THE INGREDIENTS OF ANTI-COUNTERFEITING PHARMA PACKAGES – A SURVEY STUDY BASED ON THE KANO METHODOLOGY

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Abstract

Purpose: the purpose of this paper is to identify and evaluate critical features of anti-counterfeiting pharmaceutical packages.

Research Approach: the research approach is based on a literature review and a survey study based on the Kano methodology.

Findings and Originality: critical features for anti-counterfeiting pharmaceutical packages are identified and classified in security and performance based. Only two security features related to manipulation/tamper evidence and traceability are scored as must-be requirements. The majority of performance related features are instead considered as attractive. Hence, existing products may lack these functionalities and if included in new packages, customers might be surprised or delighted.

Research Impact: the study contributes with a list of criteria to be considered to evaluate pharmaceutical packages in terms of anti-counterfeiting security and logistics related performance.

Practical Impact: developers, users and public agencies are provided with insights about how different features related to security and logistics performance are perceived by potential users.

Keywords: pharmaceutical *counterfeiting, pharmaceutical supply chains, supply chain security.*

Introduction

A counterfeit pharmaceutical is "*a drug whose labelling was deliberately prepared with misleading information in relation to the content and source*" (WHO, 2014). Experts warn that pharmaceutical counterfeiting is a growing trend that is no longer limited to developing countries but also to industrialized ones. It is difficult to determine exact figures about the magnitude of the phenomenon. Rough estimations tell that 7% of the global market is counterfeiting, reaching peaks of 50% in developing countries in Africa and Asia (Wyld, 2008, WHO, 2014).

Pharmaceutical counterfeiting is a security problem that may cause disruptions and quality concerns in a supply chain (Marucheck *et al.*, 2011). If fake pharmaceuticals are detected, products in storage at retailers and distributors need to be recalled and disposed. Obviously, this will cause monetary losses due to disposal procedures, shortages, unnecessary transportation, loss of brand image and lost sales (Urciuoli, 2010, Marucheck *et al.*, 2011). Fake medicines may also have harmful effects on consumers' health. For example, the United Nations reported a loss in revenues for providers of malaria medicine of US $348 (Wilson & Fenoff, 2011). Similarly, the WHO indicated that approximately 700 000 Africans die annually from consuming counterfeited anti malaria and tuberculosis medicines mostly originating from China and India (Wilson & Fenoff, 2011).

Due to this, the pharmaceutical industry is intensively working to develop new packages to comply with more stringent regulations and also to ensure the proper verification of packages and pharmaceutical products at retailers or hospitals (Marucheck *et al.*, 2011). Pharmaceutical packages have the important role to reduce counterfeiting risks, protect the brand and ensure the safety of patients. Previous research has repeatedly indicated the necessity for cost-effective solutions to ensure increased security at lower costs (Sheffi, 2001, Lee and Wang, 2005, Rice and Spayd, 2005). In addition, benefit-costs analyses, both qualitative and quantitative have been performed to evaluate the impacts of security measures (Urciuoli, 2011, Urciuoli *et al.*, 2013). Yet, there is still too much uncertainty about how to design anti-counterfeiting packages that can improve security while reducing costs in a pharmaceutical supply chain. In particular, there is no previous research showing the critical security and cost-efficient criteria to consider in pharmaceutical packages. Hence, the research question of this paper is: what are the critical security and efficiency criteria to consider in pharmaceutical packages?

By means of a literature review and a survey based on the Kano methodology, the purpose of this paper is to develop a reliable and robust framework for the evaluation of anti-counterfeiting pharmaceutical packages. The framework is meant to consider both security and efficiency impacts as recommended in previous literature. In addition, this paper will review and discuss the most critical factors to include in packages and provide with recommendations for practitioners and future research.

Literature Review

Security – Anti-Counterfeiting measures

In this section four main security features to prevent and detect counterfeiting in pharmaceutical supply chains are proposed (King & Zhang, 2007, Shah et al., 2010):

- **Manipulation/Tamper Evidence.** Tamper evidence consists of irreversibly indicating any attempt at removing and substituting or breaking and concealing nameplates, product marking, or a seal placed on packaging or other housing etc. tamper evidence features may be developed in manner to provide evidence through naked eye screening or automated alarm systems.
- **Authentication.** Authentication consists of the verification process of several security features placed on marked products, packages, documents etc. features for authentication could be of overt (visible) or covert (hidden and therefore not visible). The identification/authentication of a security feature could be done by naked eyes or by means of a testing device. For instance, barcode scanners or radio frequency tags with encrypted data may automate the authentication process. Experts believe that a good security feature should allow any layperson to easily and plausibly authenticate a product in order to strengthen confidence in the brand.
- **Replication.** It refers to the hardness experienced by counterfeiters to replicate or purchase a similar package and the security features on it. Skilled designers could replicate a package and produce it. Similarly the security features on the package could also be redesigned, produced and/or purchased from Asian suppliers. Hence, technologies used to secure the packages or their content should be hurdle and expensive to copy or falsify. A known technique to deter replication is through the usage of covert features.
- **Traceability.** It refers to the ability to trace products or components in supply chains to preserve security by verification of origin, authenticity and quality attributes. Published research emphasize the use of an uniquely identifiable traceable resource unit (TRU) in tracing of batches (Moe, 1998), or an identifiable unit (IU) regarding products or components that must be identifiable in every system used (Bollen et al., 2007). Implementation of

machine-readable identification technologies (e.g. barcodes, QR codes, data matrix codes) (Manos and Manikas, 2010) or Radio Frequency Identification technology (RFID), which allows automatic non-visible identification (Jones et al., 2005; Martinez-Sala et al., 2009; Zhou, 2009) and verification of product quality attributes (e.g. humidity, temperature etc.) (Abad et al. 2010), have been put forth to improve traceability. In addition, visible or non-visible technologies for identification and product verification can be used to prevent fraud and anti-counterfeiting of products (Sun et al., 2014; Ringsberg, 2013; Ting & Tsang, 2012)

Normally the above features can be freely combined in a package in order to harden the target and provide with multiple layers of security (Urciuoli, 2010). Finally, it ought to be noted that often the above technologies for tamper evidence, authentication and traceability may be used also for forensic purposes, i.e. allowing definite authentication by specialists and ultimately obtain findings that hold up in court.

Logistics performance

To study the impact of specific packages' features on logistics performance as a whole, it is important to account for the total cost of logistics activities. These costs cannot be taken isolated from each other's since they are highly dependent, i.e. reducing one cost factor could increase other cost components and vice versa. Previous published studies have tried to capture main costs that are representative for the logistics function. Those considered in this paper are the factors found in the literature that easily can be associated to costs derived from the implementation of new consumer packages (i.e. primary) in a pharmaceutical supply chain. These factors are:

- **Transportation.** Logistics processes imply that products and packages are moved from the point of production to the point of consumption. Costs related to transportation depend on the transport mode chosen as well as the volume/weight of packages (Lambert et al., 2001).
- **Warehouse handling.** From production to retailers, products and packages need to be stored. The greater time is between production and consumption, the larger amount of inventory will be needed. Larger inventories may also imply that handling costs in moving packages within warehouses increase. Warehousing costs include: rent, heat, personnel, depreciation on investments, necessary resources to move pallets (e.g. forklifts), capital tied up etc. In addition, good packaging improves the interface with handling machines in warehouses and because of this allows efficient utilization of storage space and transportation units (Jahre & Hatteland, 2004).
- **Volume/weight ratio.** Volume determines how well the package fits transport units (e.g. secondary and tertiary packages) while minimizing the presence of "air" and increasing economies of scale in storage and transport. At the same time, lower weight facilitates handling in warehouses and implies lower transportation costs and reduced fuel consumption during transport.
- **Order Processing and Information exchange.** In logistics processes to purchase orders, handle them, monitor shipments, monitor customers' demand etc. require that specific information systems are in place and correctly integrated along the whole supply chain. In particular IT systems should be able to i) trace the history, process and location of an product by means of captured information, ii) unique identify products, iii) monitor specific product attributes, and iv) to exchange and share information between different supply chain actors. Because of this, several frameworks have been published (e.g. Storöy et al., 2013; Regattieri et al., 2007) that eases interoperability in the exchange and communication of information (Salampasis et al., 2013). Order processing implies costs in terms of order transmission, order reception, verification and handling. At the same time internal and external communications (e.g. notifications of carriers and customers shipping information and product availability) across companies in the supply chains is an added cost (Lambert et al., 2001). Many authors have pointed that serialization and automated procedures to

identify products may heavily benefit supply chains in terms of reliability, resilience and delivery speed (Ringsberg & Mirzabeiki, 2013; Hafliðason et al., 2012; Hafliðason et al., 2012).

- **Manufacturing.** Costs for production of packages and pharmaceuticals are indicated as lot quantity costs occurring in the context of production. These costs may sensibly vary depending on changes in production lot size and procurement costs of materials and other components used for assembling medicines in packages.
- **Marketing and brand promotion.** Marketing attributes include package design and colours that make the product more attractive to consumers. These attributes may directly affect sales, hence incrementing revenues (Jahre & Hatteland, 2004).
- **Waste and disposal.** Pharmaceutical packages have to be returned to pharmacies and processes for waste and disposal are initiated. Waste and disposal is important for an environmental perspective, since the material composing the package can be reused, avoiding dumping in landfills. Additionally, a specific design of packages may also facilitate dismantling and disposal processes (Jahre & Hatteland, 2004).
- **Transport and storage damage.** Attributes related to shape, volume, weight, construction design and materials used that influence the risk for damages during transportation or when consolidated in transport units such as pallets used for storage in warehouses (Jahre & Hatteland, 2004).

Methodology

The methodological approach is made of a literature review and a survey based on the Kano methodology. The literature review was performed to identify, collect and structure previous work relevant to determine security and efficiency criteria to be considered for pharmaceutical packages. The databases used for the searches include google Scholar, ABI/Inform, Scopus and Springer Link. Keywords include: “packages counterfeiting”, “pharmaceutical counterfeiting”, “anti-counterfeiting packages”, “security” AND “packages”, “supply chain efficiency” AND “packages”, “transport performance” and “packages”. Results from the searches were used to generate a set of four criteria to evaluate packages anti-counterfeiting features and eight corresponding to supply chain, logistics and transport performance. The security criteria include: manipulation/tamper evidence, authentication, replicability and traceability. The efficiency criteria were: transportation costs, warehouse handling costs, volume/weight efficiency, order processing/information costs, manufacturing costs, marketing and brand promotion, waste and disposal and transport and storing damage.

The Kano methodology was used to evaluate customer satisfaction by identifying requirements into six main categories (Table 1): must-be requirements (M), one-dimensional (satisfier) requirements (O), attractive (delight and surprise) requirements (A), indifferent requirements (I), reverse requirements (R) and questionable answers (Q) (Kano et al., 1984; Crostack et al., 2010). The ultimate goal of the approach is enhance understanding about how different products or services attributes affect customers' satisfaction (Kano et al., 1984).

Category	User description	Design action
Must-be requirements (M)	A lack of Must-be product attributes causes customer dissatisfaction. Improvement of Must-be product attributes would however not make much difference since it just must be incorporated and function	Incorporate the products attribute and guarantee its functionality.

	normally.	
One-dimensional (satisfier) requirements (O)	One-dimensional products attributes requires attention, since improvement of products design increases customer satisfaction and product functionality	Increase the functionality of the one dimensional products attribute.
Attractive (delight and surprise) requirements (A)	An Attractive product attributes increases customer satisfaction, but lacks in functionality.	Improve the functionality of the attractive products attribute.
Indifferent requirements (I)	An indifferent product attribute does not provide either satisfaction or dissatisfaction for the customer.	Observe indifferent product attributes based on that customers evaluate product attributes differently.
Reverse requirements (R)	A reverse product attribute causes customer dissatisfaction.	Exclude reverse product attributes.
Questionable (Q)	This category consists of questionable results. Answers are not supposed to fall in this category. If they do, it is probably because of an incorrectly phrased or misunderstood question.	No actions required.

Table 1 Kano categories, user description and design actions (MacDonald et al. 2006)

Relevant packages' attributes used in the evaluation of requirements were identified through review of appropriate literature, but also through discussions between the authors' and the participants of a consortium working on a research project, SMEDPACK, with the aim to improve security of pharmaceutical packages. Once the list of packages attributes was determined, a survey instrument was developed. As recommended by Kano (2001) each question comprised two different statements formulated for every product attribute; one functional statement (a positive statement aiming to score the level of customer satisfaction when customer product attributes requirements are fulfilled), followed by a dysfunctional statement (a negative statement illustrating the customer emotional reaction if product attribute requirements are disregarded) (Bergman and Klefsjö, 2007; MacDonald et al., 2006; Kano et al., 1984). The responses to each question were measured with a 5-points Likert scale with the following alternatives (Kano, 2001; Kano et al., 1984): 1) I like it that way, 2) It must be that way, 3) I am neutral, 4) I can live with it that way and 5) I dislike it that way.

The questionnaire was published on a website and a selected group of experts was asked to test it. According to the comments received, question items were corrected or removed. The final survey instrument was made of three main blocks: the first to collect the demographics profile of respondents; the second had functional and dysfunctional questions to measure the perception of security criteria (8 questions); the third block was made of functional and dysfunctional questions to measure the perception of performance criteria (16 questions). The link to the survey website was sent to members of the SMEDPACK project consortium, comprising a total of 47 experts and professionals working within 1) public and regulatory agencies and 2) private actors engaged in packaging development, security labelling and advanced printing techniques. The gathered responses amounted to 20, corresponding to a response rate of 42.5%.

Analysis

The collected answers related to the security criteria to be included in new pharmaceutical packages unveils that respondents perceive *manipulation/tamper evidence* (38.9%) and *traceability* (38.9%) as must-be requirements (Table 2). Features for *visual/automated verification* of authenticity of pharmaceutical packages (41.2%) are perceived as attractive. Finally, security features that are difficult to replicate, (replication 47.1%), are perceived as one-dimensional (Table 2).

	A	O	M	I	R	Q	Total (%)	Kano Category
Manipulation	11.1	33.3	38.9	16.7	0	0	100	M
Visual/automated verification	41.2	35.3	5.9	17.6	0	0	100	A
Replication	17.6	47.1	11.8	23.5	0	0	100	O
Traceability	16.7	22.2	38.9	22.2	0	0	100	M
Note: A = Attractive, O = One-Dimension, M = Must-Be, I = Indifferent, R = Reverse, Q = questionable.								

Table 2 The Kano classification of security criteria.

The examination of the criteria related to efficiency measurements reveals instead that the majority of these features are perceived as attractive (Table 3). These are in order features to reduce *warehouse handling* costs (55.6%), *order processing/information* exchange costs (47.1%), *transport* costs (44.4%), and features to improve *volume/weight* efficiency (44.4%). Package features to improve *marketing and brand promotion* of the products is also scored as indifferent. Finally, features related to *manufacturing* costs reduction (36.8%), *waste and disposal* (41.2%) and *transport & storing damage* (35.3%) are scored as one-dimensional (Table 3).

	A	O	M	I	R	Q	Total (%)	Kano Category
Transport	44,4	33,3	0	22,2	0	0	100	A
Warehouse handling	55,6	11,1	5,6	27,8	0	0	100	A
Volume/weight efficiency	44,4	22,2	5,6	27,8	0	0	100	A
Order processing/Information	47,1	17,6	5,9	23,5	5,9	0	100	A
Manufacturing	26,3	36,8	15,8	15,8	0	0	100	O
Marketing and Brand promotion	17,6	0	0	70,6	11,8	0	100	I
Waste and Disposal	23,5	41,2	11,8	17,6	5,9	0	100	O
Transport & Storing damage	23,5	35,3	17,6	17,6	0,0	5,9	100	O
Note: A = Attractive, O = One-Dimension, M = Must-Be, I = Indifferent, R = Reverse, Q = questionable.								

Table 3 Kano classification of performance criteria.

Discussion and Conclusions

Only the two security-related features, manipulation/tamper evidence and traceability, are perceived by all respondents as must-be requirements for pharmaceutical packages. However, if removed they would cause strong customer dissatisfaction, but when introduced they will probably not increase customers' satisfaction, since these specific features are taken for granted. Visual/automated verification of authenticity of packages is the only security criteria commonly perceived as attractive by the respondents; while, half of the efficiency criteria are perceived as attractive: features to reduce costs for transportation, warehouse handling, volume/weight ratio and order processing/information exchange. The interpretation of the findings indicates that available products on the market lack these functionalities. Hence, if a new pharmaceutical package would lack either of these features it would not imply any change in customers' satisfaction. Since they are requested by customers they will probably surprise customers and significantly increase their satisfaction if added

to new pharmaceutical product packages. The criteria that were scored as one-dimensional include one security feature; replication, and three that were performance-related; reduction of manufacturing costs, facilitation of waste and disposal processes and reduction of transport and storage damages. These features require special attention, since improving those increases customer satisfaction and product functionality. However, if the pharmaceutical packages lack any of these features or if the features somehow have bad functionality, they may cause major customer dissatisfaction. Finally, only one feature scored as indifferent; marketing and brand promotion. Hence, related, technologies and techniques seem not provide any customer satisfaction or dissatisfaction.

Developers of pharmaceutical packages are recommended to incorporate must-be requirements into their package prototypes, i.e. security features for detecting manipulation/tamper evidence and traceability. This is in order necessary to develop packages that are ready for the market. Packaging developers are also recommended to evaluate the possibility to improve the functionalities of features that scored as attractive. In particular, radio frequency tags or 2D data matrix codes allow for visual/automated verification of authenticity, while reducing order processing/information exchange costs. At the same time, new design and lighter material may reduce costs for transportation, warehouse handling and resources utilization. There is a huge potential to develop a package that will delight and surprise customers. Other features related to how packages are manufactured and disposed may lead to dissatisfaction. For example, pharmaceutical packages could be designed in a manner to be easily assembled and dismantled. Likewise materials and shapes should be selected in a manner to reduce procurement costs but also costs for disposal. Finally, design and material of pharmaceutical packages may influence damages during transportation and storage. This feature is also one-dimensional, i.e. bad functionality may lead to dissatisfaction. Hence, shapes and materials should be selected in a manner to avoid quality problems due to too fragile materials or shape structures that do not allow consolidation or stacking in pallets.

From a scientific perspective, the study contributes with a list of criteria to be considered to evaluate pharmaceutical packages in terms of anti-counterfeiting security and logistics related performance. In addition, by applying the Kano methodology, it offers an overview of how these features are perceived and scored by a selected group of experts and professionals in the pharmaceutical sector. In particular, contrarily to previous research, the findings highlight the role of security features in packages that are classified as must-be, one-dimensional and attractive requirements. The majority of features related to logistics performance are perceived as attractive or even indifferent (marketing and brand promotion) from a customers' satisfaction perspective. On the contrary, packages features for reduction of damages, waste and disposal and manufacturing may have major implications. The survey used in this paper targeted a limited amount of professionals in the pharmaceutical sector in Sweden, hence, generalization to an international level is not possible. In addition, the majority of the respondents were not users of the packages but developers or professionals from public and regulatory bodies. Hence, future research should be performed in order to collect data from larger groups of respondents including users of packages, e.g. pharmaceutical manufacturers, distributors, retailers, hospitals/clinics and patients.

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References

- Abad, E., Palacio, F., Nuin, M., Gonzalez de Zarate, A., Juarros, A., Gomez, J.M., Marco, S., (2009), "RFID smart tag for traceability and cold chain monitoring of foods: demonstration in

an intercontinental fresh fish logistic chain", *Journal of Food Engineering*, No. 93, pp. 394-399.

- Bollen, A., Riden, C., & Cox, N. (2007), "Agricultural supply system traceability, part I: role of packing procedures and effects of fruit mixing, *Biosystems Engineering*, Vol. 98, No. 4, pp. 391-400.
- Crostack, H-A., Kern, C. & Refflinghaus, R. (2010), "The suitability of Kano's method for the requirements of the cutlery industry - Results of a case study associated with an approach to widen Kano's theory", *International Journal of Quality and Service Sciences*, Vol. 2, No. 3, pp. 352-368.
- Hafliðason, T., Ólafsdottir, G. & Bogason, S. (2012), "Criteria for temperature alerts in cod supply chains", *International Journal of Physical Distribution & Logistics Management*, Vol. 42 No. 4, pp. 355-371.
- Jahre, M., & Hatteland, C.J. (2004) "Packages and physical distribution: Implications for integration and standardisation", *International Journal of Physical Distribution & Logistics Management*, Vol. 34 No. 2, pp.123 – 139.
- Jones, P., Clarke-Hill, C., Comfort, D., Hillier, D. & Shears, P. (2005), "Radio frequency identification and food retailing in the UK", *British Food Journal*, Vol. 107, No. 6, pp. 356- 360.
- Kano, N., Seraku, N., Takahashi, F. & Tsuji, S. (1984), "Attractive quality and must-be quality", Hinshitsu, *The Journal of the Japanese Society for Quality Control*, Vol. 14 No. 2, pp. 667-681.
- Kano, N. (2001), "Life cycle and creation of attractive quality", *Proceedings of the 4th International QMOD (Quality Management and Organizational Development) Conference*, Linköping, Sweden.
- King, B. & Zhang, X., (2007). "Applying RFID to Secure the Pharmaceutical Supply Chain", *International Journal of Security and its applications,* 1**,** 71-84.
- Lee, H.L. & Wang, S., (2005). "Higher supply chain security with lower costs: lessons from total quality management", *International Journal of Production Economics,* 96**,** 289-300.
- Marucheck, A., Greis, N., Mena, C. & Cai, L., (2011). "Product safety and security in the global supply chain: Issues, challenges and research opportunities", *Journal of Operations Management,* 29**,** 707-720.
- Rice, J.B. & Spayd, P.W., (2005). *Investing in supply chain security: collateral benefits*.
- Shah, R.Y., Prajapati, P.N. & Agrawal, Y.K., (2010). "Anticounterfeit packaging technologies", *Journal of Advanced Pharmaceutical Technology & Research,* 1**,** 368-373.
- Sheffi, Y., (2001). "Supply chain management under the threat of international terrorism", *International Journal of Logistics Management,* 12**,** 1-11.
- Urciuoli, L., (2010). "Supply chain security—mitigation measures and logistics multi-layered framework", *Journal of Transportation Security,* 1**,** 1-28.
- Urciuoli, L., (2011). "Investing in transport security solutions: using the quantitative risk assessment (QRA) approach", *International Journal of Risk Assessment and Management,* 15**,** 275-298.
- Urciuoli, L., Sternberg, H., Ekwall, D. & Nyquist, C., (2013). "Exploring security effects on transport performance", *International Journal of Shipping and Transport Logistics,* 5**,** 303-321.
- WHO, (2014). *General information on counterfeit medicines* [online]. World Health Organization. Available from: http://www.who.int/medicines/services/counterfeit/overview/en/ [Accessed Access Date 2014].
- Wyld, D.C., (2008). "Genuine medicine?: Why safeguarding the pharmaceutical supply chain from counterfeit drugs with RFID is vital for protecting public health and the health of the pharmaceutical industry", *Competitiveness Review,* 18**,** 206-216.
- Zhou, W. (2009), "RFID and item-level information visibility", *European Journal of Operational Research*, Vol. 198, pp. 252-258.