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What are Authentic Pharmaceuticals Worth?

Matthieu Schapranow, Jürgen Müller, Martin Lorenz,
Alexander Zeier and Hasso Plattner
Hasso Plattner Institute, Enterprise Platform and Integration Concepts Chair, Potsdam
Germany

1. Introduction

Radio Frequency Identification (RFID) technology is named as a possible basis for future anti-counterfeiting by providing enhancements of existing business processes [Choi & Poon (2008)]. Hereby, the use of unique Electronic Product Codes (EPCs) [EPCglobal Inc. (2010)] for identification improves processing times during goods receipt and enables automated product tracking and tracing. The EPC is used to refer to a concrete item instance in a software system. For example, it identifies a concrete bottle of analgesic that was manufactured on May. 01, 2011 at 07:03 a.m. In contrast, currently used barcodes identify a class of pharmaceuticals, e.g. all analgesics of a certain manufacturer. RFID technology shows prevailing advantages in contrast to barcodes, RFID tags can be read without establishing a direct line of sight, multiple tags can be read simultaneously, and they can cope with dirty environments [Stiehler & Wichmann (2005); White et al. (2007)].

In the following, we refer to an RFID-aided supply chain when dealing with an supply chain solution that build on good's tracking and tracing functionality by integrating RFID technology [Schapranow et al. (2009)]. In context of the pharmaceutical supply chain, the integration of tracking functionality is widely considered, e.g. two-dimensional data matrix or RFID technology, since this specific industry is confronted with increasing counterfeit rates [European Commission Taxation and Customs Union (2009)]. However, advantages of using RFID technology only apply when all participants of the supply chain seamlessly integrate tracking solutions based on it.

Fig. 1 models components within an RFID-enabled company to support anti-counterfeiting using the Fundamental Modeling Concepts (FMC) [Knöpfel et al. (2005)]. These components can be established to track and trace goods on item level without media breaks. Since the depicted architecture switch is connected with high monetary investments, costs have to be accommodated by all participants of the supply chain [Schapranow, Nagora & Zeier (2010)]. Different levels of technology acceptance to transform towards an RFID-enabled company can result in exclusion of participants from the supply chain. We expect especially Small and Mid-sized Enterprises (SMEs) to be confronted with financial barriers to participate in global RFID-aided supply chains [Müller, Faust, Schwalb, Schapranow, Zeier & Plattner (2009)]. However, a gap-less integration of RFID technology at all supply chain participant sites is the basis for consistent tracking and tracing on item level in real time.

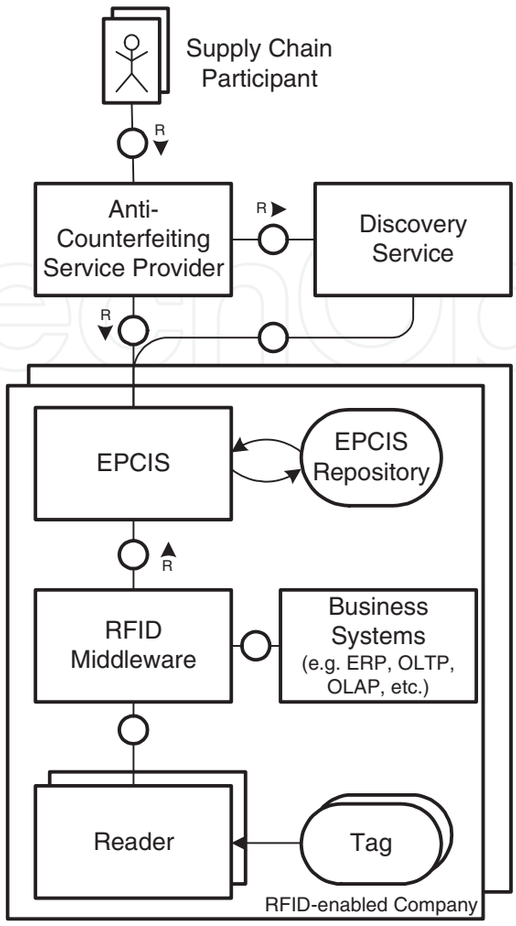


Fig. 1. FMC Block Diagram: Anti-counterfeiting Components of RFID-enabled Companies

We contribute by sharing our research results for enabling an integer RFID-aided supply chain. We focus on the business perspective and present concrete costs for RFID-enablement of supply chain participants and for operating a dedicated architecture for anti-counterfeiting. Our research activities are motivated by concrete requirements of the pharmaceutical industry. We present operating models to establish an RFID-aided supply chain while keeping initial infrastructure investments for involved supply chain parties at a moderate level. We discuss approaches for on-premise and on-demand operating models sharing hardware and software resources for cost-saving reasons. We identify cost-drivers for the proposed operating models, discuss cost-saving potentials, and define the amortization by product surcharges.
In the rest of our work we do not focus on how RFID technology may help to improve current pharmaceutical business processes, such as drug prescription, controlling of medication, or observation of patients. Instead, we stress on necessary adaptations to perform the transformation towards an RFID-aided supply chain. It is the key-enabler to observe product flows and to detect counterfeits by systematically analyzing the recorded movement of goods.
The rest of our contribution is structured as follows: Sect. 2 presents counterfeit challenges of the pharmaceutical industry from which we draw the motivation of our work. We define supply chain roles and their tasks within an RFID-aided supply chain to support automated

anti-counterfeiting in Sect. 3. In Sect. 4 we perform a quantitative analysis of initial and operational investments for transforming towards an RFID-aided supply chain. Our work concludes in Sect. 5 by summarizing our finding and providing an outlook towards possible payment models.

2. Challenges in pharmaceutical supply chains

RFID technology is nowadays named to be the successor of existing tracking techniques such as scanning of one-dimensional barcodes [White et al. (2007)]. Making use of RFID tags results in various advantages. Tags can be read without establishing a direct line of sight, multiple tags can be read simultaneously, and they can cope with dirty environments. The logistics sector is currently one of the first implementers to guarantee traceability of fast-moving goods, e.g. life-saving pharmaceuticals, blood preservations, or organ donations. Tracking goods is an important factor for participants in global supply chains, i.e. RFID technology helps to keep goods moving on the road instead of keeping them in costly stocks [Schlitter et al. (2007)]. Compared to existing semi-automatic solution, e.g. scanning of barcodes, the implementation of RFID technology reduces time to process incoming and outgoing goods at all involved intermediate stations by enabling automatic product identification [Bovenschulte et al. (2007)].

Pharmaceutical counterfeits introduce the risk of harming human-beings, e.g. when applying wrong doses, invalid or missing active ingredients or poison combinations for people with certain risks [Bos (2009)]. In the context of global pandemic infections, such as pandemic influenza type H1N1 in 2009 or H5N1 in 2008, the impacts of counterfeits become visible [World Health Organization (2009)]. Illicit drug use is a major problem in the U.S. for years, e.g. approx. 20 million people used illicit drugs in 2007 and more than every fifth person between 18 and 20 contributed to this statistics [Barthwell et al. (2009)]. These drug-abusing people order prescription-based pharmaceuticals via the Internet without having a valid prescription of consulting a doctor. In case the expected medical effect does not occur, therapies are hard to develop, because pharmaceutical ingredients cannot be traced to an authentic manufacturer.

In terms of intellectual rights and property management new aspects of product tracking such as counterfeit detection become relevant. Upcoming regulations will force manufacturers, retailers, and pharmaceutical business partners to be reliable for products showing their company logo or involvement. Tracking of their products through the entire supply chain becomes necessary. A reliable tracking mechanism is the first step in fighting counterfeits of pharmaceutical products. Studies show that expensive products, such as cancer fighting drugs and drugs for AIDS therapies, suffer from product counterfeits with increasing rates. But also generic products are increasingly subject to plagiarism.

Pfizer reported experiences with RFID-based implementations to guarantee authenticity of its Viagra pills already in 2006 [U.S. Pharmaceuticals Pfizer Inc. (2006)]. These activities indicate ambitions of pharmaceutical manufacturers to validate the use of RFID technology as a possible way to protect their products.

Product counterfeits arrive in the United States (U.S.) of America and the European Union (EU) with steady increasing rates. A high level of integrity in the supply chain is the basis for reliable product tracking to reduce the amount of counterfeit cases. In the following, insights about the current pharmaceutical market situation in the European Union and the United

States are presented. They support the motivation to design innovative RFID implementations focusing on security aspects to be an integral aspect.

2.1 Threats in European Union

The EU consists of 27 member states since it has been extended lately in 2007 and the youngest member states Bulgaria and Romania joined. Its population covers approx. 500 million citizens, which is approx. 7.5 percent of the world's population. Yearly, approx. 30 billion packages of pharmaceuticals are manufactured for the entire European market [Müller, Pöpke, Urbat, Zeier & Plattner (2009)].

In 2007, a total of 43,671 reported counterfeit cases with approx. 80 million involved articles were reported. In contrast to 2007, a total of 49,381 counterfeit cases, i.e. an increase of 13 percent, with approx. 180 million involved articles, i.e. an increase of 125 percent, were reported in 2008 (European Commission Taxation and Customs Union). A fraction of 6.5 percent of all reported cases and approx. five percent of all articles were associated with the pharmaceutical sector. The European Commission reports an increase of 118 percent for pharmaceutical counterfeits detected at EU borders in 2008 compared to 2007. In addition to the categories CDs/DVDs and cigarettes, the pharmaceutical sector holds the third place according to growth rates of intercepted articles.

To stress the increase of detected pharmaceutical counterfeits, we provide the following quote:

> In a two-month period, more than 34 million tablets were seized, including fake antibiotics, anti-cancer, anti-malaria and anti-cholesterol medicines, painkillers and erectile dysfunction medication. [IP Crime Group (2008)]

The aforementioned quote underlines that by a single joined operation more than 30 million pharmaceutical counterfeits were detected at the borders of the EU. More than 90 percent of intercepted articles are suspicious in terms of trademark infringement. More than 50 percent of all articles were intercepted during import procedures, whereas most articles were detected in air transportation. The category of life-style drugs is reported to be number one regarding detected counterfeits [IP Crime Group (2008)].

India is named as the top source of counterfeit pharmaceutical products contributing more than 50 percent of all detected articles [Shukla & Sangal (2009)]. This development is constant for years. The example of India shows that counterfeiters in countries with low law regulation benefit from pandemic diseases, such as influenza H1N1 in 2009, because consumers buy medicines preventively via the Internet [World Health Organization (2009)].

2.2 Threats in the United States

The United States Federal Food and Drug Administration (FDA) detected more than 21 counterfeit cases between 2001 and 2003 [Food and Drug Administration (2004)]; in 2004 this number almost tripled with 58 confirmed cases [Food and Drug Administration (2005)]. In contrast to this development, in the years 1997 to 2000 the number of detected counterfeits did not exceed six per year. This outlines two aspects. On the one hand, the number of pharmaceutical counterfeits increases. On the other hand, counterfeit detection methods are continuously improved and former undetected counterfeits can be detected meanwhile.

An estimated number of 7,000 deaths are connected with counterfeit medicines in the United States per year [Jenkins et al. (2007)]. Health damages result in legal consequences for the manufacturer and loss of the company's reputation. To emphasize potential monetary impact,

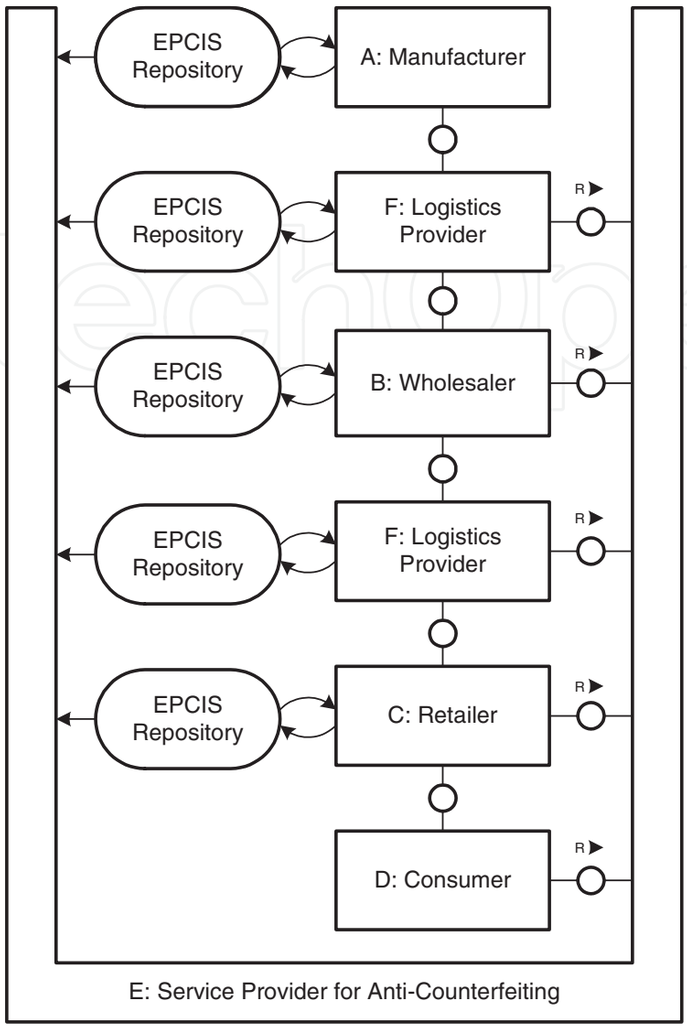


Fig. 2. FMC Block Diagram: Roles in the Pharmaceutical Supply Chain

Merck's medical vioxx evoked human damages and five billion USD were paid to avoid a lawsuit [Merck & Co. Inc. (2007)].

In 2004, it was estimated that more than 500 billion USD were traded in counterfeits, i.e. seven percent of the world trade in the same period [ICC Policy Statement (2004)]. It is stated, that this equals an increase of 150 billion USD in comparison to 2001 while the worldwide merchandise trade increased by approx. 50 billion USD in the same time, i.e. only one third of the increase traded in counterfeits [Staake et al. (2005)].

At this point, it is important to highlight that estimations about the monetary impact of counterfeits vary drastically. This fact underlines that only a small number of counterfeits can be detected nowadays and that the number of unreported cases is hard to derive. Technical improvements in counterfeit detection and goods protection help to increase the amount of detected cases by implementing new barriers to entrance counterfeits into large markets.

2.3 Sizing details for an RFID-aided pharmaceutical supply chain

The given case studies for the pharmaceutical industry in the U.S. and the EU highlight potential risks introduced by counterfeits and the need for active product protection. A high level of supply chain integrity is the basis for reliable product tracking and to support anti-counterfeiting. In the following, we focus on the European pharmaceutical supply chain, whereas similar conclusions can be drawn for the U.S. market. The European pharmaceutical supply chain consists of approx. 2,200 pharmaceutical manufacturers, 50,000 wholesalers, and 140,000 retailers [Müller, Pöpke, Urbat, Zeier & Plattner (2009)]. Every supply chain participant stores events e^* capturing the Electronic Product Code (EPC) [EPCglobal Inc. (2010)] of a certain item in an EPC Information Services (EPCIS) repository [EPCglobal Inc. (2007)] for all manufactured and processed goods.

A total amount of more than 30 billion pharmaceutical goods is manufactured in the pharmaceutical supply chain for the EU on yearly basis, whereas the half of them is available on prescription [Müller, Pöpke, Urbat, Zeier & Plattner (2009)]. As a result, we can derive an average daily production/handling rate of approx. 37,879 pharmaceutical goods that are produced per manufacturer, approx. 1,667 goods are handled per wholesaler, and approx. 595 goods are handled per retailers in the European pharmaceutical supply chain. To determine a lower threshold for the expected amount of captured EPC events for 30 billion pharmaceutical goods, we assume a minimal supply chain consisting of a pharmaceutical manufacturer with 360 production days per year and 24/7 manufacturing line, two wholesalers, a single retailer, and a customer. The manufacturer will capture at least a production and a shipping event for a certain pharmaceutical good. Both wholesalers will capture one event for goods receipt and goods shipment and two events that observe product movements within their stock locations. The retailer will capture a goods receipt event and a selling event, e.g. when a customer buys a medicine in the pharmacy. The customer will invoke an anti-counterfeiting check just in the pharmacy before buying the product, which results in a single check event. Ultimately, it sums up to eleven relevant captured EPC events distributed across the supply chain. As a result, a lower threshold of approx. 10,610 captured relevant events per second need to be expected across the entire global supply chain, each with an average size of 182 bytes [Schapranow, Müller, Zeier & Plattner (2010)].

A FMC model depicting the RFID-aided supply chain of the pharmaceutical industry is drawn in Fig. 2. It contains supply chain roles A to E and the involvement of a dedicated service provider for anti-counterfeiting. The service provider accesses individual EPCIS repositories of supply chain participants that are involved in handling a certain good to derive its virtual product history [Schapranow, Müller, Zeier & Plattner (2010)]. We agree that reliable product tracking and tracing across the entire supply chain can be implemented using RFID [Bundesverband Informationswirtschaft, Telekommunikation und neue Medien (2005)], but this technology is not designed to be immunized against threats, such as cloning, spoofing or eavesdropping [Schapranow et al. (2009)]. It is very important that customer profiles cannot be derived, because besides customers' privacy the entire supply chain would become vulnerable.

We agree that reliable product tracking and tracing across the entire supply chain can be implemented with the help of RFID solutions and open interfaces for supply chain participants [Bundesverband Informationswirtschaft, Telekommunikation und neue Medien (2005)]. However, RFID was not designed for secured data exchange of confidential details.

Hence, security threats exist, e.g. the possibility of cloning, spoofing or eavesdropping of tag reader communication to inject counterfeits [Schapranow et al. (2009)]. Possible measures against threats, e.g. mutual authentication, may reduce the probability for a certain threat [Schapranow, Zeier & Plattner (2010)].
We want to support the usage of RFID by introducing reliable IT infrastructure components that help to identify counterfeits by analyzing available event data, e.g. analysis of the goods path through the supply chain, suspicious ordering of actions, and semantic errors. We consider customer's privacy worthy of protection. From our perspective, customer profiling by combining checkout data with captured event data must be prevented to increase the acceptance of this anti-counterfeiting technique.
On the one hand, the presented scenario of the pharmaceutical industry underlines the need for reliable anti-counterfeiting mechanisms to prevent counterfeit injection. On the other hand, the pharmaceutical industry suffers from privacy concerns of end consumers while implementing RFID technology for tracking and tracing [Schapranow et al. (2009)]. We focus on the pharmaceutical industry in the following to support the fast adoption of RFID technology. We agree that this technology can contribute to establish an integer global pharmaceutical supply chain by establishing a permanent product trace. However, automated anti-counterfeiting is only feasible for expensive pharmaceuticals unless costs for RFID tags and components exceed an empiric threshold of less than about ten percent of the product's retail price.

3. Impacts of anti-counterfeiting for supply chain participants

The following section outlines our considerations for an anti-counterfeiting architecture based on location-based event data. The heart of the architecture builds a dedicated service provider for anti-counterfeiting as depicted in Fig. 1. It performs checks on event data for a given pharmaceutical good that is uniquely identified by its EPC. Furthermore, the service provider protects the privacy of inquirers and supply chain participants that handled a certain product as a kind of facade. On the one hand, queries are not directly sent to supply chain participants, i.e. the service provider prevents derivation of business relationships. On the other hand, supply chain participants cannot derive good's holder identity, e.g. to trace the good's complete path in the supply chain once it left the manufacturer.
Fig. 2 depicts the flow of data between roles involved in an RFID-aided supply chain to support anti-counterfeiting. Supply chain roles are described in further detail in subsequent sections focusing their business activities as participant of an RFID-aided supply chain.

3.1 Role A: Manufacturer

The manufacturer role consists of two separated tasks: product assembly and product creation. In terms of the product assembly it acts as an end consumer, i.e. consuming partly assembled products and removing them from the supply chain.
The task product creation is responsible to bring products alive. In this context the task of the manufacturer involves the creation of the product's meta data representation for the RFID-aided supply chain, which is covered by the following tasks.
The following steps are only required once a new product is created and can be considered as optionally if partially assembled product are consumed by the manufacturer.

1. Equip the product with a proper RFID tag to create the handling unit, i.e. the physical connection between the product and its tag. A handling unit can also be a transportation unit, such as a box or a container that groups multiple goods together.
2. Determine next available unique EPC for the created product. Therefore, the EPCIS repository of the manufacturer needs to be contacted.
3. Initialize the RFID with RFID-specific data, i.e. mandatory data, e.g. EPC, and optional data, e.g. authentication data.
4. Establish the virtual product history for the certain good by storing the creation event in the manufacturer's event repository.

Continue the business process on the manufacturer's site and capture events where the product's handling unit is involved. The following task is required for all kinds of products.

5. Capture all events defining the path at manufacturer's locations.

3.2 Role B: Wholesaler

The wholesaler's receives goods from various manufacturers, disassembles the handling units partially and reassembles them to new more specific handling units for certain retailers, such as hospitals or pharmacy chains.
The following tasks are required to contribute to the virtual product history.

1. Capture the goods receipt event.
2. Capture goods movement events within local storage, e.g. unpacking or new placing. All events are stored in the local event repository.
3. Equally to goods receipt processing the goods shipment is performed and. Corresponding captured events are stored in the local event repository.

3.3 Role C: Retailer

The retailer receives goods packed in so-called handling units, e.g. boxes or pallets. The latter are delivered by logistics provider from manufacturers, other retailers or wholesalers. Retailers use their local or more often a hosted event repository for storing captured events. The latter is available on subscription basis [Müller, Schapranow, Helmich, Enderlein & Zeier (2009)]. The retailer's task is to separate goods and sell them either to end consumers or to other retailers. When a product is sold to the end consumer the product history typically ends with the deactivation of the RFID tag at the point of sales [Schapranow et al. (2009)].

1. Receive handling unit and capture the goods receipt.
2. Unpack received handling unit recursively and process all contained goods individually, i.e. store events for all goods in the local event repository.
3. Capture the shipping event at the point of sales.

3.4 Role D: End consumer

The supply chain role end consumer occurs only once for a product and defines its sink. The end consumer in terms of the RFID-aided supply chain performs no additional tasks. In case of recall actions or warranty services, details about the product's path in the supply chain can be used to detect further cases. However, due to customer privacy concerns, we propose to deactivate tags after the end consumer passes the point of sales [Schapranow et al. (2009)].

3.5 Role E: Service provider

The service provider performs specific tasks not performed by other supply chain roles. It is responsible for counterfeit detection, e.g. by performing plausibility checks on the virtual product history with the help of the EPC of a certain product.
The service provider is provided by a trusted third party and can be contacted by any supply chain participant. It needs to contact the distributed discovery service to identify supply chain parties involved in handling a certain item [Müller et al. (2010)]. This requires a set of subsequent queries to retrieve event data from event repositories of involved parties. The service provider retrieves all event data via the discovery service and aggregates them to materialize the virtual product history [Schapranow, Müller, Zeier & Plattner (2010)].
In case of counterfeit detection the service provider returns the value $counterfeit$ and the product is removed from the supply chain for further investigations.
If the virtual product history is evaluated to be valid *authentic* is returned. If the outcome of the counterfeit detection cannot be derived automatically, e.g. in case of network partitioning or temporary failures, *unknown* will be returned to indicate the need for manual processing.
We define a function $service_{counterfeit}$ in Equation 1 performing checks with the help of a given epc_i. It returns either one of the results authentic a, counterfeit c, or unknown u.

$$service_{counterfeit} : epc_i \mapsto (epc_i, \{a, c, u\}) \tag{1}$$

3.6 Role F: Logistics provider

Logistics providers are responsible for transportation of handling units, i.e. moving them from a location to another location. On the route various intermediate locations are passed while the transportation is performed in a certain transportation time.
The logistics provider exposes details for transported goods, which involves capturing events at the start and end location of the transport. If the logistics provider additionally exposes details about intermediate locations, we refer to it as a logistics provider with real-time tracking capabilities [Zeier et al. (2008)]. A logistics provider in context of an RFID-aided supply chain performs the following tasks.

1. Capture all events at intermediate locations characterizing the path of a good in this part of the supply chain.

4. Quantitative analysis of EPC networks

After having discussed qualitative requirements in the prior section, we focus on quantitative considerations for supply chains based on RFID technology in the following. We present in detail the service provider for anti-counterfeiting and its impact on operative costs. A dedicated service provider performing anti-counterfeiting checks is anticipated. It provides a unified way for each supply chain participant to check authenticity of pharmaceutical goods based on their EPCs stored on RFID tags. From our perspective, an independent party should provide this service, which is not part of the pharmaceutical supply chain in order to guarantee trust for all participants. The operation of the service provider implies additional costs, i.e. surcharges for handled pharmaceuticals have to be considered. We present a model to identify costs by involving the amount of data transferred via the communication network.

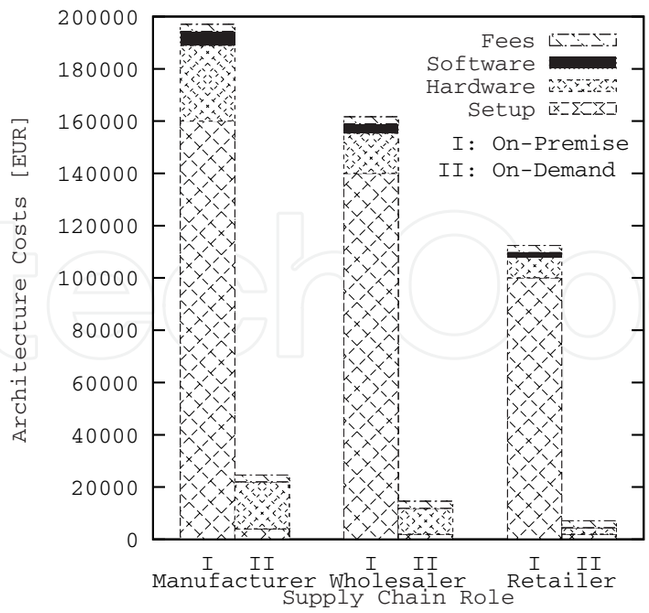


Fig. 3. Comparison of Costs for RFID-enablement per Supply Chain Role

Additionally, we compare the two operating models on-premise and on-demand for required RFID infrastructure components within participating companies.

4.1 Cost drivers for RFID-enablement in companies

For RFID-enablement of companies an initial monetary investment is required depending on the company's role within the supply chain. For example, a manufacturer requires both RFID reading and writing devices being capable to initialize RFID tags when new products are produced. In contrast, a retailer only needs to be equipped with RFID reading devices. Detailed results of our research for concrete costs are given in Sect. 6.

The initial investments for RFID-enablement are visualized in Fig. 3. It highlights the potential cost savings during enablement phase by using an on-demand operating model due to the reduced setup and implementation costs. In addition, it shows that costs for hardware components remain almost constant since this is required on-site equipment, e.g. RFID reader and writer devices. Tab. 1 contains the detailed criteria for comparison of investments for an on-premise solution with investments for a comparable on-demand solution. We divide costs accordingly to individual supply chain roles and categorize them using the following criteria [Schapranow, Nagora & Zeier (2010)].

- **Hardware** describes required investments associated with infrastructure components for establishing an RFID-aided supply chain, e.g. servers, RFID writing and reading devices, network components, etc.
- **Software** describes required investments for software operating the hardware, especially required licenses.
- **EPC Fees** describes required investments to operate as provider for certain EPC intervals, e.g. license fees for GS1 [GS1 Germany GmbH (2010)].

	Costs [EUR]	A: Manufacturer I	A: Manufacturer II	B: Wholesaler I	B: Wholesaler II	C: Retailer I	C: Retailer II
Hardware		28,906	17,988	15,339	9,880	7,929	2,470
RFID writers	3,526	3x		-		-	
RFID readers	913	6x		8x		2x	
Antennas	161	12x		16x		4x	
Workstations	3,261	2x	-	1x	-	1x	-
Servers	1,898	2x	-	1x	-	1x	-
Routers	300	2x	-	1x	-	1x	-
Software	908	6x	-	4x	-	2x	-
EPC Fees	2,650	1x		1x		1x	
Implementation	400	400x	10x	350x	5x	250x	5x
Total [EUR]		197,004	24,638	161,621	14,530	112,395	7,120

Table 1. Cost Distribution per Supply Chain Role: On-premise (I), On-demand (II)

- **Implementation** describes required investments for setting up the RFID infrastructure, e.g. costs for consulting, configuration of software and hardware respectively, implementation tasks, etc.

4.2 Role A: Manufacturer

Tab. 1 shows, that implementation costs contribute by approx. 80 percent to the total costs for supply chain role manufacturer, followed by hard- and software costs with approx. 15 percent. Applying a Software-as-a-Service (SaaS) solution results in reduction of costs for hard- and software components, such as workstations, servers, routers, and special software licenses, which have no longer to be paid by the manufacturer. Furthermore, the implementation effort for an on-demand solution is reduced since the configuration of existing hardware devices with the manufacturer, e.g. RFID reading and writing devices, is only required on-site. Although these on-site devices are required in a SaaS solution to scan items or write tags, they are reconfigured in a SaaS solution to transmit all incoming data directly to the on-demand solution hosted in the provider's cloud and to receive data from it.

Ultimately, this reduces initial investments for a SaaS solution by approx. 87 percent compared to an on-premise solution for the supply chain role manufacturer. Nevertheless, we expect that the SaaS approach to be uninteresting for manufacturers, because of related monthly rates for the on-demand solution. From our perspective, especially the manufacturer will benefit from an on-premise solution, because of the bulk amount of manufactured products per year, which need to be processed. Besides, the manufacturer typically owns a complex IT infrastructure consisting of enterprise applications, which have to be operated independently from participating in an RFID-aided supply chain. Its IT landscape consists of various enterprise systems, such as enterprise resource planning or customer relationship management systems, which are already administered by trained personnel. Thus, an initial investment with lower monthly fees will be more attractive for manufacturers.

4.3 Role B: Wholesaler

The effort of implementing RFID technology at the wholesaler's site when applying an SaaS solution equals less than 1.5 percent of the implementation costs required for an on-premise

solution as given in Tab. 1. By eliminating the need for huge on-site hardware investments in combination with the lower required administration effort, a SaaS solution helps to save more than 90 percent of the initial investment for the supply chain role wholesaler.
We believe, wholesalers will adopt a SaaS solution, because they primarily belong to the category of SMEs that these business models address. We expect the savings for initial investments also to be reflected by monthly saving, since the ratio of manufacturers and wholesalers in the European pharmaceutical supply chain is approx. 1:25. In other words, there are 25-times more wholesalers than manufacturers, which also reflect the amount of handled items.

4.4 Role C: Retailer

Comparable saving potentials exist for the supply chain role retailer. Approx. 93 percent of the implementation costs required for an on-premise solution can be saved when using an on-demand solution as shown in Tab. 1. Adding the savings introduced by eliminating investments for local hardware and the reduced on-site implementation effort, the total saving of initial investments are approx. 93 percent for the supply chain role retailer. This supply chain role belongs especially to the SMEs within the pharmaceutical supply chain, which are addressed by a SaaS solution. From our perspective, we expect monthly savings for a SaaS solution to be comparable to the savings for the initial investments, since the ratio of wholesalers and retailers in the European pharmaceutical supply chain is approx. 1:3.

4.5 Cost evaluation

Leveraging on-demand solutions reduces required implementation costs of a comprehensive and expensive on-premise solution. We compared the setup costs per supply chain role within the pharmaceutical supply chain between an on-premise and an on-demand solution. Independent from the role within the supply chain, costs savings for the initial investments of 80 percent and more can be achieved when applying an on-demand solution. Although the operation of an on-demand solution will be connected with monthly operational fees, we believe that the presented reduction for initial investments are the key enabler to increase the acceptance of RFID technology and supports SMEs to participate in RFID-aided supply chains without huge financial hurdles.

4.6 Amortization period

In the following, we derive required product surcharges to redeem initial investments for RFID-enablement in the European pharmaceutical supply chain. Let $p = 30$ billion products describe the annual manufacturing rate of pharmaceuticals available on-prescription, r describe the supply chain role, and x_r as defined in Equation 2. We assumed $a = 5$ years to describe the amortization period for all initial investments s_r.

$$x_r = \frac{s_r \cdot |r|}{a \cdot p} \tag{2}$$

Tab. 2 compares the required surcharges per product and role for an on-demand and an on-premise setup [Schapranow, Nagora & Zeier (2010)].
Based on the configuration of the supply chain as given in Sect. 4 the following total costs arise. Applying a SaaS solution for all roles of the pharmaceutical supply chain will result in

Supply Chain Role	$\|r\|$	On-demand x_r [EUR]	On-premise x_r [EUR]
Manufacturer	2,200	0.0004	0.0029
Wholesaler	50,000	0.0048	0.0539
Retailer	140,000	0.0066	0.1049

Table 2. Product Surcharges per Supply Chain Role for Amortization, a=5 years

a very low surcharge per item of

$$0.0004\ EUR + 2 * 0.0048\ EUR + 0.0066\ EUR = 0.0166\ EUR.$$

In comparison, an RFID-aided supply chain built on a purely on-premise solution requires a surcharge per item of

$$0.0029\ EUR + 2 * 0.0539\ EUR + 0.1049\ EUR = 0.2156\ EUR.$$

We expect to implement a combined solution of the given examples. A supply chain configuration consisting of manufacturers applying an on-premise solution and wholesalers as well as retailers accompanying an on-demand solution, the surcharge per item is given by

$$0.0029\ EUR + 2 * 0.0048\ EUR + 0.0066\ EUR = 0.0191\ EUR.$$

By applying this combined supply chain configuration it is possible to reduce the surcharge per item to less than 10 percent of the purely on-premise costs. Assuming an average pharmaceutical product price of 7.13 EUR. The expected surcharge per item for on-demand and the combined configuration are of 0.02 EUR resp. 0.22 EUR for on-premise, which equals 2.7 permille resp. 3.1 percent of the initial product price [European Commission (2008); Schapranow, Nagora & Zeier (2010)]. In all cases, the surcharge remains below our assumed empirical threshold of approx. 10 percent of the product's retail price as stated in Sect. 2.
The given surcharges are required to amortize the initial investment for RFID-enablement only. Regular costs, such as operational costs, maintenance costs for RFID devices, cost for RFID tags, monthly fees for subscription in an on-demand solution, etc. need to be added individually since they are not part of the given calculations.

5. Conclusions and outlook

In the given work, we considered RFID technology as the key-enabler for an integer and counterfeit-resistant pharmaceutical supply chain [Zeier et al. (2009)]. The pharmaceutical industry draws the motivation for our research activities due to the increasing number of detected pharmaceutical counterfeits within industry countries. We draw our business considerations for RFID-enablement of participants in an integer pharmaceutical supply chain. We shared our qualitative analysis of EPC networks architectures and compared operative factors. Based on our analysis, we derived costs for operating a dedicated service provider for anti-counterfeiting within an RFID-aided supply chain and compared possible models to operate this instance.
We expect that the acceptance of RFID technology depends on costs for RFID-enablement and its business advantages. For the given pharmaceutical case study, we expect RFID technology

to support authentic pharmaceuticals and automatic anti-counterfeiting by evaluating a good's product history. Ultimately, we compared required costs for RFID-enablement in an on-premise setup with an on-demand setup and derived per product surcharges for amortization of anti-counterfeiting in RFID-aided supply chains. The outcome of our research activities clearly depicts that initial investments for RFID enablement do no contribute to major product surcharges.

Our future research activities will focus on payment models for operation of the service provider for anti-counterfeiting. We will analyze the following payment models:

1. General post-payment models, e.g. once a month for large wholesalers,
2. Individual payment models, e.g. per anti-counterfeiting check for small wholesalers, or
3. Pre-payment models, e.g. for retailers when a predefined balance on an account can be used for checks.

6. Appendix A: Component Costs

Tab. 3 contains selected RFID components for RFID-enablement of a pharmaceutical company. We selected these components for pricing assumptions[1]. The given assumption can also be used for further industries. However, components may vary individually for specific industries and setups, which result in different costs per component and/or total costs.

[1] We assume USD 1.4184 = 1.0000 EUR

Component	Article	Costs [EUR]
Reader Equipment		
Device	Alien 9800 [RFIDSupplyChain.com LLC (n.d.b)]	913.00
Antenna	Alien 915 MHz Circular Antenna [RFIDSupplyChain.com LLC (n.d.a)]	101.00
Cable	Alien ALX-408 Extension Cable [RFIDSupplyChain.com LLC (n.d.d)]	44.00
Holder	Alien ALX-407 Mounting Bracket [RFIDSupplyChain.com LLC (n.d.c)]	16.00
Printer	Zebra R110Xi [IDAutomation.com Inc. (n.d.)]	3,526.00
Middleware		
Workstation	HP Workstation xw9400 [Hewlett Packard (n.d.)]	3,261.00
Software	IBM Websphere RFID Premise Server [IBM Corporation (n.d.)]	908.00
Internet Access		
Server	HP ProLiant DL380 G5 [macle GmbH (n.d.)]	1,898.00
Router		200.00
Network Cable		100.00
EPCIS		
Fosstrak	[Fosstrak (2009)]	open-source
Internet Access		2,298.00
EPC Fee	[GS1 Germany GmbH (2010)]	2,650.00
ONS		
Internet Access		2,298.00
Verification Server		
Internet Access		2,298.00
Tag	Thin Propeller Label[TAGnology RFID GmbH (n.d.)]	0.37
Consulting	Man-Day	400.00

Table 3. Costs Per RFID Component

7. References

Barthwell, A. G., Barnes, M. C., Leopold, V. R. & Wichelecki, J. L. (2009). National Survey on Drug Use and Health, *Technical report*, Center for Lawful Access and Abuse Deterrence.

Bos, J. V. D. (2009). Globalization of the Pharmaceutical Supply Chain: What are the Risks? – The FDA's Difficult Task, *Society of Actuaries*, pp. 23–26.

Bovenschulte, M., Gabriel, P., Gaßner, K. & Seidel, U. (2007). RFID: Prospectives for Germany – The State of Radio Frequency Identification-based applications and their Outlook in National and Internat. Markets.

Bundesverband Informationswirtschaft, Telekommunikation und neue Medien (2005). White Paper RFID Technologie, Systeme und Anwendungen, http://www.bitkom.org/files/documents/White_Paper_RFID_deutsch_11.08.2005__final.pdf[2].

Choi, S. & Poon, C. (2008). An RFID-based Anti-counterfeiting System, *International Journal of Computer Science* 35(1).

EPCglobal Inc. (2007). EPCIS Standard 1.0.1, http://www.gs1.org/gsmp/kc/epcglobal/epcis/epcis_1_0_1-standard-20070921.pdf[2].

EPCglobal Inc. (2010). Tag Data Standard 1.5, http://www.gs1.org/sites/default/files/docs/tds/tds_1_5-standard-20100818.pdf[2].

European Commission (2008). Pharmaceutical Sector Inquiry Preliminary Report.

European Commission Taxation and Customs Union (2009). Report on EU Customs Enforcement of IP Rights, http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/2009_statistics_for_2008_full_report_en.pdf[2].

Food and Drug Administration (2004). Counterfeit Drug Task Force Report.

Food and Drug Administration (2005). Counterfeit Drug Task Force Report.

Fosstrak (2009). Project License, http://www.fosstrak.org/epcis/license.html[2].

GS1 Germany GmbH (2010). Preise für die Nutzung des Leistungspaketes GS1 Complete, http://www.gs1-germany.de/service/gs1_complete/preisliste/index_ger.html[2].

Hewlett Packard (n.d.). HP Workstation xw9400, http://h20195.www2.hp.com/V2/GetDocument.aspx?docname=4AA0-4798EEE&doclang=EN_GB[2].

IBM Corporation (n.d.). Software Pricing, https://www-112.ibm.com/software/howtobuy/buyingtools/paexpress/Express?P0=E1&part_number=D0A4DLL,D0A4QLL,D0A4WLL,D0A4YLL,D0A5LLL,D0A5NLL,&catalogLocale=de_DE&Locale=de_DE&country=DEU&brand=ws&PT=html[2].

ICC Policy Statement (2004). The Fight against Piracy and Counterfeiting of Intellectual Property, http://www.iccwbo.org/home/intellectual_property/fight_against_piracy.pdf[2].

IDAutomation.com Inc. (n.d.). Zebra R110Xi RFID Printer Encoder, http://www.idautomation.com/rfid/Zebra-RFID-Printer.html[2].

IP Crime Group (2008). IP Crime Report, http://www.ipo.gov.uk/ipcreport08.pdf[2].

Jenkins, J., Mills, P., Maidment, R. & Profit, M. (2007). Pharma Traceability Business Case Report.

Knöpfel, A., Gröne, B. & Tabeling, P. (2005). *Fundamental Modeling Concepts. Effective Communication of IT Systems*, John Wiley.

macle GmbH (n.d.). HP Proliant DL380 R05, `http://www.macle.de/hp.html`[2].

Merck & Co. Inc. (2007). Settlement agreement, `http://www.merck.com/newsroom/vioxx/pdf/Settlement_Agreement.pdf`[2].

Müller, J., Faust, M., Schwalb, D., Schapranow, M.-P., Zeier, A. & Plattner, H. (2009). A Software as a Service RFID Middleware for Small and Medium-sized Enterprises, *Proceedings of the 5th European Workshop on RFID Systems and Technologies*, VDE.

Müller, J., Oberst, J., Wehrmeyer, S., Witt, J. & Zeier, A. (2010). An Aggregating Discovery Service for the EPCglobal Network, *Proceedings of the 43th Hawai'i Conference on System Sciences*, Koloa, Hawaii, USA.

Müller, J., Pöpke, C., Urbat, M., Zeier, A. & Plattner, H. (2009). A Simulation of the Pharmaceutical Supply Chain to Provide Realistic Test Data, *Proceedings of 1st International Conference on Advances in System Simulation*, IEEE.

Müller, J., Schapranow, M.-P., Helmich, M., Enderlein, S. & Zeier, A. (2009). RFID Middleware as a Service – Enabling Small and Medium-sized Enterprises to Participate in the EPC Network, *Proceedings of the 16th International Conference on Industry Engineering and Engineering Management*, Vol. 2, pp. 2040–2043.

RFIDSupplyChain.com LLC (n.d.a). Alien 915 MHz Circular Antenna (ALR-9611-CR), `http://www.rfidsupplychain.com/-strse-13/Alien-915-MHz-Circular/Detail.bok`[2].

RFIDSupplyChain.com LLC (n.d.b). Alien 9800 EPC Multiprotocol RFID Fixed Reader, `http://www.rfidsupplychain.com/-strse-98/Alien-9800-EPC-Multiprotocol/Detail.bok`[2].

RFIDSupplyChain.com LLC (n.d.c). Alien ALX-407 Antenna Mounting Bracket, `http://www.rfidsupplychain.com/-strse-195/Alien-ALX-dsh-407-Antenna-Mounting/Detail.bok`[2].

RFIDSupplyChain.com LLC (n.d.d). Alien ALX-408 Antenna Extension Cable, `http://www.rfidsupplychain.com/-strse-196/Alien-ALX-dsh-408-Antenna-Extension/Detail.bok`[2].

Schapranow, M.-P., Müller, J., Zeier, A. & Plattner, H. (2009). Security Aspects in Vulnerable RFID-Aided Supply Chains, *Proceedings of 5th European Workshop on RFID Systems and Technologies*, VDE.

Schapranow, M.-P., Müller, J., Zeier, A. & Plattner, H. (2010). RFID Event Data Processing: An Architecture for Storing and Searching, *Proceedings of the 4th International Workshop on RFID Technology - Concepts, Applications, Challenges*.

Schapranow, M.-P., Nagora, M. & Zeier, A. (2010). CoMoSeR: Cost Model for Security-Enhanced RFID-Aided Supply Chains, *Proceedings of the 18th International Conference on Software Telecommunications and Computer Networks*, IEEE.

Schapranow, M.-P., Zeier, A. & Plattner, H. (2010). A Dynamic Mutual RFID Authentication Model Preventing Unauthorized Third Party Access, *Proceedings of the 4th International Conference on Network and System Security*.

Schlitter, N., Kähne, F., Schilz, S. T. & Mattke, H. (2007). Potentials and Problems of RFID-based Cooperations in Supply Chains, *Innovative Logistics Management: Competitive Advantages through new Processes and Services*, Erich Schmidt Verlag GmbH & Co., Berlin, pp. 147–164.

Shukla, N. & Sangal, T. (2009). Generic Drug Industry in India: The Counterfeit Spin, *Journal of Intellectual Property Rights* 14: 236–240.

Staake, T., Thiesse, F. & Fleisch, E. (2005). Extending the EPC Network: The Potential of RFID in Anti-Counterfeiting, *Proceedings of the ACM Symposium on Applied Computing*, ACM, New York, NY, USA, pp. 1607–1612.

Stiehler, A. & Wichmann, T. (2005). RFID im Pharma- und Gesundheitssektor. Vision und Realität RFID-basierter Netzwerke für Medikamente, Berlecon Report.

TAGnology RFID GmbH (n.d.). Impinj Thin Propeller Label 3.875" x 0.5", `http://www.rfid-webshop.com/product_info.php/info/p482_Impinj-Thin-Propeller-Label.html`[2].

U.S. Pharmaceuticals Pfizer Inc. (2006). Anti-Counterfeit Drug Initiative Workshop and Vendor Display, `http://www.fda.gov/OHRMS/DOCKETS/dockets/05n0510/05N-0510-EC21-Attach-1.pdf`[2].

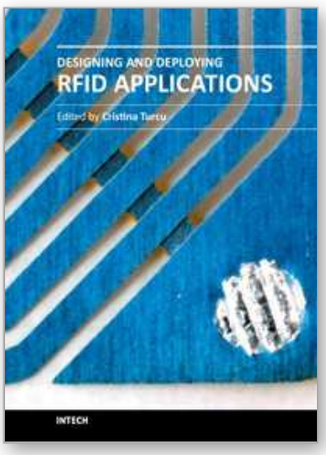
White, G. R., Gardiner, G., Prabhakar, G. & Razak, A. A. (2007). A Comparison of Barcode and RFID Technologies in Practice, *Journal of Information, Information Technology, and Organizations* 2.

World Health Organization (2009). Warning on purchase of antivirals without a prescription, including via the Internet, `http://www.who.int/medicines/publications/drugalerts/Alert_122_Antivirals.pdf`[2].

Zeier, A., Hofmann, P., Krüger, J., Müller, J. & Schapranow, M.-P. (2009). Integration of RFID Technology is a Key Enabler for Demand-Driven Supply Network, *The IUP Journal of Supply Chain Management* 6(3, 4): 57–74.

Zeier, A., Knolmayer, G., Mertens, P. & Dickersbach, J. (2008). *Supply Chain Management Based on SAP Systems*, Springer.

[2] All online references were checked on Apr. 28, 2011.



Designing and Deploying RFID Applications

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Radio Frequency Identification (RFID), a method of remotely storing and receiving data using devices called RFID tags, brings many real business benefits to today world's organizations. Over the years, RFID research has resulted in many concrete achievements and also contributed to the creation of communities that bring scientists and engineers together with users. This book includes valuable research studies of the experienced scientists in the field of RFID, including most recent developments. The book offers new insights, solutions and ideas for the design of efficient RFID architectures and applications. While not pretending to be comprehensive, its wide coverage may be appropriate not only for RFID novices, but also for engineers, researchers, industry personnel, and all possible candidates to produce new and valuable results in RFID domain.

InTech Europe
University Campus STeP Ri
Slavka Krautzeka 83/A
51000 Rijeka, Croatia
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