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Data Sharing in Pharmaceutical Supply Chains – Case European Medicines Verification System

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Abstract. We study the perceived value derived from data sharing activities by the representatives of a Nordic pharmaceutical company in the introduction of the European Medicines Verification System (EMVS). The system is an end-to-end verification protocol that would potentially enable the pharmaceutical companies to access the sales-point data from within the system, while maintaining the control of their own data. The benefits of the system are most notably in developing data sharing with the wholesalers and end-customers. Development of data sharing practices might enable more transparent logistics, and more targeted services and products.

Keywords. Data Sharing, Pharmaceutical Industry, European Medicines Verification System, Supply Chains

1. Introduction

Data sharing is a growingly important practice throughout all industries. Data can be multiplied, shared and reproduced among different actors within supply chain by using boundary resources to create new operational efficiencies, business opportunities and network effects [1–4]. However, the control of data, or "to whom it belongs to", remains inherently important, and the question of keeping proprietary rights of data within the company is faced when creating new industrial data sharing platforms [5]. Having a clearly defined set of rules for data sharing is essential as data sharing can easily eliminate the competitive advantage that can be gained from asymmetric information [6].

One such industrial data-sharing platform that maintains the proprietary rights of the company data, European Medicines Verification System (EMVS), was introduced to pharmaceutical industry in February 2019 [7]. The platform was the first end-to-end verification system initiated by industry stakeholders to ensure the safety of the pharmaceutical products throughout the supply chain. In the platform, the proprietary data belongs only to the party that has provided it. Therefore, other parties in the system cannot see each other's data in the system. The system does not include personal patient data. Access to data is controlled by European Medicines Verification Organization

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EMVO, which is responsible for the governance of the European hub of the system. That each actor maintains the control of their own data is the most important design principle. The European Hub provides some centralized reporting, but it is only for national medicine verification authorities.

Unlike the medicine safety systems introduced in the United States or in other countries, the EMVS was implemented in collaboration with multiple stakeholders from within the pharmaceutical industry, who also fund the system. It is therefore interesting to analyze what possibilities different actors see for this kind of system. Typically, safety-control systems are created by governmental organizations, and other external value created by this kind of more transparent system has not been seen as a priority.

We set out this interview study to examine the value of data sharing perceived by representatives of a pharmaceutical company situated in the Nordics (NPC) and by data sharing experts, prior to the deployment of the system. We investigate what the new elements for data sharing that the EMVS provides could enable in pharmaceutical industry. Data sharing between pharmaceutical company and other stakeholders in the supply chain - wholesalers, pharmacies, and end-customers - is studied.

2. Data and Methods

Our research data include 20 semi-structured in-depth interviews with 11 informants from the NPC and with 9 external industry expert informants (Table 1). Main themed questions concerned data sharing and medicine discovery, delivery, selling, and usage. The identity of informants is masked to ensure the confidentiality of informants. No ethical approval was required for the study.

Table 1. The roles of informants and the types and lengths of interviews.

№	NPC / External	Title of the informant	Type of interview Face-to-face / Remote	Length (min)
1	NPC	Representative of case company at EFPIA	FTF	45
2	NPC	Serialization project portfolio manager	FTF	25
3	EXT	Researcher	FTF	50
4	NPC	Head of digitalization	Remote	48
5	EXT	Researcher	FTF	47
6	EXT	Researcher	Remote	42
7	EXT	Director of industrial policy	Remote	46
8	EXT	Researcher	FTF	40
9	NPC	Head of region partner sales	Remote	24
10	NPC	Former business intelligence manager	Remote	32
11	NPC	Business director in OCC Business	FTF	38
12	NPC	Business development director	FTF	58
13	EXT	Key account manager in healthcare unit	FTF	85
14	NPC	Senior legal counsel	Remote	43
15	EXT	Researcher	FTF	45
16	NPC	Head of business IM, R&D and end user solutions	FTF	27
17	EXT	CMO	FTF	68
18	EXT	Key account manager	FTF	48
19	NPC	Director of drug safety	Remote	44
20	NPC	Legal counsel	Remote	32

The experts were chosen based on the purposeful sampling method. The main criteria for external informants was that they were widely known as experts of data sharing either in pharmaceutical industry or other industry with already established data

sharing practices, such as the retail industry. The interviews were conducted during February – June 2018, prior the legislation concerning the EMVS came into action. Author LL conducted the interviews. Themed questions were modified.

The transcribed interviews were treated as text and coded by using Atlas.ti software. The coding was done in two rounds. Firstly, data was divided via descriptive coding to data sharing and medicine discovery, delivery, selling, and usage categories. The second round of coding used the open coding method, pertaining to the linkage of all the quotations in each category to a sub-category.

3. Findings and Discussion

Figure 1 represents the three relationships in the EMVS that pharmaceutical manufacturers, such as our case company NPC, have with other stakeholders. The interviews provided insight for all these relations.

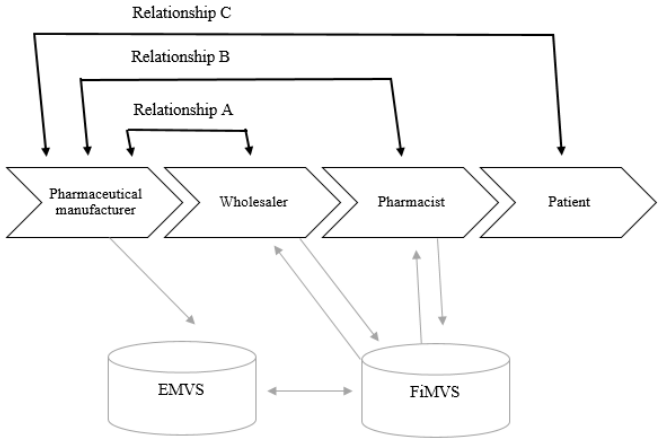

Figure 1. Data sharing between other stakeholders in the medicines verification system

In the interviews, two big drivers to motivate data sharing were recognized. Firstly, societies struggle with increasing medicine costs, creating pressure to provide evidence of cost-effectiveness. Secondly, developing a new medicine is a long process, which may normally take over ten years. However, the data collection methods and technologies have improved remarkably during the past decade, so **the process can be developed to be faster and cheaper**. For both of these issues**, collection of real-time data of the end-customers becomes essential**. Easier access to end-customer data might replace some parts in clinical studies to shorten their timespan. Rise of personalized medicine and digital treatments also increases the need for data sharing.

We discovered that the perceived potential value of the system is most notably in developing data sharing with the wholesalers and end-customers. By sharing data with the wholesalers, the logistics become more transparent, and with the end-customers, it helps pharmaceutical companies to develop more targeted services and products to the end-customers. Table 2 summarizes the key findings from the interviews.

Table 2. Perceived value of data sharing regarding the relationship types

Relationship type	Perceived value	Data sharing prospects and required actions
Wholesalers (Relationship A)	Large	The EMVS is already driving common standards for giving serial numbers for individual pharmaceutical packages. Aggregating serial numbers to distinguish between different brands of pharmaceuticals should be implemented to make the logistics more transparent and help data sharing between these stakeholders. Serial numbers could be used to improve tracking of medicine flow from wholesalers to pharmacies.
Pharmacies (Relationship B)	Minor	The medical companies will be able to achieve information on when each medicine package is sold, as the serial number of the package is then annulled from the central hub. However, companies are already performing demand projections based on the pharmacy order data.
End customers (Relationship C)	Large	All the medicine packages include the data matrix (the QR code enabling the tracking of the product), which can also be used by end users to obtain new information of the product. This data could also be linked with other personal information of the end user with their permission, to achieve greater value in interaction. Pharmaceutical companies could offer applications enabling this interaction, and use this data to enable solutions of e.g. personalized medicine.

4. Discussion and Conclusions

Pharmaceutical companies may create new value by offering digital data and information of their products to develop more targeted services and products to end-customers. However, data sharing is a tool, not a solution. New tools take a lot of iteration to get everything right – solutions take even more iteration. In pharmaceutical industry, this is doubly true due to compliance, risk mitigation and fraud issues.

To conclude, the new medicines verification system provides opportunities to increase traceability of products and develop data sharing in supply chains. The traceability systems originally stemming from industries where private actors have been interested in protecting their products from counterfeits, such as mobile phone industry, can also create new societal value in industries where the counterfeits have wider externalities, such as the effects of counterfeit drugs on public health.

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