

## Law for Medicinal Products in Human Medicine (2007) and related regulations relevant to the activities of pharmaceutical manufacturers and distributors in Bulgaria

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**Notes:**

1. This List includes all major regulations related to medicinal products as referenced (Column 1) in the Law for Medicinal Products in Human Medicine ("Drug Act 2007").
  2. This List excludes only regulations related to medicinal products containing narcotic substances.
  3. The titles in Column 2 are cited as published in the State Gazette (if already promulgated) or as working titles according to the text in the Drug Act 2007.
  4. The regulations marked in blue have been officially promulgated. Their full valid versions in Bulgarian are available at the web site of Top Management Advisors Ltd.: [www.tma-bulgaria.com](http://www.tma-bulgaria.com).
  5. The size of each regulation is given in Column 3 as number of words in the original as published in the State Gazette.
  6. Top Management Advisors Ltd. provides professional translations of the basic texts (Price List or a package proposal available on request).
  7. Analysis of Bulgarian pharmaceutical legislation are provided on a subscription bases or on specific request.
- For any information related to pharmaceutical regulatory affairs, please write to: [pharma@tma-bulgaria.com](mailto:pharma@tma-bulgaria.com).

Reference in the Drug Act	Name and date of issue	Number of words
	<b>Law for Medicinal Products in Human Medicine</b> (State Gazette No. 31/13.04.2007, Nos. 65/22.07.2008 and 71/12.08.2008, Nos. 10/6.02.2009, 23/27.03.2009, 41/ 2.06.2009, 88/6.11.2009 and 102/2212.2009)	<b>46733</b>
Article 1 (11)	Positive Drug List (State Gazette No.24/31.03.2009)	
Article 9(1)	Regulation on the treatment of an individual patient with a medicinal product that has not been authorised for placement on the market on the basis of a special order by a medical facility for inpatient treatment	
Article 15(2)	Rules of procedure for the activities of the Pharmacopoeia Committee (State Gazette No.6/23.01.2009)	<b>1386</b>
Article 16(4)	Rules of procedure for the organization and the activities of the Supreme Pharmacy Council (State Gazette No. 71/1.08.2007)	<b>792</b>
Article 17(4)	Statute of the Bulgarian Drug Agency (State Gazette No 52/10.07.2009).	<b>4651</b>
Article 21(2)	Tariff of the fees collected in accordance with the Drug Act (State Gazette No.106/14.12.2007)	<b>4905</b>
Article 42	Regulation No.27/15.06.2007 on the requirements to the data and documentation for marketing authorisation and registration of medicinal products (State Gazette No. 54/03.07.2007)	<b>3975</b>
Article 47(5)	Rules of procedure for the terms and conditions of the activities of the specialized committees: 1. Committee for Medicinal Products; 2. Committee for Immunological Medicinal Products; 3. Committee for Homeopathic Medicinal Products; 4. Committee for Herbal Medicinal Products; 5. Committee for Radiopharmaceuticals; 6. Committee for Medicinal Products for Paediatric Applications; 7. Committee for Advanced Therapy Medicinal Products.	
Article 47(6)	Lists of experts apart from the committee members	
Article 69(5)	Regulation No. 35/22.08.2007 on the terms, conditions and requirements to the documentation for granting a Batch Release Certificate for a medicinal product by the Bulgarian Drug Agency (State Gazette No. 71/31.08.2007)	<b>1254</b>
Article 82(3)	Regulation No. 31/12.08.2007 on establishing guidelines for Good Clinical Practice (State Gazette No. 67/17.08.2007)	<b>20345</b>

Reference in the Drug Act	Name and date of issue	Number of words
Article 107(7)	Rules of procedure for the terms and conditions for work of the Central Ethics Committee to the Council of Ministers pursuant to the Law for Medicinal Products in Human Use (State Gazette No. 81/09.10.2007)	1186
Article 152	Regulation No. 15/17.04/2009 on granting a manufacturing/import authorisation and the principles and requirements of Good Manufacturing Practice for all type medicinal products, medicinal products intended for clinical trials and for active substances (State Gazette No. 38/22.05.2009)	70634
Article 170	Regulation No.38/13.09.2007 on the requirements to the data on the packaging and leaflets of medicinal products (State Gazette No. 77/25.09.2007)	4433
Article 178	Regulation No.3/04.03.2008 on the criteria on classification of medicinal products and the requirements to the documentation for amendment in the classification (State Gazette No. 28/14.03.2008)	2004
Article 179 (1)	List of the medicinal products which are subject to medical prescription in the territory of the Republic of Bulgaria	
Article 191(2)	Regulation No. 2/05.02.2008 on the requirements to the collection, confirmation and provision of information of adverse drug reactions and to the content and format of urgent reports for notification of adverse drug reactions and periodic safety reports (State Gazette No. 24/04.03.2008)	6336
Article 198	Regulation No. 39/13.09.2007 on the principles and requirements of Good Distribution Practice (State Gazette No. 77/25.09.2007)	2870
Article 207(1), point 6	Regulation on the conditions and procedures for the supply of medicinal products to physicians and doctors of dental medicine if no pharmacy is available in a given location / Regulation on storage and sales of medicinal products by physicians and doctors of dental medicine when no pharmacy is available in a given location	
Article 219(2)	Regulation No 28/23.12.2008 on the structure, the procedures and the organization of activities in the pharmacies and the lists of medicinal products (State Gazette No. 109/23.12.2008)	8267
Article 219(2)	List of the medicinal products which can be sold in pharmacies (Regulation No 28; State Gazette No.109/23.12.2008)	582
Article 219(2)	List of the cosmetics which can be sold in pharmacies (Regulation No 28; State Gazette No.109/23.12.2008)	203
Article 221	Regulation No 4/20.03.2009 on the conditions and procedures for dispensing and prescribing medicinal products (State Gazette Nos. 21/20.03.2009 and 91/17.11.2009)	6987
Article 232(1)	List for storage of medicinal products by physicians and doctors of dental medicine	
Article 234(1)	List of medicinal products which can be sold through automatic public dispensers (Regulation No 28; State Gazette No.109/23.12.2008)	212
Article 243	Regulation No 29/23.12.2008 on the conditions and procedures for the organization of activities in a health store [дрогерия] (State Gazette No. 109/23.12.2008)	1156
Article 249	Regulations on the requirements to advertising of medicinal products	
Article 251 (3)	Rules of procedure for the terms and conditions of the Expert Committee on Advertising	
Article 259(6)	Regulation on the terms and conditions for work of the Drug Prices Committee (State Gazette No. 100/30.11.2007)	940
Article 260(1)	Regulation on the conditions, rules and procedures for regulating and registration of the prices of medicinal products (State Gazette No. 104/11.12.2007)	4996
Article 262(4)	Regulation No 10/24.03.2009 on the conditions and procedures for reimbursement of the medicinal products referred to in point 1, Article 262 (4) of the Drug Act, medical devices and diet foods for special medical purposes (State Gazette Nos. 10/24.03.2009, 34/08.05.2009, 38/22.05.2009, 40/29.05.2009 and 9/2.02.2010)	3303

Reference in the Drug Act	Name and date of issue	Number of words
Article 264	Regulation on the conditions, procedures and criteria for inclusion, amendments and/or exclusion of medicinal products from the Positive Drug List and the terms and conditions for the work of the Committee on the Positive Drug List (State Gazette No. 110/21.12.2007; Nos 19/13.03.2009 and 41/2.06.2009)	4286
Article 265(4)	Rules of procedure for the terms and conditions for work of the Transparency Committee pursuant to the Drug Act (State Gazette No. 108/19.12.2007)	1162
Article 273(1)	Regulation № 36 / 22.08.2007 for the terms and conditions for taking samples of medicinal products for state control, conduction of the trials and their payment (State Gazette No. 71/31.08.2007)	2174
Article 274(1)	Regulation № 9 / 23.04.2008 on the conditions and procedures for suspension and withdrawal of medicinal products for which there is evidence of non-conformity with the requirements of quality, safety and efficacy (State Gazette No. 45/13.05.2008)	2674
Article 274(2)	Regulation on the conditions and procedures for removal, rework or use of medicinal products for other purposes	
Article 297	Regulation on imposing an order for expropriation of medicinal products to the benefit of the state	
<b>TOTAL VOLUME</b>		<b>208446</b>