Assessing the implementation of serialisation in pharmaceutical industry in Greece: a qualitative approach

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Abstract: In a competitive environment such as the pharmaceutical sector the necessity for visibility of the supply chain is currently not only an idea in regulators' minds but also a challenge for the key stakeholders. The aim of the study is to reflect the current status of serialisation implementation in the pharmaceutical industry, discover interests and expectations and explore the post implementation environment. A stakeholder analysis was conducted to assess the importance of each stakeholder. Furthermore, to discover interests and expectations, analyse the status and explore what is coming next when serialisation will be effective, personal in-depth interviews with subject material experts took place. Our results indicate that manufacturers, CMOs and re-packagers are most impacted, and serialisation is a necessity for regulation compliance. Its implementation aims to bring important changes, the impacts are gradually visible and the journey until it is fully implemented will last for some years to come.

Keywords: serialisation; regulations; counterfeit; stakeholder analysis; pharmaceutical industry; supply chain; qualitative analysis; stakeholder identification; stakeholder prioritisation; stakeholder mapping; Greece.

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1 Introduction

Introduction of falsified and counterfeit drugs directives into the drugs supply chain is one of the major issues the pharmaceutical industry globally faces. Issues of public health as a result of consumption of such drugs (from ineffective treatments to death of patients) as well as financial losses for the legitimate pharmaceutical industry emphasise the necessity of engagement in these directives. In order to react to this phenomenon, several regulations were issued enforcing that all drugs must be serialised. Furthermore, pharmaceutical companies are called to strengthen their track and trace systems in order to provide the required traceability for every prescription drug in the market. In a study on asymmetry on stakeholders' perceptions, Torres (2019) shows that pharmaceutical organisations perceived differently the cost and benefits from traceability projects. Organisations involved experience neither organisational nor technological proximity, impacting negatively collaboration in the inter-organisational project. Nonetheless, the proximity of the stakeholders in the medicine traceability project proved to be a significant factor in the success of the inter-organisational performance.

Accordingly, the pharmaceutical industry is at the state of implementing serialisation in order to comply with the regulations. Considering the strict timelines until serialisation will be mandatory for every prescription drug, this project will be on the top of every stakeholder's agenda principally for the manufacturers, who are expected to be mainly impacted. As a result, a number of supply chain aspects will be impacted for the process to take place. Turner et al. (2018) examined the nature of supply chain complexity and

investigate how managers respond to supply chain complexities that can either be operationally deleterious or strategically beneficial. Their findings further demonstrate that a framework can aid managers in conceptualising and addressing supply chain complexity. In addition, pharmaceuticals supply chain management requires special expertise to transport the medicinal products due its unique features of demand, supply and sensitivity towards quality (Kumar and Jha, 2019). In addition, the concept of green supply chain management is being implemented in greater scale, with rising trends in the hotel industry (Pratyameteetham and Atthirawong, 2017).

This study assesses the implementation of serialisation in pharmaceutical industry in Greece, discovers the current state of the project and the challenges that the industry faces both internally and externally. Furthermore, taking into consideration the real-world constraints, it is attempted to present how business executives see the post implementation environment, what are their expectations and what are challenges the industry will face when serialisation will be in practice. Dengleri et al. (2019) undertook a study of the Greek pharmaceutical industry and analysed the financial performance of six pharma companies in Greece. Their findings stress the prolonged effects of the financial crisis on the pharma industry, with forecasts demonstrating similar trends to historical valuations and performance indicators of liquidity, debt and profitability. Alsaad et al. (2018) had studied the value creation of IT on the supply chain in pharmaceutical industry in Jordan. In addition, companies of the pharmaceutical industry also need to maintain a healthy level of cash holdings, a key attribute that affects the profitability of the corporations and the stakeholder relationship (Dimitropoulos et al., 2019). Indeed, stakeholder engagement and relationship management, internal and external, is vital for the value creation of a corporation (Giacomarra et al., 2019; Marques et al., 2019).

The principal approach of this study is a qualitative analysis consisting of a stakeholder analysis and conduction of personal interviews with the identified stakeholders to accomplish the objectives set. In addition to this, quantitative data are cited to back up the importance of serialisation implementation and the expected added value for the pharma supply chain.

The remainder of the study is organised as follows: section two is devoted to the literature review, section three is focused on the data and methodology, section four relates to the analysis of results, the discussion of the findings for the study are in section five and section six is devoted to the conclusion of the study.

2 Literature review

The literature review provides a discussion about the implementation of serialisation in the pharmaceutical industry in scope of regulators, standard associations, manufacturers, equipment suppliers etc. It debates what is expected to be the gains for the industry, the regulatory requirements and the timelines for the pharmaceutical industry to conform to the regulations. Although the discussion about it started a long time ago it is still not yet implemented in a big scale. Therefore, sources are mainly limited to regulations, equipment supplier's solutions proposals as well as reports deriving from countries already experienced serialisation implementation.

2.1 Serialisation

According to Wajsman et al. (2016) the pharmaceutical industry presents approximately €10 billion loss annually due to counterfeit medicines in the EU marketplace, corresponding to 4.4% of the sector's sales. The World Heath Organization estimates that between 1–10% of medicines are spurious/falsely labelled/falsified/counterfeit (SFFC) with some areas of the world having an incidence as high as 30% or more. The main aim of the pharmaceutical companies of delivering effective treatments to patients and their commitment to public health and safety is being compromised by counterfeit and falsified medicines. Therefore, it is obvious that the pharmaceutical industry more than any other industry has adopted track and trace methods and serialisation among them. As it was mentioned above pharma industry is affected due to large profits of the illegal industry due to numerous and expensive treatments and medicines. Furthermore, the fragmentation of the supply chain due to the constantly larger number of intermediates (wholesalers and retailers) increases the possibility of development of alternative routes and markets according to Barchetti et al. (2009). A typical pharmaceutical supply chain and secondary illegal routes as well are described in the next section.

To this day, information that is printed on every carton is "human readable data" such as a lot number and expiration date for the information of the patient and a data matrix, a two-dimensional barcode that includes all this information. Upon the implementation of serialisation, a unique serial number (alpha, number or a combination of them) will be printed along with the other attributes on down to the lowest unit of sale, the case. The next stage of serialisation implementation is serialisation of bigger units of sale like carton and pallet. Norfeldt et al. (2019) suggest a new concept of cryptopharmaceuticals where pharmaceutical products are connected in a patient-specific blockchain of individual dosage units. Taking into consideration the threat for the public health, the great loses for the pharmaceutical industry and the increasing phenomenon (according to European Medicines Agency more and more medicinal products are being falsified), implementation of serialisation is considered to be critical for the fight against counterfeit and falsified drugs.

2.2 Global regulatory framework and timeline for the implementation of the regulations

The counterfeit and falsified products problem was growing faster during the last decades but at the same time the knowledge about it and the measures taken are also improving in the direction to restrict it. National laws were issued demanding a high traceability level in the pharmaceutical supply chain from manufacturing to distributing. Regulatory requirements are already fully or partially embraced, creating worldwide a complex environment for all key players of the pharmaceutical supply chain. Different regulatory frameworks are setting them challenges to ship serialised drugs to markets complying with the local laws.

One of the first attempts of increasing the traceability of the prescription drugs in order to have a better control of the market is the law issued in Italy in 2000. According to Biffoli (2008) the application of a special sticker containing a serial number and bar code to each unit of sale, and the recording and archiving of each serial number was required. Since Bollini law was issued, other EU countries according to Rotunno et al. (2014) attempted also an early implementation of the serialisation idea including Belgium

(Code National(e) Kode) using unique identification number made up of seven digits that is granted to each product for each form of packing and the 13-digit CIP in France. Similar attempt was done also in Greece by National Drugs Organization enforcing the use of a genuine sticker including a unique 12-digit serial number. Developing countries that faced bigger challenges in terms of having many more illegal products in their drug supply chain had to implement it sooner to mitigate risks and loses. For example, Turkey has 7 years of experience of serialisation implementation whereas in Brazil and China it's mandatory since December 2016 and December 2015 respectively.

According to 'H.R. 3204 Drug Quality and Security Act' (2013) item-level serialisation will be mandatory by November 2017 for all prescription drugs that are aimed at the US market.

The description of the global regulatory framework related to serialisation, summarised in Figure A1 (Appendix A) from the first attempts until now demonstrates that there is a period for the interested parties before implementation of serialisation becomes mandatory.

2.3 Drug supply chain description

First step in the drug supply chain is the manufacturing of the finished product. After product leaves the manufacturer's premises it goes into the distribution, passing through wholesalers, re-packagers, hospitals and pharmacies ending up to the patient. This is a version of a quite simple path. It can be more complex with more than one intermediate in its way to the patient. The complexity of the supply chain, the existence namely of many intermediate stations, is one reason more that makes implementation of serialisation a necessity. The typical drug supply chain as presented by Smith et al. (2015) is shown in Figure A2 of Appendix B. Directives imposed (Commission Delegated Regulation (EU) 2016/16, Drug Quality and Security Act, H.R. 3204) set the new requirements for the safety attributes in order to have a better overview of the medicinal products routes in the supply chain. Serialisation mainly (unique sales unit identification) as well as tamper-evident seals are extra measures to deter entry of non-authentic drugs into the supply chain. Identification of a product pack is achieved by printing a randomised serial number most commonly using a 2D barcode. Furthermore, in order for the serial number to be effective, a data sharing and management system is required. Information about product's destination or its previous statuses is available for every authorised stakeholder within the supply chain to be able to control and verify product's authenticity. In a typical supply chain presented in Figure A2 all stakeholders between manufacturer and patient along the legal route have also the responsibility to control and verify case authenticity before it reaches the patient.

2.4 Business challenges

Regulatory serialisation mandates have come in force some years ago with the intention of preserving the public health. At the same time pharmaceutical industry expects to take advantage of the potential benefits that will be derived from serialisation. Nevertheless, implementation of serialisation comes with big challenges for those that are moving in the direction to comply with the regulations; challenges are summarised in investment costs, data handling, supply chain complexity and CMOs and are cited in more detail below. According to Sanghavi et al. (2016) many pharmaceutical companies in Greece

have invested millions the last decades to upgrade their packaging lines aiming to increase their productivity, efficiency and status in a very competitive international environment. In order to comply with the regulations more investments will be required to install and validate serialisation cutting edge technology. Business processes are about to change with the implementation of serialisation as well as the way finished products are managed. According to Sanghavi et al. (2016) estimations in order to introduce serialisation to a packaging line will be required from $250,000 to $1,000,000 per line depending on the complexity and level of pre-existing automation. Downtimes, lower productivity during installation phase and first steps of its operation are also major challenges that the manufacturers already face or will face in the future. Finally finished goods and warehouse management involving both serialised and non-serialised products will be a difficult task until serialisation is fully implemented worldwide. The increase of investments, temporary decrease of productivity and efficiency and significant changes in business processes are about to apply more pressure to pricing and profit margins according to Sanghavi et al. (2016).

Another challenge the pharmaceutical industry might face is the handling of the CMOs. It is very typical that pharmaceutical companies due to restricted capacity employ contract manufacturers, which could be proven to be a great challenge for both pharmaceutical companies and CMOs to meet demand, maintain their profit margins and avoid turnover decrease.

Another issue of significant importance is data management. In order to comply with the directives data should be kept for many years after the drug production. Data will need to be easily accessible to achieve compliance including national authorities' inspections and customer audits. Handling of serialisation data will be a challenge for the industry; however, all this amount of data will be used to support business processes. Sanghavi et al. (2016) debates that for this reason all this information should be readily accessible and highly responsive. Finally, as the complexity of the drug supply chain increases, it should be assured that all the generated data is exchanged among the players of the chain without disruptions. In order to achieve the expected results, a common 'language' is required.

2.5 Added value for the pharmaceutical supply chain

Implementation of serialisation could not only give all key players of the pharmaceutical supply chain competitive advantages but could also add value to the quality of public health. Below the added value deriving from the implementation of serialisation is briefly described.

Despite the key driver of the regulations issued, the prevention of public health, it will bring benefits for the organisations that will implement it. The implementation of serialisation would provide a big amount of data for the marketed drugs. This will have important value for all involving stakeholders in order to support decision making for the promotion of public health. Therefore, the necessity to comply with the regulations is not the only stimulus for the implementation of serialisation.

According to Sanghavi et al. (2016) areas of value include better patient care, inventory visibility, the ability to identify diversions in the supply chain, and improved business processes in areas such as: reverse logistics, returns processing, product recall, product authentication, and brand protection.

Rotunno et al. (2014) debates that track and trace systems and especially serialisation and aggregation can in fact be implemented to materials management and inventory control, sales and distribution monitoring, counterfeit, diversion, and theft prevention. Serialisation assures the entry only of legal products deterring falsified, counterfeit, stolen or smuggled products. It prevents expired, prohibited or recalled products from entering the supply chain. Despite the fact that for the majority of the key players of the pharmaceutical supply chain material management is carried out by using an ERP system, the implementation of serialisation will contribute to a better shelf life and inventory control. It will work as an additional measure to an organisation's quality system to control the materials and products flow in a warehouse and play a supplementary role to avoid additional costs due to inadequate material management e.g. drugs expiration dates or disposal of expired ones.

Another expected application of serialisation is the improvement of sales and distribution monitoring. Serialisation would be a very useful tool not only as an extra assurance for the quality of the product but also for reducing direct and indirect costs. Data obtained from serialisation will provide a full knowledge of the route of the product in the supply chain from the manufacturer (when, where and who produced it) to the patient. Control of the supply chain is performed currently using track and trace systems. However, serialisation requires more information providing full traceability, essential information that is required to optimise returns and recalls, expediting procedures and reactions times minimising the risk of lost sales and protecting of the brand at the same time.

Finally, the expected business added value of the implementation of serialisation is the main reason for the falsified/counterfeit directives enforcement, the battle against counterfeit drugs, the diversion and the prevention against theft. Upon the implementation of the project using databases, drugs data could be at any time verified by anyone from the manufacturer up to the pharmacist. Collected data could also serve as a tool to avoid direction of drugs to markets that could be sold more expensive than others while medicines acquired by thefts could not be returned to the legitimate supply chain.

Several studies, Barchetti et al. (2009) and Moreno et al. (2011) debated the positive impact of these systems on production processes and supply chain efficiency. Referring to logistics and supply chain efficiency, traceability technologies are found to be non-invasive. They do not actually affect the work of carriers except for a partial slowing down, which, even in an application where reliability and delivery time are the main competitive according to Moreno et al. (2011) is largely compensated by cost reduction, compliance achievement, and safety enhancement.

Collection and availability of data facilitates according to World Health Organization (2016) an efficient supplies management at all health system levels and the development of specific. Consequently, expenditure for the medical products that burdens national systems is expected to reduce. Finally, it ensures the safety of the patients using medical products by minimising the risks, since it assures that only products manufactured in a quality system circulate in the supply chain.

2.6 Stakeholder analysis

Freeman (1984) defines stakeholders in the commercial arena as "any group or individual who can affect or is affected by the achievement of the organisation's objectives, showing some congruence. Stakeholders include interested groups who are affected by

the issue or those whose activities strongly affect the issue; those who possess information, resources and expertise needed for strategy formulation and implementation; and those who control the implementation of the various responses FAO (2007).

Stakeholder analysis, as a management tool is used to scan the internal and external organisational environment. It can be used to obtain a complete knowledge of the objectives and intentions of the all interested parties for an organisation or a project, behaviours, interrelations between them as well as to understand their role in the organisation and in decision making (Brugha and Varvasovszky, 2000). All data obtained from the stakeholder analysis are used for understanding needs and expectations of the stakeholders for the project and how these expectations could be met, being useful for developing new strategies or change policies for the implementation of the project. In this research data will be used to understand what the stakeholders expect from the implementation of the project, the level of their participation and analyse the impact of the implementation of serialisation on each of the stakeholders independently and onto the pharmaceutical industry in Greece in total.

Stakeholder theory is developed for different areas including several models. Briefly Donaldson and Preston (1995) argued that the stakeholder theory has advanced and has been justified in the management literature based on its descriptive accuracy, instrumental power, and normative validity.

According to Buchholz and Rosenthal (2005) stakeholder theory is in some respects responsible for the theoretical development of several fields like management studies, business administration, public policy and international development. Although the roots of the stakeholder theory are in strategic management, since then it has been implemented in fields like corporate social responsibility, ethics, health, information technology, marketing, research management, project management etc.

Furthermore, non-identification of the stakeholders or deficient consideration of their expectations and needs or the relations between them could be a failure reason for a project. Project Management Institute (2008) argues that "managing a project includes adapting the specifications, plans and approaches to different concerns and expectations of the various stakeholders". It becomes obvious that most of the project management researches conclude that stakeholder analyses play a key role in the successful implementation of a project.

2.7 Applying stakeholder theory to the research

Taking into consideration the literature review, the stakeholder analysis applied in this research is a simple analytical approach that consists of three out of four steps: Stakeholder identification, Prioritisation and Mapping. The conceptual framework for the Stakeholder Theory applied in this study is shown in Figure A3 (Appendix D).

2.7.1 Stakeholder identification

The first step of stakeholders' analysis is the identification of the stakeholders. According to Mitchell et al. (1997) there is a need for a theory of stakeholder identification that can reliably separate stakeholders from non-stakeholders, as each group will exist within a complex network of intertwining relationships. It's a very important stage, since this is the step of the stakeholder analysis when stakeholders are identified taking into consideration the project being studied. In terms of serialisation many different

stakeholders can be identified. It is obvious that except for those that are directly involved to the supply chain, from the manufacturer to the patient, other groups participate in the project one way or another such as regulators, standard associations, equipment suppliers and material suppliers, each one having his own expectations. At this stage and according to Walker et al. (2008) stakeholders are identified after taking into account the specific parameters of the project that suggest the way they influence or are impacted by the project. Furthermore, in order for the impact of the project to be identified Mitchell et al. (1997) argues for the importance of stakeholders' identification.

2.7.2 Stakeholder prioritisation

In terms of prioritisation of the stakeholders according to Elias et al. (2002) three factors are used for the evaluation of the importance of stakeholders: Power, Proximity/Legitimacy and Urgency. Mitchell et al (1997), based on Freeman's theory, developed the theory of stakeholder salience. Walker et al. (2008) proposed the quantification of these factors used to assess the importance of the stakeholders using an ordinal scale of 1–5. Moreover, the stakeholders could be classified as internal or primary and external or secondary having as basic criterion or the classification their link to the project. In addition, a differentiation of the external stakeholders is suggested into public and private. McElroy and Mills (2000) propose a more detailed five-levelled model: active opposition, passive opposition, non-committed, passive support and active support. The differentiating factor in this case is the role of the stakeholder in decision making. This study will categorise stakeholders depending on their viewpoint on the success of the project.

2.7.3 Stakeholders' mapping

Stakeholders' mapping is to take place using data collected from stakeholders' identification and prioritisation. There are several techniques of conducting stakeholders' mapping available in the literature, with usual tools being matrices/grids. Johnson and Scholes (2002) introduced the later very commonly used power/interest matrix that was modified to be applicable to project management. Furthermore, discussions over salience model on Mitchell et al. (1997) and Bourne and Walker (2006) introduced the classification using power, urgency and proximity as attributes. They used proximity instead of legitimacy in order to avoid legitimacy's restriction. Nonetheless, it's possible that being attached to traditional power-based matrices, other attributes and the dynamic nature of stakeholder environment are not considered. 2D matrices are most frequently used due to their relevant easier application. In a two dimensions matrix, characteristics like power-interest, importance for success-expectations and much more are used to classify stakeholders giving the capability to separate area to many different segments in order to have a more analytical categorisation. Finally, more sophisticated mapping tools can be found in the literature such as 3D matrices using characteristics described above but because of their complexity they are not very commonly used. During mapping, relations between stakeholders will be displayed, achieving to visualise not only stakeholders' characteristics but also their relations. It's obvious that power-based matrices have strengths and weaknesses examining every time which is the most appropriate tool for the case. The current literature on serialisation is restricted to regulations and project analysis by solution providers and consultants. Thus, the

experience from the serialisation application in other countries and the use of other methods are concluded in the expected added value and business challenges that organisations will face. In this study, since serialisation is in the implementation phase, the standpoint and level of readiness of the interested parties in Greece is given. Challenges that the organisations in Greece face is demonstrated by the literature review. Finally expected added value from the serialisation application in Greece and the post implementation environment is delivered.

3 Data and methodology

3.1 Qualitative vs. quantitative research

Indeed the number of the experts in this field of pharmaceutical serilaisation is restricted. The study aims to understand and analyse the impact of the implementation of a project on an industry and not to test a hypo study or make predictions. The nature of the results of the research are industry-specific making it difficult to generalise to other populations or industries. Findings due to the features of the study could be a guide for other countries using the experience of the implementation of the project in Greece. Data that is possible to be gathered is words, experiences and opinions showing the subjectivity of the field's experts and not numbers and statistics where objectivity is needed. Finally, the report that will be delivered as a consequence of the collected data and the type of the expected results would be, in the case of a qualitative analysis, a narrative report including directly the opinion of the research participants and in the case of a quantitative analysis a report with statistical analysis, correlations and comparisons of values. Qualitative and quantitative data are gathered according to the following procedure:

- secondary data – regulations, consultant reports, studies about the impact of serialisation from countries having the experience of using it
- stakeholder analysis
- in-depth interviews with stakeholders identified in the stakeholder analysis.

3.2 Stakeholder analysis

Stakeholder analysis is to be conducted according to the literature review and by assessing their power on the project writing down their interests and expectations. In the next step using a model reviewed in the literature stakeholders are to be put in a map with regards to their interest for the implementation of the project and their power to influence or being impacted by the successful implementation of serialisation. Mapping is going to be conducted not only as an integral part of the stakeholder analysis that provides qualitative attributes for the deeper understanding of the project implementation but also as a tool that is going to be used to decide for the sample selection.

3.2.1 Stakeholder identification

The first step of the stakeholder analysis is about to identify the stakeholders involved. A list of all possible stakeholders is to be created. Individuals or groups that may participate in the project, people that could be impacted or could be able to influence the

implementation of the project will be written down. An initial assessment is to be made with the description and complete understanding of the drug supply chain (legal and illegal route of the drugs). Answering the question of what the challenges are derived from the implementation of the project could also be helpful to identify stakeholders. People involved in a project, either it's about a project within an organisation or it includes the supply chain in total, develop relations independently if they oppose or support the project. As such, this could provide some help, during the initial stakeholder identification, in order to be able to identify more stakeholders using the relations between them.

3.2.2 Stakeholder prioritisation

Once the list of stakeholders is created, the next step is to identify stakeholder's interests and expectations and assess their power and importance for the implementation of the project. Although this stage of the stakeholder analysis is proved to be very important for the knowledge obtained for the individuals or groups identified in the previous step, it's also affected by the limitations of the study. According to Schmeer (1999) stakeholders to be interviewed are to be prioritised, since the resources of the study are limited. The importance of the identified stakeholders is to be evaluated using the three factors introduced by Elias et al. (2002), Mitchell et al. (1997) and Walker et al. (2008). These factors are: Power – the stakeholder has power to influence the success implementation of the project, Proximity/Legitimacy – how and how much is a stakeholder impacted by an action or a change in the implementations parameters imposed by the regulators, Urgency – will the stakeholder be ready or have the attitude to proceed to solve a problem or react to an action alone or by taking into account other stakeholders? Finally, according to Walker et al. (2008) stakeholders are going to be ranked taking into consideration the three above mentioned factors on a relative ordinal scale of 1–5 using the table in Figure 1. In case a stakeholder is identified to have negative interest for the successful implementation of the project the ranking methodology is to be reassessed.

Interests, expectations and importance are summarised in the following table:

Figure 1 Tool for stakeholder analysis

Stakeholder	Interests / Expectations	Importance

Source: Table adapted from Applegate (2008)

3.2.3 Stakeholders mapping

Once data for the identified stakeholders is gathered, classification of them regarding their importance or level of interest for the successful implementation of the project will follow.

More analytical with the use of the matrix (Figure 2) the identified stakeholders can be classified into four categories regarding their importance for the success of the project and their interests and expectations for it. Stakeholder's position is plotted on the matrix according to the following guidelines:

A Stakeholders with low interest for the project and low power to influence the success of the project are classified in this area. Furthermore, these are individuals that face small impact from the implementation of the project.

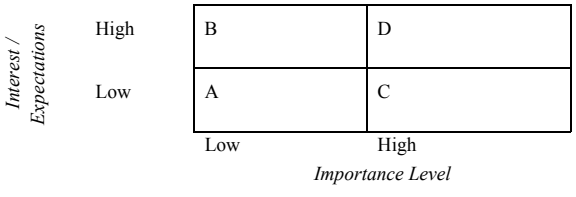
B Stakeholders classified in this category have a high interest but low power as the stakeholders of segment.

C This segment includes people with high power and low expectations of the project. Due to their power to oppose or defend the successful implementation of the project, their participation in the project is significant.

D The last segment of the matrix incorporates key players.

This segment includes the most crucial stakeholders that hold high power to influence the project outcomes but also the impact of the implementation of the project is also high. Finally, key players have also high expectations for the project that are to be fulfilled. Nonetheless since the project is dynamic, during the implementation phase, it is reasonable that the level of interest, firstly, and power, secondly, could possibly change moving stakeholders to other segments in the power-interest matrix.

Figure 2 Importance-interest matrix



3.3 Design of interviews

3.3.1 Interview selection

Since the interviews were selected as the main methodology of the research, the type of interview is a vital tool. Using an unstructured interview as a research tool has the risk of not focusing on the research questions and not covering topics that lead to the research objectives fulfilment. However, the design of a completely structured interview will not allow the necessary data collection owing not only to the volume of information needed but also to the study limitations for reaching several experts in this field. Therefore, implementing semi-structured interviews allows for an interview guide that can be prepared before planned interviews which in turn helps the interviewer and the interviewee to be prepared in contrast to the unstructured interviews. Being both prepared will ensure the quality of the conversation as well as the freedom to express their views in their own terms. Semi structured interview has been chosen as this kind of interview offers topics to the interviewee, to extract interviewee's ideas on the topic of interest, ensuring that the participant in the survey has a close overview of the topics to be discussed.

3.3.2 Identifying respondents

Respondents that are to participate in the research are going to be identified in the first step of stakeholder analysis. Respondents due to their position, field of expertise or engagement with the project, have a good knowledge of the implementation of the project. Finally, a respondent may be anyone from the identified stakeholder group taking into consideration the limitations of the study. The main requirement for the stakeholder group representative is not only the understanding of serialisation as a project imposed by the regulators but also her/his involvement with the implementation of the project.

3.3.3 Sampling

As it was mentioned before, in the stakeholder analysis section, the results from the analysis will be the guide to decide who will participate in the survey as well as to determine the number of the participants. According to Flick (2009) the interviewees should have the necessary knowledge and experience of the issue or object at their disposal for answering the questions in the interview. Sample size and the allocation of the interviewees to the stakeholder groups are to be decided with regards to the results of the stakeholder analysis e.g. in the stakeholder groups with more power and interest, more interviewees will be allocated.

3.3.4 Preparing the interviews

Once the relevant stakeholder groups have been identified, the interview guide is properly formed to bring out the necessary information to fulfil the objectives of the study. The interview guide considering moral and ethical issues is communicated to the participants of the survey before the interview conduct. The establishment of ethical guidelines is communicated both at the design phase and during conducting the interview. Interviews are conducted per telephone or whenever is possible in person. During interviews notes will be taken when the interviewee does not permit tape recording; notes or transcription will be communicated to the interviewees after the discussion to confirm that their opinion comments were accurately captured. Finally, besides the topics communicated to the interviewees, questions and necessary clarifications are also prepared to increase the quality of the extracted information.

4 Analysis of results

4.1 Stakeholder analysis

4.1.1 Stakeholder identification

As a first step of the stakeholder analysis the participants of the pharmaceutical supply chain are identified. There is an initial assessment of their role in the drugs chain and how they are or will be involved in serialisation. Identification of the stakeholders is accomplished following the drug end to end flow across the pharmaceutical supply chain.

Raw materials manufacturers: Active pharmaceutical ingredients (API) and excipients manufacturers are the start point of the supply chain. However, they are a very crucial part of the pharmaceutical supply chain, they are not until now in the scope of

serialisation and for this reason raw materials manufacturers will not be further examined.

Packaging material manufacturers: Manufacturers that supply finished goods manufacturers or re-packagers with packaging materials. They do not produce, transfer, store, or distribute medicinal products, they participate "indirectly" to the pharmaceutical supply chain. Possible changes in the case patterns due to serialisation could involve them as strategic partners of the manufacturers.

Finished product manufacturers: One of the most vital parts of the pharmaceutical supply chain. Product manufacturers transform raw materials to finished product. According to FDA (2017) a manufacturer is also defined the approved application holder, or co-licensed partner of the approved application holder who obtained the product directly from the application holder or person who manufactured the product. They are involved in the project more than the other stakeholders. As far as they are concerned finished product manufacturers must invest, design, plan, control and implement the project in order to comply with the regulations and be able to ship to any market that serialisation is enforced. Their engagement to the project and its implementation will not only have an impact on the organisation but also influence their partners in the supply chain.

CMOs: Due to the restricted capacity of finished product manufacturers, in order to meet demand, they collaborate with contract manufacturers for the production of intermediate or finished product. They are involved at the same level in the project with finished goods manufacturers. Thus they are impacted by the regulations enforcement and their readiness, at the time regulations will be effective, will influence also other players of the supply chain.

Re-packagers: Contract manufacturers that are involved with the packaging of intermediate products. FDA (2017) defines a re-packager as person who owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction. Similar with finished product manufacturers and CMOs, they are fully involved in serialisation.

Wholesalers/Distributors: According to FDA (2017) wholesalers/distributors are engaged in distribution of a drug to or receipt of a drug by, a person other than a consumer or patient, with certain exceptions. They are at some point impacted from the serialisation implementation. They are called on the one hand to manage data received from their suppliers and send them to the next stage of the supply chain. After serialisation wholesalers will be able to count on aggregation data received from manufacturers.

3PLs: An entity that owns, rents, or leases a facility where it warehouses product, but does not take ownership of, or direct the sale or disposition of the product, is a 3PL under DSCSA. Third-party logistics providers will participate in the new landscape that takes shape with the implementation of serialisation. Since 3PLs do not take ownership of the product it is not expected that serialisation will have a great impact. However, in case 3PLs manage tasks on behalf of their pharmaceutical customers they'll have to adopt a serialisation solution.

Transporters: Transporters are responsible for transporting finished products, raw materials, packaging materials to the next step of the supply chain. For the quality of the product to be assured, logistic companies have to comply with the quality system of their

"customer". Regarding serialisation there will be a verification of the shipped goods and product status update like every downstream supply chain actor.

Pharmacies: Pharmacies, either physical or electronic, are the last step of the pharmaceutical supply chain before patient. They are not involved in serialisation in a great extent except the last status verification before medicines end to the patient's hands.

Hospitals: Hospitals are also the end of the drug flow providing finished products to patients. As pharmacies, they are the last verifier of the drug, before it is dispensed to the patient.

Equipment/solution providers: Equipment manufacturers or local representatives that provide machinery to the manufacturers. FDA (2017) considers a solution provider to be a person or entity that provides other entities hardware, software, or systems solutions to help achieve compliance with the requirements under DSCSA. They are not a direct actor of the pharmaceutical supply chain but in terms of serialisation, their capability and readiness to provide with proper solutions for packaging lines to comply with the regulations play a crucial role for the implementation of the project.

Standards associations: Organisations that develop and maintain global standards for business communication. Regarding serialisation, standard associations introduce identification systems accepted from all key players of the pharmaceutical supply chain and serve as an ally for the manufacturers to comply with the regulations.

National medicines regulatory authorities: MRAs are responsible for the regulation and control of medical products such as medicines, vaccines, blood products and medical devices (World Health Organization). They are the regulators that enforced the falsified/ counterfeit laws. MRAs' role in serialisation will be the control of the implementation during inspections.

4.1.2 Stakeholder prioritisation

At the next step of the stakeholder analysis a list including all the identified stakeholders of the project is cited. Interests, expectations and importance of each stakeholder identified are described and finally stakeholders are ranked based on their importance for the project using the three factors introduced in the literature review: Power, Proximity / Legitimacy and Urgency. Furthermore, interests and expectations are written down and ranked also on a scale of 1–5 in order to proceed with stakeholders' mapping. Finally, under assessment qualitative attributes are summarised in Table 1.

Packaging materials manufacturers as mentioned in the stakeholders' identification are barely impacted from the implementation of the project. The upcoming application of serialisation will possibly bring some changes in the cases' patterns. However, this kind of requirements is common and is not expected to impact their production lines. Therefore, it seems that they do not have any power to influence in any way the project and the other stakeholders. Packaging materials manufacturers don't have any expectations for the quality or timelines of the deliverables and their interests are restricted to the successful accomplishment of the project from their strategic partners' point of view.

Table 1 Stakeholders ranking- prioritisation

Stakeholder	*Interests/Expectations*	*Importance*
Packaging materials manufacturer	1	1
Finished product manufacturer	5	5
CMOs	5	3
Repackagers	5	4
Wholesalers/distributors	4	2
3PLs	3	2
Transporters	2	1
Pharmacies	2	2
Hospitals	2	2
Equipment Providers	4	5
Standard associations	2	4
National Medicines Regulatory Authorities	1	5

Finished product manufacturers, as cited in the previous section, are highly impacted by the enforcement of the regulations and their position in the pharmaceutical supply chain makes them capable to influence others. Since according to Grand View Research (2016) it is expected that more than 75% of medicine supply by 2018 will be serialised, the necessity to comply with the regulations will be of major significance. However, implementation of serialisation seems at first sight to involve upgrading packaging lines upgrade but technically is affecting a series of business processes in the organisation. Project teams had or have to be built and close cooperation of different departments is required for a successful project delivery. Nevertheless, manufacturers' expectations for the project are not restricted only to internal stakeholders. Cooperation with both upstream and downstream actors of the supply chain is needed. Thus, except from their interest and necessity to comply with the regulations, manufacturers expect that the increased product traceability will lead to a more efficient supply chain. It is expected that besides the fall of their losses due to the decrease of the counterfeit medicines, it will help to increase efficiency of their packaging lines. Furthermore, a more efficient supply chain is expected to make business processes as warehouse management and recalls more efficient with benefits both for the patient and them. The big amount of data that serialisation will generate, will not only make recalls an easier task but it is also expected that processes like deviations investigation, customer complaints investigation as well as batch releases will be carried out in a more efficient way. Taking into consideration the necessity to comply with the regulations, manufacturers should follow any change in the serialisation attributes proposed by the regulators. Finally, it is obvious that manufacturers seem to be a very powerful link of the pharmaceutical supply chain since their success in the implementation of serialisation could have a great impact on the success of the project totally.

Contract manufacturers appear to be impacted at the same level with manufacturers. Challenges from the implementation of serialisation both in the internal and external environment are expected to change business processes. Big capital investments are needed and a cross functional work would be a necessity. Contract manufacturers and

especially the smaller organisations may not be able to cover the cost of implementation (equipment upgrade, downtimes for installation and validation and possibly the temporary decrease of packaging lines efficiency). Since many of the CMOs have strategic partnerships with manufacturers, their capability to meet deadlines will be very important for an unhindered continue of their collaboration. Potential failure could bring them out of the packaging business or draw away also their partners who will not be able to meet demand. Summarising, the level of the implementation of the project could cause changes in partnerships or impacts on future deals. Manufacturers, in an attempt to support strategic choices, could absorb some of the costs of their CMOs or re-packagers. Thus this could mean bigger capital investments from the manufacturers and closer collaboration with these CMOs. It's obvious that besides their interest for the successful delivery of the project that will bring profits to a part of the legitimate supply chain, maintaining of successful partnerships or making new deals enabled by the application of serialisation are among their expectations.

Re-packagers, having packaging as the only business activity, will be impacted a lot from the implementation of serialisation. At a first glance re-packagers are expected to lose if they do not meet the regulatory requirements on time. Their incapability to ship serialised products could restrict them to have contracts only for markets that accept non serialised products, status that will not last for a long time due to the rapid expansion of the serialisation regulations worldwide. On the other hand, being ready when the regulations will be effective could give them a competitive advantage. The experience of countries that already implemented serialisation demonstrates that re-packagers could take advantage of the potential inability of manufacturers and CMOs adding to their activities the serialisation and aggregation of already packaged products. As a consequence, their ability to be ready on time will define their strategy enabling them to maintain their current contracts or expand their customer list.

The roles of the *Wholesalers/Distributors* like the other downstream supply chain actors are within the serialisation framework responsible to comply with the regulatory requirements, verifying the authenticity of the product. Furthermore, inventory management, data management (serial numbers) and reporting will be among the tasks in daily routine when serialisation is effective. Among their interests about the project is the verification of the received data and how they are going to rely on the upstream aggregation data. However, they don't seem to have power to influence either the successful implementation of the project or the other stakeholders.

Indeed, the*3PLs* in order to comply with the regulations need not only to implement a serialisation solution but also make changes in business processes are needed. In the frame of serialisation application it is possible that 3PLs will be connected to the national database, like every other downstream supply chain downstream actor, to verify the authenticity of the product and update the product status before the product is shipped to the next station within the supply chain.

Hospitals and pharmacies are the end point participant in the supply chain before treatment is dispensed to the patient. The only change for them is expected to be the verification of the status of the drug that they are going to dispense. As all pharmaceutical supply chain actors, they will have access to a database to confirm the authenticity of the product. There is no participation of pharmacies and hospitals in the implementation

phase of the project. Finally, for the above-mentioned reasons these stakeholders do not seem to have any power to influence the progress, success or quality of the research.

Equipment solution providers, as cited before, do not directly belong to the pharmaceutical supply chain but their interests for the implementation of serialisation place them in the serialisation stakeholders' group. The solutions that they are providing to manufacturers, CMOS, re-packagers and 3PLs are substantially the core of the project. Appropriate planning to manage their capacity and resources to deliver solutions on time is proven to be very crucial. Late expression of interest of their customers could result to late delivery or rejection of adopting the project. For equipment manufacturers the success of the project is restricted to the delivery of the equipment and sometimes maintenance contracts for the provided system or solutions for the data management needed in the near future. They are widely impacted since they must meet higher demand in a short period of time. As far as they are concerned their deliverables and the quality of them could define the success of the implementation for other stakeholders like manufacturers, CMOs etc. Equipment providers are supposed to be sensitive to changes of the regulations since any change in serialisation parameters is possible to cause reconfigurations in the system and as a result delays in project delivery.

Standard associations work in parallel with the national medicines regulatory authorities to assist manufacturers. Their importance in the pharmaceutical supply chain is that they provide their business partners a common language to support processes worldwide. Such means of communication such as barcodes, standards and serial numbers are not only proposed by the regulators, but also totally accepted by the other supply chain key players. In case of serialisation this means of communication between supply chain stakeholders could be critical for the successful implementation of the project.

National Medicines Regulatory Authorities are the agencies that issued the laws and directives and set the implementation period for the supply chain actors that are impacted to be prepared when the regulations will be effective. Among their interests is of course the compliance to the regulations as well as the control of the system after the grace period.

4.1.3 Stakeholder mapping

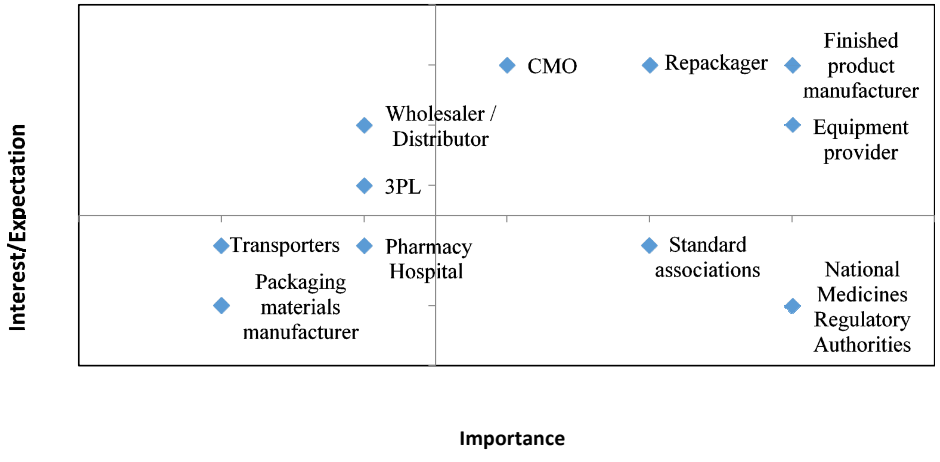
Following the stakeholder prioritisation and according to the mapping matrix indicated in the literature review, stakeholders are classified according to their importance and expectations of the study, shown in Figure 3.

4.2 Interviewees selection

According to the stakeholder analysis and the annotation that the analysis focused on the implementation phase finished product manufacturers, equipment providers, CMOs, and re-packagers are classified as the most crucial stakeholders. These stakeholders according to the stakeholder analysis are impacted at a high level from the implementation of the project and at the same time hold power to influence it. Following the stakeholders mapping and taking into consideration the limitations of the study the interviewees' pattern is consisting of three manufacturers, two equipment providers and two CMOs. Due to the similarity of the re-packager's activity with the CMOs and since

CMOs are contract manufacturers both for manufacturing and packaging, one more CMO will be interviewed.

Figure 3 Stakeholder mapping (see online version for colours)



5 Study findings

Manufacturers: Three interviews took place with respective subject material experts representing drug manufacturers in Greece in order to accomplish the objectives of this study. On the question of what implementation of serialisation means for their organisation, all three interviewees answered, without much consideration, that it is an obligation for the organisation in order to comply with the regulations. At a second stage they identified the possible benefits for their organisations fact that highlights the difficulties of the project and the long period from the regulation's enforcement until the benefits of serialisation will be cognizable. One of the interviewees emphasised that "manufacturers are mostly impacted by the regulations enforcement", besides that "they should be the first in the pharmaceutical supply chain to implement serialisation" stated another interviewee. All of them paid attention to the big investments needed analysing one of them the fact that "it could be tough for the small players to deal with it". Besides that, concerns are expressed for a possible decrease of competitiveness. Their packaging lines efficiency is expected to decrease since an extra step in the packaging process will be added due to serialisation. Furthermore, setup times and time to restore breakdowns are estimated to increase at least for some time. Finally warehouse personnel are also affected adding extra tasks in their responsibilities or change the way they are working currently.

Regarding the current status that manufacturers have, one of the interviewees responded that they already received the equipment for the second packaging line while the first one is validated and ready to use when it will be required. The other two organisations are in the phase of receiving their first lines. All the respondents had formed project teams, created URSs either at a corporate or at site level and proceeded with the equipment provider selection. After the delivery of the first lines the interviewees describe that there is much to work to be done including installation and

validation of the equipment for all the lines, training of the relevant personnel while they consider a trial period very important. It is worth to be mentioned that all of them estimate that more than a half of the project is remaining.

However, according to the interviewees, implementation of serialisation is still in an early stage, they have a positive outlook about the project successful on time completion for their organisations. As the biggest internal challenge, during the implementation phase, according to an interviewee is to start changing processes slowly before the application of the project. After that, several processes will be imposed to change and "the attempt of the project team to convince people is really challenging" refers the interviewee.

Finished product manufacturers, as one of the first actors in the drug flow, have many downstream supply chain key players and a few upstream. Thus, coordination with the upstream and downstream trading partners is significant. The interviews participants mentioned that they are already in conversations with their packaging materials providers, but it is too early to conclude to a case pattern. On the other hand, as they highlighted, they are monitoring (one of them with the use of a questionnaire) their CMOs and re-packagers to have a close overview of their partner's level in serialisation implementation.

The interviewees confirm the complexity of the project as described in the literature review and stakeholder analysis. Project teams responsible for the site's serialisation implementation consist in any case of production, technical, IT, and QA with IT playing a significant role in the project. Nevertheless, as well as the above-mentioned other departments also participate in the project like procurement and financial services, planning, logistics etc. All the interviewees agreed that the project is mainly IT more for the implementation phase and less when serialisation is in "operation mode".

Finished product manufacturers, as all representatives that participated in the interviews are expecting that, when the packaging lines will be called to produce serialised products, they will not avoid problems. However, all are optimistic that after training sessions for the relevant personnel and experience building human errors will decrease.

CMOs: To gain insight of how CMOs in pharmaceutical industry in Greece face serialisation, a subject material expert of a CMO company was interviewed. Implementation of serialisation is firstly seen as a necessity to comply with the regulations. Since industry is in the implementation phase currently, CMOs like every other stakeholder do not have the chance to gain from the added value serialisation is expected to bring with. Firstly, they are expecting that plenty of time will be needed to install and qualify the necessary equipment. Operators, technicians and other relevant personnel should be trained appropriately. Due to systems complexity and changes in the workflow confusions will be created and as a result downtimes and lower packaging line efficiency will appear. In order for human errors to be avoided appropriate operating procedures should be written and a special reference is made by the interviewee about the necessity of training. Impact of the implementation of serialisation is not restricted to production or packaging but it will affect the majority of processes in the site until product is dispatched. The current status of the organisation according to the interviewee is the application of a pilot program in order to cover a small demand of customers that ship to markets that serialisation is effective. However this pilot program is much simpler than the one that is going to be installed, it contributes to the identification of errors

assisting to a smoother transition to the main system solution. Installation of the first packaging lines is about to start until all available packaging lines are capable to produce serialised products. The interviewee appeared certain that the organisation will be able to meet deadlines since serialisation is mandatory from the beginning of 2019 and onwards for organisations' main markets. Besides that, there is a pilot program installed that could satisfy the demand in a specific manner. The interviewee has identified the lack of experts in the field as the biggest internal challenge of the organisation. For all personnel involved in the project, as the interviewee mentioned "serialisation is a new idea and has to be built from the foundations". Besides that, solution manufacturers and providers are also beginners for a system that has not been tested in normal production conditions. Regarding external challenges that might appear the interviewee highlights the fact that all stakeholders (organisations' trading partners) have started. The organisation is a downstream supply actor that its readiness could influence manufacturers for example but is not exposed at a high level in a possible delay of their upstream partners' implementation. According to the interviewee "since the project has a global directive about its implementation in all sites of the organisation directions for implementing are coming from corporate departments". User requirement specifications (URS) for the system and policies have been prepared and sent down to all sites. Project teams have been created consisting of Production, QA, Technical services and IS in order to implement the project depending on the local requirements and unique characteristics. The interviewee marks the difficulties the organisation will face in the post implementation phase: "It would be a tough period for all especially production department until serialisation will be a daily routine for packaging personnel". Furthermore, besides continuous training that is proven to be self-evident, special attention should be paid from all directly involved personnel in order for mistakes to be avoided. It is highlighted that all this data obtained will improve many processes such as investigations for deviations from the procedures and customer complaints investigations. It will be more effective to having in parallel the ability to proceed to a corrective or preventive action. Finally, special attention is paid to the release process expecting that generated data will be an extra safety measure making the release of batch an easier task.

Equipment/Solution providers: To explore the impact of serialisation implementation on the equipment providers, two representatives of the biggest European houses in Greece were interviewed. They are local representatives of both equipment manufacturers and software solution providers and regarding serialisation they represent alliances formed for this reason. According to one of the interviewees "in the next two years 4000 new packaging lines will be delivered in Europe". As a result, it is obvious that Europe is and will be in the rush of the project implementation to meet deadlines. Due to the high demand and restricted capacity there are already bottlenecks in their manufacturing lines observed. According to the interviewees there is a high order accumulation and the short time period creates delays for them and their CMOs also. Nevertheless among the positive impacts is that the implementation of the project "boosted the pharmaceutical equipment market" and as a result increased the annual turnovers of the equipment manufacturing houses. Both interviewees demonstrated that the manufacturing lines of the companies they represent have approached the limits of their capacity. As a consequence in combination with the bottlenecks created, expansion of the lead times is a very common phenomenon for the projects that are currently starting. One of the

interviewers underlined the fact that while lead times one year ago were four to six months now they are almost eighteen months.

According to the interviewees, all the pharmaceutical supply chain main participants in Greece, such as the manufacturers, CMOs and re-packagers, which must install new equipment for serialisation have already selected the equipment provider. To the majority of them, equipment manufacturers have provided pilot programs to meet the demand temporarily of countries that serialisation is already routine like South Korea or Turkey. One interviewee referred that "those that started the procedure six months ago have already installed and validated their first line". Nevertheless, equipment providers are in the phase of delivering the first packaging lines. Individual projects have been assigned from the manufacturers to the equipment providers. Thus currently they have an overview of what is done and what remains to be done. According to their estimations they are at the beginning of the project and many more packaging lines are to be delivered. Furthermore, one of the interviewees debates that deliveries will be intensified in Q3 of 2018, since most of their customers hope that they will have the packaging lines until October in order to have time for tests and a trial period. Both interviewees seem to be confident that they will deliver all the packaging lines that are handling currently by the end of Q3. As for the equipment that is ordered this period will have obviously an increased lead time.

As for the internal challenges one of the interviewees describes as most challenging the coordination between two organisations, hardware manufacturer and software solution providers, to provide one common combined solution. Moreover, they point out the necessity for efficient project management to deliver the maximum number of projects on time. Continuous communication with the customers from the design of the system until the delivery is critical to assure meeting the timelines and having high quality deliverables. However, while it seems to beevident, equipment providers identify communication as a very challenging procedure.

Taking into account the complexity of the project not only because of the implementation and application but also because of the design, configuration and setup of the system, many different departments should participate. According to both interviewees, sales, designers, software engineers, project engineers and field engineers, QA as well project managers for the coordination are among the stakeholders. In addition, one of the representatives highlighted the importance of the coordination between the hardware manufacturer and the software provider for avoiding problems and delays. However, the role of the equipment providers stops with the project delivery from one interviewee's point of view, "there will be a mess at the beginning of serialisation until all get used to it". Both of them highlight the necessity of training to mitigate the risks regarding the first period of its application.

6 Conclusions

Implementation of serialisation in the pharmaceutical industry brings great changes and it is expected to affect among others the whole drug supply chain. It is one of the latest trends in pharma industry and although it is not new as a concept its complete implementation would be a great challenge that could last for many years. Pharmaceutical industry in Greece is in the implementation phase with the majority having just started or accomplished a small part of it. The industry faces the challenges

and difficulties of a new project expecting to be ready for the time regulations will be effective.

6.1 Contribution to theory and practice

Serialisation, besides the reason of regulation enforcement and the protection of public health, will add value to the organisations that implement it. It is expected to increase the visibility and efficiency of the supply chain, reduce costs, improve sales and distribution monitoring and benefits will also be seen in the national system medicine expenditure. Stakeholder analysis identified and ranked the most important for the project stakeholders that are highly interested about its implementation success. These were, according to the stakeholder analysis, manufacturers, CMOs and re-packagers. Both from the stakeholder analysis and the interviews interests, expectations and importance were identified. It was highlighted that the key driver for the project implementation is the compliance with the regulations; however, stakeholders are expecting to yield benefits in favour of their organisation.

Stakeholders have just started the serialisation journey. On the one hand manufacturers and CMOs are at best in the installation of the first packaging line having much more to accomplish until they fully implement the project. On the other hand, equipment providers have many lines to be delivered. Nevertheless, stakeholders estimate that they will be ready basing their optimism to the long period ahead for the regulations to be effective. Finally, even if they will not be fully ready, they seem to be optimistic to meet the demand since a big part of their capacity is upgraded to ship serialised products. Post implementation environment is foreseen to be difficult at the beginning due to the complexity of the project. However, stakeholders that are going to apply serialisation, expect its benefits after an adaptation period. Implementation of serialisation is of course a compliance activity for the pharmaceutical industry to conform to the regulations.

6.2 Limitations

Serialisation is not yet fully implemented in the pharmaceutical industry in Greece; it's at the stage of implementation and this led to the choice of conducting in depth interviews. Furthermore, the fact that interviewees should have an expertise in the field (a fact that is required when conducting in depth interviews) reduces the number of available SME's in the Greek pharmaceutical industry. Furthermore, the small number of manufacturers and wholesalers and the availability of the experts in the field is also a constraint. Finally, it is to be considered that due to confidentiality many experts are not comfortable to discuss their strategic choices and more so their financial issues.

6.3 Future research

Serialisation should be interpreted as an opportunity to change business processes and a useful tool for improvement to take full advantage of the capabilities of the new system. The findings of the research could be the basis of further research for the stakeholders' engagement both for a successful completion of the implementation of the project and as a reference for future researches for the effectiveness of serialisation application.

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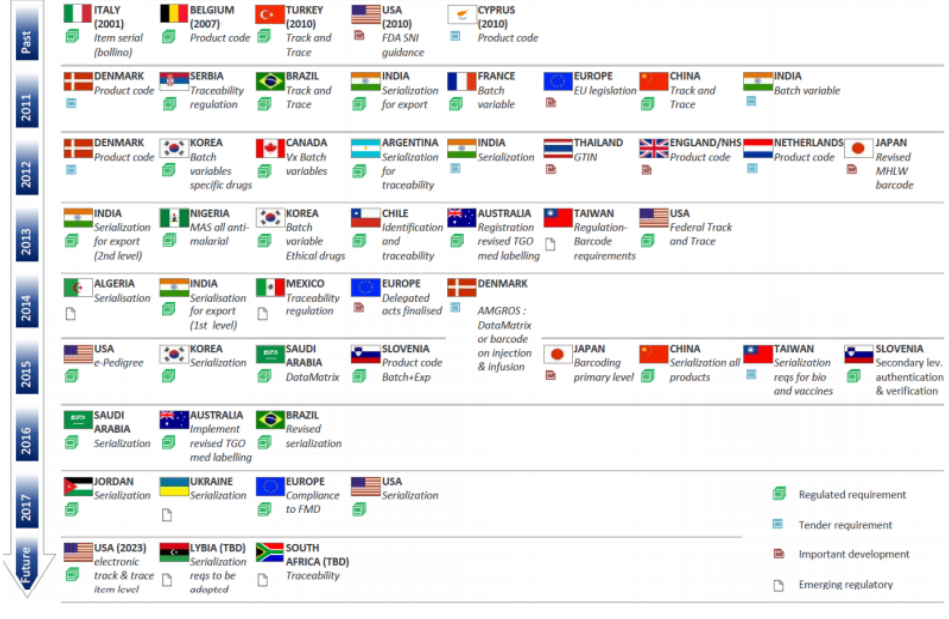
Appendix A

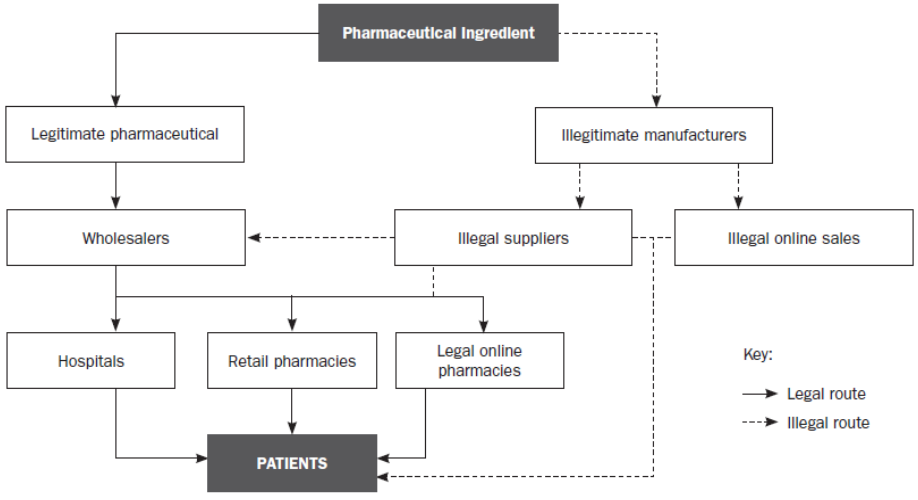
Figure A1 Global requirements summary (see online version for colours)



Source: Rotunno et al. (2014)

Appendix B

Figure A2 Typical drug supply chain



Source: Smith et al. (2015)

Appendix C

Interview agenda – Topics for discussion

"Assessing the implementation of serialisation in pharmaceutical industry in Greece: A qualitative approach"

Objectives of the interview

- Discover interests, expectations, challenges and importance of each stakeholder for the implementation of the project.
- Examine the activities already performed by each stakeholder for the implementation of serialisation in the pharmaceutical industry in Greece and also assess the level of readiness to face the new regulatory requirements.
- Explore the post implementation environment.

Topics for discussion

- What is the implementation of serialisation for your organisation and how do you expect to affect your organisation and the industry in general?
- Current stage of the organisation on serialisation?
- How confident are you to meet the project timescales?
- Internal business challenges

- External business challenge
- Aspects of the project
- Post implementation environment

Appendix D

Figure A3 Conceptual framework of stakeholder theory (see online version for colours)