E-business in the Regulation of Medicines in Serbia

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This article describes the application of electronic business (e-business) in the regulation of medicines in Serbia, as one of the e-government services of Serbia. In addition to the development of the information society of Serbia, the article puts forward a methodological framework for the development of e-services, through the use of rational unified process methodology. The unified modeling language notation was used for the description of the system model. The article presents modeling of the process of marketing of medicines. The analysis of the marketing of medicines in Serbia was carried out from 2004 through 2007 by the Medicines and Medical Devices Agency of Serbia (the Agency for Medicines). We present the results of performance analysis of the development of e-business in the regulations concerning medicines, conducted by the Agency for Medicines in April 2007 and March 2008. The findings identify e-business as of particular significance in medicine regulation in Serbia.

Key Words
Health; E-business; E-government; Regulation of medicines

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INTRODUCTION

In recent years Serbia has seen the development of electronic business (e-business) and the introduction of regulations concerning medicines and medical devices as an e-government service (e-service). This article deals with the development of e-business in the regulations concerning medicines and medical devices, as a subsystem of e-government in Serbia. In addition, the study presents demographic data on Serbia. We put forward a framework of e-government of Serbia, as well as a methodological framework for the management of e-government projects and the development of e-services, through the use of RUP (rational unified process) methodology. The unified modeling language (UML) notation was used for the description of the system model. The article presents modeling of the process of marketing of medicines for human use, as well as the development of the information subsystem underpinning it.

After a period of research in the area, a fully functional prototype was developed and put to use by the Medicines and Medical Devices Agency of Serbia (the Agency for Medicines), which was established under the Law on Medicines and Medical Devices (the Official Gazette of the RS, no. 84/2004) as a Serbian public agency.

The results of the analysis of the marketing of medicines that was carried out for the years 2004–2007, presented in this study, emphasize the importance of e-business in the improvement of the business process of monitoring the marketing and consumption of medicines, as an e-service in Serbia.

We present the results of performance analysis of the development of e-business in the regulations concerning medicines and medical devices, conducted by the Agency for Medicines in April 2007 and March 2008. The analysis employed the methodology for performance assessment, briefly outlined below.

INFORMATION SOCIETY AND E-GOVERNMENT IN SERBIA

According to the Republic Statistical Office, which processed the data on the administrative territorial division of Serbia (Table 1) on January 1, 2008, Serbia covers an area of 88,361 km^2 with a population of 7,498,001 (1). The capital of Serbia is Belgrade, with 1,576,124 inhabitants.

The Republic of Serbia pays special attention to information technologies (IT) in all of its development strategies. The concept of an information society implies a significant role played by information and knowledge (2).

The development strategy of e-government in Serbia is put forward in the following docu-

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TABLE 1

Basic Data on the Administrative and Territorial Organization of Serbia

Territory	Area (km^2)	Districts	Municipalities	Settlements
Serbia	88,361	29	194	6,169
Central Serbia	55,968	17	120	4,253
Vojvodina	21,506	7	45	467
Kosovo and Metohija	10,887	5	29	1,449

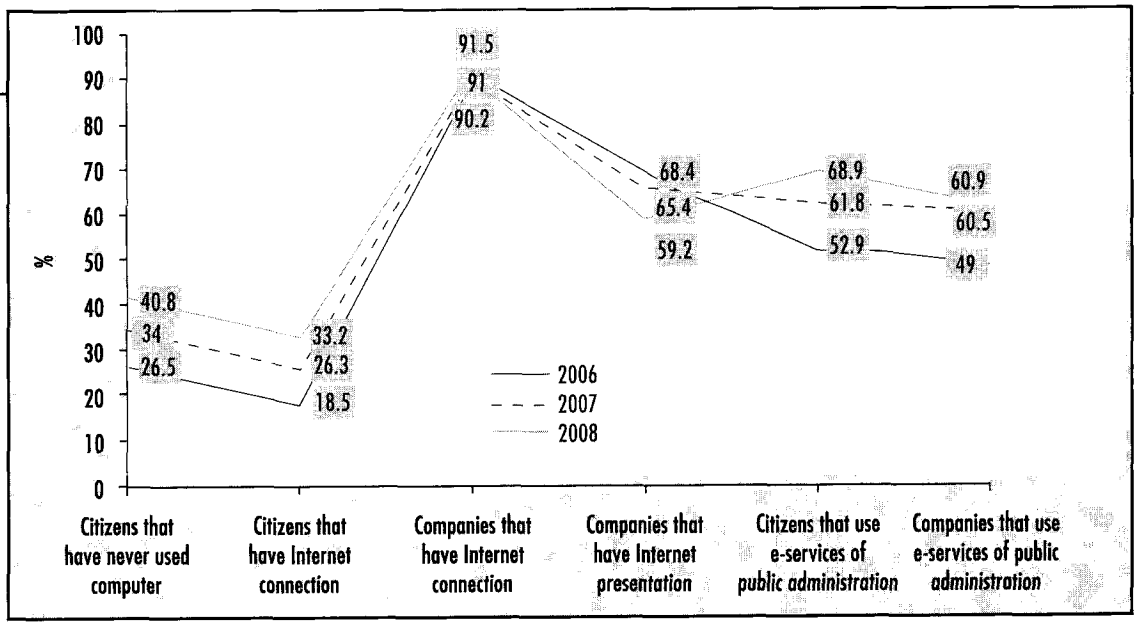
ments: the Serbian National Strategy for the Accession of Serbia to the European Union (2005), the Strategy for the Development of Information Society in Serbia (2006) and the National Strategy of Sustainable Development (2008).

The Strategy for the Development of Information Society in Serbia calls for making the state administration more accessible to the public and industry by providing modern public services on the Internet. The strategy sets goals for the development of an information society, specifies a necessary institutional framework, and develops the strategy for the establishment of effective national communication and information infrastructure (2).

The results of surveys of the use of IT in Serbia, conducted by the Institute of Informatics and the Internet of the Republic of Serbia, in 2006, 2007, and 2008 (EUROSTAT methodology) are given in Figure 1. In Serbia, 33.2% of households are connected to the Internet, which is a 6.9% increase compared to 2007, and 14.7% in 2006. E-services are used by 60.9% of all enterprises connected to the Internet, which is an increase of 0.4% over 2007, and 11.9% over 2006 (2). The survey also showed that over 260,000 people make use of electronic government services, which is approximately 30,000 more than in 2007 and 70,000 more than in 2006. As many as 92.4% of the respondents who use e-government services have been looking up information on public institutions' websites in the last 3 months—71.1% downloaded official forms, and 57.4 forwarded filled-in forms. All of the above show

FIGURE 1

The use of Internet e-government services in Serbia (3).



that interest exists, but also that there are difficulties in the development of an information society in Serbia (3).

FRAMEWORK OF E-GOVERNMENT IN SERBIA

Methods, techniques, standards, and process models in the area of e-business and quality management were used in the research of the elements of e-government and the development of the elements of the framework.

The e-government system in Serbia has a single center responsible for strategic decisions, monitoring and management of operations, comprising three phases: accepting the need to change, the transitional phase, and the implementation of the model of a single window (2). The concept of e-government in Serbia envisages interactive electronic services suited to the needs of the public and economy (2).

The framework of e-government in Serbia is a set of regulations that must be followed in all e-government projects and that can technically be implemented in the form of information databases, consisting of documentation and relational bases. The strategic level of the framework is a hierarchy of goals and e-government projects. Business processes are described at the business level of the framework; e-government services are described at the e-government level; and technical elements are described at the technical level of the framework, which includes the specification of the database, program modules, hardware server, client hardware, and the network.

E-BUSINESS IN THE PHARMACEUTICAL SECTOR AND HEALTH CARE IN SERBIA

E-business is a new model of conducting business, based on modern operation organization and the application of contemporary IT, the use of the Internet in business, digitalization of operations, and the use of cryptographic protective measures (4).

E-business is defined as exchange of information through electronic networks as a support for business processes, both within organizations and with external stakeholders (5).

The forms of conducting business are as follows: business to business (B2B), business to customer (B2C), customer to customer (C2C), customer to business to customer (C2B2C), and business to business to customer (B2B2C). In e-government, the following forms are in use: government to customer (G2C), government to business (G2B), government to government (G2G), government to employees (G2E), and others (6).

For successful functioning in the pharmaceutical sector and health care, e-business is of great importance in the domain of information management (7).

Online access to information produces considerable savings to pharmaceutical and health care organizations by lowering costs of transport and storage of information. Health is the only aspect of everyday life that is of concern to all members of a society. Everyone wants to have proper medical care, less costly and equally efficient. This can be achieved through the use of the Internet and e-health (8).

So far there have been no official analyses of the application of e-business in the pharmaceutical sector and health care of the Republic of Serbia. One survey by the Agency for Medicines of the use of the Internet in the pharmaceutical sector and health care (survey research method) was conducted from February to March 2008. It covered the citizens of Serbia. There were 571 respondents: 288 men (50.4%) and 283 women (49.6%). The question was: Are you interested in receiving health-related information over the Internet? The results of the survey in six age categories are given in Figure 2. The largest number of respondents was in the category over 50 years of age (24.3%). Of those, the total number of men who answered yes was 40%, and no was 60%. The total number of women who answered yes was 48%, and no was 52%.

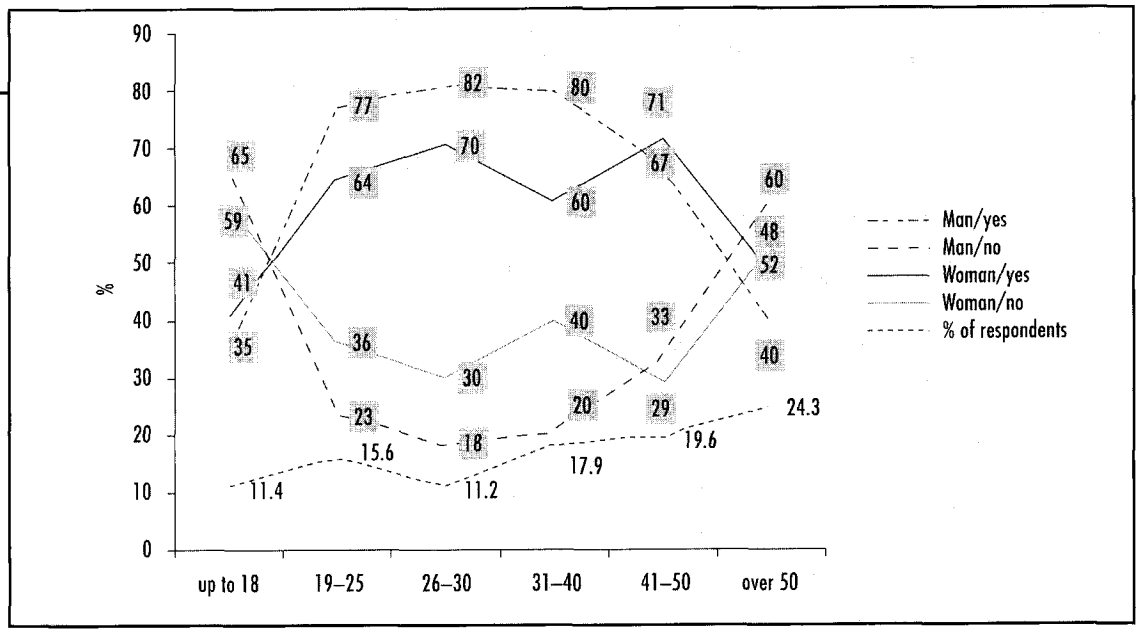
METHODOLOGY

This section deals with the methodological framework for the development of e-service.

Kerzner defines a project as a sequence of

FIGURE 2

Answers to the question: "Are you interested in receiving health-related information over the Internet?" according to age group of respondents.



activities and tasks with a goal to be achieved, certain specifications, and a set beginning and end as well as limited finances, which spends resources and is multifunctional (9).

THE METHODOLOGY OF MANAGING E-GOVERNMENT

The methodology of managing e-government projects includes its entire life cycle from planning to the implementation of the system, in accordance with RUP methodology.

RUP is a set of partially ordered steps toward the main goal—to deliver to users effectively and within a planned framework a system that fully satisfies their needs. RUP methodology principles are iterative and incremental and consist of four phases: initialization, elaboration, construction, and transition. It should be noted that each phase can be iterated indefinitely (10).

UML notation was used for the representation of the system model. UML is a standard modeling language on RUP methodology (11). UML consists of the following types of diagrams illustrating static and dynamic properties of the system: use case diagram, class diagram, sequence diagram, cooperation diagram, state diagram, activity diagram, diagram of components, and diagrams of disposition (12).

METHODOLOGY OF THE DEVELOPMENT OF E-SERVICE

The methodology of the development of e-service is connected to the e-government framework and describes the whole process of development of an e-service.

The process includes initial analysis and the development of the business model (process flow chart and the technique event-driven process chain), system model (use case diagram, interaction diagrams, class diagram, and entity relationship diagram), and technology model (architecture diagram), implementation, and introduction.

METHODOLOGY FOR THE ASSESSMENT OF PERFORMANCE

Methodology for the assessment of performance is an approach to measuring indicators through the use of different methods (interview, survey, Internet survey, telephone survey, mail survey, mobile phone survey, monitoring websites) and techniques for data processing (SPSS, electronic table presentation, data mining, SAS/STAT and MS ACCESS programs, OLAP). The statistical research process includes: preparation of the outline research plan, collecting and processing data, and presentation of statistical information.

CASE STUDY: E-BUSINESS IN THE AGENCY FOR MEDICINES

This section deals with the development of the subsystem of e-business in the regulations concerning medicines and medical devices, as one of the e-services in Serbia. The methodology for the development of e-government projects, for the development of e-services, and for measuring performance were applied. E-business in the regulations concerning medicines and medical devices is an e-service within the e-government of Serbia. Marketing of medicines is one of the business processes under the regulations concerning medicines and medical devices. The e-business of the Agency for Medicines under the project E-government envisages interactive electronic services suited to the needs of the public, state bodies, and business subjects (manufacturers, representatives, agents for medicines and medical devices, and health care and pharmaceutical institutions).

MODELING PROCESS OF E-BUSINESS OF THE MEDICINES AGENCY

Out of a variety of processes and information flows in the process model, this study demonstrates the model of business process of identification of users of the Agency for Medicines and monitoring marketing and consumption of medicines. As the first step of the development of G2B, G2C, and G2G operations, web applications were installed, as a part of the subsystem of the information system, developed through the following phases: planning, specification of request, representation of use case, design, implementation, and analysis of results. The following technology was selected: PHP program language, Linux operating system, Apache web server, and MySQL database. We summarize steps in modeling this business process; because UML is not itself the subject of this investigation, but rather its application, not all types of UML diagrams are explained, but only some diagrams of the system model.

The application Identification of the Users of the Agency for Medicines makes use of the G2B form of conducting business. The application allows inspection, entry, modification, and deletion of information about the beneficiaries of the service, as well as contact with the persons representing the beneficiaries (contact persons for marketing medicines, or contact persons for monitoring the marketing, or those who are in charge of reporting undesirable side effects).

The application Marketing of Medicines for Human Use uses the G2B form of conducting business. Monitoring marketing of medicines for human use is regulated by the Law on Medicines and Medical Devices. The application enables survey, entrance, and modification of information on registered medicines, as well as entering the data on the marketing of medicines. Marketing authorization for medicines requires access to this part of the information subsystem through the website of the Medicines Agency, with the user name and password. The main abstraction "Medicine" should comprise the following:

1. The name of the medicine, its classification and identification code (Anatomical Therapeutic Chemical or ATC, and EAN code), form, dosage, and package
2. Internationally unprotected name of the medication, its generic name or the chemical formula of the active ingredient
3. The name and address of the manufacturer
4. The quantity of the medication
5. The number of the decision under which the license for marketing the medication was issued for its importance for the purposes of research and medical application
6. The name of the legal entity for whom it is imported

Data gathered for a particular time period are analyzed applying the unified classification of medicines ATC and the DDD (defined daily dose) methodology, in accordance with the recommendations of the World Health Organization. This method of data processing secures identification and presentation of financial, statistical, and epidemiologic indicators of the consumption of medicines in a community.

The model of use cases is presented by de-

FIGURE 3

Diagram and connections of detailed use case (the process of entering the medicine market).

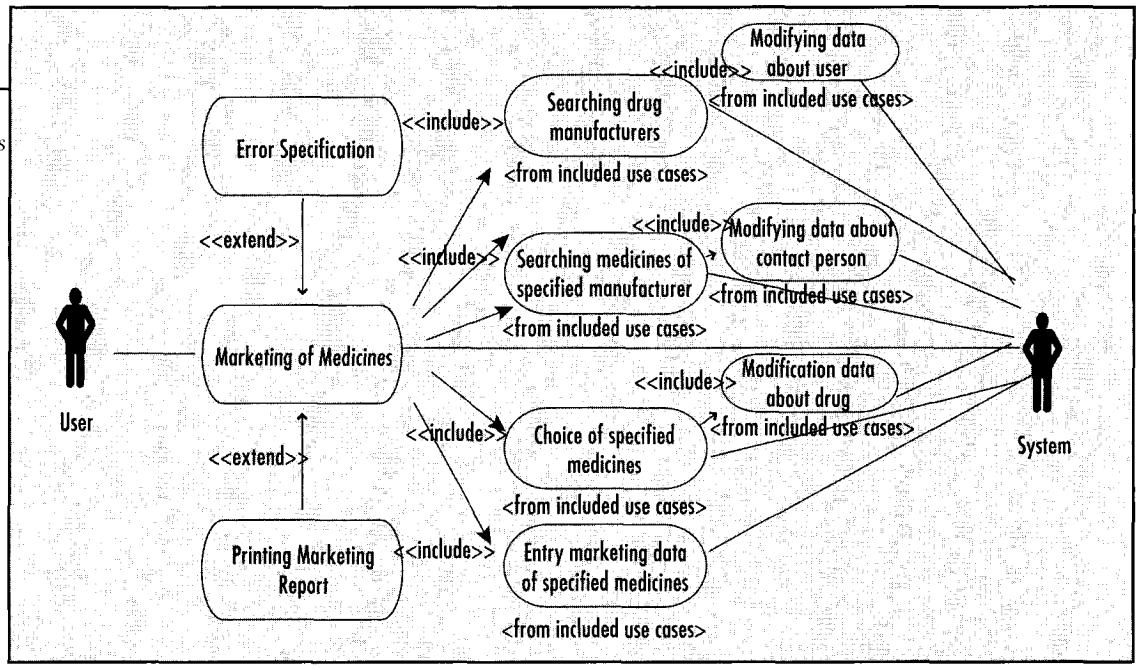
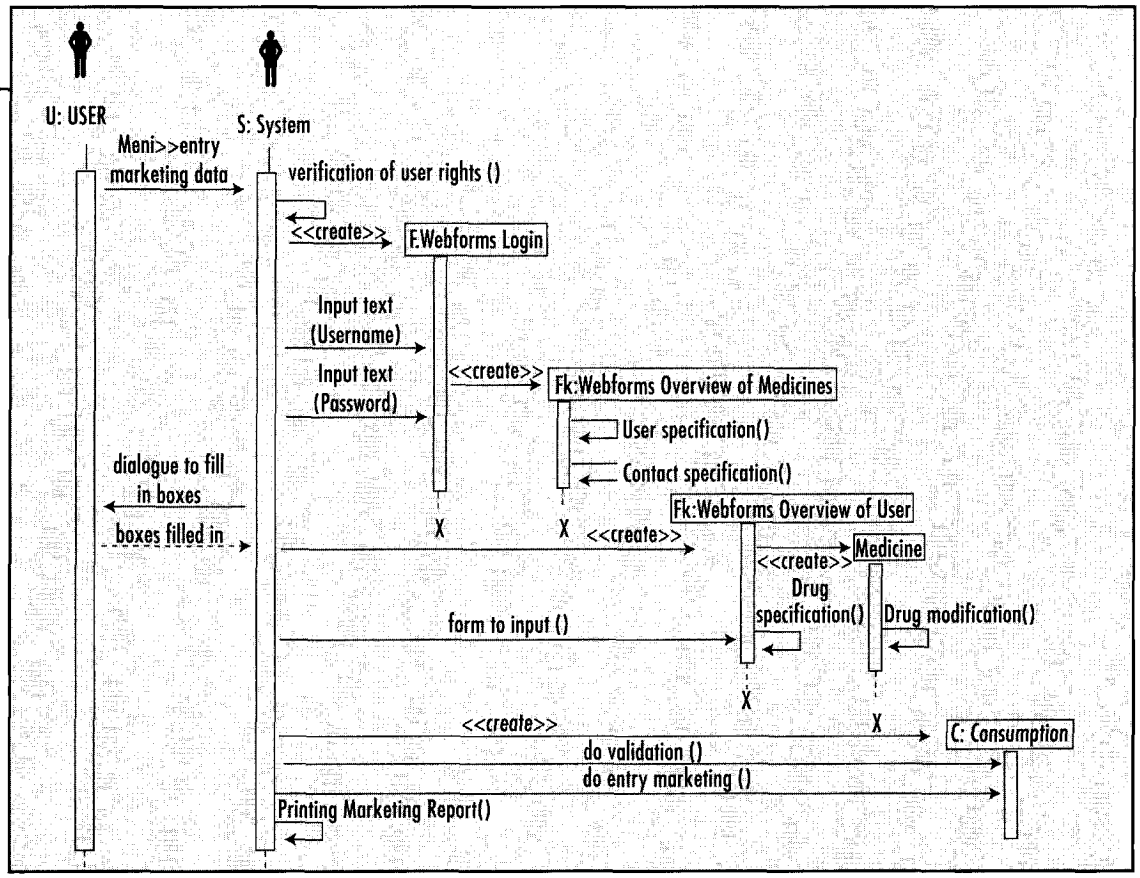


FIGURE 4

Sequence diagram of the process of entering the medicine market.



tailed diagrams of use cases. This article gives a detailed use case of the application of the medicine marketing process (Figure 3). It also presents a marketing sequence diagram (Figure 4), describing the dynamic characteristics of the system. The implementation phase includes coding, installation, and configuration of the above technology.

RESULTS

This section deals with the results of the analysis of marketing of medicines in Serbia and the results of the analysis of performance assessment of the development of e-business by the Agency for Medicines.

RESULTS OF THE ANALYSIS OF MARKETING OF MEDICINES IN SERBIA

The use of e-business in monitoring marketing of medicines during 2004, 2005, 2006, and 2007 yielded the following results:

In 2004 and 2005, 98.5% of those under obligation to submit marketing information complied, and in 2006 and 2007 the percentage rose to 99% of the total number. In 2007, the manufacturers in the territory of Serbia accounted for 47.59% of the total turnover, while the share of foreign manufacturers was 52.41%.

The collection and processing of the data on the marketing and consumption of medicines by financial parameters gives the view of finances set aside and spent on medicines 2004–2007. In 2004 total marketing of medicines for human use amounted to €339,279,303.77; in 2005 it stood at €380,716,701.39; and in 2006 it was €510,833,609.54, while the overall marketing of medicines in 2007 was €687,588,174.80. This means that the marketing of medicines in Serbia rose by 124.49% from 2004 to 2007, 75.23% from 2004 to 2006 and 32.87% from 2004 to 2005 (13–15).

Further processing of the data yielded a more precise analysis in euros of the share of ATC groups in the overall marketing of medicines in Serbia 2004–2007. Table 2 shows clearly that in Serbia, in the 4-year period, the most money was spent on medicines for cardiovascular diseases (group C). Every year the results are published in the publication Marketing of Medi-

TABLE 2

Marketing by ATC Groups in Euros for 2004–2007

ATC	2004	2005	2006	2007
C[a]	78,716,560.68	83,563,755.96	122,295,930.1	158,399,085.9
J[b]	67,878,724.78	71,441,413.54	93,319,443.34	117,067,753.1
N[c]	43,386,221.92	46,209,924.73	58,497,506.16	82,961,630.26
A[d]	36,398,728.41	42,705,722.38	58,420,537.69	73,518,781.48
B[e]	24,157,233.19	32,768,760.97	42,017,472.23	65,662,945.3
L[f]	20,706,563.5	23,212,998.72	30,880,850.76	49,424,984.02
M[g]	19,166,161.32	23,120,837.31	30,704,048.78	41,554,536.72
R[h]	17,085,139.96	19,756,504.36	28,775,481.14	32,647,927.64
G[i]	8,882,035.00	10,623,024.84	14,331,649.8	28,377,567.22
H[i]	8,003,084.44	8,905,297.745	11,275,386.08	11,028,781.97
D[k]	5,105,375.17	7,426,319.259	7,883,326.221	10,607,667.46
S[l]	4,356,947.74	595,065.6597	6,391,538.389	8,507,489.967
V[m]	5,105,375.17	4,489,046.443	5,327,885.842	7,093,563.319
P[n]	690,298.78	677,761.705	718,709.1287	735,460.4198
Total	339,279,330.8	380,852,027.2	510,839,765.6	687,588,174.8

[a]Cardiovascular system; [b]anti-infectives for systematic use; [c]nervous system; [d]alimentary tract and metabolism; [e]blood and blood-forming organs; [f]antineoplastic and immunomodulating agents; [g]musculoskeletal system; [h]respiratory system; [i]genitourinary system and sex hormones; [j]systematic hormonal preparations, excluding sex hormones and insulins; [k]dermatological; [l]sensory organs; [m]various; [n]antiparasitic products, insecticides, and repellents.

cines for Human Use, and submitted to the Ministry of Health of the Republic of Serbia and to international organizations.

RESULTS OF THE PERFORMANCE ASSESSMENT OF THE DEVELOPMENT OF E-BUSINESS BY THE AGENCY FOR MEDICINES

The analysis was conducted applying the performance assessment methodology, briefly outlined in an earlier section. There were two analyses altogether, carried out by the Agency for Medicines. The first one was in April 2007, the second one in March 2008. The combination of the following methods was used for collecting data: survey, Internet survey, mail survey, and interview. The data were processed by computer. The results of the analyses were published on the site of the Agency for Medicines and submitted in the form of a report to international organizations.

The survey for the first analysis was of health professionals of Serbia. The questionnaire was developed to measure the research questions and was translated into Serbian. It was placed on the website for a 2-week period in April 2007, after a media advertisement had run with only the URL. In the first part of the questionnaire, concerning knowledge about the Agency for Medicines, the respondents could choose between Yes, No, and No Answer. The second part concerned questions about the website, and the answers offered were: Never, Daily, Weekly, Monthly, Good, Bad, or Medium, and so on. The third part comprised questions about general opinions of the publications of the agency, offering the following answers: Yes, No, and No Answer, or Never, Daily, Weekly, Monthly, Good, Bad, or Medium. Out of a total of 300 distributed questionnaires, 100 were returned in this period, which is 33%. The second part of the questionnaire dealt with personal interviews with health care workers from a patients' association. The questions concerned the use of computers, the Internet, the websites and publications of the Agency for Medicines as well as the cooperation between the patients' association and the agency.

The survey for the second analysis was of manufacturers of medicines, and concerned the satisfaction of the beneficiaries of the service. In this case, the questionnaire, which consisted of four parts, was sent by electronic and traditional mail to designated addresses. The first part of the questionnaire concerned general information about the user of the service, while the second concerned general opinions of the services provided by the Agency for Medicines, to which the client answered Yes or No. In the third part, clients could choose answers to the questions concerning their satisfaction with the service between Very Satisfied, Satisfied, Dissatisfied, and Very Dissatisfied. In the fourth part, clients had a chance to give suggestions and recommendations for the improvement of the quality of services provided. The questionnaire was sent to 276 clients' addresses altogether, either to available email addresses (215) or by regular mail (61 questionnaires). They were sent on March 26, 2008, and the answers were collected by May 16, 2008. Of all questionnaires sent, 92 responses arrived. They were closely analyzed.

The results for both questionnaires were processed with a spreadsheet application to determine average qualities and to create graphical presentations for the parameters studied. Most questions were multiple choice with two options to choose from.

DISCUSSION

In the first part of the analysis concerning the assessment of the performance of e-business, most of the respondents were pharmacists (51%) and doctors (23%). The questions used in the evaluation of the first data set and the results obtained are presented in Figure 5. There are results from the yes/no questions (number answering yes, number answering no, no answer). It could be noted that 72% of health care organizations operate a website, and 28% do not have an Internet presence. Also, 93% of health care organizations use the application Marketing of Medicines, and 5% do not use it, while 2% of respondents did not answer.

As regards the results of other questions

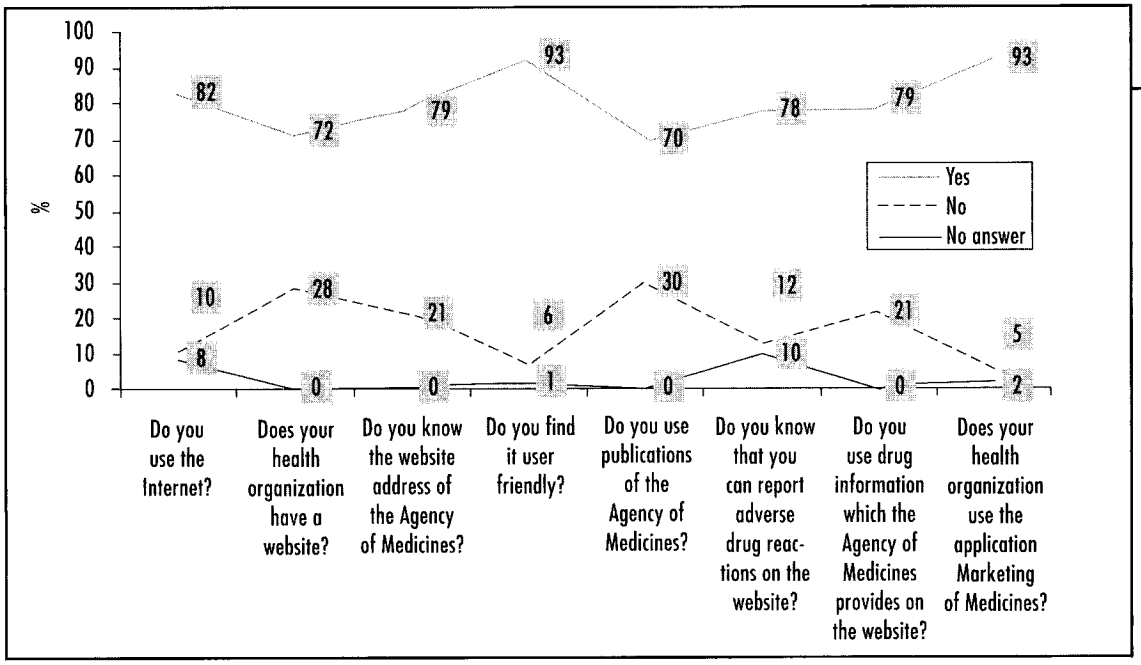


FIGURE 5

Results from the yes/no questions for the first study.

about the site of the Agency for Medicines, it is significant that the respondents stated that the agency's site was visited daily by 10%, weekly by 31%, and monthly by 31%, while 28% of respondents never made use of the site. The most often visited functional area of the site was medicines (46%), followed by medical devices (36%), clinical testing (10%), and publications (5%).

The analysis of responses in the second part of the questionnaire shows that 95% of the clients were satisfied with the services provided by the agency; 88% of clients were of the opinion that the service required was always fully provided; 11% disagreed; and 1% did not give an opinion. In relation to notifications published on the site, 79% of clients thought that they were clear and precise; 81% thought that the agency site was simple to use and that desired information was readily available; while 15% disagreed with this, and 4% did not respond. The analysis of the responses in the third part of the questionnaire led to the conclusion that the clients were satisfied with the amount and content of information supplied at the first contact with the Agency for Medicines (65%), as well as the quality of service of the agency (65%). As regards the manner in which complaints are dealt with, 47% of the clients were satisfied, 16% were very satisfied, 1% were very dissatisfied, 10% were dissatisfied, and 26% did not respond. The analysis of the fourth part of the questionnaire shows that in 2008 there were more negative client responses and more suggestions for general improvement of services than in 2007; it is also noticeable that clients are more interested in the improvement of the operation of the Agency for Medicines.

The results of the survey show as of particular significance the application of IT in health care and the pharmaceutical sector, as well as the considerable interest in the agency's site for medicines, especially for marketing and consumption and the quality and safety of medicines. As for suggestions made by the respondents in the second part of the questionnaire in the second survey, the most important are the ones for the improvement of the quality of service of the Agency for Medicines through the simplification of the procedure for the registration of medicines and better communication with clients through the use of the Internet and its services. The results of the third and fourth parts of the questionnaire in the second survey show a positive reaction of the clients as regards the improvement of the quality of work. Clients are generally dissatisfied with the

length of time for the provision of service and the manner complaints about the quality of service are received; they are very satisfied with the training provided so far in the regulation of medicines. Special effort will be put into better organization, better functioning of the website, and a greater amount of information published.

CONCLUSION

The development of e-business in the area of the regulations concerning medicines, as a subsystem of the e-government of Serbia, 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 medicines.

In addition to the development of an information society in Serbia, and a short survey of marketing of medicines in Serbia, this article presents the methodological framework for the development of e-service in Serbia.

E-business in the regulation of medicines is one of the e-services in Serbia, and marketing of medicines is one of the business processes in the regulations concerning medicines.

The article gives a concrete example of the application of the methodology by the Agency for Medicines as a public Serbian agency. It also provides a summary of steps involved in modeling business processes concerning the marketing of medicines in Serbia, illustrating them with several UML diagrams describing the system model.

Precisely defined and fully documented RUP methodology, as well as the consistency of UML notation, are some of the reasons why this particular combination was selected for the implementation of the project. Apart from the project of e-business in the regulations of medicines, the methodology and the diagrams can also be used in other projects related to the development of e-government and e-health care in Serbia, as a template for the development of similar systems based on the application of RUP methodology and UML notation.

E-government based on a unified approach to process modeling and software design covers the whole life span and bridges the gap between business modeling and IT.

The implementation of such a system produces a series of technological, functional, and economic advantages, such as improved management of documents in state administration and the health care system, an open, flexible, configured, and user-friendly system, and integration with other information systems, as well as the possibility of automation of integrated processes.

The development of methodology in G2G, G2B, and G2C networks can contribute to the achievement of a higher level of quality of products and services, as well as to collaborative decision making, on the basis of valid and updated information, in addition to more effective functioning in state bodies, health, and pharmacy.

The analysis of results of the development of e-business in regulations concerning medicines, presented in this study, shows that there have been significant changes and advances toward the development of an information society in Serbia.

The development of e-business in the regulation of medicines under the project of e-government in Serbia is expected to bring about modernization and the improvement of the quality of service, as well as efficiency, transparency, and effectiveness of work in health care and the pharmaceutical sector of Serbia.

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