ORIGINAL ARTICLE

COUNSELING ON THE USE OF PERSONAL MEDICAL DEVICES AND DRUG-DELIVERY PRODUCTS – A TRADITIONAL OR EXTENDED COMMUNITY PHARMACY SERVICE?

TAGNE RATASSEPP[1], ALINA SHAGANDINA[2], JUHA TURUNEN[3], RIITTA AHONEN[4], PEEP VESKI┼[2], JYRKI HEINÄMÄKI[2], DAISY VOLMER[2]*

[1]*Medical Device Department, Estonian Health Board, Põllu 1a, 50303 Tartu, Estonia*
[2]*Department of Pharmacy, Faculty of Medicine, University of Tartu, 1 Nooruse Street, 50411 Tartu, Estonia*
[3]*Farenta Oy, Äyritie 16, 01510 Vantaa, Finland*
[4]*School of Pharmacy, Faculty of health Sciences, University of Eastern-Finland, P.O. Box 1627, 70211 Kuopio, Finland*

**corresponding author: daisy.volmer@ut.ee*

Manuscript received: January 2014

Abstract

The use of personal medical devices (PMDs) and various drug-delivery products (DDPs) is rapidly growing in primary health care worldwide. The aims of the present survey were to assess the attitudes of community pharmacists on counselling on the use of PMD/DDP, and to investigate the connection between self-evaluated knowledge on counselling and the implementation of new extended community pharmacy services regarding PMDs/DDPs. A descriptive cross-sectional questionnaire-based survey using an internet-based *eFormular* survey platform was conducted in Estonian community pharmacies between May-June 2012. Of the delivered questionnaires (n = 356) 137 were returned having a response rate of 38.5%. More than half of the respondents considered the PMD/DDP counselling services as a traditional community pharmacy service. The majority of the respondents (89.9%) reported a wide public interest in the self-screening of health indicators and in the use of PMDs for these purposes. Only 24.8% of community pharmacists reported having problems in this specific counselling area. Nevertheless, 67.2% of the responders considered their professional knowledge insufficient for providing extended services. There is a clear need to improve the knowledge of community pharmacists in PMD/DDP counselling services, and consequently to support the quality of respective services.

Rezumat

Utilizarea dispozitivelor medicale personale (DMP) şi a diverselor dispozitive de eliberare a medicamentelor (DEM) creşte rapid în asistenţa medicală primară la nivel internaţional. Obiectivele prezentului studiu au fost de a evalua atitudinea farmaciştilor comunitari privind consilierea în utilizarea DMP/DEM şi de a investiga legătura dintre autoevaluarea cunoaştinţelor de consiliere şi implementarea de servicii extinse ale farmaciei comunitare referitor la DMP/DEM. Un studiu descriptiv transversal, având la bază un chestionar, desfăşurat folosind o platformă disponibilă prin intermediul internetului „eFormular", a fost realizat în farmaciile comunitare estoniene în perioada mai-iunie 2012. Dintre chestionarele trimise (n = 356), 137 au fost returnate, având o rată de răspuns de 38,5%. Mai mult de jumătate dintre respondenţi consideră serviciile de consiliere DMP/DEM ca fiind un serviciu tradiţional al farmaciei comunitare. Majoritatea respondenţilor (89,9%) au raportat un interes public crescut privind *autoscreening*-ul indicatorilor de sănătate şi utilizarea de DMP în aceste scopuri. Doar 24,8% din farmaciştii comunitari au raportat că au probleme în acest domeniu specific de consiliere. Cu toate acestea, 67,2% au considerat cunoştinţele lor profesionale ca fiind insuficiente pentru furnizarea de servicii extinse/suplimentare. Se simte clar o necesitate de îmbunătăţire a cunoştinţelor farmaciştilor referitor la serviciile de consiliere DMP/DEM şi, prin urmare, de a susţine calitatea serviciilor respective.

Keywords: counselling service, pharmacy, personal medical device, drug-delivery product

Introduction

With the rapid development of medical technology (MT), the number of new personal medical devices (PMDs) and drug-delivery products (DDPs) is expected to significantly increase in primary health care in the near future [1].

Medical technology (MT) – the use of novel technology to develop highly sophisticated electronic products or medical devices for application in healthcare markets [23].

Medical device (MD) – any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or

compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means [24].

Personal medical device (PMD) – not defined in the European medical device legislation. PMDs could be described as portable, consumer-focused technologies that can be used at home for health and fitness trending, chronic disease management, and elderly patient monitoring [25].

Combined product (device) (CP) – is a device that incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action that is ancillary to that of the device [24].

Drug-delivery product (DDP) – is a device that is intended to administer a medicinal product within the meaning of the medicinal product directive [24].

Several studies have shown that the use of PMDs and DDPs can be challenging and difficult for the patients [2-5]. Therefore, the demand for counselling on the correct and safe use of these devices by the health care professionals is expected to increase in the future.

To date, only limited and fragmented information is available about the role of community pharmacies in dispensing and counselling on PMDs. A few reports have been published on pharmacy-led counselling on the use of DDPs. Recent studies on inhaled medicinal products highlighted a lack of knowledge and communication skills of community pharmacists in counselling on inhalation devices [2-6]. Lemmens-Gruber et al. and Asakura et al. reported patient acceptance and issues of pharmacy-led education of the DDPs used in the management of diabetes [6-8]. Another important area regarding the pharmacy-led counselling services is blood pressure monitoring with PMDs. Learning more about the professional knowledge of the community pharmacists about PMDs and DDPs could serve as a valuable tool in the development of future extended community pharmacy services. Proper counselling is also important to improve patient compliance and adherence [9, 10].

In Estonia, the DDPs are available only in community-pharmacies. Today, community pharmacies in Estonia provide convenient and fast handling electronic medical device cards, which are similar to prescriptions of medicinal products, and they serve as the basis for reimbursement of medical devices [11]. With the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border health care in Estonia, community pharmacies as a legal distribution source of medical devices have similar responsibility as currently in the case of medicinal products to provide full counselling and to assure safe and appropriate use of PMDs [12].

The aims of the present survey were: to assess the attitudes and professional knowledge of the community pharmacists on PMD/DDP counselling, and to investigate the association between self-evaluated knowledge on counselling and implementation of new extended community pharmacy services regarding PMDs/DDPs.

Materials and Methods

Setting and survey design

A questionnaire-based survey was conducted among the Estonian community pharmacies in May-June 2012 by using an internet-based *eFormular* survey platform (Figure 1) [13].

One survey instrument per pharmacy was asked to be filled in by the representative of professional pharmacy staff (e.g. pharmacy manager, pharmacist or assistant pharmacist – a specialist graduated three year pharmacy training at the University of Applied Sciences in Tallinn) having an everyday practical experience on e.g. customer service, counselling patients, or supplying. As only a small number of assistant pharmacists participated in the survey the results have been described all together with pharmacists´ data.

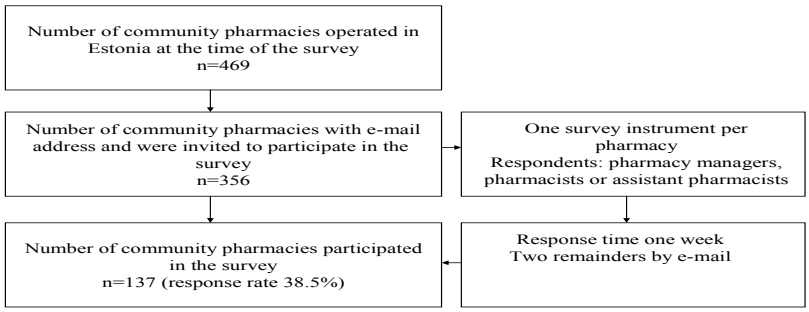

Figure 1.
The survey protocol and survey sample

Survey instrument

Survey instrument was developed by using the survey models applied in our previous survey on the services provided by the community pharmacies in Estonia [14]. Initial development and evaluation of the survey instrument was performed by the panel of the researches having an expertise in Medical technology, Social pharmacy and Health statistics. Face validity test was undertaken among a small number (n = 10) of the registered practicing community pharmacists.

The structured survey instrument contained a total of 28 (mainly multiple-choice) questions and attitude statements in the following areas: selection and counselling of medical devices at community pharmacy; professional knowledge of community pharmacists on the PMD/DDP counselling available in their community pharmacy; and demographic indicators of the community pharmacies (i.e. availability and provision of extended services connected with the use of PMDs) and community pharmacists. In this paper only the results describing the community pharmacists´ perception and self-assessed knowledge about PMD/DDP counselling and PMD extended services have been presented.

In the present survey, the evaluated products were classified as PMDs (e.g. diagnostic and monitoring electronic devices, nursing aids for chronic patients, children, breast feeding mothers, etc.) and DDPs (e.g. inhalers used in case of asthma, insulin pens and medicinal products in a spray container etc.). The combined products (CP) were not included into the present survey. The "counselling service of PMD/DDP" was defined as a professional activity taken by the community pharmacists to counsel in the use of PMDs/DDPs. The "extended service" on PMDs was defined as a provision service of the disease screening by means of PMDs available at the community pharmacy.

Data analysis

Raw data were collected and initial data analysis was performed using the *eFormular* database. For more detailed statistical analysis, IBM SPSS Statistics v. 19.0.0.2 was used. Cross tabulations and Chi Square tests were implemented to evaluate statistical correlations between pharmacy characteristics, demographic data of the respondents and their replies. Statistical significance was set at the level of $p < 0.05$.

Results and Discussion

In the past two decades, medical technology has evolved rapidly and the number of new PMDs and DDPs adopted in primary health care has grown significantly. In many countries, these preparations are mainly purchased from community pharmacies, and consequently, pharmacists will have a central role in counselling when the number of PMDs and DDPs increases in the future. This survey assesses the current level of involvement of community pharmacies in providing such services in Estonia. To our knowledge, there are no studies to date on the extent and level of involvement of community pharmacies in providing counselling on the use of PMDs.

Demography

The total number of the community pharmacies that participated in this survey was 137 (38.5%) (Figure 1). A total of 98.5% (n = 135) of the respondents were female and only 1.5% (n = 2) were male. Majority of the respondents were pharmacy managers (60.6%; n = 83) having an average age of 46-60 (60.0%; n = 83). 32.8% (n = 45) of the respondents were between the ages of 31-45, and 29.9% (n = 41) were dispensing pharmacists. Less than 10% was represented by the age groups < 30 years and > 60 years, and the group of assistant pharmacists.

Indicators of the survey pharmacies

The pharmacy location was quite equally divided between city centre and suburb, shopping centre and rural regions. By the annual number of prescriptions, a little more than half of the participating pharmacies were small to medium size community pharmacies. Of the participating pharmacies, more than half were currently providing or had a further intention to start providing the PMD extended services for determination of health indicators. Majority of the participating pharmacies did not have a separate room for the extended services. Approximately one third of the respondents informed that they do not currently provide and/or have not any plans to provide extended services about health indicators in the future at their pharmacy (Table I).

Table I

Indicators of the responding community pharmacies in 2012 (n = 137)

Pharmacy indicators	n	%
Annual number of prescription		
< 10 000	38	27.7
10 001-25 000	56	40.9
25 001-50 000	29	21.2
> 50 000	14	10.2
Pharmacy location		
City centre	43	31.4
Rural area	38	27.7
Suburb	28	20.4
Shopping centre	28	20.4
Provision of extended services about health indicators		
Yes	59	43.1
Has intention to provide	24	17.5
No	54	39.4
Separate room for extended services		
No	109	79.6
Yes	14	10.2
Available in the future	14	10.2

Pharmacists´ perception towards the pharmacy-led PMD/DDP counselling services

According to the respondents (community pharmacists), the customers today expect that there is a large selection of PMDs and the corresponding counselling services available in the community pharmacies in Estonia. More than half of the respondents 56.2% (n = 77) considered the PMD dispensing and counselling as the traditional community pharmacy service (Figure 2). Moreover the majority of the respondents 89.9% (n = 123) reported public interest towards self-screening of their health indicators and the use of PMDs in these purposes. PMD dispensing and counselling was considered as a traditional service especially by larger pharmacies (64.6%), compared to 34.2% of the smallest pharmacies, dispensing < 10 000 prescriptions annually (p = 0.001). In addition, 50.0% of the largest pharmacies (> 50 000 prescriptions) perceived that profits effect the provided selection of PMD-related services. Only 22.0% of all the other pharmacies mentioned that profits are related to the selection, p = 0.021.Of the pharmacies located at town centres, suburbs and shopping centres, 51.5% reported providing extended services. However, only 21.1% of the pharmacies situated at countryside provided these services (p = 0.001).

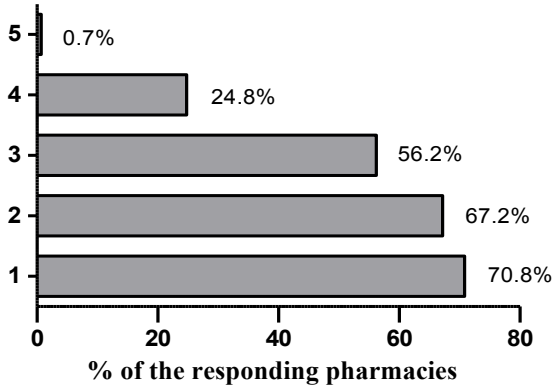

Figure 2.

Factors affecting the selection of PMDs in the community pharmacies in Estonia according to the community pharmacists: (1) General interest of pharmacy customers towards different PMDs; (2) Interest of pharmacy customers towards particular PMD; (3) The sale and counselling on PMDs has been traditional community pharmacy service; (4) The sale of PMDs is profitable for community pharmacy; (5) Do not know.

The respondents (community pharmacists) considered health care professionals (pharmacists, physicians and nurses) to be the most frequently used public information sources regarding the use of PMDs and DDPs in Estonia (Figure 3). Surprisingly, less than half of the respondents named the Internet as a common public information source about PMDs/DDPs for customers.

The dispensing and PMD/DDP counselling appears to be a traditional practice in community pharmacies in Estonia. An interesting finding in the present survey was that almost 90% of the surveyed community pharmacists reported a broad public interest towards self-screening of the health indicators, and the use of PMDs for these purposes in Estonia. Therefore, pharmacy-led disease screening with PMDs could be an important extended service in community pharmacies in the future. Pharmacists can be considered as the key group of health care professionals to support patient self-monitoring with PMDs, and also as the last link to ensure compliance with drug therapy. The combination of pharmacist intervention with home-monitoring has been shown to improve, e.g. blood pressure control in patients with uncontrolled hypertension [15, 16]. Regarding the management of patients with type 2 diabetes the survey circles held at community pharmacies were shown to be effective for participants in learning how to self-monitor glucose, to interpret the results, and to act upon them [17]. In another survey, the diabetes patient-management program, including education in the use a blood glucose meter, timing to check blood glucose, and target levels, led by the community pharmacy was shown to be beneficial for patients with type 2 diabetes [18].

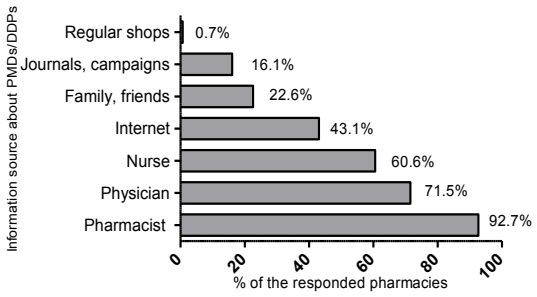

Figure 3.

Community pharmacists views on the most common public information sources about PMDs used by the pharmacy customers in Estonia

Professional knowledge about PMDs/DDPs and respective community pharmacy services

By self-evaluation to the open question, survey respondents regarded their current general professional knowledge on PMDs as good to medium 55.5% (n = 76) and satisfactory to poor 44.5% (n = 61), any of the respondents did not consider their professional knowledge about PMDs excellent. Especially young respondents (90.9% of those 30 years or younger) perceived their knowledge good or medium, p = 0.011 when compared to other age groups. Of the respondents, only 5.8% (n = 8) considered their knowledge as

'good' concerning the PMDs available in their community pharmacy and as 'poor' concerning novel PMDs. However, the surveyed community pharmacists were rather self-confident in the evaluation of service quality about counselling on the use of PMDs. Of the respondents, only 24.8% (n = 34) reported having problems in counselling on PMDs occasionally. These problems were mainly due to factors not related to the pharmacist, such as the unconcerned customer (57.7%, n = 79), or insufficient or unintelligible package information leaflet (38.0%, n = 52). Less than half of all respondents (43.1%, n = 59) mentioned insufficient knowledge of the pharmacist her/himself as a reason for such problems.

Self-assurance of all responding pharmacists was surprisingly low when they were asked about their professional knowledge on performing the extended PMDs pharmacy services. Of the respondents, only 32.8% (n = 45) regarded their professional knowledge as appropriate for providing disease screening tests with PMDs. In those pharmacies where provision of extended services was reported, 47.5% of the community pharmacists regarded themselves competent to offer respective service. In contrary, in those pharmacies where extended services were not available, only 21.8% of the respondents were confident about their professional knowledge on PMD extended services (p = 0.004).

The survey participants had a clear understanding of the responsibility of the community pharmacists while planning or already serving corresponding extended services. Here, community pharmacists saw possibilities for more effective interactions with other health care professionals in the prevention or monitoring of different (chronic) diseases (Figure 4).

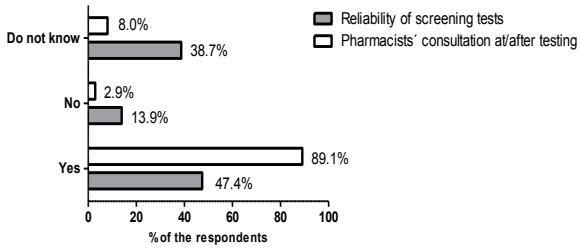

Figure 4.
Reliability of and need for the pharmacy consultation at/after the disease screening tests with PMDs

Of the respondents, 68.6% (n = 94) would charge a formal fee from the customers for extended services. The formal fee suggested by the respondents was between 2–5 EUR, and this amount would cover expenses for operation and counselling on PMDs, not to gain income for pharmacy.

The survey respondents were not very confident (by self-evaluation) in counselling on the use of PMDs/DDPs. These findings are similar to recent studies reporting the role of community pharmacists in educating the use of the inhaler in asthma management. These studies showed that most patients are not educated enough by community pharmacists in the use of inhaler DDPs since many pharmacists lack skills and knowledge on inhaler administration technique [19-21]. Interestingly, even though more than half of the surveyed pharmacies provide, or are planning to provide extended services, only less than one third of the respondents considered their professional knowledge appropriate for providing disease screening tests with PMDs. It could be assumed that current screening tests (mostly measuring blood pressure) are performed with a few consultations about use of medication, lifestyle, or other important aspects. The pharmacists' limited access to patients' health records could serve as a barrier to the counselling on clinical aspects as the respective information could only be received from the patient. However, previous studies have demonstrated low interest among pharmacy customers towards extended community pharmacy services in Estonia, and thus customers are not open to provide required information to the pharmacist [14]. Nevertheless, further training regarding PMDs and DDPs will be needed for the community pharmacists to improve their skills and knowledge on counselling of patients. In this survey, more than half of the surveyed respondents admitted insufficient professional knowledge for provision of extended community pharmacy services with PMDs.

The present survey has some limitations. The response rate was 38.5%, meaning that approximately 1/3 of the community pharmacies (n=469) operating in Estonia at the time of the survey were participating in the survey. As the responding community pharmacies followed the pattern of pharmacies operating in Estonia during the study (i.e. location and annual number of prescriptions) [22], the results can be considered as trustworthy for describing the current situation and future trends in PMD/DDP services in Estonia.

Another limitation was perhaps related to the non-equal representation of the pharmaceutical staff in the participating community pharmacies. An exceptionally high number of the pharmacy managers responded to the present questionnaire, and very few of the respondents were assistant pharmacists, despite the fact that they are more likely to be responsible for the daily counselling on the PMDs. This bias could be explained by the fact that the pharmacy managers reached the survey call first. The pharmacy managers, however, should be familiar with all relevant aspects related to

PMD/DDPs – supplying them to pharmacy, counselling use of and assurance of the quality of named products.

Conclusions

In this survey, more than half of the responding pharmacists considered the PMD dispensing and counselling as the traditional community pharmacy service which indicates the established position of the corresponding PMDs in community pharmacies. The survey participants understood the responsibility of the community pharmacists in providing PMD extended services. There is a clear need to improve the knowledge and skills of pharmacists in PMD/DDP counselling. Increased knowledge in this area and public interest towards disease screening could serve as a good starting point for providing of high-quality PMD extended services in Estonia.

Acknowledgements

The authors would like to thank all Estonian community pharmacies who participated in the survey and Dr. Cristina Rais for Romanian translations.
This research was supported by the European Social Fund's Doctoral Studies and Internationalisation Programme DoRa.

References

1. Sorenson C., Kanavos P., Medical technology procurement in Europe: A cross-country comparison of current practice and policy. *Health Policy*, 2011; 100: 43-50.
2. Basheti I.A., Reddel H.K., Armour C.L., Counseling about turbuhaler technique: needs assessment and effective strategies for community pharmacists. *Respir Care*, 2005; 50: 617-623.
3. Menckeberg T.T., Hugtenburg J.G., Lammers J.W., Knowledge of actions of inhaled corticosteroids in patients who did not persist drug treatment early. *Int. J. Clin. Pharm.*, 2012; 34: 277-281.
4. Bosnic-Anticevich S.Z., Sinha H., So S., Reddel H.K., Metered-dose inhaler technique: the effect of two educational interventions delivered in community pharmacy over time. *J. Asthma*, 2010; 47: 251-256.
5. Kaae S., Søndergaard B., Haugbølle L.S., Sustaining delivery of the first publicly reimbursed cognitive service in Denmark: a cross-case analysis. *Int. J. Pharm. Pract.*, 2010; 18: 21-27.
6. Lemmens-Gruber R., Hahnenkamp C., Gössmann U., Evaluation of educational needs in patients with diabetes mellitus in respect of medication use in Austria. *Int. J. Clin. Pharm.*, 2012; 34: 490-500.
7. Asakura T., Seino H., Jensen K.H., Patient acceptance and issues of education of two durable insulin pen devices. *Diabetes Technol. Ther.*, 2008; 10: 299-304. doi:10.1089/dia.2007.0268.
8. Asakura T., Seino H., Nakano R., A comparison of the handling and accuracy of syringe and vial *versus* prefilled insulin pen (FlexPen). *Diabetes Technol. Ther.*, 2009; 11: 657-661. doi:10.1089/dia.2009.0006.
9. Stockwell Morris L., Schulz R.M., Patient compliance – an overview. *J. Clin. Pharm. Ther.*, 1992; 17: 283-295.
10. Negru D.S., Cristea A.N., Petculescu A.M., Minimal consultation provided to patients presenting symptoms in the Romanian community pharmacy. *Farmacia*, 2010; 58: 601-610.
11. Medicinal Products Act. http://www.legaltext.ee/et/andmebaas/paraframe.asp?loc=text&lk=et&sk=en&dok=X90009K4.htm&query=ravimiseadus&tyyp=X&ptyyp=RT&pg=1&fr=no
12. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2011:088:SOM:en: HTML
13. *eFormular*. http://www.eFormular.com
14. Volmer D., Bell J.S., Janno R., Change in public satisfaction with community pharmacy services in Tartu, Estonia, between 1993 and 2005. *Res. Social Adm. Pharm.*, 2009; 5: 337-346.
15. Mehos B.M., Saseen J.J., MacLaughlin E.J., Effect of pharmacist intervention and initiation of home blood pressure monitoring in patients with uncontrolled hypertension. *Pharmacotherapy*, 2000; 20: 1384-1389.
16. Cavaco A.M., Romano J., Exploring pharmacists' communication with customers through screening services. *Patient Educ. Couns.*, 2010; 80: 377-383.
17. Sarkadi A., Rosenqvist U., Study circles at the pharmacy - a new model for diabetes education in groups. *Patient Educ. Couns.*, 1999; 37: 89-96.
18. Nau D.P., Ponte C.D., Effects of a community pharmacist-based diabetes patient-management program on intermediate clinical outcome measures. *J. Manag. Care Pharm.*, 2002; 8(1): 48-53.
19. Kritikos V., Armour C.L., Bosnic-Anticevich S.Z., Interactive small-group asthma education in the community pharmacy setting: a pilot study. *J. Asthma*, 2007; 44: 57-64.
20. Basheti I.A., Armour C.L., Bosnic-Anticevich S.Z., Evaluation of a novel educational strategy, including inhaler-based reminder labels, to improve asthma inhaler technique. *Patient Educ. Couns.*, 2008; 72: 26-33.
21. Soroceanu V., Popescu I., Georgescu A., Development of consumption of medicines in two pediatric hospitals in Bucharest during economic and financial recession in 2009 and 2010. *Farmacia*, 2013; 61(4): 800-810.
22. State Agency of Medicines, pharmacy statistics. http://www.sam.ee/en/pharmacy-statistics
23. Definition of Medical Technology. http://www.washingtonlifescience.com/industry/definition_medtech.htm
24. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF
25. Definition of Personal Medical Device. http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_047329.hcsp?dDocName=bok1_047329