

Рекомендована д.ф.н, професором П.Д.Пашиєвим

UDC 333.13:615.256.3

RESEARCH OF THE ASSORTMENT AND EVALUATION OF CONSUMER CHARACTERISTICS OF COMBINED ORAL CONTRACEPTIVES AT THE PHARMACEUTICAL MARKET OF UKRAINE

T.V.Trunova

National University of Pharmacy

The analysis of the Ukrainian pharmaceutical market of combined oral contraceptives by the composition, the form of production, manufacturer, determination of the need for contraceptives at the social level has been performed. The analysis of consumer characteristics has been conducted according to such criteria as intended use efficiency, social significance, practical usefulness, safety and harmlessness, aesthetics, etc.; it will provide protection of the reproductive health of women, which is in close correlation with the state of health in general.

Transition to the market economy and problems in the social and economical area caused by it, as well as the absence of the state social policy aimed at the country's population reproduction have negatively influenced on many aspects of family and maternity. That is why the care for saving the population's reproductive health is one of the basic tasks of our state. Evidence of troubles in this area is the data about implementation of the reproductive function of women: deterioration of the health of pregnant women and parturients, and it considerably determines the high percentage of reproductive losses, a significant incidence of gynecological morbidity and sexually transmitted diseases [13]; a relatively high level of abortions and complications caused by them. An alternative to abortions, as it is well known, is the use of effective contraception methods. In this connection it should be underlined that contraception is not a limitation of the birth rate, but a method for its regulation, an ability to make reproductive plans as for the number of children and timing of their birth [3, 5, 10, 11, 14].

Experimental Part

The research of the assortment of combined oral contraceptives at the pharmaceutical market of Ukraine, identification of the leading countries-manufacturers, as well as analysis of consumer characteristics of these drugs have been performed.

This study has examined the modern methods of medication contraception as recently both in this country and abroad, new generations of this group of drugs appear.

OCs are tablets with a different content of hormones to be taken daily in certain sequence. They have their classification by the amount and type of the hormone that they contain [6].

According to the ATC international classification these drugs belong to the anatomical group G – medicines for the genitourinary system and sex hormones, the pharmacological group G03 – hormones of the sexual glands and medicines used with the pathology of the sexual sphere, the therapeutic pharmacological group G03A – hormonal contraceptives for systemic application, the therapeutic chemical subgroup G03A A – estrogens and gestagens in the fixed combinations [4].

In the process of work the data from the State Register of Medicines [2] were used; on its basis we analyzed the range of products of this group (Table) [15].

Results and Discussion

Thus, 28 medicines are registered in Ukraine. The whole range of oral contraceptives is represented only by foreign medicines. The leading manufacturers are Germany and Hungary (see Fig.). Combined oral contraceptives (COC) are produced only in two dosage forms – tablets and dragee. In the form of dragee there are only four medicines – «Logest», «Femoden», «Triquilar» and «Minisistone». The primary packing of OCs is a blister. This is a type of packing if of pre-formed plastic. It has a neat appearance, reliability and safety during storage, provides the opportunity to review the appearance of products without damaging the package itself, easy to use and carry, creates the possibility of taking certain portions of the content without contaminating the rest, contains the information about the drug. The outer packing has the name of the country, the name of the manufacturer, the trade mark and address, the name of the medicine, a dosage form, the drug quantity and a dose, the route of administration, storage conditions, shelf life, the batch number, the registration number, the bar code.

The name of the medicine is indicated in Ukrainian (and Russian), as well as Latin (and/or English). The name of the medicine and the international non-proprietary name stand out among all the labeling sings. For this purpose manufacturers use a bigger and bold font, vivid colours, choose a comfortable label place to read on the label or on one of the sides of the package. Around the name there are no signs that could make it difficult to read.

Properties of goods, which cause their ability to meet the specific needs of the population, are revealed in the process of use or consumption and are called the consumer ones. For successful implementation of any drug the main

The current range of oral contraceptives

No.	Name	Dosage form	Composition	Manufacturer
1	2	3	4	5
1.	LINDYNETTE 30	Coated tablets, No. 21 (21x1), No. 63 (21x3) in blisters	1 tablet contains 0.075 mg of gestodene and 0.03 mg of ethinylestradiol	Gedeon Richter Plc., Hungary
2.	Lindynette 20	Coated tablets, No. 21 (21x1), No. 63 (21x3) in blisters	1 tablet contains 0.075 mg of gestodene and 0.02 mg of ethinylestradiol	Gedeon Richter Plc., Hungary
3.	Tri-regol 21+7	Combi-Pack: Coated tablets, No. 28 (28x1), No. 84 (28x3)	1 pink tablet contains 0.05 mg of levonorgestrel and 0.03 mg of ethinylestradiol; 1 white tablet contains 0.075 mg of levonorgestrel and 0.04 mg of ethinylestradiol; 1 dark-yellow tablet contains 0.125 mg of levonorgestrel and 0.03 mg of ethinylestradiol; 1 reddish-brown tablet contains 76.05 mg of ferrum fumarate	Gedeon Richter Plc., Hungary
4.	Tri-regol	Coated tablets No. 21 (21x1), No. 63 (21x3)	1 pink tablet contains 0.05 mg of levonorgestrel and 0.03 mg of ethinylestradiol; 1 white tablet contains 0.075 mg of levonorgestrel and 0.04 mg of ethinylestradiol; 1 dark-yellow tablet contains 0.125 mg of levonorgestrel and 0.03 mg of ethinylestradiol;	Gedeon Richter Plc., Hungary
5.	RIGEVIDON	Coated tablets, No. 21x1, No. 63 (21x3)	1 tablet contains 0.15 mg of levonorgestrel and 0.03 mg ethinylestradiol	Gedeon Richter Plc., Hungary
6.	MERCILON®	Tablets No. 21 in blister	1 tablet contains 0.02 mg of ethinylestradiol, 0.15 mg of desogestrel	N.V.Organon, Netherlands; Organon LTD., Ireland
7.	MARVELON®	Tablets No. 21x1, No. 21x3 in blisters	1 tablet contains 0.15 mg of desogestrel and 0.03 mg of ethinylestradiol	Organon LTD., Ireland; N.V.Organon, Netherlands
8.	REGULON®	Coated tablets, 0,15 mg/0,03 mg No. 21 (21x1), No. 63 (21x3) in blisters	1 coated tablet contains 0.15 mg of desogestrel and 0.03 mg of ethinylestradiol	Gedeon Richter Plc., Hungary
9.	NOVINET	Coated tablets, 0,15 mg/0,02 mg No. 21 (21x1), No. 63 (21x3) in blisters	1 coated tablet contains 0.15 mg of desogestrel and 0.02 mg of ethinylestradiol	Gedeon Richter Plc., Hungary
10.	FEMODEN®	Dragee No. 21 in blisters	1 dragee contains 30 mcg of ethinylestradiol and 75 mcg of gestodene	Bayer Pharma AG, Germany Bayer Weimar GmbH & Co. KG, Germany
11.	RIGEVIDON 21+7	Coated tablets, No. 28 (28x1), No. 84 (28x3)	1 white tablet contains 0.15 mg of levonorgestrel and 0.03 mg of ethinylestradiol; 1 reddish-brown tablet contains 76.05 mg of ferrum fumarate	Gedeon Richter Plc., Hungary
12.	SILUETTE®	Film coated tablets, No. 21 (21x1), No. 63 (21x3) in blisters	1 tablet contains 2 mg of dienogest, 0.03 mg of ethinylestradiol	Gedeon Richter Plc., Hungary
13.	TRIQUILAR®	Dragee No. 21	1 pack contains: 21 (6 light-brown, 5 white, 10 yellow) dragee; 1 light-brown dragee contains 0.030 mg of ethinylestradiol; 0.050 mg of levonorgestrel; 1 white dragee contains 0.040 mg of ethinylestradiol; 0.075 mg of levonorgestrel; 1 yellow dragee contains 0.030 mg of ethinylestradiol, 0.125 mg of levonorgestrel	Bayer Schering Pharma AG, Germany Schering GmbH & Co. Productions KG, Germany Schering AF, Germany
14.	MINISISTONE	Dragee No. 21	1 dragee contains 0.03 mg of ethinylestradiol and 0.125 mg of levonorgestrel	Jenapharm GmbH & Co. KG, Germany a company of group Bayer Schering Pharma AG, Germany Schering GmbH & Co. Productions KG, Germany Jenapharm GmbH & Co. KG, Germany a company of group Bayer Schering Pharma AG, Germany

Table continued

1	2	3	4	5
15.	DAYLLA	Film coated tablets, 3 mg/0.02mg No. 21 (21x1), No. 63 (21x3) in blisters with a box for blister storage	1 tablet contains 3 mg of crystalline drospirenone and 0.02 mg of micronized ethinylestradiol	Gedeon Richter Plc., Hungary
16.	MIDIANA	Film coated tablets, No. 21 (21x1), No. 63 (21x3) in blisters	1 tablet contains 3 mg of drospirenone, 0.03 mg of ethinylestradiol	Gedeon Richter Plc., Hungary
17.	LOGEST®	Coated tablets, No. 21	1 tablet contains 20 mcg of ethinylestradiol, 75 mcg of gestodene	Bayer Schering Pharma AG, Germany; Delpharm Lille S.A.S. France for Schering AG, Germany, France; Delpharm Lille S.A.S., France for Bayer Schering Pharma AG, Germany; France/Germany Schering AG, Germany
18.	BELARA	Film coated tablets, No. 21, No. 21x3	1 tablet contains 2 mg of chlormadinone acetate, 30 mcg of ethinylestradiol	Grunenthal GmbH, Germany
19.	JEANINE®	Coated tablets, No. 21 (21x1), No. 63 (21x3) in blisters in a cardboard package	1 coated tablet contains 30 mcg of ethinylestradiol and 2 mg of dienogest	Bayer Weimar GmbH & Co. KG, Germany Jenapharm GmbH & Co. KG, Germany
20.	JAZ	Coated tablets, No. 28 (24+4) in blisters	1 pack contains 28 tablets (24 light-pink tablets and 4 white placebo tablets). 1 light-pink tablet contains 0.02 mg of ethinylestradiol (as clatrate with betadex) and 3 mg of drospirenone	Bayer Pharma AG, Germany; Bayer Weimar GmbH & Co. KG, Germany
21.	CHLOE	Coated tablets + Tablets – placebo, combi-pack No. 28 (28 (21+7)x1); No. 84 (28 (21+7)x3) in blisters	1 coated tablet contains 2 mg of cyproterone acetate, 0.035 mg of ethinylestradiol; Placebo tablet – lactose monohydrate, povidone, sodium carboxymethyl starch (type A), anhydrous colloidal silicium dioxide, aluminum oxide, magnesium stearate	Zentiva, Czech Republic
22.	YARINA®	Coated tablets, No. 21 (21x1) in blisters	1 tablet contains 0.03 mg of ethinylestradiol, 3 mg of drospirenone	Bayer Pharma AG, Germany; Bayer Weimar GmbH & Co. KG, Germany
23.	JAZ PLUS	Coated tablets, No. 28 (24+4) in blisters	1 pink tablet contains 0.02 mg of ethinylestradiol (as clatrate with betadex), 3 mg of drospirenone, 0.451 mg of levomefolate calcium	Bayer Pharma AG, Germany; Bayer Weimar GmbH & Co. KG, Germany
24.	DIANE-35	Coated tablets, No. 21 in blisters	1 coated tablet contains 0.035 mg of ethinylestradiol, 2 mg of cyprotherone acetate	Bayer Pharma AG, Germany; Bayer Weimar GmbH & Co. KG, Germany
25.	DARYLIA	Film coated tablets, 3 mg/0.02 mg, No. 28 (1x24+4), No. 84 (3x24+4) in blisters with a flat cardboard box for blister storage in a cardboard package	1 active tablet contains 3 mg of 100 % crystalline drospirenone + 0.02 mg of 100 % micronized ethinylestradiol 1 placebo tablet contains no active substances	Gedeon Richter Plc., Hungary
26.	YARINA® PLUS	Coated tablets, No. 28 (21+7) in blisters	1 pack contains 28 coated tablets (21 orange tablets and 7 light-orange tablets) 1 orange tablet contains 0.03 mg of ethinylestradiol, 3 mg of drospirenone and 0.451 mg of levomefolate calcium 1 light-orange tablet contains 0.451 mg of levomefolate calcium	Bayer Pharma AG, Germany; Bayer Weimar GmbH & Co. KG, Germany
27.	ARTITIA	Coated tablets, No. 21 (21x1), No. 63 (21x3) in blisters	1 tablet contains 0.075 mg of gestodene, 0.02 mg of ethinylestradiol	Haupt Pharma Munster GmbH, Germany; Zentiva, Czech Republic
28.	LOGEST®	Dragee No. 21	1 dragee contains 20 mcg of ethinylestradiol and 75 mcg of gestodene	Delpharm Lille S.A.S., France for Bayer Schering; Pharma AG, Germany, France/Germany

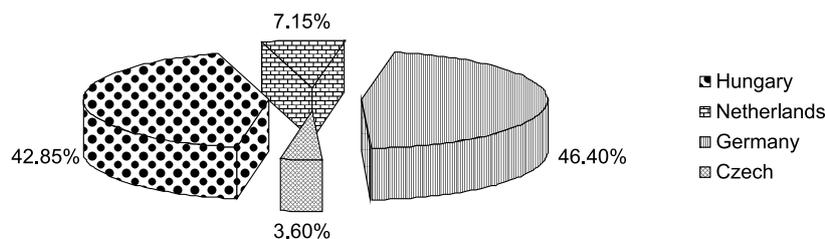


Fig. The structure of the COC market by the countries-manufacturers.

condition is the high estimation of its quality by a consumer [9]. Consumer properties of combined oral contraceptives were analyzed according to several indicators [8]. One of them is functional properties, i.e. effectiveness of their intended use. For the correct choice of hormonal contraceptives a person must necessarily consult a gynecologist, who according to the diagnostic data prescribes a drug that is most suitable for a particular patient.

When choosing a hormonal oral contraceptive the certain studies should be carried out, among which determination of the hormones level in the blood is obligatory. A repeated consultation of a gynecologist is recommended in about 3 months after taking tablets. This is necessary in order to monitor the effect of hormonal substances and to determine overall health. One of the consumer factors is the social significance of combined oral contraceptives. These products allow controlling fertility and regulate the ability to implementation of reproductive plans as for children and terms of their birth. They also play an important role in keeping woman's reproductive health. The practical benefit of COCs is their rapid action and high performance. The medicines are easy to use and in no way adversely affect the sensation during intercourse (unlike some other methods of contraception); these drugs are prevention of some causes of infertility [12]. Before use each woman should be acquainted with disadvantages of the drug since many consumers mistakenly believe that COCs protect against infections, sexually transmitted diseases, and administration of the drugs can be made in a chaotic manner. Combined oral contraceptives are taken daily at the same time. As with any medication, oral contraceptives have their safety and harmlessness indicators. Side effects while taking modern hormonal contraceptives are rare and even if they appear, it occurs in the first months of administration, and subsequently they are terminated or significantly mitigated. Side effects of hormonal contraceptives include nausea, the mammary glands tension, a slight increase in weight, intermenstrual bleeding and others. Severe complications while taking hormonal contraceptives (hypertension, thromboembolism, liver pathology) are extremely rare and mostly occur in unexamined patients [16].

Administration of hormonal contraceptives should be stopped and seek medical advice in case of the sudden attack of severe headache, pain behind the breastbone, blurred vision, shortness of breath, appearance of jaundice, increased blood pressure over 160/100 mm Hg. [1, 7].

From there we can conclude that the risk of taking oral contraceptives is much lower than the risk of complications during abortions. Aesthetics is also one of the

most important consumer properties. Modern oral contraceptives are available in the form of blisters containing 21 (21 medicines, which is 75% of the assortment) or 28 tablets (7 medicines – 25% of the assortment). For convenience, manufacturers usually put arrows on the plate corresponding to the sequence of taking tablets (especially it is important when using a two- or three-phase medicines) or on the packing days of the week (in monophasic medicines) are indicated. A consumer by instructions of the manufacturer easily and conveniently takes the drug on cycle days, where it is clearly explained which tablet on which day should be taken. Most drugs («Yarina», «Regulon», etc.) have the so-called special «case», in which a patient can insert a blister with tablets and carry around in the purse for a timely and convenient use. Packs of COCs have a bright and aesthetic colouring, which is attractive to patients. The medicines themselves have a different colour. For example, if the plate has 28 tablets, then 21 of them are painted with one colour and the remaining 7 (placebo) – with another. If we analyze the medicine «Jaz», the blister contains 28 tablets, 24 of them are pink with letters «DS» – active tablets with the active ingredient and 4 are white tablets labeled with «DP» – inactive (placebo). For example, in «Diane-35» they are mildly yellow. The medicine is available in a calendar pack of 21 tablets, which are in blister packing: cells are made of PVC film and coated by aluminum foil with a coating. For a consumer one of the most important factors is the expiration date. In this group of drugs the shelf life is 3 years at the temperature below 25°C out of reach of children. One of the first indicators, which people pay attention to when choosing any product is its consumer characteristics, their features should be evaluated and analyzed by manufacturers before the entry to the pharmaceutical market.

CONCLUSIONS

Based on the objectives of the WHO program on the reproductive health, modern contraceptives should be more widely implemented into public health practice in our country to prevent unwanted pregnancy and the reproductive health of women. In this article attention is paid to the analysis of the Ukrainian pharmaceutical market of combined oral contraceptives by the composition, the form of production, manufacturer, as well as determination of the need for contraceptives at the social level. The analysis of consumer characteristics has been conducted according to such criteria as intended use efficiency, social significance, practical usefulness, safety and harmlessness, aesthetics, etc.; it will provide protection of the reproductive health of women, which is in close correlation with the state of health in general.

REFERENCES

1. Васнецова О.А. Медицинское и фармацевтическое товароведение. – 2-е изд., перераб. и доп. – М.: ГЭОТАР-Медиа, 2009. – С. 135-136.
2. Державний реєстр лікарських засобів [Електронний ресурс]. – Режим доступу: <http://www.drlz.kiev.ua/>
3. Дремова Н.Б. // Фармація. – 1999. – №3. – С. 27-29.
4. Компендіум 2011 – лікарські препарати / Під ред. В.Н.Коваленко, А.П.Вікторова. – К.: МОПІОН, 2011. – 2320 с.
5. Крылова О.В. Разработка комплекса маркетинговых исследований контрацептивных средств: Автореф. дис. ... канд. фармацев. наук. – М., 2006. – 138 с.
6. Кукес В.Г. Клиническая фармакология / Науч. ред. А.З.Байчурина. – 2 изд., перераб. и доп. – М.: ГЭОТАР МЕДИЦИНА, 1999. – 528 с.
7. Стрелков В.Н. Фармацевтическое товароведение: учебное пособие для фармацевтических вузов и факультетов / В.Н.Стрелков. – 2-е изд., перераб. и доп. – Пятигорск: Пятигорская ГФА, 2008. – С. 55-59.
8. Товар и его потребительские свойства. Характеристики свойств и их показателей [Электронный ресурс]. – Режим доступа: <http://www.webstarstudio.com/marketing/theor/gos/2.htm>
9. Derman R. // Gynecol. Surv. – 1989. – Vol. 44, №9. – P. 662-668.
10. Handbook of family planning / Ed. by N.Loudon. – Edinburgh; New York: Churchill Livingstone, 1991. – 472 p.
11. Improving access to quality care in family planning. Medical eligibility criteria for contraceptive use. – Geneva: WHO, 1996. – 144 p.
12. Kleinman R. Hormonal contraception. – London: IPPF Medical Publications, 1990. – 122 p.
13. Mishell D.R. // N. Engl. J. Med. – 1989. – Vol. 320. – P. 777-787.
14. Senanayake P., Kramer D.G. // Amer. J. Obstet. Gynec. – 1980. – №138. – P. 852.
15. Smith M.C. Principles of Pharmaceutical Marketing. – 3rd ed. – Philadelphia, PA: Lea & Febiger, 1983. – 529 p.
16. Vessey M.P. // Methods Int. Med. – 1993. – Vol. 32. – P. 222-224.

УДК 333.13:615.256.3

ИССЛЕДОВАНИЯ АССОРТИМЕНТА И ОЦЕНКА ПОТРЕБИТЕЛЬСКИХ СПОСОБНОСТЕЙ КОМБИНИРОВАННЫХ ОРАЛЬНЫХ КОНТРАЦЕПТИВОВ НА ФАРМАЦЕВТИЧЕСКОМ РЫНКЕ УКРАИНЫ

Т.В. Трунова

Проведен анализ украинского фармацевтического рынка комбинированных оральных контрацептивов по составу, форме выпуска, фирме-производителю, определению потребности в противозачаточных средствах на социальном уровне. Был проведен анализ потребительских свойств по таким критериям, как эффективность использования по назначению, социальная значимость, практическая полезность, безопасность и безвредность, эстетичность и т.д., что в результате обеспечит сохранение репродуктивного здоровья женщин, которое находится в тесной взаимосвязи с состоянием здоровья в целом.

УДК 333.13:615.256.3

ДОСЛІДЖЕННЯ АСОРИМЕНТУ ТА ОЦІНКА СПОЖИВЧИХ ВЛАСТИВОСТЕЙ КОМБІНОВАНИХ ОРАЛЬНИХ КОНТРАЦЕПТИВІВ НА ФАРМАЦЕВТИЧНОМУ РИНКУ УКРАЇНИ

Т.В. Трунова

Проведено аналіз українського фармацевтичного ринку комбінованих оральних контрацептивів за складом, формою випуску, фірмою-виробником, визначенням потреби в протизаплідних засобах на соціальному рівні. Був проведений аналіз споживчих властивостей за такими критеріями, як ефективність використання за призначенням, соціальна значимість, практична корисність, безпечність та нешкідливість, естетичність тощо, що в результаті забезпечить збереження репродуктивного здоров'я жінок, яке знаходиться в тісному взаємозв'язку зі станом здоров'я в цілому.