Constitutional judgment 3-4-1-55-14

JUDGMENT
in the name of the Republic of Estonia

Case number	3-4-1-55-14
Date	18 May 2015
Formation	Chairman: Priit Pikamäe; members: Indrek Koolmeister, Saale Laos, Jüri Põld and Tambet Tampuu
Case	Review of the constitutionality of subsection 1 of § 2, subsection 1 of § 3 of and the Annex to Regulation No. 36 of the Government of the Republic of 21 February 2005 “Threshold values for mark-up in wholesale and retail trade of medicinal products and procedure for implementation thereof”
Basis for proceedings	Request no. 16 by the Chancellor of Justice of 27 November 2014
Hearing	Written procedure

OPERATIVE PART

To dismiss request no. 16 by the Chancellor of Justice of 27 November 2014.

FACTS AND COURSE OF PROCEDURE

1. On 16 December 2004, the Riigikogu adopted the Medicinal Products Act (MPA) that entered into force on 1 March 2005. In subsection 1 of § 15 of the MPA, the legislature authorised the Government of the Republic to establish threshold values for mark-up in wholesale and retail trade of medicinal products and the procedure for the implementation thereof. Subsections 2 and 3 of § 15 of the MPA clarified the conditions of the authorisation. Clauses 4 and 5 of subsection 3 of § 15 of the MPA provide for the mandatory ranges of the weighted average mark-up.

2. On 1 March 2005, Regulation No. 36 of the Government of the Republic of 21 February 2005 "Threshold values for mark-up in wholesale and retail trade of medicinal products and procedure for implementation thereof" entered into force. In 2010, the Government of the Republic amended its Regulation No. 36 of 21 February 2005, recalculating the threshold values of the mark-up from Estonian kroons to euros.

3. In September 2014, the Estonian Pharmacies Union submitted to the Chancellor of Justice an application for examining the constitutionality of Regulation No. 36 of the Government of the Republic of 21 February 2005.

4. The Chancellor of Justice found that subsection 1 of § 2 and subsection 1 of § 3 of and the Annex to Regulation No. 36 of the Government of the Republic of 21 February 2005 are unconstitutional, because they do not comply with the ranges of the weighted average mark-up established in clauses 3 and 4 of subsection 3 of § 15 of the MPA.

5. On 20 October 2014, the Chancellor of Justice submitted to the Government of the Republic Proposal No. 29 to bring the contested provisions into compliance with the Constitution. The Government of the Republic did not formulate an opinion on the proposal received from the Chancellor of Justice.

6. On 27 November 2014, the Chancellor of Justice submitted to the Supreme Court Request No. 16 to declare the contested provisions unconstitutional and repeal them.

7. The Constitutional Review Chamber of the Supreme Court asked for the opinions of the parties to the proceedings regarding the constitutionality of subsection 1 of § 2 and subsection 1 of § 3 of and the Annex to Regulation No. 36 of the Government of the Republic of 21 February 2005 as well as subsections 1 to 3 of § 15 of the MPA.

REQUEST BY CHANCELLOR OF JUSTICE

8. The contested provisions that establish the threshold values of the mark-up for the wholesale and retail trade of medicinal products infringe the freedom of enterprise of undertakings operating in the field of the trade in medicinal products, which is secured by § 31 of the Constitution. If the medicinal product pricing of retail and wholesale undertakings was free and undertakings could apply the mark-up at their own discretion, the market would regulate the mark-up in a state of competition.

9. Under subsection 1 of § 3 of the Constitution, the governmental authority is exercised solely pursuant to the Constitution and laws that are in conformity therewith. Under clause 6 of § 87 of the Constitution, the Government of the Republic has the right to issue regulations as administrative instruments for general application solely based on law. These provisions of the Constitution set out the parliamentary reservation that places decisions important from the point of view of fundamental rights within the competence of the legislature. If the principle of the legal basis has been violated upon restricting a fundamental right, including if an infringement of a freedom arises from a regulation of the executive, which is in conflict with the law, it follows that the fundamental right has been restricted in conflict with the Constitution.

10. The legislature has decided to regulate pricing in the field of trade in medicinal products, authorising the Government of the Republic to that end under § 15 and, on the conditions set out in the section, to limit the wholesale and retail trade mark-up of medicinal products. Discretionary powers must be exercised in accordance with the limits of the authorisation, the purpose of the discretionary powers and the general principles of law, taking into account important circumstances and weighing justified interests. The legislature has limited the discretionary powers of the executive. Subsections 2 and 3 of § 15 of the MPA clarify the principles that must be taken into account upon establishing threshold values of the wholesale and retail mark-up of medicinal products.

11. Under subsection 2 of § 15 of the MPA, the Government of the Republic must take into account four circumstances upon establishing the threshold values of the mark-up of medicinal products: 1) the accessibility of the medicinal products to the end user arising from geographical reasons; 2) the accessibility of the medicinal products to the end user arising from financial reasons, 3) the risks involved in distributing the medicinal products, and 4) the weighted average mark-up of medicinal products in wholesale and retail trade. Thus, the regulatory authority must balance the interests of the undertaking and the consumer upon making a discretionary decision. While the undertaking is interested in as high a profit as possible in a situation where the mark-up is unlimited, the consumer is interested in limiting the mark-up applied by undertakings as much as possible, without the availability of medicinal products suffering as a result thereof. Thereby the regulatory authority cannot simply act based on the interests of the end consumer, but must also ensure that engaging in retail and wholesale trade in medicinal products does not become unprofitable, given the risks relating to marketing medicinal products. Thus, indirectly, ensuring justified profitability or a sufficient mark-up should serve the interests of the end consumer because if the regulation of prices did not ensure sufficient profitability for undertakings in a particular field and as a result thereof engaging in business in the field was not economically profitable, the respective goods or services would become unavailable due to the absence of supply to the consumer. Thus, in principle, providing undertakings with a reasonable mark-up helps to ensure that medicinal products are available to the end consumer.

12. While clauses 1 and 2 of subsection 3 of § 15 of the MPA contain unambiguous rules the adherence to which can be inspected directly, clauses 4 and 5 of subsection 3 of § 15 of the MPA set aims with regard to

the attainment of which one can express an opinion only by assessing the turnover of various price groups of medicinal products retroactively. The Government of the Republic has the discretionary powers only within these ranges and it must, by weighing the opposing aims specified in subsection 2 of § 15 of the MPA, decide how high threshold values of the mark-up to allow in the wholesale and retail trade in medicinal products. When doing that, the regulator must, in accordance with subsection 3 of § 15 of the MPA, also take into account that the mark-up of medicinal products of different price groups would create equal interest in handling all medicinal products in wholesale and retail trade.

13. The contested regulation uses the regressive mark-up model, i.e. the higher the price of the package of a medicinal product, the smaller the permitted mark-up percentage. With this mark-up model, the regulator has tried to level the income earned from the handling of medicinal products and thereby make the wholesalers and retailers of medicinal products equally interested in marketing less expensive and more expensive medicinal products. The threshold values provided for in the regulation are based on the average weighted mark-up, but the mark-up applied to specific undertakings may differ from the average. For instance, if an undertaking is only engaged in the wholesale of expensive packages of medicinal products (with a purchase price of over 12.78 euros), the permitted mark-up is merely 3%. At the same time, upon wholesale of merely inexpensive packages of medicinal products (with a purchase price of up to 1.65 euros), the permitted mark-up is 20%, and that of packages of medicinal products with a purchase price of 0.65 to 1.28 euros is up to 40%.

14. Regardless of the choices of an individual undertaking (e.g. the decision to handle more medicinal products of the more expensive group) and overall developments in the market of medicinal products (structural rise in the prices of medicinal products, placing more complex and expensive medicinal products on the market), the provision delegating authority demands that the threshold values established by the regulation ensure a weighted average wholesale mark-up of 7-10% and a weighted average retail mark-up of 21-25% in the market of medicinal products. Therefore, the threshold values in force cannot be justified by arguing that an undertaking could have focused merely on the sale of medicinal products that belong to the range where the mark-up is higher. If undertakings really acted in such a manner, they would have to avoid selling medicinal products belonging to the more expensive price ranges, as a result of which more complex and expensive medicinal products would become unavailable to the end user. Creating such motivation in wholesalers and retailers of medicinal products would conflict with the provision delegating authority, i.e. clause 3 of subsection 3 of § 15 of the MPA. Assessing the compliance of the contested provisions with the provision delegating authority, there is no need to identify how the average weighted mark-up relates to the mark-up of an individual undertaking and what the undertaking's opportunities are to influence the formation of the mark-up by its choices.

15. From the provisions of the MPA, one can derive the obligation of the Government of the Republic to monitor whether the established threshold values of the mark-up are within the prescribed limits. The Government is required to amend the regulation if the actual average mark-up remains below the threshold prescribed by the law. According to the annual data published by the Ministry of Social Affairs, the weighted average mark-up in wholesale trade in medicinal products calculated on the basis of turnover was 6.7% in 2005, 6.4% in 2006, 6.1% in 2007, 5.7% in 2008, 5.4% in 2009, 5.2% in 2010, 5.3% in 2011, 5.1% in 2012, and in retail trade it was 19.2% in 2005, 18.7% in 2006, 18.51% in 2007, 17.3% in 2008, 16.2% in 2009, 16.2% in 2010, 15.9% in 2011 and 15.8% in 2012. An analysis carried out by the Ministry of Social Affairs indicates that the weighted average wholesale or retail mark-up of medicinal products has never reached the minimum rates secured by the law ever since the regulation was established in 2005.

16. The law does not stipulate how fast the Government of the Republic must react based on information submitted to it. Given the complexity of predicting the weighted average mark-up rate, the Government of the Republic has some leeway in amending the regulation. A situation where a regulation impeding the attainment of the mark-up rate prescribed by the MPA has been in force for over nine years cannot be in accordance with the law. The regulation of the Government of the Republic should have been amended for the purpose of implementing the statutory provision delegating authority and, therefore, the regulation is in conflict with the law by now.

OPINIONS OF PARTIES

Minister of Social Affairs

17.-26. [Omitted.]

Minister of Justice

27.-30. [Omitted.]

Constitutional Committee of the Riigikogu

31.-37. [Omitted.]

Social Affairs Committee of the Riigikogu

38.-39. [Omitted.]

Additional opinion of the Chancellor of Justice

40.-41. [Omitted.]

CONTESTED PROVISIONS

42. Subsection 1 of § 2 and subsection 1 of § 3 of Regulation No. 36 of the Government of the Republic of 21 February 2005 “Threshold values for mark-ups in wholesale and retail trade of medicinal products and procedure for implementation thereof” [RT I 2005, 12, 55; 2010, 60, 407]:

§ 2. Mark-up of medicinal products in wholesale trade
(1) A proportional mark-up is applied upon wholesale trade in medicinal products. The threshold values of the mark-up are set out in the Annex.

§ 3. Mark-up of medicinal products in retail trade

(1) A proportional mark-up and a fixed mark-up are applied upon retail trade in medicinal products. The threshold values of the mark-up are set out in the Annex.”

43. Annex to Regulation No. 36 of the Government of the Republic of 21 February 2005 “Threshold values for mark-ups in wholesale and retail trade of medicinal products and procedure for implementation thereof”:

1. Threshold values of the mark-up upon wholesale trade in medicinal products:

Purchase price of a single original (in euros)	Threshold value of mark-up (%)
Up to 1.60	20
1.61-2.88	15
2.89-6.39	10
6.40-12.78	5
Over 12.78	3

2. Threshold values of the mark-up upon retail trade in medicinal products:

Purchase price of a single original (in euros)	Proportional mark-up (%)	Fixed mark-up (in euros)
Up to 0.64	0	0.38
0.65-1.28	40	0.38
1.29-1.92	35	0
1.93-2.56	30	0
2.57-3.20	25	0

3.21-6.39	20	0
6.40-44.74	15	0
Over 44.74	0	5.11

OPINION OF CHAMBER

44. The Chancellor of Justice has submitted to the Supreme Court a request that subsection 1 of § 2 and subsection 1 of § 3 of and the Annex to Regulation No. 36 of the Government of the Republic of 21 February 2005, which restrict the mark-up upon the wholesale and retail trade in medicinal products, be declared unconstitutional and be repealed. The Chancellor of Justice finds that the contested provisions are in conflict with the authority-delegating provision serving as the basis for the regulation, because the threshold values of the mark-ups set out therein do not ensure the weighted average mark-up within the ranges provided for in clauses 4 and 5 of subsection 3 of § 15 of the MPA.

45. First of all, the Chamber takes a view on whether the constitutionality of the authority-delegating provision serving as the basis for Regulation No. 36 of the Government of the Republic of 21 February 2005 can be examined by the Supreme Court in the present case (I). Next, the Chamber will discuss the authority-delegating provision (II) and express an opinion on how to assess the compatibility of Regulation No. 36 of the Government of the Republic of 21 February 2005 with the authority-delegating provision (III).

I

46. Under the first sentence of subsection 1 of § 3 of the Constitution, governmental authority is exercised solely on the basis of the Constitution and laws that are in conformity therewith. It follows from the principle of the general statutory reservation expressed in this provision that the legislature must make all important decisions in matters concerning fundamental rights. The delegation of a matter that falls within the competence of the legislature to the executive and the interference of the executive in fundamental rights is permitted only on the basis of an authority-delegating provision that is provided by law and in accordance with the Constitution. The general statutory reservation is also expressed by clause 6 of § 87 of the Constitution, which gives the Government of the Republic the right to issue regulations on the basis of and for the implementation of laws. According to the first sentence of subsection 1 of § 3 of the Constitution, a regulation is in conflict with the Constitution if it has been issued on the basis of an unconstitutional authority-delegating provision as well as if the regulation has been issued without any authority-delegating provision or if the regulation is not in accordance with the authority-delegating provision.

47. The principle of the general statutory reservation is clarified by subsection 1 of § 89 of the Administrative Procedure Act (APA), which states that a regulation is lawful if it is in accordance with the law in force and complies with the formal requirements and if it has been issued on the basis of the authority-delegating provision by the administrative authority specified in the authority-delegating provision in accordance with the procedure provided by law. Under subsection 1 of § 90 of the APA, a regulation can be issued on the basis of a provision delegating authority and in accordance with the limits, spirit and purpose of the provision.

48. In the request submitted to the Supreme Court, the Chancellor of Justice contested only the compliance of the provisions of the regulation of the Government of the Republic with the authority-delegating provision. Since in the course of adjudicating the case, the Chamber came to doubt whether the authority-delegating provision complies with the Constitution, the Chamber also asked for an opinion of the parties to the proceedings on the constitutionality of the authority-delegating provision.

49. The Chamber finds that in the present case the Supreme Court cannot assess the constitutionality of the authority-delegating provision that serves as the basis for the contested regulation. The competence of the Supreme Court includes repealing an unconstitutional legislative act or a provision thereof (the second sentence of subsection 3 of § 149 of the Constitution, subsection 2 of § 152 of the Constitution and clause 1 of § 2 of the JCRPA). The right of the Chancellor of Justice to submit to the Supreme Court a request for abstract review of a provision of law for the purpose of repealing a legislative act or a provision thereof arises from § 142 of the Constitution and clause 1 of subsection 1 of § 6 of the JCRPA.

50. Based on subsection 1 of § 142 of the Constitution and §§ 17 and 18 of the Chancellor of Justice Act, the proceedings in the Supreme Court must be preceded by pre-litigation proceedings that give the authority that adopted or issued the instrument a chance to review the instrument and bring it into compliance with the Constitution (see the 24 December 2002 judgment of the Constitutional Review Chamber of the Supreme Court in case no. 3-4-1-10-02, para. 19). Before submitting the request to the Supreme Court, the Chancellor of Justice made a proposal to the Government of the Republic to bring the contested provisions of Regulation No. 36 of the Government of the Republic of 21 February 2005 in accordance with the Constitution.

51. Since the Chancellor of Justice has not made a proposal to the Riigikogu to bring the authority-delegating provision of the MPA, which serves as the basis for Regulation No. 36 of the Government of the Republic of 21 February 2005, into compliance with the Constitution, the Supreme Court is not competent to assess the constitutionality of the authority-delegating provision in the present case that involves an abstract review of provisions of law. Subsection 1 of § 142 of the Constitution provides for a procedural rule aimed at protecting the competence of the authority that adopted a legislative act and the Chamber does not see any reason for making an exception to this rule in the present case (cf. the 10 May 2013 order of the Constitutional Review Chamber of the Supreme Court in case no. 3-4-1-3-13, paras. 29-30).

52. In view of the above, the Chamber will review the case to the extent requested by the Chancellor of Justice, assessing the compliance of the contested provisions of the regulation of the Government of the Republic with the authority-delegating provision serving as the basis for the regulation.

II

53. In the present case, an answer must be found to the question of whether the contested provisions of Regulation No. 36 of the Government of the Republic of 21 February 2005 are in accordance with the authority-delegating provision. First, the Chamber will discuss the authority-delegating provision and its purpose.

54. The authority of the Government of the Republic to establish the threshold values for mark-ups in wholesale and retail trade in medicinal products and procedure for implementation thereof arises from subsection 1 of § 15 of the MPA. In subsection 2 of § 15 of the MPA, the legislature has set out the general principles with which the Government of the Republic must take into account upon establishing the threshold values, while more detailed criteria have been set out in subsection 3 of § 15 of the MPA. Upon issuing a regulation based on § 15 of the MPA, the Government of the Republic must, thus, ensure the more general aims of the authority-delegating provision in the framework of more specifically formulated limits of delegation (see the 31 October 2013 judgment of the Administrative Chamber of the Supreme Court in case no. 3-3-1-84-12, para. 30).

55. Upon establishing the threshold values for mark-ups, the Government of the Republic must take into account the accessibility of the medicinal products to the end user arising from geographical and financial reasons, the risks involved in distributing the medicinal products, and the weighted average mark-up of medicinal products in wholesale and retail trade (the first sentence of subsection 2 of § 15 of the MPA). In addition, the proportionate and fixed mark-ups must be applied (clause 1 of subsection 3 of § 15 of the MPA), the threshold value of the mark-up per one proprietary medicinal product must not exceed 6.40 euros (clause 2 of subsection 3 of § 15 of the MPA), the mark-up for different price groups must create equal interest for handling all medicinal products in wholesale and retail trade (clause 3 of subsection 3 of § 15 of the MPA), and the weighted average mark-up must remain within the statutory ranges (clauses 4 and 5 of subsection 3 of § 15 of the MPA).

56. Section 15 of the MPA obligates the Government of the Republic, by establishment of the threshold values for mark-ups of medicinal products, to secure opposing interests whereby protecting one may mean the infringement of another (see the 31 October 2013 judgment of the Administrative Chamber of the Supreme Court in case no. 3-3-1-84-12, para. 29). The establishment of the threshold values for mark-ups for trade in medicinal products infringes the freedom of enterprise (§ 31 of the Constitution), fundamental right to property (§ 32 of the Constitution) and freedom of contract (§ 19 of the Constitution) of sellers of medicinal products (cf. the 31 October 2013 judgment of the Administrative Chamber of the Supreme Court in case no. 3-3-1-84-12, para. 38). In a situation where no thresholds have been established, the wholesalers and retailers of medicinal products could apply to medicinal products a mark-up that they themselves find necessary, given the market conditions. Based on the purposes of the authority-delegating provision, it can be concluded that the purpose of such an infringement of the fundamental rights is to ensure the availability of medicinal products to the consumer, which is a part of the right to the protection of health secured in subsection 1 of § 28 of the Constitution.

57. In the request, the Chancellor of Justice argued that the provisions of the regulation of the Government of the Republic are unconstitutional to the extent that the threshold values for mark-ups established in them do not ensure the weighted average mark-up within the statutory ranges. Next, the Chamber will address the issue of the weighted average mark-up and the purpose thereof in greater detail.

58. According to the second sentence of subsection 2 of § 15 of the MPA, the weighted average mark-up means the average mark-up, expressed as a percentage, of medicinal products sold in different price categories, weighted by the share of turnover in terms of sales value expressed in wholesale purchase prices in each price group. Under subsection 3 of § 15 of the MPA, the weighted average mark-up in wholesale trade must remain between 7-10% (clause 4) and the weighted average mark-up in retail trade must remain between 21-25% (clause 5). Since, according to the second sentence of subsection 2 of § 15 of the MPA, the weighted average mark-up is calculated on the turnover of the entire market in medicinal products, § 15 of the MPA does not regulate the average weighted mark-up of individual wholesalers or retailers of medicinal products. Thus, it does not follow from § 15 of the MPA that sellers of medicinal products must obtain a mark-up of at least 7% for all medicinal products in wholesale trade and at least 21% in retail trade (cf. the 31 October 2013 judgment of the Administrative Chamber of the Supreme Court in case no. 3-3-1-84-12, para. 33).

59. The weighted average mark-up is a macroeconomic indicator aimed at, in a regulated market of medicinal products, giving the state information about the profitability of the operations of sellers of medicinal products. Such a conclusion is confirmed by the explanatory memorandum of the draft Medicinal Products Act: “[I]t is the obligation of the state to ensure sustainability in this business and the economic justifiability of restrictions established on the freedom of enterprise for the purpose of verifying the cost of medicinal products in such a manner that it is in accordance with the Constitution” (the original text of the explanatory memorandum to draft act 360 SE of the 10th composition of the Riigikogu). By establishing the minimum average weighted mark-up in clauses 4 and 5 of subsection 3 of § 15 of the MPA, the legislature wanted to prevent a situation where the limitation of the mark-up for medicinal products would disproportionately infringe the fundamental rights of sellers of medicinal products. On the other hand, if the weighted average mark-up exceeded the maximum permitted in clauses 4 and 5 of subsection 3 of § 15 of the MPA, it would, according to the estimate of the legislature, disproportionately infringe the right to the protection of health secured by § 28 of the Constitution.

60. Upon establishment of the threshold values for mark-up, the Government of the Republic can merely forecast the monetary turnover of the wholesale purchase prices of sellers of medicinal products, which serve as the basis for calculating the weighted average mark-up. Therefore, the weighted average mark-up set out in clauses 4 and 5 of subsection 3 of § 15 of the MPA is a future-looking statistical aim that the Government of the Republic must attain by establishing the threshold values. The compliance of such a forecast-based decision with the range set out in the authority-delegating provision can only be assessed retroactively (cf. the 31 October 2013 judgment of the Administrative Chamber of the Supreme Court in case no. 3-3-1-84-12, paras. 28 and 35). The MPA does not explicitly state how and during which time it must be assessed whether the weighted average mark-up remains within the range provided for in clauses 4 and 5 of subsection 3 of § 15 of the MPA. According to the third sentence of subsection 2 of § 15 of the MPA, the Ministry of Social Affairs has merely the obligation to annually carry out an analysis of the weighted average mark-up.

III

61. Next, the Chamber will take a view on how to assess the compliance of the regulation of the Government of the Republic with the authority-delegating provision.

62. The Chancellor of Justice submits that the contested provisions of the regulation of the Government of the Republic are in conflict with the authority-delegating provision because, according to the annual analyses carried out by the Ministry of Social Affairs, the weighted average mark-up percentage has remained below the minimum established in clauses 4 and 5 of subsection 3 of § 15 of the MPA since 2005.

63. According to the Ministry of Social Affairs, the weighted average mark-up in wholesale trade in medicinal products calculated on the basis of monetary turnover was 6.7% in 2005, 6.4% in 2006, 6.1% in 2007, 5.7% in 2008, 5.4% in 2009, 5.2% in 2010, 5.3% in 2011, 5.1% in 2012, 5.07% in 2013, and in retail trade it was 19.2% in 2005, 18.7% in 2006, 18.51% in 2007, 17.3% in 2008, 16.2% in 2009, 16.2% in 2010, 15.9% in 2011, 15.8% in 2012 and 15.80% in 2013. The Chamber finds that, solely on this basis one cannot draw the conclusion that the contested provisions of the regulation of the Government of the Republic have been in conflict with the authority-delegating provision since 2005.

64. In the opinion of the Chamber, the contested provisions of the regulation of the Government of the Republic would be in conflict with the authority-delegating provision if it was possible to identify that the threshold values for the mark-up of medicinal products established in them do not allow for attaining the weighted average mark-up within the ranges set out in the authority-delegating provision (cf. the 31 October 2013 judgment of the Administrative Chamber of the Supreme Court in case no. 3-3-1-84-12, paras. 34 and 35). According to the estimate of the Chamber, in a situation where, by an authority-delegating provision, the legislature has obligated the Government of the Republic to ensure the attainment of a statistical aim, it is also important which tools the legislature has given to the executive for the fulfilment of the obligation. Since the aim of the weighted average mark-up is to ensure reasonable profitability of sellers of medicinal products, the definitions serving as the basis for calculation of the weighted average mark-up must be formulated in such a manner that they allow for objectively assessing profitability and for the gathering of data which the executive needs in order to make a forecast-based decision.

65. Under subsection 4 of § 15 of the MPA, by March 1 each year, wholesalers are required to submit to the Ministry of Social Affairs a consolidated turnover report concerning the medicinal products not subject to medical prescription and medicinal product subject to medical prescription, except veterinary medicinal products, dispensed during the preceding year. The turnover report must set out the sales volume of medicinal products expressed in sales in packaging, the turnover expressed in wholesale purchase prices (without value added tax) and the turnover from products sold to retail pharmacies expressed in pharmacy purchase prices (without value added tax). The turnover data expressed in wholesale purchase prices must be grouped into price groups that constitute the basis for the wholesale mark-up, and the turnover data expressed in pharmacy purchase prices must be grouped into price groups that constitute the basis for the retail mark-up.

66. According to the second sentence of subsection 2 of § 15 of the MPA, the weighted average mark-up is calculated on the basis of the monetary turnover in terms of wholesale purchase prices. Based on the purpose of the weighted average mark-up, it is important to know the price that the wholesaler paid upon buying the medicinal products if the weighted average mark-up is to be calculated. If the wholesaler received a discount upon buying medicinal products, but the wholesaler submits to the Ministry of Social Affairs the pre-discount price as the purchase price, the "purchase price" does not reflect the wholesaler's actual costs and, thus, distorts the size of the monetary turnover. The MPA does not specify the purchase price in greater detail and, as a result thereof, the data submitted to the executive may not reflect the actual situation and the weighted average mark-up calculated on the basis thereof may not give an adequate picture of the market situation.

67. Also, the MPA does not provide that a wholesaler should separately indicate the portions of the turnover arising from the sale of medicinal products from one wholesaler to another and from the export of medicinal products. It follows from a comparison of the data of the State Agency of Medicines and the Ministry of Social Affairs that the mutual sale of medicinal products between wholesalers accounts for approx. a third of the wholesale turnover (the analysis carried out by the Ministry of Social Affairs of weighted average mark-ups in wholesale and retail trade in medicinal products, December 2014, Table 3). However, the mutual sale between wholesalers affects the weighted average mark-up, because both sellers report purchase turnover and the purchase turnover of medicinal products of the respective price groups is multiplied, as a result of which the weighted average mark-up decreases.

68. The contested regulation merely establishes the highest mark-up that a seller of medicinal products may apply upon the sale of medicinal products, but it cannot be precluded that the actual mark-up applied is smaller. Since no data are gathered from retailers of medicinal products separately, the pharmacy purchase price is also the retailer purchase price based on which the turnover of the retailers is calculated. The MPA does not specify if a wholesaler must indicate the maximum permitted sales turnover or the actual turnover in the report submitted to the Ministry of Social Affairs (i.e. if the maximum permitted mark-up or a lower mark-up was applied). The Ministry of Social Affairs has also asked wholesalers to submit data on the actual mark-up (actual sales), but since no such obligation arises from law, wholesalers do not usually submit the data (the analysis carried out by the Ministry of Social Affairs of weighted average mark-ups in wholesale and retail trade in medicinal products, December 2014, sections 2 and 6).

69. The Government of the Republic has established the threshold values for mark-up based on the regressive mark-up model. This means that the higher the price of the package of a medicinal product, the smaller the permitted mark-up percentage. With the help of such a mark-up model, the Government of the Republic has tried to level the income earned from handling medicinal products and, thus, make retailers and wholesalers equally interested in distributing medicinal products of lower as well as higher price groups (the aim specified in clause 3 of subsection 3 of § 15 of the MPA) (the analysis carried out by the Ministry of Social Affairs of weighted average mark-ups in wholesale and retail trade in medicinal products, December 2014, page 1).

70. Based on the regressive mark-up, the mark-up percentage of an undertaking depends on the price group of the medicinal products that the undertaking sells. If an undertaking is focused only on the sale of more expensive medicinal products, the mark-up percentage permitted to it is lower than the permitted mark-up percentage of an undertaking focused merely on the sale of less expensive medicinal products. The

attainment of the statistical aim set out in clauses 4 and 5 of subsection 3 of § 15 of the MPA does not, thus, depend solely on the threshold values for mark-up established by the Government of the Republic. The evolution of the weighted average mark-up is influenced by the price group where the medicinal products sold on the market belong, i.e. the economic decisions of the market participants (cf. the 31 October 2013 judgment of the Administrative Chamber of the Supreme Court in case no. 3-3-1-84-12, para. 34).

71. In addition, the weighted average mark-up, as set out in the second sentence of subsection 2 of § 15 of the MPA, may not necessarily be a suitable criterion for assessing the profitability of sale of medicinal products. Under § 15 of the MPA, the basis for calculation of the weighted average mark-up is not the income earned from handling medicinal products, but the purchase prices of medicinal products based on which the mark-ups of medicinal products are weighted. The permitted mark-up percentage of medicinal products with a higher purchase price is lower, but income from the mark-up of more expensive medicinal products may be higher in absolute figures. Reduction of the weighted average mark-up percentage may not, therefore, demonstrate that the profitability obtained from mark-ups has decreased. Instead, reduction of the weighted average mark-up percentage may indicate that more expensive medicinal products have been sold in comparison with the previous period.

72. The formation of the weighted average mark-up is, thus, influenced largely by the economic decisions of the market players, which the executive cannot control by establishing threshold values for mark-up. Thereby it is important to take into account that the establishment of threshold values for mark-up is the only tool that the legislature has placed at the disposal of the Government of the Republic for the purpose of attaining all the opposing aims of the authority-delegating provision simultaneously. The definitions serving as the basis for calculating the weighted average have not been sufficiently defined at the level of the MPA, as a result of which the data submitted to the Ministry of Social Affairs may not reflect the actual profitability of sellers of medicinal products.

73. In view of the above, the Chamber is of the opinion that in a situation where it is not possible to clearly identify that the contested provisions of the regulation of the Government of the Republic do not allow for attaining one of the aims of the authority-delegating provision serving as their basis, i.e. to ensure the profitability of sellers of medicinal products within the ranges specified in clauses 4 and 5 of subsection 3 of § 15 of the MPA, there is no ground for declaring the contested provisions unconstitutional. Based on clause 6 of subsection 1 of § 15 of the JCRPA, the Constitutional Review Chamber dismisses the request of the Chancellor of Justice.
