# SUPPLY CHAIN RISK MANAGEMENT FOR SENSITIVE HIGH VALUE GOODS

**Tim Jesse Brandt**
Hochschule RheinMain, Germany
E-mail: TimJesse.Brandt@hs-rm.de

**Sascha Düerkop**
Hochschule Fulda - University of Applied Sciences, Germany
E-mail: Sascha.Dueerkop@w.hs-fulda.de

**Benjamin Bierwirth**
Hochschule RheinMain, Germany
E-mail: Benjamin.Bierwirth@hs-rm.de

**Michael Huth**
Fulda University of Applied Sciences, Germany
E-mail: michael.huth@w.hs-fulda.de

Received: May 14, 2019
Received revised: July 23, 2019
Accepted for publishing: July 31, 2019

***Abstract***

Vulnerable high value goods require a particular risk-averse transportation along the whole supply chain. Pharmaceuticals and other lifesaving goods, such as medical equipment, are often sensitive to temperate deviations, shocks, delays or other risks that are less influential for consumer goods. Every, sometimes even minor, aberration might result in a significant risk for the end consumer, the patient.

In this article we develop a holistic supply chain risk management concept (SCRM) for vulnerable high value goods. We also apply this concept to evaluate pharmaceutical supply chains. Our approach maps the capabilities and the risks of all participants and their logistical processes, which define the specific supply chain, to a common operations model and ultimately derives a risk score for the entire supply chain.

To evaluate the risk of a certain supply chain for a specific good, the overall chain is modelled using the SCOR (Supply Chain Operations Reference) model, which describes every particular process and activity of a specific supply chain. The capabilities of the supply chain partners, the product-specific and legal requirements, as well as all risks implied by the routing are mapped to the SCOR-based process. Subsequently, all described factors enable the calculation of a single risk indicator for each step along the supply chain. The final model allows for evaluating the overall risk of a planned shipment, given a predefined routing.

**Key words:** Supply Chain Management, Risk Management, SCOR model, Pharma

## 1. INTRODUCTION

In today's global economy supply chains span all over the world – suppliers and customers are allocated worldwide. The manufacturing of products is divided and split over different locations across the world. Customers demand the same products around the globe.

The risks that have an impact on pharma supply chains are various. Temperature deviations during storage or transport of pharmaceutical goods account for losses of billions of dollars every year and, much worse, losses of lives (Sykes, 2018, pp. 154–170). Thefts of pharmaceutical goods, especially during transport, account for an estimated loss of about 31 million Euro in Europe every year (Ekwall et al., 2016, pp. 1-16). According to Kumar et al. (2018), between 6 and 10% of all pharmaceuticals are counterfeit products, posing another substantial risk to the pharma industry.

For pharmaceutical and other life-saving goods, this induces high requirements to the logistics and storage of these products. They can be temperature, shock or humidity sensitive. These conditions have to be met at all times, otherwise the items will be damaged. The consequences from damages can go from being medically less effective to adverse impacts negatively affecting the health of a patient, ultimately causing even loss of lives.

This is the main reason why production and transport of medical products are highly regulated all around the world with different regulation. The World Health Organisation and the European Union, for instance, implemented strict guidelines governing the manufacturing (World Health Organization, 2011; European Commission, 2004) and the distribution (World Health Organization, 2010; European Commission, 2013) of pharmaceutical goods.

The industry is obligated to assess the risks of a transport from source to sink prior to the shipment. Today this is a highly complex procedure in which all logistics service providers (LSP) need to be audited and evaluated based on their risks. In the procedure of implementing a new lane, it happens that more LSPs than necessary are audited, as some might not fit the requirements.

Since the evaluation of an LSP requires abundant resources, this study proposes a model that enables a pharmaceutical company to evaluate the partners along its supply lane prior to the auditing of the partners. With the proposed approach, suitable partners along the whole supply chain can be chosen based on a scientifically justifiable base and with significantly lower investments. Further, the approach does provide a full risk assessment along the supply chain, giving the decision-maker a powerful tool to anticipate risks connected to the routing and the partners involved.

## 2. LITERATURE REVIEW

To the best of our knowledge, there is no scientific literature that specifically explores the risk management of pharma supply chains by using a SCOR model. Thus, we will instead briefly review the existing literature that covers at least the combination of two of the aspect relevant to our work.

As Zsidin and Henke (2019, p. 1) state in the opening chapter: "throughout history we have been challenged with managing risk in our supply chain". Naturally, scientific efforts to manage risks in supply chains are thus as old as supply chain management itself (Zsidin & Henke, 2019) and can be defined as the management of "any risks for the information, material and product flows from original supplier to the delivery of the final product for the end user" (Jüttner et al., 2003, p. 7). Managing such risks does, in particular, not mean that such risks are necessarily prevented or handled in any specific way. Supply chain risk management is more generally understood as identifying, assessing and mitigating risks to enable the supply chain management to be prepared for as many eventualities as possible and define strategies and make projections based on the inherit risks of the supply chain. This generic process is detailed e.g. in Tummala and Schoenherr (2011, pp. 474-483). The tools of supply chain risk management are diverse and range from very basic qualitative tools, such as brainstorming, to sophisticated quantitative methods, such as social network analysis. Huth et al. (2017) provide a catalogue of methods used in supply chain risk management, while Fan and Stevenson (2018, pp.205-230) review the existing scientific literature and concepts on supply chain risk management and Jereb et al. (2013, pp. 56-73) propose the use of a publicly available risk catalogue to identify supply chain risk. Düerkop and Huth (2018) give an extensive overview of risks concerning the logistical infrastructure. Mehralian et al. (2012, pp. 209–219) argue that such infrastructural risks are just one factor for pharma supply chain risks, with the choice of the right suppliers and logistical partners and their qualifications being similarly, or even more, crucial. Nevertheless, Bucalu and Jereb (2017, pp. 42-49) conclude, based on a regional survey in Slovenia, that risk management, even in the vulnerable and sensible pharma sector, is still not a prime focus of supply chain managers.

The literature on modelling pharma supply chains with the Supply Chain Operations Reference (SCOR) model is mostly modelling a specific national or regional pharma supply chain with the SCOR approach, e.g. for Morocco (Essajide & Ali, 2017), Iran (Rajabzadeh et al., 2013, pp. 193–205) or India (Kumar et al., 2015, pp. 743-770). Martinelly et al. (2009, pp. 436-456) describe a SCOR modelling approach in a broader scope, although only for the internal logistics of a hospital.

The SCOR model is, in contrast, regularly used as a supply chain risk management tool. Cagliano et al. (2012, pp. 817-840) use a SCOR model to identify and analyse risks along a supply chain. McCormack et al. (2008, pp. 1-32) develop a method to define internal and supply chain wide risk management strategies alongside a SCOR model. Finally, Badr and Stephan (2007, pp. 288-296) use the SCOR model to combine the two disciplines of supply chain risk management and security management and Abdolghasemi et al. (2015, pp. 280-302) develop a new supply chain risk management tool that maps the SCOR process to a Bayesian network.

## 3. OVERVIEW OF THE MODEL

The purpose of the model is to calculate a risk score for the entire transportation chain of a specific good on a specific supply lane, using specific partners and a specific

routing. While the product itself and the supply lane, consisting solely of a source and sink relation, are usually fixed for any transportation planned, the exact routing and the potential logistical partners are not. Thus, varying the routing and partners, which are often interdependent, several options of shipping the same good from the same source to the same sink can be compared to minimize the overall risks of the logistical process.

The relevant risks may arise for a variety of reasons. They may be attributed to the lane, the geographic locations along the route, the specifics of the product or directly to the partners of the lane.

Therefore, the lane needs to be modelled in a generic way, so the partners are comparable and their out- and incoming processes can be matched. Since the Supply Chain Operations Reference (SCOR) model provides this with standard metrics to measure the performance, the SCOR-model was chosen as generic process modelling tool.

As influence parameters on the risk score three categories were determined: 1. Requirements, 2. Capabilities, and 3. External risk factors.

In the following sections these categories are explained and matched to each other. On that basis, an algorithm can be defined to calculate the risk score.

## 4. MODEL

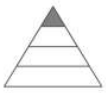
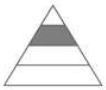
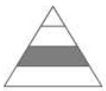
In this chapter we explain the different elements which are then joined into the risk assessment model. First, we describe the SCOR model which is used to model the logistical process. Afterwards the influencing parameters are shown, and finally the model is developed.

### 4.1. SCOR for pharma transport

The SCOR model is a supply chain management model developed by the Supply Chain Council which was founded in 1996 and is now part of US-based company APICS.[1] The SCOR model consist of four levels. The first level defines the processes types, the second level is the configuration level and the third level describes the process elements (see **Pogreška! Izvor reference nije pronađen.**; Huang et al., 2005, pp. 377-394). The fourth level is not in scope of SCOR, and can be used to model specific and detailed activities within the process elements.

[1] APICS – The Association for Operations Management (formerly American Production and Inventory Control Society)

**Figure 1.** The SCOR framework

| | Level | | Examples | Comments |
|---|---|---|---|---|
| | # | Description | | |
| Within scope of SCOR | 1  | Process Types (Scope) | Plan, Source, Make, Deliver, Return and Enable | Level-1 defines scope and content of a supply chain. At level-1 the basis-of-competition performance targets for a supply chain are set. |
| | 2  | Process Categories (Configuration) | Make-to-Stock, Make-to-Order, Engineer-to-Order Defective Products, MRO Products, Excess Products | Level-2 defines the operations strategy. At level-2 the process capabilities for a supply chain are set. (Make-to-Stock, Make-to-Order) |
| | 3  | Process Elements (Steps) | • Schedule Deliveries<br>• Receive Product<br>• Verify Product<br>• Transfer Product<br>• Authorize Payment | Level-3 defines the configuration of individual processes. At level-3 the ability to execute is set. At level-3 the focus is on the right:<br>• Processes<br>• Inputs and Outputs<br>• Process performance<br>• Practices<br>• Technology capabilities<br>• Skills of staff |
| Not in scope | 4  | Activities (Implementation) | Industry-, company-, location- and/or technology specific steps | Level-4 describes the activities performed within the supply chain. Companies implement industry-, company-, and/or location-specific processes and practices to achieve required performance |

Source: Supply Chain Council, 2012

Level 1 consists of the six core process types (see APICS 2018):

- Plan,
- Source,
- Make,
- Deliver,
- Return and
- Enable.

In order to implement the generic process, the used process steps need to be defined. The SCOR model was developed for production industry, where the focus lies on the production of goods. In this use case the post-production transport of pharmaceutical goods to the wholesaler or customer is in focus. Therefore, only logistical process steps were taken into account and clustered. The main used process types were "Source", "Deliver" and "Enable", and the level 2 process "make-to-order", was presumed as "Make"-process. The process, however, was not entirely developed over all process steps, as only in such a simplified way it was feasible to test the model. However, the process is not in focus of this paper.

### 4.2. Requirements

In each process step, tasks need to be executed. The selection of the required tasks can derive from different sources. This is defined as requirements. The source of the requirements can be divided into three categories: requirements related to the specifications of the product, the specifications of the business or regulatory specifications. In this section, the different origins of the requirements are discussed and presented.

### *4.2.1. Regulatory*

Depending on the good, the transport process can be highly regulated. In case of pharmaceutical transports there is a globally valid regulation of the WHO and, where applicable, additional national or regional regulations (European Commission, 2013; Silveira, 2017; USP, 2009). These regulations have a tremendous impact on the requirements a transport has to fulfill.

For a transnational shipment, several regulations may also be active and have to be fulfilled. In that case each process step has to be connected to a geographic location, which must be matched with the active regulation.

The splitting of the regulations developed around 500 requirements of different granularity for each regulation. Depending on the granularity of the risk algorithm the set of requirements has to be chosen.

In our research, we developed eight main categories the examined regulations had in common, thus which have to be fulfilled by the LSPs of pharmaceutical goods. These are:

1. Quality Management,
2. Personal & Training,
3. Premises & Equipment,
4. Documentation,
5. Returns/Complains/Theft,
6. Outsourcing,
7. Self-inspections, and
8. Transport.

### *4.2.2. Product*

Product requirements are (transport-related) requirements indicated by the product specification. Pharmaceutical products consist of “living” ingredients, for example molecules, which can be destroyed when exposed to unfavorable conditions. Therefore, these have to be handled with special care. Different attributes have to be maintained during transport, for example temperature, humidity or vibrations. If the transport of a product does not match these requirements, the product might have to be scrapped to avoid any harmful impact to the patient. Such product requirements have to be fulfilled over the whole transport lane and by every partner at all times.

Furthermore, the packaging of the products has to be considered. The packing is the first protection against external impacts. Depending on the kind of packaging, it is possible, that product specifics are irrelevant to be further controlled during transport. For example, if a product is packed in an active cooling device, which energy source outlast the transport time by far, it can be assumed that any temperature-related requirements can be ignored.

### *4.2.3. Business*

The final source of requirements is the business itself. Pharmaceutical companies usually have their very own corporate constraints, which can be different

or stricter than possibly applied external regulations. These occur as a result of experiences made or based on the physical location of the company. These constraints, implicit or explicit, can have an influence on the transport and on the capabilities needed to be admitted serving another company.

Businesses can have multiple locations which are located in one or more countries. Therefore, business constrains need to be classified by the site for which they are applicable. Such classifications can range from "only for one location", over "only in one or more countries" to "global constraint", which applies for all business units.

They can also only be active for one process step, only special products or management processes. An example could be a special loading ramp or specifications for loading vehicles.

Each business has their own requirements documented. For the generic model, they should have a similar granularity as the external requirements and have to be created together with business experts who can deliver input. This is not discussed any further in this paper, since this is part of the development of the tool.

### 4.3. Capabilities

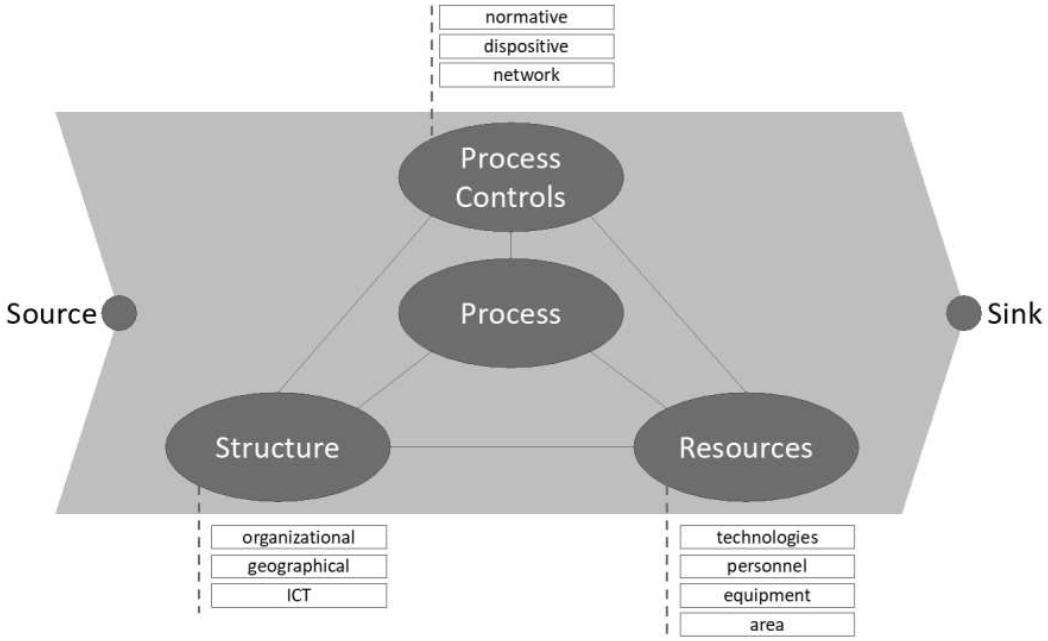
The requirements, arising from the process, have to be fulfilled by the LSPs. Requirements are fulfilled with capabilities. Capabilities are tools, processes, resources, structures, etc. a company can buy, implement or build in order to be capable to fulfill a task. Capabilities can be available in different variations and granularities. For the model, the granularity of the capabilities must be matched with the granularity of the requirements. Otherwise, a matching or risk calculation would not be feasible.

For the model, the capabilities of a company have to be matched to the sites of it. A company can have global capabilities, for example a quality management system which is implemented throughout the corporation, or site-specific capabilities, for example a loading or cooling feature or back-up system that is a physical infrastructure in place at a single or some sites.

A structure for process capabilities can be derived from the process chain model as shown in **Figure 1** (Käppner 2002). Three aspects have to be considered for capabilities, each supplied with subcategories:

- *Processes:* normative, dispositive, network;
- *Structures:* organizational, geographical, information- and communication technology; and
- *Resources:* technologies, personnel, equipment, area.

**Figure 1**. Process chain model




Source: authors' representation based on Käppner (2002)

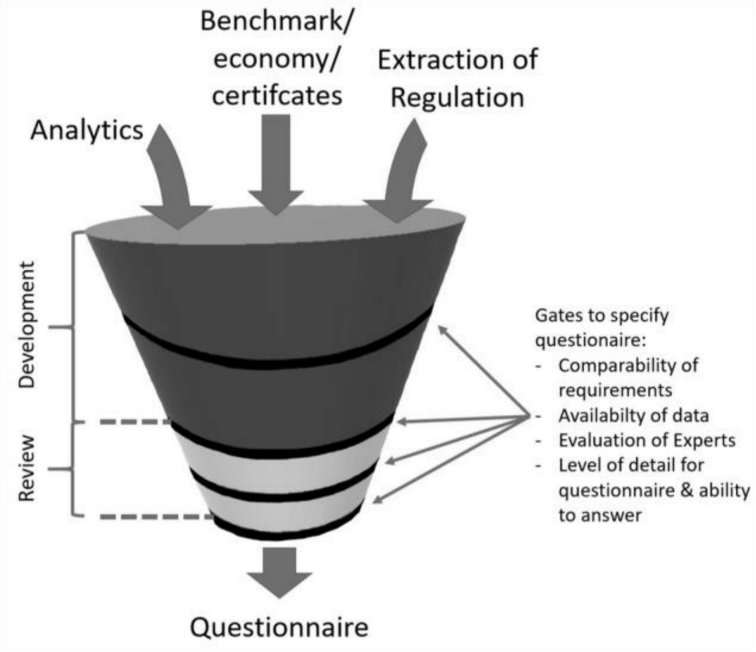
A company can match a requirement with a capability. If a requirement is not met, this implies a risk. In particular, unmet requirements do not necessarily lead to failure of the process; they just increase the risk of failure. A pharmaceutical good that has to be transported at room temperature might well meet that requirement even if the temperature is not actively or passively controlled at any point, if the transportation is geographically routed through regions with favorable climate conditions. If the same transport, however, is being placed on the tarmac of an airport in an extremely cold or hot region for hours, while in transit, it is likely to be heavily affected and will not meet the requirements anymore. Capabilities can meet one or more requirements; requirements can be met by one or more capabilities. Thus, requirements and capabilities are connected with a m-to-n connection with $m,n \in \mathbb{N}_{(>0)}^{\wedge}$ .

For the model, the capabilities of a company have to be enquired and attributed to the relevant sites. To avoid a complex auditing process, the capabilities could be retrieved in a more efficient way, e.g. by using a questionnaire. This would be an efficient and easily applicable way to gather the main capabilities of a company, across various sites in different locations.

The required capabilities need to be developed for the model, as mentioned above in a suitable granularity. One approach to do this, is the use of the so-called funnel. This approach was used to address the wide scope of the research for different capabilities and to ensure nothing is missed out. The structure, which includes different quality gates to pass, enables a process to compress and sharpens them, so a matching granularity with the requirements can be found.

With this in mind, the funnel can be "filled" from different angles: with benchmarks, evaluations of regulations and certificates or analytics of different tools or companies, always considering the different process chain elements (see **Pogreška! Izvor reference nije pronađen.**).

**Figure 3.** Schematic funnel, to develop questionnaire for capabilities




Source: authors

A certificate is a proof of the ability to perform a special task, the presence of certain knowledge or the compliance with certain standards in the overall operations.

Certificates can be considered as "stand-alone" capabilities or as "pre-selection" of the capabilities contained in the questionnaire. The use depends on the implementation of the algorithm and the complexity of the risk model. In the development phase of the model it was used as a pre-selection method. Subsequently, the certificates had to be matched with the capabilities. This connection can be established by analyzing the certificates in detail.

For the model, the possession of a certificate gives the company the connected capabilities. For example, in section 0 eight categories for regulatory requirements were developed, one category being "quality management". ISO:9000 is a norm for a standardized quality management. Companies have the possibility to get certified by ISO:9000. Should a company be certified, the requirement for having a quality management would be satisfied. These questions can then be skipped in the questionnaire.

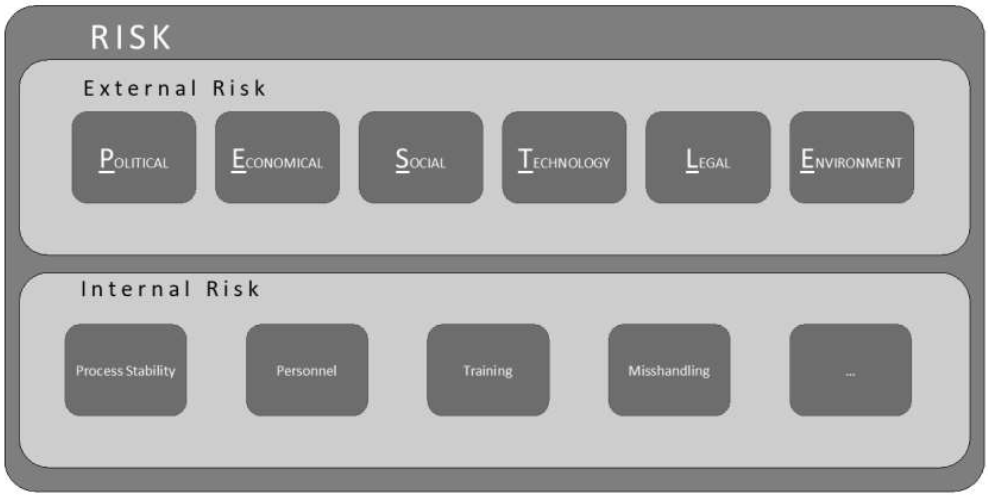
### 4.4. Risks

In this section the different risk categories are shown and explained (see **Figure 2**). Risks concerning the used logistical infrastructure, and the usage of it, are an additional threat to every transport, including those of pharmaceutical goods (see Düerkop & Huth 2017, p.14).

Apart from such external risks, a number of internal or internalized risks have an impact on the transportation process. There is a range of efforts to identify the best logistics partner or service provider to ensure a certain quality of the process (see Liu

et al. 2013, pp. 3963–3976; Liu et al. 2014a, pp. 2327–2344; Liu et al. 2014b, pp. 6608–6626). As logistics outsourcing is already the norm rather than the exception, such risks of mismanagement or mishandling by a contracted partner is a major internal or, by contract, internalized risk. While the financial risk of any physical damage caused by a subcontractor can be mitigated by a sufficient regulatory and contractual framework, the possible damage to patients that mishandled pharmaceutical goods can cause cannot be mitigated.

**Figure 2.** Risk categories




Source: authors

*4.4.1. External Risks*

The external risks can be quantified by external, and often publicly available, datasets. While the following paragraph does describe a few of such external risks and does provide some possible datasets to use, it should be understood as being incomplete. As the scope of this work is mainly to provide an insight into the general setup of the supply chain risk management process, along the SCOR model, it cannot go into detail for most external risks.

4.4.1.1. Political Risks

The most relevant political risk for the transportation of pharmaceutical goods, as argued above, is theft or, more generally, crime. The most complete and reliable data sources, such as the UNODC (2017) statistic on homicide, however, do consider crimes that are not only not specific enough, but might lead to a gross miscalculation of risks. While the homicide rate in Poland, for example, is one of the lowest in Europe, the country is amongst the ones with the most cargo theft incidents in Europe, according to Morai Logistics (n.d.). Thus, the best available indicator for cargo theft risks remains the more specified Incident Information Service (IIS) of the Transported Asset Protection Association (2018), filtered to theft incidents. The nature of this source, however, which relies on incident reports by its members (Transportation Asset Protection Association, 2019) inherits a strong negative bias for countries and

territories with more members who actively provide reports. As a result, analyzing the database indicates that cargo theft nearly exclusively occurs in North America and Europe as well, proving the negative bias.

To get an indicator of the security of a region or country, the travel security advice of the Foreign and Commonwealth Office (2019) of the UK government was used. While those official travel advice datasets are also occasionally politically motivated, as Sharpley et al. (1996, pp.1-7) argue, they do reflect the current overall security situation better than most comparable sources.

Measuring corruption, another major threat for logistics operations, Transparency Internationals (2018) Corruption Perception Index (CPI) is taken into account. The CPI itself is a meta-index, based on several data sources to avoid a bias as good as possible.

Finally, the ease of trading across borders is taken into account by analyzing the Ease of Doing Business report of the World Bank (2019b). While this report measures the time and costs associates to trades between the major cities in both concerned countries only, and thus must deviate a lot from the time and costs associates to trade between very rural regions of the same countries, it gives a very reliable indicator potent enough to allow a ranking of the ease of trading across borders.

#### 4.4.1.2. Social Risks

Social risks are usually defined as all risks that inherit the risk for individuals and groups of individuals to lose their current social status. Thus, social risks, by definition, initially hit individuals or groups of individuals.

While individuals and even group of individuals usually are not potent enough to debilitate the logistical infrastructure or even successfully prevent a logistical transportation entirely, a realized loss of social status can eventually lead to severe reactions of individuals and groups of individuals who then directly turn against the successful fulfilment of a logistical operation, for example by labour strikes or active blockades.

A list of examples of such social risk realization can be found in Düerkop and Huth (2017).

Social risks are often individual events and there is no database that is able to be considered a base for a scientifically justified risk management. Thus, social risks will not be further considered.

#### 4.4.1.3. Technological Risks

Accidents are a major source of risk for any logistical transportation. Not only may goods and loads directly be affected and damaged or entirely destroyed by accidents, but regularly hundreds of other trucks, vessels, trains or cargo planes are indirectly affected and sometimes severely delayed. Especially cool-chain goods might subsequently be damaged by such delays, if they are not actively cooled.

Data availability on accidents and crashes, however, remains a major challenge to consider such risks. For air cargo transportations, the International Air Transport Association (2015) publishes a safety report regularly. This report, in particular, lists

all accidents by region and by airline for the last decade, including, but not limited to, air cargo flight incidents. As accident numbers are quickly and drastically decreasing over the last few decades, the data, however, became too scarce to be a valid base to predict the future. Additionally, the regions monitored are continental regions, which is a far too broad basis to derive detailed risk scores for specific subregions, countries or even airports.

Data for train or sea freight accidents is not available on a global or even continental level at all. Road accident statistics are available, published annually by the World Health Organization (2019), but only consider fatal accidents and might thus not represent the actual risk of the occurrence of an accident. While Germany, e.g., had less road fatalities than Italy and France in 2016, nearly twice as many people got injured by accidents than in Italy and nearly six times as many as in France, suggesting that Germany does not necessarily have less road accidents than Italy or France, but a lower rate of those end fatally, according to the European Road Safety Observatory (2019, pp. 205-230).

Other technological risks, such as the frequency and severeness of energy blackouts (World Bank 2019a)[2] and cyber-attacks (International Telecommunications Union 2017), are well available, but have less impact on transportations in general. Thus, they will be considered in the following, but are one of the less weighted factors.

Finally, statistics on airport performances and road congestions are only collected by private companies and regularly suffer either from a strong bias or a non-publication of the methodology underlying the published data.

#### 4.4.1.4. Conclusion

While geographical risks, as mentioned above, are a major factor and well-researched, it is still difficult to retrieve reliable and scientifically justifiable data. Many datasets, including those of international institutions, are biased by design, and in many cases, the publishers do proactively admit that bias. It is simply impossible to get reliable and neutral data on car accidents or theft incidents in some places, especially in very restrictive countries that would not allow access to neutral international data mining institutions, such as the United Nations or World Bank. Thus, many data from countries like Eritrea[3] or Turkmenistan[4] is retrieved from local, sometimes governmental, institutions, who report data to the international institutions, while almost all data is missing from North Korea. Thus, such data, by design, is biased and could potentially be manipulated by the governmental institutions who mine the data on the ground.

Similar data uncertainties exist, often even to a bigger extend, for other risks that were considered within this study, such as the risk for strikes, currency devaluation risk, legal risks and weather and natural disaster related risks, which are not further

2 http://www.doingbusiness.org/content/dam/doingBusiness/media/Annual-Reports/English/DB16-

3 E.g. all data from the "Ease of Doing Business Reports" of the World Bank on Eritrea is mined by the local law firm "Berhane Gila-Michel Law Firm", see World Bank (2019c); p. 246

4 E.g. all car incident data on Turkmenistan is entirely reported by the Ministry of Health and Medical Industry of Turkmenistan and the State Committee on Statistics, see World Health Organization (2018); p.253

considered, as their description would not lead to significantly new insights for this study.

*4.4.2. Internal Risks*

Internal risks, and internalized risks, include all risks that directly stem from the quality of the operations of all partners in the supply chain. Due to the increased complexity of even a single supply lane from a single origin to a single destination, the number of LSP partners within such a chain is increasing rapidly. All partners within that supply chain, which are defined through the SCOR model, do inherit own risks. While a worker in the origin warehouse might make an erroneous labelling of a shipment, a worker of an airline might place a temperature-controlled shipment on the apron for too long to guarantee the temperate restrictions are still met. Similarly, all other partners could potentially damage pharmaceutical goods or cause delays.

Subsequently, potential partners along a supply lane need to be graded in some way to allow the supply chain manager of the pharmaceutical company to choose the right partners along a pre-defined lane. While capabilities of potential partners, often guaranteed by the compliance with certain regulatory frameworks, like the EU GDP, give an indication which risks are addressed by the potential partner, they are not sufficient to take a qualified and risk-averse decision alone. An airline could, e.g., have the capability of doing all transports 100 % actively temperature-controlled at all times. At the same time, however, the company could be well-known for using badly trained employees that regularly set the wrong temperature for the active-cooled transportation boxes. Then, subsequently, the capability of the availability of active-cooled transport boxes at all times does not necessarily lead to a likelihood of 0 % for a temperature deviation.

To take internal and, by cooperation internalized, risks into account, the model does consider rather subjective ratings and risk estimations for potential partners along the supply chain. Those risk estimations, which are an input to the model, are weighted and taken into account during the core algorithm to result in the output overall risk assessment of the supply lane.

## 4.5. Model definition

The developed model (see **Pogreška! Izvor reference nije pronađen.**) is supposed to be able to calculate a risk score for using a specific supply chain. In the previous sections, the different elements of the model are explained. In this section, the elements are connected to form the overall model and show the result of the research.

Different partnering companies perform single or multiple steps of the process chain. Depending on these processes, requirements, stemming either from the process, the product, the business, or the regulation, arise and need to be fulfilled. Thus, a link between the process and the requirements need to be established.

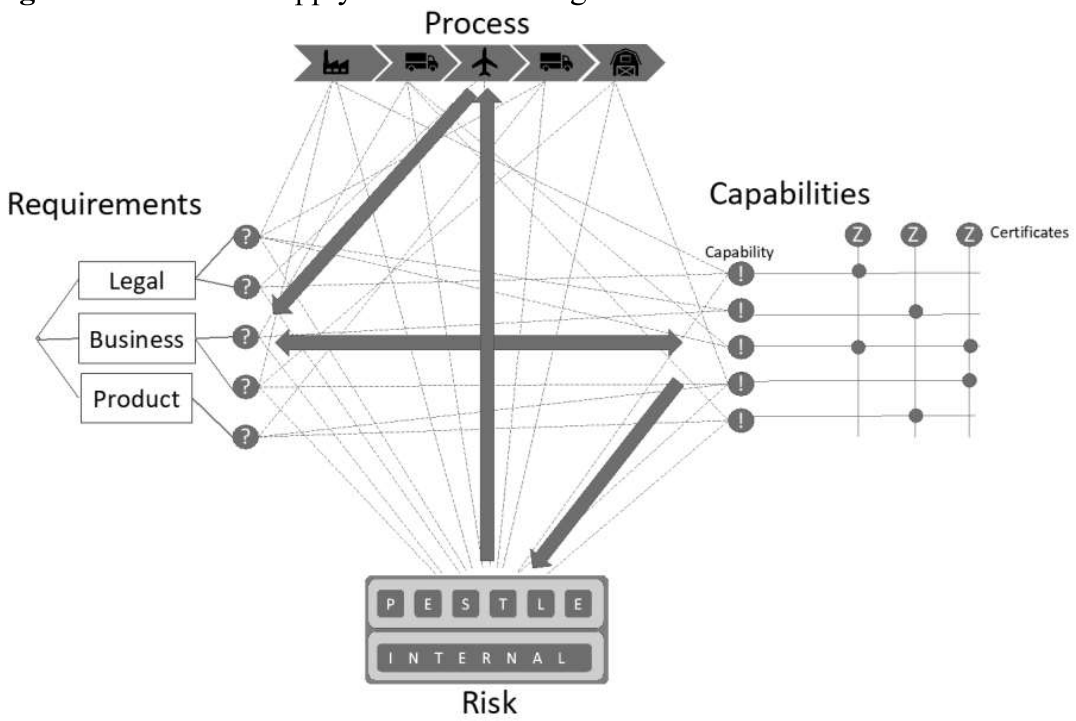
The availability to fulfill the requirements is demonstrated by the present capabilities of the company. Therefore, as stated previously in section 0, the connections between the requirements and the fulfilling capabilities have to be known.

If requirements can or cannot be fulfilled, this must be reflected in the risk score.

In summary, the following links were identified during the research:

- *Process ⇔ Requirement*
- *Requirement ⇔ Capability*
- *Capability ⇔ Risk*
- *Risk ⇔ Process*

**Figure 5.** Model for supply chain risk management




Source: authors
* the lines symbolize the many connections, the arrows one connection thread

Links can have different parameters, depending on the link and the algorithm. Via the link information, like a geographic- or process-location, can be transmitted or dependencies, like the need for a specific capability, can be implemented. This depends on the specific modulation and implementation of the model.

In order to implement the model, the following steps have to be taken, assuming all requirements, capabilities and risks-factors are already developed:

1. Development of process
   A generic process, in this use-case the pharma-lane, has to be developed. All relevant process steps need to be identified, so risk scores can be calculated for these.
2. Matching of process and requirements
   For each process steps, the requirements have to be formulated.
3. Matching of requirements and capabilities
   For all requirements, the possible "solving"-capabilities have to be identified and connected. Depending on the algorithm, these capabilities have to be weighted.
4. Calculation of risk / learning algorithm

The risk calculation needs to be applied. Depending on whether the algorithm is self-learning or not, two approaches could lead to success:

a. Self-learning-algorithm: the algorithm has to be trained with real data of transports
b. Trained algorithm: evaluation and weighting of the capabilities and connections between requirements and capabilities need to be done by experts.

### 4.6. Algorithm

While not within the scope of this publication, it will be briefly outlined how an algorithm can derive a risk score $RS_k$ for each process-step $P_k$ of a selected routing inside a supply chain and thus, ultimately, for the whole supply chain.

For every step of the supply chain, the following sets of parameters $P_i$ present the input of the algorithm:

- the geographical location of the process
- the product, including its container or packaging
- the selected logistics partner performing the specific step
- the type of the process

Based on this input, a risk assessment algorithm can now derive the following secondary parameters:

- the external risks based on the geographical location
- the internal and internalized risks based on the selected partner and the type of process
- the capabilities based on the selected partner
- the requirements based on the product

The algorithm now compares those secondary parameters to derive the risk score $RS_k$ for the specific step of the SCOR process **Pogreška! Izvor reference nije pronađen.**). The calculation of the specific risk score has dependencies to the specific modelling of the risk, requirements and capabilities and is not further discussed. Jereb (2013, pp.86-93), for example, shows how a specific risk score can be calculated.

$$\boldsymbol{RS_k} := \boldsymbol{Risk}\,(\boldsymbol{P_k}) := \boldsymbol{\Phi}\begin{pmatrix} \boldsymbol{ExternalRisk}(\boldsymbol{P_k}) \\ \boldsymbol{InternalRisk}(\boldsymbol{P_k}) \\ \boldsymbol{Capabilities}(\boldsymbol{P_k}) \end{pmatrix} \quad (1)$$

with

$$ExternalRisk\,(P_k) := \Phi_{ext}\begin{pmatrix} Location(P_k) \\ Requirements(P_k) \end{pmatrix};$$

$$InternalRisk\,(P_k) := \Phi_{int}\begin{pmatrix} SC{-}Partner(P_k) \\ Requirements(P_k) \end{pmatrix} \quad \text{and}$$

$$Capabilities\,(P_k) := \Phi_{Cap}\big(SC - Partner(P_k)\big)$$

with

$$Requirements\ (P_k) := \Phi_{req}\begin{pmatrix} Location(P_k) \\ Product(P_k) \\ SC-Partner(P_k) \end{pmatrix}$$

Hereby, risks are one-dimensional and can are understood as the product of probability and severity. $\Phi$, $\Phi_{\text{ext}}$, $\Phi_{\text{int}}$, $\Phi_{\text{cap}}$ and $\Phi_{\text{req}}$ are functions, which map its parameters to a risk score, which are not further discussed here.

As an example, we can assume that the lane is a ground transport on a truck from Osijek, Croatia to Timisoara, Romania via Serbia with one cross-docking point. The product is a pharmaceutical good that needs to be transported and stored in a temperature range between two and eight degree Celsius and is stored in a simple box, that is not actively cooled. The chosen partner shall be a logistics company called "OsiTimLog". The secondary parameters in this example are thus:

- all geographical risks for crossing the border from Croatia to Serbia and from Serbia to Romania,
- all geographical risks that apply to Osijek, Northern Serbia and Timisoara,
- the risks linked to the company OsiTimLog,
- the capabilities of OsiTimLog,
- all requirements for chilled products in simple boxes.

Any of such parameters will now significantly influence the outcome of any algorithm. Should OsiTimLog, for example, have the capability "uses only chilled trucks" it would get a significantly better risk score than without such capability. If the Serbian-Romanian border is known to cause massive delays, the risk rating might become much worse, etc.

Once every single step of the SCOR process is assessed in the described way the $S_{lane}$ is setup $\boldsymbol{RSlane=RS1, RS2,\ldots, RSi}$

(2). The whole supply lane can be assessed by simply taking either the mean risk score $\boldsymbol{RiskScore} := \sum_{k=1}^{n} \boldsymbol{w_k R_k}$ with $\boldsymbol{w_k}$ being weight parameters.

(3) or the worst risk score along the supply lane $\boldsymbol{RS_{lane,worst} := max(RS_{lane})}$ (4). The weights $w_k$ can be chosen by the supply chain manager of the company and are company specific.

Given the mechanisms of the algorithm, it is further capable of displaying the "worst leg" of and the "worst partner" along the supply lane, giving the decision maker an important base to mitigate the overall risks by changing either the routing or the partner for a part of the supply lane.

In **Pogreška! Izvor reference nije pronađen.** a mockup of a possible algorithm is shown.

$$\boldsymbol{RS_{lane} = \{RS_1, RS_2, \ldots, RS_i\}} \quad (2)$$

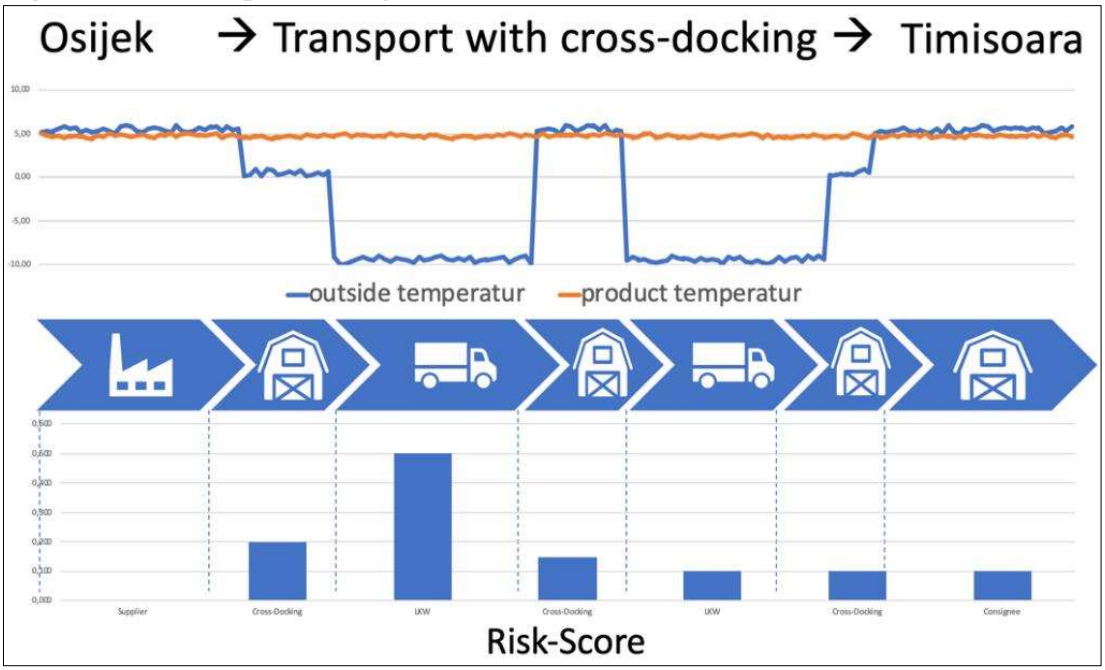
$\boldsymbol{RiskScore} := \sum_{k=1}^{n} \boldsymbol{w_k R_k}$ with $\boldsymbol{w_k}$ being weight parameters. (3)

with

$$\sum_{k=1}^{n} w_k = 1$$

$$RS_{lane,worst} := max(RS_{lane}) \quad (4)$$

**Figure 6.** Mock-Up of the algorithm




Source: authors

*On the top the outside and inside temperature of the shipment is shown. Below the different, generic process steps with the associated, specific risk-scores.

## 5. CONCLUSION

In this paper, a basic model for the risk calculation of a transport supply chain was developed. Considering all processes and requirements, a path was shown to develop capabilities to address these and to implement an algorithm to compute a risk score.

Going forward, this model needs to be implemented and tested with detailed, real data. The considered use-case was from the pharmaceutical industry, which could be generalized for other sensitive high-value goods as electronics, livestock or perishable goods (e.g. flowers, vegetables).

Furthermore, the used SCOR-process is a good model for comparison of industrial companies but is not yet adapted to logistical process were the production is not in focus. Either the SCOR model could be adapted to a “logistic-SCOR” or a logistics reference model should be developed instead.

**Acknowledgement** This research has been funded by the Hessen State Ministry for Higher Education, Research and the Arts in the framework of "Landesoffensive zur Entwicklung Wissenschaftlich-Ökonomischer Exzellenz (LOEWE)" (project id 555/17-37).

## 6. REFERENCES

Abolghasemi, M., Khodakarami, V., & Tehranifard, H. (2015) *A new approach for supply chain risk management: Mapping SCOR into Bayesian network*. Journal of Industrial Engineering and Management (JIEM), 8(1), pp. 280-302

APCIS (2018) SCOR app (Version 2.1) [Mobile application software]. Retrieved from https://play.google.com/store/apps/details?id=apics.org.scor

Badr, Y., & Stephan, J. (2007). *Security and risk management in supply chains.* Journal of Information Assurance and Security, 2(4), pp. 288-296

Bucalo, N. & Jereb, B. (2017) *Risk Management in the Pharmaceutical Industry in Slovenian Companies*. Logistics & Sustainable Transport, Vol. 8, No. 1, pp.42-49

Cagliano, A. C., De Marco, A., Grimaldi, S., & Rafele, C. (2012) *An integrated approach to supply chain risk analysis*. Journal of risk research, 15(7), pp. 817-840

Düerkop, S., & Huth, M (2017) *Transportation under Threat–A PESTLE Analysis for Critical Logistical Infrastructures*. ICTA2017, p.14

Ekwall, D., Brüls, H., & Wyer, D. (2016) *Theft of pharmaceuticals during transport in Europe. Journal of Transportation Security*, 9(1-2), pp. 1-16

Essajide, L., & Ali, R. (2017) *Planning and Modelling of Pharmaceuticals Wholesale-Distributors Supply Chain Using SCOR Model: A Moroccan Case Study.* International Journal of Management Sciences and Business Research, Vol. 6, Issue 3

European Commission (2004) *Commission Directive 2003/94/EC of 8 Oct 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use*. Official Journal of the European Union 2004; L26/22–26

European Commission (2013) *Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use*. Official Journal of the European Union 2013/C 242/01

European Road Safety Observatory (2019) *Annual Accident Report 2018*

Fan, Y and Stevenson, M (2018) *A review of supply chain risk management: definition, theory, and research agenda*. International Journal of Physical Distribution and Logistics Management, 48 (3). pp. 205-230

Foreign and Commonwealth Office (2019) Foreign travel advice. Retrieved online: https://www.gov.uk/foreign-travel-advice

Huang, S. H., Sheoran, S. K., & Keskar, H. (2005) *Computer-assisted supply chain configuration based on supply chain operations reference (SCOR) model*. Computers & Industrial Engineering, 48(2), pp. 377-394

Huth, M., Düerkop, S., & Romeike, F. (2017). *RIMA-KIL–Risikomanagement für kritische Infrastrukturen in der Logistik: Abschlussbericht.* Retrieved online: https://fuldok.hs-fulda.de/opus4/frontdoor/deliver/index/docId/653/file/Discussion+Paper+No+19+RIMA-KIL+Abschlussbericht.pdf

International Air Transport Association (2015) Safety Report 2014. Retrieved online: http://www.aviation-accidents.net/report-download.php?id=90003

International Telecommunications Union (2017) *Global Cybersecurity Index (GCI) 2017*

Jereb, B. (2013) *Risk assessment model respecting segments of the public*. Montenegrin Journal of Economics, 9(3), p. 75-94

Jereb, B., Ivanuša, T. & Rosi, B. (2013) *Systematic Thinking and Requisite Holism in Mastering Logistics Risks: the Model for Indendifying Risks in Organisations and Supply Chain*, Amfiteatru Economic Journal, Vol 15, Issue 33, pp.56-73

Jüttner, U., Peck, H., & Christopher, M. (2003) *Supply chain risk management: outlining an agenda for future research*. International Journal of Logistics: Research and Applications, 6(4), 197-210. p.7

Käppner, M., Laakmann, F., Stracke, N. (2002) *Dortmunder Prozesskettenparadigma-Grundlagen*

Kumar, R., Agarwal, A., & Shubhankar, B. (2018) *Counterfeit Drug Detection: Recent Strategies and Analytical Perspectives*. Int J Pharma Res Health Sci, 6(2), 2351-58

Kumar, A., Mukherjee, K., & Adlakha, A. (2015) *Dynamic performance assessment of a supply chain process: a case from pharmaceutical supply chain in India*. Business Process Management Journal, 21(4), pp. 743-770

Liu, W., Ge, M., & Yang, D. (2013) *An order allocation model in a two-echelon logistics service supply chain based on the rational expectations equilibrium*. International Journal Of Production Research, 51(13), pp. 3963–3976

Liu, W., Ge, M., Xie, W., Yang, Y., & Xu, H. (2014a) *An order allocation model in logistics service supply chain based on the pre-estimate behaviour and competitive-bidding strategy*. International Journal Of Production Research, 52(8), pp. 2327–2344

Liu, W., Liu, C., Xu, X., & Bao, X. (2014b) *An order allocation model in multi-period logistics service supply chain based on cumulative prospect theory and capacity matching constraint*. International Journal Of Production Research, 52(22), pp. 6608–6626

Martinelly, D. C., Riane, F., & Guinet, A. (2009) A Porter-SCOR modeling approach for the hospital supply chain. International Journal of Logistics Systems and Management, 5(3-4), pp. 436-456

McCormack, K., Wilkerson, T., Marrow, D., Davey, M., Shah, M., & Yee, D. (2008) Managing risk in your organization with the SCOR methodology. The Supply Chain Council Risk Research Team, pp. 1-32

Mehralian, G., Rajabzadeh Gatari, A., Morakabati, M., & Vatanpour, H. (2012) *Developing a suitable model for supplier selection based on supply chain risks: an empirical study from Iranian pharmaceutical companies*. Iranian journal of pharmaceutical research : IJPR, 11(1), pp. 209–219

Morai Logistics (n.d.) *Looking at the impact of cargo theft and possible solutions*. Retrieved online: http://morailogistics.com/wp-content/uploads/Morai-Logistics-eBook-Cargo-Theft.pdf

Rajabzadeh Ghatari, A., Mehralian, G., Zarenezhad, F., & Rasekh, H. R. (2013) *Developing a model for agile supply: an empirical study from Iranian pharmaceutical supply chain*. Iranian journal of pharmaceutical research: IJPR, 12(Suppl), pp.193–205

Sharpley, R., Sharpley, J., & Adams, J. (1996) *Travel advice or trade embargo? The impacts and implications of official travel advice*. Tourism Management, 17(1), pp.1-7

Silveira, L. (2017) *Boas Práticas de Distribuição e Armazenagem e Boas Práticas de Transporte de Medicamentos*. Consulta Publica N 343 GGFIS

Sykes C. (2018) *Time- and Temperature-Controlled Transport: Supply Chain Challenges and Solutions*. P & T: a peer-reviewed journal for formulary management, 43(3), pp. 154–170

Transported Asset Protection Association (2018) Membership Brochure. Retrieved online: https://www.tapa-global.org/fileadmin/public/downloads/Membership/Tapa_Membership_Brochure_2018.pdf

Transported Asset Protection Association (2019) Member companies. Retrieved online: https://www.tapa-global.org/membership/member-companies.html

Transparency International (2018) Corruption Perception Index 2017. Retrieved online: https://www.transparency.org/news/feature/corruption_perceptions_index_2017

Tummala, R., & Schoenherr, T. (2011). *Assessing and managing risks using the supply chain risk management process (SCRMP)*. Supply Chain Management: An International Journal, 16(6), pp. 474-483

UNODC (2017) *Intentional Homicide Victims*. Retrieved online: https://dataunodc.un.org/crime/intentional-homicide-victims

USP (2009) *<1079> Good Storage and Shipping Practices.* United States Pharmacopeia 32–National Formulary 27. In The United States Pharmacopeial Convention.

World Bank (2019a) *Ease of Doing Business Report: Getting electricity*. Retrieved online: http://www.doingbusiness.org/content/dam/doingBusiness/media/Annual-Reports/English/DB16-Chapters/DB16-CS-GE.pdf

World Bank (2019b) *Ease of Doing Business Report: Trading across borders*. Retrieved online: http://www.doingbusiness.org/data/exploretopics/trading-across-borders

World Bank (2019c) *Ease of Doing Business Report 2018: Reforming to Create Jobs.* Retrieved online: http://www.doingbusiness.org/content/dam/doingBusiness/media/Annual-Reports/English/DB2018-Full-Report.pdf

World Health Organization (2010) *WHO good distribution practices for pharmaceutical products*. WHO Technical Report Series, No. 957, Annex 5

World Health Organization (2011) *WHO good manufacturing practices for pharmaceuticals products: main principles*. WHO Technical Report Series, No. 961, Annex 3

World Health Organization (2018) *Global status report on road safety 2018*

Fan, Y., & Stevenson, M. (2018) *A review of supply chain risk management: definition, theory, and research agenda*, International Journal of Physical Distribution & Logistics Management, 48(3), pp.205-230

Zsidin, G.A. & Henke, M. (2019) *Research in Supply Chain Risk: Historical Roots and Future Perspectives*. In: Zsidin, G.A. & Henke, M. (2019): Revisiting Supply Chain Risk. Springer Series in Supply Chain Management 7, Springer, Cham, Switzerland. p.1