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Opinion of Bulgarian Pharmacists on Drug Delivery Systems, Orodispersible and Pediatric Dosage Forms

Todor Naydenov[1], Assena Stoimenova[2], Margarita Kassarova[3], Maria Kamusheva[2*], Plamen Dimitrov[4] and Guenka Petrova[2]

[1]*Bulgarian Pharmaceutical Union, Sofia, Bulgaria, 36 Dragan Tsankovblv*
[2]*Department of Social pharmacy and Pharmacoeconomics, Faculty of Pharmacy, Medical University - Sofia, Bulgaria*
[3]*Department of pharmaceutical sciences, Faculty of pharmacy, Medical University-Plovdiv, 15-A Vasil Aprilovblvd*
[4]*National Centre of Public Health and Analyses, Acad. Ivan Evst, Bulgaria*

Abstract

Understanding of the specific characteristics of the pediatric patients and the pediatric dosage forms is crucial for the pharmacists' decisions in their everyday practice. Pharmacists' knowledge about the newest drug delivery system and orodispersible dosage forms could be essential for the adequate provision of particular pharmaceutical consultation about administration of the medicinal product. The purpose of our study was to assess the awareness, knowledge and attitude of the Bulgarian pharmacists towards drug delivery systems, orodispersible dosage forms and pediatric dosage forms as well as the pharmacists' role in consultation process for the newest dosage forms. The study was conducted amongst pharmacists from various regions in Bulgaria during 2013. Excel processed the questionnaires and SPSS programs, ANOVA analysis and chi-square test of independence were performed to evaluate the statistical significance of the differences in the collected data and to prepare descriptive statistics. 274 pharmacists have been surveyed about their attitude towards pediatric and orodispersible dosage forms. For the main part of the respondents, organoleptic properties and the price of the pediatric dosage forms are essential. The pharmacy industry representatives remain a main source of information about the new drug delivery dosage forms. The advantages of the orodispersible dosage forms are their fast effect and better taste than the others forms. According to the significant part of the respondents, the future role of the pharmacists will be in the development of new drug delivery forms and this will lead to an increase of the need for more pharmaceutical consultations, which should be paid. According to the survey's results there is an evidence for the significant role of the pharmacists in the therapeutic process for every patient. The future is of the innovative dosage forms and drug releasing systems which application may be a challenge – a challenge which could be overcome with the active participation of the high qualified pharmacists in the community pharmacy in Bulgaria.

Keywords: Orodispersible dosage forms; Pharmacy industry representatives; Pharmacists; Pharmaceutical consultations

Introduction

Children are very specific group of patients that requires a specific and individual therapeutic approach. They are not just "small adults" especially when their diseases have to be treated with a particular medicinal product. Knowledge about pharmacokinetic and dynamic response should provide safe and effective pharmacological treatment for children. The specifics of the children's physiology require suitable dosage formulations – oral liquids, powders or capsules [1-5].

Incomplete knowledge of the changes of the physiological condition hinders the ability to predict pharmacokinetic and pharmacodynamics behavior of novel and traditional pediatric medicinal products. There are incentives according to the regulatory agencies for the pharmaceutical industry in development of pediatric formulations [6].

The lack of pediatric formulations is as a result of the technology and market conditions. The pediatric patients need specific doses according to their age and weight so the development of age-adapted dosage forms is a great challenge for the scientists. In addition, the taste of the medicine could make the specific pediatric patient refuse to take it. The market and the economic reality are also a challenge – the pediatric market is about 20-25% of the total adult market [7,8].

In some patients who cannot swallow, such as the elderly, stroke victims, bedridden patients and who refuse to swallow, such as pediatric, geriatric and psychiatric patients – the administration of fast disintegrating drug delivery system improve patients' compliance. A fast disintegrating drug delivery system can be a tablet that dissolves or disintegrates in the oral cavity without need of water or chewing. These are also called orodispersible, quick dissolving or rapid disintegrating tablets. Bioavailability of these drugs is significantly greater than those observed from conventional tablet dosage form and the fast disintegrating drug delivery systems are an important new way of drugs' administration [9-15].

Day and Maiti (2010) claim that some people are not aware of fast disintegrating drug delivery systems. Therefore, pharmacists are responsible to spread the knowledge regarding this system. It is the pharmacist's duty to consult the patients for the use, advantages, storage and maintenance of the drugs. The pharmacist could be a primary source of relevant drug information [16-19].

Therefore understanding of the specific characteristics of the pediatric patients and the pediatric dosage forms is crucial for the particular pharmacists' decisions in their everyday practice.

***Corresponding author:** Maria Kamusheva, Department of Social pharmacy and Pharmacoeconomics, Faculty of Pharmacy, Medical University - Sofia, 2 Dunav Street, 1000 Sofia, Bulgaria, Tel: +359 886428154; E-mail: maria.kamusheva@yahoo.com

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Pharmacists' knowledge about the newest drug delivery system is crucial in order to provide the adequate pharmaceutical consultation for the drugs' administration.

The consultation is believed to be the main responsibility of the pharmacists [20]. Pharmacists' interventions are able to change the parents' knowledge, attitude and practice towards pediatric drug dosage forms and the prescribing pattern [21].

Munzenberger (2011) et al. claim that most pharmacists believe it is their responsibility to provide information on pediatric issues. The authors conclude that additional pediatric training is beneficial if the pharmacists want to provide meaningful recommendations to caregivers including the selection and use of products intended for children [22].

Studies which observe the level of pharmacists' knowledge, their professional opinion about different dosage formulations, the sources of information that they apply in their everyday practice are not published in the scientific literature. Such kind of information is with significant meaning and could be useful for the purposes of taking decisions for patients' compliance improvement, for development and implementation of new dosage forms, as well as for inclusion and financing of pharmaceutical consultation as one of the most essential responsibilities of the pharmacist.

The purpose of this study was to assess the awareness, knowledge and attitude of the Bulgarian pharmacists towards drug delivery systems and orodispersible dosage forms, pediatric dosage forms as well as the pharmacists' role in consultation process for the newest dosage forms.

Materials and Method

The study was conducted in 2013 amongst pharmacists from different regions in Bulgaria. The pharmacists were surveyed anonymously at several continuous education events. Questions were set on the advantages of the pediatric dosage forms and especially of orodispersible dosage forms; the goal of the development of new dosage forms; the sources of information about the newest drug delivery systems; the meaning of the pharmaceutical consultations; the inappropriate way of administration of orodispersible dosage forms and others. Excel and Statistical Package for Social Science (SPSS) programs processed the questionnaires and ANOVA analysis and chi-square test of independence were performed to evaluate the statistical significance of the differences in the collected data and to prepare descriptive statistics for the sample.

The following research hypotheses were tested:

1. Are the preferences to the dosage form influenced by the pharmacists' characteristics?

2. Do the specialization and work experience influence over their knowledge about the dosage forms?

3. Is there an association between the populated area and the used sources of information?

4. Is there any association between work experience, specialization and inappropriate administration?

5. Is there any association between the populated area and the sources of information about orodispersible tablets?

6. Do the work experience, populated area influence over the particular answers given by the respondents?

Results and Discussion

Demographic characteristics of the pharmacists

The number of respondents, gender, work experience, populated area: 274 master pharmacists were been surveyed of their attitude towards pediatric dosage forms and orodispersible dosage forms.

Distribution of the respondents according to their work experience is shown in Table 1. The average work experience was 25 years, for the male – 13.9 ± 13.9 years and for the female – 26.6 years ± 13.0. 83.6% of the surveyed pharmacists were female (Table 2). 2 male pharmacists and 31 female out of 274 respondents have specialization (Figure 1).

17 of the respondents have specialization in Organization and economics of the pharmacy. 35.8% of the respondents were pharmacies' owners, 22.3% were pharmacists who work in a pharmacy not owned by pharmacist and 20.8% - in a pharmacy owned by a pharmacist (Figure 2).

56.2% of the respondents practiced in a regional town, 24.5% - in non-regional town, 3.60% - in a village (Figure 3).

Characteristics of the pediatric dosage forms: 72.9% of the respondents shared the opinion that the organoleptic properties of the dosage forms have crucial role about the success of the pediatric dosage forms. For 73.4% this is the most appropriate administration of the medicines, 33.2% - the frequency of drug-intake, 21.5% - the price.

According to 43.10% prescription and dispensing of the orodispersible tablets for children have increased in the last years. For 25.90% there is no change (Figure 4).

The goal of the development of new drug forms: A significant part of the respondents considered that the goal of the development of new dosage forms was to optimize the biopharmaceutical and

	Gender											
	Man			Woman			NA			Total		
	Mean	Median	SD	Mean	Median	SD	Mean	Median	SD	Mean	Median	SD
Work experience (years)	13.9	8.5	13.9	26.6	28.5	13.0	39.0	39.0	.	25.0	27.0	13.8

Table 1: Distribution according to work experience.

Gender							
Man		Woman		NA		Total	
N	Row%	N	Row%	n	Row%	n	Row%
42	15.3%	229	83.6%	3	1.1%	274	100.0%

Table 2: Distribution according to the gender.

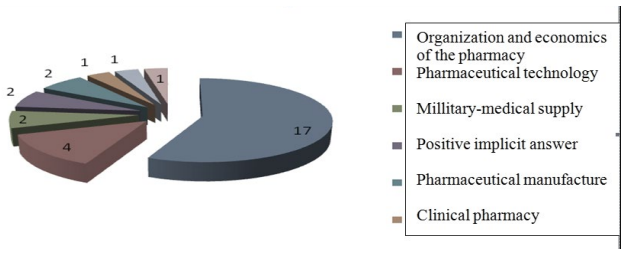

Figure 1: Distribution of the respondents according to their specialization.

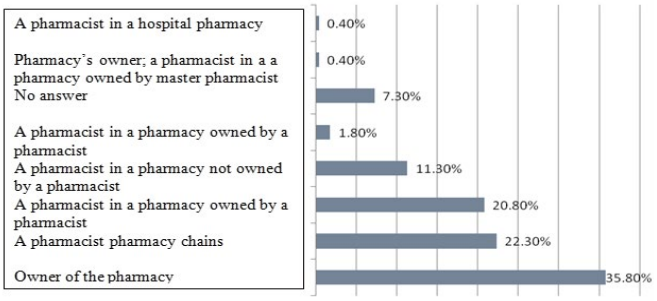

Figure 2: Distribution according to the workplace.

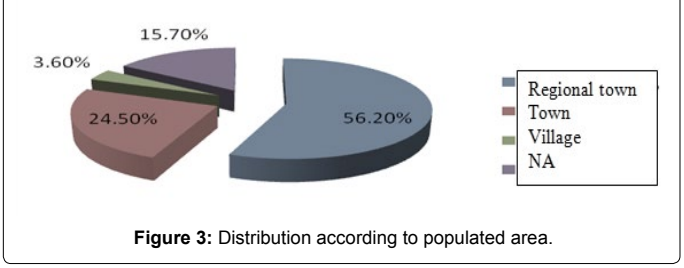

Figure 3: Distribution according to populated area.

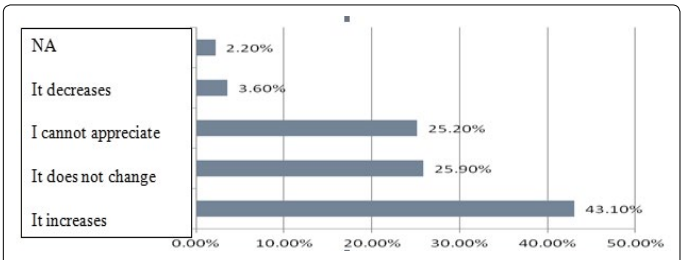

Figure 4: Do you think that in the recent years there is a change of a quantity of prescribed and dispensed orodispersible tablets for children?

pharmacokinetics characteristics of the medicines (58.4% and 52.6%, respectively). According to 48.2% of the respondents, the new forms will reduce the adverse drug reactions and 30.3% of the surveyed pharmacists shared the opinion that it will increase patients' compliance.

A main source of information used: For 45.3% of the respondents SPC (Summary of product characteristics), for 43.8% - internet, 42% - continuing education and for 33.9% - patients' leaflet – were indicated as main sources of information about new drug delivery systems. The medical sales representatives informed an essential percentage of the pharmacists (70.4%) about the new Drug Delivery System (DDS). Some of the pharmacists have answered that in the process of the feedback in communication with the patients they have learned more about new DDS, others – by their colleagues who work in the pharmaceutical manufacture. According to two of the respondents, it is hard for the patients to understand the leaflet of the medicinal product.

Assessment of the DDS's characteristics: An assessment of the DDS's characteristics has been performed. 69.7% found the fast effect as the main advantage of the orodispersible tablets; 54.4% - no requirement for water intake; 39.8% - the application in case of patients with esophageal problems and 21.2% - found the better taste as advantage of the orodispersible forms.

Advantages of the orodispersible tablets: 84.3% of the pharmacists consider that orodispersible tablets are suitable for patients with swallowing problems; 61.7% - for patients who travel frequently; 51.1% - for children; 33.9% - for patients with nausea; 28.1% - for elderly patients. 61.7% of the respondents would recommend orodispersible tablets as a first choice form and 38% - according to the disease of the patient.

35% of the pharmacists believe that patients' compliance is going to increase in case of intake the orodispersible form, 7.3% - better compliance and better reputation of the pharmacy.

Reasons for inappropriate administration: According to the pharmacists, the possible reasons for inappropriate administration of the orodispersible tablets are: the size of the tablets, improper administration; low health culture of the patients; lack of explanation by the physicians; overdosing in pediatric patients because of the better taste; intolerance to the taste. 51.10% of the respondents shared that they have never established inappropriate administration of these dosage forms (Figure 5).

The changing role of the pharmacists in a pharmacy practice, new therapeutic approaches, the role of continuing education, consultation: According to 71.2% of the pharmacists, the future role of the pharmacists is going to change, 78.8% consider that new therapeutic approaches will be implemented and 50.8% - that the pharmacists will be overloaded. Consultations of the patients will be essential according to 80.7% of the respondents and 67.9% shared they should be reimbursed. 73.8% consider that more time is needed to consult the patients. 85.8% of the respondents think pharmacists should acquire more knowledge that is new and continuing education has to contain essential and innovative topics.

38.4% consider that the physicians do not explain enough to the patients about the administration of orodispersible tablets. 88.5% of pharmacists always inform and consult the patients about the dispensed medicines. According to 82.9% of the respondents the holders of marketing authorization of the medicinal products can help in providing pharmaceutical consultations. Inappropriate instructions by the physicians and misunderstanding of the patient's leaflets are the main reasons for inappropriate usage of the medicines according to 77.85% and 68.6%, respectively.

Only 7 respondents have sent recommendations to the marketing authorization holders of the medicinal products. These recommendations are for providing the access to these new forms (through decrease in their price); implementation of smaller packets with one dose; continuing education about the specific characteristics of these orodispersible forms.

Statistical analysis

We have found no association between the choice of the dosage

forms with appropriate organoleptic properties, the frequency of the administration and minimal impact of patients' health, the use in all pediatric groups with the respondents' characteristics.

No associations exist between the opinion of the respondents about the suitable way of administration and their work experience. All of the respondents assessed in a high-level comfortable way of administration of the pediatric dosage forms – this approval is greater in the pharmacists who have work experience between 1 and 9 years (83.3%) The respondents with specialization considered that the comfortable way of administration has a great importance (p=0.038). There is no difference within the separated pharmacists with specialization.

Specialization influences the extent of the assessment of pharmacokinetic parameters in the process of development of new dosage forms (p=0.056).

The length of the work experience has an association with the extent of assessment of the pharmacokinetics characteristics in the process of development of new dosage forms (p=0.003). The respondents with the work experience 10-19 years note this parameter as the most important. This importance decreases with an increase of the length of the work experience (Figure 6).

The workplace and populated area have an association with the increase of patients' compliance in the process of development of new dosage forms (p=0.011 and p=0.046, respectively). This parameter was with great importance (37.4%) for the owners of the pharmacies and for the pharmacists who work in pharmacies owned by pharmacists (40.4%), for 38.8% of them who are from regional towns.

A significant association exists between the length of the work experience and workplace with the opinion about improvement of compliance in development of new dosage forms (p=0.002) and (p=0.022) respectively. 50% of the respondents with work experience 1-9 years, 51.4% - 10-19 years, give a great importance of this parameter. 34.7% of the pharmacist's owners of the pharmacies, 29% - who work in pharmacies owned by pharmacists and 9.7% - in pharmacies not owned by pharmacists.

We found an association between the available specialization of the pharmacists and inappropriate administration of the orodispersible tablets (p (Sig.) =0.017). The respondents with specialization (23.5%) consider that they register fewer cases of inappropriate administration of these dosage forms in comparison with the pharmacists without specialization (30.8 %).

A significant association exists between the use of patients' leaflets as a source of information for orodispersible tablets and the populated area (p=0.012). Mainly the pharmacists from the smaller towns and the villages use the leaflet.

Our study showed association between work experience and the pharmacists' opinion about the future role of the pharmacist in the development of new dosage forms (p=0.014). 71.2 % of the respondents think that the pharmacists' role will be changed by the development of new dosage forms: 76.7% with 1-9 years wok experience; 62.9% -10-19 years and 70.6% in the next group. The pharmacists with the greatest optimistic opinion are with work experience more than 40 years – 81.3%.

15.4% of the respondents without specialization and 20.6% of the respondents with specialization do not consider that the new DDS are going to create new therapeutic approaches (p=0.000).

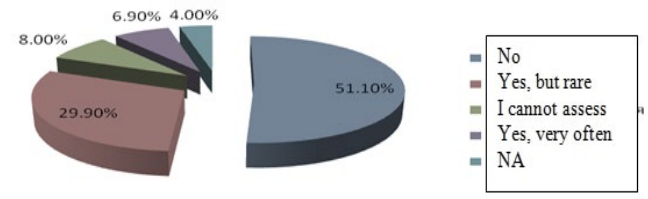

Figure 5: "Have you ever established inappropriate administration of the orodispersible dosage forms?"

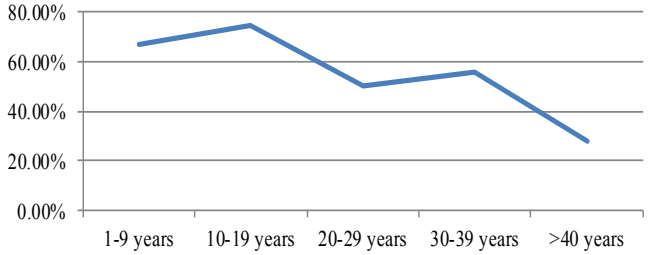

Figure 6: The importance of pharmacokinetics characteristics parameters in development of new dosage forms in associations with the length of the work experience.

32.5% of the respondents without specialization and 26.5% with specialization, stated that the pharmacists have to spare more time to consult the patients (p=0.000). 42.9% of the male respondents and 30.1% of the female respondents consider that the duration of consultation will be longer (p=0.013).

A statistical association exists between specialization and the opinion about the need of new knowledge for the development of pharmaceutical technology (p=0.000), and between specialization and the opinion about the implementation of innovative topics in continuing education (p=0.000). 83% of the respondents without specialization and 76.5% with specialization, think that it is necessary such a topic to be included in the continuing education.

61.8% of the respondents with specialization and 68.8% - without, consider that consultations should be paid (p=0.000).

26.2% of the male respondents and 38.4% of the female ones have answered positive about the necessity of additional consultations (p=0.014).

A significant association exists between the opinion about the opportunity the marketing-authorization holders (MAH) to support the process of providing the pharmaceutical consultations and specialization and workplace of the respondents (p=0.000). 40.8% of the pharmacies' owners and 71% of the respondents who work in pharmacies not owned by pharmacists consider that MAH have the opportunity to help.

Discussion

1. A significant part of the respondents thinks that organoleptic properties are very important for the pediatric dosage forms. According to every 5th pharmacist the price is also a significant factor. The pediatric patients have more complex needs to receive medicinal products in the most proper dosage form in order to be reduced the unpleasant taste and to be improved the patient's compliance.

2. A great part of the pharmacists recognizes that there is increasing in the use of orodispersible pediatric forms. According to the pharmacists, the main advantages of the orodispersible forms are their fast effect and better taste and according to every 3rd pharmacist these forms are suitable in case of oropharyngeal problems. The pharmacists have a great level of acceptance of orodispersible forms and they appreciate different advantages and the advantage about patients' compliance. The faster absorption of the active ingredient, the faster relief of the symptoms and the easier administration are significant advantages of the orodispersible dasage form and make them more preferred by the patients. The convenience in implementation of a particular medicinal product and the simplified and improved dosage form are associated with higher compliance and they give possibilities to achieve a significant therapeutic success.

3. The medical sales representatives are identified as a main source of information about new drug delivery forms of the medicinal products. The pharmacists in the community pharmacies are overloaded. The participation of the medicine representatives in the process is crucial – they are in the most of cases the primary source of information for the most innovative dosage forms and help to the pharmacists to enhance their knowledge.

4.A significant part of the pharmacists think that the future role of the pharmacists will be in development of new drug delivery forms and 78.8% of the respondents think that new therapeutic approaches would be created. A significant part of the pharmacists conclude that with the development of new drug delivery forms the need for more pharmaceutical consultations about their use will become greater. 80.7% of the respondents think that the patients will need consultations with the pharmacists; 73.8% - the pharmacist have to spend more time for consultations. 85.8% - that the pharmacists have to acquire new knowledge and 82.1% - the continuing education has to contain topical issues. A significant part of the pharmacists considers that the pharmaceutical consultation should be financed. Giving pharmaceutical consultations to the patients about the right use of a particular dosage form has its crucial role in the pharmaceutical practice. There is a significant need of high-qualified pharmacists as well as conducting continuous education in order to enhance the pharmacists' knowledge for the newest dosage form. This could ensure the appropriate drug usage and could help to avoid noncompliance.

Limitations

1. The heterogeneity of the questions asked to the pharmacists leads to lack of possibility for overall conclusion. More précised and concrete questions covering a specific topic could give in more details the current situation in the community pharmacy's sector.

2. Lack of prior researches on the topic in Bulgaria cannot give the opportunity for comparison and juxtaposition.

3. There is irregular distribution of the respondents according to their workplace (town, village) which probably cannot clearly represent the real situation.

Conclusion

There is an evidence for the great acceptance of the innovative dosage forms which have numerous advantages according to the survey's results. The pharmacists have a significant role in the therapeutic process of every patient because they are drug information specialists and can consult the patients for the action and the characteristics of each dosage forms. The collaboration between the medicine representatives, the physicians and the pharmacists could lead to better therapeutic results for the patients, especially for the pediatric patients. The future is of the innovative dosage forms and drug releasing systems which application may be a challenge – a challenge which could be overcome with the active participation of the high-qualified pharmacists in the community pharmacy in Bulgaria.

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