



CERTIFIED TRANSLATION FROM POLISH

[The translation pertains to an Act amending the Act on counteracting drug addiction and the Act on State Sanitary Inspection printed in the Journal of Laws No. 213 [Dziennik Ustaw]. A hard copy of the Act consisting of three pages is attached to this translation.]

[At the top of every page there is a heading with subsequent page numbers from page 15103 to 15105 worded as follows:]

Journal of Laws No. 213

15103

Item 1396

1396

ACT

of 8 October 2010

**amending the Act on counteracting drug addiction
and the Act on State Sanitary Inspection**

Article 1. The Act of 29 July 2005 on counteracting drug addiction (Journal of Laws No. 179, item 1485 as further amended¹) shall be amended as follows:

1) in Article 4:

a) point 27 shall be worded as follows:

“27) substitute drug - a substance of natural or synthetic origin in any physical state or a product, plant, mushroom or any part thereof containing such a substance, used instead of a narcotic drug or a psychotropic substance or for the same purposes as a narcotic drug or a psychotropic substance, whose manufacture and placing on the market is not governed by separate regulations; substitute drugs are not governed by regulations on the general safety of products;”;

b) points 34 and 35 shall be worded as follows:

“34) placing on the market - supply of narcotic drugs, psychotropic substances, precursors or substitute drugs to third parties, whether free of charge or in return for payment;

35) manufacture - activities aimed at generating narcotic drugs, psychotropic substances, precursors or substitute drugs, refining thereof, extraction of resources and intermediate products and obtaining salts thereof;”;

¹ Amendments to this Act have been published in Dz. U. of 2006 No. 66, item 469 and No. 120, item 826, of 2007 No. 7, item 48 and No. 82, item 558, of 2009 No. 18, item 97, No. 63, item 520, No. 92, item 753 and No. 98, item 817 and of 2010 No. 28, item 146 and No. 143, item 962.



2) in Article 9.7.5, the full stop shall be replaced by a comma and point 6 shall be added, reading:

“6) collecting and analysis of information on new trends in the use of narcotic drugs, psychotropic substances and substitute drugs.”;

3) in Article 13.2.4.h, the semicolon shall be replaced by a comma and letter i shall be added, reading:

“i) competent for the matter of economy.”;

4) Article 15.1 shall be worded as follows:

“1) monitoring and coordinating state policy actions related to narcotic drugs, psychotropic substances, precursors and substitute drugs.”;

5) in Article 20, section 3 shall be added, reading:

“3. It shall be prohibited to advertise and promote foods or other products through suggesting that they:

- 1) have effects of psychotropic substances or narcotic drugs or
- 2) their consumption, even misuse, may cause effects similar to the use of psychotropic substances or narcotic drugs.”;

6) Articles 23 and 24 shall be worded as follows:

“Article 23.1. Ministers competent for the matters of health, higher education, public finances, internal affairs, transport, labour and science and the Minister of Justice provide conditions for conducting scientific research into drug addiction as well as statistical and epidemiological research.

2. Scientific centres conducting research into drug addiction, in so far as it is necessary to conduct such research, may possess, store and purchase narcotic drugs, psychotropic substances, their preparations, category 1 precursors and substitute drugs.

3. Scientific centres, referred to in Section 2, shall:

- 1) purchase narcotic drugs, psychotropic substances or their preparations and category 1 precursors from a pharmaceutical wholesaler as per demand;
- 2) keep records of possessed narcotic drugs, psychotropic substances or their preparations, category 1 precursors and substitute drugs;
- 3) store possessed narcotic drugs, psychotropic substances, preparations thereof as well as category 1 precursors and substitute drugs in such a way to prevent them from being stolen or destroyed.

4. Minister competent for health matters in agreement with Ministers competent for internal affairs, science, public finances and higher education



shall adopt, by way of a regulation, a code of conduct to be followed by the scientific centres referred to in section 2 of this Article in handling narcotic drugs, psychotropic substances, their preparations, category 1 precursors and substitute drugs, including the necessity of preventing access of third parties thereto.

Article 24.1. Ministers competent for the matters of health, education, internal affairs, public administration, public finances, transport, labour as well as the Minister of National Defence and the Minister of Justice shall ensure that a sufficient number of staff is prepared to perform tasks referred to in Article 2.1.

2. Organizational units of government administration, organizational units of Prison Service, Military Police and higher education schools which provide training for individuals referred to in section 1 may possess, store or purchase narcotic drugs, psychotropic substances their preparations, category 1 precursors and substitute drugs in quantities necessary for providing such training.

3. Organizational units of government administration and Military Police performing operational and reconnaissance activities may come into possession of narcotic drugs, psychotropic substances, their preparations, category 1 precursors and substitute drugs in quantities necessary for conducting research to ascertain that an offence has been committed or the ban referred to in Article 44b has been violated.

4. Organizational units or other entities conducting research with the application of narcotic drugs, psychotropic substances, their preparations, category 1 precursors and substitute drugs, in order to identify or ascertain that an offence has been committed or the ban referred to in Article 44b has been violated, may possess, store or purchase the aforementioned substances in quantities necessary for conducting such research.

5. Units and entities referred to in sections 2-4 shall:

- 1) purchase narcotic drugs, psychotropic substances or their preparations and category 1 precursors from a pharmaceutical wholesaler as per demand;
- 2) keep records of possessed narcotic drugs, psychotropic substances, their preparations, category 1 precursors and substitute drugs;
- 3) store and use for training purposes possessed narcotic drugs, psychotropic substances, their preparations, category 1 precursors and substitute drugs in such a way to prevent them from being stolen or destroyed;
- 4) destroy narcotic drugs, psychotropic substances, their preparations, category 1 precursors and substitute drugs in such a way to prevent unauthorised individuals from access thereto.



6. Minister competent for health matters in agreement with Ministers competent for internal affairs, public finances, higher education and the Minister of Justice shall adopt, by way of a regulation, specific terms and conditions of purchasing and coming into possession, storing and using for training purposes narcotic drugs, psychotropic substances, their preparations thereof, category 1 precursors and substitute drugs by units or entities referred to in sections 2-4 as well as conditions of storing narcotic drugs, psychotropic substances, their preparations, category 1 precursors and substitute drugs, destruction methods thereof by units or entities referred to in sections 2-4, including securing these substances against access of third parties thereto.”;

7) title of Chapter 5 shall be worded as follows:

“Precursors, narcotic drugs, psychotropic substances and substitute drugs”;

8) following Article 44a, Articles 44b and 44c shall be added, reading:

“Article 44b. It shall be prohibited to manufacture and place on the market substitute drugs on the territory of the Republic of Poland.

Art. 44c. 1. In the event of ascertaining manufacture or placing on the market of a substitute drug or a product suspected to be a substitute drug, the appropriate state sanitary inspector applies accordingly provisions of Article 27c of the Act of 14 March 1985 on State Sanitary Inspection (Journal of Laws of 2006 No. 122, item 851, as further amended²).

2. State Sanitary Inspector informs the public of issuing a decision referred to in Article 27c.1 of the Act referred to in section 1.”;

9) Following Chapter 6, Chapter 6a shall be added, reading:

“Chapter 6a
Financial penalty

Art. 52a. 1. Whoever manufactures or places on the market a substitute drug on the territory of the Republic of Poland shall be subject to a financial penalty between PLN 20,000 and PLN 1,000,000.

2. The financial penalty referred to in section 1 shall be imposed, by way of a decision, by the appropriate state sanitary inspector. The decision is enforceable immediately.

3. When imposing the financial penalty, referred to in section 1, the appropriate state sanitary inspector shall consider in particular the quantity of the substitute drug which has been manufactured or placed on the market.

² Amendments to the consolidated text of this Act have been published in Dz. U. of 2006 No. 104, item 708, No. 143, item 1032, No. 170, item 1217, No. 171, item 1225 and No. 220, item 1600, of 2007 No. 176, item 1238, of 2008 No. 227, item 1505 and No. 234, item 1570, of 2009 No. 18, item 97, No. 20, item 106, No. 92, item 753 and No. 157, item 1241 and of 2010 No. 21, item 105, No. 81, item 529, No. 130, item 871, No. 182, item 1228 and No. 213, item 1396.



4. Within the scope not regulated by the provisions of the Act, the financial penalty, referred to in section 1, shall be subject to provisions of Chapter III of the Act of 29 August 1997 - General Tax Regulations (Journal of Laws of 2005 r. No. 8, item 60, as further amended³); however, the body referred to in section 2 shall enjoy tax office rights.

5. The financial penalty referred to in section 1 shall constitute state budget income.”;

10) Article 68 shall be worded as follows:

“Article 68. Whoever engages in advertising or promotion contrary to the ban referred to in Article 20. 1 or 3 shall be subject to a financial penalty, limitation of liberty or deprivation of liberty of up to a year.”.

Art. 2. In the Act of 14 March 1985 on State Sanitary Inspection (Journal of Laws of 2006 No. 122, item 851, as further amended⁴), after Article 27b, Article 27c shall be added, reading:

”Art. 27c. 1. In the event of a reasonable suspicion that the product poses a threat to human health or life, the appropriate state sanitary inspector shall, by way of a decision, order withdrawal of the product from the market for the period necessary to conduct an assessment and research into its safety, however, not longer than 18 months.

2. Provisions of section 1 shall not be applied to products whose manufacture and placing on the market is governed by separate regulations, excluding the regulations on the general safety of products.

3. In the event of issuing the decision referred to in section 1, the appropriate state sanitary inspector shall:

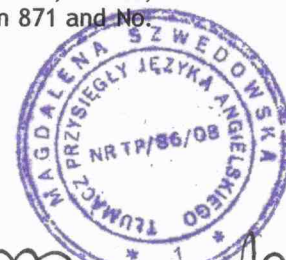
1) impound the product;

2) order to discontinue operations on the premises where the product is manufactured or placed on the market for the period necessary to remove the threat, not longer than 3 months

4. Costs necessary to conduct the assessment and research referred to in section 1 shall be borne by the party to the proceedings.

³ Amendments to the consolidated text of this Act have been published in Dz. U. of 2005 No. 85, item 727, No. 86, item 732 and No. 143, item 1199, of 2006, No. 66, item 470, No. 104, item 708, No. 143, item 1031, No. 217, item 1590 and No. 225, item 1635, of 2007 No. 112, item 769, No. 120, item 818, No. 192, item 1378 and No. 225, item 1671, of 2008 No. 118, item 745, No. 141, item 888, No. 180, item 1109 and No. 209, items 1316, 1318 and 1320, of 2009 No. 18, item 97, No. 44, item 362, No. 57, item 466, No. 131, item 1075, No. 157, item 1241, No. 166, item 1317, No. 168, item 1323, No. 213, item 1652 and No. 216, item 1676 and of 2010 No. 40, item 230, No. 57, item 355, No. 127, item 858, No. 167, item 1131, No. 182, item 1228 and No. 197, item 1306.

⁴ Amendments to the consolidated text of this Act have been published in Dz. U. of 2006 No. 104, item 708, No. 143, item 1032, No. 170, item 1217, No. 171, item 1225 and No. 220, item 1600, of 2007 No. 176, item 1238, of 2008 No. 227, item 1505 and No. 234, item 1570, of 2009 No. 18, item 97, No. 20, item 106, No. 92, item 753 and No. 157, item 1241 and of 2010 No. 21, item 105, No. 81, item 529, No. 130, item 871 and No. 182, item 1228.



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5. In the event of ascertaining that the product does not pose a threat to human health or life, the costs borne pursuant to section 4 are reimbursed to the party to the proceedings.

6. In the event of ascertaining that the product poses a threat to human health or life, the appropriate state sanitary inspector shall prohibit, by way of a decision, manufacture or placing on the market of the product and shall order to withdraw the product from the market and its destruction at the cost of the party to the proceedings.

7. The collection of receivables, referred to in section 4, shall be performed pursuant to debt collection laws in public administration.”.

Art. 3. The existing implementing regulations issued pursuant to Article 23.4 and Article 24.6 of the Act referred to in Article 1 shall remain in full force and effect until new implementing regulations are adopted pursuant to Article 23.4 and Article 24.6 of the Act referred to in Article 1, as has been worded herein; however, not longer than for the period of 12 months since the date of entering this Act into force.

Article 4. The Act shall enter into force 14 days after its promulgation.

President of the republic of Poland: B. Komorowski

I, the undersigned, Magdalena Szwedowska, Sworn Translator of English and Polish, listed at number TP/86/08 in the Register of Sworn Translators kept by the Ministry of Justice of the Republic of Poland, affix my signature and seal to certify this to be a true and accurate translation of the attached copy of the document in Polish presented to me.

Register no. 18/2011

Warsaw, 28 March 2011



Magdalena Szwedowska