The Importance of digital transformation processes in medicines regulatory authorities for E-Health

Tatjana Stojadinovic

eDevelopment and IT Management
Medicines and Medical Devices Agency of Serbia
Belgrade, Serbia
tatjana.stojadinovic@alims.gov.rs
0000-0002-8952-2205

Ilija Antovic

University of Belgrade
Faculty of Organizational Sciences
Belgrade, Serbia
ilija.antovic@fon.bg.ac.rs
0000-0002-2673-6628

Abstract— The purpose of this article is to explore the digital transformation processes in medicines and medical devices legislative. The goal of this paper is to introduce the relationship of e-business in the medicines regulation with e-pharmacy and e-health in order to improve public health. The methodology for the development of e-services, methods for modeling and analysis of business processes, the reference model of e-business in the medicines regulation, e-services for import license for medicines are the main scientific contributions of this work. This paper shows a case study which refers to e-services development for medicines in the marketing authorization, implemented in Medicines and Medical Devices of Agency of Serbia, which is a major professional contribution of this work. This research is based on a qualitative case study – the project "Digital transformation on business processes in medicines and medical devices regulation" conducted from year 2018. to 2022.

Keywords - digital health, e-pharmacy, medicines

I. INTRODUCTION

Electronic business (E-business) is a modern form of business for an organization. The concept of e-business is represented and applicable in all activities and areas1. In a few decades, digital technologies have transformed the way communication, business, production of goods and services function, and the way people live and work. For developing countries, the digital economy is a way to stimulate economic growth, raise capital and labour productivity, reduce transaction costs and facilitate access to global markets. The development of digital technologies brings numerous benefits to society in terms of wealth creation, technological advancement and improved quality of life.12

Medicines regulation is a process encompassing various activities that aim to ensure the safety, efficacy and quality of medicines, as well as the appropriateness and accuracy of product information. Medicines regulation is public policy that restricts private sector activities to attain social goal set by a given country2.

The development of e-business in the medicines regulation, as one segment of e-government, envisages interactive electronic services tailored to the needs of citizens, government units, state administration, regulatory and educational institutions and businesses. Methodology for the development of e-services on the e-government portal and demonstration a study of the application of this method in the part of medicines and medical devices is very important for e-health and the-government development3.

The purpose of the research is analysis that encompasses application of e-business in medicines and medical devices regulation and the application of the method in development of e-services and e-submission in medicines regulatory authorities for process import licenses for medicines and medical devices in Serbia. This testing of e-readiness of the pharmaceutical industry for the project of e-submission that was implemented in April 2021 in the period with COVID in Serbia (RS). The significance of this paper is that it is one of the first e-services initiatives in RS.

II. DEFINITIONS AND METHODS

A. Definitions

This subchapter will show the definitions of e-business, e-health, e-pharmacy and e-government.

E-business is the exchange of standardized electronic messages between natural and legal persons in negotiating, contracting, purchasing, sales, payments, communication with the administration and the courts, and in all other business transactions for which the law allowed its application1.

E-Government uses the application of information technology to improve: efficiency, productivity, transparency and accountability of the Government in dealing with: citizens, businesses, industry, government units and private officials. E-government can be seen from the online access to services to tools for the construction and reconstruction of democracy4.

E-government is a Web-based technology that uses the local government as a communication channel, which is offered to visitors, business partners, local governments and employees. Business models, which are used in the development of e-government, are G2C (Government to Customer), G2B (Government to Business), G2G (Government to Government)...

E-pharmacy as a segment of e-health is the application of electronic commerce in the pharmaceutical industry, which encompasses on the one hand the business of companies in the pharmaceutical industry and pharmacies. Increased use of information technologies and the Internet provides powerful tools and makes them available to citizens, government agencies, and pharmaceutical industry around the world. As a result, there are changes in organizations, as well as in relationships between businesses, citizens and state authorities.

The development of e-business in the area of the regulations concerning medicines, as a subsystem of the e-government of RS, provides a unified environment for communication, better dissemination of information about medicines, and online education for health care workers as well as more effective operation in the health care and pharmaceutical sector, including the realization of the concept of e-government in the segment of regulation of medicines11.

B. Methods

This article does not contain any studies with human or animal subjects performed by any of the authors. This chapter will show the methodology of developing software in e-government and previous research on e-services.

Software design methods are specific strategies that propose and provide a set of notations which are used with the method as a description of the process that should be used when monitoring methods and a set of guidelines for the use of the method5.

This section will describe the methods, methodologies and software development models, which are used in e-government. Particular attention will be devoted to the life cycle of software and business intelligence, and SOA (Service Oriented Architecture7) and BPM (Business Process Modelling). The methods of the life cycle of the attention will be devoted to a single method of software development process. The integrated framework, which will be displayed and used in this paper, is based on the use of RUP (Rational Unified Process) methodology and agile methodologies, business intelligence (BI) with the principles of data mining and data warehousing, BMPL (Business Process Modelling Language) and UML (Unified Modelling Language) - notation and reengineering business processes. The main principles are incremental and iterative development, active participation of users, based on the development of models, testing and cooperation. The paper consolidated methods, techniques, standards and process models in the field of e-business and access to quality analysis, modelling and design of the portal system of the authorities od RS. Software Life Cycle Processes (SLCP)9 can be perceive through its processes, i.e. activities that make this process as well as through its models, methods and strategies. SLCP are defined by a number of reasons, including increasing product quality, facilitating human understanding and communication, support process improvement, and support management processes. Methods for SLCP can be said to describe the process of software development through its individual operations or processes.

BI is a set of tools and applications that enable the creation of a system for the collection, analysis and dissemination of business information, with the aim of making better business decisions6.

In SOA programming is based on the process approach and represents a higher step in the development of software engineering. SOA describes the concepts, architecture and procedural framework to ensure cost effective development, integration and maintenance of IS. SOA does not represent a radically new architecture, but rather the evolution of the well-known distributed architecture and integration methods.

BPM refers to the design, management and execution of the business process, and its strength lies in the unification and expansion of existing process oriented techniques and technologies..

III. RESEARCH

A. Case study

This research is based on a qualitative case study on the 2018-2022 project “Digital transformation processes in medicines and medical devices regulation”. The project holder is the Medicines and Medical Devices Agency of Serbia (ALIMS), RS Ministry of Health and RS Government. The project includes several actors: project team of Agency, a project manager, manager of Agency as a member of team, Office of Information Technology and Electronic Government in RS in the Prime Minister's Office formed 27.07.2017 (Directorate of Electronic Government until 27.07.2017) and Coordination Body for digitalization of health formed at December 2021. The results of the research can be applied in any European medicines regulatory authority.

B. Research aproach

The aim of research was to develop a national platform in RS, as the country on the Balkan Peninsula in the South-Eastern Europe, for the development of e-pharmacy, which enables the integration of regulatory bodies in the medicines and medical devices regulation and institutions of the pharmaceutical industry. The data studied in this paper are focused on the data of the institutions that first began using the e-services of the Agency government portal of RS. Among the various roles and interviewed respondents are the directors of the pharmaceutical industry institutions, information technology directors in the institutions of the pharmaceutical industry, responsible persons for submitting requests for obtaining a license for medici-

nal products and medical devices in the institutions of the industry, civil servants, and directors of state institutions. At the national level, the Project Electronic Application Submission of Client Support supports the development of the government portal in RS, which will enable the improvement of services to the pharmaceutical industry and citizens and contribute to the economic development of the country. The project is in line with the Electronic Administration Development Strategy and the Action Plan for the implementation of the Open Access Initiative. The project contributes to better implementation of the Public Administration and Public Health Reform Strategy and provides closer approximation to the best European and global practice in the field of good governance. The project is one of the aims of National Project: Digital Health in RS, which Program was adopted in December 2021. This chapter will show analysis and application of e-business in the medicines and medical devices regulation and the application of the method in development of e-services and e-submission in ALIMS from the previous chapter.

C. Analysis of application methods for digital transformation business processes for medicines

This subchapter shows analysis that encompasses application of e-business in the medicines and medical devices regulation and the application in RS. For medicines and medical devices regulation, e-business is used for collecting, recording, storing and securing data, and information about medicines is a source of necessary information for the daily work of doctors, pharmacists and other health workers. The development of e-business in the medicines regulation, as one segment of e-government of RS provides interactive e-services tailored to the needs of citizens, public authorities, regulatory and educational institutions and industry (producers, importers, representations, health care and pharmaceutical institutions).

The goal of this approach is the integration of e-government and the segment relating to the medicines regulation, ensuring the efficiency of process of modelling and model implementation, which should result in models that must be explicit, understandable, modular and can be effectively amended and supplemented, distributed and placed on a variety of computing platforms and operating systems in e-government8.

Without e-business in the medicines regulation it is impossible to develop e-health and e-pharmacy. Providing information on medicines is one of the e-services in the medicines regulation. Information about medicines is coming from routine sources, specific non-routine, library sources and research sources. Information on medicines, which must be precise and authoritative data are necessary for the daily work of doctors, pharmacists and other health workers in general and special branches of medicine, pharmacists in the production, medicines and pharmacies, as well as other professionals involved in health care, regulatory bodies. Integration of business in the medicines and medical devices regulation, government, health and ePharmacy in RS (Figure 1) uses e-business models to better communication, better management of documents and records in public administration, the pharmaceutical industry and the health system, as well as the achievement of measures directly connected to savings in dealing with several aspects (time - efficiency, money - economy). Networking of institutions in the field of information on medicines and medical devices affects how efficiently the business of ALIMS and health institutions, patients or the pharmaceutical industry is, which leads to a significant reduction in total costs and time saving. ALIMS was ready from the start to participate in the initiative to open data and thus enable that information on medicines and medical devices, and integration with other data, to get more value and become useful to other state bodies and institutions.

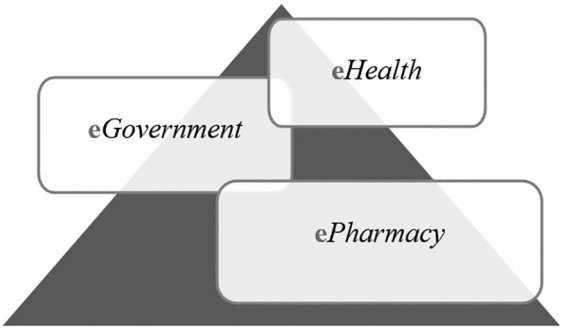


Fig. 1. Models of e-business between eHealth, eGovernment and ePharmacy

IV. RESULTS AND DISCUSSION

In this chapter, the results of the case study will be presented, as well as the preparatory phase of launching e-services development initiative in RS. This chapter will show concluding analysis and finding that encompasses application of e-business in the medicines and medical devices regulation and the application of the method in development of e-services and digital transformation business processes in ALIMS from the previous chapters.

A. Results of the preparatory phase-application of the methods

ALIMS is a public agency in RS, authorized (among other) to issue marketing authorizations, decide on their variations, renewals for human and veterinary medicine, as well as the registration of marketing authorizations for medical devices, quality control of medicines and medical devices that meet the requirements for efficiency, quality and safety. Transparency of the work is reflected through the portal of ALIMS where they meet all the criteria of functionality, defining the guidelines for making Web presentations of the state administration.

ALIMS participates in the development of eGovernment portal RS. The latest e-services "Downloading reg-

istry of medicines and medical devices" is set in 2015 on National Portal of eGovernment. State agencies and legal entities can retrieve the registry of medicines for use in human and veterinary medicine, as well as a registry of medical devices for which the ALIMS issued a marketing authorization, with the use of a qualified digital certificate. The aim of this service is to download data on medicines and medical devices in digital, machine-readable formats that can be used for further work and use in other state bodies and legal entities, especially in the context of the development of the e-Health of RS. Register of medicines and medical devices in the form of e-Service enable downloading of the codebook data on medicines and medical devices from the ALIMS database that are updated on a daily basis. This way ALIMS achieves more benefits for almost all sectors of society: new business and economic opportunities - turning data into economic systems at all levels and new innovative solutions - combining data from multiple sources, which then creates new values.

At the end of 2018 ALIMS has started a new project „Digital transformation business processes“ that will enable the integration of ALIMS and pharmaceutical industry, and includes e-submission request of clients in the pharmaceutical industry on the easiest way by selecting the appropriate eServices and completing the application form, which was given the opportunity to submit the attached documentation in electronic form with certain requirements. The basic idea of this project is to enable clients wishing to apply electronically. The vision of the project is to develop application forms for eGovernment portal where customers will be able to electronically fill patterns i.e. customer requirements and deliver them electronically with all the accompanying documentation. The project includes the development of about 60 eServices ALIMS and allows the pharmaceutical industry to operate without physical arrival at the location ALIMS by applying for the appropriate electronic service ALIMS. This is reached by using a digital certificate, which provides training and leads to the pharmaceutical industry when it comes to the development and application of informational technologies and provides additional support for the development of the same in RS.

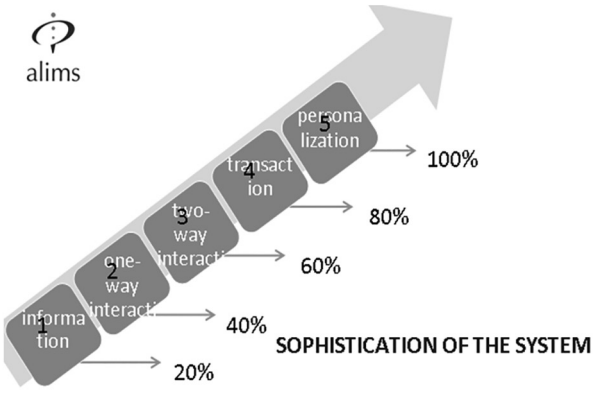


Fig. 2. Phase of sophistication of the portal

The functional area of e-services is enabled on the home web page of the ALIMS site and contains a list of all names of e-services published on the own portal of e-government inside the highest stages of sophistication: interaction, transacton and personalization (Figure 2).

The most important result is an increase in the number of completed applications form import licences form medicines and medical devices, for exmple on Figures 3 is attached example for number of solved request for medical devices.

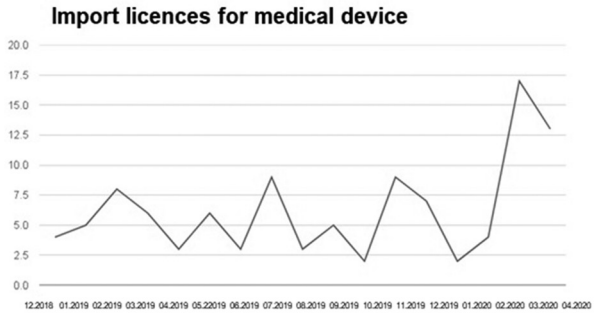


Fig. 3. Import licence for medical devices from December 2018 to 2020

B. Performance analysis and results

For the future of e-government, e-health and e-business in the medicines regulation in RS it is important to use the experience of other countries, with consideration of their successes and failures, as well as adapting this knowledge characteristics of socio-economic environment in RS.

Equally important is the cooperation with the Ministry of Health and the Government of RS, because in this way there is a solution that information subsystem of e-business in the medicines regulation integrates into the overall IS of e-government of RS leading into single architecture, which can be reached by working together and forming an agreement of all stakeholders, starting from the government, through the non-governmental sector, academic institutions, to the citizens themselves.

A good example of application of this project is open data about medicines and medical devices in human and veterinary medicine registered by the agency, whose main activity is the control of medicines and the placing of medicines on the market. ALIMS was among the first to adopt the concept of open data and thus contribute to the achievement of benefits for the economy in general, economic entities, state authorities, scientific community and other segments of the society in RS.

The registers of human and veterinary medicine and medical devices are presented in the forms of structured, open data formats and are presented as electronic services on the national portal of eGovernment.

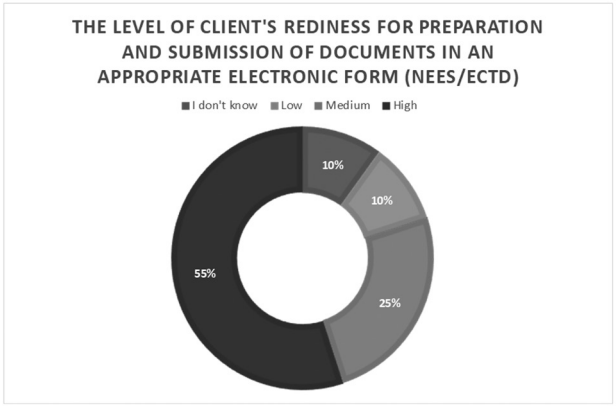
This data, which ALIMS made open additional en-

hanced through services such as the search for registered medicines and medical devices and issued certificates that exist from before, help monitor and respond to an adverse reaction to drugs and medical devices and identify fake medical products, and significantly make it easier for businesses in this area to do all this in order to achieve better health of the citizens of RS.

Based on open data sets for medicines and medical devices, some web applications and mobile applications have already been developed as Mediately databases of medicines.

The survey relating to the testing of e-readiness of the pharmaceutical industry for the project of e-submission was implemented in November 2020. The questionnaire was sent to all pharmaceutical institutions with a term of one month for an answer. Of the total number of participants, the survey was completed by 52% of participants. Most of the participants are familiar with the concept of electronic storage of data / documents and with the guidelines on the subject of filing documents (Figure 4).

The Agency's intention to move to an electronic system of communication was supported the most. The proposal to organize workshops and conferences on this subject in order to inform and educate the clients on time, in order to better and more successful transition to the new system of application was also well supported.



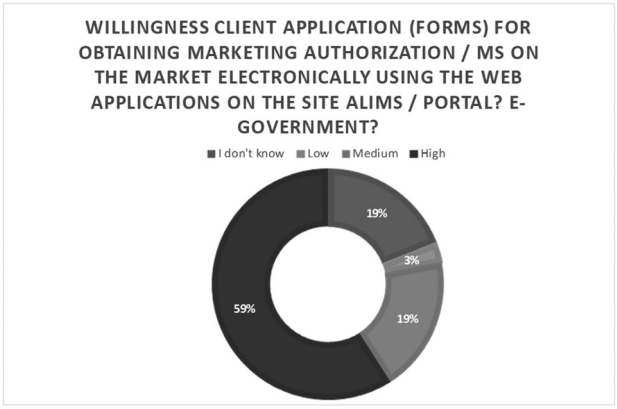


Fig. 4. The testing of e-readiness of the pharmaceutical industry in RS

V. CONCLUSION

This study confirms several benefits and challenges described in previous studies regarding e-services as described above. This is interesting, because at this moment there are few studies on e-services initiatives, especially in RS, where initiative e-government development and digital transformation has been launched and in its infancy. What this study highlights and contributes to, in addition to confirming the above studies, are the main lessons in terms of: The importance of actors who drive and realize initiatives, and the ability to overcome challenges, as well as the issue of private and public actors, together with the way a certain division of work is made when e-services or applications based are developed as part of a channel strategy. The methodology for the development of e-services, methods for modelling and analysis of business processes and reference model of e-business in the medicines regulation as one of the subsystems of e-government process met model in the context of e-government, life cycle business system design on the e-government network web portal and e-business in the medicines regulation, are the main scientific contributions of this work. Developing web software for e-business development in the medicines regulation, as subsystem of the e-government implemented in ALIMS are the main professional contributions of this paper. Improving e-business and digital transformation business processes in the medicines regulation, as a subsystem of e-government would have to aim: the development of interfaces and support for model specification systems through interaction with citizens, the economy, healthcare, pharmaceuticals and other public authorities, support the adopted modelling standards, integration of e-business in the medicines regulation, the e-government, e-health and e-pharmacy in RS, application of methods and techniques of life cycle business model which are presented in the paper, agile methods and application of SOA, BI, and BMP. The "e-filling clients' requests ALIMS" will enable the integration of ALIMS with pharmaceutical industry and provide electronic submission of customer requirements and questions, thus achieving significant savings for ALIMS as for the pharmaceutical industry in the RS.

In this way ALIMS fulfils its mission - to promote and improve the health of people and animals, as well as to contribute to the realization of the fundamental human right to access to quality, safe and effective medicines and medical devices.

Digital transformation of business processes in ALIMS provides a unique environment for communication, better information about medicines, education via Internet for health workers, as well as the more efficient operations in the healthcare and pharmaceutical industries and the realization of the concept of e-government in segment which regulates medicines and medical devices areas.

Based on the research in this paper, it can be concluded that e-services guarantees greater transparency of the work of state bodies, stimulates efficiency in government

and beyond, and enables citizens, companies and organizations to use public information several times for different purposes.

E-services strengthen entrepreneurship, influencing the development of innovative products and services, providing alternatives for decision-making in management, planning and science, and contributing to the creation of a knowledge-based economy.

Analysis and research conducted in the case study described in this paper point to the conclusion that the goal of the state should be that e-services of state farmers receive a useful value through the mixing of datasets in related institutions, the data of which are of great importance. The useful value of the data has been increased during the combination of data, which leads to the direct benefit of the public, the economy and the institutions themselves, State bodies of RS. In all the above ways, the state fulfils its mission - to promote and improve the business of all sectors, as well as to contribute to the achievement of the basic human right to access quality, accurate and efficient information.

The final goal of digitalization will be the next step and that: integration of eGovernment, eHealth and ePharmacy for the purpose of Human Health. That are realized for the benefit of the state, health system, economy and patients, and which are carried out through the improvement of cooperation between Ministry of Health, Agency, health and state institution, educational institution and patients with the use of open data and open eServices and G2B, G2C and G2G electronic forms application.

REFERENCES

[1] Ivkovic M., Radenkovic B. Internet and contemporary business. Belgrade: Mihajlo Pupin; 1998.

[2] Pejovic G, Filipovic J, Tasic Lj, Marinskovic V. Towards medicines regulatory authorities' quality performance improvement: value for public health. The International Journal of Health planning and management 2016; 31: E22-W40.

[3] Stojadinovic T, Radonjic V, Radenkovic B. E-business in the Regulation of Medicines in Serbia, Drug information journal 2010; Drug Information Association, Inc., Printed in USA, ISBN 0092-8615; Vol.44, No.2, pp.177-187.

[4] Gonnet P. The future of informatics as a sciantific discipline. Cepis: Upgrade, The European Online Magazin for the IT professional, Vol.II, No.4, August 2001, pp. 37-39.

[5] Budgen D. Software Design. Addison-Wesley, International Computer Science Series; 2004.

[6] Quinn Kevin. Establishing a Culture of Measurement – A Practical Guide to Business Intelligence: Information Builders; 2007.

[7] Emig C, Weisser J, Abeck S. Development of SOA-Based Software Systems – an Evolutionary Programming Approach. IEEE Computer Society; 2006.

[8] Stojadinovic T, Vanevski I, Radovanovic Lj. E-services in regulation on medicines and medical devices, XV International symposium Reshaping the Future Through Sustainable Business Development and Enteproureship SymOrg 2016, Symposium proceedings ISBN 978-86-7680-326-2, p.415-422.

[9] IEEE Computer Society Professional Practices Committee. SWEBOK, Guide to the Software Engineering Body of Knowledge. The Institute of Electrical and Electronics Engineers, Inc.2004.

[10] Irani Z, Love P, Montazemi R. e-Government: past, present and future. European Journal of Information Systems 2007; Pages 103-105.

[11] Stojadinovic T, Radonjic V, Radenkovic B. E-Business in the Regulation of Medicines in Serbia. Drug Information Journal. 2010;44(2):177-187. doi:10.1177/009286151004400209

[12] Veselinovic P, Stanisic N. Development and perspectives of digital economy in the Republic of Serbia, 10th Scientific Conference ''Jahorina Business Forum 2021: South-East Europe in the Vortex of the 2020 Crisis, Disruptive Innovations, Policies and Measures for Sustainable Economic Growth, Proceedings of the Faculty of Economics in East Sarajevo, 2021, 22, pp. 61-67