Constitutional judgment 3-4-1-2-13

EN BANC

JUDGMENT
in the name of the Republic of Estonia

No. of the case	3-4-1-2-13
Date of judgment	9 December 2013
Formation	Chairman: Priit Pikamäe; members: Tõnu Anton, Jüri Ilvest, Peeter Jerofejev, Henn Jõks, Ott Järvesaar, Eerik Kergandberg, Hannes Kiris, Indrek Koolmeister, Ants Kull, Villu Kõve, Lea Laarmaa, Jaak Luik, Ivo Pilving, Jüri Põld, Harri Salmann and Tambet Tampuu
Court Case	Review of the constitutionality of subsections 1 to 3 of § 42^1 “Restrictions on issue and amendment of activity licence of general pharmacy” of the Medicinal Products Act.
Basis for procedure	Request no. 9 of the Chancellor of Justice of 9 January 2013
Hearing	Oral

Participants in proceedings	Indrek Teder (Chancellor of Justice) and Hent Kalmo (Deputy Chancellor of Justice/Advisor to Chancellor of Justice); Maret Maripuu (Member of the *Riigikogu*) as a representative of the *Riigikogu*; Dagmar Rüütel (Head of the Medicine Department) and Helen Tralla (Head of Legal Affairs) as representatives of the Ministry of Social Affairs; Juhan Põldroos (Head of the Supervisory Department) as a representative of the Estonian Competition Authority; Anne Läns (Advisor) as a representative of the Association of Estonian Cities; Kai Kimmel (Member of the Management Board) as a representative of the Estonian Pharmacists' Association; and Ants Nõmper (Attorney-at-Law) as a representative of the Estonian Pharmacies Association
Date of hearing	17 September 2013

OPERATIVE PART

1. To declare subsections 1 to 3 of § 42^1 of the Medicinal Products Act unconstitutional and repeal these.

2. To postpone the entry into force of this judgment by six months.

FACTS AND COURSE OF PROCEDURE

1. On 13 April 2005, the *Riigikogu* passed the Narcotic Drugs and Psychotropic Substances Act and Other Related Acts Amendment Act (383 SE and 567 SE), which added § 42^1 "Restrictions on issue and amendment of activity licence of general pharmacy" to the Medicinal Products Act (MPA) and provided the entry into force of this section on 1 January 2006.

2. On 19 September 2012, the Chancellor of Justice made proposal no. 20 to the *Riigikogu* for bringing subsections 1 to 3 of § 42^1 of the MPA into conformity with the Constitution. The *Riigikogu* supported the proposal on 16 October 2012. Therefore, on the same day the President of the *Riigikogu* assigned, on the basis of § 152 of the *Riigikogu* Rules of Procedure and Internal Rules Act, the Social Affairs Committee to initiate a draft act to bring the Medicinal Products Act into conformity with the Constitution.

3. On 9 January 2013, the Chancellor of Justice submitted to the Supreme Court a request for repealing subsections 1 to 3 of § 421 of the MPA. The Supreme Court received the request on 10 January 2013.

4. On 22 April 2013, the Constitutional Committee of the *Riigikogu* submitted in its supplementary opinion a request for suspending proceedings in the constitutional review case until a resolution on amending restrictions on the freedom of establishment has been passed in the *Riigikogu*. On 24 April 2013, the Supreme Court asked for an opinion about the request from the Social Affairs Committee of the*Riigikogu*. The Supreme Court received the opinion on 9 May 2013.

5. By its order of 28 May 2013, the Constitutional Review Chamber of the Supreme Court dismissed the request of the Constitutional Committee of the *Riigikogu* for suspending proceedings and also referred the request of the Chancellor of Justice for adjudication to the Supreme Court *en banc*.

6. The hearing of the Supreme Court *en banc* was held on 17 September 2013.

REQUEST OF CHANCELLOR OF JUSTICE

7. The restrictions in subsections 1 to 3 of § 42^1 of the MPA on the issue and amendment of an activity licence of a general pharmacy (restrictions on the freedom of establishment) are unconstitutional, since they violate the freedom to conduct a business provided for in § 31 of the Constitution and the general fundamental right of equality provided for in subsection 1 of § 12 of the Constitution.

8. Restrictions on the freedom of establishment infringe particularly the freedom to conduct a business provided for in § 31 of the Constitution. To provide the general pharmacy service, i.e. for retail sale of medicinal products, an undertaking must hold a respective activity licence. As from the entry into force of the contested provisions on 1 January 2006, these restrictions limit the issue of a required activity licence. According to the case law of the Supreme Court, these provisions do not grant any right of discretion – if the conditions set out therein exist, then it is not possible to issue an activity licence (the judgment of the Administrative Chamber of the Supreme Court of 16 April 2007 in case no. 3-3-1-5-07, point 13). The provisions hinder the provision of the general pharmacy service, i.e. the establishment of a new general pharmacy, extending activities by creating a new structural unit or changing the place of business of an existing general pharmacy or a structural unit thereof. The contested provisions constitute a so-called market lock. This means that following the entry into force thereof the general pharmacy service market has been locked for new entrants to the market or for those who wish to extend their activities.

9. In addition to the pharmacy service market, the restrictions on the freedom of establishment also lock the wholesale market of medicinal products, thus restricting the freedom of the undertakings to conduct a business there. Competing on a wholesale market requires access to general pharmacies as retail sellers of medicinal products. The market locking impact that the restrictions on the freedom of establishment exert on the wholesale level has become possible, since already before the entry into force of the disputed restrictions on 1 January 2006 the retail as well as the wholesale market of medicinal products had been divided mainly between two undertakings that supply medicinal products to most of the existing general pharmacies. Such a situation on the retail and wholesale market of medicinal products is acknowledged by the National Audit Office (Organisation of compensation of medicines. Report of the National Audit Office to the*Riigikogu (available in Estonian)*. Tallinn, 6 September 2012, pp. 40-44), but also by the Competition Board (proposals for supplementation sent to the Ministry of Economic Affairs and Communications in order to improve competition on the medicinal products market *(available in Estonian)*, 18 September 2009).

10. Restrictions on the freedom of establishment also adversely affect the interests of consumers, who may rely on the freedom to conduct a business. Following from § 31 of the Constitution, the state must create the environment for the functioning of a free market, which will, in turn, provide consumers with the availability of goods or services, better quality and more favourable prices. The Supreme Court is also of the same opinion (the judgment of the Administrative Chamber of the Supreme Court of 18 December 2002 in case no. 3-3-1-66-02, point 13). The market lock caused by restrictions on the freedom of establishment may result in a situation where consumers are not provided with the best choice of medicinal products at the most favourable prices. This is confirmed by the aforesaid report of the National Audit Office.

11. The contested provisions also infringe the fundamental right of equality provided for in § 12 of the Constitution. These restrictions on the freedom of establishment give the undertakings that operated on the general pharmacy market before the entry into force of the restrictions and that can continue their operations an unjustified advantage over the undertakings that would like to enter the market or extend their activities later.

12. Due to their impact on operating on the pharmacy and wholesale markets as well as on consumers, the infringements caused by the restrictions on the freedom of establishment are very intensive. The infringement of the freedom to conduct a business caused by the restrictions on the freedom of establishment is not eliminated and its intensity is not reduced by the possibility given to the State Agency of Medicines in subsections 4 to 7 of § 42^1 of the MPA to make, upon the proposal of a local authority, in some events an exception to the restrictions or to organise the issue of an activity licence due to the fact that the basis for the restrictions has lapsed. In places where the prerequisites for making an exception exist, the pharmacy licence holders do not have sufficient interest in establishing a general pharmacy due to the lack of demand. In places of sufficient demand, however, exceptions are not applicable according to the interpretation provided to the act in the State Agency of Medicines. During the term of validity of the provisions, the State Agency of Medicines has not granted any of the proposals made by local authorities. However, if the exception is still to be applied, then, according to the State Agency of Medicines, it is not ensured that, due to the

provisions of drawing lots laid down in subsection 6 of § 42^1 of the MPA, the right to open a general pharmacy transfers to a person who has the required abilities and actual wish.

13. The purpose of the restrictions on the freedom of establishment in the most general terms is to perform the obligation arising for the state from subsection 1 of § 28 of the Constitution to ensure the protection of everyone's health. The more detailed purpose of the restriction on the freedom of establishment as a whole is to ensure for the protection of health, first, more equal and better availability of the pharmacy service outside cities and, second, to ensure, on the one hand, the quality of the pharmacy service and, on the other hand, consistent provision thereof in regions of stiff competition between the service providers. The Supreme Court has also seen and considered legitimate such purposes of restrictions on the freedom of establishment (the judgment of the Administrative Chamber of the Supreme Court of 16 April 2007 in case no. 3-3-1-5-07, points 14 and 15).

14. Avoiding excessive competition on the pharmacy market may not be considered as an independent legitimate purpose of the restrictions on the freedom of establishment, although the Supreme Court has held the opposite (the judgment of 16 April 2007 in case no. 3-3-1-5-07, points 14 and 15). Restriction of competition cannot be an independent legitimate purpose, since free competition is a public benefit that generally ensures the best quality and availability of a service through the optimal balance between supply and demand. Restriction of competition can only be a means for achieving a legitimate purpose, in this case, for protecting health.

15. Restrictions on the freedom of establishment have not proved appropriate to ensure more equal and better availability of the pharmacy service, particularly outside cities. This is proved mainly by the statistics of the State Agency of Medicines on the number of general pharmacies in cities and in rural areas, according to which the number of rural pharmacies has been on a constant decrease and by the beginning of 2012 it has reduced in total by 20 general pharmacies. In his supplementary opinion the Chancellor of Justice noted as a reply to the evidence, which showed that the reduction in the number of rural pharmacies stopped, that it is not possible to claim that there is a cause-and-effect relationship between the slowdown and the validity of restrictions on the freedom of establishment. Compared to the period prior to the restrictions, the number of general pharmacies has increased in cities and the number of rural pharmacies has continued its decrease, which already started two years before establishing the restrictions. The slowdown in the closure speed can be explained by the fact that the number of general pharmacies reached the limit that corresponds to the current demand – if the general pharmacies supported by local authorities are to be left aside, only those have remained on the market that are economically profitable, taking into account demand. No studies have been carried out about the connection between the preservation of rural pharmacies and the restrictions and no such studies have been undertaken in the last seven years either.

16. Economic principles also confirm in more general terms that restricting access to the market does not increase the availability of the service in a restriction-free region. When the market achieves balance, it may be presumed that supply in a restriction-free region will reduce due to the lack of demand. An undertaking will consider establishing a pharmacy in a reduction-free region only if it can expect minimum required revenue from its investment. However, according to the State Agency of Medicines, operation during the validity of restrictions on the freedom of establishment confirms that even if any revenue could be expected, undertakings wish to open general pharmacies in profitable urban regions, not in rural areas. Thus, the decision to provide the pharmacy service in rural regions is affected directly by economic considerations but also by other factors, like the availability of other services necessary for life, changes in the number of the population, infrastructure and local conditions, the existence of a doctor, and the availability of premises that comply with the requirements.

17. In any event, restrictions on the freedom of establishment are not necessary to ensure more equal and better availability of the pharmacy service, particularly outside cities. Alternative, but even more efficient measures to be considered include various measures aimed at increasing the number of rural pharmacies, like the obligation imposed on urban undertakings to run general pharmacies in less attractive regions and supporting rural pharmacies.

18. The infringement of fundamental rights arising from a proportional encumbrance would, on the whole, be smaller than in the event of restrictions on the freedom of establishment. The imposition of respective obligations would result in an infringement of the freedom to conduct a business only for those undertakings that benefit from the restriction on the freedom of establishment. At the same time, this would result in the harmonisation of competitive conditions, i.e. equal treatment of all undertakings. Such balancing obligations have been used, for instance, in Spain, Norway, Finland and Denmark.

19. The activities of local authorities who have directly supported running pharmacies in various manners also show the need for measures that support rural pharmacies. In his supplementary opinion the Chancellor of Justice notes that it is possible to presume, on the basis of the evidence provided regarding the operation of rural pharmacies (see, for instance, the opinion of the Association of Municipalities of Estonia), that in the current market situation the persistence of a general pharmacy in sparsely populated rural areas depends directly on outside aid, not on the impact of restrictions on the freedom of establishment.

20. The state can also foster the activities of rural pharmacies through measures aimed at the medicinal products market. The Minister of Social Affairs could leave local social welfare institutions, whose demand accounts for a considerable portion of the turnover of rural pharmacies as retail undertakings, off the list of persons with the right to wholesale purchase of the medicinal products set out in subsection 1 of § 28 of the MPA. The amendment to the Medicinal Products Act that permits distance selling of medicinal products may also jeopardise the condition of rural pharmacies. The use of the aforesaid measures of the medicinal products market confirms that the restrictions have not been aimed systematically at ensuring more equal and better availability of the pharmacy service. However, it must be kept in mind that the obligation of the state is not to ensure, at any cost, the manageability of existing general pharmacies, but to still ensure the availability of medicinal products in regions where demand for the pharmacy service is insufficient.

21. Also, restrictions on the freedom of establishment have not proved appropriate for ensuring the quality of the pharmacy service in regions of stiff competition between service providers. This is certified by the fact that, in order to ensure the quality of the pharmacy service, the Medicinal Products Act has already established (mainly for the performance of obligations arising from Directive 2011/83/EC of the European Parliament and of the Council, as amended) other regulatory measures, such as the provisions of safety for medicinal products, requirements for the import and marketing of medicinal products, and the conditions and procedure for the provision of the pharmacy service. The adherence thereto is ensured by the requirements of the marketing authorisation of medicinal products and the activity licence of the pharmacy and supervision over the fulfilment thereof, whereas a violation of the requirements may be penalised or result in the revocation of the activity licence. There is no reason to think that the restrictions on the freedom of establishment would also contribute to ensuring quality. However, the so-called free market share of the pharmacy market, i.e. the share in which the Medicinal Products Act has established minimum requirements or which has not been regulated at all, is subject to general market rules. The restrictions on the freedom of establishment that limit competition impair the quality of the pharmacy service in this respect, since due to the reinforced demand the service provider does not have any economic stimulus to increase the quality, incl. to provide less expensive medicinal products.

22. Even if the restrictions on the freedom of establishment may be appropriate in order to ensure the consistent provision of the pharmacy service in regions of stiff competition between the service providers, such restrictions are at any rate not necessary for achieving the purpose. An alternative measure to be considered is permitting free competition. According to economic principles, if there is, firstly, demand for a product or a service and, secondly, this demand is high, and, thirdly, the entry into the market has not been hindered, there is always somebody on the market who provides the product or the service and the consumer will get it. According to the 2011 annual report of the Estonian Health Insurance Fund (p. 61), there is a firm and growing demand for the pharmacy service. This is also confirmed by an increase in the sales figures of general pharmacies. It is true that permitting free competition may result in a change in undertakings that provide the service. However, this will not give rise to a situation where in a profitable region all general pharmacies will terminate their activities and the service will not be available at all. The person of an undertaking is not important for a consumer and in the event of constant sufficient demand the service of a

required level of quality is also ensured. Permitting free competition improves the availability of the pharmacy service in places where a sufficient number of people move around and where there is therefore demand, but where until today it has proved impossible to open a general pharmacy due to the restrictions on the freedom of establishment (e.g. suburban regions, where demand has arisen or increased after the imposition of the restrictions on the freedom of establishment) or where, in order to circumvent the restrictions on the freedom of establishment, the place of business must be shifted by 500 metres in the manner provided for in subsection 2 of § 42^1 of the MPA.

23. To ensure the consistent provision of the pharmacy service, on some occasions precise exceptions that balance competition could also be established. These can be considered alternative measures to the general restrictions on the freedom of establishment currently in force and to the free competition suggested in the previous point. Such measures could prove necessary if the assumption holds good that in the free market conditions on some occasions the provision of the pharmacy service could turn out to be so intense that this would use up too many of the limited resources (qualified pharmacists) required for the provision of the pharmacy service and would thus make it difficult to provide the service in some regions of sufficient, but still lower, demand. In the event that due to some objective prerequisites (e.g. the number of tourists) the supply of the service could appear to be higher than the needs of inhabitants, due to which a qualified workforce could concentrate namely in such places, the State Agency of Medicines could, when issuing or amending activity licences of the general pharmacy service, have an opportunity of tying such activity licences, which are presumably profitable, but of low value from the point of view of public health, to the requirement for running a branch pharmacy somewhere in the countryside, where it would be necessary, but not sufficiently profitable.

24. The assessment of the reasonableness of the restrictions on the freedom of establishment, i.e. weighing public health and the freedom to conduct a business, is useless, since, on the basis of the provided evidence, the restrictions have not proved either appropriate or necessary for achieving their purposes. If there is no compelling evidence which certifies that the restrictions on the freedom of establishment are appropriate or necessary for promoting public health, the validity thereof cannot be justified in any manner by the great weight of public health as a constitutional value.

25. However, in a supplementary opinion sent to the Supreme Court in reply to other opinions sent to the court, the Chancellor of Justice has also given arguments concerning the assessment of reasonableness. When assessing reasonableness, the abolition of the restrictions on the freedom of establishment need not be considered as a market liberalisation measure whose proportionality should be weighed. This is not a measure that would open to competition an economic sector that has never been subject to free market rules, but an elimination of a restriction imposed on a fundamental freedom. Therefore, comparison with the situation in Sweden is not relevant either, since it was in Sweden where the state monopoly of sales of medicinal products was terminated in the economic sector that was closed until then. The example of the United Kingdom, where in 2005 the restrictions imposed on the establishment of general pharmacies were abolished and in 2012 they were partially re-established, is also irrelevant. There the state did not let the market concentration grow too high, while in Estonia most of the general pharmacies were already under the control of two wholesalers at the moment when the pharmacy market was locked by the disputed provisions.

26. In his supplementary opinion the Chancellor of Justice emphasises in respect of assessing the proportionality of the restrictions on the freedom of establishment more generally that this must be done according to the *in dubio pro libertate* principle, i.e. any doubts about the impact of the restrictions must be interpreted for the benefit of the freedom to conduct a business. As a result of adhering to this principle, the *Riigikogu* must prove, if it wishes that these provisions remain in force, that the disputed provisions have contributed to achieving the purpose attributed to them. No such evidence is included in the various opinions submitted to the Supreme Court.

27. The repeal of the restrictions on the freedom of establishment would infringe the rights of the pharmacy undertakings currently operating on the market, since they would be deprived of the legal protection against competition. However, this infringement is justified by the freedom to conduct a business, the equal

treatment of third persons and fair competition as a public interest. Fair competition has, in turn, a favourable impact on the availability of medicinal products to the final consumer, which contributes, on the whole, more to the promotion of public health than the restrictions on the freedom of establishment do.

OPINIONS OF PARTIES

28.–99. [Not translated.]

CONTESTED PROVISIONS

100. Subsections 1 to 3 of § 42^1 "Restrictions on issue and amendment of activity licence of general pharmacy" of the Medicinal Products Act (RT I 2005, 2, 4; RT I, 17.04.2013, 6):

"(1) Upon issue of an activity licence of a general pharmacy to a general pharmacy, upon amendment of an activity licence of a general pharmacy in connection with the establishment of a new structural unit with the place of business in a city, or upon change of the place of business of a general pharmacy or a structural unit thereof in a city, the restriction in force is that new activity licences of a general pharmacy must not be issued for operation in the corresponding city, new structural units of a general pharmacy must not be established, or the place of business of a general pharmacy, including a structural unit of the general pharmacy, must not be changed if, according to the State Agency of Medicines and the Statistical Office, there are fewer than 3000 inhabitants in this city per general pharmacy, including a structural unit of a general pharmacy.

(2) The restriction specified in subsection 1 of this section does not apply upon amendment of an activity licence of a general pharmacy in connection with changes in the place of business of the general pharmacy or a structural unit of the general pharmacy, provided that the new place of business is not farther away than 500 metres from the previous place of business.

(3) In settlements that are not cities, activity licences of a general pharmacy for opening a pharmacy must not be issued and a structural unit of a general pharmacy must not be opened at a distance closer than 1 kilometre to an already existing general pharmacy or a structural unit thereof. The specified restriction is also in force if the place of business of a general pharmacy or a structural unit thereof is changed."

OPINION OF COURT *EN BANC*

101. To adjudicate the case, the Court *en banc* will, first, discuss the infringement of fundamental rights (I) and, second, identify the legitimate purpose of the infringement (II). Thereafter, the Court *en banc* will assess the proportionality of the infringement in respect of the legitimate purpose, more precisely the appropriateness (III) and necessity (IV) thereof. Finally, the Court *en banc* will decide on the need for postponing the entry into force of the judgment (V).

102. The parties to the proceedings claim that the European Court of Justice has permitted the disputed restrictions on the freedom of establishment and that the Administrative Chamber of the Supreme Court has already found the provisions to be constitutional. The Court *en banc* holds that the case law of the European Court of Justice does not determine the adjudication of this case. The European Court of Justice has held that Article 49 of the Treaty on the Functioning of the European Union (TFEU) does not, in principle, preclude restrictions that depend on the number of inhabitants and distance, but the Article may preclude the restrictions in so far as they prevent the creation, in any geographical area with particular demographic characteristics, of a sufficient number of pharmacies capable of providing an appropriate pharmaceutical service, which it is for the national court to verify (see operative parts of the Order of the European Court of Justice of 6 October 2010 in case no. C-563/08 and Order of 17 December 2010 in case no. C-217/09). Thus, the European Court of Justice has assessed that such restrictions on the freedom of establishment are, in principle, permissible, but not required. It must also be kept in mind that a Member State may safeguard the freedom to conduct a business in broader terms than the European Union law. Also, the permissibility of the assessment of constitutionality of a provision or a decision on the substance thereof is not precluded by the fact that a Chamber of the Supreme Court has implemented the provision. Attention must be paid to the fact that the constitutionality of the same provision may also change over time, since the impact of the provision may differ depending on actual circumstances (cf. e.g. the judgment of the Supreme Court*en banc* of 15 July 2002 in case no. 3-4-1-7-02, point 29).

I

103. In his request the Chancellor of Justice relies on the freedom to conduct a business provided for in § 31 of the Constitution and on the fundamental right of equality provided for in subsection 1 of § 12 of the Constitution. The undertakings that operated on the general pharmacy market before the entry into force of the restrictions on the freedom of establishment have an advantage over the undertakings that want to enter the market or extend their activities later. The Chancellor of Justice also refers to restricting the freedom to conduct a business through the infringement of the rights of the consumer and through the indirect impact on the wholesalers' activities, particularly to difficulties in entering the market.

104. Next, the Court *en banc* will analyse whether the contested provisions infringe the freedom to conduct a business safeguarded by § 31 of the Constitution.

105. Section 31 of the Constitution provides the right to engage in entrepreneurial activity; the law may provide conditions and procedures that circumscribe the exercise of this right (the first and the second sentence). The freedom to conduct a business safeguarded by the Constitution has several aspects. On the one hand, this ensures everybody's right to engage in entrepreneurial activity, i.e. in an activity whose purpose is, above all, obtaining revenue from the production or sales of goods, the provision of a service, etc. On the other hand, the state must ensure the legal environment for the functioning of the free market in order to protect an undertaking against unlawful activities of other undertakings in preventing competition or jeopardising business activities. However, free competition that forms a part of the freedom to conduct a business protects not only other undertakings' freedom to conduct a business, but also the consumer. Free competition is based on the presumption that competition ensures the best service or goods at the best price.

106. Following from subsection 1 of § 29 of the MPA, 'pharmacy service' means the following: the retail sale or other dispensing of medicinal products together with related counselling as well as the preparation of medicinal products as magistral formulae and officinal formulae and dividing them up into retail packaging. Sales, production and provision of services are entrepreneurial activities. Thus, the provision of the pharmacy service is within the protection zone of the freedom to conduct a business provided for in § 31 of the Constitution.

107. Subsections 1 and 3 of § 42^1 of the MPA provide for demographic and geographical restrictions for issuing an activity licence of a general pharmacy. These are additional conditions for the requirement of subsection 2 of § 29 of the MPA, under which the pharmacy service may be provided only in pharmacies holding a corresponding activity licence and in structural units thereof. The general pharmacy service can be provided only by holding an activity licence and subsections 1 and 3 of § 42^1 of the MPA establish a restriction on obtaining an activity licence. Thereby, the pharmacy licence holders who already operate cannot also establish a new general pharmacy (hereinafter also pharmacy) in any other manner than under the conditions of the restrictions on the freedom of establishment of general pharmacies provided for in the contested provisions. Thus, these provisions directly infringe the freedom to conduct a business.

108. Although subsections 1 and 3 of § 42^1 of the MPA provide for different restrictions in cities and settlements that are not cities, the restrictions have been provided for in both of the categories for the same purpose. The contested provisions were established, as a whole, with the purpose of ensuring the availability of medicinal products particularly in rural regions, thereby hindering the accumulation of pharmacies in cities (see point 118 of this judgment). Therefore the Court *en banc* considers the restrictions provided for by both of the subsections as a uniform one.

109. Besides the direct restriction on the freedom to conduct a business, the restriction on the freedom of establishment also infringes the interests of consumers at least through the fact that the provisions hinder establishing pharmacies in the quantity and at the places desired by undertakings so that it could be easier for the consumer to buy medicinal products.

110. The impact of the restriction on the freedom of establishment on wholesalers must also be acknowledged through the following: in a situation where the establishment of pharmacies is restricted and a large share of the existing pharmacies form a chain, while being tied to the existing wholesalers, it is probably difficult for a new wholesaler to find a sufficient number of wholesale purchasers. Thus, subsections 1 and 3 of § 42^1 of the MPA also indirectly infringe the freedom to conduct a business.

111. According to the Court *en banc*, it is questionable whether the restriction on the freedom of establishment of pharmacies has an impact on the choice and price of medicinal products. The price of medicinal products has been regulated by law. The choice of medicinal products does not depend only on the pharmacy, but also on wholesalers and manufacturers of medicinal products. In order for a medicinal product to be placed on the market, it must complete the national procedure, which entails costs for the manufacturer. On a small market the manufacturer may have no interest in bearing the costs, especially in the event of medicinal products that are used little. When selling to a large market, the manufacturer is obviously more eager to sell the medicinal product at a more favourable price, since it can sell a larger quantity and the costs of entry into the market are easier to make up for. Thus, even if the restrictions on the freedom of establishment affect the prices and choice of medicinal products, the impact is limited.

112. The allegations of the parties to the proceedings that the existing pharmacies must be protected against excessive competition mean, in the context of fundamental rights, relying on the freedom to conduct a business, requesting interference from the state for safeguarding the freedom to conduct a business. The freedom to conduct a business does not generally guarantee any profit or manageability for existing enterprises. The freedom to conduct a business protects an undertaking's opportunity to function in the market conditions without any unjustified interference from the state (cf. the judgment of the Constitutional Review Chamber of the Supreme Court of 28 April 2000 in case no. 3-4-1-6-00, point 11). According to the Court *en banc*, the right to interference from the state, incl. to the restriction of competition, can be derived from the freedom to conduct a business only in the events where engagement in a certain type of entrepreneurial activity would be impossible merely under the operating conditions of the market. The pharmacy service is not a service that could be supplied only if the service can be provided without any competition or with little competition (see the discussion below in point 133). Thus, pharmacy licence holders do not have any right, on the basis of the freedom to conduct a business safeguarded by the Constitution, to require from the state any interference with the functioning of the pharmacy market in order to ensure their market share.

113. The Court *en banc* discussed above in points 107 to 110 the infringement of the freedom to conduct a business arising from subsections 1 and 3 of § 42^1 of the MPA. In addition to that, the Chancellor of Justice also contested subsection 2 of § 42^1 of the MPA, which provides for an exception to subsection 1. It follows from this provision that the restriction set out in the first subsection does not apply upon amendment of an activity licence if the new place of business is not farther away than 500 metres from the previous place of business. Thus, this is an exception, when the restriction on the freedom of establishment is not applied and, following from that, it seems as if there were no infringement. On the other hand, this provision is inseparably connected with subsection 1 of the same section since, in the event of the unconstitutionality and invalidity of subsection 1, the validity of subsection 2 would cease to have any sense. Thus, it is relevant to also involve subsection 2 of the same section in the review of constitutionality of subsection 1 of § 42^1 of the MPA.

114. The Chancellor of Justice submits that the restrictions on the freedom of establishment also infringe the fundamental right of equality provided for in § 12 of the Constitution. It arises from the first sentence of subsection 1 of § 12 of the Constitution that everyone is equal before the law. The Court *en banc* holds that although upon establishment of a new pharmacy the restrictions on the freedom of establishment are in force equally to everyone, the undertakings that established their pharmacies before the restrictions on the freedom of establishment were imposed gained an advantage. The undertakings that wish to establish pharmacies only now, cannot establish them, due to the restrictions on the freedom of establishment, in any place they desire. Since they are in a worse condition than the pharmacy licence holders that have been on the market

before, then their fundamental right of equality has been infringed. However, the infringement of the fundamental right of equality needs no separate assessment; it must be taken into account when assessing whether the infringement of the freedom to conduct a business is reasonable (cf. the judgment of the Supreme Court *en banc* of 13 November 2012 in case no. 3-1-1-45-12, point 29).

II

115. Next, the Court *en banc* will examine the legitimate purpose of the infringement of the freedom to conduct a business arising from subsections 1 to 3 of § 42^1 of the MPA.

116. The second sentence of § 31 of the Constitution provides that the law may establish conditions and procedures that circumscribe the exercise of the freedom to conduct a business. This means that the freedom to conduct a business is a fundamental right of the simple reservation of law that may be restricted for any reason in compliance with the Constitution.

117. The Chancellor of Justice sees a wider purpose of the restriction in the obligation arising for the state from subsection 1 of § 28 of the Constitution to ensure the protection of everyone's health; in narrower terms, more equal and better availability of the pharmacy service outside cities as well as to ensure the quality and consistent provision of the pharmacy service in regions of stiff competition between the service providers. According to the Chancellor of Justice, the purpose of avoiding excessive competition on the pharmacy market is not legitimate. Other parties to the proceedings see the legitimate purpose of the restriction similarly to the Chancellor of Justice; the need to preserve the pharmacy network in rural regions is pointed out separately. Unlike the opinion of the Chancellor of Justice, avoiding excessive competition is also considered a legitimate purpose.

118. Supplementation of the Medicinal Products Act with § 42^1 was justified in the explanatory memorandum of the draft Act to Supplement the Medicinal Products Act with § 43^1 (567 SE of the 10th *Riigikogu*) as follows: "By today, the constant asymmetrical concentration of pharmacies from rural regions to cities has reached the extent that makes it necessary to establish requirements for more uniform distribution of pharmacies in order to ensure the territorial availability of medicinal products, particularly in rural regions. In addition, it is necessary to establish a geographical restriction in settlements in order to ensure the existence of sustainable pharmacies that are able to manage. The initiators are of an opinion that the geographical restriction set out in the draft act does not become too harassing for inhabitants. The initiators are rather of an opinion that restricting the establishment of new pharmacies in places where there is already a sufficient number thereof (e.g. in Tallinn) hinders the concentration of pharmacies in city centres.

Respective demographic and geographical restrictions have also been provided for in legislation of Member States of the European Union (e.g. Austria, Belgium, Spain, Greece, France, Latvia, etc.) in order to avoid the accumulation of pharmacies in more densely populated areas and the reduction of the pharmacy service in less densely populated regions."

119. Taking into account that set out by the parties to the proceedings and in the explanatory memorandum of draft act no. 567, the Court *en banc* holds that the purpose of the restriction on the freedom to conduct a business established by the contested provisions is, in brief, ensuring the availability of the pharmacy service in the whole state.

120. The availability of the pharmacy service means the availability of medicinal products along with counselling. Based on the Medicinal Products Act, consumers can buy medicinal products only through general pharmacies – either from the pharmacy on the spot or by way of distance selling (Division 4 of Chapter II of the MPA). In addition to other requirements, pharmacies are required to counsel the use of the medicinal product both on the spot as well as in the event of distance selling. Thus, the availability of medicinal products is ensured only through the pharmacy service. The availability of medicinal products is related to everyone's right to the protection of health (subsection 1 of § 28 of the Constitution). Since the

purpose of infringement as such can be derived from the Constitution, this is legitimate for the infringement of the freedom to conduct a business.

121. Thereby, availability does not mean the availability of medicinal products at affordable prices (the Court *en banc* discussed the price of the medicinal products in point 111 above), but the opportunity to get the pharmacy service in a geographically close location.

122. The quality of the pharmacy service is not ensured by restrictions on the freedom of establishment and ensuring the quality of the pharmacy service cannot be considered a purpose of infringement. The quality requirements for providing the pharmacy service and, in broader terms, for handling medicinal products are ensured in another manner. The Medicinal Products Act regulates safety of medicinal products and the form and content of the pharmacy service, imposing, *inter alia*, requirements for premises and the counselling obligation on pharmacies. The Medicinal Products Act also contains provisions that ensure the fulfilment of quality requirements with the help of the requirements for marketing authorisations and activity licences, administrative supervision and penal law sanctions. Adhering to the quality requirements provided by law is an obligatory prerequisite for providing the pharmacy service.

123. It is not relevant to examine the availability of the pharmacy service separately in cities and in rural areas, although it is presumed that there are problems with the availability of the pharmacy service namely in rural areas. The frontier does not run between rural areas and cities. The places where the demand for the pharmacy service is high in economic terms and the places where the demand for running a pharmacy is low – insufficient in economic terms (e.g. also suburbs, new settlements) – are in a different situation. Therefore, as a legitimate purpose of infringement, it is not relevant to differentiate the availability of the pharmacy service in rural regions and in cities, but the purpose to be pursued is ensuring the availability of the pharmacy service in the whole state. The fact that the demand for the pharmacy service differs in terms of regions must be taken into account when assessing various aspects of the proportionality of the restrictions on the freedom of establishment.

124. The purpose of ensuring a consistent supply of the pharmacy service in places of stiff competition between the service providers can be called, in other words, the availability of the pharmacy service in regions of stiff competition. The availability of the pharmacy service means that the service is available constantly.

125. However, the requirement for availability must not be understood so that each village in Estonia should have its own pharmacy. Taking into account the population density in Estonia, it cannot still be considered sufficient if the pharmacy service is available only in regions of such high demand where running a pharmacy is clearly profitable.

126. The Court *en banc* is of an opinion that restricting excessive competition may be an independent legitimate purpose if the availability of the pharmacy service were not ensured without that. In a situation where there is sufficient demand for the pharmacy service and it is possible to enter the market, it is highly probable that there are always undertakings that wish to supply the service. In light of the above, the Court *en banc* is of an opinion that in the present case the legitimate purpose of the infringement of the freedom to conduct a business is not a restriction of excessive competition.

127. Since the legitimate purpose of the infringement has already been identified, next, the proportionality of the infringement must be assessed. The examination of the proportionality of the infringement involves the assessment of the appropriateness, necessity and reasonableness of the infringement in respect of the legitimate purpose of the infringement.

III

128. First, the Chamber will examine the appropriateness of the restriction for achieving the purpose. A

measure that fosters the achievement of a purpose is appropriate. For the purposes of appropriateness, a measure, which in no way fosters the achievement of a purpose, is indisputably disproportional (see the judgment of the Constitutional Review Chamber of the Supreme Court of 6 March 2002 in case no. 3-4-1-1-02, point 15).

129. The Court *en banc* must weigh and assess the impact of the restriction on the freedom of establishment in respect of the purpose despite the fact that it is not possible to claim with certainty what the situation would have been like if no restrictions on the freedom of establishment had been established as from 1 January 2006 or what the situation will be like if the restrictions on the freedom of establishment are repealed now.

130. The parties to the proceedings have given three key arguments about the inappropriateness of the restrictions on the freedom of establishment: 1) the number of rural pharmacies has been on a constant decrease during the validity of the restrictions on the freedom of establishment; 2) the restrictions on the freedom of establishment do not lead undertakings to continue or take up running pharmacies in areas where demand is insufficient; 3) regions of high demand do not require any restrictions on the freedom of establishment, since the availability of the pharmacy service is ensured there by the functioning of the market rules. The parties to the proceedings claim the following about the restrictions on the freedom of establishment as an appropriate measure: 1) the decrease in the number of rural pharmacies has decelerated; 2) due to a scarcity of pharmacists and assistant pharmacists the restrictions on the freedom of establishment in force in cities hinder the relocation of pharmacists from rural areas to cities to possible new workplaces and this also prevents the closure of pharmacies in rural areas caused by leaving pharmacists.

131. Since the establishment of pharmacies and thus their total number is limited due to the restrictions on the freedom of establishment, the examination of proportionality is largely related to the number of pharmacies, which is, in turn, related to the availability of the pharmacy service. The number of pharmacies characterises the number of places where it is possible to get the pharmacy service. The Court *en banc*uses the data of the State Agency of Medicines as a basis. According to the State Agency of Medicines, the number of rural pharmacies in Estonia in 2003 was 156, in 2004: 166, in 2005: 162, in 2006: 156, in 2007: 147, in 2008: 144, in 2009: 138, in 2010: 132, in 2011: 128, and in 2012 and in 2013: 127 (here and hereinafter all numbers of the pharmacies have been set out as of 1 January of the respective year). According to the Estonian Pharmacies Association, new rural pharmacies have been opened as well. In cities, the number of pharmacies in 2003 was 313, in 2004: 308, in 2005: 318, in 2006 and in 2007: 376. Thereafter there was a smooth decline in the number of urban pharmacies, reaching in 2012 to 342 pharmacies and increasing by 2013 to 348 urban pharmacies. The contested provisions entered into force on 1 January 2006.

132. First, the Court *en banc* will examine the appropriateness of the restrictions on the freedom of establishment for ensuring the availability of the pharmacy service in regions of high demand (i.e. of sufficient demand within the economic meaning for running a pharmacy).

133. If there is high demand for a product or a service and the entry into the market has not been hindered, there is presumably always somebody on the market who provides the product or the service and an interested consumer can use the service or buy the product. An exception is the fields of activity where the provision of a product or a service results in such high costs that there is interest in the provision of the product or the service only if the number of people interested in buying it is very high. The practice confirms that the pharmacy service is not a service of such type. When the Legislature imposed on the establishment of pharmacies in cities the limit of one pharmacy per 3000 inhabitants, it presumed that in the event of such a number of inhabitants the demand is sufficient in order to run a pharmacy profitably or at least without making a loss. The number of pharmacies established in cities is approximately as high as permitted by the restrictions on the freedom of establishment (e.g. according to the State Agency of Medicines, as at 1 January 2013 there were 126 pharmacies in Tallinn, where the number of inhabitants was according to the Statistical Office about 395 000, i.e. one pharmacy per about 3100 inhabitants; at the same time in Tartu there were 42 pharmacies and about 97 000 inhabitants, i.e. one pharmacy per about 2300 inhabitants). It

follows from the aforesaid that undertakings also have interest in providing the pharmacy service in the event of a relatively small number of inhabitants. Thus, provided that the entry into the market is not hindered, there are always providers of the pharmacy service in regions of high demand.

134. The demand for the pharmacy service on the Estonian market as a whole is sufficient; to be more exact, the demand therefor has been on a constant increase. In 1998, the consumption amounted to approximately 500 daily intakes per thousand inhabitants a day, but in 2005 to about 650 and in 2012 to almost 1000 daily intakes per thousand inhabitants a day (according to the data of the State Agency of Medicines on medicinal products in the event of which the daily intake has been determined). Thereby, the sales figures have also increased. In 2005, the sales of all general pharmacies in Estonia in the event of sales of medicinal products amounted to 128 million euros (total sales along with other goods sold in pharmacies 158 million euros), in 2010 and in 2011 the sales of medicinal products was 189 million euros (total sales 235 and 240 million euros, respectively), but in 2012 the turnover of medicinal products amounted to 203 million euros (total sales 261 million euros – data of the State Agency of Medicines). In 2012, the increase in the sales of medicinal products was about 7.4% (the increase in the total sales by about 8.8%) compared to the preceding year. The increased demand and sales preclude a situation where, due to the changed state of the market, pharmacies would have found themselves today in a situation where the provision of the service would be economically possible or practical only if a very large quantity of people consumed the service and, in order to ensure that, the state should interfere.

135. Those who support the restrictions on the freedom of establishment as a suitable measure submit that the pharmacy market is a specific market where the general market principles are not valid. The argument to be agreed with is that the provision of the pharmacy service is considerably more regulated than conventional trade, since the state has established certain rules for the price and handling of the goods, for premises, the staff, etc. It is also a fact that, particularly due to the small territory of Estonia, the Estonian pharmacy market is different from the pharmacy markets of other countries. However, these arguments indicate by no means as if, due to the unique characteristics of the (Estonian) pharmacy market, the demand would not spark the supply. Thus, the general market rule that if there is a demand there are also suppliers works also on the pharmacy market.

136. The supporters of the restrictions on the freedom of establishment also argue that permitting free competition may bring along a change in undertakings that provide the service, since the non-competitive undertakings leave the market. This is true, but in an area of high demand it does not give rise to a situation where all pharmacies would terminate activities there and the pharmacy service would become unavailable. As the Court *en banc* noted in point 112 above, the freedom to conduct a business does not generally ensure any market share for an undertaking. From the consumer's point of view it does not make any difference who provides the service.

137. In light of the above, the Court *en banc* holds that the restrictions on the freedom of establishment are not appropriate for ensuring the availability of the pharmacy service in areas of high demand.

138. Next, the Court *en banc* will examine the appropriateness of the restrictions on the freedom of establishment for ensuring the availability of the pharmacy service in areas of low demand. Although, according to the Court *en banc*, it is more proper to examine areas of low demand, not to use the approach that makes a distinction between urban and rural pharmacies (see point 123 above), it is still the latter approach that must be followed in the event of the number of pharmacies. The reason behind that is that there are no statistics about the number of pharmacies in areas of high and low demand or about the areas that should be regarded as areas of low demand at all.

139. First, arguments related to the decrease in the number of rural pharmacies will be examined.

140. As the statistics set out in point 131 above reveal, in 2005 there were 162 rural pharmacies and in 2013 only 127. The parties to the proceedings who consider the restrictions on the freedom of establishment inappropriate have concluded therefrom that the number of rural pharmacies has reduced regardless of the

validity of the restrictions on the freedom of establishment. However, the supporters of the restrictions argue that if the restrictions on the freedom of establishment had not been in force, the number of rural pharmacies would have decreased even faster.

141. The Court *en banc* holds that it cannot be concluded from the deceleration of the decrease in the number of rural pharmacies that this is due to the validity of the restrictions on the freedom of establishment. There are no empirical data that would confirm the existence of a cause-and-effect relationship between the validity of the restrictions on the freedom of establishment and a slower decrease in the number of pharmacies. Thus, the claim that without the restrictions on the freedom of establishment the number of rural pharmacies would have decreased faster has not been proved. The number of rural pharmacies increased last in 2004 (166 pharmacies compared to 156 pharmacies in 2003). Two years before the restrictions on the freedom of establishment entered into force, the number of rural pharmacies fell by four and six pharmacies (in 2005 and in 2006 respectively, compared to the preceding year), and in the first years when the restrictions were in force the number fell by seven, three, six and six pharmacies (in 2007, 2008, 2009 and 2010 respectively, compared to the preceding year). Thus, the actual deceleration of the decrease in the number of rural pharmacies can be noticed only in the last three years – the number has decreased by four and three pharmacies and remained the same (in 2011, 2012 and 2013 respectively, compared to the preceding year). Taking into account such statistics of decrease, it is arbitrary to claim that the decrease in the number of rural pharmacies stopped only as a result of imposing the restrictions on the freedom of establishment as from 1 January 2006.

142. The decrease in the number of pharmacies decelerates rather due to the fact that the number of rural pharmacies has reached the limit that corresponds to the current demand in different places. This opinion is supported by the comparison of the maps of the population density (changes) and the map of the location of pharmacies. (See maps of population density: on the website of the Statistical Office about 2005 and 2011); maps of population change: Noorkõiv, R., Loodla, K. (Geomeedia), Rahvastiku võimalikud arengutrendid 2012–2030 (a survey ordered by the Ministry of the Interior), 2012, p. 33; also: Pilte rahvaloendusest, Statistical Office, 2013, p. 150 (both of these available on the web); map of pharmacies: on the website of the State Agency of Medicines.)

143. Local authorities' aid to rural pharmacies operating in their area does not also support the claim that the decrease in the number of rural pharmacies has decelerated under the impact of restrictions on the freedom of establishment. In the 2012 budget report of local authorities, nine rural municipalities with a total of ten pharmacies as of 3 December 2013, plus the City of Tallinn (Tallinn supports the provision of the pharmacy night shift service and gives pensioners a discount on pharmacy goods – p. 9 and 178 of the explanatory memorandum of the 2013 draft budget of the City of Tallinn; budget reports of local authorities are available on the website of the Ministry of Finance), have indicated costs under "Pharmaceutical products – pharmacies". However, it does not mean that this is the only support provided by local authorities to pharmacies. For instance, this year Kullamaa established, on the initiative of the rural municipality, a pharmacy to which a room has been let in the community centre for one euro a month, i.e. below the market price (see article "Kullamaa people soon to have a pharmacy again" in the *Lääne Elu* newspaper of 5 January 2013 *(available in Estonian)*; the price of the rent according to Kullamaa Rural Municipality Government). This year, Tõstamaa also opened a pharmacy to whom the rural municipality gave premises for use without charge. In addition, the rural municipality pays the public utility costs of the entire health centre, where the pharmacy is also located (see article "Tõstamaa has its own pharmacy again" in *Pärnu Postimees* of 11 April 2013 *(available in Estonian)*; information about the rent and public utility costs from Tõstamaa Rural Municipality Government). However, in the event of Kullamaa or Tõstamaa Rural Municipality no cost has been set out under "Pharmaceutical products – pharmacies" in the budget report of local authorities for Q1, Q2 or Q3 of 2013 (in the event of Tõstamaa, costs have been set out under "Other health care, incl. health care administration"). Thus, the aid to pharmacies is broader than the direct financial support indicated in the budget reports. It is obvious that local authorities support pharmacies in order to ensure their economic manageability and the constant provision of the service in the region.

144. In addition, it must be noted that, unlike rural pharmacies, it is not possible to talk about a decrease in

the number of urban pharmacies. It is true that the number of pharmacies in cities has decreased from 2006 to 2012 (in 2013, the number increased for the first time). However, it is remarkable that, compared to the preceding year, in 2006 the number of pharmacies increased in cities by 58, i.e. about 18% (from 318 to 376). This was a large discrepancy from the conventional development, compared to the relative stability of the number of urban pharmacies in three preceding years and the smooth decline that followed it. The abrupt change was caused by the imposition of restrictions on the freedom of establishment. The Narcotic Drugs and Psychotropic Substances Act and Other Related Acts Amendment Act, which added the contested provisions to the Medicinal Products Act was passed on 13 April 2005 and published in the *Riigi Teataja* on 10 May 2005. Thus, on 1 January 2006 the entry into force of the restrictions on the freedom of establishment was known more than seven months in advance. It is more than likely that the sudden increase in the number of pharmacies in this period was caused by the fact that before the entry into force of the restrictions on the freedom of establishment there was a wish to establish as many pharmacies as possible, since later this would not have been possible any more. Pharmacists' statements in the media also confirm this (see article "Stiff competition in establishing new pharmacies at end of year" in the *Äripäev* newspaper of 13 February 2006 (*available in Estonian*)). Thus, in 2006 the number of pharmacies increased sharply due to the imminent entry into force of the restrictions on the freedom of establishment and, compared to the period prior to the adoption of the restrictions on the freedom of establishment, the number of urban pharmacies has by now actually increased (from 318 to 348). The number of rural pharmacies, however, has decreased since 2005 and the decline continued until the previous year.

145. In light of the above, the Court *en banc* holds that changes in the number of pharmacies in cities and in rural regions do not by themselves confirm the appropriateness of the restrictions on the freedom of establishment for ensuring the availability of the pharmacy service in regions of low demand.

146. In the context of ensuring the availability of the pharmacy service in regions of low demand, the Court *en banc* will next also examine the argument that the shortage of pharmacies there is caused by low demand.

147. The Court *en banc* discussed in points 133 to 135 above the market rule that in a place of high demand there is also always someone to supply the service. The specificity of the pharmacy market does not indicate in any manner that the provision of the pharmacy service should be continued or started in a place of no sufficient demand if there are no measures that compensate for the lack of the demand. The data of the State Agency of Medicines about participating in the competition for opening new pharmacies also shows that undertakings wish to open pharmacies particularly in profitable urban areas of high demand.

148. The Court *en banc* holds that, based on the size of the demand, restrictions on the freedom of establishment are not appropriate for continuing or taking up the provision of the pharmacy service in areas of low demand.

149. Last, the Court *en banc* will analyse the arguments related to the scarcity of pharmacists in the context of ensuring the availability of the pharmacy service in regions of low demand.

150. The parties to the proceedings, who consider the restriction on the freedom of establishment appropriate, claim that due to a scarcity of pharmacists the restrictions on the freedom of establishment in force particularly in cities hinder the relocation of pharmacists from rural areas to cities to possible new workplaces. Thus, the restrictions on the freedom of establishment prevent the closure of pharmacies in rural areas caused by leaving pharmacists.

151. Following from subsection 3 of § 29 of the MPA, the pharmacy service may be provided only by pharmacists and assistant pharmacists registered by the Health Board. According to the register of pharmacists and assistant pharmacists, in the month the judgment is made (December 2013) there are 914 assistant pharmacists and 1317 pharmacists (in total 2231) in Estonia. According to the website of the State Agency of Medicines, at the same time there are 480 general pharmacies in Estonia. Thus, there are about 1.9 assistant pharmacists and about 2.7 pharmacists per pharmacy, in total about 4.6 pharmacists per pharmacy. Some of the pharmacies are open on only one or some days of the week (e.g. in Kullamaa one

day a week for four hours, in Eidapere one day a week for two hours, in Ruusmäe two days a week for 8.5 hours in total – according to the websites of the respective rural municipalities), while pharmacies in large shopping centres are often open seven days a week for 12 hours a day. Given that a working week is 40 hours long, a pharmacy open on seven days for 12 hours a day needs at least 2.1 pharmacists (not taking into account the compulsory break during the working day); however, in large pharmacies there is more than one pharmacist at work at a time. The data of a survey ordered by the Estonian Pharmacies Association and performed by PWC indicates that in 2012 an average rural pharmacy in Estonia was open for 45 hours a week and an urban pharmacy was open for 70 hours a week. The survey shows that the pharmacies in Estonia were open a total of 30 075 hours a week (according to the opening hours per 2012 and the number of pharmacies as of 1 January 2013, i.e. 45 * 127 + 70 * 348). Considering the current number of pharmacists, there are approximately three full-time pharmacists per pharmacy in Estonia (not taking into account the compulsory break during a working day; calculated as follows: the number of pharmacists multiplied by the number of hours of a full working week and by dividing the result by the opening hours of pharmacies, i.e. 2231 * 40 : 30 075). It can be claimed already on the basis of these calculations that there is also a lack of pharmacists today.

152. The current scarcity of pharmacists is also confirmed by the parties to the proceedings (see the report of the Social Affairs Committee of the *Riigikogu* "Overview on ensuring availability of high-quality and sustainable pharmacy service according to proposal no. 20 of the Chancellor of Justice concerning the restriction on amending the issue of an activity licence of a general pharmacy", 18 June 2013, point 9 (*available in Estonian*); point 2.2.2.2 of the survey ordered by the Estonian Pharmacies Association and performed by PWC, p. 2 of the opinion of the Ministry of Social Affairs). The scarcity of pharmacists arose no later than in 2005 following the passing and prior to entry into force of the restrictions on the freedom of establishment, when the number of pharmacies in cities increased about 18% compared to the earlier situation (see the article in the *Äripäev* newspaper referred to in point 144).

153. Thus, the scarcity of pharmacists in Estonia has already lasted for a longer period of time. Despite that the closure of rural pharmacies has been gradual and, according to the Court *en banc*, this has been caused particularly by the relocation of the population (see point 142 above) and the lack of supporting measures in areas of insufficient demand. The Court *en banc* admits that, following the abolition of the restrictions on the freedom of establishment, new pharmacies could be established in cities, which would also generate the need for an additional qualified workforce. The increasing scarcity of the workforce would, in turn, create pressure for pay raises, which may motivate rural pharmacists to relocate from rural regions to cities more than before. At the same time, due to the regulated prices of medicinal products and restricted sales of other goods in pharmacies, pharmacy licence holders cannot obviously grant a high pay raise.

154. In light of the above, the Court *en banc* is of an opinion that the restrictions on the freedom of establishment are not appropriate for ensuring the availability of the pharmacy service in regions of high demand. The Court en *banc* admits in the event of regions of low demand that it is not impossible that a lack of restrictions on the freedom of establishment would give rise to a higher demand for pharmacists than before, which would result in the closing of more rural pharmacies.

IV

155. Since in the previous point the Court *en banc* considered it possible that the restrictions on the freedom of establishment may have a certain impact on ensuring the availability of the pharmacy service in areas of low demand, the necessity of the restrictions on the freedom of establishment will also be reviewed in this respect below.

156. A restriction is necessary if it is not possible to achieve a purpose by some other measure which is less burdensome on a person but which is at least as effective as the former. It is also important to consider how much different measures burden third persons as well as differences of expenditure for the state (see e.g. the judgment of the Constitutional Review Chamber of the Supreme Court of 6 March 2002 in case no. 3-4-1-1-

02, point 15). Next, the Court *en banc* will look for alternative measures that would contribute more or at least equally to the availability of the pharmacy service in areas of low demand than the restrictions on the freedom of establishment, while being thereby less burdensome.

157. Better availability of the pharmacy service could be ensured by an obligation of pharmacy licence holders in regions of high demand to also provide the pharmacy service in regions of low demand. The availability of the pharmacy service could be ensured either by the existence of a permanent pharmacy or for example with the help of a pharmacy bus. These would be provisions where gaining an advantage would also entail an obligation for an undertaking (at least in some of the events). An obligation to run a pharmacy in a determined place of low demand could be imposed on those who obtain a licence for running a pharmacy/pharmacies in a place of especially high demand or such an obligation could be related to the sales either in a specific pharmacy or in pharmacies belonging to a group. A situation in which an undertaking gains the right to run a pharmacy or pharmacies in a favourable place and this entails an obligation to run a pharmacy in a place of low demand, restricts the freedom to conduct a business less than a situation where it cannot run a pharmacy at all. Thereby the freedom of enterprise of only those undertakings is infringed, who have gained an advantage with the right to run a pharmacy in a place of high demand. This will harmonise the competitive conditions of undertakings and they would be subject to equal treatment. As this measure infringes the freedom to conduct a business less, it would thereby ensure the existence of (additional) pharmacies in regions of low demand more than the restrictions on the freedom of establishment in their valid form do. Thus, this is an alternative measure.

158. It would be possible to establish aid to pharmacies in regions of low demand. The aid could be granted either by the state or local authorities or an aid fund could be set up, into which pharmacies of regions of high demand could pay a fixed fee or as a percentage of sales. Thereby, the Legislature should decide whether ensuring the availability of the pharmacy service is the task of the state or local authorities. The aid would contribute more to achieving the purpose of the availability of the pharmacy service in regions of low demand than the restrictions on the freedom of establishment do.

159. However, when supporting undertakings through the state as well as through a local authority, the state aid rules arising from the EU law must still be taken into account. Under the Competition Act (CA) and the Treaty on the Functioning of the European Union, state aid means any aid granted through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods (§ 30 of the CA, Article 107 of the TFEU). An exception has been provided in respect of "*de minimis* aid" (§ 33 of the CA). It follows from the act that if the aid granted to a single undertaking does not exceed 200 000 euros over any period of three fiscal years or, in the event of an undertaking that provides a service of general economic interest, 500 000 euros, the aid is not deemed to be state aid. The pharmacy service must be considered a service of general economic interest. Taking into account the fact that the annual turnover of one general pharmacy is on average about 550 000 euros (the total turnover of pharmacies in 2012 divided by the number of pharmacies on 1 January 2013), it is also obvious that the aid for three years cannot be of such an amount that the state aid rules should be applied. Hence, the aid would be permissible. At the same time this would mean additional costs to the state or local authorities. Thus, it is true that aid granted by the state or a local authority would contribute more to ensuring the purpose, but this would entail other negative impacts. The Legislature may decide to establish such aid, but this measure cannot be considered an alternative, less restrictive measure when reviewing the constitutionality of the restrictions on the freedom of establishment.

160. If aid were paid to pharmacies in regions of low demand through the aid fund into which payments are made by pharmacies in regions of high demand, this would have a similar impact on the freedom to conduct a business as the measure described in point 157 has. If aid is of the proper amount and only in the place where the provision of the pharmacy service would otherwise not be economically practical, this would also not result in any competitive advantage or unequal treatment. Thus, aid is an alternative measure that restricts the freedom to conduct a business less and helps achieve the purpose more.

161. In previous points the Court *en banc* discussed two alternative measures that restrict the freedom to

conduct a business less and contribute more to achieving the purpose than the restrictions on the freedom of establishment do. There may be more measures or combinations thereof. However, since relevant alternative measures have been found, it is not necessary to look for any additional possibilities in the constitutional review procedure. The Court *en banc* holds that restrictions on the freedom of establishment are not necessary for ensuring the availability of the pharmacy service in the whole state.

162. The reasonableness of the restrictions on the freedom of establishment is reviewed only if the restriction is appropriate and necessary for achieving the purpose. Since the Court *en banc* held that the appropriateness of the restriction is questionable and the restriction is definitely not necessary for achieving the objective, then the reasonableness of the restriction on the freedom to conduct a business is not reviewed in the present case. In light of the above, the Court *en banc* holds that restrictions on the freedom of establishment are not proportional for ensuring the availability of the pharmacy service in the whole state.

163. The Court *en banc* noted in point 114 above that the infringement of the fundamental right of equality must be reviewed together with the reasonableness of the infringement of the freedom to conduct a business. If a restriction infringes one fundamental right disproportionately, the restriction is unconstitutional regardless of whether the infringement of any other fundamental right is proportional or not. Following from that, it is now not necessary to provide any additional discussion of the fundamental right of equality.

164. In light of the above, the request of the Chancellor of Justice must be granted and subsections 1 to 3 of § 42^1 of the MPA must be declared unconstitutional and repealed under clause 2 of subsection 1 of § 15 of the Judicial Constitutional Review Procedure Act (JCRPA).

V

165. Under subsection 3 of § 58 of the JCRPA, the Supreme Court has the right to postpone for up to six months the entry into force of a judgment that declares a legal instrument or a provision thereof unconstitutional and repeals it. The postponement of the entry into force of a judgment must be reasoned.

166. The Estonian Pharmacies Association requested that in the event of granting the request of the Chancellor of Justice the judgment be postponed by six months in order for the Parliament to receive an opportunity to terminate the procedure initiated for amending the Medicinal Products Act.

167. The Social Affairs Committee of the *Riigikogu* has drawn up a report (see point 152 above) in which a proposal is made, *inter alia*, for forming a working group that would develop criteria for assessing the need for the pharmacy service and determine quality indicators of the pharmacy service as well as prepare the amendments to law arising therefrom. In its letter of 23 September 2013 to the Supreme Court, the Social Affairs Committee of the *Riigikogu* notified that a survey was ordered from Geomedia to assess the availability of the pharmacy service and find out the extent in which local authorities should support pharmacies. This indicates that the Legislature considers it necessary to amend the provisions of availability of the pharmacy service currently in force and is engaged in developing new ones.

168. As the Court *en banc* held above, there are regions of low demand in Estonia, where the provision of the pharmacy service is not economically possible or practical without the measures that compensate for insufficient demand. Thus, it is necessary to provide for measures that ensure the availability of the pharmacy service in places of low demand. The Supreme Court can only declare the contested provisions unconstitutional and repeal them.

169. It was admitted above that the restrictions on the freedom of establishment may hinder the relocation of rural pharmacists to cities as the number of urban pharmacies is relatively stable due to the restrictions on the freedom of establishment (see point 153 above). This means that repealing restrictions on the freedom of establishment without providing any other measures could result in more active closure of rural pharmacies. Thus, repealing restrictions on the freedom of establishment immediately could impair the availability of the

pharmacy service.

170. The experience gained from imposing the restrictions on the freedom of establishment must also be taken into account. The potential impact of the restrictions on the freedom of establishment might not have been achieved due to the fact that in the period between passing the restrictions and their entry into force many pharmacies were established in cities in deviation from the conventional development of the market. If the restrictions on the freedom of establishment are repealed immediately, the expectation of the market participants for new provisions of unknown substance will result in their unforeseeable behaviour.

171. It is also important to avoid a situation in which the possible steps to be taken by market participants following immediate repeal of restrictions on the freedom of establishment would make laying down new constitutional provisions more complicated than they are upon immediate transfer from the restrictions on the freedom of establishment.

172. Furthermore, immediate repeal of the contested provisions could restrict disproportionately the freedom of pharmacists to conduct a business. If, following the repeal of the restrictions on the freedom of establishment without laying down other measures, a large number of pharmacies is established so that running pharmacies in Estonia as a whole resulted, due to the increased labour costs, total area of pharmacies, etc., largely in a loss, it would in all probability be only big pharmacy chains that could bear the loss and it would in practice be impossible for pharmacists to run pharmacies.

173. Following the aforesaid, under subsection 3 of § 58 of the JCRPA, the Court *en banc* will postpone the entry into force of this judgment by six months. Thus, the judgment will enter into force on 9 June 2014.

The judgment includes two dissenting opinions from a total of four Justices, which have not been translated.
