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Full name and/or number of the statute (in original language):

Ustawa o cenach z 5 lipca 2001 r.

Translation of the name:

The Act on prices of 5 July 2001

Reference in Official Journal (if appropriate):

Dziennik Ustaw 2001 no. 97/105

Date of coming into force:

11.12.2001

Subsequent amendments:

Text:

The Act on Prices

of 5 July 2001

Article 1

1. This Act specifies:
   1) principles and procedure of setting prices for goods and services,
   2) methods of providing information on the quality features and prices of goods and services offered;
   3) consequences of failure to comply with the provisions hereof.
2. This Act shall not apply to:
   1) prices in trade between natural persons none of which is a business entity,
   2) prices determined pursuant to separate acts to the extent regulated therein.

Article 2

1. Prices for goods and services shall be agreed by parties to an agreement, save as provided in Section 2.
2. Limitations on free determination of prices may be introduces only on the basis of Articles 4, 5 and 8.

Article 3

1. Whenever used in this Act the terms listed below shall have the following meanings:
   1) price – the value expressed in monetary units, which the buyer is obliged to pay to the business entity for goods or services; the price shall include VAT and excise duty if, under separate provisions, sales of the goods (services) are subject to such taxation,
   2) unitary price of goods (services) – the price determined for a unit of specified goods (services), the amount or number of which is expressed in units of measure within the meaning of the provisions on measures,
   3) quality features of goods (services) – the features, ingredients, technical parameters of goods (services) and their compliance with a specified norm or another normative document within the meaning of separate provisions,
   4) setting of prices – agreeing on prices between parties to an agreement or their determination pursuant to Articles 4, 5 and 8,
   5) in-patient medical services – medical care establishments referred to in Article 2 Section 1 Sub-section 1 of the Act on Medical Care Establishments of 30 August 1991,
   6) trade margin – the difference between the price paid by the buyer and the price paid earlier by the business entity, resulting form the costs and profit of the business entity; the trade margin may be expressed in amounts or in percentage,
   7) official price and official trade margin – the trade price and margin determined in a regulation issued by a competent administrative authority or in a resolution issued by the legislative body of a competent territorial self-government authority,
   8) business entity – entity conducting business activity within the meaning of the Act on Economic Activity of 19 November 1999, as well as persons conducting agricultural production activity, including agricultural cultivation, animal breeding, horticulture, market gardening, forestry and inland fishery,
   9) goods – things, including energy and transferable proprietary rights,
   10) services – actions performed for remuneration listed in the classifications issued on the basis of the provisions on public statistics.
2. Wherever referred to in this Act:
   1) the price shall also mean tariff rate,
   2) the trade margin shall also mean commission,
   3) inspection authority shall mean a body of the Trade Inspection, the Inspection of Agricultural Produce Purchasing and Processing, the Pharmaceutical Inspection, the Sanitary Inspection and the Veterinary Inspection.

Article 4

1. In the event of special threats to the proper functioning of the State economy the Council of Ministers may specify in a regulation an inventory of goods and services for which official prices and official trade margins shall be determined, save as provided in Articles 5 and 8.
2. In the inventory referred to in Section 1, the Council of Ministers shall include goods and services of major importance in the consumers' costs of maintenance and shall specify the time period in which the official prices and official trade margins shall be applied.
3. The Minister of Finance determines in a regulation the official prices and official trade margins for the goods and services listed in the inventory referred to in Section 1, tak-

ing into account the balance of interests of consumers and business entities engaged in the production of, and trading in such goods and provisions of such services.

Article 5

1. Official wholesale and retail prices shall be determined for pharmaceuticals and medical materials included, pursuant to the provisions on public health insurance, in the inventory of basic and supplementary medicaments and the inventory of medicaments and medical materials prescribed free of charge, for flat fee or partial charge in connection with contagious and mental diseases, mental retardation and certain chronic, congenital and contracted diseases.
2. The official wholesale and retail prices shall also be determined for other pharmaceuticals and medical materials included by the inventory referred to in Section 3.
3. The Minister of Health and Social Welfare, after consultation with territorial health care authorities (*kasy chorych*), may specify in a regulation the inventory of pharmaceuticals and medical materials not included by the inventories referred to in Section 1 if they are used only in in-patient services and are fully subsidised by the State, taking into account:
   1) material share of a particular pharmaceutical or medical material in the expenditures of in-patient services establishments on pharmacology, diagnostic or care of the sick,
   2) big significant in the therapy conducted.
4. The Minister of Heath and Social Welfare in consultation with the Minister of Finance shall determine in a regulation the official wholesale and retain prices for the pharmaceuticals and medical materials included in the inventories referred to in Sections 1 and 3, taking into account the balance of interests of consumers and business entities engaged in the production of, and trading in such pharmaceuticals and medical materials as well as the financial standing of the social insurance system pursuant to the criteria set out in Article 7 Section 3.

Article 6

1. Business entities engaged in the production of, and trading in the pharmaceuticals and medical materials included in the inventories referred to in Article 5 Sections 1 and 3:
   1) shall submit information necessary for determination of official prices at the request of the Minister of Health and Social Welfare,
   2) may file requests for determination of official prices with the Minister of Health and Social Welfare.
2. The Minister of Health and Social Welfare in consultation with the Minister of Finance shall specify in a regulation:
   1) the scope of information and requests referred to in Section 1, which shall include in particular:
      a) business name of the business entity, its seat and address,
      b) name of the pharmaceutical or medical material,
      c) requested price together with reasons,
      d) costs of production,
      e) the volume of supplies executed prior to the submission of the information or the filing of the request and the volume of supplies planned thereafter,
      f) daily costs of the therapy and average costs of a standard therapy,
      g) structure and volume of sales on the territory of Poland,
   2) the manner of, and the time limits for the submission of information as well as the procedure and time limits for the consideration of requests and information, providing that

the maximum time limit for the consideration of a request or information may not exceed 90 days counted from the date of their submission, however where the data necessary to determine the official price must be supplemented, such time limit shall be counted from the date of receipt of supplemented data and where the procedure of determination of the official price is conducted simultaneously with the consideration of request for inclusion of a particular pharmaceutical in the inventories referred to in Article 5 Section 1, the overall time limit may not exceed 180 days counted from the date of receipt of complete information. In the case of requests for reduction of the official price the procedure of determination of the price may not exceed 30 days.

Article 7

1. In the Ministry of Health and Social Welfare a Committee for Management of Medicaments, hereinafter referred to as the "Committee", shall be formed.
2. The Committee shall consist of three representatives of the Minister of Health and Social Welfare, the Minister of Finance and the Minister of Economy, each. The Committee may be joined by three representatives of territorial health care authorities appointed according to the procedure specified in Section 8 Sub-section 4. Member of the Committee as well as their spouses, descendants and ascendants in a first line may not be owners of, hold shares or interest in, or be member of the governing bodies of companies and business entities engaged in the production of, and trading in pharmaceuticals and medical materials.
3. The Committee's duties shall include the preparation and presentation to the Minister of Heath and Social Welfare of opinions with respect to the determination of inventories and official prices of pharmaceuticals and medical materials, taking into account the following criteria:
   1) price levels in the countries with similar national income per capita,
   2) price competition,
   3) impact of the medicament on the direct costs of treatment,
   4) the volume of supplies executed prior to the submission of information or the filing of a request and the volume of supplies planned thereafter,
   5) costs of production,
   6) proven effectiveness of the medicament,
   7) significance of the medicament in the prevention of diseases posing serious epidemic and civilization threats,
   8) the wholesale margin calculated by a wholesaler on the official wholesale price shall amount to 9.91%, however if the interest rates determined by the Monetary Policy Council decrease by more than 30% in comparison to their amount as on the effective date hereof, such margin should be decreased by at least 10%,
   9) the retail margin applied by pharmacies shall be as follows:

Wholesale price in PLN	Retail margin deducted from wholesale price
0-3.60	40%
3.61-4.80	PLN 1.44
4.81-6.50	30%
6.51-9.75	PLN 1.95
9.76-14.00	20%
14.01-15.55	PLN 2,80
15.56-30.00	18%
30.01-33.75	PLN 5.40
33.76-50.00	16%

50.01-66.67	PLN 8.00
66.68-100.00	12%
Exceeding 100.00	PLN 12.00

however, if the average retail margin applied by pharmacies in the trade in the pharmaceuticals and medical materials referred to in Article 5 Section 1 decreases by more than 3 percentage points, the above amounts may be increase to the level ensuring the application of the average margin as on the effective date hereof.

4. The Minister of Heath and Social Welfare in consultation with the Minister of Finance shall announce the wholesale and retail margin adopted to determine the official wholesale and retail prices for the pharmaceutical and medical materials referred to in Article 5 Sections 1 and 2, in accordance with the provisions of Section 3 Sub-sections 8 and 9.
5. The Committee shall prepare in a resolution the opinions referred to in Section 3 on the basis of the information and requests referred to in Article 6 Section 1 and the request filed pursuant to the provisions on public health insurance for the inclusion of a particular pharmaceutical and medical material in the inventories referred to in Article 5 Section 1.
6. The Committee shall inform the business entity of the reasons for rejection of its request for the inclusion in the inventories referred to in Article 5 Section 1 or the requested official price. The business entity may apply within 14 days following the receipt of the above opinion for reconsideration of the request or information:
   1) with respect to the determination of inventories – to the Minister of Health and Social Welfare,
   2) with respect to the determination of official price – to the Minister of Health and Social Welfare acting in consultation with the Minister of Finance.
7. The procedure referred to in Section 6 shall not be regulated by the provisions of the Code of Administrative Procedure.
8. The Minister of Health and Social Welfare shall specify in a regulation:
   1) the rules of the Committee specifying its organisation, manner and procedure of operation, as well as the manner of appointing the Committee Chairman,
   2) the instructions regarding organisational and technical services to the Committee,
   3) the principles of financing the Committee's operation,
   4) the procedure of appointing the representatives of territorial health care authorities.

Article 8

1. The community council (*rada gminy*) may determine official prices for transport services by public transport and by taxis within the community. In the Capital City of Warsaw, those rights shall be vested with the Council of Warsaw.
2. The *powiat* council may determine official prices for transport services by public transport within the *powiat*.
3. The community council shall specify the price zones (tariff rates) applicable for taxi transport of persons and goods.

Article 9

Official prices and official trade margins shall be maximum prices and trade margins unless a competent public administrative authority determines otherwise in the provisions issued pursuant hereto.

Article 10

1. Subject to special provisions, while determining the contractual price and applying the official price, the business entity shall be obliged to specify in writing, in the form accessible to the buyer, detailed quality features of the goods (services) and indicate their country of origin if the goods have been brought to the Polish customs territory.
2. The Council of Ministers, after consultation with a relevant association of producers and an organisation established to protect interest of consumers, shall specify in a regulation the inventory of goods (services) to which the obligation to specify detailed quality features of goods or services or indicate their country of origin shall not apply where the discharge of such obligation would constitute excessive encumbrance for the business entity due to the special conditions of sales or the features of goods.

Article 11

1. The business entity which is a producer shall be obliged to reduce the price if the goods do not comply with the required quality features referred to in Article 10 Section 1 or are defective by reason of decreased amount, mass or volume or damage unless, despite of the due diligence exercised in compliance with the standards for such kind of sales, the business entity could not be aware of the defect. The same obligation shall apply to the seller of goods.
2. The price should be reduced in proportion to the defects and damages referred to in Section 1.
3. The business entity shall be obliged to demonstrate the reasons for the price reduction or inform the consumer of such reasons in the manner customary in the place of offering the goods, also if it not the same as the place of sales.
4. The inspection authority, having discovered in an inspection the defects or damages referred to in Section 1 and the absence of appropriate price reduction, shall determine their kind and degree in a decision, which may be appealed against pursuant to the provisions of the Code of Administrative Procedure.
5. In the event the decision referred to in Section 4 become final:
   1) the inspection authority shall immediately to the competent local tax office for the commencement of proceedings and issuance of the decision referred to in Article 13 Section 4.
   2) the business entity applying the excessive price shall bear the costs of investigation conducted in the course of proceedings referred to in Section 4 and in Article 13 Section 4.

Article 12

1. The goods to be sold in the retail shall be marked with a price.
2. Subject to the provisions of Section 3, in retail outlets and service outlets unitary prices of goods and services shall be displayed in the manner providing simple and doubt-free information about their amount, and in the case of official prices – also their kind (official price) and the reasons for price reductions.
3. The Minister of Finance in consultation with the Minister of Economy and after consultation with the President of the Office for Protection of Competition and Consumers shall specify in a regulation detailed instructions for the display of goods and services and the manner of marking the goods to be sold with a price, including the cases where within a specified time period no marking of the price or display of unitary prices is required, taking into account the need to ensure accessibility of the information about the price and, in particular, the cases where the marking of the price or display of unitary

prices is impeded by the features of the goods, the kind of outlet or the scope of activity conducted by the business entity.

Article 13

1. The business entity which failed to reduce the price in the cases referred to in Article 11 or by applying the prices or trade margins, breached the provisions hereof and in this way obtained an undue amount, shall be oblige to return such an amount to the buyer.
2. Should either a competent inspection authority authorised under separate provisions to inspect the features of goods or an inspection authority authorised under separate provisions to inspect the application of prices and trade margins discover in the course of inspection that the undue amount referred to in Section 1 has not been returned to the buyer, the business entity shall be obliged, subject to the provisions of Section 3, irrespective of the obligation towards the buyer, to pay to the State budget an additional amount equal to 150% of the undue amount. The obligation to pay the additional amount to the State budget shall apply also to the business entity where such business entity returned the undue amount in the course of inspection.
3. The undue amount shall not be handed over to the State budget if the person entitled to such an amount is unknown. If the business entity pays the undue amount prior to the commencement of inspection by a competent authority, the provisions of the additional amount shall not apply.
4. The decision regarding determination of the undue amount and the additional amount, both subject to a transfer to the State budget, shall be issued by a tax office having jurisdiction over the business entity's seat or address of residence at the request of the inspection authority, which has discovered the facts referred to in Sections 1 and 2.
5. A tax inspector, who in the course of inspection has discovered the irregularities referred to in Sections 1 and 2, shall issue a decision specifying the undue amount referred to in Section 3 and determining the additional amount referred to in Section 2, both subject to a transfer to the State budget. Where the buyer is known, the tax inspector shall issue with respect to the irregularities discovered the findings of the inspection and deliver them to the competent tax office.
6. The decision specifying the undue amount and determining the additional amount may not be issued if a period of five years has expired by the end of the year in which the incorrect price or trade margin was collected.
7. The proceedings on prices referred to in Sections 4-6 shall be accordingly regulated by the provisions of Chapters III and IV of the Tax Regulation Act of 29 August 1997.
8. Payments with respect to the undue and additional amounts referred to in Section 5 shall constitute income of the State budget and shall be made to the account of the tax office having jurisdiction over the seat or address of residence of the business entity obliged to make them.

Article 14

1. If the business entity persistently fails to perform the obligations referred to in Article 12, the voivodship inspector of the Trade Inspection shall impose on such a business entity in a decision a pecuniary penalty constituting the equivalent of an amount ranging from EURO 1,000 to EURO 5,000.
2. The decision referred to in Section 1 may be appealed against to the General Inspector of the Trade Inspection.

Article 15

The following amendments shall be introduced to the Act of Public Health Insurance of 6 February 1997:

1) in Article 37:
   a) in Section 5, in the introductory sentence the words: "The Minister of Health and Social Welfare, after consultation with the Supreme Medical Board and the Supreme Pharmaceutical Board (*Naczelna Rada Lekarska, Naczelna Rada Aptekarska*)" shall be replaced with the words: "The Minister of Health and Social Welfare, after consultation with territorial health care authorities, the Supreme Medical Board and the Supreme Pharmaceutical Board",
   b) Section 6 shall take on the following wording:
      "6. The regulation referred to in Section 5 shall be issued by the Minister of Heath and Social Welfare, considering in particular the need to ensure public health care, accessibility of medicaments and safety of their application, as well as the financial standing of the social insurance system.";
2) in Article 38, Section 8 shall take on the following wording:
   "8. The Minister of Health and Social Welfare, after consultation with territorial health care authorities, shall determine in a regulation the limits for prices for the medical materials referred to in Article 39 Section 1.";
3) in Article 39, Sections 1 and 2 shall take on the following wording:
   "1. The persons who suffer from contagious or mental diseases or are mentally retarded or suffer from certain chronic, congenital or contracted diseases, may be prescribed medicaments and medical materials free of charge, for flat fee or partial charge.
   2. The Minister of Health and Social Welfare, after consultation with territorial health care authorities, the Supreme Medical Board and the Supreme Pharmaceutical Board, shall specify in a regulation;
      1) the inventory of diseases referred to in Section 1,
      2) the inventory of medicaments and medical materials, due to the diseases specified in the inventory referred to in Sub-section 1, may be prescribed free of charge, for flat fee or partial charge, considering in particular the need to ensure public health care, accessibility of medicaments and safety of their application, as well as the financial standing of the social insurance system.";
4) after Article 39, Articles 39a and 39b shall be added with the following wording:
   "Article 39a. 1. The producer or importer of medicaments and medical materials, hereinafter referred to as the "applicant" may file with the Minister of Health and Social Welfare requests for their inclusion in the inventories referred to in Article 37 Section 5 Sub-section 1 and Article 39 Section 2 Sub-section2.
   2. The requests referred to in Section 1 shall include in particular:
      1) the applicant's business name, seat and address,
      2) name and requested price of the medicament or medical material,
      3) volume of supplies executed prior to the filing of the request and planned thereafter,
      4) daily costs of the therapy and average costs of a standard therapy,
      5) reasons for the request and the requested price.
   3. The requests referred to in Section 1 shall be considered by the Committee for Management of Medicaments, acting pursuant to Ar-

ticle 7 of the Act on Prices of 5 July 2001, hereinafter referred to as the "Committee".

4. In the case a request is rejected, the Committee shall notify the applicant thereof, indicating the reasons for such a decision. The applicant may, within 14 days following the receipt of such a decision, apply to the Minister of Health and Social Welfare for reconsideration of the request.
5. The proceedings referred to in Section 4 shall be carried out pursuant to the provisions of the Code of Administrative Procedure.

Article 39b. The Minister of Health and Social Welfare shall specify in a regulation:

1) a detailed scope of information contained in the requests referred to in Article 39a Section 1,
2) the manner of submission and the procedure and time limits for the consideration of requests referred to in Article 39a Section 1, providing in particular that the maximum time limit for the consideration of a request may not exceed 90 days counted from the date of its submission, however where the data necessary to include a particular pharmaceutical and medical material in the appropriate inventory must be supplemented, such time limit shall be counted from the date of receipt of supplemented data and where the procedure of inclusion of the pharmaceutical and medical material in the inventories referred to in Article 37 Section 5 Sub-section 1 and Article 39 Section 2 Sub-section 2 is conducted simultaneously with the consideration of information or request for determination of the official price, the overall time limit may not exceed 180 days counted from the date of receipt of complete information.

Article 16

The proceedings commenced and not terminated to the effective date hereof shall be regulated by the provisions hitherto existing.

Article 17

Until the executory provisions specified herein are issued, however in no event longer than for one year following the effective date hereof, the executory provisions issued on the basis of the following acts shall remain in force:

1) the act referred to in Article 19,
2) the hitherto existing provisions of Article 37 Section 5 and Article 39 Section 2 of the act referred to in Article 15.

executory acts

Article 18

1. In order to prepare for the first time the opinion regarding determination of official prices and trade margins for imported pharmaceuticals and medical materials included in the inventories referred to in Article 37 Section 5 Sub-section 1 and Article 39 Section 2 of the act referred to in Article 15, with the wording existing prior to the effective date hereof, the Committee may apply to the business entities engaged in the trade in such pharmaceuticals and medical materials for the information necessary to prepare such opinions.
2. The information referred to in Section 1 shall be submitted in the scope and withing the time limit indicated by the Committee.

Article 19
The Act on Prices of 26 February 1982 shall cease to be in force.

Article 20
This Act shall come into force after a lapse of 3 moths following the announcement date, save for Article 7 and Article 18, which shall come into force after a lapse of 30 days following the announcement date.