Draft

ACT
AMENDING AND SUPPLEMENTING THE MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

(Promulgated in the State Gazette [SG]) No 31 of 2007; amend. and suppl., No 19 of 2008; Decision No 5 of the Constitutional Court of the Republic of Bulgaria of 2008 – No 65 of 2008; amend. and suppl., No 71 of 2008, Nos 10, 23, 41, 88 and 102 of 2009, Nos 59 and 98 of 2010, Nos 9, 12, 60, and 61 of 2011, Nos 38, 60 and 102 of 2012, No 15 of 2013, Nos 1 and 18 of 2014; Decision No 1 of the Constitutional Court of the Republic of Bulgaria of 2015 – No 12 of 2015; amend. and suppl., No 48 of 2015, No 43 of 2016, Nos 85 and 103 of 2017, Nos 84, 91 and 102 of 2018, Nos 17 and 64 of 2019, Nos 17, 52, 67, 103 and 105 of 2022, No 62 of 2022, Nos 84 and 88 of 2023, Nos 16 and 39 of 2024)

§ 1. In Article 17(5)(12a), the words ‘at the request of the holder of an authorisation for wholesale distribution’ shall be added at the end.

§ 2. In Article 23, subparagraph (2a) shall be inserted:

‘(2a) except in the cases referred to in subparagraph (1), a medicinal product may be placed on the market after obtaining a parallel import authorisation under this Act or a parallel distribution notification submitted to the European Medicines Agency.’

§ 3. Article 54 shall be amended and supplemented as follows:

1. Everywhere after the words ‘the certificate of registration’ it shall be added ‘/the authorisation of parallel import’.

2. In subparagraph (2), the word ‘two’ shall be replaced by ‘three’.

3. In subparagraph (4), a second sentence shall be inserted:

‘The notification shall indicate the specific unforeseeable circumstances to which the suspension is due.’

§ 4. In Article 55, subparagraph (6a) shall be inserted:

‘(6a) The restriction under subparagraph (6) on the period of one year shall not apply to medicinal products in respect of which an application has been made under Article 59a.’

§ 5. Article 68(1) shall be amended and supplemented as follows:

1.In point (10):

(a) the text preceding letter (a) shall be amended as follows:

‘(10) on a daily basis, up to 11.59 a.m., shall provide to the BDA through the specialised electronic system under Article 217b(1), information about:’;

(b) in letter (a), the words ‘included in the Positive list of medicines’ shall be replaced by ‘subject to prescription, indicating the code and serial number of the product within the meaning of Article 4(b)(i) and (ii) of Commission Delegated Regulation (EU) 2016/161 for each supplied packaging’;

(c) in letter (d), the words ‘included in the Positive list of medicines’ shall be replaced by ‘subject to prescription, indicating the code and serial number of the product within the meaning of Article 4(b)(i) and (ii) of Commission Delegated Regulation (EU) 2016/161 for each supplied packaging of which is a marketing authorisation holder’;

(d) letters (e) and (f) shall be inserted:

‘(e) the notifications referred to in Article 54(1), (2) and (4) of medicinal products subject to medical prescription;

(f) the quantities indicated per medicinal product subject to medical prescription for which delivery has been refused, the application number referred to in Article 217b(10) sent by the holder of the authorisation for wholesale distribution of medicinal products.'.

2. Point (11) shall be amended as follows:

'(11) shall provide to the BDA for all medicinal products authorised for use in the country, including in case of change of circumstances, through the specialised electronic system under Article 217b(1), information on the product code and serial number within the meaning of Article 4(b)(i) and (ii) of Commission Delegated Regulation (EU) 2016/161 for medicinal products defined therein, from the moment the medicinal product is published in the Positive list of medicines, respectively in the register of price limits of medicinal products sold with medical prescription or from the occurrence of the change of circumstances.'

3. Point (12) shall be inserted:

'(12) shall submit to the BDA via the specialised electronic system under Article 217b(1) by 1 March of the current year information on the quantities of medicinal products, subject to prescription, which it has planned to supply.'

§ 6. Article 150 shall be amended and supplemented as follows:

1. In subparagraph (2):

a) point (1) shall be amended as follows:

'(1) the full name and personal identification number (PIN) or foreigner personal number (FPN) of the persons under Article 148(2) and Article 149 for the inspection, ex officio, by the BDA of the presence of employment contracts concluded with them; documents for practical experience and work experience for the persons under Article 148(2) and Article 149, if they are not ascertained by a concluded employment contract;

(b) Points (1a) and (1b) shall be inserted:

'(1a) the number of the diploma or the electronic number of the higher education diploma (EED) of the persons referred to in Article 148(2) and Article 149, where it was issued after 1 January 2012; a notarized copy of the higher education diploma in the Republic of Bulgaria, where it was issued by 1 January 2012; the number of the certificate of recognition of higher education qualifications entered in the register of academic recognition kept by the National Centre for Information and Documentation, where the diploma has not been issued by a higher education institution in the Republic of Bulgaria or a notarized copy of that certificate, where it is not entered in that register;

(1b) a notarized copy of a document attesting to a recognised speciality for the persons referred to in Article 149;'

(c) points 6 and 7 shall be repealed.

2. Subparagraph (6) shall be inserted:

'(6) the Bulgarian Drug Agency shall, ex officio, establish the facts relating to the existence of:

1. an environmental impact assessment on the basis of data on its number, date and issuer, which shall be indicated in the application referred to in subparagraph 1;

2. authorisation by the Nuclear Regulatory Agency – in the event of a request for the manufacture of radiopharmaceuticals or medicinal products subjected to ionising radiation during their manufacture, on the basis of the number and date of the authorisation, which shall be indicated in the application referred to in subparagraph 1.'

§ 7. Article 156a shall be amended and supplemented as follows:

1.Subparagraph (1) shall be amended as follows:

'(1) In the event of a change referred to in Article 156(1)(1) and (2), the applicant shall provide:

1. the PIN or FPN of the persons under Article 148(2) and Article 149 for the inspection, ex officio, by the BDA of the presence of employment contracts concluded with them; documents for practical experience and work experience for the persons under

Article 148(2) and Article 149, if they are not ascertained by a concluded employment contract;

2. the number of the diploma or the electronic number of the higher education diploma (EED) of the persons referred to in Article 148(2) and Article 149, where it was issued after 1 January 2012; a notarized copy of the higher education diploma in the Republic of Bulgaria, where it was issued by 1 January 2012; the number of the certificate of recognition of higher education qualifications entered in the register of academic recognition kept by the National Centre for Information and Documentation, where the diploma has not been issued by a higher education institution in the Republic of Bulgaria or a notarized copy of that certificate, where it is not entered in that register;'

3. a notarized copy of a document attesting to a recognised speciality for the persons referred to in Article 149.'

2. In subparagraph (3), point (2), the words 'details of the number, date and issuer of' shall be added at the beginning.

3. A comma shall be put at the end of subparagraph (4) and the words 'and shall, ex officio, determine the existence of an environmental impact assessment' shall be added.

§ 8. Article 162(2) shall be amended and supplemented as follows:

1. Point (4) shall be amended as follows:

'(4) the full name and the PIN or FPN of the person under Article 161(2)(1) for the inspection, ex officio, by the BDA, the full name, of the presence of employment contract concluded with him/her; documents for practical experience and work experience for the person under Article 161(2)(1), if they are not ascertained by a concluded employment contract;

2. Point (4a) shall be inserted:

'(4a) the number of the diploma or the electronic number of the higher education diploma (EED) of the persons referred to in Article 161(2)(1), where it was issued after 1 January 2012; a notarized copy of the higher education diploma in the Republic of Bulgaria, where it was issued by 1 January 2012; the number of the certificate of recognition of higher education qualifications entered in the register of academic recognition kept by the National Centre for Information and Documentation, where the diploma has not been issued by a higher education institution in the Republic of Bulgaria or a notarized copy of that certificate, where it is not entered in that register;'

§ 9. In Article 165a, subparagraph (1) shall be amended as follows:

'(1) In the event of a change referred to in Article 165(1)(1), the applicant shall submit:

1. the full name and the PIN or FPN of the person under Article 161(2)(1) for the inspection, ex officio, by the BDA, the full name, of the presence of employment contract concluded with him/her; documents for practical experience and work experience for the person under Article 161(2)(1), if they are not ascertained by a concluded employment contract;

2. the number of the diploma or the electronic number of the higher education diploma (EED) of the persons referred to in Article 161(2)(1), where it was issued after 1 January 2012; a notarized copy of the higher education diploma in the Republic of Bulgaria, where it was issued by 1 January 2012; the number of the certificate of recognition of higher education qualifications entered in the register of academic recognition kept by the National Centre for Information and Documentation, where the diploma has not been issued by a higher education institution in the Republic of Bulgaria or a notarized copy of that certificate, where it is not entered in that register;'

§ 10. In Article 167(1), in the text before point 1, the words ‘point 2’ shall be replaced by ‘point 1’.

§ 11. In Article 195a, after the word ‘pharmacy’, the words ‘or drugstore’ shall be added.

§ 12. Article 199(1) shall be amended and supplemented as follows:

1. Point (3) shall be amended as follows:

‘(3) the full name and PIN or FPN of the responsible Master of Pharmacy under Article 197(2) for performing an inspection, ex officio, by the BDA of the presence of employment contract concluded with him/her; documents for work experience of the responsible Master of Pharmacy under Article 197(2), if it is not ascertained by a concluded employment contract;’

2. New points (4) и (5) shall be inserted:

‘(4) the number of the diploma or the electronic number of the higher education diploma (EED) of the persons referred to in Article 197(2), where it was issued after 1 January 2012; a notarized copy of the higher education diploma in the Republic of Bulgaria, where it was issued by 1 January 2012; the number of the certificate of recognition of higher education qualifications entered in the register of academic recognition kept by the National Centre for Information and Documentation, where the diploma has not been issued by a higher education institution in the Republic of Bulgaria or a notarized copy of that certificate, where it is not entered in that register; criminal record certificate or similar document of the responsible Master Pharmacist under Article 197(2), if he/she is not a Bulgarian citizen;’.

3.Point (6) shall be amended as follows:

‘(6) a declaration that the person is entitled to use the premises where individualised data is recorded for the Document of Use, depending on its type, and, if the Document is subject to registration, an act, volume and year and the Registry Office where it is entered shall be indicated;’

§ 13. Article 207(1) shall be amended and supplemented as follows:

1. In point (8), a comma is inserted after the words ‘active substance’ and the words ‘and packaging’ are replaced by ‘packaging, batch number, serial number referred to in Article 4(b)(ii) of Commission Delegated Regulation (EU) 2016/161 and national identification number of the medicinal product referred to in Article 259(1)(12)’.

2. In point (15):

(a) the text preceding letter (a) shall be amended as follows:

‘(15) on a daily basis, up to 11.59 a.m., shall provide to the BDA through the system under Article 217b(1), information about:’;

(b) in letter (a), the words ‘included in the Positive list of medicines’ shall be replaced by ‘subject to prescription, indicating the code and serial number of the product within the meaning of Article 4(b)(i) and (ii) of Commission Delegated Regulation (EU) 2016/161 for each supplied packaging’;

(c) in letter (c), the words ‘included in the Positive list of medicines’ shall be replaced by ‘subject to prescription, indicating the code and serial number of the product within the meaning of Article 4(b)(i) and (ii) of Commission Delegated Regulation (EU) 2016/161’;

(d) letter (d) shall be repealed;

(e) letter (e) shall be amended as follows:

‘(e) the quantities indicated per medicinal product subject to medical prescription exported, including exports within the meaning of Article 217a(3), the country in which the export took place and the product code and serial number within the meaning of Article 4(b) (i) and (ii) of Commission Delegated Regulation (EU) 2016/161 for each packaging exported;’;

(f) letter (f) shall be inserted:

‘(f) the quantities indicated per medicinal product subject to medical prescription for which delivery has been refused and the application number referred to in Article 217b(10) sent by the holder of the authorisation for retail distribution of medicinal products.’

§ 14. Article 215 shall be amended and supplemented as follows:

1. Subparagraph (1) shall be amended as follows:

‘(1) In order to receive an authorisation for parallel import on the territory of the Republic of Bulgaria the person under Article 213 submits an application to the executive director of the BDA stating the Member State/Member States, from which they will make the parallel import of the medicinal product.’

2. In subparagraph (2), point (4), the words ‘the Member State from which’ shall be replaced by ‘the Member State/the Member States from which’.

3. A new subparagraph (6) shall be inserted:

‘(6) All the Member States from which the medicinal product is imported into the territory of the Republic of Bulgaria shall be entered in the parallel import authorisation.’

4. The current subparagraph (6) shall become subparagraph (7).

§ 15. Article 216 shall be amended as follows:

‘Article 216 (1) The authorisation for parallel import on the territory of the Republic of Bulgaria is issued within 45 days of the date of submission of the documents to the BDA.

(2) When the BDA requests additional information from the applicant, the term under subparagraph (1) ceases until the said information is received.

(3) When the BDA requests that the regulatory body of the MS, from which comes the parallel import, submits information related to the issuing of the authorisation for use of the imported medicinal product, the term under subparagraph (1) is extended with 45 days.

(4) If, within the term under subparagraph 3, the BDA does not receive the requested documents, the procedure for issuing an authorisation for parallel import on the of the Republic of Bulgaria is terminated.

(5) The issued authorisations for parallel import on the territory of the republic of Bulgaria are published on BDA’s web page.

(6) The authorisation for parallel import has a five-year validity. After the expiry of this period, the authorisation may be renewed in accordance with the procedure laid down in Article 215. Following its renewal, the authorisation becomes indefinite.

(7) If there is a change in the circumstances related to the issued parallel import authorisation, its holder submits an application to the BDA under Article 215 with attached documents related to the change.

(8) The parallel import authorisation shall be terminated or modified accordingly upon the termination of the authorisation for use of the medicinal product in a Member State from which parallel import takes place.

(9) The holder of the parallel import authorisation shall notify the BDA within one month if the authorisation for use of the medicinal product in the Member State from which the parallel imports takes place has been suspended.

(10) The parallel import authorisation is not terminated automatically when the holder of the authorisation for use of the medicinal product, placed on the market on the territory of the Republic of Bulgaria, terminates it or does not renew it, for reasons other than those under Article 276 or Article 277.’

§ 16. Article 216a shall be amended and supplemented as follows:

1. In subparagraph (1), after the words ‘in the event of an exceptional epidemic situation due to the epidemic spread of a communicable disease under Article 61(1) of the Health Act’, a comma shall be inserted and it shall be added ‘as well as in the event of an identified shortage of a specific medicinal product under Article 217c(1)’.

2. In subparagraph (3), the words ‘the Member State from which’ shall be replaced by ‘the Member State/the Member States from which’.

5. Subparagraphs (6), (7) and (8) shall be repealed.

§ 17. Article 216b shall be inserted:

‘Article 216b. (1) the person referred to in Article 213 shall notify the Executive Director of the BDA in writing within 14 days of the cessation of his/her activity.

(2) The Executive Director of the BDA shall, by order, suspend, revoke, modify or terminate the parallel import authorisation:

1. at the request of the person referred to in Article 213 who has obtained a parallel import authorisation;

2. where it is found that the parallel import authorisation does not comply with the conditions under which it has been granted;

3. upon receipt of the notification referred to in subparagraph 1;

4. in the event of any of the circumstances referred to in Article 276(1), (2), (3) and (8).

(3) Upon expiration of the period of validity of the parallel import authorisation or upon its termination, the medicinal product may be sold until the available quantities in the country are exhausted, but not more than one year from the date of expiration or termination, except in the cases where the reasons for termination are related to the safety of the medicinal product.

(4) The order referred to in subparagraph (2) shall be subject to appeal in accordance with the procedures of the Administrative Procedure Code.’

§ 18. Article 217 shall be amended and supplemented as follows:

1. In point 5:

(a) the text preceding letter (a) shall be amended as follows:

‘(5) on a daily basis, up to 11.59 a.m., shall provide to the BDA through the specialised electronic system under Article 217b(1), information about:’;

(b) letter (a) shall be amended as follows:

‘(a) the quantities of medicinal products, subject to prescription, imported in parallel into the territory of the Republic of Bulgaria, of which it is the holder of the parallel import authorisation, indicating the product code and serial number within the meaning of Article 4(b)(i) and (ii) of Commission Delegated Regulation (EU) 2016/161 for each package;’;

(c) in letter (b), the words ‘included in the Positive List of Medicines’ shall be replaced by ‘subject to prescription, for which it is the holder of the parallel import authorisation, indicating the product code and serial number within the meaning of Article 4(b)(i) and (ii) of Commission Delegated Regulation (EU) 2016/161 for each supply’;

(d) letter (e) shall be amended as follows:

‘(e) the quantities available in storage facilities indicated by medicinal products, subject to prescription, of which it is the holder of the parallel import authorisation, indicating the product code and serial number within the meaning of Article 4(b)(i) and (ii) of Commission Delegated Regulation (EU) 2016/161 for each package;’;

2. Point (6) shall be amended as follows:

‘(6) shall provide to the BDA for all medicinal products authorised for parallel import in the country, including in case of change of circumstances, through the specialised electronic system under Article 217b(1), information on the product code and serial number within the meaning of Article 4(b)(i) and (ii) of Commission Delegated Regulation (EU) 2016/161 for medicinal products defined therein, from the moment the medicinal product is published in the Positive list of medicines, respectively in the register of price limits of medicinal products sold with medical prescription or from the occurrence of the change of circumstances.’

3. Point (8) shall be inserted:

‘(8) submit to the BDA via the specialised electronic system under Article 217b(1) the notifications under Article 54(1), (2) and (4) of the medicinal products, subject to prescription.’

§ 19. In Article 217a(4), the words ‘included in the Positive list of medicines’ shall be replaced by ‘subject to prescription’.

§ 20. Article 217b shall be amended and supplemented as follows:

1.In subparagraph 1, the words ‘included in the Positive list of medicines’ shall be replaced by ‘subject to prescription’.

2. In subparagraph (3):

(a) In point 1, the words ‘Article 68(1)(10) and (11)’ shall be replaced by ‘Article 68(1)(10) to (12)’ and the words ‘Article 217(5) and (6) shall be replaced by ‘Article 217, points (5), (6) and (8)’.

(b)The following points (4) and (5) shall be inserted:

‘(4) information on registered requests to marketing authorisation holders and holders of authorisation for wholesale distribution of medicinal products, or to holders of a parallel import authorisation, in the cases referred to in subparagraph (10).

5. information on registered refusals to supply medicinal products, subject to prescription, on requests made by holders of an authorization for wholesale distribution for medicinal products and holders of an authorisation for retail distribution for medicinal products to holders of an authorisation for wholesale distribution of medicinal products, or to holders of a parallel import authorisation, respectively.’

3.In subparagraph 4, the words ‘included in the Positive list of medicines’ shall be replaced by ‘subject to prescription’.

4. In subparagraph 5, the words ‘included in the Positive list of medicines’ shall be replaced by ‘subject to prescription’, the number ‘65’ shall be replaced by ‘100’ and the number ‘6’ shall be replaced by ‘12’.

5. Subparagraphs (9) and (10) shall be inserted:

‘(9) The specialised electronic system under subparagraph 1 provides a possibility for holders of authorisation for retail distribution of medicinal products to obtain information on stocks in the warehouses of holders of authorisations for wholesale distribution of medicinal products of medicinal products, subject to prescription.

(10) Where a prescribed medicinal product, subject to prescription, is not available in the pharmacy, upon verification in the system under subparagraph 1 and via it, the Master of Pharmacy shall send an application to the relevant holder of authorisation for wholesale distribution of medicinal products, who has the medicinal product and is obliged to make the delivery within 24 hours from the date of receipt of the application.’

6. The former subparagraphs (9) and (10) shall become subparagraphs (11) and (12), respectively.

§ 21. Article 217c shall be amended and supplemented as follows:

1. In Article 217c, the words ‘included in the Positive list of medicines’ shall be replaced by ‘subject to prescription’.

2. In subparagraph (2), a second sentence shall be inserted:

‘The list under subparagraph 1 also includes medicinal products, subject to prescription, notified under Article 54(2) and a notification under Article 54(4), as well as medicinal products included in the list of specific shortages published on the website of the European Medicines Agency, subject to prescription.’

3. The following subparagraph (4a) shall be inserted:

‘(4a) Medicinal products under subparagraph (2), second sentence shall be excluded from the list under subparagraph 1 after 3 months from the expiry of the term of the temporary cessation.’

§ 22. Article 217f:

'Article 217f. (1) Apart from the cases referred to in Article 217a(4), by way of exception and for reasons related to the protection of the health of the public, the export of medicinal products from the territory of the Republic of Bulgaria may be temporarily prohibited by order of the Minister for Health.

(2) The order referred to in subparagraph 1 shall be issued on the basis of an analysis by the Ministry of Health which shows that there are insufficient quantities of medicinal products available to meet the needs of the population. The analysis shall be based on data from the National Health Information System referred to in Article 28d(1) of the Health Act and/or the Bulgarian Drug Agency and/or Regional Health Inspectorates and/or other agencies.'

§ 23. Article 219 shall be amended and supplemented as follows:

1. In subparagraph 1, the words 'health promotion in accordance with Article 1(8) of the additional provision of the Health Act' shall be inserted after the words 'providing consultation,'.

2. Subparagraphs (5) and (6) shall be inserted:

'(5) The person authorised for the retail sale of medicinal products, including the medical institution under Article 222(4), is obliged to:

1. supply with medicinal products only by wholesalers who have received an authorisation/certificate for registration for wholesale trade in medicinal products under the procedure of this Act;

2. provide medicinal products only to the population, except in the cases under Article 222(5) and Article 237.

(6) Medicinal products subject to medical prescription shall be available only on presentation of a prescription, except in the cases under Article 222(4) and (5).'

§ 24. Article 227f shall be amended as follows:

'Article 227f. (1) The National Pharmaceutical Card shall be approved by a decision of the Council of Ministers on a proposal from the Minister for Health.

The data in the National Pharmaceutical Card shall be maintained (2) and updated with an information system that ensures connectivity with the necessary registers and databases defined in the methodology referred to in Article 227b(5).

(3) The requirements for the construction, conditions and procedure for the maintenance, renewal and connectivity of the information system referred to in subparagraph 2 shall be laid down in the regulation referred to in Article 28d(6) of the Health Act.

(4) When updating the National Pharmacy Card, Article 227b(2), (3), (4) and (6) shall not apply.'

§ 25. Article 232 shall be amended as follows:

'Article 232. (1) The doctors and dentists of a medical institution for outpatient care under Article 8(1)(1)(a) or under point 2(a) of the Medical Institutions Act may store medicinal products according to a list defined by the Minister for Health.

(2) When a populated area does not have a pharmacy, the persons mentioned in subparagraph (1) may store and sell medicinal products only if they have an authorisation to do so. The conditions and procedures for the supply, storage and sale of medicinal products shall be laid down by regulation of the Minister for Health.

(3) The storage and sale of medicinal products in the cases referred to in subparagraph (2) shall be carried out after a licence for the storage and sale of medicinal products issued by the director of the relevant Regional Health Inspectorate, for which the persons referred to in subparagraph (1) shall submit an application form to the director of the relevant Regional Health Inspectorate, indicating:

1.the number of the certificate of registration referred to in Article 40 of the Medical Institutions Act issued by the Executive Agency Medical Supervision;

2. address of the medical institution for outpatient care referred to in Article 8(1)(1)(a) or point (2)(a) of the Medical Institutions Act.

(4) The application referred to in subparagraph 3 shall be accompanied by:

1. the number of the diploma or the electronic number of the higher education diploma (EED) of the relevant doctors/doctors of dental medicine, where it was issued after 1 January 2012; a notarized copy of the higher education diploma in the Republic of Bulgaria, where it was issued by 1 January 2012; the number of the certificate of recognition of higher education qualifications entered in the register of academic recognition kept by the National Centre for Information and Documentation, where the diploma has not been issued by a higher education institution in the Republic of Bulgaria or a notarized copy of that certificate, where it is not entered in that register;'

2. a power of attorney, where the application is submitted by an authorised person.

(5) The Regional Health Inspectorate shall, ex officio, establish the circumstances relating to the presence of:

1. the number of the certificate of registration referred to in Article 40 of the Medical Institutions Act issued by the Executive Agency Medical Supervision;

2. address of the medical institution for outpatient care referred to in Article 8(1)(1)(a) or point (2)(a) of the Medical Institutions Act.

(6) Within 7 days of receipt of the application, a committee appointed by the Director of the Regional Health Inspectorate shall carry out a check of the storage conditions in accordance with the regulation referred to in subparagraph (2). When it finds that the requirements of the order under subparagraph (2) are not followed, the Regional Health Inspectorate gives instructions and defines a term for corrections within seven days of the inspection.

(7) Within 3 days of the completion of the inspection referred to in subparagraph 6, the Director of the Regional Health Inspectorate shall issue a licence for the storage and sale of medicinal products on the basis of a model or make a reasoned refusal.

(8) The refusal referred to in subparagraph (7) shall be subject to appeal in accordance with the procedures of the Administrative Procedure Code.

(9) The Director of the relevant Regional Health Inspectorate shall, by order, terminate the authorisation referred to in subparagraph (7):

1. in the event of failure to comply with the storage conditions and the conditions for the sale of medicinal products;

2. when a pharmacy is opened in the territory of the same settlement;

3. at the request of the person referred to in subparagraph (1);

4. if the medical establishment is deleted in accordance with Article 45 of the Medical Institutions Act.

(10) The order referred to in subparagraph (9) can be appealed in accordance with the Administrative Procedural Code. The appeal does not lead to a suspension of the implementation.

(11) The Regional Health Inspectorate shall keep a register of authorisations issued for the storage and sale of medicinal products by the persons referred to in subparagraph (1), containing:

the number and date of the authorization issued;

2. the number of the certificate of registration referred to in Article 40 of the Medical Institutions Act issued by the Executive Agency Medical Supervision;

3. the address of the medical institution for outpatient care;

4. date of terminating the authorisation and the reasons to do so;

5. observations on the recorded circumstances.

(12) The register referred to in subparagraph (11) shall be published on the website of the relevant Regional Health Inspectorate.

(13) In the event of a change in the circumstances entered in the register, the persons referred to in subparagraph (1) shall be obliged to notify the Regional Health Inspectorate within 7 days.

(14) Upon termination of the authorisation under subparagraph (9), the medicinal products may be sold to persons holding an authorisation for wholesale distribution of medicinal products.'

§ 26. Article 232a shall be amended as follows:

1. The text before point (1) shall be amended as follows:

'Holders of the authorisation for retail distribution of medicinal products and the persons referred to in Article 207(1)(5a)(b) 'a' on a daily basis, up to 11.59 a.m., shall provide to the BDA through the specialised electronic system under Article 217b(1), information about:'

2. In point (1), the words 'included in the Positive list of medicines' shall be replaced by 'subject to prescription'.

3. In point (2), the words 'included in the Positive list of medicines' shall be replaced by 'subject to prescription, indicating the code and serial number of the product within the meaning of Article 4(b)(i) and (ii) of Commission Delegated Regulation (EU) 2016/161 for each prescribed/sold packaging.'.

4. In point (3), the words 'included in the Positive list of medicines' shall be replaced by 'subject to prescription'.

5. Point (4) shall be inserted:

'(4) the requests for the supply of medicinal products, subject to prescription, to the holder of an authorisation for wholesale distribution of medicinal products, with the quantities specified therein.'

§ 27. Article 238a shall be inserted:

'Article 238a. A person who has obtained an authorisation for retail distribution of medicinal products in a drugstore may not be the holder of an authorisation for wholesale distribution of medicinal products granted in accordance with this Act.'

§ 28. In Article 239(4), a comma shall be inserted at the end and the words 'which may not be less than 10 working days' shall be added.

§ 29. Article 240(4) shall be repealed.

§ 30. In Article 258, subparagraph (6) shall be inserted:

'(6) The powers of the President in his/her absence or when he or she takes statutory leave shall, on a case-by-case basis, be exercised by a member designated by a decision of the Council referred to in subparagraph (3).'

§ 31. In Article 259a(3), the words 'National Health Insurance Fund (NHIF), Ministry of Health and BDA' shall be replaced by 'National Health Insurance Fund (NHIF) and Ministry of Health'.

§ 32. In Article 262^{1}(2), third sentence shall be inserted:

'The type of medicinal products from parallel import shall be determined in accordance with that of the identical or similar medicinal product in accordance with Article 214.'

§ 33. Article 270(1) shall be supplemented as follows:

1. In point (1), at the end, it shall be added '(written or electronic)'.

2. Point (1a) shall be inserted:

‘(1a) access to the automated information systems, products and records of inspected persons when the inspection is carried out on the spot.’

3. New subparagraph (5) shall be inserted:

‘(5) When carrying out their control functions, the officials – inspectors and experts, as determined by orders of the director of the BDA, the chairperson of the National Council on Prices and Reimbursement of Medicinal Products or the director of the respective Regional Health Inspectorate, have the right to access the information under Article 217b(3)(4) and (5) and Article 217b(10), subject to a duty to maintain the confidentiality of the data.’

§ 34. In Article 272(2), a second sentence shall be inserted:

In the case of a coercive administrative measure under subparagraph 1(1) or (3), establishments and facilities shall be sealed by affixing permanently fixed certifying signs prohibiting access to them.’

§ 35. In Article 284(3), after the words ‘by order’ it shall be added ‘under Article 272(2)’.

§ 36. In Article 284d, subparagraph (3) shall be inserted:

‘(3) A person who fails to fulfil his/her obligations under Article 68(1)(10), letter (e) and Article 68(1)(12), respectively under Article 217(8) shall be punished by a fine of 10 000 to 20 000 BGN, or, if the same infringement is repeated, by a fine of 20 000 to 50 000 BGN.’

§ 37. Article 284h shall be amended as follows:

‘Article 284h. Failure to comply with the obligation to protect the secrecy of non-public data in the specialised electronic system referred to in Article 217b(1) shall be punishable by a fine of BGN 5 000 to BGN 10 000 on the officials concerned and, if the same infringement is repeated, a fine of BGN 10 000 to BGN 20 000.’

§ 38. Article 284k shall be inserted:

‘Article 284k. A wholesaler of medicinal products who fails to fulfil its obligation under Article 217b(10) shall be liable to a financial penalty of BGN 5 000 to BGN 10 000 or, if the same infringement is repeated, to a financial penalty of BGN 10 000 to BGN 15 000.’

§ 39. Article 285c shall be repealed.

§ 40. Article 287 shall be amended and supplemented as follows:

1. Paragraph 1a is inserted:

‘(1a) AA retailer who supplies medicinal products, with the exception of the medicinal products under subparagraph 2, to a wholesaler or to other persons in violation of the requirements of this Act or its implementing regulations, shall be punishable by a fine, respectively, a pecuniary penalty of 5 000 to 10 000 BGN, and in the event of a repeated infringement, from 15 000 to 20 000 BGN.’

2. In subparagraph 5, the words ‘subparagraphs 1, 2’ shall be replaced by ‘subparagraphs 1, 1a, 2’, and after the words ‘by order’ it shall be added ‘under Article 272(2)’.

Transitional and final provisions

§ 41. Within three months of the entry into force of this Act, the Minister for Health brings the ordinance under Article 217b(9) into compliance with the requirements of this Act.

§ 42. Within 6 months of the entry into force of the amendments under Article 41, the specialised electronic system under Article 217b(1) and the systems of the holders of authorisations for use of medicinal products, holders of authorisations for parallel import, holders of authorisations for wholesale distribution of medicinal products, holders of authorisations for retail distribution of medicinal products, medical institutions under Article 222(4)(1) and (2), the centres and hospices under Article 222(4)(3) and (4) and the medical institutions under Article 222(6) shall be brought in compliance with the requirements of this Act and the ordinance under Article 217b(9).

§ 43. In the **Act on the professional organisation of Masters of Pharmacists** (prom. SG No 75 of 2006; amend. and suppl., SG No 105 of 2006, No 31 of 2007, Nos 13 and 71 of 2008, No 41 of 2009, Nos 98 and 101 of 2010, Nos 102 of 2018, No 64 of 2019 and No 85 of 2020) the following additions shall be made:

1. In Article 28(3)(2), the words ‘and written reports’ shall be added after the word ‘complaints’.

2. In Article 41(2), the words ‘and written reports’ shall be added after the word ‘complaints’.