EMBAJADA
DE ESPAÑA

OFICINA ECONÓMICA Y
COMERCIAL DE ESPAÑA
SOFIA

ESTUDIO DE MERCADO:
SECTOR FARMACÉUTICO
EN BULGARIA

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1. INTRODUCCIÓN

Para empezar, es importante destacar la complejidad del sistema médico y sanitario, en general, en Bulgaria, especialmente estos últimos años, en los que el país se encuentra inmerso en un enmarañado proceso de reforma de este sector. El Proyecto de Reforma del Sector Sanitario fue aprobado en junio de 2000 y se prevé que su puesta en marcha se prolongue hasta octubre de 2005. Uno de los aspectos clave es la privatización de hospitales, clínicas y centros médicos de diversa entidad, pero aún no existen grandes logros al respecto.

RESUMEN DE LOS INDICADORES PRINCIPALES			
	Valor	Año	Ranking Mundial
Población (millones)	7,9	2002	66
PIB per cápita (USD)	1.985	2002	62
Gasto sanitario per cápita (USD)	92	2002	66
Gasto sanitario (%PIB)	4,7	2002	69
Camas hospitalarias por 1.000 habs	6,7	2001	21
Especialistas médicos por 1.000 habs	4,7	2001	3
Mercado de equipos médicos (millones USD)	71	2004	63
Mercado de equipos médicos per cápita (USD)	9	2004	62
Crecimiento de mercado (%)	8,4	2004	-

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2. ANÁLISIS DEL FUNCIONAMIENTO Y SITUACIÓN DEL SECTOR

2.1. GASTO SANITARIO

En la actualidad, Bulgaria tiene un gasto que asciende aproximadamente al 4% del PIB. En 2002, supuso 720 millones de USD (92 USD per cápita). Comparativamente, el gasto per capita es muy inferior al de Polonia, Hungría y Grecia (aunque similar al de Rumanía, Rusia y Ucrania).

Es difícil estimar el gasto privado en sanidad, aunque si cabe afirmar que el sector privado está creciendo en importancia. Sigue siendo latente la necesidad de crear una red hospitalaria privada, pero ya se observa un número creciente de empleados médicos que ofrecen consultas privadas en instituciones públicas.

No obstante, hay que recordar que el bajo poder adquisitivo que predomina en Bulgaria confina el gasto privado a zonas urbanas de importancia, y aun así es relativamente pequeño.

2.2. PRECIOS Y REEMBOLSO

La reforma del sistema de reembolso en Bulgaria está en sus fases iniciales. Aunque el objetivo es alcanzar una harmonización con la UE, el progreso se ha visto frenado por la falta de recursos financieros y técnicos.

El Gobierno mantiene una lista esencial de medicamentos, en torno a los 175, que dan tratamiento a 85 enfermedades distintas. La mayoría de los productos en esta lista tienen un reembolso del 50% o 100%. La lista se actualiza periódicamente. Asimismo, el Gobierno gestiona un sistema de control de precios. Los precios se establecen por una Comisión Especializada de Precios, que forma parte del Ministerio de Sanidad. Los precios son publicados en la Gaceta Estatal. El precio de venta al por menor se calcula utilizando la siguiente fórmula: p*recio del fabricante + 2% para el importador + 4% para el mayorista + 3% de transporte + 21% para la farmacia + arancel + IVA.* Normalmente, los precios de los medicamentos de producción local se ajustan por debajo que los importados.

A mediados de 2003, el ministro de sanidad rechazó la petición de modificar los criterios utilizados para la inclusión de medicamentos en la lista, solicitada por la Asociación de Fabricantes Extranjeros de Medicamentos (AFPMB). Según esta asociación, la lista era demasiado pequeña y la selección dependía demasiado de factores fármaco-económicos, y no sólo en la calidad, seguridad y eficacia, y mostraron su preocupación por la consecuente limitación de asistencia sanitaria. Asimismo, se comentó que las regulaciones en vigor creaban obstáculos burocráticos y una falta de transparencia que resultarían en periodos de registro mucho más largos.

Otro frente se ha centrado en los precios de los medicamentos reembolsables, con los fabricantes haciendo lobby para incrementar los precios. Esta reacción viene provocada por la legislación que

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estipula conformidad con las Buenas Prácticas de Fabricación, necesitando para ello una importante inversión por parte de los productores. Balkanpharma y Sopharma intentaron aumentar sus precios en un 30%, pero el Gobierno no parece apoyar estas subidas, y el Ministerio de Sanidad amenazó con no registrar aquellos medicamentos que hubieran sufrido un aumento de precios por encima del 19,9%. No obstante, en 2000, dos de los grandes productores negociaron un incremento del 30% en los precios de 70 de sus medicamentos sin prescripción (OTC).

Desde julio de 2001, el Fondo Nacional de Seguridad Social ha obligado a los pacientes a presentar un nuevo librillo de prescripciones en su farmacia cuando se trata de medicamentos reembolsados. Esto aparece como consecuencia de la práctica común por parte de los médicos de repartir recetas ficticias o innecesarias.

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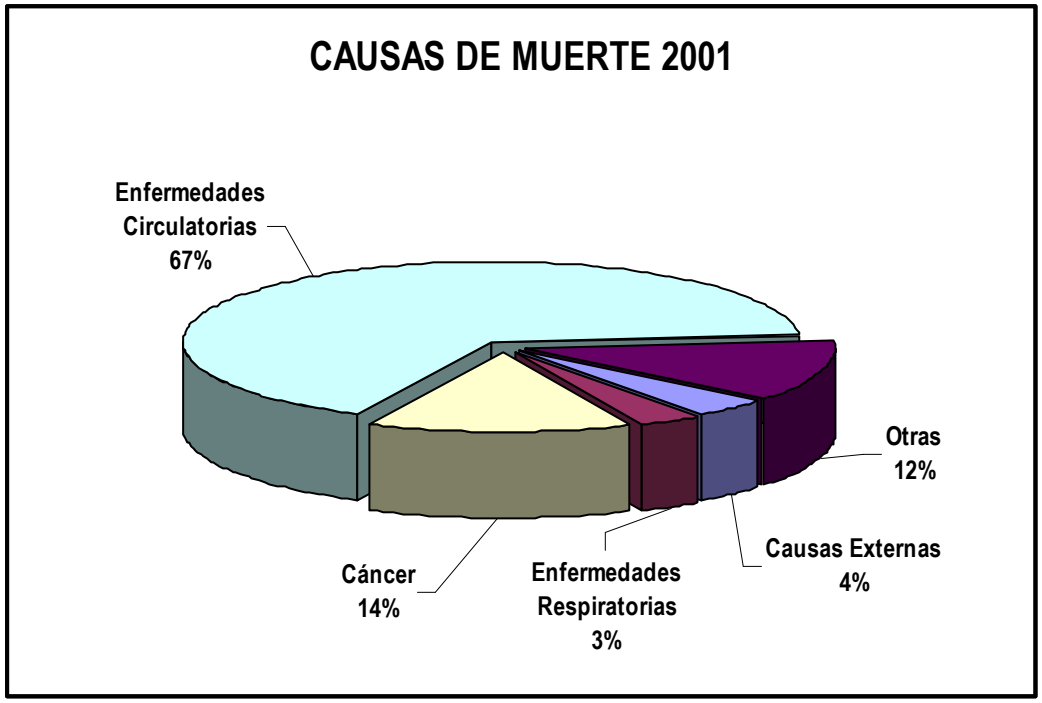
3. ANÁLISIS DE LA DEMANDA

3.1. CAUSAS DE MUERTE



	Number of Deaths		Per 100,000pop.	
	2000	2001	2000	2001
Infectious and parasitic diseases	720	687	8.8	8.7
Neoplasms	15,343	15,513	187.8	196.0
Endocrine, nutritional, metabolic, immunity disorders	2,135	2,009	26.1	25.4
Diseases of blood and blood forming organs	156	163	1.9	2.1
Mental disorders	250	228	3.1	2.9
Diseases of the nervous system and sense organs	779	893	9.5	11.3
Circulatory diseases	76,297	74,866	933.8	946.1
Respiratory diseases	4,500	3,696	55.1	46.7
Digestive diseases	2,974	2,942	36.4	37.2
Genitourinary diseases	1,068	1,029	13.1	13.0
Complications of pregnancy, childbirth and puerperium	13	13	0.2	0.2
Diseases of the skin and subcutaneous tissue	29	32	0.4	0.4
Diseases of musculoskeletal system & connective tissue	51	36	0.6	0.5
Congenital anomalies	274	273	3.4	3.4
Perinatal conditions	323	288	4.0	3.6
Signs, symptoms and ill-defined conditions	5,522	5,329	67.6	67.3
External causes	4,653	4,371	57.0	55.2
Total	115,087	112,368	1,408.6	1,420.0

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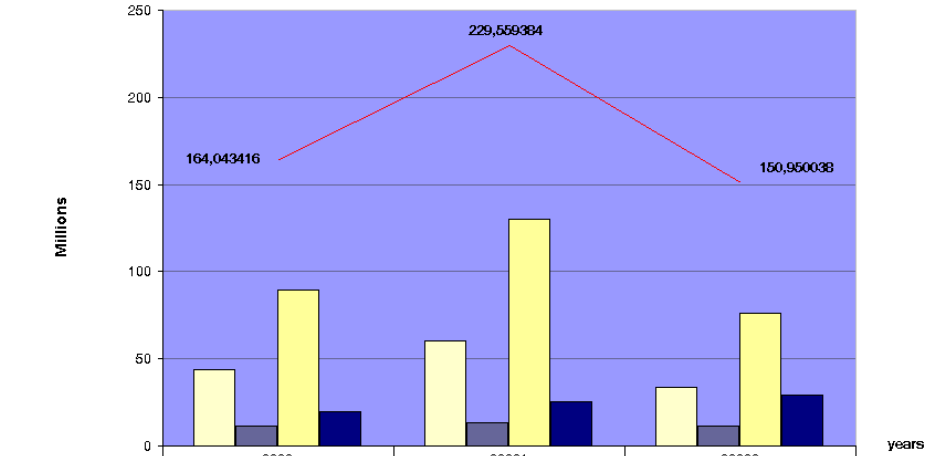
3.2. ANÁLISIS DEL CONSUMO

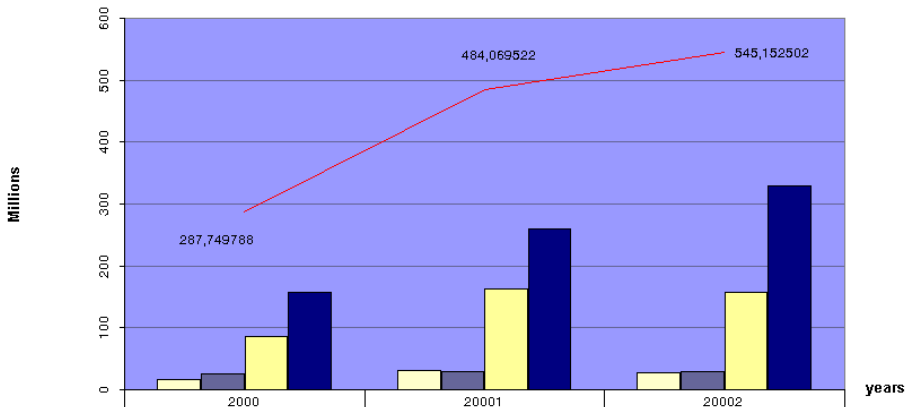
Consumption of medicinal products in Bulgaria for the period 2000 – 2002.
Comparison between OTC and Ethical products, expressed in number of packs for locally produced and imported products



	2000	20001	20002
OTC-Bulgarian	43685405	60465852	33923177
OTC-Imported	11578363	13631930	11726491
Ethicals-Bulgarian	89250756	130322197	75937529
Ethicals-Imported	19528892	25139405	29362841
Total	164043416	229559384	150950038

Fuente: BDA

Consumption of medicinal products in Bulgaria for the period 2000 – 2002.
Comparison between OTC and Ethical products expressed in leva. Value is on the base of CIP price for imported MP and ex works price for locally produced MP.



	2000	20001	20002
OTC-Bulgarian	17060940	31835881	27339103
OTC-Imported	26397067	30130262	29694709
Ethicals-Bulgarian	86384484	162569788	158185298
Ethicals-Imported	157907297	259533591	329933392
Total	287749788	484069522	545152502

Fuente: BDA

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3.3. MEDICAMENTOS CON PRESCRIPCIÓN

En 2000, el medicamento de prescripción más vendido, fabricado por una multinacional, medido en número de cajetillas, fue Berlin-Chemie con el antidiabético Maninil, cuyo consumo ascendió a 287.279. Otros productos líder fueron otro antidiabético de Berlin Chemie, Siofor (211.669), el glicérido cardiaco de Roche, Lanitop (191.920) y anti-ansiolítico de Sanofi-Winthrop, Tranxene (175.040).

Según el Agencia de Medicamentos Búlgara, la freCuente aparición de productos antidiabéticos entre los medicamentos más vendidos se debe a una acumulación de stock.

VENTAS DE LOS PRINCIPALES MEDICAMENTOS CON PRESCRIPCIÓN FABRICADOS POR MULTINACIONALES (POR NÚMERO DE CAJETILLAS, AÑO 2000)

DENOMINACIÓN PRODUCTO	DENOMINACIÓN GENÉRICO	FABRICANTE	Nº CAJETILLAS
MANINIL	glibenclamide	Berlin-Chemie	287.279
SIOFOR	metformin	Berlin-Chemie	211.669
LANITOP	medigoxin	Roche	191.920
TRANXENE	clorazepate	Sanofi-Winthrop	175.040
HEMOFIL M	antihemophiliac factor, factor VIII, monoclonal	Baxter	174.933
DURACEF	cefadroxil	Bristol-Myers Squibb	167.237
MONOTARD	insulin zinc suspension	Novo Nordisk	150.310
CEFATREXYL	cephalexin	Bristol-Myers Squibb	148.663
TERTENSIF	indapamide	Servier	124.717
TEGRETOL	carbamazepine	Novartis	113.123
BERLIPRIL	enalapril	Berlin-Chemie	112.276
GLUCOBAY	acarbose	Bayer	110.300
ROCHEPHIN ROCHE	ceftriaxone	Roche	108.680
LUDIOMIL	maprotiline	Novartis	98.305
PANADOL BABY & INFANT	paracetamol	SmithKline Beecham	94.944
BECOTIDE	beclomethasone	Glaxo Wellcome	88.230

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RELANIUM	diazepamum	Glaxo Wellcome	86.200
BRINERDIN	reserpine, clopamide & dihydroergocristine	Novartis	85.769
CORDARONE	amiodarone	Sanofi-Winthrop	84.886
PRIMOLUT N	noresthisterone	Schering AG	84.399
CORVITOL	metoprolol	Berlin-Chemie	83.136
ANAFRANIL	clomipramine	Novartis	82.231
CLARITINE	loratadine	Schering-Plough	82.194
RENITEC	enalapril	Merck Sharp & Dohme	78.578
KARDIKET RETARD	n/a	Schwarz-Pharma	77.554
VOLTAREN RETARD	diclofenac sodium	Novartis	77.549
PREDUCTAL	trimetazidin	Servier	76.015

Fuente: Espicom Business Intelligence

Sin tener en cuenta los principales fabricantes multinacionales, el medicamento que mejor se vendió en 2000 por volumen fue el antibiótico de Biochemie, Ospamox (970.216). Otros incluyen un tratamiento para infecciones urinarias también de Biochemie, nitroglicerina producido por ICN Octibar, y un tratamiento para trastornos cardiovasculares de Slovakfarma.

VENTAS DE LOS PRINCIPALES MEDICAMENTOS CON PRESCRIPCIÓN FABRICADOS POR OTROS PRODUCTORES (POR NÚMERO DE CAJETILLAS, AÑO 2000)

DENOMINACIÓN PRODUCTO	DENOMINACIÓN GENÉRICO	FABRICANTE	Nº CAJETILLAS
OSPAMOX	amoxicillin	Biochemie	970.216
OSPEXIN	cefalexin	Biochemie	468.031
NITROGLYERCIN	nitroglyercin	ICN Octiabr	442.700
AGAPURIN	pentoxifylline	Slovakofarma	372.218
BISEPTOL	co-trimoxazole	Polfa Pabianice	170.539
EGLONYL	sulpiride	Alkaloid	150.080

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MACROPEN	amoxycillin/flucloxacillin	KRKA	142.616
GENTAMICIN	garamycin	Biochemie	130.701
OSPEN	phenoxymethylpenicillin	Biochemie	122.781
FLUCINAR	flucocinol	Jelfa SA	107.393
HALOPERIDOL	haloperidol	Gedeon Richter Ltd	94.143
STANDACILLIN	ampicillin	Biochemie	91.605
RELANIUM	diazepamum	Glaxo Wellcome Poznan	90.000
CAVINTON	vinpocetine	Gedeon Richter Ltd	86.499
MYDOCALM	tolperisone	Gedeon Richter Ltd	74.064

Fuente: Espicom Business Intelligence

3.4. MEDICAMENTOS SIN PRESCRIPCIÓN (OTC)

A principios de 2000, se pasa una ley permitiendo la venta de un número determinado de productos OTC (sin prescripción) en las droguerías. Estos son:

- aspirina
- paracetamol
- multi / vitaminas por via oral (dependiendo de la concentración y tamaño del envase)
- laxantes
- preparados para trastornos menores de la piel
- pastillas no antibióticas para la garganta
- hierbas medicinales
- insecticidas y repelentes
- condones
- mecanismos intrauterinos
- diagnósticos in vitro

El producto OTC más vendido en Bulgaria en 2000, en volumen de cajetillas, fue Upsarin + Vit. C de Bristol-Myers Squibb, con un consumo de 1.1634.128 cajetillas. Otros productos estrella incluyen Fervex Adultos de Bristol-Myers Squibb (1.152.137 cajetillas), Validol de Farmak (789.100 cajetillas) y Xylometrazoline fabricado por Pharmaceutical Works Warsaw (689.385 cajetillas).

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VENTAS DE LOS PRINCIPALES MEDICAMENTOS SIN PRESCRIPCIÓN (OTC) (POR NÚMERO DE CAJETILLAS, AÑO 2000)		
DENOMINACIÓN PRODUCTO	**FABRICANTE**	**Nº CAJETILLAS**
UPSARIN + VIT. C	Bristol-Myers Squibb	1.634.128
FERVEX ADULTS	Bristol-Myers Squibb - UPSA	1.152.137
VALIDOL	Farmak	789.100
XYLOMETAZOLINE	Pharmaceutical Works Warsaw	689.385
MUCOSOLVAN	Boehringer Ingelheim	649.388
MEZYM FORTE	Berlin-Chemie	543.236

Fuente: Espicom Business Intelligence

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4. ANÁLISIS DE LA OFERTA

4.1. TAMAÑO DE LA OFERTA

BALANZA COMERCIAL DE MEDICAMENTOS, 1997-2001 (MILES DE USD)					
	1997	1998	1999	2000	2001
Sulphonamides	-122	-257	-285	-275	-410
Provitamins & vitamins	393	3.207	-2.682	-2.438	-2.088
Pituitary (anterior) hormones	0	0	0	0	0
Cortisone, hydrocortisone, prednisone & prednisolone	0	0	0	0	0
Halogenated derivatives of adrenal cortical hormones	-73	0	0	0	0
Other adrenal cortical hormones	-58	-149	-314	-243	-282
Insulin	-93	0	0	0	0
Oestrogens & progestogens	0	0	0	0	0
Other hormones	-28	-104	-32	-12	-27
Glycosides	-386	-709	-540	-699	-708
Opium alkaloids	-1.377	-693	-1.020	-1.230	-1.642
Quinine	-242	0	0	0	0
Other cinchona alkaloids	-88	-88	-118	0	-50
Caffeine	0	0	0	0	0
Ephedrines	-31	0	-16	-51	-10
Theophylline & aminophylline	-42	-166	-224	-136	-163
Rye ergot alkaloids	-14	-34	-14	-43	-68
Nicotine	0	0	0	0	0
Other vegetable alkaloids	-154	-208	-154	-30	-237
Penicillins	-239	-506	-325	-244	-141
Streptomycins	50	24	0	0	0
Tetracyclines	0	-65	-65	61	28
Chloramphenicol	0	210	82	0	60
Erythromycin	420	-98	-419	5	-61

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Other antibiotics	13.064	16.931	12.406	17.150	16.879
Glands, other organs & extracts	0	0	60	0	0
Antisera & other blood fractions	-4.720	-5.567	-8.359	-5.433	-5.908
Vaccines (human)	-1.847	-3.213	-298	-1.183	-2.262
Vaccines (veterinary)	-320	-81	-925	-840	-1.196
Other antisera, vaccines	-214	-312	-754	-1.048	-509
Subtotal raw materials	**3.879**	**8.122**	**-3.996**	**3.311**	**1.205**
Medicaments not in dosage form/retail packs:	0	0	0	0	0
Penicillins, streptomycins	354	54	0	0	0
Other antibiotics	1.339	1.294	57	323	1.575
Insulin	0	60	30	0	0
Other hormones	0	48	14	62	-12
Alkaloids	20	232	438	634	402
Other medicaments	1.165	-1.299	859	-291	-314
Subtotal	**2.878**	**389**	**1.398**	**728**	**1.651**
Medicaments in dosage form/retail packs:	0	0	0	0	0
Penicillins, streptomycins	-674	-4,004	-5,801	-5,225	-6,651
Other antibiotics	-1,774	-11,123	-14,347	-13,789	-11,180
Insulin	-7,527	-11,024	-9,838	-7,107	-14,357
Other adrenal cortical hormones	-672	-2,125	-1,891	-2,282	-2,646
Other hormones	-1,807	-3,864	-4,666	-6,769	-7,248
Alkaloids	6,192	2,972	-2,360	-2,851	-1,938
Vitamins or provitamins	-2,877	-5,139	-5,485	-6,445	-7,689
Other medicaments	15,421	-13,703	-35,572	-44,228	-89,321
Subtotal	**6,282**	**-48,010**	**-79,960**	**-88,696**	**-141,030**
Total	**13,039**	**-39,499**	**-82,558**	**-84,657**	**-138,174**

Fuente: Espicom Business Intelligence

4.2. PRODUCCIÓN

La industria farmacéutica búlgara está representada principalmente por dos asociaciones:

- Asociación de Fabricantes Búlgaros de Medicamentos (ABPhM – www.abphm.bg), y
- Asociación de Fabricantes Internacionales de Medicamentos (AIPP).

Apenas existen fabricantes extranjeros operando en el mercado búlgaro, principalmente limitado a un número de fabricantes locales bajo licencia.

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La producción local ha visto un incremento progresivo en los últimos años, reflejando el proceso de modernización del mercado búlgaro. En 2002, las ventas de medicamentos de producción local ascendieron a 95,4 millones de USD – un 34,1% del gasto total del mercado -comparado con los 75,5 millones de USD en 2000. Cabe destacar, que la producción local es principalmente de genéricos, que tienen una presencia considerable en el mercado búlgaro debido a su bajo coste y la inadecuado legislación sobre propiedad intelectual y patentes, aunque esta práctica esté disminuyendo a la par que se van implantando las reformas en el sector sanitario.

La privatización ha jugado un papel importante en los últimos años: las 4 empresas más importantes del sector – Sopharma, Pharmacia, Troyapharm y Antibiotic – han sido parcialmente privatizadas y suponen un 95% de la producción nacional. Otra de las privatizaciones más importantes fue la de Biovet en 2000, fabricante de medicamentos y productos veterinarios, ahora controlado por Bulgarian Pharmaceutical Company. En 1998, se privatizó Unipharm, dejando al Estado con tan solo un 1,6% de las acciones.

BALKANPHARMA (www.balkanpharma.com)

En su origen, Balkanpharma, producto de la privatización por Pharmaco (Islandia), se dedicaba casi exclusivamente a la distribución. Sin embargo, tras la compra de los 3 fabricantes de medicamentos más importantes de Bulgaria (Pharmacia, Antibiotic, y Troyanpharm), se ha convertido en uno de los fabricantes y distribuidores más grandes. Cuenta con aproximadamente 4.500 empleados.

- Dupnitza AD (antiguo Pharmacia)

  Con capacidad para producir más de 150 medicamentos distintos, cuenta con 7 patentes registradas, 42 marcas, y 8 contratos para la producción bajo licencia de 14 medicamentos de multinacionales (Bayer, Roche y Merck Sharp & Dohme).

- Razgrad AD (antiguo Antibiotic)

  Produce más de 100 productos terminados, y provee el 60% del mercado doméstico de antibióticos. Exporta a Europa Occidental, Europa del Este, EE.UU., Korea del Norte, la antigua Unión Soviética y Oriente Medio. Tiene 40 marcas de productos, y 2 contratos bajo licencia (uno de Schering-Plough).

- Troyan AD (antiguo Troyanpharm)

  Cuenta con un portfolio de más de 160 productos, con 15 patentes registradas, 83 marcas y registros para más de 129 productos en 16 países.

En los últimos dos años, Balkanpharma ha realizado grandes inversiones, modernizando sus instalaciones de producción abrió 2 plantas de en 2002 y 2003 respectivamente). Las provisiones de ventas para 2003 es de 145 millones de USD, y la empresa busca expandir su presencia en los mercados extranjeros.

Entre los nuevos medicamentos, se encuentran los siguientes principios activos: Azithromycin; Fluoxetine; Glucosamine hydrochloride; fluconazol; glipizide; Ibuprofen; Lovastatin; Loratadine; Ambroxol; Pentoxifylline; Paracetamol; Enalapril; Sotalol.

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SOPHARMA (www.sopharma.bg)

Con su base en Sofia, Sopharma es uno de los fabricantes líder en el sector de medicamentos. En su origen una empresa estatal, Sopharma fue privatizada en agosto de 2000 por Elpharma. En la actualidad cuenta con aproximadamente 1.600 empleados.

Con ventas que ascienden a 33 millones de USD en 2002, y con 15% de la cuota de mercado, Sopharma exporta principalmente a Rusia (58% de las exportaciones) seguido por Ucrania (24%). También cabe destacar Polonia, Kadsastán y Latvia.

Los productos estrella de Sopharma abarcan las áreas de cardiología, analgésicos narcóticos, alergia, pulmonar, vitaminas, anti-inflamatorios, neurología y psiquiatría, gastroenterología, espasmos, y dermatología.

UNIPHARM (www.unipharm.bg)

Establecida en 1983 y privatizada en 1998. Produce y distribuye una gama amplia de productos. En 2000, sus ventas ascendieron a 3,8 millones de USD y para 2001 se preveían un aumento a 5,5 millones de USD. Aproximadamente el 15% de sus ventas anuales es reinvertido en investigación y desarrollo (I+D). Cuenta con una plantilla de 150 empleados.

Su actividad de fabricación se divide en dos líneas fundamentas: medicamentos sólidos (85% de su producción total) y medicamentos líquidos. Es el principal fabricante de soluciones de acetatos y bicarbonatos para hemodiálisis en Bulgaria.

Trabaja en estrecha colaboración con los distribuidores más importantes del país: Hygia Ltd; Sanita; Trading JSC; Commercial League JSC; Sting Ltd.; Libra S.A; Global Medical Ltd; Kaliman RT Ltd y S&D Pharma.

La fusión del consorcio Unipharm y Sopharam en 2000 marcó el inicio de uno de los grupos con más fuerza dentro del mercado búlgaro, aunque ambas empresas operan como entidades independientes.

4.3. EXPORTACIÓN

Debido a la crisis económica rusa, las exportaciones en 1999 sufrieron un descenso significativo, aunque en 2000 se recuperaron parcialmente. En 2001 vuelven a perder fuerza, descendiendo un 4% hasta alcanzar los 63,4 millones de USD.

La mayoría de las exportaciones son de productos terminados con un 66,7% en 2001 y las materias primas representa representan gran parte del resto de exportaciones (29,5%).

Los antibióticos suponen aproximadamente el 33% de las exportaciones.

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EXPORTACIONES DE MEDICAMENTOS, 1997-2001 (MILES DE USD)					
	1997	1998	1999	2000	2001
Sulphonamides	53	110	18	16	20
Provitamins & vitamins	2,227	6,259	161	84	0
Pituitary (anterior) hormones	0	0	0	0	0
Cortisone, hydrocortisone, prednisone & prednisolone	0	0	0	0	0
Halogenated derivatives of adrenal cortical hormones	0	0	0	0	0
Other adrenal cortical hormones	0	0	0	0	0
Insulin	0	0	0	0	0
Oestrogens & progestogens	0	0	0	0	0
Other hormones	0	0	0	0	0
Glycosides	0	0	0	0	125
Opium alkaloids	0	0	0	0	0
Quinine	0	0	0	0	0
Other cinchona alkaloids	0	0	0	0	0
Caffeine	0	0	0	0	0
Ephedrines	0	0	0	0	0
Theophylline & aminophylline	0	0	0	0	0
Rye ergot alkaloids	0	0	0	0	0
Nicotine	0	0	0	0	0
Other vegetable alkaloids	0	0	0	0	0
Penicillins	364	64	7	167	122
Streptomycins	50	24	0	0	0
Tetracyclines	0	0	0	61	28
Chloramphenicol	0	210	82	0	60
Erythromycin	437	0	0	134	0
Other antibiotics	14,020	17,786	13,205	18,295	17,616
Glands, other organs & extracts	0	0	60	0	0
Antisera & other blood fractions	0	0	0	0	0
Vaccines (human)	1,012	268	612	201	59
Vaccines (veterinary)	196	447	0	75	0
Other antisera, vaccines	628	660	243	371	698
Subtotal raw materials	**18,987**	**25,828**	**14,388**	**19,404**	**18,728**

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Medicaments not in dosage form/retail packs:					
Penicillins, streptomycins	354	54	0	0	0
Other antibiotics	1,501	1,353	258	378	1,575
Insulin	0	60	30	0	0
Other hormones	0	48	64	164	20
Alkaloids	20	232	438	634	402
Other medicaments	1,409	939	1,227	666	404
Subtotal	**3,284**	**2,686**	**2,017**	**1,842**	**2,401**
Medicaments in dosage form/retail packs:					
Penicillins, streptomycins	622	284	199	252	514
Other antibiotics	3,049	1,94	1,589	1,493	1,347
Insulin	0	0	0	108	51
Other adrenal cortical hormones	0	0	14	0	50
Other hormones	378	365	242	165	262
Alkaloids	8,842	5,999	4,349	7,296	7,588
Vitamins or provitamins	579	12	217	463	730
Other medicaments	42,687	34,128	24,339	35,054	31,754
Subtotal	**56,157**	**42,728**	**30,949**	**44,831**	**42,296**
Total	**78,428**	**71,242**	**47,354**	**66,077**	**63,425**

Fuente: Espicom Business Intelligence

Por destino, Rusia recibe el 48,3%, Bielorusia 5,3%, Alemania 5,1%, España 4,9% y Reino Unido un 2,1. A España y AlemaniA a se exportan principalmente materia prima para antibióticos, al Reino Unido medicamentos que no semi-terminados, y a Rusia y Bielorrusia se exportan medicamentos terminados.

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Fuente: Espicom Business Intelligence

4.4. IMPORTACIÓN

Las importaciones han crecido considerablemente en los últimos años en Bulgaria, incrementando un 208,3% desde 1997 hasta 2001. Este crecimiento ha sido impulsado principalmente por los medicamentos terminados, 37,3% en 2001, comparado con el incremento de 8,9% en las materias primas, y el descenso del 32,7% en productos semi-terminados.

La importación principal son los productos terminados, que supusieron más del 90% del total en 2001, con un valor de 183,3 millones de USD. Las materias primas representan un 8,7% en 2001, por un valor de 17,5 millones de USD.

IMPORTACIONES DE MEDICAMENTOS, 1997-2001 (MILES DE USD)					
	1997	1998	1999	2000	2001
Sulphonamides	175	367	303	291	430
Provitamins & vitamins	1,834	3,052	2,843	2,522	2,088
Pituitary (anterior) hormones	0	0	0	0	0
Cortisone, hydrocortisone, prednisone & prednisolone	0	0	0	0	0

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Halogenated derivatives of adrenal cortical hormones	73	0	0	0	0
Other adrenal cortical hormones	58	149	314	243	282
Insulin	93	0	0	0	0
Oestrogens & progestogens	0	0	0	0	0
Other hormones	28	104	32	12	27
Glycosides	386	709	540	699	833
Opium alkaloids	1,377	693	1,020	1,230	1,642
Quinine	242	0	0	0	0
Other cinchona alkaloids	88	88	118	0	50
Caffeine	0	0	0	0	0
Ephedrines	31	0	16	51	10
Theophylline & aminophylline	42	166	224	136	163
Rye ergot alkaloids	14	34	14	43	68
Nicotine	0	0	0	0	0
Other vegetable alkaloids	154	208	154	30	237
Penicillins	603	570	332	411	263
Streptomycins	0	0	0	0	0
Tetracyclines	0	65	65	0	0
Chloramphenicol	0	0	0	0	0
Erythromycin	17	98	419	129	61
Other antibiotics	956	855	799	1,145	737
Glands, other organs & extracts	0	0	0	0	0
Antisera & other blood fractions	4,720	5,567	8,359	5,433	5,908
Vaccines (human)	2,859	3,481	910	1,384	2,321
Vaccines (veterinary)	516	528	925	915	1,196
Other antisera, vaccines	842	972	997	1,419	1,207
Subtotal raw materials	**15,108**	**17,706**	**18,384**	**16,093**	**17,523**
Medicaments not in dosage form/retail packs:					
Penicillins, streptomycins	0	0	0	0	0
Other antibiotics	162	59	201	55	0
Insulin	0	0	0	0	0
Other hormones	0	0	50	102	32
Alkaloids	0	0	0	0	0
Other medicaments	244	2,238	368	957	718

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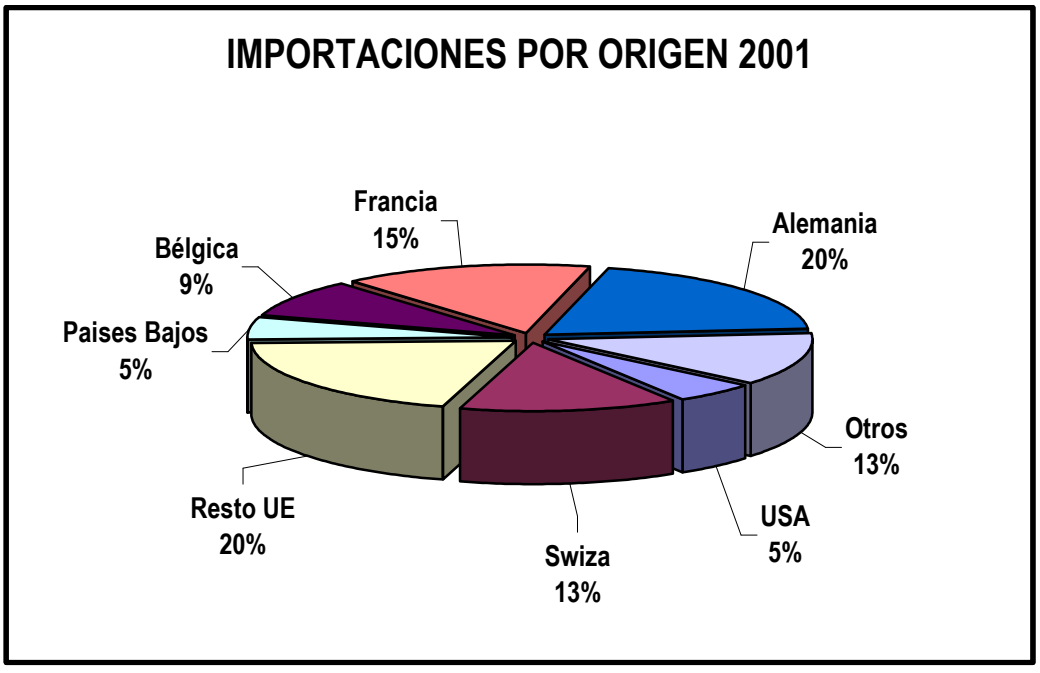
Subtotal	**406**	**2,297**	**619**	**1,114**	**750**
Medicaments in dosage form/retail packs:					
Penicillins, streptomycins	1,296	4,288	6,000	5,477	7,165
Other antibiotics	4,823	13,063	15,936	15,282	12,527
Insulin	7,527	11,024	9,838	7,215	14,408
Other adrenal cortical hormones	672	2,125	1,905	2,282	2,696
Other hormones	2,185	4,229	4,908	6,934	7,510
Alkaloids	2,650	3,027	6,709	10,147	9,526
Vitamins or provitamins	3,456	5,151	5,702	6,908	8,419
Other medicaments	27,266	47,831	59,911	79,282	121,075
Subtotal	**49,875**	**90,738**	**110,909**	**133,527**	**183,326**
Total	**65,389**	**110,741**	**129,912**	**150,734**	**201,599**

Fuente: Espicom Business Intelligence

Por origen, el principal proveedor es la UE, con aproximadamente el 70% del total en 2001 (139,4 millones de USD). Alemania es el principal proveedor tanto a nivel de la UE como a nivel general, con una cuota del 19,6% (39,3 millones de USD). Otros proveedores importantes de la UE son Francia, Bélgica y los Países Bajos, que representan el 15,3%, 9% y 5,3% del total, respectivamente. Fuera de la UE, Suiza supuso el 13,4% de las importaciones, convirtiéndola en el tercer proveedor más importante de Bulgaria.



Fuente: Espicom Business Intelligence

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En materia prima, Suiza es el principal proveedor en 2001, con un total de importaciones valorado en 4,4 millones de USD (25% del total de importaciones de materias primas). En segundo lugar, están Alemania y Francia, ambos con una cuota de 17,5%. En general, la UE representa aproximadamente el 60% del total, por valor de 10,3 millones de USD.

El principal proveedor de productos terminados en 2001 fue Alemania, con 36.2 millones de USD (19,8% del total de importaciones de medicamentos terminados). Otros proveedores importantes son Francia, Suiza y Bélgica, con cuotas de l 15,2%, 12,3% y 9,6% respectivamente. En general, la UE representa un 70% de los productos terminados, por valor de 128,5 millones de USD.

4.5. CANALES DE DISTRIBUCIÓN

Los medicamentos en Bulgaria se han distribuido tradicionalmente por dos canales principalmente: farmacias estatales y farmacias privadas. Sin embargo, modificaciones recientes al Acta de Medicamentos Búlgaro, han alterado la estructura del sistema de distribución. A principios de 2000, se aprobaron leyes que permitieron la apertura de droguerías por primera vez, con permiso de vender un número limitado de productos OTC (ver apartado 3.4.), aunque no de medicamentos que requieren prescripción médica. Asimismo, la legislación aprobada estipuló que las ciudades y pueblos de menos de 5.000 habitantes sólo pueden tener una farmacia.

En marzo de 2001, el National Insurance Bank asignó 56,9 millones de USD a la compra de medicamentos para ser distribuidas a través de farmacias con las que tenía firmados contratos.

En 1998, había 2.860 farmacias en Bulgaria, 60 más que en 1997 y más del doble comparado con 1990. Las farmacias privadas suponen el 75% del total en 1998.

CANALES DE DISTRIBUCIÓN 1900-1998					
	1990	**1995**	**1996**	**19997**	**1998**
Farmacias	1.163	2.773	2.588	2.800	2.860
Privadas	*0*	*1.838*	*1.717*	*1.980*	*1.945*
Farmacias satélite y sucursales	3.596	1.429	744	490	490
Droguerías	117	110	103	123	135
Privadas	*0*	*24*	*31*	*52*	*82*

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5. ASPECTOS INSTITUCIONALES

5.1. REGISTRO DE MEDICAMENTOS

Bajo la supervisión del Ministerio de Sanidad, la Agencia Búlgara de Medicamentos (Bulgarian Drug Agency, BDA) es la entidad con mayor autoridad reguladora.

Todos los productos farmacéuticos disponibles en el mercado doméstico y los productos exportados tienen que obtener una autorización del BDA. Asimismo, el BDA es responsable de la pre y post vigilancia del mercado, los procesaos de producción y distribución, los ensayos clínicos y la publicidad.

El **Ley de Medicamentos** búlgara de 1995 es la base legislativa de la reglamentación farmacéutica, actualizada en varias ocasiones para homogeneizar los procedimientos con las directivas de la UE.

REGISTRO – APROBACIÓN

Los requisitos de registro fueron actualizados por última vez en abril de 2001 (Regulación Nº 17, *ver anexo 6.3.*).

Todos los documentos han de tramitarse en el BDA, por triplicado, acompañados por un cheque correspondiente a las tasas.

Los fabricantes extranjeros de medicamentos pueden registrar productos sólo después de establecer una oficina de representación.

El proceso normalmente se demora 12 meses. En caso de ser aprobado, el fármaco (medicamento) es registrado por un periodo de 5 años, tras el cuál hay que proceder a su renovación. En caso de que el producto no se fabrique localmente o no se importa por un periodo de 2 años, el registro se retirará.

SOLICITUD DE NUEVOS REGISTROS

Se tiene que solicitar un nuevo registro en los siguientes casos:

- Cambio de tipo y/o cantidad del principio activo;
- Cambio en la forma farmacéutica;
- Cuevas indicaciones.

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AUTORIZACIÓN DE PUBLICIDAD (MARKETING)

Para obtener la autorización de publicidad, es requisito hacer entrega de los siguientes documentos al BDA, por triplicado:

- Datos administrativos;
- Datos químicos y farmacéuticos;
- Datos tóxico-farmacológicos;
- Datos clínicos.

ENSAYOS CLÍNICOS

En septiembre de 2000, el BDA actualizó las regulaciones sobre las pruebas clínicas.

El patrocinador de la prueba clínica ha de estar registrado en Bulgaria, aunque también se puede nombrar a un representante legal.

Asimismo, el patrocinador tiene que garantizar inmunidad a los investigadores involucrados así como a los pacientes.

El BDA es el responsable de llevar a cabo las inspecciones de los procesos e instalaciones de las pruebas clínicas.

POST-VIGILANCIA DEL MERCADO

Función llevada a cabo por los departamentos especializados del BDA.

Su principal objetivo es recolectar, evaluar y analizar informes de reacciones adversas de medicamentos. La información es reenviada al Ministerio de Sanidad, y en caso de problemas en el uso, a la Comisión de Fármacos (Drug Committee). El Centro trabaja en estrecha colaboración con organismos internacionales.

Las inspecciones se pueden llevar a cado en cualquier momento y en cualquier parte, según la legislación vigente. Los inspectores estatales que tengan autorización, pueden solicitar toda la documentación relacionada con la actividad del producto, recoger muestras para posterior análisis y pueden frenar el proceso de producción, pruebas clínicas, importación, exportación, distribución y comercio del medicamento.

Como parte de las modificaciones en el Acta de 1995, se ha implantado la penalización de aquellos que fabriquen o comercien con medicamentos sin licencia.

PUBLICIDAD

Regulado por departamentos especializados del BDA. La función principal es la aprobación preliminar de todos los materiales de publicidad con propósito de ser distribuidos a los mass-media y en revistas de comercio.

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Los nombres de las empresas farmacéuticas y sus representantes que han violado las leyes de publicidad de medicamentos se hacen públicos en la página web del BDA: www.bda.bg

5.2. PROPIEDAD INTELECTUAL Y PATENTES

Existe una provisión para la protección de patentes farmacéuticas en Bulgaria desde 1992, bajo el Acta de Patentes Búlgara. El acuerdo bilateral entre Bulgaria y EE.UU. permite cierta protección de aquellos productos con una patente cualificada en EE.UU. No obstante, la legislación sobre patentes sigue siendo inadecuada, según la industria internacional.

A pesar de las críticas, el gobierno no parece tener intención de llevar a cabo reformas, ya que el país sigue dependiendo de genéricos baratos, de fabricación local, muchos de los cuales probablemente no estarían permitidos bajo una regulación más restrictiva de la UE.

5.3. ENVASE Y ETIQUETADO

ENVASE

En el caso de que sea la *primera* vez que se registra el producto, el diseño / maqueta del embalaje exterior junto con el texto (etiquetado) ha de adjuntarse a la solicitud y resto de documentación que se presentan para el registro.

Durante el proceso, el envase propuesto es analizado por varios expertos, y una vez que se aprueba la versión final del embalaje exterior, se adjunta a la licencia como apéndice.

Cualquier cambio posterior iniciado por el titular de la Licencia, tiene que solicitar aprobación al BDA como variación de la licencia.

ETIQUETADO

El etiquetado de los productos farmacéuticos viene regulado por la Ordenanza 7 de junio de 2000, sobre la información obligatoria que debe contener el envase / embalaje y los prospectos (anexo 6.4), actualizado por última vez en marzo de 2004.

Es obligatorio la utilización del búlgaro en el embalaje exterior, así como en el prospecto para el paciente. El uso de pegatinas / etiquetas, salvo en casos extraordinarios, no están autorizadas por diversos motivos (importación paralela, irregularidades, etc), lo que implica que el texto del etiquetado ha de estar impreso directamente en el embalaje exterior. El contenido del embalaje exterior debe incluir los siguientes apartados (para más detalle, consultar la regulación sobre etiquetado y prospectos en el anexo 6.4):

1. Denominación del medicamento y denominación común;
2. Composición cualitativa y cuantitativa, en principios activos por unidad de administración;
3. Forma farmacéutica y contenido en peso, volumen o unidades de administración;

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4. Relación cuantitativa de los excipientes que tengan acción o efecto conocidos;
5. Forma de administración y, si fuera necesario, la vía de administración;
6. Advertencia: “Manténgase fuera del alcance de los niños”;
7. Advertencias especiales, cuando el medicamento las requiera;
8. Fecha de caducidad expresada claramente (mes y año);
9. Precauciones particulares de conservación, en su caso;
10. Precauciones especiales de eliminación de los productos no utilizados o de los residuos derivados de estos productos, en su caso;
11. Nombre y dirección del titular de la autorización del medicamento;
12. Código Nacional de Medicamentos (Bulgaria);
13. Identificación del lote de fabricación;
14. Condiciones de prescripción;
15. La indicación de uso, en su caso (para especialidades farmacéuticas publicitarias);

Para el acondicionamiento primario, no se exige que el etiquetado esté en búlgaro, aunque es preferible que aparezca en uno de los idiomas principales de la UE (inglés). Debe incluir, mediante etiquetas / pegatinas, los siguientes datos:

1. Denominación del medicamento;
2. Nombre del titular de la autorización del medicamento (se puede abreviar);
3. Fecha de caducidad;
4. Identificación del lote de fabricación.

Cuando el acondicionamiento primario contenido en un embalaje exterior sea tan pequeño que no permita la inclusión de los datos mencionados en el párrafo anterior, deberá llevar como mínimo la información siguiente:

1. Denominación del medicamento, y en su caso, composición cualitativa y cuantitativa, en principios activos por unidad de administración;
2. Vía de administración, en su caso;
3. Forma de administración;
4. Fecha de caducidad;
5. Identificación del lote de fabricación;
6. Contenido en peso, en volumen o en unidades.

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6. ANEXOS

6.1. DIRECTORIO

ORGANIZACIONES GUBERNAMENTALES

BULGARIA DRUG AGENCY
26 Yanko Sakazov Blvd, 1504, Sofia, Bulgaria.
Tel: +359 2 943 40 46. Fax: +359 943 44 87.
Email: bda@bda.bg Web: www.bda.bg

BULGARIAN MEDICAL ACADEMY
1 G Sofiisky Street, Sofia, Bulgaria.
Tel: +359 2 51 621. Fax: +359 2 51 73 57.
Ministry of Health, Sveta Nedelya Square 5, 1000
Sofia, Bulgaria. Tel: +359 2 981 18 30. Fax: +359 98126 39
Web: www.mh.government.bg

NATIONAL HEALTH INSURANCE FUND (NHIF)
1 Krichim Street, 1407 Sofia, Bulgaria.
Tel/Fax: +359 2 965 91 52
Email: kandreev@nhif.bg Web: www.nhif.bg

ASOCIACIONES

ASSOCIATION OF BULGARIAN PHARMACEUTICAL MANUFACTURERS (ABPHM)
47 Ovcha Kupel Blvd, Sofia 1618, Bulgaria.
Tel: +359 2 955 90 04. Fax: +359 2 955 90 07.
Web: www.abphm.bg

ASSOCIATION OF INTERNATIONAL PHARMACEUTICAL PRODUCERS (AIPP)
Ewlogi Georgiev Blvd 62, Sofia 1124, Bulgaria.
Tel: +359 2 442 300. Fax: +359 2 943 3178.

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6.2. TOP 20 IMPORTADORES BÚLGAROS DE MEDICAMENTOS 2002

Nº	IMPORTACIÓN EN MILES DE USD	EMPRESA	CIUDAD
1	31.454	COMMERCIAL LEAGUE CO. LTD-NATIONAL PHARMA CENTRE	SOFIA
2	13.199	SANITA TRADING LTD	VARNA
3	10.075	BIOMEDA 2000 LTD	PLOVDIV
4	8.734	MAGINED LTD	SOFIA
5	8.720	HIGIA LTD	PLEVEN
6	7.494	ALEX PLUS 2000	SOFIA
7	6.397	MAIMEX PLC	SOFIA
8	6.337	AGROENGINEERING-90 LTD	SOFIA
9	4.269	STING LTD	RAZGRAD
10	4.097	SOLVAY-BULGARIA AD	SOFIA
11	3.665	KALIMAN RT LTD	SOFIA
12	3.593	SND CHEMICALS BULGARIA HOLDING	SOFIA
13	3.585	TRADECONSULT LTD	SOFIA
14	3.521	FARMEXPRESS LTD	PAZARDJIK
15	3.302	BALKANPHARMA HOLDING PLC	SOFIA
16	3.185	ROSSIN – 90 – ROSITSA SLAVEIKOVA & CO	SOFIA
17	3.013	GLOBAL MEDICAL LTD	SOFIA
18	2.817	ARISHOP-VALENTIN ARIZANOV P.M.	SOFIA
19	2.423	BALKANPHARMA-DUPNITSA SA	DUPNITSA
20	2.242	BAYER BULGARIA	SOFIA

Fuente: Top BG Exporters/Importers (Bulbrockers Sofia Ltd.)

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1.- COMMERCIAL LEAGUE CO. LTD-NATIONAL PHARMA CENTRE
bul. G.M. Dimitrov 1 - 1172 Sofia; Tel: (003592) 9625451; 9625452; Fax: 9625059
e-mail: ce@comleague.com web: www.comleague.com
Established: 1991
Capital: 50000
Profit: 2571000 (2001)
Number of employees: 800
Import regions: North America, Mexico; West and Central-West Europe; South-West and South Asia, Indian Ocean
Bulstat: 030276307
Executives: Toni Vekov (Exec. Director)
Contact Persons: Daniela Georgieva (Sales dept.)
Trade Mark: TURGOR
I Cosmetics and personal hygiene products (trade)
Cosmetics and creams (trade)
Toilet products for babies (trade)
Dental care products (trade)
I Pharmaceuticals (trade)
Medicines (trade)
Vitamins, hormones and organ extracts (trade)
Veterinary preparations (trade)
Warehouse services, specialised
Warehousing and distribution services, medical and pharmaceutical goods
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2.- SANITA TRADING LTD
ul. Tsarevets 5 - 9000 Varna; Tel: (0035952) 382393; 303850; Fax: 501979
e-mail: sanita@sanita.bg
Established: 1993
Capital: 85000
Profit: 1055000 (2001)
Number of employees: 400
Bulstat: 103267194
Executives: Tatyana Ninova Drakulova (Exec. Director); Dimitar Georgiev Dimitrov (Exec. Director)
Sales Office: Sofia 1612, ul. Vidlich 2, tel.: (003592) 9585850, fax: 9586414
Pharmaceuticals (trade)
Medicines (trade)
Homeopathic medicines (trade)
Serums and vaccines (trade)
Vitamins, hormones and organ extracts (trade)
Warehouse services, specialised
Warehousing and distribution services, medical and pharmaceutical goods
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3.- BIOMEDA 2000 LTD
ul. Nedyalka Shileva 31 - 4000 Plovdiv; Tel: (0035932) 609919; 609999; Fax: 609949
e-mail: biomeda@plovdiv.itd.net
Established: 2000
Profit: 393000 (2001)
Number of employees (approx.): 51-100
Import regions: West and Central-West Europe
Export regions: Central-East and East Europe
Bulstat: 115580147
Vat N: 1166116712
Executives: Hristo Simeonov Kolev (Manager)
I, E Pharmaceuticals (trade)
Medicines (trade)

4.- MAGINED LTD
bul. Cherni vrah 18a - 1407 Sofia; Tel: (003592) 655053; 9633097; Fax: 9633842
Almacén: c/ Goritza, 8 – Sofia, Tel./fax: (003592) 9559711, 9559718, 9559963
Bulstat: 121293002
Executives: Magdalina Stoyanova Dafinova (Manager)
Pharmaceuticals (trade)
Medicines (trade)
Vitamins, hormones and organ extracts (trade)

5.- HIGIA LTD
Ul. Karlovo 23 – Pleven; Tel: (0035964) 898724; Fax: 898721
e-mail: hgpleven@higia.bg web: www.higia.bg
Bulstat: 824133892
Executives: Bencho Mitev Benchev (Manager)

6.- ALEX PLUS 2000
j.k. Obelia 1, bl. 109, vx. A, ap. 27 – Sofia;
Bulstat: 130385026
Executives: Alexander Yordanov Berbanov (Manager)

7.- MAIMEX PLC
bul. Akademik Ivan Beshkov 15 - 1431 Sofia; Tel: (003592) 591128; 596164; Fax: 9581038

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FAX: (00359-2) 971 20 63

e-mail: info@maimex.bg web: www.maimex.bg
Established: 1979
Capital: 58000
Number of employees: 181
Import regions: North America, Mexico; West and Central-West Europe; Central-East and East Europe
Bulstat: 121541348
Vat N: 2221007533
Executives: Rumen Makaveev (Exec. Director); Vladimir Yordanov Balanov (Exec. Director); Valentina Sobadjiev (Economic)
Management Board: Tsanko Peevski (Chairman); Vladimir Balanov
I Food products (trade)
Baby food (trade)
I Pharmaceuticals (trade)
Medicines (trade)
Homeopathic medicines (trade)
Serums and vaccines (trade)
I Hospital, medical, dentistry and veterinary equipment (trading)
Medical and surgical instruments (trade)
Medical and surgical equipment (trade)
Electro-medical equipment (trade)
Dental laboratory equipment and supplies (trade)
I Physiotherapy and rehabilitation equipment and prostheses (trading)

8.- AGROENGINEERING-90 LTD
ul. Postoyanstvo 67a - 1111 Sofia; Tel: (003592) 9602699; 9602799; Fax: 9711159
e-mail: agro90@interkraft.net
Established: 1990
Capital: 5000
Number of employees: 16
Bulstat: 000639140
Vat N: 1223035546
Executives: Vesselina Filipova (Manager)
Pharmaceuticals (trade)
Medicines (trade)

9.- STING LTD
BlVD. Bulgaria Nº48 – 7200 Razgrad; Tel: (0035984) 27533
Blvd.. Aasen Yordanov, 6 – 1000 Sofia, Tel./ fax: (003592) 97031
E-mail: stingph@mobikom.com
Bulstat: 116512633
Executives: Georgi Alexandrov Zdravkov (Manager); Alexander Georgiev Zdravkov (Manager); Ivan Georgiev Zdravkov (Manager)
Importa medicamentos y material médico

10.- SOLVAY-PHARMA JSC
Ul. Haidushka Gora N 48ª, j.k. Krasno Selo – Sofia; Tel: (003592)9582029; Fax: 9582110
e-mail: office@solvay-pharma.bg web: www.solvay-pharma.bg

11.- KALIMAN RT LTD
ul. Vihren 34 - 1618 Sofia; Tel: (003592) 9559131; 9559282; Fax: 9559529
e-mail: kaliman@kaliman-bg.com web: www.viventi.bg
Established: 1991
Profit: 328000 (2001)
Number of employees: 213
Bulstat: 121120513
Vat N: 2221007762
Executives: Todor Dochev Dochev (Exec. Director)
I Pharmaceuticals (trade)
Medicines (trade)
Vitamins, hormones and organ extracts (trade)
Warehouse services, specialised
Warehousing and distribution services, medical and pharmaceutical goods
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12.- SND CHEMICALS BULGARIA HOLDING
Blvd. Dragan Tsankov 36 – Sofia; Tel: (003592) 9713364
Bulstat: 121682815
Executives: Ludmil Stoyanov Ptrinski (Manager)

13.- TRADECONSULT LTD
ul. Todor Kableshkov 16 – 1618 Sofia; Tel: (003592) 9158060, 9554457, 9555748, 9555631, 9555792, 9555734; Fax: 9158050; e-mail: tconsult@netel.bg
Executives: Toncho Atanasov Tonchev (Manager)

14.- FARMEXPRESS LTD
ul. Tsaritsa Joanna 3 - 4400 Pazardjik; Tel: (0035934) 442256; 440253; Fax: 400412
e-mail: farmexpress@farmexpress.bg web: www.farmexpress.bg
Established: 1993

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Capital: 5000
Profit: 315000 (2001)
Import regions: North America, Mexico; West and Central-West Europe
Bulstat: 822097127
Vat N: 1131033369
Executives: Luben Staev (Manager)
I Cosmetics and personal hygiene products (trade)
Dental care products (trade)
I Pharmaceuticals (trade)
Medicines (trade)

15.- BALKANPHARMA HOLDING PLC
bul. Maria Luiza 2, TzUM Business Center - 1000 Sofia; Tel: (003592) 9807892; 9809515; Fax: 9810301
e-mail: headoffice@balkanpharma.com web: www.balkanpharma.com
Established: 1993
Capital: 26192470
Number of employees: 4400
Bulstat: 831042432
Vat N: 1220001535
Executives: Christian Sverison (Exec. Director)
Pharmaceuticals (trade)
Medicines (trade)
Holding companies
Holding companies, industrial

16.- ROSSIN – 90 – ROSITSA SLAVEIKOVA & CO
yl. Simeonov Vek Nº7, bl. 228, vh. G, et. 2, ap. 36 – 1111 Sofia ; Tel: (003592) 720515, Fax: 701884
Bulstat: 831013854
Executives: Stefan Georgiev Dimitrov (Manager); Positsa Pervanova Slaveikova (Manager)

17.- GLOBAL MEDICAL LTD
ul. Zvezditsa 1 - 1618 Sofia; Tel: (003592) 9571058; Fax: 9571047
e-mail: globmed@bulinfo.net
Established: 1991
Capital: 10000
Profit: 69000 (2002)
NetSales: 22640000 (2002)
Executives: Georgi Hristov Matov (Manager)
Pharmaceuticals (trade)
Medicines (trade)
Vitamins, hormones and organ extracts (trade)

18.- ARISHOP-VALENTIN ARIZANOV P.M.
ul. Prof. Assen Zlatarov 1 - 1504 Sofia; Tel: (003592) 9461737; 9461779; Fax: 9461282
e-mail: arishop@techno-link.com
Profit: 553000 (2001)
Number of employees (approx.): 51-100
Bulstat: 121190479
Vat N: 1222002229
Executives: Valentin Arizanov (Manager)
Representative office: UPSA, France
I Pharmaceuticals (trade)
Medicines (trade)
Vitamins, hormones and organ extracts (trade)

19.- BALKANPHARMA-DUPNITSA SA
ul. Samokovsko shosse 3 - 2600 Dupnitsa; Tel: (00359701) 58333; Fax: 58555
e-mail: pilieva@dup.balkanpharma.com
Established: 1954
Capital: 663098
Profit: 28452000 (2001)
Number of employees: 1951
Export regions: North America, Mexico; West and Central-West Europe
Bulstat: 819364374
Vat N: 1101000784
Executives: Ivan Urumov (Exec. Director)
E Barbiturates, sulphonamides, glycacoides, alkaloides and antibiotic preparations
Sulphacetamide
Sulphadiazine
Sulphaguanidine
Sulphamerazine
Sulphanilamide
Sulphotiazoles
E Pharmaceutical preparations for the cardio-vascular system, central and autonomic nervous system. Anaesthetics
Anaesthetics, basal
Anaesthetics, inhalation
Anaesthetics, intravenous
Anaesthetics, spinal
Anaesthetics, local
Analgesics
Anti-pyretics
Asthma preparations
Anti-rheumatic preparations
Blood decompressants

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Cardiovascular products
Coronary vasodilators
Stimulants and anti-depressive agents for the central nervous system
Hypnotics, opiates
Sedatives and tranquillisers
Muscle relaxants and their antagonists
Parasympathomimetics
Sympathomimetics
Neurological preparations
E Pharmaceutical preparations for metabolism, nutrition, alimentary systems. Pharmaceutical preparations for urology, dermatology, gynaecology and obstetrics
Antacids and preparations for gastric ulcers
Anti-obesity preparations, anorectics
Cholagogues, choleretics, hepatoprotectors
Cholesterol reducing agents
Foods and nutrients, pharmaceutical
Laxatives and purgatives
Anti-diabetic pharmaceuticals
Anabolic agents
Pharmaceuticals for urinary tract disorders NES
Dermatological fungicides and keratolytics
Anti-pruritics
Pharmaceuticals, gynaecological and obstetric, NES
Iron preparations, medical
E Packaging and filling services for the pharmaceutical and cosmetics industries
Tablet packaging services
Ampoule filling services, pharmaceutical industry
Capsule filling and packaging services, pharmaceutical industry
Collapsible tube filling services, pharmaceutical industry
Cosmetic product packaging services

20.- BAYER BULGARIA
ul. Rezbarska 5 - 1510 Sofia; Tel: (003592) 9454957; 9434614; Fax: 9454902
e-mail: bayerbg@unisoftbg.com web: www.bayer.de
Established: 1990
Profit: 703000 (2001)
Number of employees: 46
Bulstat: 121258695
Vat N: 3220042064
Executives: Jorg Syrzisko (Manager)
Representative office: Bayer AG, Germany
Foreign representative offices
Foreign representative offices, sales and technical support

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6.3. MINISTRY OF HEALTH REGULATION NO. 17 OF 19 APRIL 2001 ON THE REQUIREMENTS TO THE DOCUMENTATION FOR MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

Chapter I
GENERAL PROVISIONS

Article 1. This Regulation specifies the requirements to the documentation, which shall be submitted for marketing authorization of proprietary and pharmaceutically equivalent medicinal products, manufactured in the country or abroad.

Article 2. Documentation for marketing authorization of medicinal products, variation and renewal of marketing authorization shall be presented in Bulgarian, English or Russian language.

Chapter II
MANDATORY DATA IN THE DOCUMENTATION FOR MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

Article 3. (1) In order to obtain marketing authorization of proprietary medicinal products the manufacturer or an authorized representative of the manufacturer shall submit to the Bulgarian Drug Agency (BDA) an application (three copies required) for marketing authorization in the form presented in Annex 1.
(2) Together with the application pursuant to paragraph 1 a dossier copy of the medicinal product shall be submitted, including:
1. Administrative data, according to Annex 2;
2. Chemical and pharmaceutical data, according to Annex 3 or 3.1;
3. Toxico-pharmacological data, according to Annex 4;
4. Clinical data, according to Annex 5.
(3) When the application for marketing authorization is submitted by virtue of point 3 of Article 33 (1) of the Act on Drugs and Pharmacies in Human Medicine (ADPHM), chemical and pharmaceutical data are not required.
(4) When the application for marketing authorization is submitted by virtue of point 1 or 2 of Article 33 (1) of the ADPHM, data demonstrating the relevant variation should be presented in the toxico-pharmacological or clinical part of the dossier.
Article 4. In order to obtain marketing authorization of medicinal products, authorized in the European Community through Centralized procedure, the persons specified in Article 3 (1) shall submit to the BDA an application (three copies required) for marketing authorization in the form presented in Annex 1.
(2) Together with the application pursuant to paragraph 1 a dossier copy of the medicinal product shall be submitted, including:
1. Administrative data, according to Annex 2.1;
2. Chemical and pharmaceutical data, according to Annex 3 or 3.1;
3. Contents of the toxico-pharmacological and clinical parts of the documentation.

Article 5. (1) In order to obtain marketing authorization of pharmaceutically equivalent medicinal products, the persons specified in Article 3 (1) shall submit to the BDA an application (three copies required) for marketing authorization in the form presented in Annex 1.
(2) Together with the application pursuant to paragraph 1 a dossier copy of the medicinal product shall be submitted, including:
1. Administrative data, according to Annex 2;
2. Chemical and pharmaceutical data, according to Annex 3 or 3.1;
3. Data for equivalence, according to Annex 6.

Article 6. In order to obtain marketing authorization of medicinal products based on

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an established prescription, documents specified in Article 5 (1) and point 1 and 2 of Article 5 (2) shall be submitted.

Article 7. In order to obtain marketing authorization of herbal medicinal products the persons specified in Article3 (1) shall submit to the BDA an application (three copies required) for marketing authorization in the form presented in Annex 1.
(2) Together with the application specified in paragraph 1 a dossier copy of the medicinal product shall be submitted, including
1. Administrative data, according to Annex 2;
2. Chemical and pharmaceutical data, according to Annex 3 or 3.2;
3. Toxico-pharmacological data, according to Annex 4 – for active substances, for which there are no scientific publications concerning their toxico-pharmacological data;
4. Summarised and updated bibliographic data about the clinical use of the active substance;
5. For a new combination of known active substances, assessment of the advantages of the proposed combination in relation to risk/benefit ratio shall be submitted.
(3) For herbal medicinal products with indications in different therapeutical area, as well as for new substance, clinical data according to Annex 5 shall be submitted.

Article 8. (1) In order to obtain marketing authorization of homeopathic medicinal products the persons specified in Article 3 (1) shall submit to the BDA an application (three copies required) for marketing authorization in the form presented in Annex 1.1.
(2) Together with the application specified in paragraph 1 a dossier copy of the medicinal product shall be submitted, including:
1. Administrative data, according to Annex 2.2;
2. Chemical and pharmaceutical data, according to Annex 3.3;
(3) For homeopatic medicinal products, designed for routes of administration other than oral and external, which have certain therapeutic indications or contain dilution less than 1/10 000 of the mother tincture (more than 1/100th of the smallest dose used in allopathic therapy), a documentation for marketing authorization of medicinal products shall be submitted.

Article 9. (1) Variations to the terms of marketing authorization of medicinal products shall be type I variations or type II variations. Type II variations shall be considered all substantial changes in the data specified in Article 3 (2).
(2) Type I variations shall be all changes other than those referred to in paragraph 1, which are specified in Annex 1.2.
(3) For type I and II variations to marketing authorization of medicinal products the persons, specified in Article 3 (1) shall submit to the BDA an application (three copies required) in the form presented in Annex 1.2, administrative data, according to Annex 2.3 and relevant to the respective type of variation documentation.
(4) Urgent safety restrictions, undertaken by the marketing authorization holder or required by the BDA are followed by type II variation procedure to the marketing authorization.
(5) For variation to marketing authorization of medicinal products, authorized in the European Community through the Centralized procedure, besides the documents according to paragraph 3 or 4, the persons specified in Article 3 (1) shall submit to the BDA the Decision of the EU Commission and the CPMP Assessment report for the relevant variation or notification for changes in the marketing authorization.

Article 10. (1) For renewal of marketing authorization according to Article 31 (1) of the ADPHM the persons, specified in Article 3 (1) shall submit to the BDA an application (three copies required) in the form presented in Annex 1.3, administrative data, according to Annex 2.4, periodic safety update report in the form according to Annex 7 and supplementary information, if necessary.

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(2) For renewal of marketing authorization of medicinal products according to Article 6, Article 7 and Article 8, except these specified in Article 7 (3) and Article 8 (3), the persons specified in Article 3 (1) shall submit to the BDA a three copy application in the form, presented in Annex 1.3 and administrative data, according to Annex 2.4, point I A, I B I and I B II.

Article 11. (1) After granting marketing authorization the persons, specified in Article 3 (1) shall be obliged to commission medical specialists to gather and assess data for observed adverse reactions, which shall be submitted to the BDA, as follows:
1. serious adverse reactions, occurring in the country - within 15 calendar days;
2. serious and unexpected adverse reactions, occurring out of the country - within 15 calendar days;
3. all other adverse reactions - within the frames of periodic safety update reports pursuant to in point 2 of Article 30a (1) of the ADPHM in the form, according to Annex 7.
(2) When requested by the BDA the persons, specified in Article 3 (1) shall submit additional information, including sales information, necessary for evaluation of the risk and the benefit associated with the medicinal product use.

TRANSITIONAL PROVISIONS

§ 1. For the purpose of this Regulation:
1. Centralized procedure is a procedure for granting an authorization to place a medicinal product on the Common market of the European Community based on an application submitted to the European Agency for the Evaluation of Medicinal Products (EMEA) and expert assessment, approved by the Committee for Proprietary Medicinal Products (CPMP).
2. Medicinal products based on an established prescription are medicinal products, manufactured on the base of established and commonly used in the medicinal practice prescriptions, with historically proven safety and efficacy. They shall not be prepared in pharmacies, but by a manufacturer of medicinal products with manufacturing authorization in accordance with Chapter II of the ADPHM.
3. Herbal medicinal products are medicinal products, which consist of herbal drugs and/or herbal drug preparations as active substances.
4. Herbal drugs are plants or parts of plants in unprocessed state, used for medicinal or pharmaceutical purposes.
5. Herbal preparation are comminuted or powdered herbal drugs, extracts, tinctures, fatty or essential oils, expressed juices, processed resins or gums, manufactured by herbal drugs and preparations by fractionation, purification or concentration.
6. New substance is a substance, which is not contained in any medicinal product authorized in Bulgaria.
7. Urgent safety restrictions are interim changes to product information by the marketing authorization holder restricting the indication(s), and/or dosage of the medicinal product, or adding contra-indications, and/or warnings due to new information bearing on the safe use of the product.
8. Unexpected adverse reaction means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.
9. Therapeutic equivalence is available when the medicinal products contain the same active substance(s) and have the same clinical efficacy and safety.
10. Biological equivalence (bioequivalence) is available when the medicinal products are in the same dosage form, in which there is no substantial differences in the degree and rate of absorption after administration of the active substance in the same molar dose and under equal conditions.

FINAL PROVISION

§ 2. This Regulation is issued in pursuance of Article 18 (2) of the Act on Drugs and Pharmacies in Human Medicine.

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Minister: I. Semerdjiev

6.4. ORDINANCE 7 OF JUNE 22, 2000 FOR THE OBLIGATORY DATA OVER THE PACKING AND IN THE LEAFLETS OF THE MEDICAL PRODUCTS AND IN THE INSTRUCTIONS FOR USE OF THE MEDICAL ARTICLES

Prom. SG. 54/4 Jul 2000, amend. SG. 52/8 Jun 2001, amend. SG. 17/2 Mar 2004

Art. 1. With this ordinance are determined the requirements with regard to the data over the packing and in the leaflets of the medical products as well as in the instructions for use of the medical articles.

Art. 2. The information over the packing and in the leaflet of the medical product as well as in the instruction for use of the medical article cannot detract from the data approved at the permission for use of the medical product and cannot contain misleading names and marks.

Art. 3.(1) The medical products except these of art. 10, 11, 13 and 15 shall contain over the secondary packing and if there is no such, over the primary packing the following data:
1. name of the medical product;
2. (amend. SG 52/01) medical substances expressed as quality and quantity for one dose unit or depending on the medical form – for given volume or mass, using the international non-patent title (INT) and if there are not such – the general accepted names;

3. medical form and quantity in one packing, expressed with the mass, the volume, the number dose units or the number of international units in one packing, depending on the medical product.
4. list of the auxiliary substances which have proven action or effect; if the product is for parenteral or local use, including eye or inhaling application, all the auxiliary substances must be pointed out;
5. way of use and when necessary way of introduction;
6. warning the medical product to be preserved at a place inaccessible for children;
7. another special warning when this is necessary for the concrete medical product;
8. date of expiration term expressed as: "expiration term: (month/year)";
if necessary shall be pointed out the term of expiration after dissolution, dilution/suspension or first opening of the packing;
9. special conditions of preservation if such are required;
10. special protection measures at throwing out unused part of the medical products or waste materials from them, if necessary;
11. name and address of the owner of the permission for use of the medical product;
12. registration number;
13. lot number;
14. way of release - marking "with physician's prescription", when the medical product is released with physician's prescription; "without physician's prescription", when the medical product is released without physician's prescription; "for hospital use" when it is released only for hospital use;
15. instructions for use for medical products which are released without physician's prescription.

(2) (amend. SG 52/01) When the product is with trade name and contains only one medical substance the name of the medical product must be followed by the international non-patent title (INT) or other generally accepted name of the medical substance. If the medical product is offered in different medical forms and/or if there are different quantities of the active substance for a dose unit, the medical form and/or the quality of the

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active substance for a dose must be written together with the name.
(3) The medical form and the way for introduction (the way of application) shall be expressed with the full standard terms published regularly by the European or the Bulgarian pharmacopeia. In case of insufficient place for the full standard terms (over blisters, strips and small packing) can be used the short standard terms published there.
(4) The secondary packing can contain symbols or images designated to illustrate the information pointed out in para 1 as well as other information corresponding to the short characteristic of the product if it is the useful for the health education, excluding advertising elements.
(5) The name of the radioactive element, the radioactivity of dose unit or fial and the internationally accepted sign for radioactivity shall be included apart from the data of para 1 for radioactive medical products. In the name of the product must be included the name or the symbol of the radionuclide.
(6) The packing should be marked with two diagonal red strips for medical products containing anaesthetic substances, and for psychotropic substances - with two blue strips. The packing shall obligatory contain instruction that the medical product is released only with special physician's prescription.

Art. 4.(1) The medical products shall contain on their primary packing all the data of art. 3, para 1.
(2) Exception from the established in para 1 shall be admitted for primary packing in the form of blister, strip or small size packing.
(3) The primary packing in the form of blister or strip put and released in secondary packing must obligatory contain the following data:
1. name of the medical product;
2. name of the owner of the permission for use of the product, could be also abbreviated;
3. date of elapse of the expiry term;
4. lot number.
(4) The secondary packing in which are put units with small primary packing (ampules etc.) on which it is not possible to write the information of art. 3, para 1, must contain at least the following data:
1. name of the medical product and when necessary quantity of the medical substance for dose unit and way of introduction;
2. way of use when necessary;
3. date of elapse of the expiry term;
4. lot number;
5. quantity in one packing: mass, volume, international units.

Art. 4a. (new, SG 17/04 – in force from Jan 1 2006) On the secondary packing of the medical products dispensed by physician's prescription the producer shall leave a free zone of sizes not less than 45 mm by 18 mm, on which distinctive marking can be affixed.

Art. 5.(1) All marks on the packing must be understandable for the patient, legible and not deleatable.
(2) (Amend., SG 52/01) The data of art. 3, para 1 shall be written in Bulgarian language with exception of the names of the medical product which shall be written in Roman. The international non-patent name of the medical substance shall be written only in Roman. The data of Art. 3, para 1, item 11 can be written with Cyrillic or Roman alphabet depending on the case.
(3) It shall be admitted the data of art. 3, para 1 to be in several languages under the condition that the provisions of para 2 are observed and the information in all the languages is equal.
(4) In case of necessity the Executive agency for the medicines can require on the packing to be included additional information.

Art. 6. The selling of the medical product without a leaflet in the secondary packing shall be prohibited. Exception shall be admitted in case that the product is sold without secondary packing and the information of the leaflet is contained on the primary packing.

Art. 7. The information in the leaflet shall obligatory comply with the short characteristic of the product and shall not contain advertising elements.

Art. 8.(1) In the leaflet of the medical products shall be contained the following information:
1. name of the medical product;

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2. full quality and quantity content, including the medical substance/ the medical substances and the auxiliary substances;
3. medical form and quantity in one packing expressed with mass, volume, number dose units or the number of international units in one packing depending on the medical product;
4. name and address of the owner of the permission for use of the medical product as well as name and address of the producer when he is not the owner of the permission for use;
5. pharmacotherapeutic group or the way of action;
6. therapeutic indications;
7. information necessary before the use of the medical product:
a) counter-indications;
b) special protection measures at use;
c) medical interactions and other forms of interactions (alcohol, smoking, foods) which could affect the effect of the medical product;
d) special warnings about the use by specific groups of patients (children, pregnant and breastfeeding, aged patients, persons with specific pathological status);
e) influence over the ability to drive and work with machines;
f) data about the auxiliary substances the knowledge of which is important for the safety and the efficiency at use of the product;
g) warning about the risk of addiction and misuse (for narcotic and psychotropic substances);

8. information about the correct use:
a) dosing;
b) way of use and if necessary way of introduction;
c) frequency of application and if necessary is noted also the appropriate time of application of the medical product;
d) duration of the treatment when it must be restricted;
e) way of action at overdosing (symptoms, urgent measures);
f) way of action in case of missing doses;
g) instructions if necessary when the stopping of the product is connected with risk;
9. description of the unwanted medical reactions which could occur at correct use of the medical product and the measures that must be undertaken in such cases;
10. special conditions for preservation when such are required;
11. expiry term and warning the product not to be used after the date of elapse of the expiry term pointed out on the packing.
12. date of the last editing of the leaflet.
(2) The Executive agency for the medicines can decide some therapeutic indications not to be mentioned in the leaflet when the dissemination of this information can have serious consequences for the patient.

Art. 9. (Amend., SG 52/01) (1) The leaflet must be written with clear and understandable terms in Bulgarian language. The name of the medical product shall obligatorily be written in Bulgarian and in Roman, and the international non-patent name - only in Roman.
(2) It shal be admitted to issue the leaflet in several languages, one of which shall obligatorily be Bulgarian, on condition that the information is equal in all languages.

Art. 10.(1) The medical products containing plants shall contain on the secondary packing the data of items 1- 3, 5 - 9, 15 - 20 of para 2 and in the leaflet - the data of art. 8.
(2) The medical products of para 1 in the cases when they are sold without a leaflet and secondary packing shall contain on the primary packing the following data:
1. name of the medical product;
2. name of the herbs and the part of the plant which is used (in Latin - for the imported species, for those produced in the country - in Latin and in Bulgarian language), quantity for one dose or of one packing;
3. medical form and quantity in one packing;
4. indications;
5. way of use and if necessary way of introduction;
6. dosing;
7. duration of the treatment (if necessary);
8. basic unwanted medical reactions;
9. information at overdosing, when necessary;
10. counter-indications, warnings, protection measures and basic medical interactions if there are such;

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11. instructions for use at pregnancy and breastfeeding when necessary;
12. warning the medical product to be preserved at a place inaccessible for children;
13. warning the medical product not to be used after the elapse of the expiry term;
14. other warnings when necessary;
15. the date of elapse of the expiry term;
16. special conditions for preservation if such are required;
17. name and address of the owner of the permission for use;
18. registration number;
19. lot number;
20. instruction for use explicitly pointing out the time of contact of the medical product with water as well as the temperature of extracting.
(3) All the data of para 2 shall be written on the packing in Bulgarian language except these of items 2 and 17. The name of the medical product shall be written with Roman and Cyrillic alphabet (or at discretion of the Executive agency for the medicines - only with the Cyrillic alphabet).

Art. 11.(1) The homeopathic medical products shall contain over their secondary packing, and if there is no such - on the primary packing the following data:
1. name of the homeopathic medical product;
2. name of the homeopathic sources in Latin language;
3. degree of dissolution using the symbols of the corresponding pharmacopeia;
4. medical form and quantity in one packing;
5. way of use and if necessary way of introduction;
6. special warnings if there are such;
7. date of elapse of the expiry term;
8. special conditions for preservation if such are required;
9.name and address of the owner of the permission for use;
10. registration number;
11. lot number;
12. mark "homeopathic medical product" - for the homeopathic specialities and mono-preparations.
(2) The packing of the homeopathic specialities designated for local application shall contain the names of all the auxiliary substances.
(3) The primary packing on which it is not possible to be written the information of para 1 shall contain all the data of items 1 - 4, 7, 11 and 12 of para 1.

Art. 12. The leaflet of the homeopathic specialities shall contain apart from the data of art. 8 also an instruction for consultancy with a physician if the patient is not influenced by the treatment.

Art. 13. The medical Art.s and the active implanted Art.s shall contain on their primary packing, and if not possible - on the secondary packing the following data:
1. name of the Art. and address of the producer;
2. information with purpose identification of the Art. and, kind of the material/materials and contents of the packing (dimensions of the Art. and number of the Art.s in one packing);
3. mark "sterile" where necessary and wat of sterilisation;
4. mark "apyrogenic" and/or "non toxic" where necessary;
5. lot number;
6. date of elapse of the expiry term expressed as "expiry term: (month/year)";
7. mark "for single use" when the Art. is for single use;
8. mark "Art. made by order" when the Art. has been made by order;
9. mark "only for clinical trial" when the Art. is designated for clinical trial;
10. special conditions for preservation and/or use;
11. special instructions for work;
12. warnings and/or protective measures at preservation, transport and application;
13. year of production - for the active implanted Art.s;
14. term of fitness after implanting when there is such.

Art. 14.(1) The instruction for use of the medical Art.s and of the active implanted Art.s shall contain:
1. the data of art. 13 without these of items 3 and 4;
2. instruction for work (information about the way of application), including information about all unwanted reactions connected with the use;
3. information giving opportunity to be avoided the risks at implanting the Art. when it is necessary;

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4. instructions in case of damage of the sterile packing and where possible - information about the appropriate way of sterilisation;
5. instructions at many-fold use, including method for cleaning, disinfecting and packing; when necessary - way of sterilisation of the Art.;
6. instruction for cleaning and sterilisation for Art.s which are sterilised before use;
7. information about the counter - indications and the necessary protective measures;
8. date of the last editing of the instruction for use.
(2) The instructions for use of the medical Art.s must be written in Bulgarian language with terms understandable for the patient except the names which can be written also with Roman alphabet.

Art. 15. The in vitro diagnostic medical Art.s shall contain on their packing the following data:
1. name of the Art.;
2. address of the producer;
3. contents of the packing and information about identification of the product;
4. mark "sterile" or degree of cleanness when necessary;
5. lot number;
6. mark "expiry term: (month/year, and when necessary - also day)" for the product and/or for the separate components if it is a set;
7. mark, that the product is for use in vitro;
8. conditions for preservation;
9. instructions for use when necessary;
10. warnings about the risks and protective measures connected with the specific characteristics of the product, when necessary;
11. mark "for self testing" when necessary.
12. information about the designation of the product when necessary.

Art. 16.(1) The instructions for use of diagnostic in vitro medical Art.s shall contain the following data:
1. name of the Art. and address of the producer;
2. contents of the packing and information about identification of the product;
3. mark "sterile" or degree of cleanness when necessary;
4. mark, that the product is for use in vitro;
5. conditions for preservation;
6. qualitative and quantitative ingredients of the active substance of the reactive or the combination and the content of other ingredients that could render influence on the measurement;
7. the conditions for preservation and expiry term after the first opening of the primary packing together with the conditions for preservation and the stability of the working reactives (the working dissolving of the reactives);
8. data about the specific characteristics - analytical and diagnostic sensitivity and specific characteristics, precision, repeatability, reproducing ability, including control over the possible interactions and limits of detection;
9. description of the special apparatus, instalment, connection and combination when necessary for the correct use of the product;
10. sample for examination - requirements for preparation of the patient, conditions for taking, transport and preservation of the sample, used anti-coagulants, detergents, conservation agents, interfering substances etc.;

11. detailed description of the procedure of fulfilment of the method, calibration;
12. reading and interpretation of the results, principle, working characteristics, limits of detection, reference materials and methods;
13. information about conducting internal quality control, including specific procedures for validation;
14. instructions in case of damages of the protection package and for use of appropriate measures for second sterilisation or decontamination;
15. instructions for cleaning, disinfecting, packing, second sterilisation or decontamination and pointing out the number of uses for Art.s for multiple use.;
16. warnings about usual and unusual risks and protective measures connected with the specific character of the product and its application, when necessary;
17. warning about possible contamination with infection agents for Art.s containing materials from human or animal origin;
18. specific instruction for the user - non specialist about Art.s for self testing;
19. date of the last editing of the instruction for use.
(2) The instruction for use of diagnostic in vitro medical Art.s shall be in Bulgarian language except

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the names which can be also written with Roman alphabet.

Additional provisions

§ 1. In the sense of this ordinance:
1. "Name of the medical product" is the name given to the product which can be:
a) freely chosen name (trade name);
b) generally accepted, together with the trade name or the name of the producer;
c) scientific name together with the trade name or the name of the producer; the name has to be different from the names of medical products already permitted for use in the country, with at least two letters; the trade name must not cause confusion with the generally accepted name of the medical substance which the medical product does not contain.
2. (Amend., SG 52/01) "Generally accepted name" is the international non patent name of the medical or the auxiliary substance (INN), recommended by WHO; if there is no such, the name from the European pharmacopeia shall be used, and it is not there - other pharmacopeia name; when there is not pharmacopeia name the generally accepted name shall be used.
3. "Quantity medical substance in dose unit" of the medical product is the content of the medical substance expressed as quantity in one dose unit (tablet, capsule) or for unit of mass or volume, depending on the medical form.
4. "Leaflet" is the information designated for the patient, accompanying the medical product.
5. "Owner of the permission for use" is the producer of the medical product or empowered representative of the producer on which name is issued the permission for use.
6. "Homeopathic medical products" are medical products obtained from homeopathic sources o plant, animal, chemical or mineral origin in compliance with homeopathic production procedure.
7. "Homeopathic mono-preparations" are homeopathic medical products containing one homeopathic source.
8. "Homeopathic specialities" are homeopathic medical products woth certain therapeutic indications containing more than one homeopathic source.
9. (new, SG 17/04) “Distinctive marking” is an image containing an individual code.

Transitional and concluding provisions

§ 2. The requirements of this ordinance shall be applied with regard to the medical products which are permitted for use under the conditions and by the order of the Law for the medicines and the pharmacies in the humanitarian medicine.

§ 3. The producers (the owners of the permission for use) shall bring the packing and the leaflets existing when this ordinance enters into force in compliance with its requirements in three years term.

§ 4. (Revoked, SG 52/01)

§ 5. This ordinance is issued pursuant to art. 4, para 3 of the Law for the medicines and the pharmacies in the humanitarian medicine (prom. SG 36/95, amend. and suppl. SG 10/2000) and repeals Ordinance No 24 of 1995 for the obligatory data contained on the packing of the medicines and the accompanying leaflets (SG 70/95).
Minister: I. Semerdzhiev¦p

ORDINANCE ¹ 7 OF JUNE 22, 2000 FOR THE OBLIGATORY DATA OVER THE PACKING AND IN THE LEAFLETS OF THE MEDICAL PRODUCTS AND IN THE INSTRUCTIONS FOR USE OF THE MEDICAL ARTICLES
Prom. SG. 54/4 Jul 2000, amend. SG. 52/8 Jun 2001, amend. SG. 17/2 Mar 2004
Art. 1. With this ordinance are determined the requirements with regard to the data over the packing and in the leaflets of the medical products as well as in the instructions for use of the medical articles.

Art. 2. The information over the packing and in the leaflet of the medical product as well as in the instruction for use of the medical article cannot detract from the data approved at the permission for use of the medical product and cannot contain misleading names and marks.

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Art. 3.(1) The medical products except these of art. 10, 11, 13 and 15 shall contain over the secondary packing and if there is no such, over the primary packing the following data:
1. name of the medical product;
2. (amend. SG 52/01) medical substances expressed as quality and quantity for one dose unit or depending on the medical form – for given volume or mass, using the international non-patent title (INT) and if there are not such – the general accepted names;

3. medical form and quantity in one packing, expressed with the mass, the volume, the number dose units or the number of international units in one packing, depending on the medical product.
4. list of the auxiliary substances which have proven action or effect; if the product is for parenteral or local use, including eye or inhaling application, all the auxiliary substances must be pointed out;
5. way of use and when necessary way of introduction;
6. warning the medical product to be preserved at a place inaccessible for children;
7. another special warning when this is necessary for the concrete medical product;
8. date of expiration term expressed as: "expiration term: (month/year)";
if necessary shall be pointed out the term of expiration after dissolution, dilution/suspension or first opening of the packing;
9. special conditions of preservation if such are required;
10. special protection measures at throwing out unused part of the medical products or waste materials from them, if necessary;
11. name and address of the owner of the permission for use of the medical product;
12. registration number;
13. lot number;
14. way of release - marking "with physician's prescription", when the medical product is released with physician's prescription; "without physician's prescription", when the medical product is released without physician's prescription; "for hospital use" when it is released only for hospital use;
15. instructions for use for medical products which are released without physician's prescription.

(2) (amend. SG 52/01) When the product is with trade name and contains only one medical substance the name of the medical product must be followed by the international non-patent title (INT) or other generally accepted name of the medical substance. If the medical product is offered in different medical forms and/or if there are different quantities of the active substance for a dose unit, the medical form and/or the quality of the active substance for a dose must be written together with the name.
(3) The medical form and the way for introduction (the way of application) shall be expressed with the full standard terms published regularly by the European or the Bulgarian pharmacopeia. In case of insufficient place for the full standard terms (over blisters, strips and small packing) can be used the short standard terms published there.
(4) The secondary packing can contain symbols or images designated to illustrate the information pointed out in para 1 as well as other information corresponding to the short characteristic of the product if it is the useful for the health education, excluding advertising elements.
(5) The name of the radioactive element, the radioactivity of dose unit or fial and the internationally accepted sign for radioactivity shall be included apart from the data of para 1 for radioactive medical products. In the name of the product must be included the name or the symbol of the radionuclide.
(6) The packing should be marked with two diagonal red strips for medical products containing anaesthetic substances, and for psychotropic substances - with two blue strips. The packing shall obligatory contain instruction that the medical product is released only with special physician's prescription.

Art. 4.(1) The medical products shall contain on their primary packing all the data of art. 3, para 1.
(2) Exception from the established in para 1 shall be admitted for primary packing in the form of blister, strip or small size packing.

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(3) The primary packing in the form of blister or strip put and released in secondary packing must obligatory contain the following data:
1. name of the medical product;
2. name of the owner of the permission for use of the product, could be also abbreviated;
3. date of elapse of the expiry term;
4. lot number.
(4) The secondary packing in which are put units with small primary packing (ampules etc.) on which it is not possible to write the information of art. 3, para 1, must contain at least the following data:
1. name of the medical product and when necessary quantity of the medical substance for dose unit and way of introduction;
2. way of use when necessary;
3. date of elapse of the expiry term;
4. lot number;
5. quantity in one packing: mass, volume, international units.

Art. 4a. (new, SG 17/04 – in force from Jan 1 2006) On the secondary packing of the medical products dispensed by physician's prescription the producer shall leave a free zone of sizes not less than 45 mm by 18 mm, on which distinctive marking can be affixed.

Art. 5.(1) All marks on the packing must be understandable for the patient, legible and not deleatable.
(2) (Amend., SG 52/01) The data of art. 3, para 1 shall be written in Bulgarian language with exception of the names of the medical product which shall be written in Roman. The international non-patent name of the medical substance shall be written only in Roman. The data of Art. 3, para 1, item 11 can be written with Cyrillic or Roman alphabet depending on the case.
(3) It shall be admitted the data of art. 3, para 1 to be in several languages under the condition that the provisions of para 2 are observed and the information in all the languages is equal.
(4) In case of necessity the Executive agency for the medicines can require on the packing to be included additional information.

Art. 6. The selling of the medical product without a leaflet in the secondary packing shall be prohibited. Exception shall be admitted in case that the product is sold without secondary packing and the information of the leaflet is contained on the primary packing.

Art. 7. The information in the leaflet shall obligatory comply with the short characteristic of the product and shall not contain advertising elements.

Art. 8.(1) In the leaflet of the medical products shall be contained the following information:
1. name of the medical product;
2. full quality and quantity content, including the medical substance/ the medical substances and the auxiliary substances;
3. medical form and quantity in one packing expressed with mass, volume, number dose units or the number of international units in one packing depending on the medical product;
4. name and address of the owner of the permission for use of the medical product as well as name and address of the producer when he is not the owner of the permission for use;
5. pharmacotherapeutic group or the way of action;
6. therapeutic indications;
7. information necessary before the use of the medical product:
a) counter-indications;
b) special protection measures at use;
c) medical interactions and other forms of interactions (alcohol, smoking, foods) which could affect the effect of the medical product;
d) special warnings about the use by specific groups of patients (children, pregnant and breastfeeding, aged patients, persons with specific pathological status);
e) influence over the ability to drive and work with machines;
f) data about the auxiliary substances the knowledge of which is important for the safety and the efficiency at use of the product;
g) warning about the risk of addiction and misuse (for narcotic and psychotropic substances);

8. information about the correct use:
a) dosing;
b) way of use and if necessary way of introduction;

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c) frequency of application and if necessary is noted also the appropriate time of application of the medical product;
d) duration of the treatment when it must be restricted;
e) way of action at overdosing (symptoms, urgent measures);
f) way of action in case of missing doses;
g) instructions if necessary when the stopping of the product is connected with risk;
9. description of the unwanted medical reactions which could occur at correct use of the medical product and the measures that must be undertaken in such cases;
10. special conditions for preservation when such are required;
11. expiry term and warning the product not to be used after the date of elapse of the expiry term pointed out on the packing.
12. date of the last editing of the leaflet.
(2) The Executive agency for the medicines can decide some therapeutic indications not to be mentioned in the leaflet when the dissemination of this information can have serious consequences for the patient.

Art. 9. (Amend., SG 52/01) (1) The leaflet must be written with clear and understandable terms in Bulgarian language. The name of the medical product shall obligatorily be written in Bulgarian and in Roman, and the international non-patent name - only in Roman.
(2) It shal be admitted to issue the leaflet in several languages, one of which shall obligatorily be Bulgarian, on condition that the information is equal in all languages.

Art. 10.(1) The medical products containing plants shall contain on the secondary packing the data of items 1- 3, 5 - 9, 15 - 20 of para 2 and in the leaflet - the data of art. 8.
(2) The medical products of para 1 in the cases when they are sold without a leaflet and secondary packing shall contain on the primary packing the following data:
1. name of the medical product;
2. name of the herbs and the part of the plant which is used (in Latin - for the imported species, for those produced in the country - in Latin and in Bulgarian language), quantity for one dose or of one packing;
3. medical form and quantity in one packing;
4. indications;
5. way of use and if necessary way of introduction;
6. dosing;
7. duration of the treatment (if necessary);
8. basic unwanted medical reactions;
9. information at overdosing, when necessary;
10. counter-indications, warnings, protection measures and basic medical interactions if there are such;

11. instructions for use at pregnancy and breastfeeding when necessary;
12. warning the medical product to be preserved at a place inaccessible for children;
13. warning the medical product not to be used after the elapse of the expiry term;
14. other warnings when necessary;
15. the date of elapse of the expiry term;
16. special conditions for preservation if such are required;
17. name and address of the owner of the permission for use;
18. registration number;
19. lot number;
20. instruction for use explicitly pointing out the time of contact of the medical product with water as well as the temperature of extracting.
(3) All the data of para 2 shall be written on the packing in Bulgarian language except these of items 2 and 17. The name of the medical product shall be written with Roman and Cyrillic alphabet (or at discretion of the Executive agency for the medicines - only with the Cyrillic alphabet).

Art. 11.(1) The homeopathic medical products shall contain over their secondary packing, and if there is no such - on the primary packing the following data:
1. name of the homeopathic medical product;
2. name of the homeopathic sources in Latin language;
3. degree of dissolution using the symbols of the corresponding pharmacopeia;
4. medical form and quantity in one packing;
5. way of use and if necessary way of introduction;
6. special warnings if there are such;

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7. date of elapse of the expiry term;
8. special conditions for preservation if such are required;
9.name and address of the owner of the permission for use;
10. registration number;
11. lot number;
12. mark "homeopathic medical product" - for the homeopathic specialities and mono-preparations.
(2) The packing of the homeopathic specialities designated for local application shall contain the names of all the auxiliary substances.
(3) The primary packing on which it is not possible to be written the information of para 1 shall contain all the data of items 1 - 4, 7, 11 and 12 of para 1.

Art. 12. The leaflet of the homeopathic specialities shall contain apart from the data of art. 8 also an instruction for consultancy with a physician if the patient is not influenced by the treatment.

Art. 13. The medical Art.s and the active implanted Art.s shall contain on their primary packing, and if not possible - on the secondary packing the following data:
1. name of the Art. and address of the producer;
2. information with purpose identification of the Art. and, kind of the material/materials and contents of the packing (dimensions of the Art. and number of the Art.s in one packing);
3. mark "sterile" where necessary and wat of sterilisation;
4. mark "apyrogenic" and/or "non toxic" where necessary;
5. lot number;
6. date of elapse of the expiry term expressed as "expiry term: (month/year)";
7. mark "for single use" when the Art. is for single use;
8. mark "Art. made by order" when the Art. has been made by order;
9. mark "only for clinical trial" when the Art. is designated for clinical trial;
10. special conditions for preservation and/or use;
11. special instructions for work;
12. warnings and/or protective measures at preservation, transport and application;
13. year of production - for the active implanted Art.s;
14. term of fitness after implanting when there is such.

Art. 14.(1) The instruction for use of the medical Art.s and of the active implanted Art.s shall contain:
1. the data of art. 13 without these of items 3 and 4;
2. instruction for work (information about the way of application), including information about all unwanted reactions connected with the use;
3. information giving opportunity to be avoided the risks at implanting the Art. when it is necessary;
4. instructions in case of damage of the sterile packing and where possible - information about the appropriate way of sterilisation;
5. instructions at many-fold use, including method for cleaning, disinfecting and packing; when necessary - way of sterilisation of the Art.;
6. instruction for cleaning and sterilisation for Art.s which are sterilised before use;
7. information about the counter - indications and the necessary protective measures;
8. date of the last editing of the instruction for use.
(2) The instructions for use of the medical Art.s must be written in Bulgarian language with terms understandable for the patient except the names which can be written also with Roman alphabet.

Art. 15. The in vitro diagnostic medical Art.s shall contain on their packing the following data:
1. name of the Art.;
2. address of the producer;
3. contents of the packing and information about identification of the product;
4. mark "sterile" or degree of cleanness when necessary;
5. lot number;
6. mark "expiry term: (month/year, and when necessary - also day)" for the product and/or for the separate components if it is a set;
7. mark, that the product is for use in vitro;
8. conditions for preservation;
9. instructions for use when necessary;
10. warnings about the risks and protective measures connected with the specific characteristics of the product, when necessary;
11. mark "for self testing" when necessary.
12. information about the designation of the product when necessary.

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Art. 16.(1) The instructions for use of diagnostic in vitro medical Art.s shall contain the following data:
1. name of the Art. and address of the producer;
2. contents of the packing and information about identification of the product;
3. mark "sterile" or degree of cleanness when necessary;
4. mark, that the product is for use in vitro;
5. conditions for preservation;
6. qualitative and quantitative ingredients of the active substance of the reactive or the combination and the content of other ingredients that could render influence on the measurement;
7. the conditions for preservation and expiry term after the first opening of the primary packing together with the conditions for preservation and the stability of the working reactives (the working dissolving of the reactives);
8. data about the specific characteristics - analytical and diagnostic sensitivity and specific characteristics, precision, repeatability, reproducing ability, including control over the possible interactions and limits of detection;
9. description of the special apparatus, instalment, connection and combination when necessary for the correct use of the product;
10. sample for examination - requirements for preparation of the patient, conditions for taking, transport and preservation of the sample, used anti-coagulants, detergents, conservation agents, interfering substances etc.;

11. detailed description of the procedure of fulfilment of the method, calibration;
12. reading and interpretation of the results, principle, working characteristics, limits of detection, reference materials and methods;
13. information about conducting internal quality control, including specific procedures for validation;
14. instructions in case of damages of the protection package and for use of appropriate measures for second sterilisation or decontamination;
15. instructions for cleaning, disinfecting, packing, second sterilisation or decontamination and pointing out the number of uses for Art.s for multiple use.;
16. warnings about usual and unusual risks and protective measures connected with the specific character of the product and its application, when necessary;
17. warning about possible contamination with infection agents for Art.s containing materials from human or animal origin;
18. specific instruction for the user - non specialist about Art.s for self testing;
19. date of the last editing of the instruction for use.
(2) The instruction for use of diagnostic in vitro medical Art.s shall be in Bulgarian language except the names which can be also written with Roman alphabet.

Additional provisions

§ 1. In the sense of this ordinance:
1. "Name of the medical product" is the name given to the product which can be:
a) freely chosen name (trade name);
b) generally accepted, together with the trade name or the name of the producer;
c) scientific name together with the trade name or the name of the producer; the name has to be different from the names of medical products already permitted for use in the country, with at least two letters; the trade name must not cause confusion with the generally accepted name of the medical substance which the medical product does not contain.
2. (Amend., SG 52/01) "Generally accepted name" is the international non patent name of the medical or the auxiliary substance (INN), recommended by WHO; if there is no such, the name from the European pharmacopeia shall be used, and it is not there - other pharmacopeia name; when there is not pharmacopeia name the generally accepted name shall be used.
3. "Quantity medical substance in dose unit" of the medical product is the content of the medical substance expressed as quantity in one dose unit (tablet, capsule) or for unit of mass or volume, depending on the medical form.
4. "Leaflet" is the information designated for the patient, accompanying the medical product.
5. "Owner of the permission for use" is the producer of the medical product or empowered

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representative of the producer on which name is issued the permission for use.
6. "Homeopathic medical products" are medical products obtained from homeopathic sources o plant, animal, chemical or mineral origin in compliance with homeopathic production procedure.
7. "Homeopathic mono-preparations" are homeopathic medical products containing one homeopathic source.
8. "Homeopathic specialities" are homeopathic medical products woth certain therapeutic indications containing more than one homeopathic source.
9. (new, SG 17/04) “Distinctive marking” is an image containing an individual code.

Transitional and concluding provisions

§ 2. The requirements of this ordinance shall be applied with regard to the medical products which are permitted for use under the conditions and by the order of the Law for the medicines and the pharmacies in the humanitarian medicine.

§ 3. The producers (the owners of the permission for use) shall bring the packing and the leaflets existing when this ordinance enters into force in compliance with its requirements in three years term.

§ 4. (Revoked, SG 52/01)

§ 5. This ordinance is issued pursuant to art. 4, para 3 of the Law for the medicines and the pharmacies in the humanitarian medicine (prom. SG 36/95, amend. and suppl. SG 10/2000) and repeals Ordinance No 24 of 1995 for the obligatory data contained on the packing of the medicines and the accompanying leaflets (SG 70/95).
Minister: I. Semerdzhiev¦p

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