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Supply Chain Management and Automatic Identification Management Convergence: Experiences in the Pharmaceutical Scenario

U. Barchetti, A. Bucciero, A. L. Guido, L. Mainetti and L. Patrono
University of Salento
Lecce, Italy

1. Introduction

The past few years have seen an explosion of interest in the main auto-identification technologies in many heterogeneous scenarios. The ability to identify and trace individual objects is essential in many business processes, such as manufacturing, logistics, ticketing, and anti-counterfeiting. These contribute substantially to validate the concept of the 'Internet of Things' (IoT), although there are many ways to describe an IoT. It can be defined as a world-wide network of uniquely addressable interconnected objects, based on standard communication protocols (1). The core idea of the concept of the IoT is to collect any useful information about the objects of the physical world and to use this information in various applications during the objects' life cycle. This feature can help organizations to improve existing internal and external business processes and also to create new ones. In many application scenarios, the two key elements that are making this revolution possible are: radio frequency identification (RFID) technology (Wikipedia Foundation) and the EPCglobal international standard (epcglobal). RFID is a rapidly developing technology that uses RF signals for automatic identification of objects. Among the different types (i.e. passive, semi-passive, and active) of RFID transponders, often called 'tags', the passive ones are used in most track and trace systems due to their higher range and very low cost, since they require no battery to operate. A typical passive RFID tag consists of an antenna and an integrated circuit chip in ASIC technology. In a passive RFID system, the reader transmits a modulated RF signal, which is received by the tag antenna. The RF voltage generated on the antenna is converted into DC (Direct Current). This voltage powers up the chip, which sends back the information that it contains.

RFID is a very interesting wireless technology able to trace and track individual objects on the whole supply chain. This autoidentification technology has recently seen growing interest from a wide range of application sectors such as retail, logistics, localization, healthcare, and pharmaceutical (2) (3). Among these, the pharmaceutical supply chain is a very interesting scenario, in which an item-level traceability is crucial to guarantee transparency and safety in the drug flow. The fragmentation of the supply chain, caused by the overwhelming growth of intermediate wholesalers and retailers involved in drug flow, is resulting in a decrease of transparency and an increase of difficulty to track and trace drugs. Furthermore, the growing counterfeiting problem raises a significant threat within the supply chain system. RFID

technology is fundamental but not sufficient to develop an efficient supply chain management (SCM) system. It is most important to adopt international standards for goods traceability in the supply chain. Another crucial aspect is related to e-business message interchange in the supply chain. Each information flow between different actors in the pharmaceutical supply chain should be performed in automatic mode. Currently, there are still some technical and economic barriers that limit the large-scale deployment of these technologies in the pharmaceutical supply chain. Some initiatives are addressing these challenges and obtaining substantial successes. The asserting of some international standards related to goods traceability, such as EPCglobal (4), GS1 (Global Standard 1) and ebXML (electronic business using eXtensible Markup Language), are some interesting examples. Even if there are already several research studies coping with the hardware and software issue of an RFID enabled tracking system, an important issue, which still remains ill analysed, at least in the particular pharmaceutical supply chain, is related to the evaluation of the impacts that these new technologies could have on the main processes of the supply chain. Therefore this chapter presents an innovative framework that tries to find a convergence point among RFID technology, EPC standards and interoperability best practices for B2B interchange. This chapter evaluates this impact in terms of certain key performance indicators (KPIs) of the proposed framework: for example in (5), the authors identify and validate key performance indicators (KPIs) that are useful to trace the impacts of RFID technology in each individual organization and in the SC as a whole even if they don't focus on a particular supply chain. By contrast, this work reports practical experiences, gained with a recent pilot project named TRUE (6), focussed on the development and validation of an open source framework able to guarantee both traceability and data interchange on the whole pharmaceutical supply chain. In this chapter the KPIs are defined both for the wholesaler and for the pharmacy retailer. The defined KPIs are based on the 'critical success factor' (CSF) of the two stakeholders. In this first step, the analysis will be qualitative, and will be aimed at identifying the best indicators for measuring the potential improvements of the proposed framework once it will be really implemented in the pharmaceutical supply chain.

2. The pharmaceutical supply chain: The AS-IS model

The first step of this work will be the analysis of the pharmaceutical applicative domain, in order to obtain a realistic picture of the actors involved and how they interact. This kind of AS-IS analysis has been carried out with the support of important actors representative of the pharmaceutical supply chain; for example, the Merck Serono company has collaborated to define the process requirements for the manufacturer. In this early phase the authors do not pretend to be exhaustive, as the specific aim was not to be complete, but, instead, to empathize the benefits obtainable by adopting innovative technologies (e.g. RFID) both for supply chain management and for tracing and tracking. The pharmaceutical supply chain, shown in Fig. 1, is a very complex scenario, with millions of medicine packs moving around the world each year. It is made up of four main stakeholders:

– Manufacturer;
– Wholesaler;
– Pharmacy Retailer;
– Disposal Service.

This supply chain, much more than others, is affected by the need for law of a strict traceability of every drug that is manufactured, distributed and consumed. Moreover, because

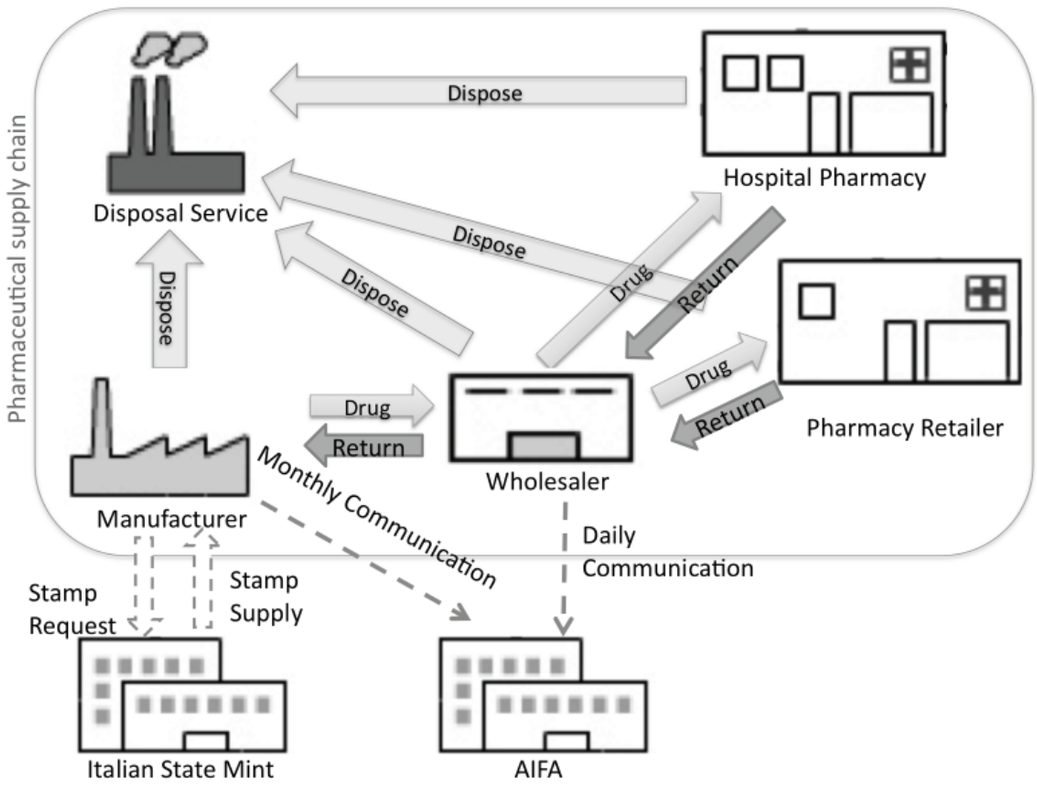

Fig. 1. Pharmaceutical Supply Chain

of the quick responsivity that the whole supply chain must guarantee in order to quickly supply drugs to each pharmacy retailer (it happens also 3 times per day), all the actors involved have the need to exchange business messages (purchase order, order confirmation, etc.) in a quick and reliable way. This vision introduces the need to understand how the traceability is strongly connected and correlated to the ones related to B2B. Currently, the main auto-identification solutions used in the pharmaceutical sector are based on optical technology such as linear or bi-dimensional (i.e. DataMatrix) bar codes.

Unfortunately, these solutions are not effective for tracing systems in the supply chain because they require line-of-sight (LOS) communication, cannot be written or read in bulk, can be easily counterfeited, limit the speed of packaging line operations, are subject to label deterioration due to humidity, etc. The item-level traceability of drugs starts just after the packages are filled during the manufacturing process. In this step, each tagged product is scanned individually on the conveyor belt and then cased to be sent to the wholesalers. The wholesalers separate the products according to their identifiers and place them onto the shelves. Wholesalers receive orders from retailers. These orders often consist of small quantities of different products; they may contain a large number of items. The products in the orders of the retailers are picked and put into some large envelope bags that are scanned and confirmed before their distribution. Upon receipt, the retail pharmacy scans the contents of each bag opening it. Some of the steps described previously go also with the exchange of business messages between actors. For example orders of the pharmacies to the wholesalers are often made electronically as well as those from wholesalers to manufacturers. Anyway there is not a loose integration between the traceability and the messages interchange

system. The wholesaler has, therefore, a wide variety of drugs that can come from different manufacturers and has as their main goal to distribute them according to the incoming requests from pharmacy retailers. Among the main characteristics of the pharmaceutical supply chain, derived from this AS-IS analysis, the most important was about the item monitoring: cases arriving at a wholesaler are opened and only one item from each case is inspected. This is done to speed up the entry check, but obviously does not guarantee that there are not missing or misplaced items inside the case. Moreover there is a constant monitoring by the Italian Department of Health (AIFA), who must be continually informed about the drug flow. In particular, the manufacturer must send monthly data about the drugs produced while the wholesaler must send information each 24 hours. Finally, The Italian State Mint (‘*Zecca dello Stato*’) provides a State Stationery Office stamp on the items. These stamps are applied only for drugs distributed in Italy and provided by the National Health Service. The stamp must quote the following information: the authorization code of the drug item, a drug description, the authorization owner, and a code that identifies the progressive numbering of the item. The last piece of information, the progressive numbering, is used only within the Pharmaceutical House; the other involved stakeholders have no reading system for this information and hence they discard it. This paragraph is aimed at giving the reader a quick but significant view of the Italian pharmaceutical sector, for this reason the level of detail has not been kept too high, while giving enough information to understand what kind of problems affect this supply chain.

3. Business-to-Business standards

The previous paragraph has shown how the pharmaceutical supply chain is characterized. It is made up of variegated actors that have different needs and different informative systems. Thus, one of the main problems is to guarantee interoperability among them, providing a flexible strategy able to support communication among the actors. B2B standards can give, sometimes, an answer to this problem. Therefore the pharmaceutical supply chain can be considered similarly to the B2B supply chain where the interoperability between companies is very important for the growth of the business. Companies need to exchange useful information in order to safeguard their economic and commercial transactions for the successful completion of their own business processes. The advent of XML has allowed the exchange of data through the internet by means of ‘simple’ structured text files but companies, in the course of time, have used XML to define legacy languages very often understood only within their own supply chain. For this reason, the methodological and technological efforts of the companies could not be used by other companies belonging to different supply chains or by new companies in the same supply chain. Therefore, there is a need for a standardization that can provide a common interchange possibly based on XML. The notations describing a business process, the interchange format and technologies that are spread out, are helpful and solve problems related to the B2B interoperability and integration for the specific supply chain. It would be particularly useful, therefore, to provide a solution that helps the user through the whole lifecycle that begins from the definition of the business process and goes up to the use of the specific message on the selected technological infrastructure. It is important, therefore, to link together different levels of analysis: at the high analysis level, it is important to identify a methodology and useful tools not only to define the business process but also to refine business processes in order to reach a detailed level according to implementation needs. At the intermediate level, it is necessary to identify a language conforming to the standards. It is necessary, therefore, to identify a mapping among the high-level messages

defined by the companies and the standard formats of message interchange defined from a B2B perspective. It is important, finally, to use the message defined according to the standard on a specific technological infrastructure. Many technological and methodological solutions are available for solving B2B problems but, to the authors' knowledge, there is no overall solution to the methodological and technological problems that, at the same time, allows maintaining the separation of concerns between methodological and technological levels. According to the authors, although it is important to link different levels of analysis, it is not useful to add complexity to what has been already designed and implemented. One needs to go towards a simplification of the use of standards, notation and technologies in order to support interoperability among companies. The authors will explain the standard methodologies, e-business vocabulary, and technologies that they have analysed.
From the business process perspective, the most important business process design notations used in both scientific and commercial circles are IDEF (7), UML (8) and BPMN (9). Among these notations, BPMN seems to be the best way to represent a company's business process and the interaction between actors inside the companies and outside the companies. With regards to the e-business vocabulary, there was an attempt by OASIS to introduce a generic vocabulary/standard useful to each supply chain partner. The standard is ebXML (10), which belongs to the ebXML framework and the main goal is to define the components that will define a specific business message. There has not been, up to the present moment, a methodology to represent neutral core components in e-business vocabulary (11). For this reason, the ebXML core component is not used by companies because each company must define its own vocabulary (using core components) and share it with other companies of the supply chain. This problem gave birth to UBL (Universal Business Language), an OASIS initiative that defines in its 2.0 version 31 business documents for different areas (12) such as sourcing, ordering, invoice and fulfilment. Finally, with regard to the architectural solutions oriented to the enterprises, the authors consider SOA (service oriented architecture). A simple SOA definition can be: a loosely-coupled architecture designed to meet the business needs of the organization (13). The reference model provided by OASIS (14) for SOA underlines some fundamental concepts that any implementation is based on (15). The SCA (service component architecture) architectural style was created in accordance with the SOA reference model. Moreover, web services was created, taking into account the concepts expressed by the SOA reference model, as a possible SOA implementation. Finally came REST, an architectural style that takes into account on the one hand the concept expressed by the SOA reference model and on the other, the most widespread technology: the Web. The REST architecture, created by Roy Fielding, seems to be very promising because it takes into account experiences acquired over the years in B2B electronic exchange and the strong points of the HTTP protocol that has made it the world's most used protocol.

4. Challenges and improvements in the B2B

The notation for business process analysis, business vocabularies, and these architectural solutions, answer to several problems that companies may face in their daily activities but does not provide a complete and integrated solution for business-driven integration problems (16).
The main problems are not only to define methodological and architectural solutions for the exchange of business messages but to link together the methodological and technological approaches in order to provide a solution that answers the needs of all the business partners: i.e., that the business partners may share a common language in order to have

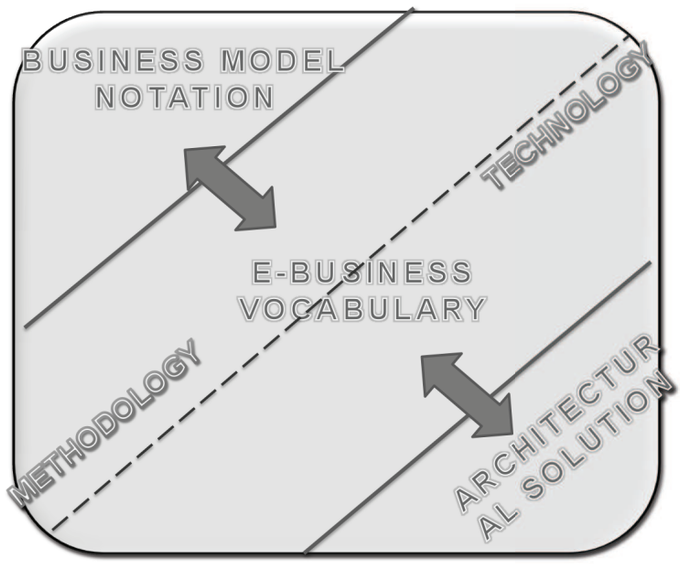

Fig. 2. Representation of the methodological and technological gaps

a communication helpful for the business. In order to identify a conceptual framework, it is important to provide a way to define business messages that, on the one hand, are not very complex for the final user, and, on the other, able to guarantee a business message representation that is easy to understand for the company's information system. There are three main open issues in the definition of the solution for these integration issues. The first is the selection of the notation for the business process design. The business messages come from the more or less complex business process of the company. The business messages may be input or output tasks for execution in the company but, very often, they are not accurately defined in the business process design and its source/target is not well identified. It would appear that BPMN is the best way to represent business messages: it has the modelling primitives useful to define the presence of a message but it does not provide the possibility to define in a formal way the exchanged message. It is easy to understand that the formal definition of a business process is not a task for the business expert but, at the same time, the definition of the process, made up by the designer, must also include the definition of the business message. The second problem is to define a language for a formal definition of a business message but it is difficult to adapt these vocabularies to the different application domains from which they are extracted. Business vocabularies may be very complex, so it is very hard to customise the language, or else it will be very generic compared with the specific application context, so the customisation task may be very difficult. The third problem is that the software architecture can manage the business process exchange efficiently but without thinking (as is right) of the message complexity or the different ways of representing the message. From these open issues, it appears that a double gap (methodological and technological) has to be bridged in order to obtain a solution for business-driven integration (Fig. 2). The e-business vocabulary covers the methodological gap between the definition of the business process and the definition of the business messages. The e-business vocabularies provide inflexible solutions for non-expert users and, very often, it is very hard to link together the business process analysis and the specific e-business vocabulary. Another aspect is the technological gap owing to the need to use a specific business language for the selected

architectural solution. This gap is because of the several technological solutions proposed in the e-business systems that are each based on a specific protocol and on complex rules (for example, ebMS vs AS2).
In several B2B research projects, the notations describing a business process, the interchange format, and technologies are helpful and solve problems related to B2B interoperability and integration for the specific supply chain. According to the authors, it is not useful to add complexity to what has been already designed and implemented. It is instead necessary to move towards a simplification of the use of standards, notation, and technologies in order to support interoperability among firms. Thus, the proposed structured conceptual approach is based on the following goals:

– to provide a high degree of freedom in the business process design and in the formalization of the specific business message;
– to suggest to the companies the use of only one technology of interchange that is flexible and easy to integrate with the company's information system.

For these reasons, the authors propose an approach (Fig. 3) based on a business-driven integration solution that takes into account three different aspects:

– the identification of a proper notation for the business process design (conceptual model);
– the identification of a proper e-business dictionary based on established standards (logical model);
– the selection of a quite simple and reliable technology for business message exchange (physical model).

This structured conceptual approach aims to individualize a possible integration among the various levels that makes the solution feasible, operational, and efficient in comparison with other solutions. The integration among the various levels can be obtained using an ontological approach based on the definition of a meta-model: starting from this meta-model, it will be possible to obtain the specific model (within the specific application context).
This model can be used in the chosen specific technological infrastructure as reference to the underlying level. In the specific case, by selecting the business process notation to use and selecting the business message interchange dictionary, it is possible to define the ontology in which there will be, with proper semantics, both the representation of the notation and the

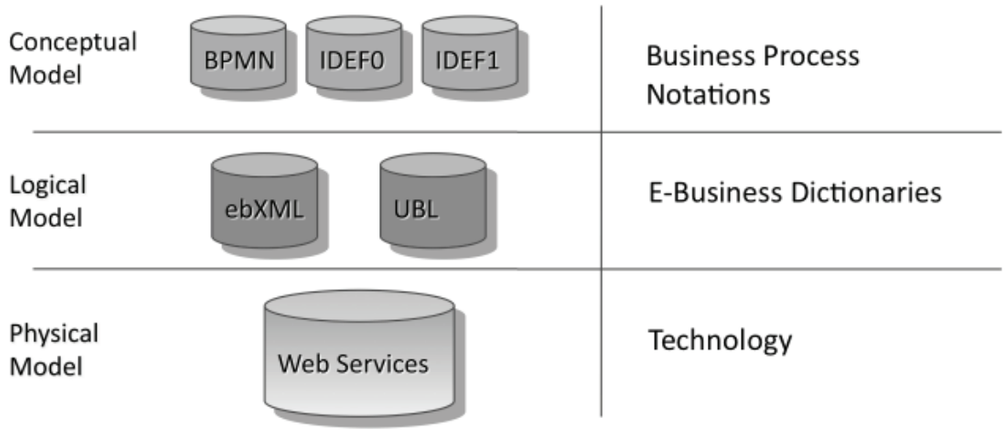

Fig. 3. Conceptual approach

representation of the specific dictionary to be used for the definition of the business messages. The obtained model can use a well defined technological infrastructure that allows business message interchange. According to the authors' experiences, it can be useful to choose a well-defined technological infrastructure that also takes into account the specific partners' needs (within the supply chains).

5. EPCglobal network architecture

B2B interoperability is not the only aspect that must be taken into account when speaking about pharmaceutical supply chain. Another important aspect is related to product traceability and identification. The drugs must be constantly checked during transport and stocking. The EPCglobal consortium, mainly represented by the GS1 (Global Standards 1) organization (gs1), defines the standards for developing a universal identification system and an open architecture able to guarantee interoperability and data sharing in a complex multi-vendor scenario. In particular, it proposes the EPCglobal network architecture, whose main feature is the use of the Electronic Product Code (EPC), a code able to univocally identify each item. This architecture comprises a set of standards for hardware devices (e.g. reader), software systems, network services, and data interfaces that allow the EPCglobal network to play a very important role in traceability systems. The EPCglobal architecture is able to guarantee effectiveness, flexibility, and scalability. Furthermore, it is important to observe that this architecture was designed to exploit all the advantages of RFID technology, but it continues to be valid also in the presence of other automatic identification solutions. In fact, it is able to provide most network services even if a linear or two-dimensional barcode is used.
Fig. 4 shows the current status of the standardization process of the EPCglobal architecture framework. The protocol stack can be divided into three parts: identity, capture and exchange. The identity portion contains the standards for the identification of tags and the translation of tag data. The capture portion contains the standards for filtering and collecting the tag data. The exchange portion contains the standards for storing and sharing collected and filtered EPC product data. Let us observe that the Discovery Service standard is in grey because it is not yet an official EPCglobal standard.
The rest of this section reports more details about the most important EPCglobal standards. In particular, the authors focus on portions that are fundamental for a traceability system: Tag Data, Low Level Reader Protocol (LLRP), Application Level Events (ALE), EPC Information Services (EPCIS), and Object Name Services (ONS).

5.1 Tag data

In the EPCglobal network the identification is based on the EPC standard that specifies a format of the EPC (epcglobal) code whose length is equal to 96 bits. The EPC code can identify 268 million companies and each company has 16 million product categories available.
Any EPC code has the following information: specification, manufacturer and price. In the Header of an EPC packet (Fig. 5), an encoding schema can be specified. The Filter and Partition Value provides a reliable reading of the EPC tag through a definition of different levels of wrapping and packing while the Domain Identifier identifies the company, the service, the stock keeping unit until pallet and package. Let us observe that the EPC standard supports all GS1 encoding schemas. This is a very important aspect that assures high scalability and flexibility. Some examples of these schemas are: General Identifier (GID), Global Trade Item Number (GTIN), Serialized GTIN (SGTIN), Serial Shipping Container Code (SSCC), etc. In particular, the SGTIN encoding schema is very useful for application scenarios

such as a pharmaceutical supply chain, in which item-level tracing is required. The SGTIN code allows of overcoming GTIN code limits through the association of a serial number to the previous GTIN.

5.2 LLRP

The LLRP layer was designed to provide an interface between the RFID reader and the middleware system. It guarantees interoperability among heterogeneous reader systems. LLRP includes several procedures that allow us to control physical parameters of both the antenna and the reader (e.g. AntennaID and RF settings). Furthermore, LLRP implements an 'anti-collisions' protocol to manage access to the wireless channel. The communication between reader and client takes place through messages. They allow us to obtain and to modify the reader configuration and to manage tag access. LLRP communication is based on the following steps:

- features discovery;
- device configuration;
- access and stock list operations setup;
- execution of stock list cycles;
- RF detection operations;
- client report returns.

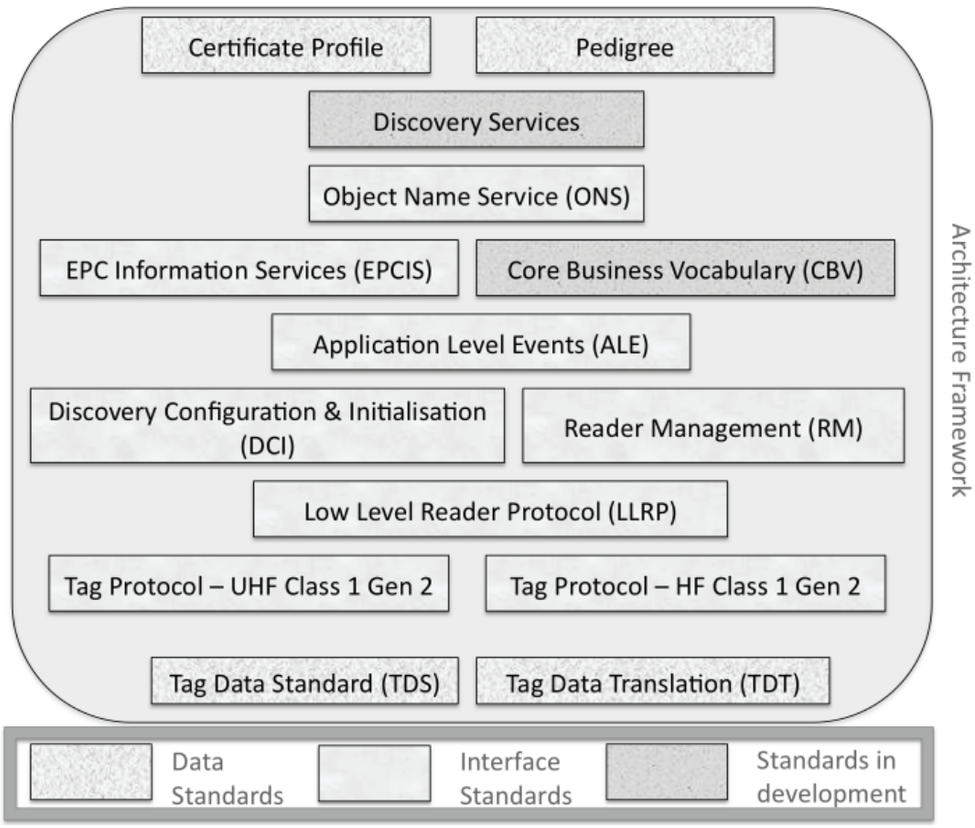

Fig. 4. EPCglobal network architecture

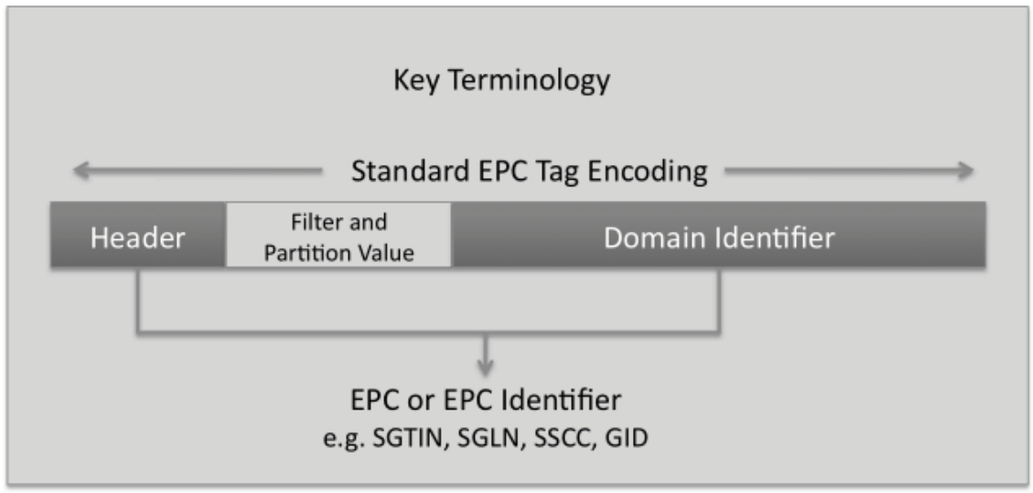

Fig. 5. EPC Code Structure

5.3 ALE

The role of the ALE interface within the EPCglobal network architecture is to provide independence between the infrastructure components that acquire the raw EPC data, the architectural components that filter and count that data, and the applications that use the data. This de-coupling is able to offer cost and flexibility advantages to technology providers and end-users. ALE, provided by EPCglobal architecture, does not depend on the data source such as RFID, linear code, data-matrix, etc. In fact, it defines the concept of a 'logical reader' layer. ALE defines a standardized format for reporting accumulated and filtered data in order to facilitate the upper layers processing. Furthermore, it enables business applications to use abstracted means to specify what, when and where particular observations have to be performed and processed by lower layers.

5.4 EPCIS

The main role of EPCIS in the EPCglobal network is to provide a repository for EPC events in order to facilitate the sharing and exchanging of traceability data among different business processes of a supply chain. EPCIS defines a standard interface to enable EPC-related data to be captured and queried using a defined set of service operations and associated EPC-related data standards, all combined with appropriate security mechanisms that satisfy the needs of user companies. EPCIS represents the core of the EPCglobal network architecture and differs from lower layers for some key aspects, such as the ability to interpret the current observations using historical data and incorporating semantic information related to the business process in which EPC data is collected. In contrast, the lower layers, such as ALE, manage just raw observations oriented exclusively towards real-time processing of EPC data. In more detail, EPCIS provides two interfaces: one for query request and the other one for capture operations. The query interface allows the trading partner to query information about any event data stored in the EPCIS-repository together with business context. Generally, each partner of a whole supply chain manages its own EPCIS server on one or more databases. However for such a decentralized architecture, since the complete information about an individual object, identified by a specific EPC, may be fragmented across multiple organizations, there is the need of lookup services for locating the providers of all these fragments that constitute the

complete lifecycle history of the object. This aspect contributes to make research on Discovery Service a very interesting challenge.

5.5 ONS

ONS is a mechanism that leverages Domain Name System (DNS) to discover information about a product and related services from the EPC. In more detail, it is able to provide pointers to authoritative information services of the manufacturer of the object identified by a given EPC. ONS is a sub-part, characterized by namespace onsepc.com (17), of DNS. In particular, as the DNS converts the domain address (i.e. URL) to the IP address, similarly, the ONS converts the EPC to the Uniform Resource Identifier (URI) of an EPCIS.

6. Description of the proposed software architecture

The adopted approach aims to define a technological infrastructure able to satisfy both SCM and traceability requirements. Two important choices for the proposed framework have been: ebXML as the proper standard to guarantee interoperability among the different firms, and EPCglobal as the proper standard to guarantee the identification and traceability of products and goods. The separation of concerns is a key aspect of the authors' approach, so they have defined an architecture that can separate, in a clear manner, competences and features from a technological perspective. This architecture is shown in Fig. 6. The data interchange system is based on ebXML and uses an application layer to guarantee an e-business messages exchanging service according to the UBL standard. Furthermore, it exploits an UDDI Discovery Service/ebXML Registry Service to find companies for e-business negotiation and agreement. The main layers of the traceability protocol stack, compliant with EPCglobal standards, are ONS, EPC-IS, ALE and LLRP. Unfortunately, the standardization of Discovery Services by EPCglobal is still pending, and therefore the current available implementation of the EPC protocol stack does not include the Discovery Service. The defined software architecture has been designed by merging the two main previous components: EPCglobal protocol stack and the ebXML for messaging services. In this way, the overall system is able to answer requests from the factory users by sending reports and information about a specific product, marked by an EPC code, or providing the possibility to perform messaging operations such as, for example, sending an order.
The overall system is based on two open-source implementations provided by the scientific community:

– The e-business message exchange sub-system is modelled by the freebXML project (http://www.freebxml.org/), which provides an open-source implementation of the ebXML standard.
– The identification and traceability sub-system is modelled by the Fosstrak framework (fosstrak), which provides an open-source RFID software platform that respects exactly the current standards provided by EPCglobal.

The overall system, thanks to the two open-source projects, is flexible and reliable, guaranteeing the separation of concerns. Furthermore, this choice allows of implementing the Discovery Service as an extension of the FossTrak open framework. The implementation of and experimenting with a Discovery Service mechanism integrated with a network architecture conforming to EPCglobal represent, of course, innovative and interesting features of this work. The authors' contribution in the field of supply chain management research is the definition of the overall architecture for the generic supply chain, the implementation

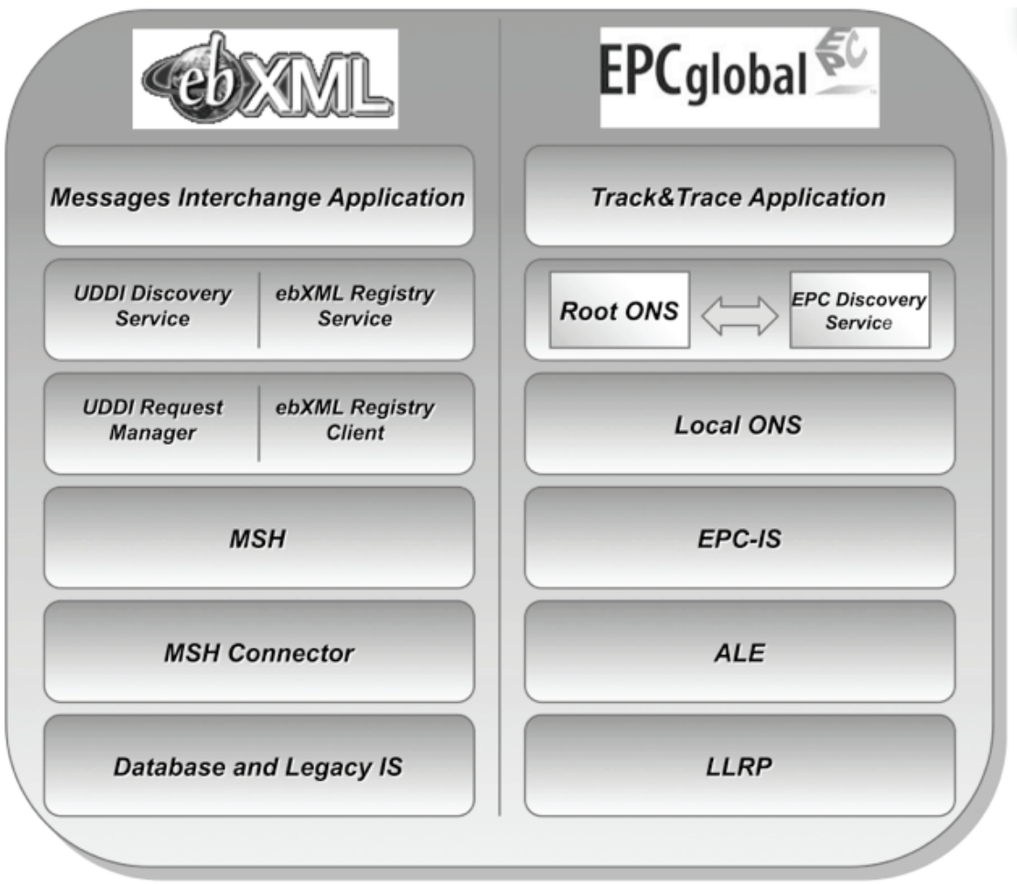

Fig. 6. Defined Software Architecture for traceability and SCM

of middleware able to obtain the proper interoperability between the two open-source implementations (freebXML and Fosstrak), and, finally, the experimentation with real-use cases taking into account the related issues of the pharmaceutical sector.

7. Discovery service implementation

Currently, the Discovery Service is not yet an official EPCglobal standard. It is recognized by the Internet Engineering Task Force (IETF) with the name of Extensible Supply-chain Discovery Service (ESDS) (18). ESDS is a protocol for infrastructure that enables track and trace applications as well as product lifecycle information systems to find multiple sources of information.

Many reasons lead to the standardization of this protocol. First of all, it is useful to allow different organizations to collect and store information relating to a particular product, to control the stored information and to decide how many and what information to make available to other organizations. This also takes into account the key principle of information sharing within a community according to which data ownership must be respected. This means that each organization can collect information within their own systems and is not required to route that information to any other organizations. In short, the ESDS allows

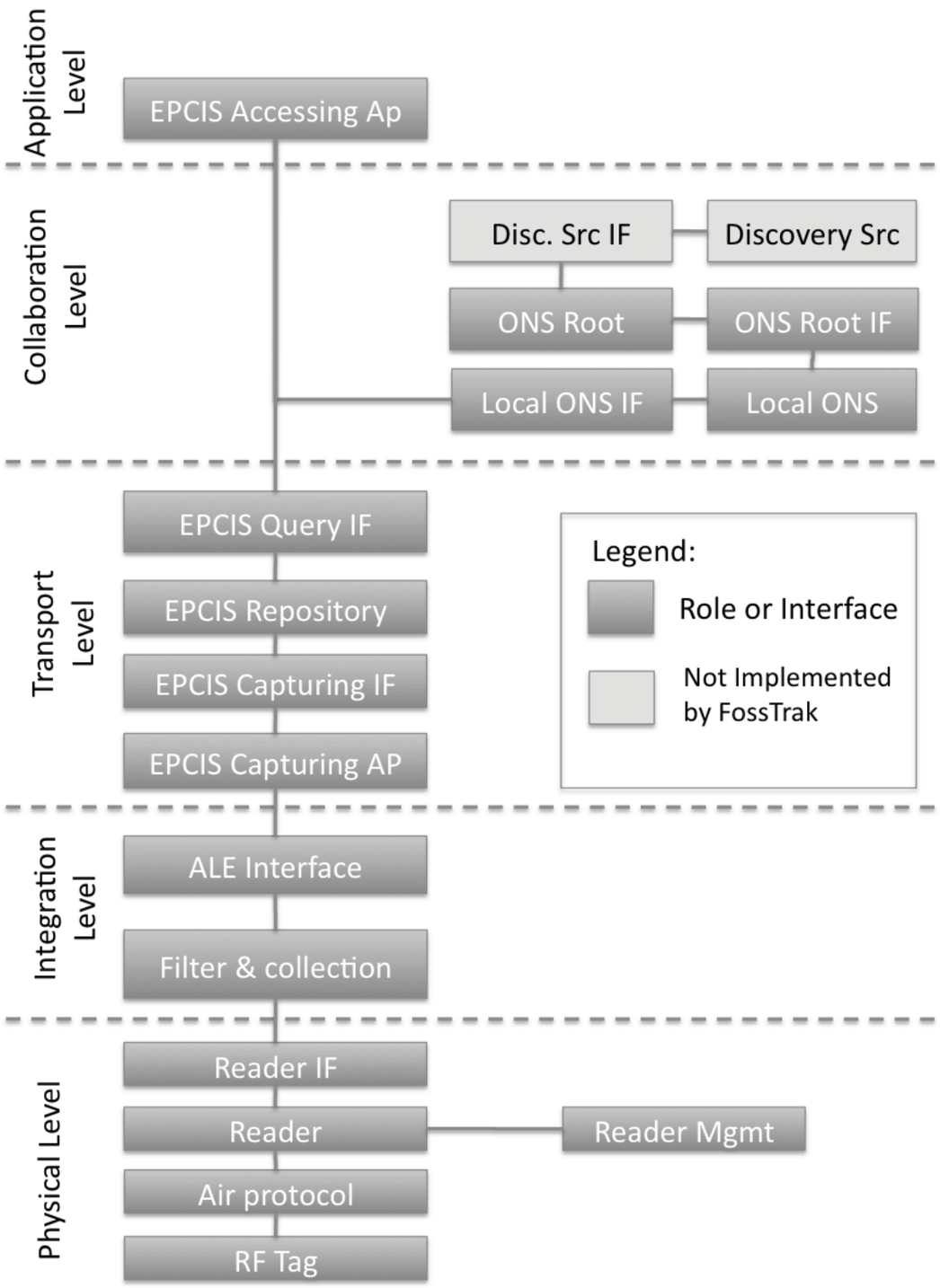

Fig. 7. FossTrak framework layered architecture.

different applications to identify various information resources and to gain a global view of information about a particular product. At a conceptual level, Discovery Services can be regarded as being somewhat analogous to a bottom-up 'search engine' for an IoT. However, there are some fundamental differences from the paradigm of public web search engines. First of all, each information provider will be able to voluntarily publish a record or registration for a particular common identifier, in order to be identified as a potential provider of information. Furthermore, the serial-level information will usually be protected and will only be made available to authorized organizations, with whom the information provider has an established trust relationship. Therefore, there may be only little information provided to non-authenticated users or directly to the general public without authentication. This approach enables the distributed management of the collected information and allows each organization to restrict who can access the data: they can specify an access control policy (which is enforced by a Discovery Service) to limit visibility of the 'link' information and additionally, they can specify and enforce an access control policy within their own information resource that holds the more detailed information. If the use of the Discovery Service is not provided, alternative solutions should be implemented to enable information sharing between trading partners. For example, the solution adopted by FossTrak enforces all members of a supply chain to store their information in a unique EPCIS server. Obviously, the ESDS should not act as an aggregator of detailed information, but should only help a customer to find the sources containing such information. In the literature, several works aim to implement a solution for the Discovery Service. In (19), the authors showed a simple, scalable discovery platform, called the Product Trace Service Platform, which is based on the EPCglobal Network and ONS specification. It is a lightweight proposal whose purpose is to allow the enterprise to develop a Discovery Service easily and quickly, and provide an effective environment to connect supply-chain applications to EPCglobal network. This platform is easy to use and easily extensible owing to the combination with ONS and the use of eXtensible Markup Language (XML), and is seamless in its response to the related EPC queries since it is based on Web Services. Reference (20) focusses on providing a first implementation of a simple, scalable infrastructure for building Discovery Services. Discovery Services are composed of a database and a set of web service interfaces. The developed application tracks the freshness of avocados across a food supply chain and allows the rerouting of products that are unsatisfactory. There is also a European project, BRIDGE (Building Radio Frequency IDentification for the Global Environment) that is focussing on an implementation of the Discovery Service. The BRIDGE project is a European Union funded 3-year Integrated Project addressing ways to resolve barriers to the implementation of RFID in Europe, based upon GS1 and EPCglobal standards. BRIDGE has several WP (work packages), among which WP2 is assigned to research the Discovery Service (21), (22). BRIDGE WP2 suggests two models. The first is the same as ESDS and provides the URL of EPCISs that holds data relevant to a specific EPC. The second is a query-relay model. It relays the EPCIS query to several EPCISs and gives a unification of the results from each EPCIS. It is a large extension of the ESDS and is convenient when results of a query from several EPCISs are needed. Observe that, unlike other works, in order to validate the proposed implementation of the Discovery Service, the authors decided to use a controlled simulation environment that is able to simulate all the most important steps of a supply chain, from the reading of a tag on the production line to its distribution to a retailer. Moreover, to further comply the proposed solution with EPCglobal standards, the authors decided to incorporate it into the FossTrak framework, which is recommended by the EPCglobal group itself, since it implements the entire protocol

stack.
The implementation and experimentation of a Discovery Service mechanism integrated with a network architecture conforming to EPCglobal have been developped as an extension of the framework FossTrak. This is an open framework that implements all interfaces and protocols defined in the EPCglobal specifications. This framework respects exactly the current standards provided by EPCglobal. Let us observe that the Discovery Service is still not implemented in the FossTrak framework because it is not yet an official EPCglobal standard. FossTrak, as shown in Fig. 7, implements the following levels of the EPCglobal network architecture:

1. Physical level: it includes all functions defined in lower layers of the EPCglobal stack. In more detail, it is responsible for the interaction with the reading and encoding procedures. This level covers standards such as Tag Data, Tag UHF Protocol and LLRP.
2. Integration level: it implements the standardized procedures to manage and control the reading devices. This level covers the standards ALE and Reader Protocol.
3. Transport level: it is the core of the architecture implementing the procedures to guarantee sharing and exchanging of traceability data. This level represents the EPCIS.
4. Collaboration level: currently, it implements only the ONS service.
5. Application level: it provides the application interfaces (API) to access or query EPCIS services.

The presented work aims at extending the FossTrak framework by adding a Discovery Service module that follows the guidelines indicated by IETF with the name of ESDS (18). It is able to overcome the restriction in the FossTrak framework of tracing systems characterized by a single organization domain (i.e. unique EPCIS server per supply chain). The purpose of the Discovery Service is to provide the references to every data source related to a specific EPC code in a supply chain composed of many partners. In the EPCglobal architecture, the privileged data source will be, obviously, the EPCIS. Different organizations can manage an object in different phases of its lifecycle, and each of them can collect and store information related to it. Similar objects, created in the same batch, could follow, during their lifecycle, different paths inside different organizations. Each organization should be able to control the information that has collected and stored and should be able to decide which information to make available to other organizations. This goal can be reached through the requesting of client authentication and the specification of access control policies for every data. To implement such a requirement, according to the ESDS, the following minimum set of commands is needed:

1. Hello: this command works as 'ping' and returns the state of the ESDS server (up or down). This method allows also the knowing of the server local time.
2. userLogin: this command allows user authentication. A session identifier keeps up the session.
3. eventCreate: this command creates a new ESDS event. This event includes the EPC code, the references to the services available and all the essential information, for example, the timestamp, the user that created or deleted an event, the supply chain to which the object belongs, and the partner who generated it.
4. eventLookup: this command allows knowing all the events associated to a specific tag, also including the services external to the Discovery Service itself.

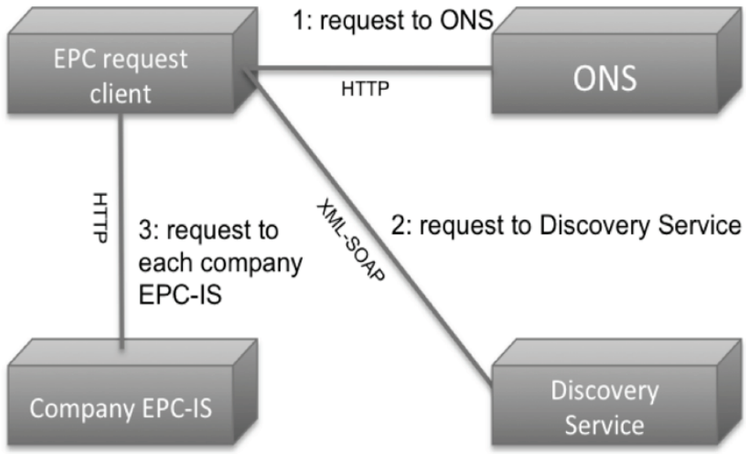

Fig. 8. Logical architecture of Discovery Platform in the large.

This implementation of the Discovery Service has been based on the WSDL (Web Service Description Language) file provided by the IETF draft and has the form of a JAX-WS (Java API for XML Web Services) web service. All the data about ESDS events is stored in a MySQL database that provides the persistence layer to the discovery platform, assuring security, stability, and robustness above all by a massive use of the stored procedure. In the extended EPC network architecture, the ONS server has been implemented by a free Windows based DNS server that supports NAPTR (Naming Authority Pointer) records (code 35). Fig. 8 shows the logic architecture implemented. It is mainly composed of the following modules:

1. ONS server for the startup phase of the Discovery Service.
2. One or more EPCIS for each organization domain.
3. An EPCIS client to insert data inside the organization EPCIS.
4. A client application to insert events inside ESDS.

As can be seen in Fig. 8, the EPC client provides three main operations:

1. Code conversion of the SGTIN tag from urn:epc:id:sgtin:manufacturerID.ObjectID.SerialID to ObjectID.manufacturerID.sgtin.id.onsepc.com form. Then a request to the ONS server will return the references to the URLs of the Discovery Service URL and of the manufacturer EPCIS.
2. EPC-Client will perform a request to the Discovery Service, asking for all the events having as ObjectID a given EPC code, correlating it with the URLs of the authoritative EPCIS. This request has a security check; only users with the right role and credentials can perform this kind of request.
3. EPC-Client will query every EPCIS server whose reference is provided by the Discovery Service, and will receive all and only the events they are authorized to read. The client will show the information retrieved.

8. Test bed for the pharmaceutical case

In order to appreciate the main benefits that the overall system implemented is able to provide to all actors of the pharmaceutical supply chain, a use case has been defined and used to carry

out an experimental validation in a controlled test environment. It has been developed with the aim of simulating the main steps of the pharmaceutical supply chain. Let us observe that an item-level tracing system of drugs starts just after the packages are filled during the manufacturing process. In this step, each tagged product is scanned individually on the conveyor belt and then cased to be sent to the wholesalers. The wholesalers separate the products according to their identifiers and place them onto the shelves. Wholesalers receive orders from retailers. These orders often consist of small quantities of different products; they may contain a large number of items. The products in the orders of the retailers are picked and put into some large envelope bags that are scanned and confirmed before their distribution. Upon receipt, the retail pharmacy scans the contents of each bag without opening it. The test bed has been defined mainly in order to validate the capability to provide a data interchange and traceability system proper to every actor of the supply chain (i.e. manufacturer, wholesaler, and pharmacy retailer). In order to simulate the pharmaceutical scenario, a controlled laboratory environment, shown in Fig. 9, has been created. It is equipped with an 'items line', a 'cases line', and a 'border gate'. The main software and hardware components used are:

1. three UHF RFID readers, the Impinj Speedway;
2. two Near Field UHF reader antennas by Impinj MiniGuardrail for the item-line;
3. four Near Field UHF reader antennas by Impinj Brickyard for the cases-line;
4. four Far Field UHF reader antennas for the border-gate;
5. two conveyor belts whose speed can be tuned in the range from 0 to 0.66 m/s;
6. HTTP Server Apache Web Server v. 2.2
7. Servlet Container Apache Tomcat v. 6.018 (Servlet, JSP, JSF)
8. DBMS MySQL v. 5.0
9. Development Framework Java 2 Enterprise Edition (Java v. 1.6).
10. Several types of passive UHF RFID tags (e.g. Thinpropeller, Cube2, Paperclip), both near field and far field, have been used in the tests.

After a preliminary setting of the test environment, the use case has been carried out. In order to test the overall system, and so both the traceability module and the interchange of business messages one, this use case can be analysed considering two separate components. For the traceability component, the use case has been defined writing unique EPC code (by using the SGTIN code) and applying RFID tag on each item. Then the transmission of EPC code to the EPCIS server is executed by the FOSSTRAK capture application. The client (the manufacturer) uses SOAPUI (Simple Object Access Protocol User Interface) libraries to insert an XML event into the Discovery Service through the web service. The ONS configuration deals with specifying the Discovery Service link and information about the company's EPCIS that first associated the EPC code with object (manufacturer). It is also necessary to set the zone and to declare local ONS IP addresses to the authority. When the wholesaler receives a tagged object, it retrieves and updates the Discovery Service information, adding its own EPCIS link to the EPC code associated to the object. The query phase is performed by any actor of the supply chain and is based on three main operations. In the ONS service operation, the client (manufacturer, wholesaler, or pharmacy retailer) retrieves the Discovery Service associated to the EPC code and the company's EPCIS (manufacturer) that first associated the EPC code. In the Discovery Service operation, the client retrieves all EPCIS links involved

in the EPC code management. Finally, in the EPCIS service operation, the client retrieves the EPCIS information of all organizations that have characterized the lifecycle of the particular tagged object. Instead, the following steps have been carried out to test the business messages interchange component:

- The pharmacy retailer sends an order request for a number of different medicines to the wholesaler.
- The wholesaler sends an order request to the manufacturer, specifying a part of the drugs requested previously from retailers, for a number of pallets for its supplies.
- The manufacturer prepares pallets, using the traceability sub-system to keep track of any package information, and the exchange sub-system to send an order response message to the distributor.
- The wholesaler receives the order response message and pallets, and verifies the correct correspondence between the received message information and the received products.
- The wholesaler prepares the drugs previously requested from the pharmacy retailer and uses the exchange subsystem to send an order response message to the retailer.
- The pharmacy retailer receives the order response message and packages, and verifies the correspondence between the received message information and the received products.

9. Methodology based on KPI

A key performance indicator (KPI) is a measure of performance very useful for evaluating the current status of an organization or for foreseeing the possible benefits obtainable by adopting an innovation in the system. KPIs are quantifiable measurements and depend on the particular organization. In order to evaluate the benefits provided by the proposed

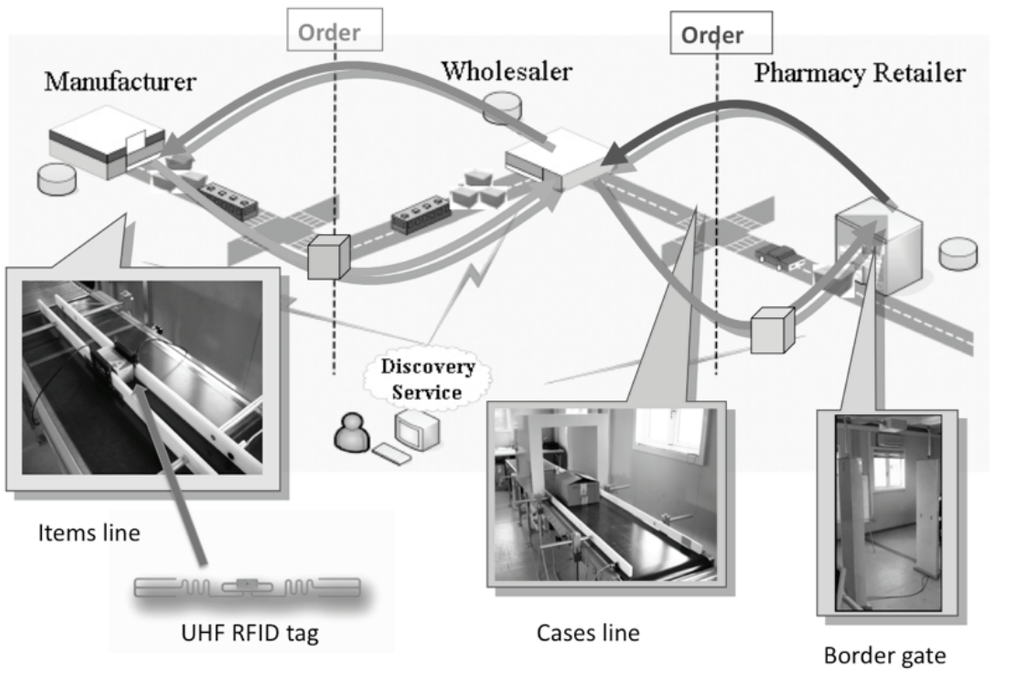

Fig. 9. Controlled test environment.

framework to each actor of the pharmaceutical supply chain, it is strategic to identify the main KPIs for the reference sector. Taking into account the considerable complexity of the pharmaceutical supply chain, this work focussed only on two stakeholders (wholesaler and pharmacy retailer). For these, the main KPIs have been identified and measured. An analysis based on KPIs is carried out by a comparison between AS-IS and TO-BE models. When the authors are not able to measure the KPI on the TO-BE model because the innovation is not yet introduced in the organization, a possible approach consists in identifying some key points where the KPI will be enhanced. This type of analysis is possible thinking about the intersection between the CSFs (critical success factors) and the KPIs both in the wholesaler and in the pharmacy. One of the original contribututions of this work is to identify the main KPIs for a complex business organization such as the pharmaceutical supply chain. The authors have defined not only KPIs but also the CSFs for the pharmaceutical supply chain. The analysis will provide a global vision of the performance and will cover both efficiency and effectiveness of the framework. A study of this type provides a final result not related to the real value of the product for the final user but it provides information about the quality of the final product and the speed and correctness of the business process. Before to define the KPI, it is important to locate the critical situation for each stakeholder of the business process. Focussing attention on the wholesaler, three different types of problems can be highlighted:

– IT problems: it is possible to automate several activities of the AS-IS that, until now, have been manual. For example when the drugs come to the wholesaler, the wholesaler states that all the items in the package are correct and the same wholesaler chooses the correct wholesaler for storing the drugs. It is clear that these and other manual activities do not provide any warrantee about the correctness of the actions.
– Supervision problems: in the AS-IS, the process is not supervised. The only check is by sending information to the AIFA but this check is not in real time and so business process problems are not immediately found.
– Flow problems: several tasks have no value for the business process. For example, when the package comes to the wholesaler, the operator state that all items in the case are undamaged and respect the order done. This task does not provide any value but it brings to an error. The business process, not presented here, is not linear: both manual and automatic efforts are involved in this phase. These features increase the difficulty of monitoring the process flow.

Instead, the main problems of the pharmacy retailer are as follows:

– IT problems: the check of the order is manual but it should be possible to check the order automatically.
– Check problem: in the AS-IS model the process is not supervised. The only check is made by sending information to the AIFA but it is not in real time and so business process problems are not immediately found.
– Flow problem: the flow in the pharmacy is not critical.

10. Evaluation of KPI

Taking into account the previous types of problem, the main CSF have been identified for the wholesaler and the pharmacy retailer. The CSFs for the wholesaler are presented in Table I. Table II contains the main CSFs identified for the pharmacy retailer.

Number	CSF	Metrics	Comment
1	Punctuality of the delivery	Time between order and delivery	Influence the Service Level Agreement
2	Timeliness	Errors/total delivered products	Influence the Service Level Agreement
3	Correctness of the return	Errors/number of returns	It is desirable that the wholesaler does not have products that come into the pharmacy from other wholesalers
4	Abatement of product losses	Number of outgoing products/ Number of incoming products	The wholesaler wants to reduce the number of lost products.
5	Correctness of the escape order	Number of products that come back/total number of orders	A correct order does not generate returned products

Table 1. CSFs for the wholesaler

Starting from the CSF analysis, it is possible to define the performance indicator for measuring system performance. The same indicators would be measured for both models (i.e. AS-IS and TO-BE). The indicators, both for the wholesaler and for the pharmacy retailer, are of three types: Quality, Service and Cost. The main KPIs identified for the wholesaler are reported in Table III.
Table IV reports the main KPIs identified for the pharmacy retailer. In order to evaluate the main indicators for the TO-BE model, a useful approach is to perform a combined analysis. In particular, connecting together KPIs and CSFs, it is possible to highlight that, for the

Pharmacy Retailer

Number	CSF	Metrics	Comment
1	Punctuality of the delivery	Waiting time for the customer	The client must have the product as soon as possible
2	Timeliness	Number of requests in stand by due to unavailability of the product	
3	Time to acquire the request	Time to dismember order	
4	Correspondence between member of product and information system	Number of orders for products already at the wholesaler's	It is possible to order product already in the wholesaler

Table 2. CSFs for the Pharmacy Retailer

wholesaler, the quality indicators are strictly related to the CSFs 'Punctuality of the delivery', 'Timeliness' and 'Correctness of the escape order' and the Service indicators are strictly related to the 'Punctuality of the delivery'; finally, the Cost indicator is strictly related to the other defined CSFs. In the same way, for the pharmacy retailer, the impact of the indicator on the punctuality of the delivery is very important, while the impact of the indicator to the other CSF is less important.

The analysis carried out on the pharmaceutical supply chain allowed us to identify the more significant KPIs and CSFs for the wholesaler and pharmacy retailer through a continuous monitoring and reporting of the main business processes for a period lasting 3 months. The measurements of these indicators, performed on the AS-IS model, have highlighted the critical points in the current management of the drug flow. The results of this analysis are not reported in this chapter because the main goal of this work was to identify the best indicators

	Indicators		
Number	Quality	Service	Cost
1	Time to escape order	Punctuality of the delivery	Average cost of order composition (cost of operator + cost of facilities)
2	Availability of the products	Number of wrong orders	Cost of order preparation
3	Accuracy in order preparation	Correctness of the order	Number of returned products of the own-company/Number of returned total products Cost of products lost
4	Number of items in input/output	Number of returned products out of date	Cost to acquire order (includes the cost of delivery)
5	Number of total escape orders	Number of products lost	Time to compose order
6	Number of total escape orders for operator	Number of come back orders/Total number of orders	Time to check order
7	Number of products simply to keep	Punctuality of the first delivery	
8	Number of products in the wholesaler	Punctuality of the second delivery	
9	Number of hours for trailer truck	Time to prepare order	
10	Number of total work hours	Number of completed orders/ Number of work areas	
11		Number of orders to manually check	

Table 3. KPIs for the Wholesaler

Indicators			
Number	Quality	Service	Cost
1	Availability of the products	Number of orders to dismember/day	Average cost of order composition (cost of operator + cost of facilities)
2	Number of available products/type of product	Number of orders to make/day	Cost of order preparation
3	Average time to have the product	Number of incorrect orders	Cost for products lost
4			Cost to acquire order (includes the cost of delivery)
5			Time to compose order
6			Time to check order

Table 4. KPIs for the pharmacy retailer

to be used to measure the potential improvements of the proposed framework once it will be really implemented in the pharmaceutical supply chain. In order to best appreciate how the proposed framework may be able to solve some of the mentioned problems in the SCM system, the values of some indicators for wholesaler and pharmacy retailer, estimated by the measurements carried out for three months, are reported briefly as follows in Table V.

KPI	Wholesaler	Pharmacy Retailer
Number of wrong orders	50	3
Correctness of the order	7 items wrong	
Time to escape order	Average: 90 min Min:1min Max:14h	
Number of drugs lost	178	

Table 5. Measurement of some indicators for the AS-IS model

These significant values allow us to assert that the use of the proposed framework will be able to solve several problems mainly because the innovations will minimize manual activities and thus minimize human errors. It is clear that the possibility of tracing at item-level every drug on the whole supply chain allows of obtaining the best flow control process, something not guaranteed in the current management system. The authors foresee that the real impact of the framework is in the quality and service indicators. It is clear that the improvement of service is immediately visible in the costs. For example the introduction of this framework reduces the time of delivery of the order (by eliminating manual checks, which are expensive both in time and in costs). The system improves the service indicators both for the pharmacy retailer and for the wholesaler. From the point of view of the pharmacy retailer, the number of orders per day will be reduced, while the wholesaler will have only to manage a minor number of incorrect orders and drugs lost.

11. Open issues

The practical experience gained from developing and testing the described research activity on the item-level traceability in the pharmaceutical supply chain has allowed us to appreciate the enormous advantages related to the use of passive UHF RFID technology and to merging the two chosen standards, EPCglobal and ebXML, into a single software architecture. The test bed has still shown some critical aspects that sometimes can degrade the performance of the overall system: in particular, operating conditions. They have crated the possibility to open a very interesting discussion with a large-scale scientific community about several areas of improvement opportunities for the future. The main issues related to the adoption of these technologies for item-level tracing systems of drugs are:

– Improving the UHF tags' performance in the presence of liquids and metals: the main features of passive UHF tags lead to the assertion that these represent the ideal choice for identification and tracing systems at item-level. Unfortunately, UHF tags could occasionally encounter problems, causing performance degradation, in the presence of materials such as liquids and metals that absorb RF energy. Some recent works (18) have demonstrated that the design of particular UHF tags is able to resolve such performance problems, obtaining optimal performance in each step of the supply chain and even in the presence of metals and liquids.

– Scalability of the EPC network: the use, on a large scale, of the EPC network for tracing systems at item-level could cause a collapse of the Discovery Service. Some proposals aim to use particular load balancing mechanisms or to define and implement a Discovery Service mechanism based on a peer-to-peer paradigm, e.g. exploiting a Distributed Hash Table (DHT), in order to improve scalability and effectiveness.

– Choice of the best standard for the business messages interchanges: there are various standard initiatives addressing the standardization of communication in exchanging information in different domains, such as RosettaNet in the electronic component industry, OAGIS in the automotive industry, CIDX in the chemical industry, and GS1 eCOM in the retail industry. At the moment, however, no document standard is sufficient for all purposes because the requirements significantly differ across businesses, industries and geo-political regions. On the other hand, the ultimate aim of business document interoperability is to exchange business data among partners without any prior agreements related to document syntax and semantics. Therefore, an important characteristic of a document standard is its ability to adapt to different contexts, its extensibility and customization. The UN/CEFACT Core Component Technical Specification (CCTS) is an important landmark in this direction, providing a methodology to identify a set of reusable building blocks, called core components, to create electronic documents. UBL was the first implementation of the CCTS methodology. Some earlier horizontal standards such as Global Standard One (GS1) XML and Open Applications Group Integration Specification (OAGIS), and some vertical industry standards such as CIDX and RosettaNet have also taken up CCTS.

– Evaluation of potential effects of the RFID on the drugs: Before having a large diffusion of RFID technologies in the pharmaceutical sector, it will be necessary to provide all guarantees to exclude every possible effect of electromagnetic waves produced by a UHF RFID system on drugs. Particular attention is focussed on the evaluation effects of tracing RFID systems on the molecular structure of biological drugs. (23). Some recent works (27) have focussed on this topic, exploiting diagnostic techniques such as high pressure liquid

chromatography (HPLC) and nuclear magnetic resonance (NMR) spectroscopy. Also the authors have a specific research activity on the topic (28)(29)(30).

– Integration and interoperability of EPC network services with the information systems of organizations: EPC network architecture tries to standardize components and interfaces to serve as a basis for RFID-driven business. Currently, only the local components specified in the EPC network architecture are being used (24). Inter-organizational collaborations on RFID-data exist, but they focus on small closed-loop applications. In order to exchange data on the network, organizations are forced to use proprietary software that connects their local EPC network stacks and thereby their businesses. The lack of standardization and high costs for developing common components over again each time is a major hindering factor for the adoption of RFID (25).
– Improvements of the security mechanisms: as soon as RFID technology becomes pervasive, the resolution of privacy and security problems will assume a crucial role. The possibility of having, especially with UHF systems, read ranges of several meters stimulates the activities of attackers. Different works (26) have been focussed on privacy protection and integrity assurance in RFID systems in order to destroy this technical barrier. Furthermore, the tag-to-reader couple does not represent the only vulnerable area. The main services of the EPC network are based on the Internet (e.g. ONS, Discovery Service, etc.), and so these tracing systems have to adopt all possible mechanisms designed to guarantee confidentiality and integrity in the data transactions through the Internet.

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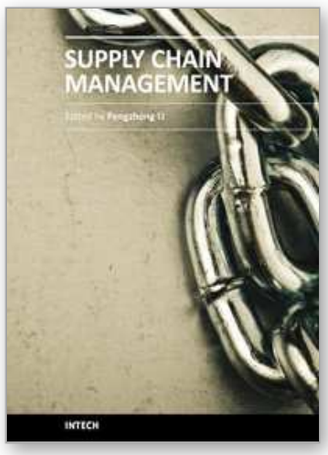

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The purpose of supply chain management is to make production system manage production process, improve customer satisfaction and reduce total work cost. With indubitable significance, supply chain management attracts extensive attention from businesses and academic scholars. Many important research findings and results had been achieved. Research work of supply chain management involves all activities and processes including planning, coordination, operation, control and optimization of the whole supply chain system. This book presents a collection of recent contributions of new methods and innovative ideas from the worldwide researchers. It is aimed at providing a helpful reference of new ideas, original results and practical experiences regarding this highly up-to-date field for researchers, scientists, engineers and students interested in supply chain management.

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University Campus STeP Ri
Slavka Krautzeka 83/A
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