A Simulation of the Pharmaceutical Supply Chain to Provide Realistic Test Data

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Abstract

The amount of counterfeit pharmaceuticals in the European pharmaceutical supply chain increased enormously in the past years. Thus, the European Commission introduced an amendment which will lead to new information systems. No realistic test data for these information systems is available yet which hinders the progress in designing and implementing appropriate information systems. We make a first step to close this gap by providing realistic test data which respects the upcoming legislative changes. For this purpose, we provide four different scenarios which differ in supply chain size and an aspect of the legal requirements which is still subject to consideration. The test data is available on the web, so researchers and software engineers can use it to evaluate their information systems.

1. Introduction and Motivation

More and more counterfeit medicinal products occur in the legal European pharmaceutical supply chain [1], [2]. Currently, imported medicinal products are only checked once, when they pass the borders of the European Community. No additional verification is possible after that [3].

The European Commission is aware of this problem and proposed an amendment of a directive related to medicinal products for human use [4]. This amendment demands to ascertain identification, traceability, and authenticity of prescription medicinal products [5]. These requirements are abstract and no guideline for an implementation is given up to now. That means that different final legal requirements which might be enacted are considered. In fact, the European Commission will evaluate different scenarios to determine which actions to be taken are most appropriate to reduce counterfeit medicinal products in Europe. The legislative procedure and evaluation will take at least until 2013 and will be followed by a transition period of several years [3]. To fulfill these requirements, the pharmaceutical supply chain has to change as follows:

- unique identifiers are attached to each package of pharmaceuticals, box, and pallet which is used
- at each step in the supply chain, the unique identifier is documented as a read event,
- traceability and to authenticity of medicinal products is enabled by analyzing the read events related to them.

The general idea is that authorized participants of the supply chain and consumers should be able to use the unique identifier to query a verification service which can verify the authenticity of a particular medicinal product. To do that, this service needs to determine all companies the product passed in the supply chain. To ensure traceability, all companies have to store the read events of all products they handle. The verification service then can gather all read events of a product and determine if this package of pharmaceuticals was produced by a certified manufacturer and handled by trustworthy distributors and retailers only.

The new legal requirements cause the need of new information systems enabling supply chain partners to share data in a secure, cost-efficient, and effective way [6]. Estimated costs to fulfill these requirements are €6 to 11 billion [3].

Building such information systems is not a trivial task. To support software engineers in designing an appropriate software architecture and testing prototypes, realistic test data is of high importance [7], [8]. From an software engineering point of view, data from a reasonably realistic subset of the European supply chain including unique identifiers and queries to the verification service would be helpful.

In this paper, we model such a subset using and extending the simulation tool Rockwell ARENA [9]. We simulate four scenarios with two varying factors: the size of the subset and an aspect of the legal requirements.

The remainder of the paper is organized as follows. In the next section we give an overview about the characteristics of the European pharmaceutical supply chain. Section 4 describes which IT systems are needed to fulfill the new requirements. Section 2 describes related work. After that we describe our simulation model in Section 5. The resulting test data is depicted in Section 6. Our paper closes with a conclusion and future work in Section 7.

2. Related Work

Discussion on how to test a computer program and select appropriate test data is nearly as old as the discipline of computer science itself [8]. As computer programs became more and more complex, test data had to become more and more complex, too. Therefore, in the area of software engineering, data generators are usually used, e.g., for benchmarking databases [10]. Another approach is to gather real data from systems in use to derive test data [11].

For testing the information systems in the future European pharmaceutical supply chain, none of the abovementioned approaches can be used. Data generators can not represent the strict temporal interdependencies of the supply chain, e.g., a product has to be produced first, then occur at a wholesaler and not until then is sold in a pharmacy. The data from real-world systems can not be leveraged because these systems do not exist.

A simulation model can handle these constraints by nature and "simulation seems to be the only viable alternative" [12]. In the area of supply chain management, simulation is widely used [13], [14]. Several authors also applied discrete event simulation to supply chain management [15], [16].

No simulation model of the European pharmaceutical supply chain with these new legal requirements exists and – to the best of our knowledge – our approach to generate test data using simulation in this area is new.

3. Characteristics of the European Pharmaceutical Supply Chain

In this section, we depict the European pharmaceutical supply chain, its volume regarding products, manufacturers, wholesalers, and retailers.

Supply chains consist of the management processes *plan*, *source*, *make*, *deliver*, and *return* [17]. The pharmaceutical supply chain follows that model except that medicinal products are not returned but destroyed once they exceed their sell-by date. The way of one specific package of pharmaceuticals through the pharmaceutical supply chain is usually composed of four tiers. These consist of one *manufacturer* who produces the package of pharmaceuticals, one *wholesaler* who buys the medicinal products resells them to another *wholesaler*, and one *retailer* which in general is a pharmacy or hospital [3].

Each year, about 30 billion packages of pharmaceuticals are produced into the European market [3]. Each of them travels throughout the aforementioned four tiers. Circa 15 billion packages of pharmaceuticals are only available on prescription. The rest are over-the-counter products [3].

Our projections indicate that the European supply chain incorporates about 2,211 manufacturers [18], 50,400 wholesalers [19], [20], and 142,000 retailers [21]–[23].

Because the production of pharmaceuticals almost never stops [20], we assume 364 production days which results in an average production rate of $15,000,000,000/2,211/364 = 18.638$ packages of pharmaceuticals per day per manufacturer.

Before shipping, manufacturers usually aggregate many packages of pharmaceuticals to a box and might also aggregate multiple boxes to a pallet. The wholesalers disaggregate pallets and/or boxes, re-aggregate them and ship boxes or pallets. Retailers only receive boxes and customers only receive packages of pharmaceuticals.

4. Information Systems to Support the Changes Caused by New Legal Requirements

The precondition to the requirements stated by the European Commission is the unique identification of each package of medicinal products. In addition, boxes and pallets also are uniquely identified. This means that technologies such as data matrices or Radio-Frequency Identification (RFID) are used [24]. The activity of placing a unique identifier on an item is referred to as *tagging*.

4.1. Needed Information Systems

The information systems which are needed are 1) reader, 2) middleware, 3) read event repository, 4) a discovery service, and 5) a verification service. Some of these information systems could be incorporated into one information system but for clarity we want to discuss them separately.

1) Reader. A reader recognizes the unique identifier of an item once it is within the readers' coverage. If RFID technology is used, the reader also can recognize containing items, e.g., all packages of pharmaceuticals in a box or all boxes and their content on a pallet. Each reader is uniquely identified by a number assigned to it. Additionally, the reader generates a command which indicates which business event happened. The reader generates read events. If an item passes the reader, the command *OBSERVE* is added to the read event. An aggregation or disaggregation results in the commands *ADD* or *DELETE*.

A read event consists of

- the unique identifier of the item in coverage (package of pharmaceuticals, box, or pallet),
- the date and time of the read event,
- the unique identifier of the reader,
- a command (OBSERVE, ADD, or DELETE).

2) Middleware. A middleware transforms the low level reader data in higher level information. This is done by using the command determined by the reader and context information of the business process to enrich the read event data with business information [25]. The middleware, e.g., determines the business step which took place at the reader. This might be the production of an item, goods receipt, packing, unpacking, goods issue, or selling an item.

3) Read Event Repository. All read events which occurred at a specific company are stored in the companies' read event repository. This ensures that the complete trace information is available once requested.

4) Discovery Service. A retailer might not know all wholesalers a particular package of pharmaceuticals passed. Thus, a discovery service is necessary to identify all relevant companies which stored information about the item of interest.

5) Verification Service. A verification service is necessary to determine the genuineness of a certain product by forwarding the unique identifier of the package of pharmaceuticals to the discovery service. Then, all information stored in the read event repositories of the relevant companies is collected. Finally an algorithm is applied which validates the product's authenticity by leveraging the trace information. Each company has the responsibility that it does not store or sell counterfeit pharmaceuticals. Due to this reason it is likely that each participant of the pharmaceutical supply chain will use the verification service at goods receipt. Furthermore the query to the verification service is stated just before the medicinal product is given to a consumer. The consumer might state a verification query to the verification service, too.

4.2. Interplay of the Information Systems and Implementation Considerations

The interplay of the information systems is depicted in Figure 1 using the Fundamental Modeling Notation [26].

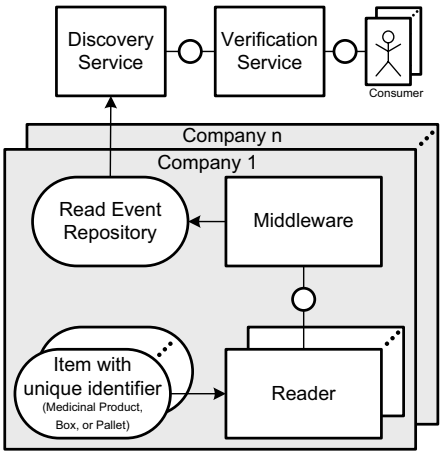

Figure 1. Interplay of the Information Systems

A possible implementation could be based on the EPC network [27] but this discussion is not in the scope of this paper. For the sake of rigor, we adopt the proposals for the EPC network for the rest of this contribution. They are related to the:

- encoding schema of the unique identifiers of packages of pharmaceuticals, boxes, and pallets [28]
- standard how to record the time of a read event [29]
- encoding of the unique reader identifier [28]
- representation of the business step identified by the middleware [29]

5. Simulation Model

In this section, we describe how we model the pharmaceutical supply chain and incorporate the upcoming legal requirements into our supply chain model. To this end, we extend ARENA using custom modules [30]. We first give an overview of the simulation model, depict limitations and assumptions, and then explain implementation details.

5.1. Overview of the Simulation

The first varying factor in our scenarios is the *scaling size* of the real-world pharmaceutical supply chain. We chose this factor because it enables researchers and software engineers to test their information systems in different orders of magnitude. One value is *1:2,000* and the second is *1:1,000*. This means that we simulate 1 (2) manufacturer(s), 25 (50) wholesalers, and 71 (142) retailers. Furthermore, each manufacturer has a production rate of 18,638 products per day, has 7 (15) product types and delivers goods to 10 (20) wholesalers. The first tier of wholesalers consist of 10 (20) companies which resell to 5 (10) wholesalers of the second tier. The second tier of wholesalers consists of 15 (30) wholesalers. Each of them delivers 15 (30) retailers. The production rate is 18,638 packages of pharmaceuticals per manufacturer per day.

The second varying factor is the legal requirement on *inference*. Inference affects the handling of aggregated goods. This factor is relevant because it clearly shows that the set of regulations and their characteristics have a large impact on the resulting information systems. If *inference is allowed*, it is sufficient to recognize the most outer container of aggregated goods while generating an OBSERVE read event. The information about containing items is inferred from read events marked with ADD or DELETE. If *no inference* is permitted, all packages of pharmaceuticals as well as boxes have to be determined at each reader (e.g. a reader at goods receipt at the wholesaler). Thus, all pallets and boxes have to be disaggregated, recognized by a reader, and re-aggregated. The resulting scenarios are listed in Table 1.

	Scale 1:2,000	**Scale 1:1,000**
Inference allowed	Scenario 1	Scenario 2
Inference not allowed	Scenario 3	Scenario 4

Table 1. Simulation Scenarios

In each scenario, we simulate seven days of the pharmaceutical supply chain starting without any packages of pharmaceuticals, boxes, or pallets present. A warmup period is not desired because complete trace information from source to sink is needed to verify product authenticity.

Our simulation model includes the actors *manufacturer*, *wholesaler*, and *retailer*. The activities taking place at each actor are listed in Tables 2, 3, and 4.

Step	Description
M_1	produce packages of pharmaceuticals
M_2	tag packages with a unique identifier
M_3	recognize unique identifier of produced goods
M_4	store the package until shipment
M_5	tag a box with a unique identifier
M_6	aggregate the packages onto a box
M_7	tag a pallet with a unique identifier
M_8	aggregate boxes onto pallets (80% chance for each box)
M_9	recognize the aggregation by a reader
M_{10}	ship the goods
M_{11}	recognize unique identifier(s) at goods issue

Table 2. Activities at the Manufacturers

Step	Description
W_1	receive goods
W_2	recognize unique identifier(s) at goods receipt
W_3	state a query to the verification service
W_4	disaggregate the pallets
W_5	disaggregate the boxes (at the last tier of wholesalers)
W_6	store goods until shipment (in average 30 days)
W_7	aggregate packages into boxes (only at the last tier of wholesalers, 50% chance for each package)
W_8	tag a pallet with a unique identifier (not at last tier wholesalers)
W_9	aggregate boxes onto pallets (80% chance for each box)
W_{10}	recognize the aggregations by a reader
W_{11}	ship the goods
W_{12}	recognize unique identifier(s) at goods issue

Table 3. Activities at the Wholesalers

Step	Description
R_1	receive goods
R_2	recognize unique identifier(s) at goods receipt
R_3	state a query to the verification service
R_4	disaggregate the boxes
R_5	recognize the disaggregation by a reader
R_6	store the goods until they are sold
R_7	sell packages of pharmaceuticals
R_8	recognize the unique identifier by a reader
R_9	state a query to the verification service

Table 4. Activities at the Retailers

5.2. Limitations and Assumptions

Despite interviews with experts and literature review, our simulation has limitations and underlies assumptions.

We do not consider imports and exports across European borders. Furthermore, our simulation does not consider different activity levels at day and night, weekends, or holidays. Additionally, we have no anomalies in the supply chain, i.e., no product is counterfeit.

We assume that the total production is equally distributed over the manufacturers. Beyond this, all percentages as well as times in Tables 2, 3, and 4 are derived from interviews and completed with assumptions. In addition, we assume that each company has exactly one read event repository. Furthermore, our manufacturers and wholesalers use boxes with ten packages each and pallets with eight boxes each.

5.3. Implementation

We used the standard capabilities of Rockwell ARENA 12.0 to implement the simulation model where possible. Given the fact that the test data has to be usable for system testing, we decided to generate two files with comma separated values (CSV) for each scenario. The first file contains all read events which occurred in the simulation and the second file stores all queries to the verification service.

The steps we could implement without any custom modules are M_1, M_4, M_{10}, W_1, W_6, W_{11}, R_1, R_6, R_7. The remaining activities are of five different types:

1) Tag packages of pharmaceuticals, boxes, or pallets with unique identifiers (M_2, M_5, M_7, W_8)
2) Recognize the unique identifiers (M_3, M_9, M_{11}, W_2, W_{10}, W_{12}, R_2, R_5, R_8)
3) Aggregate packages of pharmaceuticals to boxes or boxes to pallets (M_6, M_8, W_7, W_9)
4) Disaggregate pallets to boxes or boxes to packages of pharmaceuticals (W_4, W_5, R_4)
5) State a query to the verification service (W_3, R_4, R_9)

For each of these activities, we develop a custom ARENA module. We briefly describe each module in the following.

1) Tagging Module. The tagging module generates a unique identifier and assigns this identifier to the entity passing this module. This is done using ARENA's `Assign process`.

For packages of pharmaceuticals, we use the following encoding schema [28]:

`urn:epc:id:sgtin:MAN_ID:TYPE_ID:PROD_ID`

The single components of this encoding mean that we use a uniform resource name (`urn`) which is a Electronic Product Code (`epc`) representing a unique identifier (`id`) in the form of a serialized global trade item number (`sgtin`). The tagging module replaces `MAN_ID` with a unique identifier for the manufacturer, `TYPE_ID` by the unique identifier for a certain product type of this manufacturer , and `PROD_ID` by a serial number which is unique within this manufacturer and the related product type.

For boxes and packages we use a similar encoding schema but instead of the `sgtin` we assign a serialized shipping container code (`sscc`) to boxes and pallets:

`urn:epc:id:sscc:MAN_ID:PROD_ID`

2) Reader Module. The reader module simulates a real reader which recognizes the unique identifiers assigned by the tagging module. For each read event the reader module adds a row in the file which stores the read events. To realize this we use ARENA's `Write to file` functionality.

The unique identifier of the reader has the following encoding schema [28]:

`urn:epc:id:sgln:COM_ID:LOC_ID:READER_ID`

The reader module replaces `COM_ID` with an unique identifier of the company owning the reader, `LOC_ID` with a location inside the company and `READER_ID` by a serial number which is unique within this company.

3) Aggregation Module. The aggregation module performs the aggregations which are needed to simulate the real pharmaceutical supply chain. For this we leverage ARENA's `Batch process`.

4) Disaggregation Module. The disaggregation module performs the disaggregations which occur in the pharmaceutical supply chain. We use the `Separate process` in ARENA for this activity.

5) Query Module. The query module simulates the queries stated to the verification service. This means that the verification service is given the unique identifier of interest and the location of the reader. For each query, the query module adds a row in the file which stores the queries.

For this set of scenarios we assume that the response is always the confirmation that the product is not counterfeit. This is realistic because we did not include anomalies into the supply chain and abandon a warmup period.

Scenario Generator. For the sake of flexibility and usability regarding the creation of the different scenarios, we implemented a scenario generator. This customization of ARENA is written in Visual Basic as proposed by [30] and enables us to generate different scenarios automatically.

6. Generated Test Data

The read event file contains the following seven columns:

- the unique identifier of the recognized item
- the unique identifier of the reader identifying the item
- time and date when the read event happened
- the command generated by the reader
- the business step identified by the middleware
- the unique identifier of the parent (if the command is ADD or DELETE)

The query file contains the following four columns:

- unique identifier of the item of interest
- location of the reader (unique identifier of the reader without the READER_ID)
- time and date of the query

The test data is available at http://epic.hpi.uni-potsdam.de/Home/Simul09. Key figures of each scenario can be found in Table 5.

The production volume in scenarios 1 and 3 is half the production in scenarios 2 and 4. Sales numbers increase in the same way. The other key figures are scenario-dependent.

If inference is not allowed, the number of read events increases from 1,077,448 to 3,180,624 (scenario 1 and 3) and from 2,155,963 to 6,354,713 (scenario 2 and 4), respectively. That means that the number of read events increases approximately by factor 3. This means additional load on the information systems and has to be respected while finalizing the legal requirements.

	Scen. 1	Scen. 2	Scen. 3	Scen. 4
Items produced	130,368	260,736	130,368	260,736
Items sold	116,298	232,535	116,331	232,496
Add events	234,542	469,466	856,504	1,710,615
Delete events	229,118	458,958	844,647	1,687,089
Observe events	613,788	1,227,539	1,479,473	2,957,009
Total events	1,077,448	2,155,963	3,180,624	6,354,713
Queries	398,523	797,266	397,175	793,940
Event file (MB)	191.0	382.0	538.0	1,065.0
Query file (MB)	41.8	83.7	41.7	83,3

Table 5. Scenario Key Figures

The total volume of the test data is 2.34 GB. It is stored in a machine readable format and thus can be used to automatically test information systems.

7. Conclusion and Future Work

In this contribution, we described the upcoming legal requirements for the European pharmaceutical supply chain. Furthermore, we stressed the necessity to provide realistic test data for successfully designing and implementing new information systems which are needed to fulfill the legal requirements. To this end, we analyzed the characteristics of the European pharmaceutical supply chain and its key figures related to production volume and participants. We then described which information systems are needed once the legal requirements become obligatory. Based on this information, we developed a simulation model which is capable to simulate the European pharmaceutical supply chain incorporating the upcoming legal requirements.

To the best of our knowledge this is the first time that a set of comparable data is published which enables an objective evaluation of these new information systems. By leveraging simulation we could exemplify that the final definition of legal requirements has a huge impact on the design of related information systems.

This test data enables researchers and software engineers to apply well-known efficiency metrics of the software engineering field and gather meaningful and comparable results. By using our model and the resulting test data, researchers also do verify, validate, and accredit our work.

We propose to apply behaviour metrics (response time, throughput time, and turnaround time) as well as resource utilization metrics (foremost concerned with I/O, CPU, and memory utilization) [31].

We see future work in several directions. From a simulation point of view, the limitations of our model can be addressed, i.e., it could be extended to include anomalies

and counterfeit pharmaceuticals. Additional varying factors in the simulation like different supply chain structures or technologies to be used (data matrices or RFID) could be integrated, too.

From a software engineering point of view it is useful to have more scenarios with a different scale from about 1:20,000 (1 manufacturer with reduced production rate, 2 wholesalers, 7 retailers) for micro testing to 1:100 (22 manufacturer, 504 wholesalers, 1,420 retailers) for large scale testing. Furthermore, it is useful to have data for less and more than seven days. Finally, a test framework which uses our test data and is able to benchmark different information system implementations would be beneficial. Then, academia and industry could address the problem of implementing the needed information systems most efficiently and minimize the total costs of the overall system.

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