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## **RANGE RESEARCH AND EVALUATION OF CONSUMER PROPERTIES OF COMBINED ORAL CONTRACEPTIVES IN THE PHARMACEUTICAL MARKET OF UKRAINE**

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

Transition to the market economy and caused by it problems in social-economical area, and also the absence of the state social policy aimed at the country's population reproduction have negatively influenced 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 trouble in this area are the data about the implementation of the reproductive function of women: the deterioration of the health of pregnant women and parturients, which largely determines the high percentage of reproductive losses, a significant incidence of gynecological morbidity and sexually transmitted diseases [13]; relatively high level of abortions and complications caused by them. An alternative to abortions is, as it is well known, the use of effective contraception methods. In this connection it should be underlined that contraception is not a limitation of 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

Range research of combined oral contraceptives in the pharmaceutical market of Ukraine, identification of the leading producing countries, and also analysis of consumer characteristics of these drugs.

This study examined the modern methods of medication contraception, as recently both in our country and abroad, new generation of this group of drugs appear, the range of modern oral contraceptives (OCs) is expanded and updated.

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

According to the International Classification of ATC these drugs belong to the anatomical group G - remedies for the genitourinary system and sex hormones, pharmacological group G03 - Hormones of sexual glands and the preparations, used with the pathology of the sexual sphere, a therapeutically-pharmacological group G03A - hormonal contraceptives for systemic application, therapeutic chemical subgroup G03A A - estrogens and gestagens in the fixed combinations [4].

During the study, we used data from the National Registry of drugs [2], from which we analyzed the range of products of this group (Table) [15].

Table

<b>№</b>	<b>Name</b>	<b>Dosage form</b>	<b>Composition</b>	<b>Manufacturer</b>
1.	LINDYNETTE 30	Coated tablets, № 21 (21x1), № 63 (21x3) in blisters	1 tablet contains gestodene 0,075 mg and ethinylestradiol 0,03 mg	Gedeon Richter Plc., Hungary
2.	LINDYNETTE 20	Coated tablets, № 21 (21x1), № 63 (21x3) in blisters	1 tablet contains gestodene 0,075 mg and ethinylestradiol 0,02 mg	Gedeon Richter Plc., Hungary
3.	TRI-REGOL 21+7	Combi-Pack: Coated tablets, № 28 (28x1), № 84 (28x3)	1 pink tablet contains 0,05 mg levonorgestrel and 0,03 mg ethinylestradiol; 1 white tablet contains 0,075 mg levonorgestrel and 0,04 mg ethinylestradiol; 1 dark-yellow tablet contains 0,125 mg levonorgestrel and 0,03 mg ethinylestradiol; 1 reddish-brown tablet contains 76,05 mg ferrum fumarate	Gedeon Richter Plc., Hungary
4.	TRI-REGOL	Coated tablets № 21 (21x1), № 63 (21x3)	1 pink tablet contains 0,05 mg levonorgestrel and 0,03 mg ethinylestradiol; 1 white tablet contains 0,075 mg levonorgestrel and 0,04 mg ethinylestradiol; 1 dark-yellow tablet contains 0,125 mg levonorgestrel and 0,03 mg ethinylestradiol;	Gedeon Richter Plc., Hungary

5.	RIGEVIDON	Coated tablets, № 21x1, № 63 (21x3)	1 tablet contains 0,15 mg levonorgestrel and 0,03 mg ethinylestradiol	Gedeon Richter Plc., Hungary
6.	MERCILON®	Tablets № 21 in blister	1 tablet contains ethinylestradiol 0,02 mg, desogestrel 0,15 mg	N.V.Organon, Netherlands; Organon LTD., Ireland
7.	MARVELON®	Tablets № 21x1, № 21x3 in blisters	1 tablet contains desogestrel 0,15 mg and ethinylestradiol 0,03 mg	Organon LTD., Ireland; N.V.Organon, Netherlands
8.	REGULON®	Coated tablets, 0,15 mg/0,03 mg № 21 (21x1), № 63 (21x3) in blisters	1 coated tablet, contains desogestrel 0,15 mg and ethinylestradiol 0,03 mg	Gedeon Richter Plc., Hungary
9.	NOVINET	Coated tablets, 0,15 mg/0,02 mg № 21 (21x1), № 63 (21x3) in blisters	1 coated tablet contains desogestrel 0,15 mg and ethinylestradiol 0,02 mg	Gedeon Richter Plc., Hungary
10.	FEMODEN®	Dragee № 21 in blisters	1 Dragee contains: ethinylestradiol 30 mcg and gestodene 75 mcg	Bayer Pharma AG, Germany Bayer Weimar GmbH & Co. KG, Germany
11.	RIGEVIDON 21+7)	Coated tablets, № 28 (28x1), № 84 (28x3)	1 white tablet contains 0,15 mg levonorgestrel and 0,03 mg ethinylestradiol; 1 reddish-brown tablet contains 76,05 mg ferrum fumarate	Gedeon Richter Plc., Hungary
12.	SILUETTE®	Film coated tablets, № 21 (21x1), № 63 (21x3) in blisters	1 tablet contains 2 mg dienogest, 0,03 mg ethinylestradiol	Gedeon Richter Plc., Hungary
13.	TRIQUILAR®	Dragee № 21	1 pack contains: 21 (6 light-brown, 5 white, 10 yellow) dragee; 1 light-brown dragee contains ethinylestradiol 0,030 mg; levonorgestrel 0,050 mg; 1 white dragee contains ethinylestradiol 0,040 mg; levonorgestrel 0,075 mg; 1 yellow dragee contains ethinylestradiol 0,030 mg, levonorgestrel 0,125 mg	Bayer Schering Pharma AG, Germany Schering GmbH & Co. Productions KG, Germany Schering AG, Germany
14.	MINISISTONE	Dragee № 21	1 Dragee contains ethinylestradiol 0,03 mg and levonorgestrel 0,125 mg	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
15.	DAYLLA	Tablets, film coated, 3 mg/0,02 mg № 21 (21x1), № 63 (21x3) in blisters with a box for blister storage	1 tablet contains 3 mg crystalline drospirenone and 0,02 mg ethinylestradiol micronized	Gedeon Richter Plc., Hungary
16.	MIDIANA	Tablets, film coated, № 21 (21x1), № 63 (21x3) in blisters	1 tablet contains 3 mg drospirenone, 0,03 mg ethinylestradiol	Gedeon Richter Plc., Hungary
17.	LOGEST®	Coated tablets, № 21	1 tablet contains ethinylestradiol 20 mcg i gestodene 75 mcg	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	Tablets, film coated, № 21, № 21x3	1 tablet contains chlormadinone acetate 2 mg, ethinylestradiol 30 mcg	Grunenthal GmbH, Germany
19.	JEANINE®	Coated tablets, № 21 (21x1), № 63 (21x3) in blisters in cardboard package	1 coated tablet, contains ethinylestradiol 30 mcg and dienogest 2 mg	Bayer Weimar GmbH &Co. KG, Germany Jenapharm GmbH & Co. KG, Germany
20.	YAZ	Tablets, coated, № 28 (24+4) in blisters	1 pack contains 28 tablets (24 light-pink tablets and 4 white placebo tablets). 1 light-pink tablet contains ethinylestradiol 0,02 mg (as	Bayer Pharma AG, Germany; Bayer Weimar GmbH

			clatrate with betadex) and drospirenone 3 mg	&Co. KG, Germany
21.	CHLOE	Tablets, coated + Tablets - placebo, combi-pack № 28 (28 (21+7)x1); № 84 (28 (21+7)x3) in blisters	1 coated tablet contains Cyproterone Acetate 2 mg, ethinylestradiol 0,035 mg; Placebo tablet –lactose monohydrate, povidone, sodium carboxymethyl starch (type A), silicium dioxide colloidal anhydrous, aluminum oxide, magnesium stearate	Zentiva, Czech Republic
22.	YARINA®	Tablets, coated, № 21 (21x1) in blisters	1 tablet contains ethinylestradiol 0,03 mg, Drospirenone 3 mg	Bayer Pharma AG, Germany; Bayer Weimar GmbH &Co. KG, Germany
23.	YAZ PLUS	Tablets, coated, № 28 (24+4) in blisters	1 pink tablet contains ethinylestradiol 0,02 mg (as clatrate with betadex) Drospirenone 3 mg, Levomefolate calcium 0,451 mg	Bayer Pharma AG, Germany; Bayer Weimar GmbH &Co. KG, Germany
24.	DIANE-35	Tablets, coated, № 21 in blisters	1 coated tablet contains ethinylestradiol 0,035 mg, cyprotherone acetate 2 mg	Bayer Pharma AG, Germany; Bayer Weimar GmbH &Co. KG, Germany
25.	DARYLIA	Tablets, film coated, 3 mg/0,02 mg № 28 (1x24+4), № 84 (3x24+4) in blisters with flat cardboard box for blister storage in cardboard package	1 active tablet contains 3 mg Drospirenone crystalline 100 % та 0,02 mg ethinylestradiol micronized 100 % 1 placebo tablet contains no active substances.	Gedeon Richter Plc., Hungary
26.	YARINA® PLUS	Tablets, coated, № 28 (21+7) in blisters	1 pack contains 28 coated tablets (21 orange tablets and 7 light-orange tablets) 1 orange tablet contains ethinylestradiol 0,03 mg, drospirone 3 mg and Levomefolate calcium 0,451 mg 1 light-orange tablet contains Levomefolate calcium 0,451 mg	Bayer Pharma AG, Germany; Bayer Weimar GmbH &Co. KG, Germany
27.	ARTITIA	Tablets, coated, № 21 (21x1), № 63 (21x3) in blisters	1 tablet contains gestodene 0,075 mg, ethinylestradiol 0,02 mg	Haupt Pharma Munster GmbH, Germany; Zentiva, Czech Republic
28.	LOGEST®	Dragee № 21	1 Dragee contains ethinylestradiol 20 mcg and gestodene 75 mcg	Delpharm Lille S.A.S., France for Bayer Schering; Pharma AG, Germany, France/Germany

## Results and discussion

Thus, there are 28 preparations registered in Ukraine. All the range of oral contraceptives is represented only by foreign medicines. The leading manufacturers are Germany and Hungary (see Figure). Combined oral contraceptives (COC) are only produced in two dosage forms - tablets and dragee. In the form of dragee only four preparations presented – «Logest», «Femoden», «Triquilar», «Minisistone». Primary packaging of the OC is blister. This is a type of packaging from 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, creating the possibility of taking certain portions of the contents without polluting the rest, contains information about the drug. The outer package has the name of the country, the name of the manufacturer, trade mark and address, the name of the

medicine, dosage form, quantity of drugs and dosage, route of administration, storage conditions, shelf life, batch number, registration number, the bar code.

Name of the medicinal product is indicated in Ukrainian (and Russian) and Latin (and / or English) language. Name of the medicinal product and the international non-proprietary names stand out among all the other markings. To do this, manufacturers use a bigger and bold font, vivid colors, choose a comfortable label place to read or on one of the sides of the package. Around the titles there are no signs that could make it difficult to read.

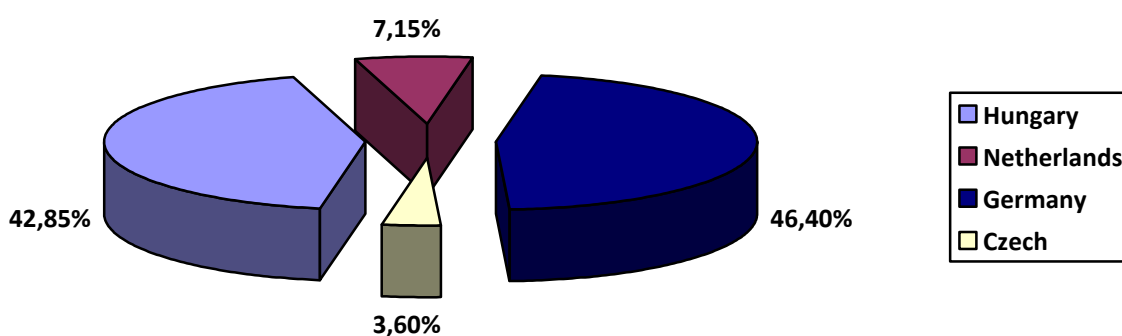


Fig. Structure of COC market by the producing countries

Properties of goods, which cause their ability to meet the specific needs of the population, manifested in the process of use or consumption, are called consumer ones. For successful implementation of any drug the main 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. the effectiveness of their intended use. For the correct choice of hormonal contraceptives person must necessarily consult at a gynecologist, who according to the diagnostic data prescribe a drug that is most suitable for a particular patient.

When choosing a hormonal oral contraceptive certain studies have to be made a must of which is determination of the hormones level in the blood. Repeated consultation of gynecologist is recommended after about 3 months of

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 the implementation of reproductive plans for children and terms of their birth. They also play an important role in keeping women's reproductive health. The practical benefit of COCs is their rapid action and high performance. The products 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 deficiencies 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 occur, it's in the first months of admission, and subsequently they are terminated or significantly mitigated. Side effects of hormonal contraceptives include: nausea, 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 at unexamined patients [16].

Hormonal contraceptives administration should be stopped and seek medical advice at 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 this 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 preparations, which is 75% of the range) or 28 tablets (7 products - 25% of the range). For convenience,

manufacturers usually put arrows on the plate corresponding to the sequence of taking tablets (especially this is important when using a two-or three-phase preparations) or on the packaging indicated days of the week (in monophasic preparations). 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.) use a special so-called "case" in which a patient can insert blister with tablets and carry around in her purse for a timely and convenient use. Packs of COCs have bright and aesthetic coloring, which is attracting patients. The drugs themselves have a different color. For example, if the plate has 28 tablets, then 21 of them are painted with one color and the remaining 7 (placebo) - another. If we analyze the preparation «Yaz», the blister contains 28 tablets, 24 of them are pink with lettering «DS» - active tablets with active ingredient and 4 white tablets labeled "DP" - inactive (placebo). For example, at «Diane-35" they are mildly yellow. The drug is available in a calendar pack of 21 tablets which are in blister package: 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 it is 3 years at a temperature below 25 ° C out of reach of children. One of the first indicators on which people pay attention when choosing any product is its consumer properties, which features manufacturers should evaluate and analyze before the release on the pharmaceutical market.

## **CONCLUSIONS**

Based on the objectives of the WHO program on reproductive health, modern contraceptives should be more widely implemented in public health practice in our country to prevent unwanted pregnancy and reproductive health of women. In this article attention was paid to the analysis of the Ukrainian combined oral contraceptives market in composition, dosage form, by the manufacturer, and also to determination the need for contraceptives at the social level. Consumer properties have been analyzed by such criteria as intended use performance, social significance, the practical usefulness, safety and harmlessness, aesthetics, etc.,

which result in saving reproductive health of women, which is strongly correlated with the state of health in general.

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

Т.В. Трунова

Проведён анализ украинского фармацевтического рынка комбинированных оральных контрацептивов по составу, форме выпуска, фирме-производителя, 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, которая находится в тесной взаимосвязи с состоянием здоровья в целом.

## **ДОСЛІДЖЕННЯ АСОРТИМЕНТУ ТА ОЦІНКА СПОЖИВЧИХ ВЛАСТИВОСТЕЙ КОМБІНОВАНИХ ОРАЛЬНИХ КОНТРАЦЕПТИВІВ НА ФАРМАЦЕВТИЧНОМУ РИНКУ УКРАЇНИ**

Т.В. Трунова

Проведений аналіз українського фармацевтичного ринку комбінованих оральних контрацептивів за складом, формою випуску, фірмою-виробником, визначенню 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 із станом здоров'я в цілому.

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