causing incidents as e.g., sinking vessel, plane crash, washing containerized cargo overboard, overturning of vehicle).

The share of each category in the total number of cases is shown in Figure 2.

**Figure 2.** The main causes of losses or damage to pharmaceuticals by frequency.



*Source:* Own elaboration.

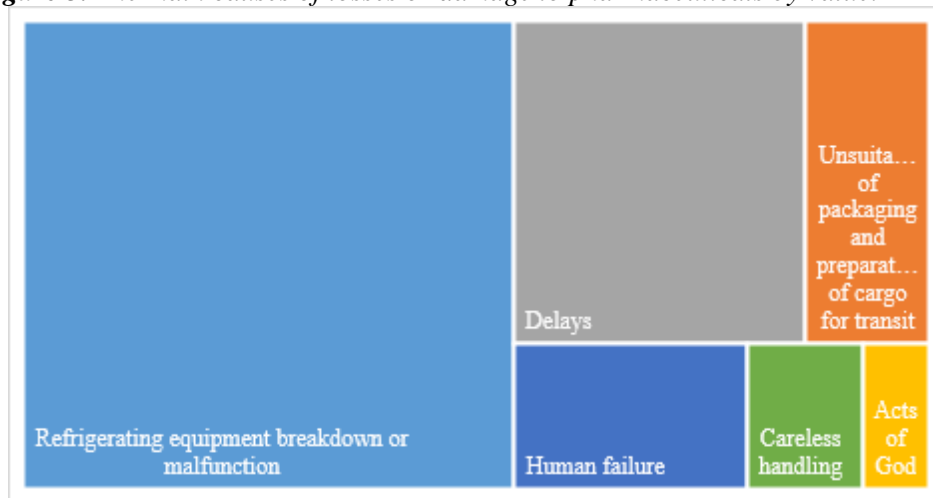
It clearly shows that, when comes to the frequency of losses and damage, it is almost evenly distributed into three categories as refrigerating equipment breakdown or malfunction, unsuitability of packaging and preparation to the transit as well as human failure, accounting together to as much as 69% in total.

In the analysed period, all losses and damage resulting in insurance claims, were valued at 6.527.296 USD. Refrigerating equipment breakdown or malfunction caused more then 56% of all claims. It can be explained by the fact, that majority of pharmaceuticals that required refrigeration are more valuable, and usually comprises vaccines or biospecimens. Lesser, but accounted to 22% claims were attributable to delays, 10 % to unsuitability of packaging (the responsibility lies with the pharmaceutical shippers to ensure appropriate packaging) and 8% to human failure.

Figure 3 shows the reported loss in value by each identified category of losses or damage to pharmaceuticals. It is not surprising, that refrigerating equipment breakdown or malfunction is responsible for such a significant share, since once it has occurred, it affects the entire cargo and its condition, usually leading to a total loss. Among analysed claims, damage resulting from delays is noteworthy. In most cases it did not concern delays to the destination that could be dangerous to

pharmaceuticals with shelf-life concerns (e.g., radioactive substances which contain active ingredients that sport half-lives).

**Figure 3.** The main causes of losses or damage to pharmaceuticals by value.



**Source:** Own elaboration.

Most of these claims resulted from excessive time laps between ground handler storage and aircraft, thus breaking the cold chain integrity, because in pharmaceuticals there is a tiny room for temperature deviation. As human failure is an important risk factor, a particular attention should be driven to proper training of personnel involved in pharmaceutical cold transport, because the best procedures and protocols will be useless if the employee is not trained.

#### 4. Conclusions

Reliable international transport of medicinal product has become paramount in the ever-growing global trade in pharmaceuticals. The research clearly shows that despite advances in cold transport logistics, pharmaceutical losses and damage continue to appear. Although not all events are preventable, many are still within human control.

It means that industry should focus on building even stronger relationships between all stakeholders, from pharmaceutical manufacturers to third-party logistics companies, shippers, airlines, ocean carriers, container terminals, airports, freight handlers, packaging companies etc., to reduce opportunities for temperature excursions.

Greater attention should also be paid towards carefully researching the factors responsible for cargo loss and damage, since a thorough understanding of them is a prerequisite for effective risk management throughout the entire transport chain.



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